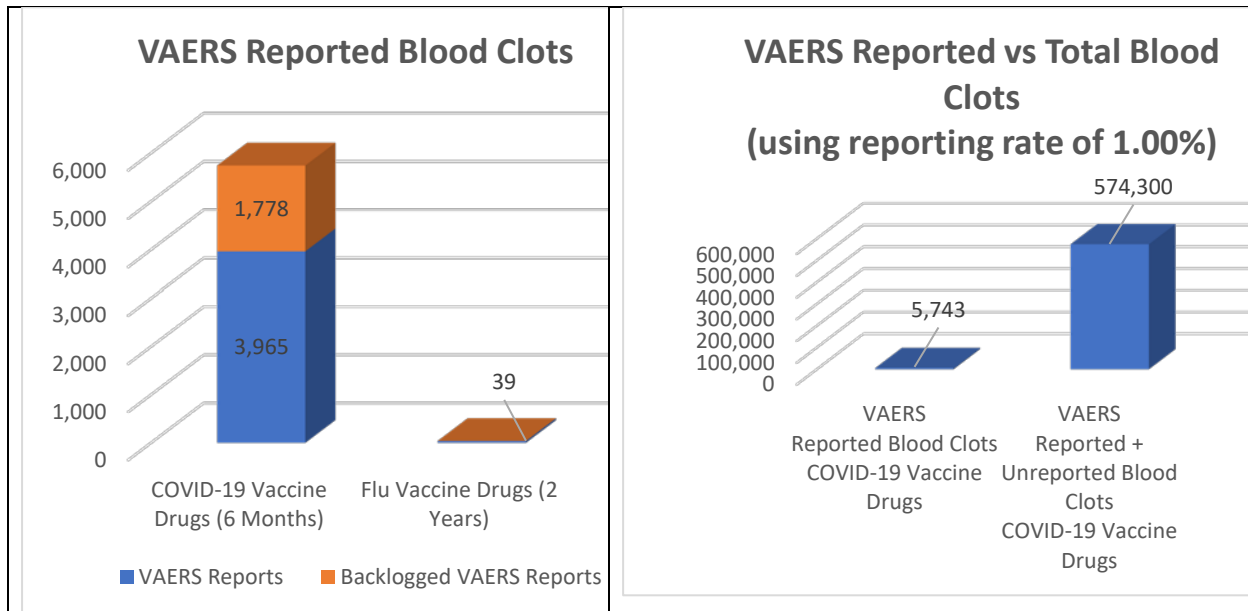


# COVID-19 Vaccine Drug Reactions: Blood Clots

Preliminary Notes – Reactions Listings Start on Page 2 Below



1. Blood clot cases Reported through June 4, 2021 in the United States to the Vaccine Adverse Event Reporting System (VAERS).
2. In order to understand the two charts above:
  - a. The VAERS COVID-19 vaccine drug reported cases + backlogged cases **versus** the flu vaccine reported cases
  - b. The VAERS reported cases versus the total cases in the United States

It is **crucial** to at least one time, carefully read through the two answers in the FAQs related to backlogged cases and then the VAERS reporting rate:

[https://www.covid19vaccinefacts.net/VAERS\\_FAQ.shtml#Backlog](https://www.covid19vaccinefacts.net/VAERS_FAQ.shtml#Backlog)

[https://www.covid19vaccinefacts.net/VAERS\\_FAQ.shtml#ReportingRate](https://www.covid19vaccinefacts.net/VAERS_FAQ.shtml#ReportingRate)

3. The cases listed below were pulled from the VAERS raw data files with a query that looked for clots and thrombosis. As you read through the cases below, it is possible that there will be an occasional erroneous case not related to blood clots. The exact query is as follows:  
(symptom\_text like "clot\*" or symptom\_text like "\* clot\*" or symptom\_text like "\* thrombosis\*" or symptom\_text like "\*thrombi\*") and symptom\_text not like "\*cloth\*" and symptom\_text not like "\*clotting\*"

## Blood Clots: COVID-19 Vaccine Drugs

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
1373779	6/4/2021	PA	57	M	2/25/2021	4/15/2021	a blood clot; blockage in the Left Anterior Descending artery; symptoms of shortness of breath; This is a spontaneous report from a non-contactable consumer or other non hcp. A 58-year-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 25Feb2021 17:30 (at the age of 57-years-old) as 2nd dose, single for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient previously took first dose of bnt162b2 on 02Feb2021 and experienced cardiac blockage. The patient did not take any other vaccines within 4 weeks prior to the COVID vaccine. On 15Apr2021 the patient experienced a blood clot, blockage in the left anterior descending artery and symptoms of shortness of breath. The events were reported as serious (life threatening). It was reported that 15Apr2021, emergency trip to ER, blockage in the Left Anterior Descending artery. This blockage was only 40% blocked in Feb2021, and suddenly in April became 99% blocked. Dr suspected a blood clot when symptoms of shortness of breath appeared suddenly. The events resulted in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Blockage in the Left Anterior Descending artery was treated with cardiac stents. The patient underwent lab tests and procedures which included COVID-19 test tested performed on an unspecified date (result not reported). The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021600543 same patient, different vaccine dose/events

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1374300	6/4/2021	WI	51	F	5/13/2021	6/3/2021	On May 15th, she got the J&J vaccine. Then on May 17th, while she was walking, she tripped on a curb and fell and then landed on her left knee. Then, this past Thursday on May 20th, she noticed swelling and pain in the left leg. She presented to urgent care the following day on Friday and had an ultrasound done that revealed blood clot in the superficial veins. Patient recalls of had a similar episode of superficial vein clot about 6 years ago. Referred to vascular and second ultrasound done revealing DVT
1374298	6/4/2021	TX		F			Presented with clots; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Presented with clots) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .5 milligram. On an unknown date, the patient experienced THROMBOSIS (Presented with clots) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Presented with clots) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications was provided by the reporter. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. Company comment: Very limited information regarding this event has been provided at this time. Further information cannot be requested.; Sender's Comments: Very limited information regarding this event has been provided at this time. Further information cannot be requested.

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1374282	6/4/2021	CA	23	M	5/21/2021	5/22/2021	<p>The vaccine is affecting young people; My son felt like he had an aneurysm in his neck/He had pain in the large artery on the right side of his neck like a myocardial inflammation or something; The right side of his neck, between the shoulder and neck, on the inside, he felt swelling, pressure pain, dull pain that comes and goes; On Tuesday, on the right side of his neck, between the shoulder and neck, on the inside, he felt swelling, pressure pain, dull pain that comes and goes; shoulder pain; On Saturday night he was feeling tired and cold; feeling cold; On Saturday his legs were very heavy and had pain, like he had blood clots or thrombosis in his veins; On Saturday his legs were very heavy and had pain; This spontaneous case was reported by a patient and describes the occurrence of THROMBOSIS (On Saturday his legs were very heavy and had pain, like he had blood clots or thrombosis in his veins) and ANEURYSM (My son felt like he had an aneurysm in his neck/He had pain in the large artery on the right side of his neck like a myocardial inflammation or something) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 027L21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included BUPROPION HYDROCHLORIDE (ZYBAN) for an unknown indication. On 21-May-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-May-2021, the patient experienced THROMBOSIS (On Saturday his legs were very heavy and had pain, like he had blood clots or thrombosis in his veins) (seriousness criterion medically significant), PAIN IN EXTREMITY (On Saturday his legs were very heavy and had pain), FEELING COLD (feeling cold) and FATIGUE (On Saturday night he was feeling tired and cold). On 25-May-2021, the patient experienced ANEURYSM (My son felt like he had an aneurysm in his neck/He had pain in the large artery on the right side of his neck like a myocardial inflammation or something) (seriousness criterion medically significant), NECK PAIN (The right side of his neck, between the shoulder and neck, on the inside, he felt swelling, pressure pain, dull pain that comes and goes), SWELLING (On Tuesday, on the right side of his neck, between the shoulder and neck, on the inside, he felt swelling, pressure pain, dull</p>



<u>VAERS_ID</u>	<u>RECVD</u>	<u>STATE</u>	<u>AGE_YRS</u>	<u>SEX</u>	<u>VAX_DATE</u>	<u>ONSET_DATE</u>	<u>SYMPTOM_TEXT</u>
							<p>pain that comes and goes) and ARTHRALGIA (shoulder pain). On an unknown date, the patient experienced VACCINATION COMPLICATION (The vaccine is affecting young people). At the time of the report, THROMBOSIS (On Saturday his legs were very heavy and had pain, like he had blood clots or thrombosis in his veins), ANEURYSM (My son felt like he had an aneurysm in his neck/He had pain in the large artery on the right side of his neck like a myocardial inflammation or something), VACCINATION COMPLICATION (The vaccine is affecting young people), PAIN IN EXTREMITY (On Saturday his legs were very heavy and had pain), NECK PAIN (The right side of his neck, between the shoulder and neck, on the inside, he felt swelling, pressure pain, dull pain that comes and goes), SWELLING (On Tuesday, on the right side of his neck, between the shoulder and neck, on the inside, he felt swelling, pressure pain, dull pain that comes and goes), FEELING COLD (feeling cold), ARTHRALGIA (shoulder pain) and FATIGUE (On Saturday night he was feeling tired and cold) outcome was unknown. No treatment information was provided. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to MOD-2021-182543 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>
1374182	6/4/2021	IL	47	F	2/11/2021	2/13/2021	<p>I had a strong reaction to the second dose (fever over 101 after taking Ibuprophen that lasted 2 days). Then I had abnormal uterine bleeding that prompted me to contact my doctor who ordered a pelvic ultrasound. The ultrasound showed what looked like possibly a clot or a cyst in the uterus. I then had a hysteroscope to further examine it and it was no longer there so it has been a clot that subsequently passed. Since then, my periods have returned to a normal timing pattern, but remain heavier than before.</p>

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1374118	6/4/2021	FL	27	F	6/3/2021	6/4/2021	I have an extremely heavy period now, I woke up and there was a huge blood clot in my underwear and I literally gushed blood I've never seen that in all my 27 years of living and I'm afraid of what the next few days of my period will be like.
1374020	6/4/2021			U			blood clot; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (blood clot) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. unknown) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (blood clot) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (blood clot) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. No concomitant medications were reported. No treatment medications were reported. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
1374541	6/4/2021	IA	50	F	5/28/2021	5/29/2021	Patient presented to the pharmacy on 6/4/21 to inform pharmacist that she did go to the emergency room on 5/29/21 due to severe shortness of breath and flu-like symptoms. She stated they did complete an EKG and did check for blood clots. She stated that they did not find anything significant and ruled out a blood clot at that time. She still states she feels tired, however the shortness of breath did resolve and she was discharged home without any further treatment necessary.

<i>VAERS_ID</i>	<i>RECVDATE</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1374007	6/4/2021			U			2 blood clots in my lungs; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of PULMONARY EMBOLISM (2 blood clots in my lungs) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced PULMONARY EMBOLISM (2 blood clots in my lungs) (seriousness criterion medically significant). At the time of the report, PULMONARY EMBOLISM (2 blood clots in my lungs) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided.; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1373294	6/4/2021	GA		F	4/18/2021		<p>pulmonary embolism/blood clots; heart problems; blood clots; mild immune response; Headache; Little chills; Really bad fatigue; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (pulmonary embolism/blood clots) in a 58-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 001C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was provided by the reporter. Concomitant products included METOPROLOL, POTASSIUM CITRATE and COLECALCIFEROL (VITAMIN D [COLECALCIFEROL]) for an unknown indication. On 18-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced PULMONARY EMBOLISM (pulmonary embolism/blood clots) (seriousness criteria hospitalization and medically significant), CARDIAC DISORDER (heart problems), DYSPNOEA (blood clots), HYPERSENSITIVITY (mild immune response), HEADACHE (Headache), CHILLS (Little chills) and FATIGUE (Really bad fatigue). The patient was treated with APIXABAN (ELIQUIS) at an unspecified dose and frequency and LEVOFLOXACIN (LOVENOX [LEVOFLOXACIN]) at an unspecified dose and frequency. At the time of the report, PULMONARY EMBOLISM (pulmonary embolism/blood clots), CARDIAC DISORDER (heart problems), DYSPNOEA (blood clots), HYPERSENSITIVITY (mild immune response), HEADACHE (Headache), CHILLS (Little chills) and FATIGUE (Really bad fatigue) outcome was unknown. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 25-May-2021: Non-significant Follow-up case booked in; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

<i>VAERS_ID</i>	<i>RECVDATE</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1373773	6/4/2021	OK		M	3/23/2021	3/1/2021	50% hearing loss; He is on the verge of suicide; insomnia; I cant live with this; can't think; it's driving me crazy; driving me insane; He is desperate; spike headaches; rash under my eyes/rash in his eyes appeared in the right eye and then got to the left eye; incredible ringing in my ears and a spike headache/high pitched ringing in my ears; This is a spontaneous report from a Pfizer-sponsored program via a contactable male consumer (patient himself). A male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on 23Mar2021 as 1st dose, single for COVID-19 immunization. The patient medical history and concomitant medications were not reported. It was reported that, caller and his 20y/o son received their first dose of the Pfizer BioNTech COVID 19 Vaccine on 23 Mar 2021. His son had a runny nose for 10 days but was fine after. However, 4 days later, on an unspecified date in Mar2021, the patient developed a rash under his eyes and he woke up with an "incredible ringing in my ears and a spike headache". Caller claims that he has never experienced that in his life. He also reported a rash under one of his eye that later on spread to the other eye, as well as insomnia on an unspecified date. He has seen his HCP and was referred to an Audiologist, who he has visited 3 times since then. He was diagnosed with 3 times % loss of hearing and 10500 Hertz tinnitus, which the Audiologist mentioned is "really high". It was also reported that, this high pitched ringing in his ears that just won't go away and its driving him crazy. He was prescribed with high dose Prednisone for 7 days, but caller mentioned "it did not help and had no effect whatsoever". His HCP wanted to be "super cautious" and recommended a brain scan this week just to make sure he didn't develop a blood clot. Caller is upset that no one can give him answers. He has reached out to CDC and asked for medical advice, but he stated that everyone is giving him the same answers - there is not enough data. He is on the verge of suicide and said, "I can't live with this for the rest of my life. I can't sleep and can't think, it's driving me crazy" on an unspecified date. Patient stated "I'm just trying to get to the end of this. I cant live like this its driving me crazy." Patient went on to mention "I'm at

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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my wits end with this it is truly driving me insane on an unspecified date. I'm not kidding. I can't sleep, I can't think, I cant function with this ringing. The rash didn't even go away under my, I've been to the dermatologist twice and they just don't know..." Patient wanted to speak to someone because "I cant spend my life with this high pitch ringing in my ears it is driving me crazy". On an unspecified date, he was desperate for answers and even tried reporting to Vaccine Adverse Event Reporting System (VAERS) but there was no way to submit it. The patient also asked about what in the vaccine could affect the auditory complex. He added that he did not get the second dose of the Pfizer covid vaccine, that the rash in his eyes appeared in the right eye and then got to the left eye. Also he mentions that this is "all over the internet and you just have to google it", that the percentage that reported this is above 10% for both Moderna and Pfizer vaccines and he estimates that is about 17% all over the world and that the DNA vaccines started since the 90's. He also mentions that he knows at least 15 more persons affected with the same side effects as him and he lives in a small town and a CEO just committed suicide because of this. Sometimes he refers at it as "tinnitus". He says that he feels miserable and this is driving him crazy. He wants to make this public and that Pfizer acknowledges this. The patient underwent lab tests and procedures which included tinnitus: 10500 Hertz which the Audiologist mentioned is "really high". The outcome of the events, incredible ringing in my ears and a rash under eyes was not recovered and for other events was unknown.

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1373764	6/4/2021	CA	60	F	4/13/2021	4/13/2021	experienced the same excruciating pain in my right knee this time; two Baker's Cysts were visible, one in each leg, only visible on the back of my right knee, but no trace of any blood clots; This is a spontaneous report from a contactable consumer (patient). A 60-year-old non-pregnant female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, lot number: unknown) via an unspecified route of administration, administered in left arm on 13Apr2021 at 07:00 (at the age of 60-year-old) as 1st dose single and second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, lot number: unknown) via an unspecified route of administration on 04May2021 (at the age of 60-year-old) as 2nd dose, single both for covid-19 immunization. Medical history included undiagnosed arthritis. The patient did not receive any other concomitant medications within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient was not diagnosed with COVID 19 prior to vaccination. On 13Apr2021 at 20:00, patient started experiencing the events. It was reported that, for twenty days, patient needed help to accomplish anything. On the 21st day, patient went out but the steps were extraordinarily painful in left knee. Her plan was to wait it out until she had the 2nd dose on 04May. Again, six days later, patient experienced the same excruciating pain in right knee this time. Two doses, both knees, unbelievable pain. The patient finally went the ER on Friday, 14May2021. After the first dose, patient suspected a Baker's Cyst. After the second dose, it measured the size of a golf ball cut in half. Trusted her research skills, she confirmed what she already knew, with an MRI scheduled and two ultrasounds done on both knees, two Baker's Cysts were visible, one in each leg, only visible on the back of right knee, but no trace of any blood clots. The patient underwent lab tests and procedures which included MRI: unknown and ultrasounds done on both knees: two baker's cysts were visible, one in each leg: size of a golf ball cut in half on an unspecified date. The adverse event resulted patient to visit the Physician Office Visit and Emergency Room Visit. The patient received treatment for the adverse event. Therapeutic measures were taken as a result of both events and treatment included with 10 mg

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Prednisone. Since the vaccination, patient has not been tested for COVID-19. The outcome of events was unknown. Follow-up attempts are needed; information about lot/batch number can be obtained.



<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1373739	6/4/2021	CA		M	4/16/2021	4/17/2021	<p>Collapsed day after vaccine first dose/Collapsed day after vaccine second dose; His left side still feels paralyzed and can't walk; legs wouldn't move, couldn't turn around; He had compression fractures L1 to L3 that were noticed on his x-ray; he collapsed and had a hard time getting up/felt bad; General malaise; His left side still feels paralyzed and can't walk; bedridden; Pain; Half of back is black from incident; Mobility got worse after first shot and then after second dose his mobility got even worse; felt like what I would call the flu; Collapsed day after vaccine first dose/Collapsed day after vaccine second dose; This is a spontaneous report received from a Pfizer sponsored program. A 72-years-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Solution for injection), via an unspecified route of administration, administered in Arm Left on 16Apr2021 (Batch/Lot Number: EP7533) as 1st dose, single dose and second dose via an unspecified route of administration, administered in Arm Left on 07May2021 14:00 (Batch/Lot Number: EW0182) as 2nd dose, single dose for covid-19 immunisation. Medical history included L1 to L3 compression fractures somewhere around 2008 to 2010, ongoing gout (from about 35 years ago) (pain in both hips and right shoulder, left shoulder some times), gouty arthritis (30 years constant pain), ongoing moderate emphysema (since 20 years ago), stroke (happened in 2010). States he was taking Warfarin at the time of the stroke and the stroke was permanent, cholesterol, smoker (20 years), excess uric acid, allergy in right sinus, cough uncontrollably, perirectal abscess and low blood pressure. Family medical history was none. States he is adopted. Concomitant medications included atorvastatin taken for blood cholesterol from an unspecified start date to unspecified date in 2021 (Taking for about 5 years, not sure if the dose is 30mg, 50mg, or 300mg, stopped after adverse event with covid vaccine), zolpidem tartrate (AMBIEN) taken for sleeping from an unspecified start date to unspecified date in 2021 at 10mg (taking for couple of decades, stopped after adverse event with covid vaccine, stated it may cause drowsiness) and allopurinol taken for gout at a dose of 300 mg, (taking for 6 or 7 years) and azelastine hydrochloride nasal spray taken for uncontrollable coughing via nasal route as 2 shots each nostril twice a day (uncontrollable coughing</p>

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caused perirectal abscess, had scope done, diagnosed as allergy. Azelastine works for cough). The patient previously took pneumonia shot and stated that it hurt like hell for a week, flu shot and got sick and also took warfarin. The patient reported that he received his first dose on 16Apr2021, then the next day he collapsed and had a hard time getting up. He also reports general malaise, "just felt bad", and "felt like what I would call the flu" for the next 5 days. On 07May2021 he received his second dose, and the same thing happened where he collapsed the next day. This time, he was not able to get up on his own and had to call 911. He was admitted to the hospital and "had 2 X-rays and a CT scan", CT of torso he reports his CT scan showed compression fractures at L1, L2, and L3 on his x-ray. He is taking a lot of Norco to treat his pain. States the music on hold is so uplifting that he wants to go cut his throat. Caller stated he was bedridden. He reported "I can't walk, I used to be able to, and now I can't". He spent 5 years in a computer testing laboratory and he knows a little about testing. He states a lot of the rules apply to conductors and automobiles. Caller stated he wants to know what happened to him. He says if he dies as a result of this, there will be mountains of paperwork. He also said if his condition is permanent, there will also be mountains of paperwork. He can't go to the bathroom and this is an issue. He was falling down and collapsing several times with both shots. He says this is a major problem. He declined being admitted to assisted living saying "if I'm going to die I'm going to die at home". Caller would like to know if anything like this has been reported before, if they got better, and what treatment they received to get better? He also asked if there were any reported deaths after vaccination? Events paralyzed, bedridden, can't walk, legs wouldn't move, couldn't turn around was reported as worsened, half of back is black from incident. The patient was taking Pfizer Covid Vaccine as needs to show he had vaccine to travel. He hasn't measured his height since compression fractures. Lost 20% on 3 vertebrae, so he might only be 5 feet 10 inches. He figures 20% would be an inch lost with his calculation. He can't reach around 180 degrees to measure himself. When asked to provide NDC, lot number and expiration date from vaccine card, caller stated he needed to use magnifying glass. He then stated that his vision is good.

VAERS\_ID RECVD STATE AGE\_YRS SEX VAX\_DATE ONSET\_DATE SYMPTOM\_TEXT

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He stated that he collapsed several times after his second shot. He says this happened approximately 2 to 3 days after the second shot. He called his doctor and was told to call 911. He went to the hospital. He was in the ER, but confirmed he was not admitted to the hospital. Outcome for collapsing after both doses, had worsened as mentioned by patient. Caller stated after the first vaccine, he noticed his left leg did not work very well. After first dose, he had trouble walking after 5 days. When he would try to move his left leg forward it would shake, not move and he had to slide it sideways across the floor. Right now he can get up and turn around before he pees all over himself and could not get to the bathroom before. Now he pees in a cooking pot. He asked to be excused while on call and stated he had to urinate again. Mobility got worse after first shot and then after second dose his mobility got even worse. Confirmed his compression fractures are an existing condition from 10 to 12 years ago. Reported he has gouty arthritis and it has been going on over 30 years and has constant pain for over 30 years but has always been able to walk and feed himself. The pain is not our fault. Reported that the malaise was better after 5 days, but his mobility went down. He has trouble walking. Sometimes knees would give out and he collapses. Caller states he now uses a walker, cane, and a wheelchair. If he has to go more than 10 feet, he has to have assistance. Treatment for Event: Norco 10-325: Takes up to 3 times per day. States the other day he had 45mg but was still in pain. This is discrepant but details were documented as provided. Caller states he is still in pain, but he can't get more without going to pain specialist. His doctor stopped atorvastatin and Ambien after adverse events with the covid vaccine. ER doctor wanted his primary doctor to review his medications since the ER doctor thought he was on too many medications. Caller tried to explain the reasons he was on the different medications. When talking about his gout: He has a picture after incident and half of his back is black, not blue, it is black. He was not in pain for about 2 years. Then he had the test to determine what was going on and that is when the pain got really bad. He has had bad pain for 35 years with gout in his hips especially, and in right shoulder. He cannot reach if something is in his right back pocket. Left shoulder sometimes. All the time with both hips. Also in

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right shoulder but if he does not use right shoulder then there is no problem. He was even thinking about getting a hip transplant due to the pain. His doctor did blood tests to find out that he had excess uric acid. He was on a medication called Uloric and it worked wonders but it is no longer made. Then it was found out that some people had bad reactions with it harming their heart and that was the end of Uloric. Then he started taking Allopurinol, states it does work but it works so little that it is almost worth not taking. When the pain is at 10 or 11 on pain scale, states what is the difference. He has an allergy in right sinus that caused to cough uncontrollably and his uncontrollable cough let to a perirectal abscess. He suggested to his doctor to stop his coughing and not worry about the abscess. He then went to ENT and stuck a scope down his nose and told him his sinus is inflamed and there is no infection, there is an allergy and cannot tell what the allergy is and will probably never find out what the allergy is, and prescribed him the Azelastine hydrochloride nasal spray. The pharmacist thinks the nasal spray is too much but states the pharmacist is not a physician and ENT doctor prescribed it. The two sprays a day works and he has not had uncontrollable coughing since then. Out of an abundance of caution he was sent to a lung doctor to get breathing test. Testing: He had two x-rays and CT scan of the torso. He does not know what x-rays showed. CT scan shows kidneys, liver, pancreas, and gall bladder are normal. Everything is normal except for the heart. It did not explain what was wrong with him. Clarifies he had the same CT scan at another facility a couple of years ago and he was told that calcium around the heart is normal. He knows that he has low blood pressure normally. Attempted to clarify if x-rays were off his chest, stated they stuck something under his back. States nothing was mentioned about his x-rays and if they looked at the x-rays they could see he has a broken back. No other vaccinations was done within four weeks prior to the first administration date of the suspect vaccine. Got sick the next day after the flu shot twice. Will never take again (unspecified flu shot). Patient reported about 4 years ago he let his doctor give him a pneumonia shot and his arm hurt like hell for a week, states he is never doing that again. When discussing Allopurinol, caller stated it was not working very well, but it had positive effect and he will continue taking it as long as his

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doctor will let him. States when taking it, the gout does not get better, it gets worse. Allopurinol, states it does work but it works so little that it is almost worth not taking. When the pain is at 10 or 11 on pain scale, states what is the difference. Caller states he was on a different medication before that worked better, but he could not continue to take it. Caller stated that microprint was difficult to read. He was able to give NDC number using magnifying glass. Product strength and count size dispensed: 300mg, 90 count. Expiration Date: Dec 2021. The sample of the product was available to be returned, if requested. Packaging was sealed and intact. Treatment for event was Norco 10-325: Takes up to 3 times per day. Caller states he is still in pain, but he can't get more without going to pain specialist. Confirms he has been in chronic pain for over 30 years due to gouty arthritis. Advised caller to retain sample of product in the event he receives Mailer within 3-10 business days for the return. Swap. Caller took 1st dose of Covid vaccine 16Apr2021 and collapsed the next day and then for the next 5 days he felt general malaise and weakness. On 07May2021 he took 2nd dose, 21 days after 1st dose, and again collapsed the next day. Stated that he needed to call 911 to help him get up and they took him to hospital where they did a scan of his torso and said he was fine. Doctor also told him that he did not have stroke, blood clot or aneurysm. Caller thinks it is neurological as he is still having trouble standing and walking and his left side feels paralyzed. He is wondering if these side effects were documented during clinical trials. Therapeutic measures were taken as a result of pain. The outcome of the events experienced collapsed day after vaccine first dose/collapsed day after vaccine second dose, legs wouldn't move, couldn't turn around, he had compression fractures L1 to L3 that were noticed on his x-ray, pain, half of back is black from incident, mobility got worse after first shot and then after second dose his mobility got even worse, felt like what i would call the flu was unknown, for the events his left side still feels paralyzed and can't walk, he collapsed and had a hard time getting up/felt bad, his left side still feels paralyzed and can't walk, bedridden the outcome was not resolved, for the event general malaise the outcome was resolving. Follow-up attempts are needed. Further information is expected.

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1373734	6/4/2021	IL	51	F	4/11/2021	4/20/2021	States her cholesterol is always 75 and is now 200; facial droop or pain in her face; noticed her arms started getting numb and swelling up; noticed her arms started getting numb and swelling up; facial droop or pain in her face; talk with the slur; tingling in her fingers; ended up in the emergency room and had a stroke; she had blood clots on the brain from the stroke; she went into the ER her blood pressure was 200/180; This is a spontaneous report from a contactable consumer (patient) and a contactable physician. A 51-year-old female patient received bnt162b2 (Lot Number: ER8730; Expiration Date: 31Jul2021), second dose via an unspecified route of administration, administered in left arm on 11Apr2021 (early in the morning) at the age of 51-year-old as 2nd dose, single for covid-19 immunization. Medical history included ventricular septal defect from an unknown date and unknown if ongoing (she was born with a hole in her heart but that had closed up and when she had the stroke, the hole opened back up and they told her she had blood clots on the brain from the stroke). There were no concomitant medications. The patient previous received first dose of bnt162b2 (Batch/Lot Number: ER2613; Expiration Date: 31Jul2021), via an unspecified route of administration, administered in left arm on 21Mar2021 single dose for covid-19 immunization. The patient experienced stroke on 20Apr2021, she had blood clots on the brain from the stroke on 20Apr2021, blood pressure was 200/180 on 20Apr2021, her cholesterol is always 75 and is now 200 on an unspecified date, facial droop on an unspecified date, her arms started getting numb and swelling up on an unspecified date, pain in her face on an unspecified date, talk with the slur/ slurred speech on an unspecified date. The events her arms started getting numb and swelling up, pain in her face and talk with the slur/ slurred speech were serious per hospitalization; stroke, she had blood clots on the brain from the stroke, blood pressure was 200/180, her cholesterol is always 75 and is now 200 and facial droop were serious per hospitalization, medically significant. The patient was hospitalized for from 20Apr2021 to an unknown date. The events require a visit to emergency room and physician office. Caller states she is calling about the Pfizer shot and had the 2nd dose on 11Apr2021 and noticed her arms started getting numb and swelling up and she did not do anything about it but

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2 days after that she called the facility where she had the Pfizer shot and they said to call her HCP and the HCP was out of town so she spoke with a nurse and was told to go to urgent care at that time. States she went to urgent care and they said her arm was swollen and to rub alcohol on it and she did that and a couple of days after that ended up in the emergency room and had a stroke. States the numbness and swelling was just the whole left side of her body and she went to the emergency room at the hospital on 20Apr2021 but on 16Apr2021 she went to the urgent care; states the numbness and swelling is better but comes and goes with the tingling in her fingers and the numbness, but her face is doing much better and she does not have the facial droop or pain in her face anymore; states her speech is back and she does not talk with the slur anymore. States the facial droop, face pain and slurred speech began when she went to the ER and that was on 20Apr2021 and is now completely resolved. Caller states the 1st dose of her Pfizer Vaccine was administered on 21Mar2021 with lot ER2613, the 2nd dose was administered on 11Apr2021 with lot ER8730; states both doses of the Pfizer Vaccine were administered in her left arm and her patient card does not have the NDC written on it but the expiry date for both doses of the vaccine is 31Jul2021. States the whole year of 2020 she was doing fine till she took the Pfizer Vaccine and that shot everything up regarding her cholesterol levels and Blood pressure which are all high; states her cholesterol is always 75 and is now 200; states she has high blood pressure and when she went into the ER her blood pressure was 200/180; states she was born with a hole in her heart but that had closed up and when she had the stroke, the hole opened back up and they told her she had blood clots on the brain from the stroke. The patient underwent lab tests and procedures which included cholesterol: 200 on 10May2021 (her cholesterol is always 75 and is now 200), blood pressure: 200/180 on 20Apr2021. The outcome of events for stroke, she had blood clots on the brain from the stroke, her blood pressure was 200/180, her cholesterol is always 75 and is now 200, tingling in her fingers were unknown, for other events was resolved on an unspecified date. Vaccination Facility Type: school. No Additional Vaccines Administered on Same Date of the Pfizer Suspect. No Prior Vaccinations (within 4 weeks).

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1373703	6/4/2021	MO	43	F	3/22/2021	3/1/2021	Has not had any energy; it's hard to breath with no oxygen in her blood; it's hard to breath with no oxygen in her blood; Had been checked for anemia in Apr2021 and told she was anemic/ iron has been low; period still ongoing and strong, really heavy bleeding with clots; prolonged bleeding with periods; This is a spontaneous report from contactable consumer (patient). A 43-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in arm left on 22Mar2021 09:00 at the age of 43-years-old (Lot Number: EN6204) as single dose for COVID-19 immunization. Historical vaccine included BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) as first dose on 01Mar2021 at the age of 43-years-old for COVID-19 immunization (Lot Number: EN6198, Anatomical Location: left arm); started period couple days early after first vaccine from Mar2021, caller reported she got the first Pfizer BioNTech vaccine and shortly afterwards she started her period, which was a couple days early, but it didn't stop for 10 days. It was really, really heavy bleeding along with clots and things. Medical history was none. The patient's concomitant medications were not reported. The caller asked if prolonged bleeding with periods was a side effect of the vaccine. She stated she had both doses of the vaccine and had this issue with both. She stated she knows there has been other woman who have come forward saying they have these things. At the time, her doctor had not heard anything about any reactions to it. Her iron has been low and she got tested for anemia and was anemic now. She has had her second period since the vaccine and was on day 16 of period. It was still going on strong and she was wondering if this was something that Pfizer has heard of happening after the vaccine. She had first BionTech vaccine on 01Mar2021 and her period started a day or two after that. It had gotten worse, but did subside. She was normally super regular and super normal with her periods. Stated she did have another small period in between the first and second vaccine, but that only lasted for a day, which was really weird for her and did not usually happen. Had the second dose 3 weeks after the first dose on 22Mar2021 and a couple days after that her period started and she was now on her period and on Day 16 and it's gotten worse. This one started early May,



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03May2021 and was also still going strong and really wants this to be resolved since going on her honeymoon soon. Caller clarified event of periods. She had been checked for anemia in Apr2021 and told she was anemic. Has also gone to specialist to see what's going on. They suggested a biopsy to rule out that there was nothing else going on. If nothing else works they are talking about doing an ablation to stop the bleeding or a partial hysterectomy, where they just take the uterus, since they know that's causing her anemia and since the bleeding won't stop long enough for her to get her blood supply back up where she needs it. Has not had any energy and it's hard to breath with no oxygen in her blood. Physician office was for period still ongoing and strong, really heavy bleeding with clots, iron low, anemic, no energy, hard to breath with low oxygen in blood, saw a specialist. The patient experienced period still ongoing and strong, really heavy bleeding with clots in Mar2021; prolonged bleeding with periods in Mar2021; had been checked for anemia in Apr2021 and told she was anemic/ iron has been low; Has not had any energy; it's hard to breath with no oxygen in her blood. The outcome of events was not recovered.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021568087 same patient/drug and different dose/event.

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1373296	6/4/2021	PA	43	M	2/3/2021	3/3/2021	<p>Blood clots in both lungs; Feels really tired all the time; Joints hurt; This spontaneous case was reported by a patient and describes the occurrence of PULMONARY EMBOLISM (Blood clots in both lungs) in a 43-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Acid reflux (esophageal) and Retinal migraine. Concomitant products included RABEPRAZOLE SODIUM for Acid reflux (esophageal), METOPROLOL for Retinal migraine. On 03-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 03-Mar-2021, the patient experienced FATIGUE (Feels really tired all the time) and ARTHRALGIA (Joints hurt). On an unknown date, the patient experienced PULMONARY EMBOLISM (Blood clots in both lungs) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 10-Apr-2021 to 15-Apr-2021 due to PULMONARY EMBOLISM. At the time of the report, PULMONARY EMBOLISM (Blood clots in both lungs) and ARTHRALGIA (Joints hurt) outcome was unknown and FATIGUE (Feels really tired all the time) had not resolved. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not Applicable. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 25-May-2021: Follow up received on 25 May 2021 contains no new information.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1373270	6/4/2021	CO		F	5/1/2021		HAVING ISSUES SPEAKING; FEVER; HEADACHE; This spontaneous report received from a parent concerned a 24 year old female. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine (suspension for injection, route of admin not reported, batch number: Unk) dose was not reported, administered on 21-MAY-2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On MAY-2021, the subject experienced fever. On MAY-2021, the subject experienced headache. Laboratory data included: Body temperature (NR: not provided) 100/101 F, CT scan (NR: not provided) No blood clots, and MRI (NR: not provided) No blood clots. On 21-MAY-2021, the subject experienced having issues speaking. The action taken with covid-19 vaccine was not applicable. The outcome of the having issues speaking, fever and headache was not reported. This report was non-serious.
1374014	6/4/2021			F			Blood clot in leg; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clot in leg) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clot in leg) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood clot in leg) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. No relevant concomitant medications were reported. No treatment information was provided. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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1373240	6/4/2021	MA		M		5/25/2021	<p>TWO BLOOD CLOTS; LEFT CALF PAIN FOR A COUPLE OF DAYS/FELT LIKE MUSCLE STRAIN; This spontaneous report received from a patient concerned a male of unspecified age. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 042A21A, expiry: unknown) dose was not reported, 1 total, administered on 03-APR-2021 to left arm for prophylactic vaccination. No concomitant medications were reported. On 25-MAY-2021, the patient experienced left calf pain for a couple of days which the patient believed that it was a muscle strain and was increasingly painful. On 28-MAY-2021, the patient was sent to the hospital to do an ultrasound and the HCP (health care professional) suggested for the patient to go to the emergency room visit because the patient had two blood clots. On 28-MAY-2021, the patient was hospitalized and was discharged on 28-MAY-2021. The patient was hospitalized for 1 day. Laboratory data included: Diagnostic ultrasound (NR: not provided) 2 blood clots. On the day of reporting, it was informed that the patient was taking treatment medications (dates unspecified) which included: Eliquis (apixaban) for blood clots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from two blood clot, and the outcome of left calf pain for a couple of days/felt like muscle strain was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210601553-covid-19 vaccine ad26.cov2.s - two blood clots in patient. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1371119	6/3/2021	FL	53	M	4/10/2021	4/19/2021	I went to Pharmacy on Aril 10 2021, after the vaccine I got fever for three days in a row, then four days with pain in my left leg. On the 19 I was not able to move my left leg with a lot of pain and a little discomfort on my right leg. Rush to the hospital and right away the found blood clots on my left leg, The ER did not check my right leg and two weeks later they found clots on the bottom part of my right leg. They gave me blood thinner and now Im taking Eliquis twice a day. Symptoms continue, I have the same pain, I dont see any improvent. I did went to work yesterday and I realize that I can do any lifting or be sitting down for at least one hour.
1372572	6/3/2021	OR	41	F	4/8/2021	4/17/2021	Tingly/numbness in right arm immediately with injection. Lasted about an hour. Fatigue and achiness the following day. 4/17-4/19 tingly and soreness in neck and shoulders. Virtual visit with doctor on 4/19 to discuss if symptoms were related to blood clots and/or vaccine. Week of 4/25 extremely swollen and sore lymph nodes. 5/4 -5/6 fever (101). COVID test 5/5 and negative result received 5/7. Fever returned higher (102.9) on 5/8. Virtual visit with doctor 5/10 to discuss fever and fatigue symptoms. 5/13 UTI test. No infection but blood in urine. Off and on fever and extreme fatigue continue along with loss of appetite and weight loss. 5/18 in person doctor visit to check symptoms, another UTI test and bloodwork. Blood work came back normal, UTI normal, still blood in urine. 5/20 X-ray to check for pneumonia (none found) and ultrasound on kidneys and bladder to check for infection, kidneys stones (none found). Also had more blood work done that day to check for mono (had as a teen with similar symptoms). 5/24 confirmed reactivated mono. Symptoms have slowly improved since 5/23. Another test is scheduled for the future to check the blood in urine again.

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1372065	6/3/2021	TX	47	F	4/27/2021	4/28/2021	Blurry vision and( flashing light in peripheral vision )right eye the next day after receiving the second dose on April 27,2021. Flashing light lasted for a week. Afterwards just blurry vision until May 30th vision became distorted and dark. Visited eye specialist 06/04/2021 and was advised to report to the CDC that blood clot was found in right eye. Treatment is now needed that involves injections to the right eye . (3 treatments in span of 10 weeks) with possible laser treatment if injections are not as effective. Eye Specialist -
1371903	6/3/2021	MI	33	F	4/28/2021	5/7/2021	Irregular menstruation and menorrhagia following COVID-19 vaccine on 4/28/2021. Had irregular breakthrough bleeding on 5/7 that lasted 3 days and then again on 5/20 - 5/27 that lasted greater than 7 days with very heavy clots which is irregular for patient. Patient convinced that it is due to COVID-19 vaccine. She reports compliance with daily OCP.
1371851	6/3/2021	OH	29	F	6/2/2021	6/2/2021	06/02/21 - Moderna vaccine administered at 3:30pm. Waited 15 mins at the HD without any reported side effects. When driving home, client states she felt dizzy. Developed fatigue around 5pm. At 8pm went to have a bowel movement and large amounts of red blood with small clots passed from rectum. Client states she had to flush 3 times d/ t the amount of blood. No stool passed. No other episodes reported. Client does state that around 2-3 am she was up to use the restroom and noted small amount of dried blood spots in her undergarment. Client states that she does have a h/o hemorrhoids since the birth of her baby but states this "definitely" was not related. Client reported feeling hot during the night with mild abdominal cramping but states she is to start her menstrual cycle soon. PHN questioned if she felt this was her menstrual cycle and client clearly states the blood was coming from her rectum. No further episodes of passing blood reported and states that she is feeling better today. Client states that she does not have a h/o of blood in stool except on occasion scant amounts from hemorrhoids. PHN encouraged client to report this finding to her PCP as well and that the PHN was going to report this to VAERS. No other s/s of bleeding reported to the PHN.

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1371845	6/3/2021	CA	48	F	4/9/2021	4/10/2021	I had the vaccine and around midnight I had fever and I thought that was normal but a week later I had a very intense headache and I still thought that was normal but I was worried because that was the time they had discontinued the Janssen vaccine. After that I had a very intense pain on my legs and some big and purple veins appeared from my knees down to my legs and some red veins on my thighs. The pain was unbearable, and I could not walk. I bought some creams and medicine but they did not help relieve the pain and I felt like my legs were burning and I decided to go to the ER. They did some vein exams and said I did not have thrombosis; they also did a blood test and a urine test and everything was normal. My legs still hurt until today and I really regret having the vaccine.
1371732	6/3/2021	NC	43	F	12/18/2020	1/29/2021	I began to have reddened areas as well as blanched (reynaud-like) areas on my hand as well as areas of what appeared to be micro vascular clots. I had swelling on one fingertip. Fingers were painful. I had something similar on my big toes
1371683	6/3/2021	WA	38	F	4/8/2021	4/9/2021	The day after, I woke up with a bad headache and I had the headache for a good 19 days. The doctors thought I was over-reacting. It was a bad headache on left side of head. I was just not feeling well. On the 19th day, it went away. I still from time to time I do still feel pain in the head on the left side. I had a lot of tightness in my left leg. In previous years, I have had blood clot in my leg and after birth in my stomachs - so with the pain in calf I called a doctor and went. They did a visual. After a lump appearing in my leg, an ultrasound was scheduled. I went Urgent care on May 10 - she ordered an ultrasound but her office didn't ever follow up with me. On 17th, I saw my Primary care and she sent me straight to get an Ultrasound - on the 18th, it revealed I had a blood clot.
1371668	6/3/2021	FL	49	F	5/7/2021	5/15/2021	Pain, swelling, stiffness and blood clot in left arm
1371598	6/3/2021	CO	34	F	4/27/2021	5/5/2021	Patient presented with abdominal pain and diagnosed with acute appendicitis, but CT scan showed incidental inferior vena caval thrombosis extending from iliac veins to IVC at level of liver.

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1371561	6/3/2021	MD	23	F	5/17/2021	5/17/2021	The first day, I was in a lot of pain all over my body, the normal aches and flu-like symptoms. I was in so much pain that I cried. Because I have fibromyalgia, my doctor advised that I go to the hospital because it hurt to touch my skin. I was sent to the ER a week later because my symptoms had lasted so long, I had a persistent headache, and they wanted to check for thrombosis.
1371455	6/3/2021	CA	54	F	3/8/2021	3/8/2021	The first vaccination dose when we went to the car we sat in the car for 15-30min. After about an hour I started to have Paraoxysmal dyskinesia and seizures (they are secondary condition to the MS). And I began to have this in the car. I started to have paralyze in both legs but my left leg began to hurt. And I began to have terrible diarrhea and I have Chron's disease and I have a Ileospomy bag (and I've had this since March of 2017). A week later after vaccination I had an infusion of Entyvio (biologic) which is regularly scheduled and happened to be a week after the shot. It helped the diarrhea. I contacted my GI doctor to ask if they could move up my infusion to so it could be after my next dose. They said all their patients are seeing diarrhea after vaccination and no they couldn't move it up. I continued to have pain in my legs, fatigue even after going up stairs, difficulty walking. In 2014 I had Sciatic in that leg and a blood clot so I thought it was due to that and never assumed it was a blood clot. And the pain was getting worse each day but I assumed it was all related to the Chron's and not a blood clot.
1372605	6/3/2021	TX	53	F	4/3/2021	4/28/2021	i had a blood clot which caused a stroke
1371273	6/3/2021	NJ	33	F	4/10/2021	4/10/2021	am facing stomach pain and some blood clots and gas problem at stomach



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1371791	6/3/2021	CA	45	F	5/11/2021	5/12/2021	THE MORNING AFTER MY VACCINE MY TOES AND LEGS WERE NUMB AND TINGLY AND FELT HEAVY AND FELT WEIRD WALKING. I HAVE NEVER FELT THIS FEELING BEFORE, IT WENT AWAY PRETTY MUCH AFTER A COUPLE DAYS AND THEN CAME BACK A WEEK LATER E VEN WORSE THEN BEFORE AND STAYED FOR AT LEAST 3 DAYS SO I WENT TO URGENT CARE AND THEY SAID IT WAS NOT A BLOOD CLOT AND THEY DIDNT KNOW MUCH ABOUT THE VACCINE. NOW OVER 3 WEEKS LATER I STILL HAVE NUMBNESS IN MY TOES AND LEGS. IT COMES AND GOES, SOME DAYS ARE WORSE THAN OTHERS.
1370997	6/3/2021	MI	75	F	5/10/2021	5/24/2021	Systemic: Blood Disorder (diagnosed by MD)-Severe, Additional Details: Patient was diagnosed with blood clot few days after J&J covid vaccine. Patient was treated in the hospital and doing better.
1370663	6/3/2021	TX	55	F			The first Pfizer shot landed me in the hospital with blood clots and pneumonia; The first Pfizer shot landed me in the hospital with blood clots and pneumonia; This is a spontaneous report from a contactable consumer (patient). A 55-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as 1ST DOSE, SINGLE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The first Pfizer shot landed patient in the hospital with blood clots and pneumonia. The outcome of events was unknown. Information about lot/batch number has been requested.

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1370660	6/3/2021	TX		F			Blood clot disorder; This is a spontaneous report from Pfizer sponsored program. A contactable female consumer (patient) reported for herself that she received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 on an unspecified date and dose 2 on 19May2021, both via an unspecified route of administration (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. Caller went on her 2nd dose today 19May2021, she was asked a question if she had a blood clot disorder, she was not asked about this on the 1st dose, and apparently, she was having a blood clot disorder on an unspecified date. She asked the people in the facility if she needed to be concerned, and they said that she didn't need to worry about it, however she wanted to make sure that everything was fine or should she watch out for something. Outcome of event was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.

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1370626	6/3/2021			F	3/31/2021		stroke; blood clots on her legs, lungs and head; blood clots on her legs, lungs and head; blood clots on her legs, lungs and head; This is a spontaneous report from a contactable consumer (patient son). A 77-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration on 31Mar2021 (Batch/Lot number was not reported) as single dose for COVID-19 immunization. Medical history was none. Historical vaccine included BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) as 1st dose on 10Mar2021 for Covid-19 immunization. After having the first dose she told him that she could not make a whole 20 minute walk as she used to, she could for 10 minutes as she felt tired. She presented a consistent cough, that was not "bad". The patient's concomitant medications were not reported. Caller stated that he would like to consult about side effects of the Pfizer Covid-19 vaccine that may have caused his mother to be passing away right now. Stated that they both received the first dose on 10Mar2021 and the second dose on 31Mar2021. A month and a week later she went to her sister's house and this Tuesday he received a phone call where they stated that she had a stroke due to blood clots on her legs, lungs and head. They just left the hospital and the nurse stated that she could have hours or a couple of days left. He would like to consult if there are any reports of these side effects. The outcome of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021568883 same patient, different dose/events

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1370597	6/3/2021	CO	72	F	5/14/2021	5/1/2021	Slight puffiness on her left cheek; Swollen lymph nodes; Light tightness in her throat; Her lymph nodes remain just a little tender but are no longer swollen; This is a spontaneous report from a contactable consumer (patient). A 72-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0179), via an unspecified route of administration in arm left on 14May2021 08:00 at single dose for COVID-19 immunisation. Medical history included triple coronary artery bypass graft (CABG) on 20Apr2019, and deep vein thrombosis (DVT) and pulmonary embolism (PE) blood clots following a surgery 2 years before. Concomitant medications included simvastatin taking for a year and a half at 100 mg one time per day for blood cholesterol, fenofibrate taking for years at 145 mg tablet one time a day by mouth for blood cholesterol, apixaban (ELIQUIS) at 5 mg tablet twice a day by mouth for blood clots from 20Apr2019, alendronate sodium (FOSAMAX) taking for about 6 months or so at 35 mg one tablet on Mondays for bone density abnormal, eicosapentaenoic acid ethyl ester (VASCEPA) at 1VM capsule, 2 capsules in the morning and 2 capsules at night, and a lot of vitamins taking for years. The patient experienced a slight puffiness on her left cheek, very swollen lymph nodes, and light tightness in her throat when she woke up on 15May2021. She said she took diphenhydramine hydrochloride (BENADRYL) which helped make her feel better. She thought she only had a mild reaction since she did not feel the need to call (with held). Patient wanted to know if she should still receive the 2nd dose based on the reaction she had with the 1st dose. They told her if she had a reaction she would have within a few minutes or an hour of getting the vaccine, she was just different, she would have reactions to some things the next day. Within a day the lymph nodes went down and she felt like it had cleared up, her lymph nodes remained just a little tender but were no longer swollen. Outcome of the events was resolving.

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1370583	6/3/2021	WI	64	F	3/22/2021	4/24/2021	<p>did get a positive COVID case after receiving the Pfizer, both of them, a month later; did get a positive COVID case after receiving the Pfizer, both of them, a month later; This is a spontaneous report from a contactable nurse (patient). A 64-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), on 24Feb2021 15:00 (Lot: EM9810) as 1 st dose, single then on 22Mar2021 10:00 (Lot: ER2613) as 2 nd dose, single; both via an unspecified route of administration in right deltoid (at the age of 64-years-old) for covid-19 immunisation. The vaccination facility type was a clinic and was not administered at a military facility. No additional vaccines administered on same date of bnt162b2 and no prior vaccinations (within 4 weeks). No events following prior vaccination. Medical history included ongoing hypertension (diagnosed more than 15 years ago), ongoing arthritis reactive (diagnosed probably 10 years ago, maybe 15 years ago), obesity (thinks too heavy for her height, not severely obese) and non-smoker (not former smoker). No family medical history. Concomitant medication included methotrexate for arthritis. On 24Apr2021, the patient experienced sore throat, severe cough, headache, body aches and fatigue which were considered non-serious. The cough lingered and she was a little bit more tired than normal, but she has some of that anyway. The patient recovered completely from everything except the fatigue, still having a little bit of fatigue, it was ongoing, not bad, improved. On 26Apr2021, the patient did get a positive COVID (Covid 19 PCR) case after receiving the Pfizer, both of them, a month later which was considered non-serious. No antibody testing and antigen test done. The patient stated that when she called her doctor, they did advise that she get the Monoclonal antibody infusion. Therapies for COVID-19 included monoclonal antibody infusion, it was a 2 to 3 hour procedure at the hospital. It was an experimental thing, she signed all the forms, it was supposed to boost all her antibodies, hopefully it boosted hers between Covid and that she should be good she was hoping. The patient went to her physician's office for a COVID test. The patient got her first symptom on 24Apr2021. The patient had been contacted that she had been exposed to somebody else who also had been immunized. The patient was with her, she contacted her</p>

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and then developed symptoms on 24Apr2021 and she didn't go in to get tested until Monday, 26Apr2021. The patient considered it very mild, but she did get the antibody infusion also when she got it. All of the events required a visit to the physician's office but not on emergency room. The patient was not hospitalized, not admitted to an intensive care unit. The patient did not display clinical signs at rest indicative of severe systemic illness. The patient monitored her oxygen levels twice a day and they were fine. They sent her a home monitoring set up, she took her vital signs twice a day for two weeks and everything was fine. The patient did not require supplemental oxygen (including high flow or ECMO) or receive mechanical ventilation. The new or worsened symptoms/signs during the COVID-19 illness experienced was cough but no on the following: multiorgan failure, respiratory, dyspnea, tachypnea, hypoxemia, COVID pneumonia, respiratory failure, acute respiratory distress syndrome. On cardiovascular, no heart failure, cardiogenic shock, acute myocardial infarction, arrhythmia, myocarditis and other. On Gastrointestinal/Hepatic, no vomiting, diarrhea, abdominal pain, jaundice, acute liver failure and other. On vascular, no deep vein thrombosis, pulmonary embolism, limb ischemia, vasculitis and other. On renal, no acute kidney injury, renal failure and other. On neurological, no altered consciousness, convulsions/seizures, encephalopathy, meningitis, cerebrovascular accident and other. On hematological, no thrombocytopenia, disseminated intravascular coagulation and other. On dermatological, no chilblains, erythema multiforme and other. The events did not require initiation of new medication or other treatment or procedure. No pre-existing diseases worsened during the SARS-COV2 infection. The patient was retired now, but she worked as an RN. The outcome of the events was recovered in 2021. The patient considered the events "did get a positive COVID case after receiving the Pfizer, both of them, a month later" were unrelated to bnt162b2. Follow-up attempts are needed. Further information is expected.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation.

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1370581	6/3/2021	NC	43	F	1/11/2021	5/7/2021	COVID-19 confirmed by positive COVID-19 test; COVID-19 confirmed by positive COVID-19 test; This is a spontaneous report from a contactable nurse (patient). A 43-year-old female patient received bnt162b2 (Pfizer-BioNTech COVID-19 vaccine), dose 2 via an unspecified route of administration on 11Jan2021 20:10 (Batch/Lot Number: EK9231, NDC numbe: 59267-1000-01) as 2nd dose, single and first dose (Lot number: EK5730) on 21Dec2020 in the left arm for Covid-19 immunization. Medical history included rheumatoid arthritis from 2007 and ongoing (diagnosed with rheumatoid arthritis when she was 27 years old, in 2007 or 2008) and ongoing immunosuppression which is related to rheumatoid arthritis. Concomitant medications included hydroxychloroquine sulfate (PLAQUENIL S); bioflavonoids nos, calcium ascorbate, hesperidin, rutoside, sodium ascorbate, zinc amino acid chelate (VITAMIN C 1000 PLUS ZINC & BIOFLAVONIDS); zinc chloride; calcium carbonate, colecalciferol (VITAMIN D 2000); naphazoline hydrochloride (EYE DROPS [NAPHAZOLINE HYDROCHLORIDE]); progesterone (PROGESTERONE) all taken for an unspecified indication, start and stop date were not reported. On 07May2021, the patient got Covid-19 after getting Covid-19 vaccine. The patient went to the Emergency Room and got an infusion by Regeneron (endevimir and casevimir) which her symptoms started improving within 5 minutes of receiving the infusion. The patient was not hospitalized/admitted to ICU. The patient did not require supplemental oxygen or receive mechanical ventilation. Patient reported that she got Covid-19 from somebody when she was in an open-air environment and her mask was off. During her Covid-19 infection, she took Benadryl 25 mg at night and Sudafed every 4 to 6 hours throughout the day. She received no sinus relief from the Benadryl or Sudafed prior to receiving the monoclonal antibody infusion. The patient display signs at rest indicative of severe systemic illness which is fever of 102 and symptoms/signs during the Covid-19 illness experience which includes dyspnea, mostly at night and had difficulty breathing due to extreme sinus congestion; diarrhea and nausea; leg pain and thought that she was getting a clot or something which patient started taking blood thinner the day after she was diagnosed with Covid-19; Covid fog where she feels really spacey and out of it

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and has been experiencing headaches and ears were so full that they felt like they were going to explode. The patient reported that she is still experiencing lingering effects of her Covid-19 infection - fatigue, Covid fog, and headaches. The patient underwent lab tests and procedures which included covid-19 test on 07may2021: positive and D-dimer negative on 07May2021 and basal metabolic rate on unspecified date with unknown result. The outcome of the events was recovering. No follow-up attempts are needed. No further information is expected.; Sender's Comments: The association between the event lack of effect (COVID-19 infection) with BNT162b2 can not be fully excluded.



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1370524	6/3/2021	MD	37	M	5/1/2021	5/2/2021	chest pains; shortness of breath, will walk up 3 stairs and gets winded; This is a spontaneous report from a contactable consumer(patient's wife). A 37-year-old male patient received second dose of bnt162b2(BNT162b2 PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Batch/Lot Number: EW0172), via an unspecified route of administration in right upper arm on 01May2021 at around like 11:00 or so as a single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Batch/Lot Number: UNKNOWN), Reporter stated the lot number for the first dose of the vaccine is either ER8734 or EK8734, she can't read the person's handwriting on the vaccine record card) via an unspecified route of administration in right upper arm on 10Apr2021 as a single dose for covid-19 immunisation. Reporter stated after the first dose of COVID 19 vaccine, her husband was pretty much out of it, like completely out of it. She was concerned and was like "are you going to wake up today?". The fatigue was very real and then his neck was super swollen on one side. and said that was the only side effects from the first one, it was nothing horrible. She confirms the fatigue was either 2 or 3 days after her husband received the first dose of the vaccine and it lasted a good 3 to 4 days where he was beyond fatigued. His neck being super swollen started pretty soon after the first dose, either the next day or 2 days later and lasted for a week or so was really sore when he touched it. The reporter stated Family Medical History Relevant to AE includes her husband mother had a heart attack in her 50s and his paternal grandpa died of hardening of arteries when he was 32 years old. On 02May2021 it was reported that patient started having chest pain really bad which it has not improved whatsoever. He was told to go to the urgent care on 03May2021 night and also reported the shortness of breath; will walk up 3 stairs and gets winded or walks across the room and his whole chest is in so much pain. The AE resulted in the visit of emergency room. The reporter reports concern and asks if she was supposed to report this to Pfizer or if any other patients have had really bad, painful chest issues. The patient underwent lab tests and procedures that included:

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cardiac enzymes and CT scan: normal, blood clot test: looked good and COVID-19: test results were lost on an unspecified dates. Therapeutic methods included: it was told him to just take Tylenol, 1000mg every 6 hours for a day. She clarifies her husband took Acetaminophen 1000mg, every 6 hours. The outcome of the events was not recovered. She confirms her husband's chest pain is about the same. No further details were provided or obtained. Description of Product Complaint: Caller received his second dose of the COVID-19 Vaccine. He started having chest pain really bad which it has not improved whatsoever. He was told to go to the urgent care Monday night. At the urgent care, they ran all the tests, like typical heart attack type tests, and everything is fine. However, the pain is still the same today. Follow-up attempts are completed. No further information is expected.

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1370522	6/3/2021	NM	76	F	3/31/2021	3/1/2021	and pain down to the foot, ankle and calf areas, after second vaccine; Headache: left side and right side of head, frontal area, feels like it is travelling from her arm to her head, after the second vaccine; Face spasms on the left side of face; after the second vaccine and it was worsened; Chills, after first and second vaccine; Injection site sore after first and second vaccine; Arm was numb, tingley and painful from the shoulder to the fingertips after first and second dose; Left side of the body had tingling, numbness; This is a spontaneous report from female contactable consumer (Patient). A 76-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE Solution for injection, lot number was not reported) via unspecified route of administration, administered in left arm on 31Mar2021 at 14:00 (at the age of 76-years-old) as single dose for COVID-19 immunization. Patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE Solution for injection Batch/Lot number: EN6204) via unspecified route of administration in left arm on 03Mar2021 at 14:00 as single dose for COVID-19 immunization and on same day patient experienced outbreak, looked like hives, on her torso and stomach area, chills, injection site sore (which subsided after 18-days), arm was numb, tingley and painful from the shoulder to the fingertips. Medical History and concomitant medications were not reported. No additional vaccines administered on same date of the Pfizer suspect. No vaccinations within 4 weeks prior vaccinations. On 31Mar2021 (same day of 2nd dose of vaccination), patient experienced face spasms on the left side of face, after the second vaccine which was intermittent in the evening, headache: left side and right side of head, frontal area, feels like it is travelling from her arm to her head and left side of the body had tingling, numbness and pain down to the foot, ankle and calf areas, along with the events of first dose, which were worsened after second dose that included chills and injection site sore (which subsided 18-days after first dose), arm was numb, tingley and painful from the shoulder to the fingertips. Patient required to visit physician office, primary care doctor for her numbness, tingling and pain. Reporter stated she was very interested in percentages in age groups who have experienced any numbness and tingling and asked if

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1370335	6/3/2021	KY	51	F	2/25/2021	3/26/2021	<p>there are any correlation with developing blood clots and would like the information to see if she needs further medical attention and to prevent a serious outcome and discuss it with her doctor and agrees to be transferred to Medical Information. The outcome of all the events was not recovered. No follow-up attempts are needed. No further information is expected.</p> <p>Blood clots in lungs, legs and brain; She cant speak or stand on her own/in diaper; This spontaneous case was reported by a non-health professional (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Blood clots in lungs, legs and brain) and PHYSICAL DISABILITY (She cant speak or stand on her own/in diaper) in a 51-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 048A21A and 022M20A) for COVID-19 vaccination. No Medical History information was reported. On 25-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 26-Mar-2021, the patient experienced THROMBOSIS (Blood clots in lungs, legs and brain) (seriousness criteria hospitalization prolonged and medically significant) and PHYSICAL DISABILITY (She cant speak or stand on her own/in diaper) (seriousness criterion hospitalization prolonged). The patient was treated with HEPARIN (intravenous) at a dose of UNK dosage form. At the time of the report, THROMBOSIS (Blood clots in lungs, legs and brain) and PHYSICAL DISABILITY (She cant speak or stand on her own/in diaper) outcome was unknown. Concomitant medications were not provided. Reporter stated that hospital is trying to send the patient to a nursing home. No further treatment information was not provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1370292	6/3/2021	TX		M			BLOOD CLOTS; This spontaneous report received from a patient concerned a male of unspecified age. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine (suspension for injection, route of admin not reported, batch number: unknown) dose was not reported, with frequency 1 total administered on 08-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced blood clots. It was reported that the patient experienced blood clots after receiving the vaccination for which the prison has failed to provide the medical treatment. The action taken with covid-19 vaccine was not applicable. The outcome of blood clots was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: covid-19 vaccine Blood clots. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1370277	6/3/2021	OH	79	F	4/3/2021		DEEP VEIN THROMBOSIS (BLOOD CLOT); FELT UNWELL; SLIGHT HEADACHE; FELT TIRED; This spontaneous report received from a patient concerned a 79-year-old female. The patient's height, and weight were not reported. The patient's concurrent conditions included penicillin allergy, and other pre-existing medical conditions included the patient had not been tested positive for covid-19 and did not had covid-19. The patient experienced drug allergy when treated with ciprofloxacin, and pethidine. On 02-Apr-2021, the patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: 1808980, and expiry: Unknown) dose was not reported, 1 total administered on left arm for prophylactic vaccination. Non-company suspect drugs included: rivaroxaban (form of admin, route of admin, and batch number were not reported) 15 mg, 2 times every 1 day, from APR-2021, and 15 mg, every 1 day, from 04-MAY-2021, frequency was not reported for deep vein thrombosis. The patient was not taking any concomitant medication while reporting. On 03-Apr-2021, the patient experienced slight headache and felt tired. On the evening of 29-Apr-2021, the patient went to the hospital where the sonogram was performed. Laboratory data included: Sonogram (NR: not provided) Not reported. On Friday, 30-Apr-2021, the patient could hardly walk and had painful leg (pain in back of legs especially calf area and spreading) and on 30-Apr-2021, was admitted to the hospital. The hospital asked her to see family doctor. After discharge, the hospital told that patient had deep vein thrombosis (blood clot). The patient was prescribed Xarelto (rivaroxaban) in hospital and the patient went to family doctor next morning. The family doctor told her to start Xarelto. She was started on Xarelto 15 mg (30mg daily) twice a day from hospital discharge. The family doctor changed the dosage due to age and small size after 5 days to 15 mg daily because patient felt unwell on twice a day dose. The patient had been on Xarelto 15 mg daily since 04-May-2021. The patient would follow up with family doctor on 07-Jul-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from slight headache on 06-APR-2021, and was recovering from deep vein thrombosis (blood clot), and felt tired. This report was serious (Hospitalization Caused / Prolonged).; Sender's

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							Comments: V0: 20210556796-COVID-19 VACCINE AD26.COV2.S- Deep vein thrombosis. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.
1371386	6/3/2021	OH	30	F	4/24/2021	6/1/2021	30yof, 36w pregnant, came to clinic on 6/1 with 2 week history of lower leg tenderness and edema. Doppler confirmed on 6/1 that patient had an acute proximal DVT in the left lower extremity, with occlusive thrombus within the distal femoral vein. She denies personal history of clot; this is her 2nd pregnancy; she notes no family history of clot; this pregnancy is complicated by excessive weight gain (current BMI 32.28 kg/m2). Pt received Pfizer COVID vaccine on 4/24/21.
1371727	6/3/2021	CA	68	F	4/6/2021	5/27/2021	Patient is a 69 year old female who was admitted on 5/27/2021 for CEREBRAL VENOUS SINUS THROMBOSIS. Patient is a 69 year old female "who lives at home with husband. Patient with a h/o DM2, hyperlipidemia, epilepsy followed by Dr. neurology outpatient, hypertension. Patient on keppra and tegretol with some episodes of partial seizures, sensitive to being off medications. Patient was in usual state of health until today. Daughter noticed around 6 PM patient was confused, altered, dizzy, not able to walk, and had left arm weakness. The patient's sister had a stroke in the past and they were concerned for this and so brought her in for evaluation when she didn't improve. Daughter thinks patient might have started having symptoms around 1 PM. Daughter reports patient was not taking her aspirin, and they never picked up the lisinopril that was prescribed for blood pressure in the past. She did have the J&J covid vaccine 6 weeks ago.

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1367537	6/2/2021	NV	77	F	5/28/2021		DEEP VEIN THROMBOSIS; PULMONARY EMBOLISM; This spontaneous report received from a patient concerned a 77 year old female. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient was not pregnant at the time of report. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, Expiry: Unknown) dose not started, 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company was unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 28-MAY-2021, the patient developed deep vein thrombosis and had pulmonary embolism throughout the body. The patient was prescribed with xarelto ((but had not started) to treat deep vein thrombosis and pulmonary embolism. The patient stated that she had no health conditions or concerns before the vaccine. The patient took no medications nor she did any pharmacy coverage. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the pulmonary embolism and deep vein thrombosis was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210558443-covid-19 vaccine ad26.cov2.s -pulmonary embolism ,deep vein thrombosis . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).



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1367226	6/2/2021	MO	43	F	3/1/2021	3/1/2021	<p>started period couple days early after first vaccine, second period since the vaccine and is on Day 16 of period; heavy bleeding along with clots and things; This is a spontaneous report from a contactable consumer. A 43-years-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Solution for injection, Batch/Lot Number: EN6198), via an unspecified route of administration, administered in Arm Left on 01Mar2021 as 1st dose, single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient had no history of all previous immunization with the Pfizer vaccine considered as suspect. On Mar2021 the patient experienced heavy bleeding along with clots and things and started period couple days early after first vaccine, second period since the vaccine and was on Day 16 of period. It had gotten worse but did subside. States she had another small period in between the first and second vaccine, but that only lasted for a day. She had the second dose 3 weeks after the first dose on 22Mar2021 and a couple days after that her period started early on 03May2021 and she is now on her period and on Day 16 and it's gotten worse. She had issues with both doses and enquired if prolonged bleeding with periods was a side effect of the vaccine and how long these periods last and if they ever end. She stated she knew there were other women with these things. She got the first Pfizer BioNTech vaccine in 01Mar2021 and shortly a day or two afterwards her period started, which was a couple days early and did not stop for 10 days. It was really, really heavy bleeding along with clots and things. She was tested for anemia in Apr2021 and her iron was low and was found to be anemic. She went to a specialist and was suggested a biopsy to rule out that there was nothing else going on. They suggested for doing an ablation to stop the bleeding or a partial hysterectomy if nothing else worked. She did not had any energy and it was hard to breath with no oxygen in blood. The outcome of the event heavy bleeding along with clots and things and started period couple days early after first vaccine, second period since the vaccine and is on Day 16 of period was unknown.</p>

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1367220	6/2/2021	TX	70	F	5/17/2021	5/17/2021	<p>felt like someone was putting pins on her head/it hurt; The joints were hurting/It was stiff; The joints were hurting/It was stiff; When she was asleep she was seeing green and another color bright shells going; someone poking her with a needle in her leg; all over her body it felt like pins going in; stiff; Her knees were hurting; headache; had a horrible feeling and felt like the walls were crawling in; pains all over the body; Eyes are hurting; This is a spontaneous report from a contactable consumer (patient). A 70-year-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection; Batch/Lot number: It is handwritten. It is either EW0186 or EWD186., Expiration date: Unknown), via an unspecified route of administration in right arm on 17May2021 as single for covid-19 immunization. The patient's medical history included has been in the hospital three times this last year. They put a lot of shots in her stomach for blood clots. Patient was hospitalized for pneumonia, hysterectomy, and COVID19. She had all the hospitalizations in 2020. When she got home after she had pneumonia, 2 days later she had COVID19 because one of her family members had it. Hospitalizations were prior to COVID shot. She has had fever shot and pneumonia shot and not had this issue. She gets the fever shot every year. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not receive any additional vaccines on same date of the Pfizer Suspect. Patient took COVID shot on 17May2021, Monday and everything was ok. It did hurt when they stuck the needle in. Eight hours later she felt like someone was putting pins on her head. She rubbed it because it hurt. The joints were hurting on her right side where they put it. It was stiff. She did exercise and started moving it because she didn't want it to be stiff. It has been hurting. When she was asleep she was seeing green and another color bright shells going. She was experiencing someone poking her with a needle in her leg. All over her body it felt like pins going in. Patient's knees were hurting. She got up in the morning and last night she had pains all over the body. For 8 hours it was stiff but then it was fine. She also had pain on the left. She has not had a fever. Patient's eyes are hurting on 17 May 2021. It is like a</p>

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1367204	6/2/2021			F	5/14/2021	5/16/2021	<p>headache, get a little and eyes hurt. She went to work Wednesday, she had a horrible feeling and felt like the walls were crawling in. She is supposed to go in three weeks for second dose. The second shot would be worse, and she feels like that will be a danger. She expressed her concerns about the second shot as she read in the paper that the second one is more stronger. She doesn't plan to get the second one. Something could happen to her with the second shot. The paper said the second shot would have side effects. The people that have done the second shot got sleepy, dizzy, and weak. She want to make sure she can get to work but was still experiencing the adverse events. The outcome of eyes are hurting was not recovered, while with other events was unknown. No follow-up attempts are needed; information about lot/batch number cannot be obtained.</p> <p>felt like a little fuzzy; Lot of discomfort; warm spots on her skin; Headache; Blood clots; itchy red rash; This is a spontaneous report from a contactable consumer (parent of the patient). A 13-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EW0185), via an unspecified route of administration on 14May2021 as 1st dose, single for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. On an unspecified date the patient experienced blood clots, really warm spots on her skin in one of her legs, front of her thigh and her knees, her arms the tip part between her elbow and wrist on both of them, like where you can feel it's warm to the touch, lot of discomfort, headache and she kind of feel like a little fuzzy like in her thinking, she said she felt like she was forgetting things like what you guys were saying. On 16May2021, she developed an itchy red rash on her legs and over her knees and on the tops of her arms from her wrist to her elbows. She has taken Benadryl to treat but it did not help. She is calling to see if this has been reported before. The outcome of events was unknown.</p>

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1367190	6/2/2021	OR	67	F	2/18/2021	2/28/2021	bradycardia and tachycardia episodes; bradycardia and tachycardia episodes; sudden onset chest pain; small vessel stroke in her brain stem; diagnosed with dysautonomia; diagnosed with POTS; Shortness of breath; fine hand tremors; burning hand syndrome; GI burning and belching / burning abdomen; GI burning and belching; blood pressure issues; chest discomfort; exercise intolerance; little waves of hot flashes; O2 sat variations; not well; light headedness and profound weakness; light headedness and profound weakness; This is a spontaneous report from a contactable nurse (patient). A 67-year-old female patient received BNT162B2 (lot number: EM9809 or EM9509) second dose on 18Feb2021 (vaccination age 67-year-old) on left arm at single dose for COVID-19 immunization. Medical history included ongoing Trigeminal neuralgia from Dec2020 (diagnosed 5 month ago after shingles vaccine), continuously being worked up by her primary for autoimmune disorders, she had a stroke in her brainstem. Concomitant medications included carbamazepine (TEGRETOL) for Trigeminal neuralgia (Has been taking for 5 months since being diagnosed with trigeminal neuralgia. She mentions its the only thing that calms the nerve down). Historical vaccine included BNT162B2 (lot number: EN5318) first dose on 25Jan2021 (vaccination age 67-year-old) on forearm left deltoid for Covid-19 immunization and shingles vaccine Shingrix on 17Dec2020 (vaccination age 67-year-old) for immunization and developed a neuropathy (3-4 days later) and trigeminal neuralgia 4 days post-shingles vaccine. 10 days post second dose of Covid vaccine (28Feb2021), she developed sudden onset of chest pain and lightheadedness and profound weakness. She was driving to her son's house and got to the nearest hospital and she was worked up for a blood clot and a heart attack. Everything came up negative but she had bradycardia. So, she was put on a 20 day monitor and she had signs of tachycardia, bradycardic episodes with activity and exercise intolerance. She is still continuing with the chest pain and she ended up in the emergency room two more times, hospitalized once, and she had a angiogram. The cardiologist gave her a diagnosis of POTS and the internal medicine gave her a diagnosis of dysautonomia. She is continuously being worked up by her primary for autoimmune disorders. Finally, her

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primary doctor threw up her hands and said "I don't know" because she continued to have other symptoms like light headedness, and shortness of breath. Of course, it is all linked to random surges of fine hand tremors and her heart would start racing where she may just be standing at the sink. Cardiology didn't want to do anything with her because she was in normal sinus rhythm. The caller explains she was told they saw a lot of tachycardia and bradycardia but she was in normal sinus rhythm, she didn't belong with a cardiologist. Five months ago, she got the shingles vaccine and developed trigeminal neuralgia 4 days post-shingles vaccine. At that point they did an MRI of the brain, thinking maybe she had MS because that is one of the side effects of MS, but she didn't. She had a normal MRI. She has been to neurology and has had a lot of testing done. She knows the long hauler's with COVID are coming up with dysautonomia. However, she has had multiple Covid tests and is very, very safe. She does not believe that she had Covid, but she does believe this may be a reaction to both the shingles vaccine with the trigeminal neuralgia and the Covid vaccine. Before these vaccines, she was on absolutely no medications and was completely healthy. These 2 vaccines, whether it's in her genetic system or whatever, but she continues to have GI burning, belching and burning hands. They did another MRI and found she had a small vessel stroke in her brain stem. There are so many things that are happening to her right now. She is also seeing rheumatology. She just is not well. Though the CDC doesn't know about her newer symptoms, she reported to the CDC what she had at the time. They haven't gotten back to her on either of them. Five months ago was the shingles vaccine and she would have thought they would have reached back out to her because it is truly too coincidental that she takes a shingles vaccine and 3-4 days later develop a neuropathy, and the shingles vaccine is supposed to prevent neuropathy. She is so active. She walked coast to coast, and now literally just even walking up a flight of stairs, her heart rate goes up to 115 to 120. She can be at rest and her heart rate can be in the 40's. She is also having blood pressure issues as well. Her blood pressure can be 89/46 and then be 152/90, so she is just kind of an "autonomic nervous system mess". Her primary care referred her to a neurologist and a rheumatologist whom

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she will be seeing Wednesday. She doesn't know what other specialties she may ended up seeing. The MRI was supposed to help find reasons for all these symptoms, but in fact, all it did was add another condition to her already perplexing condition. She submitted one report via CDC for the shingles vaccine on 17Dec2020, which three days later, she had trigeminal neuralgia. Her symptoms are ongoing and it's not disappearing like she had hoped. It keeps progressing and she keeps getting new symptoms. Sudden onset chest pain: Was 10 days after the vaccine, while driving to her son's house. She also developed light headedness and profound weakness. She went to the hospital (ER) and was sent home. 3 days later, she was still having significant chest pain so she went back into the ER. She was on a monitor that was showing all of these tachycardic and bradycardic episodes. She wasn't getting contacted but she was still having pain. The third time she went into the ER, she was admitted to the hospital. They transported her to cardiac care and they did an angiogram, which is when she was given the diagnosis of dysautonomia and POTS. The neurologist says that she does not have POTS because she is not presenting with consistent orthostatic hypotension and tachycardia when he does the TILT test. However, she has a lot of autonomic symptoms, so the doctor decided to do an MRI. Her previous doctor was doing all of this autoimmune testing that was coming back negative. She was tested for an adrenal tumor and had urine tests which got ruled out because she is surging, it is obvious she is having adrenal surges. The caller doesn't believe her doctor was convinced he would see anything on the MRI, so when he called her and told her she had a small vessel stroke in the pons/ medulla area, he thought maybe it could attribute to the symptoms. However, these new GI symptoms she is having does not fit. Therefore, they are continuing to do more studies like gastric emptying, a skin biopsy, CAT scan and an angiogram. She is meeting with a rheumatologist on Wednesday. She also adds she will probably do an MRI of the abdomen because she is having such a burning abdomen. She is waking up in the middle of the night with her abdomen just on fire. It seems like she is continuing to just add new symptoms. The chest pain goes away and she only gets it when she gets tachycardia or when she is taking a walk- it's not

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having it continuously. She had burning hand syndrome, it was burning hands in a bath, which that that lasted an hour when she was getting out of the bath and she hasn't had that since. Everything is kind of a weird conglomerate of dysfunction, like the blood pressure variations, O2 sat variations. She just wants answers. She is adjusting and adapting. But, she does want to bring this to Pfizer's attention because maybe genetically there is something in her that even though the COVID vaccine is not a live virus, the idea is to mimic the live virus to give you immunity, and long hauler's are experiencing some of these symptoms that she is having. Not that Pfizer is going to do anything differently- she is still encouraging vaccines and she is not telling many people because she doesn't want people to use this as an excuse to not get the Covid vaccine. Caller confirms the dates of all of these events were reported to the CDC. Her doctor would have all of the dates including the dates of the angiogram, ER visits, the findings, and then the testing dates. Dates are unknown by the caller. She confirms she was in the emergency room 3 times, she was admitted and transferred to Cardiac care on the third time. She believes she was admitted for 3 days. She believes she was admitted in the evening, they did the angiogram the next day and she was discharged the following day. The MRI that was sent in 01 Dec 2020 was negative for anything. The MRI that was done last Thursday, 07 May or 09May2021 showed an infarct. So, she did have an MRI that was clear in December and then the recent MRI showed the stroke. They are doing a CAT scan angiogram 28May2021. She explains she has no lifestyle history for developing a stroke. She wasn't even on baby aspirin or any statins. Now, they are now wanting to put her on statins. Before this, she had no history. She confirms her ER visits and one hospitalization were after the COVID vaccine and was all based on chest pain. The caller confirms the only thing that happened to her after the shingles vaccine was that she was in excruciating pain and then the doctor got an MRI going and determined she had trigeminal neuralgia. She was never hospitalized or went to the ER for the shingles vaccine. The chest pain she still gets on and off. Last night, she had it. She can get chest pain when she is walking. The chest pain is not continuous and consistent, it's more based on activity. Last night, her

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whole intestines were burning and she noticed "oh I'm feeling some chest discomfort". She is not worried about the chest pain anymore because she knows it is either a bradycardia that her chest is unhappy with or tachycardia that her heart is unhappy with and it's giving her discomfort. Her heart rate can literally go from 50 (which is bradycardic) to 120 in less than 5 -10 seconds. Her heart just goes racing like she is having a marathon, that's how fast it goes. It will last this way for a minute and her heart rate will eventually meander it's way down so that's why she thinks she is getting chest pain. She works with elders and wanted to keep the world and community safe. She wanted to get back into the world and see her mother who is in a nursing home. Caller mentions she was taking 200mg twice a day of the Tegretol (before the COVID vaccine). She had to up her dosage because she had another outbreak so now her dose is 300mg, twice a day. She clarifies a tooth infection flared up her trigeminal neuralgia. All of the auto immune results were negative, except the MRI, which she thinks is the only thing that was positive. She is doing an autonomic test in September. At this point, her doctor has given a diagnosis of dysautonomia and she is presenting as such. Her neurologist is needing verification and so he is not giving her a diagnosis even though she has all of the symptoms of dysautonomia. Vaccination Facility Type: administered it to their elder care home. The event chest pain required a visit to Emergency Room and Physician Office (has weekly telephone visits because she keeps getting different symptoms. They are scratching their heads trying to figure out what other testing is needed. She is now developing little waves of hot flashes and is not having a fun time. She was living a very healthy lifestyle and was always energetic previous to this). The patient was hospitalized for 3 days. Family Medical History Relevant to AEs was No, other than her mother has hereditary angioedema. She hasn't been tested so does not even know if that is significant. She knows she has been reading about long hauler's having dysautonomia and a whole array of neurological symptoms. It is kind of intriguing as well as kind of suspicious. Everything is being managed well by her primary doctor who is very concerned and is doing everything she can to try and find and answer. The caller is very curious if there is a lot of



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funding, would she be put into a link and a pool to be involved in some studies or something? Is it something genetic? There is certainly enough money out to do this work. Caller is questioning if she would get a booster given that she is questioning if she should get a booster because she doesn't know. She doesn't know if she is going to get the second shingles vaccine. She does not know what it could result in for her given these 2 complications with these 2 vaccines. Causality: Because she had the shingles vaccine and developed trigeminal neuralgia, which is a neuropathic, and then getting the Covid vaccine and having all of these symptoms, it is just too coincidental. She is going to talk to her doctor about MS since she is presenting with gut things which is more "MS-ish". MS is hard to diagnose so she doesn't know, they are still testing. At this point, because all the boxes checked besides the last MRI, she is leaning towards the COVID vaccine being the cause of her symptoms. The causality for event sudden onset chest pain was related. The outcome of the events was unknown. Information about batch/lot number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events bradycardia, tachycardia, chest pain and brain stem stroke cannot be excluded. The available information upon initial assessment is limited, especially as a definitive diagnosis was not available. The patient was reported to have pre-existing trigeminal neuralgia and previous brainstem stroke and is being worked up for autoimmune disorders; the role of these conditions in the development of the symptoms also cannot be ruled out. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

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1367185	6/2/2021	IL	34	F	3/2/2021	3/16/2021	Prolonged abnormal irregular uterine bleeding >11 days with large clots accompanied by fatigue and lightheadedness; Prolonged abnormal irregular uterine bleeding >11 days with large clots accompanied by fatigue and lightheadedness; Prolonged abnormal irregular uterine bleeding >11 days with large clots accompanied by fatigue and lightheadedness; This is a spontaneous report from a contactable nurse (patient). A 34-year-old female patient (non-pregnant) received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EN6202), via an unspecified route of administration at the age of 34-year-old administered in arm left on 02Mar2021 09:00 AM at single dose for covid-19 immunisation. Medical history included attention deficit hyperactivity disorder, post-traumatic stress disorder, anxiety, depression. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included sertraline hcl, birth control, alprazolam and trazodone, all received within 2 weeks of vaccination. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EM9810), at the left arm at the age of 34-year-old on 03Feb2021 09:00 AM for COVID-19 immunisation. The patient experienced Prolonged abnormal irregular uterine bleeding >11 days with large clots accompanied by fatigue and lightheadedness on 16Mar2021. The adverse event result in Doctor or other healthcare professional office/clinic visit. The events were serious for being medical significant. Facility where the most recent COVID-19 vaccine was administered in Hospital. Since the vaccination, the patient hasn't been tested for COVID-19. The patient underwent lab tests included COVID PCR: positive on 12Feb2021. The patient received treatment for events. The outcome of events was recovered.; Sender's Comments: Based on the temporal relationship, the association between the events abnormal uterine bleeding, fatigue, and lightheadedness with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and

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Investigators, as appropriate.

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1367182	6/2/2021	MD	53	F	5/6/2021	5/1/2021	<p>pain all up the arm/As time passed the pain progressed up her arm. She couldn't straighten arm at all/When she lifts her arm up, it is still sore/her right arm wrist also has pain; now she also has pain in her right wrist/pain has started to increase in her left arm wrist/her right arm wrist also has pain; swelling at the injection site; left shoulder inoculation site edema/edema is minimal; left ear was burning; left eye had floater; left hand and wrist were double the size of right hand/it was so swollen it was a bite/because of the swelling. She couldn't even bend her knuckles at all; swelling in the right wrist/wrist doubled the size of right hand/it was so swollen it was a bite; entire arm where the vaccine was given was red and swollen/swelling in her left arm has increased; entire arm where the vaccine was given was red and swollen.; arm was warm; she has cried; intramuscular pain; This is a spontaneous report from a contactable consumer (patient). A 53-year-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EW0182), intramuscular at the age of 53-year-old administered in arm left on 06May2021 10:40 at single dose for covid-19 immunisation. Medical history included chronic anemia, pulmonary embolism in both lungs (doesn't remember the years but she had 4 or 5 of them/maybe between 2016 and 2019), didn't have a bladder from Apr2020 (cystoscopy performed in Apr 2020), dehiscence of wounds, gastric bypass from Jul2007, two major blood clots in right arm from 2019 (because of infiltrated IV. One was 7mm and one was 8mm. A piece broke off of one of them within 24 hours and went into right lung), Smoker, allergy to antibiotics, slightly topical itch reaction to Morphine, cat scratch infection, had a reaction to IVP dye for kidney scan where her eyes started swelling. Concomitant medication included gabapentin (NEURONTIN) taken for left knee nerve pain from Mar2021 and ongoing. The patient previously took Doxycycline and experienced anaphylactic reaction, morphine and experienced slightly topical itch reaction. She received her first Pfizer COVID19 Vaccine on 06May2021 which was a Thursday. Everything was fine. Shot was in left arm. Wednesday, last week, which was six days later she woke up with her entire left hand and wrist doubled the size of right hand on 12May2021. A friend of hers is her in home nurse because caller has underlying health issues. They</p>

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thought because it was so swollen it was a bite. Caller did Benadryl and RICE treatment. As the day progressed, she had pain all up the arm on 17May2021. She had an appointment with physical therapy. They said to get to the hospital. Her nurse met her for lunch and caller's arm was warm in May2021 and her nurse said to get to the ER. They wanted to rule out a blood clot. They didn't want to admit her, but she had severe issue with her arm that day. She was given pain medication, Benadryl, and had CT scan to rule out blood clot in ER. She couldn't move her neck to the left. She was there 8 hours. While there, her left ear was burning (on 12May2021) to the point it felt someone was ripping it off. In her left eye she had floater on 12May2021, like black fuzzy lines. Everything was on the left side. She didn't hit anything in the time between receiving the injection and 6 days later. She had not done nothing out of her normal routine. It is too much of a coincidence that this is the only thing she has had in the left arm. For 2 or 3 days since last Wednesday the entire arm where the vaccine was given was red and swollen in May2021. She didn't have an immediate side effect, but 6 days later she had a great amount of side effects. She can't say it is the vaccine. She has had a flu shot every year and pneumonia shot every 5 years with no side effect. She is anaphylactic or resistant to every oral antibiotic. Even with IV antibiotics there are only certain ones that can be use, but she has to be pretreated with 50mg of IV Benadryl. She was on Doxycycline all last summer oral and IV. After 4 weeks on it she was sent home with a temp medline for IV infusion. Within 3 hours of her giving herself the next dose she had an anaphylactic reaction. Her body does not immediately react to any side effects or adverse reaction. It can be days out and it hits all of a sudden. On last Wednesday she woke up around 7AM. She felt like it woke her up because of the swelling. She couldn't even bend her knuckles at all. As time passed the pain progressed up her arm. She couldn't straighten arm at all. Everything was on that Wednesday and on the left side. She had full range of motion on the right side. The hospital said it was intramuscular and she read that could possibly be side effect. This was her first dose. Left hand and wrist were double the size of right hand: It resolved. She noticed it around 7AM as the day progressed the swelling went down a little bit. That is

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when the arm started hurting and the swelling would come back. The swelling wasn't as significant as it was first thing in the morning. She has pictures she can provide if needed. Pain all up the arm: the pain has resolved except for the top of the arm where she received the vaccine. When she lifts her arm up, it is still sore. It wasn't sore the first 2 to 3 days or immediately following the inoculation. It is still very mildly sore. They also did an ultrasound when in the ER. At home she takes, not for this issue, Gabapentin 3 times a day. It was just filled and is in the pharmacy vial and she doesn't have NDC, lot, and expiry. Caller clarified that it is Neurontin 300mg not Gabapentin. She has been on Neurontin since Mar2021. She takes it for left knee nerve pain. For the pain meds she was given in the ER and the Benadryl she doesn't have NDC, lot, or expiry. The hospital administered 100mg of Benadryl. When they did the CT scan they did it with contrast. 40 years ago she had a reaction to IVP dye for kidney scan where her eyes started swelling. Anytime she has contrast solution she is always treated with 50mg of IV Benadryl. She has a slightly topical itch reaction to Morphine. In the ER, they gave her 40mg of IM morphine because they couldn't get a line going. She basically has no veins. They gave her 50mg of Benadryl subcutaneously in the inner area. Then before the CT with contrast, they gave her another 50mg of Benadryl. What she took at home was off brand. It is called Banophen Diphenhydramine HCl 25mg antihistamine. She took one when the reaction happened. The manufacturer is Major. NDC: 09045551-59. When providing NDC caller states, "Come on eyes." Lot number: P121325. Expiry: Aug 2022. Caller just found a sugar cookie from Panera Bread to eat. She was in (withheld) in mid October to late October. Unfortunately when she was down there with her best friend her cat scratched her and caller ended up in the hospital because of cat scratch infection. Even though they were very cautious and following all the CDC guidelines and wearing mask when she came home for 5 days she had many COVID symptoms. She went for a rapid test and it came up negative. She has been tested 15 times since last year because she has had so many surgeries. The reason she got the vaccine was with her underlying health conditions she doesn't want to die. What is interesting is her husband and son both after she

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felt ill coming home had the same symptoms she did. She is scheduled to get her next dose 27May2021. Is that normal to be scheduled 3 weeks apart? Her greatest concern is her nurse provider is not familiar with her. Her GI doctor and orthopedic surgeon said she should be ok. She wants to receive both as recommended. Her concern with the second vaccine is if the side effects that she experienced could be dramatically worse or result in a horrible outcome. When she spoke to the physician and the nurses and the medical care team they said there are no studies or reports where the vaccine is causing blood clots and what she was experiencing was not associated with the vaccine. When she looked up the vaccine, it said that intramuscular issues could be a rare side effects. Her thought was that it wasn't reported that it hasn't happened. Could intramuscular issues be a rare side effect? Caller clarified that she does not have the Doxycycline or any other antibiotics that she is resistant to or had reaction with to provide NDC, lot, and expiry. The last time she had it was when she had the temp medline put in. She had the reaction and spoke to the infectious disease doctor only in hospital. She threw all the vials and all the bags away. She torn up the lot numbers. The actual bottles she soaked them and then flushed the labels down the toilet. She has chronic anemia. It has been brought to her attention lately that she has critically low iron saturation. Low saturation should be 18 and her iron saturation level was a three. She had the blood test on the same day of the vaccine on 06May2021. On the 7th she had iron infusion. The vaccine was given at 10:40AM. The blood work was drawn at 02:40PM. The iron infusion was at 9:30AM on 07May2021. She received one unit. Adds she previously reported she had gotten the Pfizer COVID 19 vaccine and six days later she had severe side effects. States she was encouraged by her health care professional to go to the ER to rule out a blood clot which she did and the result was negative. Adds when she had the first dose of the vaccine 06May2021, intramuscular in the left shoulder; she had no side effects or anything. Six days later her left hand was swollen to double the size of the right had. She took a 25mg Benadryl that did nothing, which she previously reported. Adds at lunch yesterday she spoke to a friend who is an in home care nurse who has taken care of her before because of her other

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medical problems; and she encouraged the caller to do RICE treatment; rest, ice, compression and elevation for her wrists. This friend saw the hand at lunch and noticed that the caller was unable to straighten the left elbow and arm; she had great pain in the left elbow and from the hand up the arm. All of these events were previously reported. Caller mentions she is in so much pain and her symptoms are getting worse. New events reported today include the pain has started to increase in her left arm wrist; swelling in her left arm has increased. Caller mentions the physical therapist saw the edema especially on the left shoulder at the vaccination (inoculation) site on 17May2021 and said there is still swelling and she had not noticed this before. Caller clarifies later that day around 1700PM 17May2021, the caller attended a physical therapy treatment and the therapist noticed swelling at the injection site on 17May2021 which was not previously reported. Adds as the day went on yesterday, her right arm wrist also has pain; since yesterday through last night and today it has been at a 10. Adds she has cried in May2021. Mentions she feels she has limited use of her fingers that she noticed yesterday when she had the wrist pain; even picking up things or trying to chop chicken, she can't; she doesn't think she mentioned particularly the left wrist yesterday. Her main concern today is that the pain in her left wrist has increased and now she also has pain in her right wrist on 17May2021. Caller adds she put muscle rubs on; and ice. Her pain in her wrists has not responded to the Gabapentin. She applied three different topical solutions with no improvement in her pain: Generic muscle rub from store; Natureplex Ultra Strength muscle rub; NDC 67324002-01; Jul2022; Topical 5% pure lidocaine cream; Lot 20G13C1; Jul2022; OTC from the pharmacy, no box. Voltaren Gel; Dec2019; lot WN791; unable to locate NDC due to pain in her wrist. Adds the swelling on both wrists is minimal but the pain is incredible; excruciating. Just the edema is minimal; she has kept ice on it on and off; 20 minutes on and off. Adds she has never had pain like this before. Caller mention she did speak with doctor yesterday. Adds she was greatly upset when they told her after she had explained all of her symptoms, that intramuscular joint pain had been detected in May2021. The events results in Emergency Room Visit. The patient underwent lab tests included blood test: unknown results



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							on 06May2021, Iron saturation: low (Low saturation should be 18 and her iron saturation level was a three) on unknown date, CT scan (to rule out blood clot): unknown results, ultrasound: Unknown results, COVID test: negative. The outcome of event left ear was burning and left eye had floater was recovered on 12May2021, the outcome of event Swelling of wrists, Vaccination site oedema and Wrist pain was not recovered and other events was unknown.
1367382	6/2/2021	PA	57	M	2/2/2021	2/1/2021	high blood pressure; blockage / two cardiac stents placed; This is a spontaneous report from a non-contactable consumer (patient). This 57 years old male patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 02Feb2021 at 05:00 (at 57 years of age) for COVID-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient's medical history was not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient experienced high blood pressure on 11Feb2021. The event required ER visit on 11Feb2021, physician office visit and was reported as serious per hospitalization for 3 days and as life-threatening. Cardiac cath lab was performed on 12Feb2021 and blockage was found, resulting in two cardiac stents placed. Device date: 25May2021. High blood pressure resolved with sequel on an unspecified date in 2021. Blockage outcome was unknown. On 25Feb2021 at 05:30 the patient received the second vaccination. On 15Apr2021, the patient had another emergency trip to ER, another blockage in the left anterior descending artery. This blockage was only 40% blocked in Feb2021 and suddenly in Apr2021 became 99% blocked. Dr suspected a blood clot when symptoms of shortness of breath appeared suddenly. Since the vaccination, the patient had been tested for COVID-19 (on an unknown date in 2021, with unknown results). No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021601862 same patient, different vaccine dose/events

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1367531	6/2/2021			F			<p>BLOOD CLOTS; This spontaneous report received from a consumer via a company representative concerned a female of unspecified age, race and ethnic origin. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) 1 total dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced blood clots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clots was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210553711-COVID-19 VACCINE AD26.COV2.S- Blood clots. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1367535	6/2/2021	NY		M		4/6/2021	BLOOD CLOTS IN HEART; BLOOD CLOTS IN LUNGS; BLOOD CLOTS IN LEGS; CHILLS; SORE ARM; This spontaneous report received from a patient concerned a 55 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, and batch number: 1808982 expiry: unknown) dose was not reported, administered on 06-APR-2021 for prophylactic vaccination. No concomitant medications were reported. It was reported by patient that on 06-APR-2021 patient experienced sore arm and on 07-APR-2021 patient had experienced chill. The patient stated that on 27-MAY-2021, the patient experienced chest pain which led to him hospitalization on an unspecified date. While hospitalized they discovered that he had blood clots in the heart and lungs (also reported as blood clots in the legs). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from sore arm, and chills, and the outcome of blood clots in heart, blood clots in lungs and blood clots in legs was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0:20210557848-covid-19 vaccine ad26.cov2.s-Blood clots in heart, Blood clots in lungs, Blood clots in legs. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1367352	6/2/2021	GA	65	F	4/14/2021	4/16/2021	Made her gout flare up in her whole right leg and she couldn't move it so she had to go to the emergency room; Made her gout flare up in her whole right leg and she couldn't move it so she had to go to the emergency room; Ankle pain; This is a spontaneous report received from a contactable consumer (reporting on herself). A 65-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Lot Number: EW0161; Expiration Date was not reported) via an unspecified route of administration in Arm Left on 14Apr2021, as 1st dose, single dose for COVID-19 immunization. Medical history included drug hypersensitivity from an unknown date and unknown if ongoing. There were no concomitant medications. On 16Apr2021 she was in the emergency room be-cause they were checking to be sure that she had no blood clots or a stroke. The COVID vaccine caused a reaction to her gout. Caller clarifies that the COVID vaccine made her gout flare up in her whole right leg and she couldn't move it so she had to go to the emergency room. She used to see Dr. but he retired so now she sees another Dr. She had called her doctor on 16Apr2021 about what she was experiencing and the doctor told the caller that she needed to go to the emergency room so that they could rule out a blood clot and whatever else they do in the emergency room. Probed for when this ended and caller says it ended shortly after they gave her some Tylenol. That was how she knew it was a reaction to the COVID vaccine because gout medicine takes 3 to 4 days to work but they gave her Tylenol and a prescription for ibuprofen therefore she knew what she was experiencing didnt have anything to do with gout. When she was rolled out she saw that they put that she was in there for ankle pain and they didnt put anything about gout. They also did a survey on her and said not to take the second COVID vaccine. Also the COVID nurse said for the caller to not take the second dose, too. Her doctor told her to take it because otherwise she wasnt going to get it because she knows that everyone was just a guinea pig right now. But her doctor suggested that she get it, so she did. She just wants this DSU agent to put in her report she was getting sick from it. She was allergic to penicillin and it will kill her. That was her question before going and having the COVID vaccine. But when they show you the ingredients, no one can read , no one can

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							read those ingredients. Probed for NDC, lot number and expiry date for the previous penicillin and caller declined to provide and said that this was when she was a baby and she hasnt been able to take it since then, they put on her medical records for her to not have it or she will die. The out-come for event ankle pain was unknown and for events The patient experienced made her gout flare up in her whole right leg and she couldn't move it so she had to go to the emergency room was recovered on 16Apr2021. Follow up needed, further information has been requested.
1367764	6/2/2021	WV	12	M	5/21/2021	5/25/2021	He got a superficial blood clot in left arm ?He's got the shot May 21 and I noticed he had two hard knots on left arm and there was probably about a half inch between them and as hard as a rock on that following Monday may 24,2021 , he said it was sore some more when you touched it we was told to keep an ion it make sure it didn't get any worse, turn red, swell, feel hot to the touch, and then to put a warm compresses on it ??
1367971	6/2/2021	PA	51	M	4/4/2021	4/9/2021	Exactly 5 days after the second dose of the Pfizer covid-19 vaccine, I suffered an ischemic stroke. There was a blood clot in my brain that was broken up after tPA was administered about 2 hours after the symptoms of the stroke set in. To date (May 30) I have had many tests, including 2 MRIs, CT scans, TEE, heart monitoring etc. So far, it has been called a "cryptogenic stroke" because there is no cause. The only thing different was the vaccine I received 5 days before the stroke.
1368078	6/2/2021	MO	31	F	3/16/2021	5/9/2021	Suffered a stroke on May 9, 2021. Rushed to the ER and administered TPA, then surgery was performed to get out the rest of the clot. Symptoms: Fainting, Right side paralysis, slurred speech
1368245	6/2/2021	MN	60	M	5/17/2021	5/26/2021	Patient sustained DVT on 5/26/2021 after receiving Moderna COVID-19 vaccine on 5/17/2021. patient has history of prostate cancer that was diagnosed 6 weeks ago with prostate cancer. No previous clot history.

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1368322	6/2/2021	GA	70	F	1/8/2021	1/20/2021	I woke up and 1/2 my mouth and my tongue felt numb and tingling as if I had Novocain and it was wearing off. Woke up the next day and it was still there so I called the NP. She said to go and get a CAT scan in the morning and it didn't show anything. Later in the afternoon I noticed I was dropping things and dragging my feet and got concerned it was a stroke so I drove down to a larger medical center and they did a contrast CAT scan and that showed nothing. So then they did an MRI and they found a clot. So they put me on Plavix, blood thinner and all that stuff. After a couple of days my hand and foot were fine but the numbness and tingling in my mouth is still there till now. All of this wasn't real pronounced so I didn't think it was a stroke but it was. They sent me to a Neurologist and Cardiologist.
1368387	6/2/2021	FL	46	F	4/28/2021	6/2/2021	Two blood clots.
1368447	6/2/2021	WA	47	F	5/4/2021	5/7/2021	3 days after receiving my 2nd Covid shot I had sharp pains in my chest that progressed to constant pressure. I went to Urgent Care when I also became light-headed and my left hand was going numb. They immediately did and EKG, which was abnormal, and sent me to the ER. I continued to have episodes of blood pressure and heart rate spiking with continuous chest pain. They did bloodwork, a chest X-ray, a CT scan of my lungs as well as 2 more EKG's. My bloodwork was elevated for heart enzymes and possible blood clot. 2 days later I was back in the ER for the same issues, 2 more abnormal EKG's and a chest X-ray. I saw a cardiologist 3 days later, he sent me to the ER right from his office and I had a cardiac catheterization later that same day. This whole time I'd been having chest pain and pressure, shortness of breath, fatigue, high blood pressure episodes. I was allowed to go home but have continued to have chest pain ever since with no explanation. I had bloodwork drawn again yesterday, now testing for myocarditis.
1368478	6/2/2021	TX	41	F	4/6/2021	4/7/2021	Started feeling toes on right foot numb days passed felt pain on knee swollen leg went to hospital have a DVT in leg, started blood thinner .Then I received second dose 5/8/2021 at 12:00 pm same day around 7:00pm I started feeling pain on left leg went to the hospital on 5/10/2021 have another clot on left leg

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1368486	6/2/2021	IA	61	M	4/16/2021	5/19/2021	Moderna Dose 1 3/5/21 (029A21A) Moderna Dose 2 4/16/21 (027B21A) COVID Positive 5/20/21 5/20/21: Presented to ED. The patient presents with fever. 61 year old male presents to the emergency department for a fever with an onset of 1 day. Patient was diagnosed with pancreatic cancer in April 2021. Patient states he has had 2 rounds of chemotherapy but states he could not have his 3 round last week because his white count was too low. Patient is also complaining of dull chest pain that is exacerbated with deep breathing, cough, and a headache but denies vomiting, diarrhea, neck pain, dysuria, hematuria, and nausea. Patient was diagnosed with blood clots on 05/09/2021 but states that he is not having similar symptoms to when he was diagnosed with blood clots. Patient is taking Xarelto. He has never had COVID but is vaccinated. Patient sees Dr. (Name) at the UI Oncology clinic. 5/25/21: 61-year-old male on chemotherapy for pancreatic cancer, also recently diagnosed pulmonary embolism on rivaroxaban, presents with 1 day of fever. Initially, did not have any cough or shortness of breath, was admitted to the hospital, where a chest x-ray, urinalysis and examination failed to reveal an exact source of the fever. His absolute neutrophil count was less than 500, so he was admitted for neutropenic fever. Cultures were obtained. IV antibiotics started. COVID-19 was tested and, surprisingly, came back positive. The patient has actually had both of his COVID-19 vaccines and basically, does not have pneumonia, shortness of breath, or hypoxemia. We did not use any medications for COVID while in the hospital, watching for any signs of respiratory compromise, but none developed. Blood cultures were negative. He was switched from ceftazidime to doxycycline at time of discharge. Will follow up with Dr. (Name) for his next cycle of chemotherapy. Because of his COVID-19 positivity, we will not schedule any immediate followup appointments, although the patient will call if he has persistent fever, dyspnea, or signs of hypoxemia. For the past 2 days, the T- max has been 99.9, and most the time 98.6. He was seen the day of discharge, doing quite well. Blood pressure 153/80, pulse 90, regular, oximetry 95% on room air. Glucose was 210. Discharged on Rivaroxaban 15 mg b.i.d., doxycycline 100 mg b.i.d., Robitussin AC as needed for cough, Lantus 28 units at bedtime, atorvastatin 80 mg daily, aspirin 81 mg daily.

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1367532	6/2/2021	NC	26	M	4/1/2021		<p>The patient did get 1 dose of Neupogen 480 mcg subcu while in the hospital.</p> <p>BLOOD CLOTS INTO THE LUNGS; BLOOD CLOTS ON RIGHT ARM AND SHOULDER; FLU LIKE SYMPTOMS; DISCOLORATION ON THE RIGHT ARM AND IT TURNS BLUE; SWOLLEN RIGHT ARM; This spontaneous report received from a patient concerned a 26 year old. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 207A21A, and expiry: UNKNOWN) dose was not reported, 1 total dose administered on 07-APR-2021 in left arm for prophylactic vaccination. No concomitant medications were reported. On 09-APR-2021, two days later after getting the vaccine patient had experienced flu like symptoms. After 3 weeks, patient had discoloration on the right arm and it turned blue and swollen. On 03-MAY-2021, the patient was hospitalized. Patient was administered through the emergency care on 05-MAY-2021. Then the patient got transferred to the floor. Blood clots were formed on arm, shoulder, and into the lungs. At that moment patient had shortness of breath. Patient was hospitalized for 5 days and discharged on 07-MAY-2021. Treatment medications (dates unspecified) included: apixaban. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from swollen right arm, had not recovered from discoloration on the right arm and it turns blue, blood clots into the lungs, and blood clots on right arm and shoulder, and the outcome of flu like symptoms was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0:20210554390-covid-19 vaccine ad26.cov2.s- blood clots into the lungs, and blood clots on right arm and shoulder. These events are considered unassessable. The events have a compatible/suggestive temporal relationship, are unlabeled, and have unknown scientific plausibility. There is no information on any other factors potentially associated with the events.</p>



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1366886	6/2/2021	NH	80	M	2/12/2021	2/16/2021	<p>did not get second dose due to side effects from first dose; blood clot in lung; Really bad back pain; breathing was difficult; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (blood clot in lung) in an 80-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 12-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Feb-2021, the patient experienced PULMONARY EMBOLISM (blood clot in lung) (seriousness criterion medically significant), BACK PAIN (Really bad back pain) and DYSPNOEA (breathing was difficult). On an unknown date, the patient experienced PRODUCT DOSE OMISSION ISSUE (did not get second dose due to side effects from first dose). The patient was treated with APIXABAN at an unspecified dose and frequency. At the time of the report, PULMONARY EMBOLISM (blood clot in lung), BACK PAIN (Really bad back pain), DYSPNOEA (breathing was difficult) and PRODUCT DOSE OMISSION ISSUE (did not get second dose due to side effects from first dose) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant products information was not provided. Patient experienced "really bad back pain" and "breathing was difficult". Went to see his doctor who then stated he had a blood clot in his lung. Caller stated he was then put on Eliquis and the doctor said he would have to take it for the rest of his life. Caller wanted to know if this was true or if he can eventually stop taking the Eliquis. He also wanted to know what caused him to get a blood clot. Company comment: Very limited information regarding the events has been provided at this time. Further information is expected.; Sender's Comments: Very limited information regarding the events has been provided at this time. Further information is expected.</p>

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1366580	6/2/2021	CO	72	M	3/6/2021	3/7/2021	My ankles swelled up a day later on March 7th and they are still swelled up now both ankles and up into my calves. Skin is so tight. Have had the following done on April 12th - Heart test along with Kidney and Liver test which were all good. Also had a blood test and for 73 years old I had a perfect blood test with cholesterol number at 150 and my HDH and LDL and triglycerides were all 2 to 3 times better than recommended. 12-weeks later my ankles and calves are still swelled up. On May 25th I had an Ultra Sound on both legs from the groin down and it came back with NO blood clots.
1367807	6/2/2021	MI	27	F	4/9/2021	4/9/2021	I started to feel a little intoxicated 20 minutes after the vaccine. After about 30 minutes I had rashes on my face. I was unable to walk in a straight line. I was also very emotional. I took a nap and woke up with a headache, chills and sweating, I had body aches and pain in my back. My skin was hot to the touch. I was nauseous and weak with no fever. The next day I was having shortness of breath and I thought I had blood clots.

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1366784	6/2/2021			U			<p>BELL'S PALSY; BLOOD CLOT; GUILLAIN BARRE SYNDROME; ANAPHYLAXIS; This spontaneous report received from a patient via a company representative (other manufacturer Pfizer ) concerned multiple patients. The patient height and weight was not reported .No past medical history or concurrent conditions were reported.The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported)frequency one total , dose, start therapy date were not reported for prophylactic vaccination.The batch no was not reported ,The Company is unable to performed follow up to request batch /Lot numbers. No concomitant medications were reported. On an unspecified date, the subject experienced bell's palsy, blood clot, guillain barre syndrome, and anaphylaxis. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the bell's palsy, blood clot, guillain barre syndrome and anaphylaxis was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0. 20210556206-COVID-19 VACCINE AD26.COV2.S. Bell's palsy, Blood clot, Guillain Barre syndrome. This events is considered unassessable. The events has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events. 20210556206-COVID-19 VACCINE AD26.COV2.S. Anaphylaxis. This event is labeled per RSI and is therefore considered potentially related.</p>

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1366787	6/2/2021	AZ		F	5/21/2021		<p>BLOOD CLOT; BELLY BUTTON PAIN; LOWER LEG PAIN; STOMACH PROBLEMS; This spontaneous report received from a patient concerned a 57 year old white(Not Hispanic or Latino) female. The patient's height, and weight were not reported. No past medical history was reported. The patient had no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805025,expiry: UNKNOWN) dose was not reported, administered on 09-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 21-MAY-2021, the patient experienced stomach problems(pain, cramping, bloating). On an unspecified date, the patient experienced blood clot, belly button pain, and lower leg pain. The patient did not made any changes to diet and no new medications took since getting the vaccine. The patient had tried yogurt and probiotic. Treatment medications (dates unspecified) included: bismuth subsalicylate for unknown indication. On 28-May-2021, she started taking turmeric, but so far nothing had resolved the issues. The patient had a tele visit with family doctor of medicine and would go next week wednesday. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from blood clot, and lower leg pain, and had not recovered from stomach problems, and belly button pain. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210556734.; Sender's Comments: V0 20210556510-COVID-19 VACCINE AD26.CO2.S- blood clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1366788	6/2/2021	NJ		F	5/1/2021		<p>DYSпноEA; ANGIOGRAM; FULL BLOOD COUNT; PULMONARY EMBOLISM; THROMBOCYTOPENIA; This spontaneous report received from a health care professional via a Regulatory Authority Vaccine Adverse Event Reporting System (VAERS) (VAER reference number 1313736) concerned a 74 year old female unknow ethnicity. The patient's height, and weight were not reported. The patient's concurrent conditions included penicillin allergy, sulfa allergy, asthma, obesity, dyslipidemia, and hypertension. The patient had no current illness. The patient experienced drug allergy when treated with clarithromycin, metronidazole, morphine, dipyridamole, polyethylene glycol, and tramadol. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose was not reported, 1 total administered on 08-MAY-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. Concomitant medications included amlodipine, hydrochlorothiazide, pantoprazole, and rosuvastatin calcium. On 26-MAY-2021, the patient experienced Dysпноea (shortness of breath). Patient was hospitalized. On MAY-2021, the patient had computed tomography (CT) angiogram and full blood count or complete blood count (CBC) with unknown results. The patient was diagnosed with thrombocytopenia and pulmonary embolism. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from dysпноea, pulmonary embolism, thrombocytopenia, angiogram, and full blood count. This report was serious (Hospitalization Caused / Prolonged). Version created to amend previously reported information on 28-May-2021. Upon review following information was amended: Medical Assessment Comment was updated.; Sender's Comments: V2: This spontaneous report received from a health care professional via VAERS (ID: 1313736) concerned a 74-year-old woman (ethnicity unknown) who experienced dysпноea 18 days after vaccine and pulmonary embolism and thrombocytopenia on an unknown date during the same month as vaccine. Relevant concurrent conditions included asthma, obesity, dyslipidemia, and hypertension. The patient had no current illness. Concomitant medications included amlodipine,</p>

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hydrochlorothiazide, pantoprazole, and rosuvastatin. On day 18 after vaccine, the patient experienced dyspnea and was hospitalized. On an unknown date the same month, the patient had computed tomography (CT) angiogram and complete blood count (CBC) with unknown results. The patient was diagnosed with thrombocytopenia (no platelet value reported) and pulmonary embolism. Although the underlying obesity may have contributed, based on evolving knowledge of Thrombosis with Thrombocytopenia Syndrome (TTS, per definition from source) and considering the thrombocytopenia and temporal relationship to vaccination, the events are assessed to have a plausible relationship with vaccination.

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1366848	6/2/2021	NV	65	F	2/19/2021	2/23/2021	<p>Couldn't lift arm or get of bed; Baker's cyst; Left knee has been swollen/leg feels heavy and difficult to lift; Reactive arthritis flare; didn't receive the second dose,was advised not to; Stabbing pain in upper left arm, in the crease of arm/Stabbing pain in left elbow, right elbow, forearm, upper arm, left and right groin radiating down leg, sore arm; Excruciating joint pain; Fatigue; Severe body pain; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of ARTHRITIS REACTIVE (Reactive arthritis flare) in a 65-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 007M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Streptococcal sore throat from 12-Feb-2021 to 17-Feb-2021, Shortness of breath (The patient reported no significant change in the disease condition.) in 2006, Sciatica (The patient reported a significant change in the disease condition.) in 1995 and Elbow tendinitis (The patient reported a significant change in the disease condition.) in 2017. Concurrent medical conditions included Drug allergy (Biaxin, citalopram, venlafaxine, trimethoprim, sulfamethoxazole.), Hypothyroidism (The dose is lowered from 125 mg to 112) since 1988, Asthma (The patient reported no significant change in the disease condition.) since 01-Dec-2020 and Chronic obstructive pulmonary disease (The patient reported no significant change in the disease condition.) since 01-Dec-2020. Concomitant products included OXYMETAZOLINE HYDROCHLORIDE (CLARITIN ALLERGIC) for Allergy, MONTELUKAST from 01-Nov-2020 to an unknown date for Asthma, FLUTICASONE FUROATE, VILANTEROL TRIFENATATE (BREO ELLIPTA) from 15-Jan-2021 to an unknown date for COPD and Asthma, PANTOPRAZOLE from 08-Jan-2021 to an unknown date and CIMETIDINE from 04-Jan-2021 to an unknown date for Hyperacidity, EZETIMIBE from 23-Jun-2020 to an unknown date for Hyperlipidemia, LEVOTHYROXINE SODIUM (SYNTHROID) for Hypothyroidism, PENICILLIN NOS from 12-Feb-2021 to 22-Feb-2021 for Streptococcal sore throat, BIFIDOBACTERIUM LACTIS (PROBIOTIC [BIFIDOBACTERIUM LACTIS]), CALCIUM, VITAMIN D3, VITAMIN E NOS, MAGNESIUM and VITAMIN B COMPLEX (SUPER B COMPLEX [VITAMIN B</p>

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COMPLEX]) from 04-Jan-2021 to an unknown date for an unknown indication. On 19-Feb-2021 at 8:30 AM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Feb-2021, the patient experienced PAIN (Severe body pain), ARTHRALGIA (Excruciating joint pain) and FATIGUE (Fatigue). On 24-Feb-2021, the patient experienced PAIN IN EXTREMITY (Stabbing pain in upper left arm, in the crease of arm/Stabbing pain in left elbow, right elbow, forearm, upper arm, left and right groin radiating down leg, sore arm). On 08-Apr-2021, the patient experienced PRODUCT DOSE OMISSION ISSUE (didn't receive the second dose,was advised not to). On 14-Apr-2021, the patient experienced ARTHRITIS REACTIVE (Reactive arthritis flare) (seriousness criterion medically significant) and JOINT SWELLING (Left knee has been swollen/leg feels heavy and difficult to lift). On an unknown date, the patient experienced LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (Couldn't lift arm or get of bed) and SYNOVIAL CYST (Baker's cyst). The patient was treated with PARACETAMOL (TYLENOL) at a dose of 1 dosage form; IBUPROFEN at a dose of 1 dosage form; GABAPENTIN ongoing since an unknown date at a dose of 200 mg; CELECOXIB (CELEBREX) at a dose of 200 mg; METHYLPREDNISOLONE ongoing since an unknown date at a dose of 4 mg; METHOCARBAMOL ongoing since an unknown date at a dose of 750 mg as required; FERUMOXYTOL (FERAHEME) ongoing from 06-May-2021 at a dose of 1 dosage form, first infusion; FERUMOXYTOL (FERAHEME) on 13-May-2021 at a dose of 1 dosage form, second infusion and CORTISONE ongoing since an unknown date at a dose of 1 dosage form. On 08-Apr-2021, PRODUCT DOSE OMISSION ISSUE (didn't receive the second dose,was advised not to) had resolved. At the time of the report, ARTHRITIS REACTIVE (Reactive arthritis flare), PAIN (Severe body pain), LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (Couldn't lift arm or get of bed), SYNOVIAL CYST (Baker's cyst), JOINT SWELLING (Left knee has been swollen/leg feels heavy and difficult to lift), PAIN IN EXTREMITY (Stabbing pain in upper left arm, in the crease of arm/Stabbing pain in left elbow, right elbow, forearm, upper arm, left and right groin radiating down leg, sore arm), ARTHRALGIA



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(Excruciating joint pain) and FATIGUE (Fatigue) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Mar-2021, Blood albumin (3.8-4.8): 3.7 (normal) 3.7g/dL. On 08-Mar-2021, Blood cholesterol: 172 (normal) 172 mg/dl. On 08-Mar-2021, Blood glucose (65-99): 88 (normal) 88mg/dl. On 08-Mar-2021, Blood iron (45-160): 39 (Low) Low. On 08-Mar-2021, Eosinophil count (15-500): 1003 (High) 1003 cells per microlitre. On 08-Mar-2021, Glycosylated haemoglobin increased: 6.0 (High) Unknown. On 08-Mar-2021, Haematocrit: 33.9 (Low) 33.9 %. On 08-Mar-2021, Haemoglobin (11.7-15.5): 10.6 (Low) unknown. On 08-Mar-2021, Mean cell haemoglobin (27.0-33.0): 25.2 (Low) unknown. On 08-Mar-2021, Mean cell haemoglobin concentration (32.0-36.0): 31.3 (Low) Unknown. On 08-Mar-2021, Platelet count (140-400): 396 (normal) Unknown. On 08-Mar-2021, Protein total (6.1-8.1): 5.7 normal. On 08-Mar-2021, Prothrombin time (9.1-1.2): 9.8 (normal) Unknown. On 08-Mar-2021, Red blood cell count (3.80-5.10): 4.21 (normal) unknown. On 08-Mar-2021, Red cell distribution width increased (11.0-15.0): 15.2 (High) Unknown. On 08-Mar-2021, Serum ferritin (16-288): 6 (Low) Unknown. On 08-Mar-2021, Thyroid function test: negative (Negative) thyroid was off.. On 08-Mar-2021, White blood cell count (3.8-10.8): 7.6 (normal) unknown. On 19-Mar-2021, SARS-CoV-2 test: negative (Negative) Negative. On 14-Apr-2021, Magnetic resonance imaging: unknown (Inconclusive) Bakers cyst and fluid on knee. On 26-Apr-2021, X-ray: unknown (Inconclusive) Left knee x-ray: Moderate joint effusion. On 10-May-2021, Magnetic resonance imaging: unknown (Inconclusive) Mild hand subcutaneous edema and unknown (Inconclusive) Mild diffuse flexor tenosynovitis from CMC joint level to metacarpal midshaft level. On 12-May-2021, Blood albumin (3.8-4.8): 3.6 (Low) 3.6g/dL. On 12-May-2021, C-reactive protein: 27.5 (High) Unknown. On 12-May-2021, Eosinophil count (15-500): 57 (normal) 57 cells per microlitre. On 12-May-2021, Haematocrit: 37.8 (normal) 37.8%. On 12-May-2021, Haemoglobin (11.7-15.5): 11.9 (normal) Unknown. On 12-May-2021, Mean cell haemoglobin (27.0-33.0): 25.4 (Low) Unknown. On 12-May-2021, Mean cell haemoglobin concentration (32.0-36.0): 31.5 (Low) Unknown. On 12-May-2021, Platelet count (140-400): 458 (High) Unknown. On 12-May-2021,

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Protein total (6.1-8.1): 6.6 (normal) Unknown. On 12-May-2021, Red blood cell count (3.80-5.10): 4.69 (normal) Unknown. On 12-May-2021, Red cell distribution width increased (11.0-15.0): 16.5 (High) Unknown. On 12-May-2021, White blood cell count (3.8-10.8): 8.1 (normal) Unknown. mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was withdrawn on an unknown date. The patient reported that she declined the administration of second dose and it was suggested by her physician. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This report refers to a case of Product dose omission issue for mRNA-1273, lot # 007M20A with associated AEs. Most recent FOLLOW-UP information incorporated above includes: On 17-May-2021: Follow up received on 17-May-2021 and does not contain any new information On 21-May-2021: The second follow up received on 21-MAY-2021 and contain contact details of the reporter . The suspect drug dosage regime, medical history and events of the patient is updated.The concomitant and treatment medications are added.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This report refers to a case of Product dose omission issue for mRNA-1273, lot # 007M20A with associated AEs.

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1367162	6/2/2021	TX	42	F	4/17/2021	4/17/2021	Bruises on my thighs, looks like blood clots; Bruises on my thighs, looks like blood clots; This is a spontaneous report from a contactable consumer (patient). A 42-years-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in Left Arm on 17Apr2021 11:00 at the age of 42-years-old as single dose for covid-19 immunisation. Medical history included anaemia, iron deficiency. No known allergies. Patient was not pregnant, not pregnant at time of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included iron, other vitamins such as biotin and minerals nos, vitamins nos (PRENATAL VITAMINS) within 2 weeks of vaccination. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date as single dose for covid-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced bruises on thighs, looked like blood clots on 17Apr2021. No treatment received for the events. Since the vaccination, the patient had not been tested for COVID-19. Outcome of the events was not recovered. The events assessed as non-serious. Information on the lot/batch number has been requested.

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1366867	6/2/2021	CA	70	M	1/26/2021	3/26/2021	<p>blood clot in the left lower leg; left ankle swelling; left foot pain; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (blood clot in the left lower leg) in a 70-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included METOPROLOL for Hypertension. On 26-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 23-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 26-Mar-2021, the patient experienced JOINT SWELLING (left ankle swelling) and PAIN IN EXTREMITY (left foot pain). On 12-May-2021, the patient experienced THROMBOSIS (blood clot in the left lower leg) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (blood clot in the left lower leg), JOINT SWELLING (left ankle swelling) and PAIN IN EXTREMITY (left foot pain) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 12-May-2021, Ultrasound scan: abnormal (abnormal) Diagnosed with blood clot in the left lower leg. Other concomitant medication include statin for cholesterol. Treatment medication for events included Xarelto. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (unknown) was not applicable. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1366871	6/2/2021	KY	57	F	1/19/2021	2/25/2021	<p>blood clots; leg pain due to clots; chills; diarrhea worse than when I had covid; chest pains; nerve sensations up and down back and arms; blood pressure went up; higher fever than when got covid; headaches; This spontaneous case was reported by a patient and describes the occurrence of THROMBOSIS (blood clots) in a 57-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011J20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 (Patient had Covid-19 last year in April and experienced blood clot.) in April 2020 and Thrombosis (Patient had Covid-19 last year in April and experienced blood clot.) in April 2020. Concurrent medical conditions included Hypothyroidism, Blood pressure and Allergy. Concomitant products included CETIRIZINE HYDROCHLORIDE (CETRIZINE) and FEXOFENADINE HYDROCHLORIDE (ALLEGRA) for Allergy, HYDROCHLOROTHIAZIDE and METOPROLOL for Blood pressure, LEVOTHYROXINE for Hypothyroidism, POTASSIUM for Potassium, VITAMIN B NOS, VITAMIN D NOS and ASCORBIC ACID, CALCIUM, MINERALS NOS, RETINOL, TOCOPHERYL ACETATE, VITAMIN B NOS, VITAMINS NOS, ZINC (CENTRUM SILVER [ASCORBIC ACID;CALCIUM;MINERALS NOS;RETINOL;TOCOPHERYL ACETATE;VITAMIN B NOS;VITAMINS NOS;ZINC]) for Vitamin supplementation, SAMBUCUS NIGRA (ELDERBERRY EXTRACT) for an unknown indication. On 19-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 25-Feb-2021, the patient experienced BLOOD PRESSURE INCREASED (blood pressure went up), PYREXIA (higher fever than when got covid) and HEADACHE (headaches). On 15-May-2021, the patient experienced DIARRHOEA (diarrhea worse than when I had covid). In May 2021, the patient experienced CHEST PAIN (chest pains) and PARAESTHESIA (nerve sensations up and down back and arms). On an unknown date, the patient experienced THROMBOSIS (blood clots) (seriousness criterion medically significant), PAIN IN EXTREMITY (leg pain due</p>

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
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to clots) and CHILLS (chills). On 16-May-2021, DIARRHOEA (diarrhea worse than when I had covid) had resolved. At the time of the report, THROMBOSIS (blood clots), CHEST PAIN (chest pains), PARAESTHESIA (nerve sensations up and down back and arms), BLOOD PRESSURE INCREASED (blood pressure went up), PAIN IN EXTREMITY (leg pain due to clots), PYREXIA (higher fever than when got covid), HEADACHE (headaches) and CHILLS (chills) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not reported. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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1367326	6/2/2021	PA	63	M	5/19/2021	5/1/2021	<p>Arthritis pain in back, hips, shoulders and hands; Sore arm; He is not doing anything to cause the pain; This is a program spontaneous report from a contactable consumer or other non hcp (patient himself). A 63-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE solution for injection, Batch/Lot Number: EW0185; Expiration Date: 31Aug2021), via an unspecified route of administration, administered in left arm on 19May2021 08:00AM as 1st dose, single for covid-19 immunization and would scheduled to receive the second dose on 10Jun2021. The patient's medical history included bad Arthritis, Allergic to Penicillin from an unknown date. The patient's concomitant medication included Apixaban (ELIQUIS) 25mg tablets a day patient was taking blood thinner this since he was 48-year-old. On 19 May2021 after the vaccination the patient experienced with a Sore arm, on 20May2021 then the second day after the vaccination the arthritis started for no reason and had more pain in back, hips, shoulders and hands and prior to vaccine he would had minor pain here and there, every day, but now his arthritis had really flared up badly, had to take the pain medication every day. Patient stated that He was not doing anything to cause the pain. It had stayed the same since the pain started, since patient got the vaccination, his arthritis had been getting worse. could not take arthritis medications because he had 2 blood clots for that he was on blood thinners. Patient had a type of arthritis called DISH, which was in his back and was the worst rheumatoid arthritis and osteoarthritis a person can have. Patient was in a lot of pain and took just pain killers and pain medicine as treatment as prescribed Norco by his doctor, 7.5-325 tablets to take as needed. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not test COVID-19 positive prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The outcome of the event pain in back, hips, shoulders and hands was not recovered, and the other events was unknown. Follow-up (24May2021): This is a follow-up spontaneous report from a Pfizer sponsored program. A contactable 63-year-old male consumer (patient) reported that included patient weight, age, concomitant medication, treatment received, outcome of events. No follow-up attempts are needed. No further information is expected.</p>

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1366884	6/2/2021	CT	68	F	2/20/2021	4/9/2021	<p>Fever; Permanent vision loss/ Permanent vision loss in the right eye; Another eye episode; This spontaneous case was reported by a consumer and describes the occurrence of BLINDNESS (Permanent vision loss/ Permanent vision loss in the right eye) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002B21A and 023M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was provided by the reporter. Concomitant products included PANTOPRAZOLE, METOPROLOL SUCCINATE (TOPROL), AMLODIPINE and ALPRAZOLAM (ZOLAX [ALPRAZOLAM]) for an unknown indication. On 20-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 09-Apr-2021, the patient experienced BLINDNESS (Permanent vision loss/ Permanent vision loss in the right eye) (seriousness criteria disability and medically significant) and EYE DISORDER (Another eye episode). On an unknown date, the patient experienced PYREXIA (Fever). At the time of the report, BLINDNESS (Permanent vision loss/ Permanent vision loss in the right eye) and EYE DISORDER (Another eye episode) had not resolved and PYREXIA (Fever) outcome was unknown.</p> <p>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Biopsy: normal (normal) Biopsy of artery leading to right eye. Treatment provided included Prednisone. After the second dose patient had an eye episode that did not go away after few minutes. It continued over the weekend and the patient visited a primary physician who was concerned about a stroke even though there were no stroke symptoms. From there patient was referred to cardiologist, rheumatologist and retinal specialist. Patient had shorter eye episode which began 22 days after the first vaccine and permanent vision loss began 20 days after the second dose. After six weeks of test and physician visits, a biopsy of the artery leading to right eye, the consulted cardiologist and found no problem in the heart, vascular specialist found no issues in the arteries, rheumatologist found no systemic inflammation</p>

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1367347	6/2/2021	MA	38	F	5/23/2021	5/24/2021	<p>and autoimmune condition, Retinal specialist primarily provided treatment and did not diagnosed the cause but informed that the eye damage was not caused by a clot. There was no improvement in the vision and the retinal specialist was not optimistic that the vision will return. Very limited information regarding the events has been provided at this time. Further information has been requested. This case was linked to (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 20-May-2021: Follow up was received on 20-May 2021 and updated Patient demographics, concomitant medications, batch number of vaccine, treatment medication.; Sender's Comments: Very limited information regarding the events has been provided at this time. Further information has been requested.</p> <p>This is a spontaneous report from a contactable consumer (Patient). A 38-years-old non-pregnant female patient received BNT162B2 first dose of (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Batch/Lot number: EW0186) via an unspecified route of administration, administered in left arm on 23May2021 13:00 (at the age of 38-year-old) as 1ST DOSE, SINGLE for covid-19 immunisation. Not Pregnant at time of Vaccination. Medical history included Blood clot and PE (pulmonary embolism). Patient had no known allergies. Concomitant medication(s) included Eliquis. On 24May2021 10:00, the patient experienced started a period/heavy spotting within 24 hours of vaccine after 13 days of previous period (on a 36 day cycle - period starts 23 days earlier than expected). Patient was not received any treatment. It was reported that most recent COVID-19 vaccine was administered at Pharmacy or Drug Store. Prior to vaccination, patient was not diagnosed with COVID-19. Patient did not received any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, patient has been not tested for COVID-19. No covid prior vaccination and No covid tested post vaccination. Seriousness reported as non-serious. The outcome of event was recovering. No follow-up attempts are possible. No further information is expected.</p>

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1366887	6/2/2021	OH	62	M	3/12/2021	5/19/2021	<p>Blood clot in his lung; This spontaneous case was reported by a consumer and describes the occurrence of PULMONARY THROMBOSIS (Blood clot in his lung) in a 62-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 012a21a) for COVID-19 vaccination. The patient's past medical history included No adverse event (No reported medical history). Concomitant products included BRINZOLAMIDE (AZOPT) for an unknown indication. On 12-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 19-May-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced PULMONARY THROMBOSIS (Blood clot in his lung) (seriousness criterion medically significant). At the time of the report, PULMONARY THROMBOSIS (Blood clot in his lung) outcome was unknown. No treatment information was provided. Action taken with mRNA-1273 in response to events was not applicable. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded</p>

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1366898	6/2/2021	NY	71	F	1/25/2021	4/22/2021	<p>bilateral pneumonia; acute on chronic respiratory failure; left lower extremity deep vein thrombosis; This spontaneous case was reported by a physician and describes the occurrence of ACUTE RESPIRATORY FAILURE (acute on chronic respiratory failure), PNEUMONIA (bilateral pneumonia) and DEEP VEIN THROMBOSIS (left lower extremity deep vein thrombosis) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 012LZ0A and 029L20A) for COVID-19 vaccination. Concurrent medical conditions included Food allergy (corn, dairy aid, peanuts,tomato), Drug allergy (codeine, aspirin, chlorine, tartrazine, lanolin, Plevnar, Pulmicort, penicillin.), Iodine contrast media allergy, Allergy (cat dander, yellow dye, purple dye), Latex allergy, Hypertension, COPD and Lung cancer. Concomitant products included ALPRAZOLAM, BENZONATATE, ENOXAPARIN, GABAPENTIN, HCTZ, HYDROCODONE, ACETAMINOPHEN, OMEPRAZOLE, PREDNISONE, PROCHLORPERAZINE EDISYLATE (COMPAZINE [PROCHLORPERAZINE EDISYLATE]), BECLOMETASONE DIPROPIONATE (QVAR), MONTELUKAST and CETIRIZINE for an unknown indication. On 25-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 22-Apr-2021, the patient experienced DEEP VEIN THROMBOSIS (left lower extremity deep vein thrombosis) (seriousness criterion medically significant). On 05-May-2021, the patient experienced ACUTE RESPIRATORY FAILURE (acute on chronic respiratory failure) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced PNEUMONIA (bilateral pneumonia) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 05-May-2021 due to ACUTE RESPIRATORY FAILURE and PNEUMONIA. The patient was treated with Hospice care (increased supplemental oxygen) for Pneumonia. At the time of the report, ACUTE RESPIRATORY FAILURE (acute on chronic respiratory failure), PNEUMONIA (bilateral pneumonia) and DEEP VEIN THROMBOSIS (left lower extremity deep vein thrombosis) had not</p>

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resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Apr-2021, Ultrasound Doppler: unknown (Inconclusive) unknown. On 05-May-2021, Chest X-ray: unknown (Inconclusive) unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. treatment includes IV antibiotics. concomitant medication includes duo-nebs. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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1366915	6/2/2021	VA	26	F	4/2/2021	4/2/2021	<p>No blood clot but testing shows signs of blood clot; Unable to eat; Chest pains; Red spots; Muscles feel like needles; She has not taken second dose; Fainted; hand turned red; Palpitations; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (No blood clot but testing shows signs of blood clot) and SYNCOPE (Fainted) in a 26-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 02-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Apr-2021, the patient experienced SYNCOPE (Fainted) (seriousness criterion medically significant), ERYTHEMA (hand turned red) and PALPITATIONS (Palpitations). On an unknown date, the patient experienced THROMBOSIS (No blood clot but testing shows signs of blood clot) (seriousness criterion medically significant), FEEDING DISORDER (Unable to eat), CHEST PAIN (Chest pains), RASH MACULAR (Red spots), MYALGIA (Muscles feel like needles) and INCOMPLETE COURSE OF VACCINATION (She has not taken second dose). At the time of the report, THROMBOSIS (No blood clot but testing shows signs of blood clot), SYNCOPE (Fainted), ERYTHEMA (hand turned red), PALPITATIONS (Palpitations), FEEDING DISORDER (Unable to eat), CHEST PAIN (Chest pains), RASH MACULAR (Red spots), MYALGIA (Muscles feel like needles) and INCOMPLETE COURSE OF VACCINATION (She has not taken second dose) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Coagulation test: signs of blood clot (abnormal) signs of blood clot. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. It was reported that within 3 minutes of receiving dose, patient's hand turned red and she fainted. Patient was brought to the hospital and was released a couple hours later when palpitations stopped. No medication given to treat symptoms. The patient was receiving unspecified acid reflux medication. Company comment Very limited information regarding these events has been provided at this time. Further information has been requested. Company causality for events</p>

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Thrombosis, Syncope, Erythema, Palpitations, Feeding disorder, Chest pain, Rash macular and Myalgia cannot be excluded, while company causality for Incomplete course of vaccination is assessed as not applicable.; Sender's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested. Company causality for events Thrombosis, Syncope, Erythema, Palpitations, Feeding disorder, Chest pain, Rash macular and Myalgia cannot be excluded, while company causality for Incomplete course of vaccination is assessed as not applicable.

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1366919	6/2/2021	NC	73	F	2/15/2021	3/22/2021	<p>blood clots in her legs; blood lot traveled to lungs, had a very severe case of blood clots; severe pain in her legs; could not walk; weak; feeling fatigued; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (blood clots in her legs), PULMONARY EMBOLISM (blood lot traveled to lungs, had a very severe case of blood clots) and PAIN IN EXTREMITY (severe pain in her legs) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 15-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 22-Mar-2021, the patient experienced PAIN IN EXTREMITY (severe pain in her legs) (seriousness criterion hospitalization), GAIT INABILITY (could not walk), ASTHENIA (weak) and FATIGUE (feeling fatigued). On 31-Mar-2021, the patient experienced THROMBOSIS (blood clots in her legs) (seriousness criteria hospitalization and medically significant) and PULMONARY EMBOLISM (blood lot traveled to lungs, had a very severe case of blood clots) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 31-Mar-2021 due to PULMONARY EMBOLISM and THROMBOSIS. At the time of the report, THROMBOSIS (blood clots in her legs), PULMONARY EMBOLISM (blood lot traveled to lungs, had a very severe case of blood clots), PAIN IN EXTREMITY (severe pain in her legs), GAIT INABILITY (could not walk), ASTHENIA (weak) and FATIGUE (feeling fatigued) outcome was unknown. No concomitant and treatment medications were reported. The patient had no side effects from the first dose of Moderna vaccine. The patient remained hospitalized at the time of report. Based on the current available information which shows a temporal association between the use of mRNA-1273 and the onset of the reported events, a causal relationship cannot be excluded. Fatigue is consistent with the Known safety profile of the product.; Sender's Comments: Based on the current available information which shows a temporal association</p>



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between the use of mRNA-1273 and the onset of the reported events, a causal relationship cannot be excluded. Fatigue is consistent with the Known safety profile of the product.

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1366958	6/2/2021	NY	31	F	1/1/2021	1/1/2021	KIDNEY FAILURE; Neurological disorder; Headache; anosmia; COVID-19; 2nd dose on 01Jan2021; 2nd dose on 01Jan2021; This is a spontaneous report from a contactable physician. A 31-years-old female patient received bnt162b2 (Pfizer-BioNTech COVID-19 mRNA vaccine, Formulation: Solution for injection, Batch/Lot Number: EL8982), dose 2 intramuscular, administered in Deltoid Left on 01Jan2021 as an unspecified dose for covid-19 immunisation. Patient received first dose of bnt162b2 (Pfizer-BioNTech COVID-19 mRNA vaccine, Formulation: Solution for injection, Batch/Lot number: EL0142) on 29Dec2020 via R deltoid intramuscular as unspecified route for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient had a history of diabetes: Borderline and the patient was a non-smoker/former. It was stated patient have a positive test for SARS-Cov2 and New infection Dxdt RT-PCR was done on 06Jan2021 and patient have SARS-CoV2 antibodies at diagnosis was unknown. Patient willing to be contacted again by Pfizer on the reported adverse event. It was reported that patient experienced Covid a week after the 1st dose of the vaccine. When to get the 2nd dose/tested positive for COVID 04Jan2021. There was a Renal failure on unspecified date. And no other details were provided and Neurological is Yes, and no details were provided. Other provided as Yes as headache, anosmia. The patient was not hospitalized and the patient was not admitted to an Intensive Care Unit. The patient display no clinical signs at rest indicative of severe systemic illness. The patient does not require supplemental oxygen (including high flow or ECMO) or receive mechanical ventilation. Patient does not have Mutliorgan failure, Respiratory, Dyspnea, Tachypnea, Hypoxemia and COVID-Pneumonia was Unknown, No Respiratory failure and no Acute respiratory distress syndrome (ARDS). Patient had no Cardiovascular, Heart failure, Cardiogenic shock, Acute myocardial failure, Arrhythmia, Myocarditis, Gastrointestinal/Hepatic, Vomiting, Diarrhea, Abdominal pain, Jaundice, Acute liver failure, Other, Vascular, Deep vein thrombosis, Pulmonary embolism, Limb ischemia, Vasculitis, Renal and Unknown Acute kidney injury. The was no altered consciousness, Convulsions/Seizures, Encephalopathy, Meningitis, Cerebrovascular accident.

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There was no Hematological, Thrombocytopenia, Disseminated intravascular coagulation, Other, Dermatological, Chillblains, Erythema multiforme. patient had not received any additional therapies for COVID-19. the event does not require the initiation of new medication or other treatment or procedure. Patient did not retest from the SARS-CoV2 diagnosis before the SARS-CoV2 antigen test became negative. It was reported that Laboratory Test or Diagnostic Studies: Test for SARS-CoV-2 by PCR, or other Performed on 06Jan2021 Results with units as Positive. The patient has not been taking any medications routinely prior to the event being reported. Patient do not have any pre-existing diseases worsened during the SARS-CoV2 infection. The patient had not been treated with immunomodulating or immunosuppressing medications or received any other vaccines around the time of COVID-19 vaccination. The outcome with COVID-19 was recovered and the remaining events were unknown. No follow-up attempts are needed. No further information is expected.; Sender's Comments: Based on the information available and a close temporal association, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events of Renal failure,covid 19 anosmia,headache. The case will be reassessed once new information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Committees, and Investigators, as appropriate

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1367114	6/2/2021	CO	34	M	4/3/2021	4/6/2021	swelling and tenderness in lower right leg / vasculitis; This is a spontaneous report from a contactable consumer (patient). A 34-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; Batch/Lot number and Expiration date were not reported), via an unspecified route of administration (administered on the right arm) on 03Apr2021 10:15 (at the age of 34-years-old) as 1st dose, single dose for COVID-19 immunisation. The patient's medical history was not reported. Concomitant medications included alprazolam (XANAX) and propranolol both taken for an unspecified indication, start and stop date were not reported. The patient previously took PERCOCET and experienced mild allergy. The patient didn't receive any other vaccines within 4 weeks prior to COVID vaccine. Prior to vaccination, the patient has not been diagnosed with COVID-19. The patient experienced swelling and tenderness in lower right leg / vasculitis on 06Apr2021 15:00. It was reported that 3 days after vaccination the patient experienced swelling and tenderness in lower right leg and was initially misdiagnosed as infection. After symptoms persisted for 1.5 weeks and antibiotics had no effect, it was diagnosed as vasculitis. No rheumatological issues in blood test or blood clot. PCP determined likely an immune response to the vaccine. The adverse event resulted in emergency room/department or urgent care and doctor or other healthcare professional office/clinic visit. Therapeutic measures were taken as a result of the event included antibiotics and antiinflammatory. Since the vaccination the patient has not been tested for COVID-19. The outcome of the event was recovering.

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1367128	6/2/2021	NJ	31	F	4/7/2021	4/22/2021	<p>irregularities in my menstrual cycle such as heavy bleeding and very large clots (2-3 in in size); irregularities in my menstrual cycle; terrible headache and stomach pain like none I had ever had before 10/10 pain scale; stomach pain; my sense of smell was off and still is. It's like a rancid smell?; unable to go about my daily activities; extremely fatigued; This is a spontaneous report from a contactable nurse (patient). A 31-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EP7533 and expiration date not provided), via an unspecified route of administration, administered in Arm Left on 07Apr2021 14:45 as 1ST DOSE, SINGLE for covid-19 immunisation. The patient's medical history includes Scoliosis, migraine, and COVID-19 on 13Jan2021 (lost my sense of smell for 5 days but it returned without any issues and I had only minimal symptoms). The patient was not pregnant at time of vaccination. The patient's concomitant medications were not reported. On 22Apr2021 15:00, the patient experienced terrible headache and stomach pain like none I had ever had before 10/10 pain scale. The patient took 2 tablets of 500 mg of acetaminophen to treat the pain but it had no effect. After 8 hours past I then took 3 tablets of 200 mg ibuprofen which still had no response to pain. The patient sense of smell was off and still is. It is like a rancid smell? I gave it some time to see if it would go away but it is still present. The patient also experiencing irregularities in my menstrual cycle such as heavy bleeding and very large clots (2-3 in in size). It has made me unable to go about my daily activities and I have been extremely fatigued. I have never had this issue previously and am not on any kind of medications or birth control. No treatment was given for the events except for headache and stomach pain. The outcome of the event was not recovered. The patient took the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EW0170) on 28Apr2021 administered on left arm for covid-19 immunisation.</p>

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1367379	6/2/2021	OK		M	3/23/2021	3/1/2021	runny nose; This is a spontaneous report from a contactable consumer or other non hcp. A 20-years-old male patient received BNT162B2 (: PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 23Mar2021 (Batch/Lot number was not reported) as a Single dose for covid-19 immunization. The patient past medical history and concomitant medications were not reported. The patient experienced runny nose 10 days but was fine after on Mar2021. However, 4 days later he woke up with an incredible ringing in my ears and a spike headache that he has never experienced that in his life. He also reported a rash under one of his eyes that later spread to the other eye, as well as insomnia. He has seen his HCP and was referred to an Audiologist, who he has visited 3 times since then. He was diagnosed with 50% loss of hearing and 10500 Hertz tinnitus, which the Audiologist mentioned is high. He was prescribed with high dose Prednisone for 7 days, but caller mentioned it did not help and had no effect whatsoever. His HCP wanted to be super cautious and recommended a brain scan this week just to make sure he didn't develop a blood clot. He has reached out to CDC and asked for medical advice, but he stated that everyone is giving him the same answers - there is not enough data. He is on the verge of suicide and said, I can't live with this for the rest of my life. I can't sleep and can't think, its driving me crazy. The event outcome was recovered on Apr2021. He is desperate for answers and even tried reporting to VAERS but there was no way to submit it. No follow-up attempts are needed; information about lot/batch number cannot be obtained.
1368535	6/2/2021	WV	73	M	3/6/2021	3/20/2021	Pfizer-BioNTech COVID-19 Vaccine EUA States exactly 2 weeks after received 2nd dose of Pfizer vaccine, lost feeling in his right leg. Went to the hospital. Continued to have neurological symptoms. States was diagnosed with Bell's Palsy and blood clot in right leg. States cannot ambulate without walker now. States doctors are unsure of cause of neurological issues.

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1366878	6/2/2021	NY	21	F	2/11/2021		<p>Right arm is bigger than left arm.; After 1st vaccine my right arm was little bigger than left arm but after 2nd vaccine it got worst; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PERIPHERAL SWELLING (Right arm is bigger than left arm.) and CONDITION AGGRAVATED (After 1st vaccine my right arm was little bigger than left arm but after 2nd vaccine it got worst) in a 21-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 032M20A and 024M20A) for COVID-19 vaccination. No relevant medical history was reported. Concomitant products included FLUDROCORTISONE for an unknown indication. On 11-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced PERIPHERAL SWELLING (Right arm is bigger than left arm.) (seriousness criterion hospitalization) and CONDITION AGGRAVATED (After 1st vaccine my right arm was little bigger than left arm but after 2nd vaccine it got worst) (seriousness criterion hospitalization). The patient was hospitalized on 17-Apr-2021 due to CONDITION AGGRAVATED and PERIPHERAL SWELLING. At the time of the report, PERIPHERAL SWELLING (Right arm is bigger than left arm.) and CONDITION AGGRAVATED (After 1st vaccine my right arm was little bigger than left arm but after 2nd vaccine it got worst) outcome was unknown. The patient also reported taking an unspecified birth control pill concomitantly. The patient reported going to the ER on 17-Apr-2021 due to possible blood clot in right arm. The doctor did not find any blood clot, and the patient was not prescribed anything. The patient received both scheduled doses of mRNA-1273 prior to the events therefore, action taken with the drug in response to the event is not applicable. Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-148205 (E2B Linked Report). Most recent FOLLOW-UP information incorporated above includes: On 19-May-2021: No new</p>

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							information provided.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-148205:First Dose Case
1369355	6/2/2021	OH	41	F	4/1/2021	4/1/2021	Immediate dizziness. Arm felt like dead weight. Had trouble driving to waiting area. Within 20 minutes, chest, neck, arms, and face tightened, I couldn't move my arms, paramedics found blood pressure to be very high. Was light headed for 48 hours after. Almost fell over multiple times. Arms and legs very heavy and tired easily. On 4/21/2021 my leg cramped up and went numb. Week later my chest constricted with same issue from injection day. Went to hospital. Blood pressure again elevated. Concerned of a blood clot, did chest mri and ultrasound of blood vessel in leg. No blood clot found, but new lesions in chest were found and no explanation of leg issues. As of today's date, no one can figure out why my right leg is numb from mid thigh down, but has major pain and causing me not to be able to walk and go up stairs. Feels like a constant charley horse in my calf with pain radiating through my knee and up my thigh. No injury was sustained. It happened all of the sudden while laying on the couch reading. I've seen regular doc, pt specialist, sports med doc, headed to a spine specialist next. No explanation of strange pain and numbness.
1367971	6/2/2021	PA	51	M	4/4/2021	4/9/2021	Exactly 5 days after the second dose of the Pfizer covid-19 vaccine, I suffered an ischemic stroke. There was a blood clot in my brain that was broken up after tPA was administered about 2 hours after the symptoms of the stroke set in. To date (May 30) I have had many tests, including 2 MRIs, CT scans, TEE, heart monitoring etc. So far, it has been called a "cryptogenic stroke" because there is no cause. The only thing different was the vaccine I received 5 days before the stroke.



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1367723	6/2/2021	WY	63	F	5/3/2021	5/4/2021	Less than 24 hours after receiving 2nd COVID vaccine my mother develop a weird rash that mirrors a pair of socks reaching to the knees that is red in appearance bilaterally. Then her feet began to swell to roughly triple the size of her feet. They then turned and angry red and her toes turned purple. Her feet have been sore and she at times is not able to walk on them because they are extremely sore. My mother developed what the medical professionals are calling COVID toe. She was taken to the ED 3 times in the course of 3 weeks and had appt's with PCP 2 times 1st PCP on day #4 was given a course of Fexeril which she finished as directed by PCP. Enormous swelling and redness and was treated for cellulitis and peripheral edema via ED on day #6. She has had 2 ultrasounds which have turned negative for blood clots She has had blood work that has returned negative for any concerns. She is currently waiting on results from a CT. This is still ongoing for my mom.
1369944	6/2/2021	NJ	55	F	4/21/2021	5/9/2021	Patient presented to the emergency room on 5/9/2021, approximately 3 weeks after receiving the J&J vaccine due to progressively worsening shortness of breath. She also had noted pain and swelling in the left calf and leg. In the ED she underwent CTA of the chest showing severe burden of acute PE (pulmonary embolism) with severe right heart strain, small early infarct posteromedial LLL, hepatic steatosis. Venous doppler 5/10/21 showed complete thrombosis left femoral, popliteal, posterior tibial, peroneal and anterior tibial veins, partial thrombosis of left common femoral vein. She underwent urgent thrombectomy, however, the next morning she became more hypoxic and hypotensive. She was intubated and was urgently placed on ECMO. She developed multi-organ failure. She was started on CVVH for oliguric renal failure. CT scan of her head done 3 days later showed diffuse diffuse cerebral edema, which is most likely a result of hypoxic encephalopathy. With no improvement in her mental status over the course of the next few days, she was taken off life support and died on 5/15/2021

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1369341	6/2/2021	CA	28	F	4/9/2021	4/18/2021	Review of ED notes show she received IV infusion of normal saline, and IV push of benadryl and compazine after going to the ER for severe headache on 04/17/2021. She first noticed pain when stretching the arm shortly after the IV infusion but didn't pay attention to it, then 5 day later she noticed localized swelling and redness. Patient was sent for US doppler which left cephalic vein thrombus detected on duplex US. Was treated with aspirin and had follow up doppler of UE for follow up on LUE cephalic vein thrombosis-negative 5/13/21.
1369331	6/2/2021	IL	61	M	5/12/2021	5/28/2021	Dose #1 received on 4/21/21. Dose #2 received on 5/12/21. Difficulty breathing beginning on 5/5/28/21. Diagnosed with multiple blood clots in right lung on 5/30/21.
1369298	6/2/2021	NY	45	F	5/22/2021	5/28/2021	lower extremity deep venous thrombosis
1368563	6/2/2021	CO	35	F	4/6/2021	5/6/2021	I went to the ER on 05/14/2021 because I had swelling in one ankle. I am pregnant so I was concerned. I was tested and a Deep Vein Thrombosis in my right leg. The swelling was in my left leg. There is no redness or swelling in that leg. I am taking subcutaneous injection of Lovenox 0.8 ml twice daily. I was 27 weeks pregnant at the time. I am currently experiencing injection site pain and I am seeing a maternal Fetal Medicine Specialist monthly. A birth plan has to made for when I deliver because of the medication. The diagnosis states Right Popliteal and Proximal calf DVT. Due-Date-08-09-2021 Pregnancy-First Pregnancy

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1369289	6/2/2021	AZ	56	M	5/18/2021	5/29/2021	Patient called 6/2/21 and stated that he had a blood clot on his leg and was asking if it was because of the covid vaccine that he had received on 5/18/21. Patient had self-diagnosed and at time of call, had not sought medical attention. Described as a huge, red spot on his thigh that was about the size of his hand. Located on right thigh, on top, almost by inner thigh. Stated appearance was red/rose colored, and was getting darker like a sunburn. Approximately 10 inches long and 4 inches wide. Hurts when he stands up, and rated a 5/10 for pain level. Vaccine administered 5/18/21 and symptoms appeared 5/29/21. Advised patient to seek medical care. Patient asked for contact numbers and provided Pfizer and CDC. Patient called Pfizer and representative stated that a report would be made. Noted that patient was prescribed anastrozole and this may cause venous thromboembolism in about 3% of patients. Patient was informed of this during a follow up call and advised to call prescriber, and again to seek medical attention. Prescriber was notified 6/2/21 in regards to the symptoms reported, and advised regarding possible adverse drug event.
1369075	6/2/2021	PA	69	F	5/5/2021	5/19/2021	patient reported a couple weeks after 1st moderna vaccine (she was unsure of date, I guessed on the first page of the report because I had to put an exact date). she began to feel short of breath. eventually went to hospital where she was diagnosed with blood clots in both the legs and lungs. she said dr is saying it was due to the vaccine and told her not to get the second dose. she stayed 5 days in the hospital according to her. had surgery to place a filter for the clots and is now home on oxygen around the clock.
1369067	6/2/2021	FL	68	M	3/16/2021	5/30/2021	30 May 2021 I was diagnosed as an otherwise healthy male with pulmonary embolism in the lower right lung. No predispositions to blood clots.

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1368877	6/2/2021	CT	39	M	5/3/2021	5/10/2021	1 week after the second dose, I was exercising in the early morning when suddenly my vision and hand-eye coordination were flashing, my hand appeared in a different position than where I thought it was. I tried to tell my sons to get help, but I couldn't say any words, just some repetitive mumbling. I was able to walk upstairs but couldn't speak for about 10 mins, and then everything was coming out slowly. It was about an hour before I could resume normal talking. I went to the hospital, where they gave me a CT scan, MRI, heart echo, and eventually a TEE. They said that I had a Transient Ischemic Attack, and they found a PFO in my heart that probably allowed a blood clot to travel to my brain. They also did an ultrasound of my legs when I mentioned the timing of the vaccine, to make sure there were no other clots. I am taking baby aspirin and crestor, and have an heart event monitor now for 30 days. I am also scheduled for more bloodwork and a pelvic scan. They say it is likely that they will want to close my PFO, but want to see all the test results first to rule out any other possible causes.
1368820	6/2/2021	MI	45	F	4/10/2021	4/12/2021	I started a very heavy period that lasted 25 days. I usually have a light 2 day period like clockwork. No birth control.. very normal my whole life until my shot. I had heavy bleeding along with clots of blood.
1368813	6/2/2021	OR	32	F	5/5/2021	5/6/2021	I had the vaccine and at 2 o'clock in the morning I woke with excruciating pain it felt like I broke both my legs and they swelled, more the right one than the left, I could barely walk, Tylenol did not help, the swelling got worse for over a week, the pain was the same for over a week, I still have some pain but the swelling is still there. I did not go into Urgent care until a week because I was at work and my left leg was swollen and discolored and my heart rate. They drew my blood checked my heart rate which was in the high 90s and jumped to 163. They did not know what was going on but did not think it was a blood clot so they sent me home. They did not prescribe any medications.
1368760	6/2/2021	NY	47	M	5/1/2021	5/1/2021	Blood clots right leg from calf to groin.pulmonary embolism

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1368699	6/2/2021	WI	62	M	4/6/2021	5/30/2021	patient has developed blood clot after getting the J&J shot on 4/6/2021. The patient has had a sore arm since the day he got his vaccine. According to his wife, he started to feel weak on Sunday 5/30/2021. She said his hands were cold that day too, then by Tuesday his fingers turned white, this is when she took him to the hospital and found out about the blood clot. His wife also mentioned that after examination, they found out that he has an extra rib that was pressing on the brachial artery and that might have caused the blood clot. It doesn't seem to be sure that the blood clot was caused by the covid vaccine or not
1368663	6/2/2021	TX	84	F	4/20/2021	6/2/2021	Patient is hospitalized for blood clot a month after getting second moderna shot.
1364718	6/1/2021	PA	42	F	4/29/2021	5/14/2021	2 weeks after vaccination-started bleeding clots

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1364001	6/1/2021	NJ	39	M	5/7/2021	5/13/2021	<p>pain in calf; Deep vein thrombosis; Blood Clot; This spontaneous case was reported by a physician (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (Deep vein thrombosis) and THROMBOSIS (Blood Clot) in a 39-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Deep vein thrombosis. On 07-May-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-May-2021, the patient experienced DEEP VEIN THROMBOSIS (Deep vein thrombosis) (seriousness criterion medically significant) and THROMBOSIS (Blood Clot) (seriousness criterion medically significant). On an unknown date, the patient experienced PAIN IN EXTREMITY (pain in calf). The patient was treated with APIXABAN (ELIQUIS) for Clot blood, at a dose of 1 dosage form. At the time of the report, DEEP VEIN THROMBOSIS (Deep vein thrombosis), THROMBOSIS (Blood Clot) and PAIN IN EXTREMITY (pain in calf) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-May-2021, Scan: blood clot (abnormal) blood clot. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications included unspecified anti-coagulant and antibiotic. Company comment Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1364028	6/1/2021	NJ	54	M			Stroke; Blood clots; Brain bleed; Wife found him on the floor after he collapsed; Still struggling to move left hand; Felt really weird; Acting differently; Kept rubbing his arm and saying it was burning; Wife found him on the floor after he collapsed and fell off the couch; Unable to move or talk; Can't speak / unable to talk; Can not stand up; Arm hurting like crazy / arm was killing him; This spontaneous case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (Stroke), THROMBOSIS (Blood clots), CEREBRAL HAEMORRHAGE (Brain bleed), LOSS OF CONSCIOUSNESS (Wife found him on the floor after he collapsed) and HEMIPARESIS (Still struggling to move left hand) in a 54-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. unknown) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced CEREBROVASCULAR ACCIDENT (Stroke) (seriousness criteria hospitalization and medically significant), THROMBOSIS (Blood clots) (seriousness criteria hospitalization and medically significant), CEREBRAL HAEMORRHAGE (Brain bleed) (seriousness criterion medically significant), LOSS OF CONSCIOUSNESS (Wife found him on the floor after he collapsed) (seriousness criterion medically significant), HEMIPARESIS (Still struggling to move left hand) (seriousness criterion medically significant), FEELING ABNORMAL (Felt really weird), ABNORMAL BEHAVIOUR (Acting differently), BURNING SENSATION (Kept rubbing his arm and saying it was burning), FALL (Wife found him on the floor after he collapsed and fell off the couch), HYPOKINESIA (Unable to move or talk), APHONIA (Can't speak / unable to talk), DYSSTASIA (Can not stand up) and MYALGIA (Arm hurting like crazy / arm was killing him). At the time of the report, CEREBROVASCULAR ACCIDENT (Stroke), THROMBOSIS (Blood clots), CEREBRAL HAEMORRHAGE (Brain bleed), LOSS OF CONSCIOUSNESS (Wife found him on the floor after he collapsed), HEMIPARESIS (Still struggling to move left hand), FEELING ABNORMAL (Felt really weird),

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ABNORMAL BEHAVIOUR (Acting differently), BURNING SENSATION (Kept rubbing his arm and saying it was burning), FALL (Wife found him on the floor after he collapsed and fell off the couch), HYPOKINESIA (Unable to move or talk), APHONIA (Can't speak / unable to talk), DYSSTASIA (Can not stand up) and MYALGIA (Arm hurting like crazy / arm was killing him) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Concomitant product use was not provided by the reporter. It was reported that, the patient felt really weird and was acting differently. Four days after the patient received the vaccine, his wife found him on the floor after he collapsed and fell off the couch and was unable to move or talk. He was taken to hospital and was in ICU for 5-6 days. Treatment information was not provided. Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.



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1364279	6/1/2021	NM	76	F	3/3/2021	3/3/2021	<p>Outbreak, looked like hives, on her torso and stomach area, after the first vaccine;; Chills, after first and second vaccine; Injection site sore after first and second vaccine; Arm was numb, tingley and painful from the shoulder to the fingertips, after the first and second vaccine; Arm was numb, tingley and painful from the shoulder to the fingertips, after the first and second vaccine; Arm was numb, tingley and painful from the shoulder to the fingertips, after the first and second vaccine; This is a spontaneous report received from a contactable consumer (patient). A 76-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/Lot Number: EN6204, Expiration date was not reported), via an unspecified route of administration on 03Mar2021 14:00 as 1st dose, single dose for COVID-19 immunisation. Medical history and concomitant medications were reported as none. On 03Mar2021, the patient experienced outbreak, looked like hives, on her torso and stomach area, with sequelae after the first dose, chills after first and second vaccine, injection site sore after first and second vaccine, Arm was numb, tingley and painful from the shoulder to the fingertips, after the first and second vaccine (Patient visited office). she would like to know about percentages in age groups who have experienced any numbness and tingling, and if there are any correlation with developing blood clots of this, and also, she wanted to know if she needs further medical attention and to prevent a serious outcome. The outcome of the event was recovered for urticaria on 21Mar2021, the outcome of chills was unknown. Vaccination site pain, Hypoaesthesia Paraesthesia was not recovered. No follow-up attempts are needed. No further information is expected.</p>

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1364281	6/1/2021			M	4/21/2021	4/22/2021	two blood clots inside his brain, and one on the outside/ three blood clots in and near his brain; two blood clots inside his brain, and one on the outside/ three blood clots in and near his brain; pulled neck muscle; neck pain; fevers/ fever; severe headaches/incessant headaches; swollen lymph nodes; extreme migraines/ migraine headaches; could not move his neck without the assistance of his hands/ unable to freely move his neck; eyes are still swollen; Neck swelling; The initial case was missing the following minimum criteria: no identifiable reporter. Upon receipt of follow-up information on 24May2021, this case now contains all required information to be considered valid. This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer, physician and non-contactable consumers reported that a 17-year-old male patient (also reported as 18 years old) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 21Apr2021 (Batch/Lot number was not reported) as 1st dose, single dose for COVID-19 immunisation. Medical history included prior COVID-19 infection. Before the shot, the patient was 100 percent healthy, playing and practicing basketball. There was nothing wrong with him. He didn't have a sore throat (or) any injury. The patient's concomitant medications were not reported. On an unspecified date, the patient was hospitalized with three blood clots in and near his brain that developed after he received the first dose of Pfizer-BioNTech COVID vaccine. The symptoms started after getting his first COVID-19 vaccination dose, and symptoms were initially dismissed as a pulled neck muscle. He received the vaccine on 21Apr2021 and began experiencing neck pain, fever and severe headaches on an unspecified date (also reported as "one day later"). The patient's pediatrician initially dismissed the symptoms as a pulled neck muscle. However, the patient's mother was convinced it was something else. After more than a week of symptoms and being unable to freely move his neck, the family got this diagnosis: two blood clots inside his brain, and one on the outside. The patient was healthy and well before. It was unclear how long the patient will be in the hospital. It was also stated that the patient experienced swollen lymph nodes and migraine headaches. Further reported that the day after his COVID-19 vaccine shot (on 22Apr2021), the patient

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felt his neck swelling. In the coming days, he suffered from severe headaches. He also could not move his neck without the assistance of his hands few days after the shot (unknown date). Patient suffered from fevers and incessant headaches. He started to feel swelling and pain in his neck ("that night"). Days later, he got extreme migraines, so the patient's mother took him to the emergency room. It was reported that the patient plays competitive basketball seven days a week, which means high contact physical activity that could have possibly aggravated the swelling caused by the vaccine. On Thursday (unknown date), the patient left the ICU, but his eyes are still swollen and the road ahead is uncertain. On an unspecified date, the patient was out of intensive care unit (ICU) but the clots aren't gone. He has an magnetic resonance imaging (MRI, unknown date, unknown results) to see if they shrunk. The patient is currently at home recovering (as reported). Doctor recommended that patient have a COVID Nucleocapsid antibody level drawn to determine if he had been exposed previously to the Corona virus. On an unspecified date, the patient underwent test for nucleocapsid antibodies, patient is POSITIVE for SARS-CoV-2 nucleocapsid antibodies. This indicates that he had been previously infected with Corona virus prior to his receiving the BNT162 vaccine. There is a very serious concern that previously infected persons may be at higher risk of developing post-vaccine complications that un-immune persons. The doctor believed that the prior infection in combination with the vaccine led to the blood clots in the brain. Outcome of event "two blood clots inside his brain, and one on the outside/ three blood clots in and near his brain" was not recovered, while other events were unknown. Information on the lot/batch number had been requested.

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1364304	6/1/2021	FL	77	F	2/25/2021	4/19/2021	major bleed; GI bleed; This is a spontaneous report from a contactable consumer. A 77-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection) via an unspecified route of administration, administered in Arm Left on 25Feb2021 (at the age of 77-year-old) (Lot Number: EN6200) as 2ND DOSE, SINGLE DOSE for covid-19 immunization. Medical history included first time she experienced bleeding was in 2013 because of aspirin. Stated that she decided it was a good idea to take baby aspirin so she took it on her own. She was told don't ever take aspirin ever again and she didn't have any problem until Nov2020. That was the first incident, in 2013, that told her she should not take blood thinner. They took her off the blood thinner in Nov2020. She had been taking aspirin. She lost half her blood; she lost it two settings. She sat down to take a bowel movement and was told she lost half of her blood. Not sure when she started Aspirin but she stopped it in 2013. It was mentioned that she could take aspirin. She was on a low dose of Eliquis for atrial fibrillation for prevention of a blood clots or heart attack. she had bleeding in the last year. The one that was the most was back in Nov2020; it was more pronounced. Mentioned that she went in on 12Nov2020 for the bleeding and then had to go back in because her legs were swelling. She stopped taking Eliquis in Nov2020 and from then until Apr2021 she had no bleeding. It was several years ago when she was diagnosed. She was riding her bike in the neighborhood, and felt too tired so she stopped at the doctor and went in and told them she felt weird, they couldn't get her BP and took her to the hospital and her heart rate was sky high like 250. They said she might had to have electric. She didn't have any pain but states she was psychologically freaked out by everyone running around. Mentioned that, she was first placed on dronedarone (MILTAC) 400mg twice daily to treat her atrial fibrillation; she can't remember the year. After taking it as prescribed for some time she got atrial fibrillation again. She was told by the doctor it had lost its efficacy. Concomitant medications included Fenofibrate taken for blood cholesterol, Metoprolol succinate taken for blood pressure, Vitamins NOS, Ferrous Sulfate taken for anemia, Vitamin D3 all are ongoing. The patient previously took first dose of BNT162B2 (COMIRNATY, Solution for injection, lot

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number: EL3246) on 06Feb2021 in arm left for covid-19 immunization. It was reported that, On 25Feb2021 she received her second dose of the Pfizer-BioNtech Covid-19 vaccine, on 19Apr2021 she had a major bleed and GI bleed (Hospitalization) on 19Apr2021. The patient was hospitalized for major bleed and GI bleed from 19Apr2021 to 21Apr2021. Outcome of the events was unknown. No further information expected.

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1364306	6/1/2021	NJ	86	F	2/17/2021	3/1/2021	very fatigued; pain in her feet moved up to her hands; she couldn't walk; she was bedridden; could not urinate properly, she couldn't void all the way; Incontinent; breathing was labored; she had no strength at all; This is a spontaneous report from a contactable consumer (patient's daughter). An 86-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at the age of 86 years old on 17Feb2021 (Lot number EL3302) received in her arm at single dose for COVID-19 immunization. Ongoing medical history included Low functioning kidney for probably 15 years, Platelete condition for probably 20 years, COPD since she was in her 40's, Asthma for over 40 years, Chronic heart failure for 10 or more years, high blood pressure, acid reflux, allergies, retains water, neuropathy in hands and feet, mucous in the lungs, thyroid condition, hypo for more than 20 years, bad lower back and bad left shoulder, nerves, anxiety, to sleep, to calm her nerves, walked with a walker. Concomitant medications included amlodipine ongoing for high blood pressure; ascorbic acid (VITAMIN C) ongoing; acetylsalicylic acid (ASPIRIN) ongoing for heart condition; atorvastatin ongoing; fluticasone furoate, vilanterol trifenate (BREO ELLIPTA) ongoing for asthma, COPD; buspirone ongoing; carvedilol ongoing; clotrimazole; famotidine ongoing for acid reflux; ferrous sulfate from an unspecified date to Apr2021 as Iron supplement; fluticasone propionate ongoing for allergies and asthma; fluticasone, salmeterol ongoing; folic acid ongoing; furosemide ongoing for retains water; gabapentin from Feb2021 and ongoing for neuropathy in hands and feet; guaifenesin ongoing for mucous in the lungs; hydroxyurea ongoing for her bone marrow made too many platelets; levothyroxine sodium ongoing for thyroid condition, hypo; lidocaine hydrochloride (LIDOCAINE) for bad lower back and bad left shoulder; magnesium oxide (MAG-OX) ongoing; montelukast for allergy and asthma; sertraline hydrochloride (ZOLOFT) ongoing; sitagliptin ongoing; temazepam for nerves and anxiety; linagliptin (TRADJENTA) ongoing; trazodone ongoing to sleep, to calm her nerves; valsartan for high blood pressure; vitamin D. Historical Vaccine included first dose of BNT162B2 (Lot number EK4176) on 27Jan2021 received in one of her arms for COVID-19

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immunization and experienced severe pain in her left knee. The patient received the second vaccine on 17Feb2021. A week out or so she started having pain in her feet and she was very fatigued 19Mar2021; both still ongoing, both on a week. The patient had had 2 stints at the hospital, and 2 rehabs. Both of these have very slightly improved. The patient went to the hospital due to the pain in her feet that moved up to her hands, she was very fatigued, and she couldn't walk; she was bedridden on 19Mar2021. Weeks after the shot it continued day after day after day up until 19Mar2021 where she was admitted to the hospital. The patient just had her last stint in rehab this past 2 weeks and could get up with physical therapy. Hospitalization was from 19Mar2021 to 27Mar2021. The patient could not urinate properly, she couldn't void all the way and that this occurred some time between after the second vaccine up until 19Mar2021. Those few weeks things progressed. Now she was incontinent and had to wear diapers. She urinates in diapers and defecates in diapers. The incontinence started sometime during 19Mar2021 to 27Mar2021 and it is ongoing, persisting. In the hospital they could not find anything seriously wrong with her. The patient had total fatigue and the caller begged them to give her mother a (vitamin) B12 shot. They gave it to her but there was no improvement with patient's energy. They put a catheter in her to get her kidney function back to her normal level. It was because she was not urinating properly. They ran a bunch of tests and there was not anything wrong with her. They did cardiac tests, lung tests, and XRays. The patient's breathing was labored. Started sometime after the second shot leading up to the hospital and that the patient had to be on oxygen. She said she was still on oxygen and that the labored breathing was ongoing, persisting. Reporter said all of these above listed were from 25Apr2021 to 03May2021. They did more tests but there were no answers and patient was at this point bedridden all this time; she had no strength at all, all the same symptoms were ongoing, there were no diagnoses, they were switching her meds around. The patient was on oxygen 24/7, all day when she was walking, sitting in a room in her wheelchair. The caller said she was hoping patient could get up and walk around but she was still weak. She said with time she hoped she got better on feet, got back to her normal. The outcome of the events

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1364309	6/1/2021	TX					
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were not resolved. Information on the lot/batch number has been requested.

Pulmonary embolism/ two large blood clots, one in each lung; This is a spontaneous report from a contactable consumer (patient). A 64-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in arm right on an unspecified date (Lot Number: EP6955) as single dose for COVID-19 immunisation. Medical history included high blood pressure and cholesterol abnormal, both from an unknown date and unknown if ongoing. Prior to vaccination the patient was not diagnosed with COVID-19 and since the vaccination the patient has not been tested for COVID-19. The patient's concomitant medications were not reported. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in arm right on 28Feb2021 at 08:00 (Lot Number: EN6202) as single dose for COVID-19 immunization. On 29Apr2021 at 07:00, roughly one month after second dose of vaccine, the patient couldn't breathe, sweating profusely, accelerated heart rate and chest tightness. He was diagnosed with a pulmonary embolism. He had two large blood clots, one in each lung. The events were serious, it required emergency surgery to save his life. The patient spent 2 days in ICU (Intensive Care Unit) and 3 additional days in the hospital. The doctors told to the patient that they had never seen blood clots like those and that large. The patient reported that he is now on blood thinners. The patient outcome of the event was recovering.



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1364553	6/1/2021	MD	32	M	5/22/2021	5/25/2021	<p>from 5/25/21 note: 32 y.o. male with a history of DVT (left leg; on Xarelto), recurrent PE, EtOH abuse, anxiety, and depression presents to the emergency department complaining of right leg pain since the last two days. He reports to receiving his Moderna COVID-19 vaccination three days ago. Thereafter, he noticed his leg pain to occurs. He also notes to intermittent pleuritic chest pain, but not currently. He notes that his leg is not as swollen compared to his previous DVT. He has full sensation and motor control of his digits. He admits to dizziness. He denies changes in breathing, abdominal pain, recent surgeries, recent travels, recent hospitalizations, or family history of blood clots. History is from the patient</p> <p>Old records reviewed. Last ED visit on 3/2/21 for pleuritic chest pain. Recent hospitalization 2/8 to 2/9 for pulmonary embolism in the setting of Xarelto non-compliance. US LLE Dplx (9/26/2020) DVT in the left popliteal, posterior tibial, peroneal and anterior tibial veins. US LLE Dplx (2/8/21) Nonocclusive thrombus in the left popliteal and posterior tibial veins. US RLE Dplx (5/25/21; today) DVT in the right femoral and popliteal veins.</p> <p>from 5/27/21 note: Patient is a 32 y.o. male with history of EtOH abuse and recurrent DVT/PE known to be noncompliant with Xarelto presenting to the ED with altered mental status. Of note patient was discharged from the hospital this afternoon where he was treated for DVT with heparin, previously on Xarelto but due to noncompliance was discharged with plan for Lovenox. Patient is alert and oriented x3, however intermittently not responding appropriately to questions and does not appear to be the best historian. Per EMS patient was found down, unresponsive in a bush. Patient admits that when he left hospital he went to gas station and drank "18 ounces of wine." EMS states when they arrived to scene patient had unsteady gait, frequent falls, no signs of significant head trauma. Patient was tachycardic in route and noted to be hypoxic in route. Patient currently complaining of mild headache but denies chest pain, shortness of breath, nausea, vomiting, diarrhea, abdominal pain, back pain or any further symptoms once again believe patient to be a poor historian.</p>

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1364809	6/1/2021	MI	61	M	4/21/2021	4/26/2021	Had shortness of breath and admitted to hospital for blood clot/pulmonary embolism on 4/28/21 * Hematologist suggested I should report for information purposes. Not stating this is believed to be the cause of the event - just reporting as requested
1364705	6/1/2021	NJ	57	F	1/6/2021	1/7/2021	24 hours after receiving the vaccine I experienced tachycardia. My oxygen level dropped into the 80's. I was told to get a chest x-ray. I went to urgent care on 01/07/2021 and Dr. office called me 01/08/2021 and told me to go to the Hospital. A blood clot was ruled out. I had an EKG, chest x-ray, bloodwork including a D-Dimer test and CTA scan with dye. The main concern was my low oxygen level with a high heart rate. I was in the ER on 01/08/2021 for most of the day. The hospital performed a D-Dimer test and it was elevated. After some time in the hospital my oxygen level rose and my heart rate regulated. I still have moments where my oxygen levels will drop and my heart rate will incline while resting.

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1364956	6/1/2021	MD	66	M	4/24/2021	5/18/2021	Patient admitted to referring hospital on 5/18/2021 for fatigue and SOB, found to have pulmonary embolism (CT with central pulmonary emboli with right heart strain), alteplase was given at referring hospital and was admitted to ICU for continued monitoring. Venous duplex done also revealed bilateral DVTs. Patient was doing well after fibrinolytic with heparin anticoagulation, but had sudden decompensation on 5/21 (hypotension and respiratory failure requiring intubation). Transferred to current institution for ECMO evaluation due to severe cardiopulmonary compromise. Patient deemed not ECMO candidate based on co-morbid conditions based on CT findings. He underwent mechanical thrombectomy with improvement. He was continued on heparin infusion, then had sudden decrease in platelet on 5/25 with worsening cardiopulmonary status. HITT was suspected and heparin was transitioned to argatroban. Results of heparin induced platelet antibodies (PF4 ELISA assay) and Serotonin Release assay was negative. Repeat imaging revealed increase clot burden and therefore patient underwent catheter directed thrombolysis followed by aspiration suction thrombectomy. Due to high clinical suspicion of HITT, repeat heparin induced platelet and SRA sent and pending at the time of report. Of note, patient still in hospital at the time of this report

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1364723	6/1/2021	MI	48	F	5/19/2021	5/19/2021	<p>She got her vaccine, they had her wait an additional 15 minutes. She had tingling sensation the entire time and she went home. Around 5:27 she looked at her arm, it was bruised, it felt like alligator skin, rough to touch when she touched it and started to get little blisters around it. It looks like her skin is burnt like she had been in a fire. She went to the Medical Center and they told her that it was a local reaction and outlined it with a marker, and gave her an ice pack, which seemed to make it worse. They gave her Naproxen and then she decided to leave as they didn't do anything, and said that she said it was a local reaction and that was going to get the second vaccine. She went home so on 5/20/21 she went to Hospital. She saw DO in the ER. She had chest pain, shortness of breath and two very large blisters on her arm with fluid in it when she was seen there. She was informed that whoever gave her the vaccine did not go in far enough and that they gave her the vaccine in the tissue and not the muscle. They did EKG, and they did blood work to see that it was no blood clots or in her lymph nodes, and said that it was a severe reaction from the vaccination, and that they had never seen anything like that before. On 5/21/21 she went to her PCP, she drained the numerous blisters that she had on her arm, she prescribed her Clindamycin, Motrin 600 mg, a skin cream Kenalog, she also gave her some aquaphor cream as well. She does not feel that this has helped much. Even after she drained the blisters, which the fluid was clear. She has been taking numerous pictures. The blisters came back, not as large but came back. The blisters would drain when she would take a shower and it was tannish in color and she called her PCP who told her to continue to take the antibiotics. She also bought some OTC cream, and an aloe vera plant which seems to be helping. She says that the dark skin has peeled off and the skin is pinkish and raw looking, which is a large area on her arm where every bump was. She said that the area is really really bad and is embarrassed to show her arm.</p>

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1363987	6/1/2021	MN	56	F	5/10/2021	5/10/2021	<p>blood clot from ankle the groin; flu like symptoms; difficulty walking; soreness in Left arm; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (blood clot from ankle the groin) in a 56-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 005C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 10-May-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 10-May-2021, the patient experienced THROMBOSIS (blood clot from ankle the groin) (seriousness criterion medically significant), INFLUENZA LIKE ILLNESS (flu like symptoms), GAIT DISTURBANCE (difficulty walking) and MYALGIA (soreness in Left arm). The patient was treated with RIVAROXABAN (XARELTO) ongoing since an unknown date for Clot blood, at an unspecified dose and frequency. At the time of the report, THROMBOSIS (blood clot from ankle the groin), INFLUENZA LIKE ILLNESS (flu like symptoms), GAIT DISTURBANCE (difficulty walking) and MYALGIA (soreness in Left arm) outcome was unknown. No concomitant medications were provided. The patient went to the ER after experiencing the blood clot (from her ankle to the groin area) and was provided treatment with Xarelto. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1363841	6/1/2021	IL		F		4/7/2021	<p>PULMONARY EMBOLISM; DEEP VEIN THROMBOSIS ON LEGS AND RIGHT ARM; FAST HEART RATE; This spontaneous report received from a patient concerned a 38 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included allergy to penicillin, non alcohol user, and non smoker. The patient had no drug abuse or illicit drug usage and allergy to vactrum. The patient experienced drug allergy when treated with hydrocodone bitartrate/paracetamol. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1A0501A expiry: UNKNOWN) dose was not reported, 1 in total administered at left arm on 15-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, the patient had heart rate and she went to emergency room and was sent home with unspecified medication. On 21-AMY-2021, the patient was admitted with pulmonary embolism and deep vein thrombosis on legs and right arm. Patient was discharged on Eliquis for 6 month. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from pulmonary embolism, and fast heart rate, and the outcome of deep vein thrombosis on legs and right arm was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210554600-COVID-19 VACCINE AD26.COV2.S-pulmonary embolism, deep vein thrombosis on legs and right arm. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>
1364674	6/1/2021	WI	21	F	4/12/2021	5/14/2021	<p>Patient developed a deep vein thrombosis approximately one month after receipt of vaccine. Of note, was on an oral contraceptive prior to this. No other history of VTE or smoking, or other coagulation disorders in family.</p>

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1363815	6/1/2021	NC	58	M	4/9/2021		<p>BLOOD CLOT IN LUNG; BILATERAL FEET AND HAND NUMB; BILATERAL HANDS AND LEGS SWOLLEN; SLEPT FOR 6 HOURS AFTER SHOT; TIRED; This spontaneous report received from a patient concerned a 58 year old male. The patient's weight was 285 pounds, and height was 56 inches. The patient's concurrent conditions included high blood pressure, depression, diabetes, flea bites allergy, peanut allergy, alcohol consumer, non smoker, heart disorder, nerve pain, mood disorder, fluid retention and pain. He had no known drug allergies. He did not have any drug abuse/illicit drug use. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 207A21A, expiry: 23-JUN-2021) dose was not reported, 1 in total administered to right deltoid on 09-APR-2021 for prophylactic vaccination. Concomitant medications included hydralazine 25mg BID (twice a day) for blood pressure, metformin hydrochloride 500mg BID for diabetes, Baby Aspirin (acetylsalicylic acid) EC (enteric coated) for heart disorder, escitalopram 10mg daily for mood disorder, gabapentin 100mg TID for nerve pain, and celecoxib 200mg 1 tablet a day as needed for pain. olmesartan medoxomil 40mg daily for blood pressure, amlodipine besilate 10mg daily for blood pressure, furosemide 40mg daily for fluid retention, potassium chloride ER (extended release) 20 Meq TID (thrice a day) and metoprolol succinate ER 50mg daily for an unknown indication. On the same day vaccination, the patient slept for 6 hours after shot and was tired. On 16-APR-2021, the patient experienced bilateral hands and legs swollen. On 19-APR-2021, the patient had bilateral feet and hands numb. On 21-APR-2021, he went to the emergency room (ER) and was hospitalized. He had following test done. Covid-19 test and EKG (electrocardiogram) results not provided, sonagram of legs showed no blood clots, computerized tomography (CAT) scan found blood clots in lungs. He was put on IV fluids and oxygen. He had blood clots in lungs, he could not specify if both lungs had it. He was discharged the next day without oxygen. He was put on Eliquis (apixaban) 5mg BID for 3 months. He was hospitalized for a day. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from slept for 6 hours after shot, and tired on 09-APR-2021, had not recovered from bilateral hands and legs</p>

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swollen, and bilateral feet and hand numb, and the outcome of blood clot in lung was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0 20210554313- COVID-19 VACCINE AD26.COV2.S- blood clot in lung, bilateral hands and legs swollen and bilateral feet and hand numb. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).



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1363773	6/1/2021	CA	59	F	4/1/2021		<p>CONTINUED TO BLEED; HAEMORRHAGIC STROKE; VOMITING; HEADACHE; PLATELET COUNT DECREASED; BIOPSY SOFT TISSUE; BRAIN SCAN ABNORMAL; POSSIBLE CEREBRAL VENOUS SINUS THROMBOSIS; BRAIN COMPRESSION; BRAIN STEM HAEMORRHAGE; BRAIN STEM SYNDROME; CEREBRAL HAEMORRHAGE; HEMIPLEGIA; SEIZURE; This spontaneous report received from a health care professional via a Regulatory Authority Vaccine Adverse Event Reporting System (VAERS) (VAER reference number 1244328 and 1199143) concerned a 59 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included pre-diabetic. It was unknown if patient was taking any prescriptions, over-the-counter medications, dietary supplements, or herbal remedies at the time of vaccination. No allergies to medications, food, or other products was reported. The patient was not pregnant at the time of vaccination. The patient did not have an adverse event following any previous vaccine. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805020, and batch number: 1805020 expiry: UNKNOWN) dose was not reported, administered on 20-MAR-2021 (also reported as 27-MAR-2021) for prophylactic vaccination. Anatomical vaccination site were not reported. No concomitant medications were reported. On 03-APR-2021, one week after vaccination, the patient had headache and vomiting. On 05-APR-2021, the patient had seizure due to hemorrhagic stroke. On an unspecified date, the patient experienced brain compression, brain stem haemorrhage, brain stem syndrome, cerebral haemorrhage, hemiplegia, possible cerebral venous sinus thrombosis, biopsy soft tissue, and brain scan abnormal, and was hospitalized. On 06-APR-2021, the patient had a surgery to remove pressure on brain and brain stem (craniectomy). The surgeon noted alarmingly low platelet counts (results unspecified). The patient had platelet transfusion. The patient was hospitalized for '4 days'. The patient continued to bleed on 06-APR-2021 and 07-APR-2021. The patient was removed from life support on 08-APR-2021. The patient died on 08-APR-2021. It was unknown if autopsy was performed. Laboratory data reported following: Brain scan was abnormal and showed abnormal, multi-focal</p>

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brain bleeds and increased compression of brain. On 07-APR-2021, Brain scan abnormal which showed increased bleeding and brain stem injury. On 08-APR-2021, the patient died from possible cerebral venous sinus thrombosis. Laboratory data (dates unspecified) included: Biopsy soft tissue (NR: not provided) unknown, Pathology test (NR: not provided) unknown. On 08-APR-2021, the subject died from possible cerebral venous sinus thrombosis. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of possible cerebral venous sinus thrombosis, brain compression, brain stem haemorrhage, brain stem syndrome, cerebral haemorrhage, hemiplegia, seizure, haemorrhagic stroke and continued to bleed on 08-APR-2021, had not recovered from headache, vomiting, and platelet count decreased, and the outcome of biopsy soft tissue and brain scan abnormal was not reported. This report was serious (Death, and Hospitalization Caused / Prolonged). This case, involving the same patient is linked to 20210441454. Additional information was received on 24-MAY-2021. Following information was added and incorporated into the narrative. Additional events of haemorrhagic stroke and continued to bleed were added, seriousness of events platelet count, vomiting, and headache was updated, additional reference numbers were added, additional vaccination date added in narrative, labeling updated, and course of event and laboratory data updated. It was determined that Manufacturer Case Number 20210441454 was a duplicate of this case. All relevant information regarding this case will be submitted under Manufacturer Case Number 20210500861. Upon review, the following information was amended: events biopsy soft tissue and brain scan abnormal was updated from non-serious to serious as this was on the earlier VAERS report.; Sender's Comments: V2: Additional information received regarding updates in seriousness of events, labeling, course of events, case identifier; and additional events of hemorrhagic stroke and "continued to bleed" did not alter prior assessment. This fatal spontaneous report (VAERS ID 1244328) concerned a 59- year- old female who experienced vomiting, headache and seizures and was hospitalized for brain compression, brain stem hemorrhage, brain stem syndrome, cerebral hemorrhage,

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hemorrhagic stroke, hemiplegia, possible cerebral venous sinus thrombosis 16 days after Janssen COVID-19 vaccine was administered for prevention of symptomatic SARS-CoV-2 virus infection. The patient's height, and weight were not reported. The patient was pre-diabetic with no known allergies. Concomitant medications were not reported. Biopsy soft tissue was done (results not reported) and brain scan showed multifocal brain bleeds and increased compression of brain; the patient underwent neurosurgery. The platelet count was decreased (result not reported) and received platelet transfusion. Follow-up scan next day showed increased/continued bleeding and brain stem injury and a day later she died from possible cerebral venous sinus thrombosis. It was unknown if an autopsy was performed. Although the subject's pre-diabetic status may have contributed, based on evolving knowledge of Thrombosis with Thrombocytopenia Syndrome (TTS, per definition from Brighton Collaboration - BC) and considering the low platelet count and temporal relationship to vaccination (BC Criteria level 5), the events are assessed to have a plausible relationship with vaccination.; Reported Cause(s) of Death: POSSIBLE CEREBRAL VENOUS SINUS THROMBOSIS

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1363774	6/1/2021	MN	61	F	3/12/2021		<p>PLATELET COUNT INCREASED; EXCRUCIATING HEADACHE; INTRAOCULAR PRESSURE DECREASED; ANGIOGRAM NORMAL; ARTERIOGRAM CAROTID NORMAL; THROMBOCYTOPENIA; ARTERY BURST BEHIND HER EYE; OCULAR DISCOMFORT; PERIORBITAL SWELLING; EYE PAIN; ACHES AND PAINS; This spontaneous report received from a patient concerned a 61 year old female, ethnicity unknown. The patient's height, and weight were not reported. The patient's past medical history included hypertension, hypothyroidism, and intermittent pancytopenia, and concurrent conditions included metronidazole allergy, hashimoto's disease, and microscopic colitis. The patient was previously treated with metronidazole. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805018, and expiry: UNKNOWN) dose was not reported, administered on 09-MAR-2021 for prophylactic vaccination. Concomitant medications included amlodipine, levothyroxine, losartan, rosuvastatin calcium, and ubidecarenone. On 09-Mar-2021, the patient got the vaccine and after few days she had aches and pains (very mild reaction) and went to bed early. The patient thought she was fine. On 18-Mar-2021, 04:00, she woke up with an excruciating headache above her left eye in her eyebrow. The patient wondered if it was an aneurysm and took 2 tablets of extra strength Tylenol and it helped. The patient stated that after every 5-6 hours, excruciating headache came back. The patient had the same headache for over a week. The patient got tested for Covid-19 and it was negative. The patient thought she had sinus problems but had no other symptoms. On 30-Mar-2021, the patient woke up with headache. Her eye was killing her, was sore and swollen, and felt like it was going to burst and her left eye was swollen shut in a couple of hours. The patient narrated it was excruciatingly painful. The patient's husband drove her to urgent care, where ophthalmology tested the pressure: right eye was normal (she thinks it was 18-normal) and the left eye was 51 (normal is 14-19), units unspecified (intraocular pressure decreased). The eye doctor started prednisone and the patient had a CT scan and lab work done. MRI was also ordered but they were unable to do it right away. On unspecified date in Dec/2020 the platelets were 349 in December and came</p>

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down to 64, which was very low (low threshold was 150) (thrombocytopenia). The CT scan was performed, they thought she had a cavernous carotid fistula and she was scheduled for an angiogram for a further diagnosis on 01-Apr-2021. The angiogram determined she did not have fistula. The patient was admitted to the hospital after the angiogram and on 02-April-2021, MRI was done. All throughout the process, the ophthalmologist, radiologist and internist all thought it was related to the Janssen COVID-19 vaccine. The prednisone started working and the pressure started dropping in her eye. The patient states that doctors think an artery burst behind her eye. After discharge, the patient was taking prednisone which was helping. On the 13th, she was watching television and saw that the vaccine was being put on hold due to the women with clots whose progression matched hers exactly (severe headaches, low platelets, and required attention). She was on prednisone for a month. Laboratory data (dates unspecified) included: COVID-19 virus test negative (NR: not provided) negative, CT scan (NR: not provided) Not reported, and Platelet count (NR: not provided) 64 (units unspecified). Treatment medications (dates unspecified) included: prednisone, and paracetamol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from thrombocytopenia, intraocular pressure decreased, ocular discomfort, periorbital swelling, and eye pain, excruciating headache on 02-APR-2021, and aches and pains on 12-MAR-2021, and the outcome of artery burst behind her eye was not reported. This report was serious (Hospitalization Caused / Prolonged, and Disability or Permanent Damage). Additional information was received on 25-MAY-2021 following information was updated and incorporated into case narrative: Other identification number, patient contact details, events- Aches and pains, artery burst behind her eyes, excruciating headache, Tylenol drug was added, hospital details was added and narrative was updated accordingly.; Sender's Comments: V1: Additional information updated identification number,hospital details,events- Aches and pains, artery burst behind her eyes, excruciating headache,This updated information does not change the causality of previously reported events. 20210502268-COVID-19 VACCINE AD26.COV2.S-Artery burst behind her eye. Follow-up

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received regarding Clinical Details. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY 20210502268-COVID-19 VACCINE AD26.COV2.S-Excruciating headache. Follow-up received regarding Clinical Details. This event(s) is labeled per RSI and is therefore considered potentially related. 20210502268-covid-19 vaccine ad26.cov2.s-Thrombocytopenia, Intraocular pressure decreased, Ocular discomfort, Periorbital swelling, Platelet count increased, Eye pain, Angiogram normal, Arteriogram carotid normal. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY, UNDERLYING DISEASE

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1363777	6/1/2021	OR	64	F	5/4/2021		<p>BLOOD CLOT IN BRAIN; BLOOD CLOT IN RIGHT LUNG; BLOOD CLOT IN STOMACH AND NECK; This spontaneous report received from a patient concerned a 64-year-old, female. The patient's height, and weight were not reported. The patient's past medical history included tendonitis in right shoulder, surgeries on right shoulder and concurrent conditions included arthritis in right shoulder, non-smoker, abstains from alcohol, and seasonal allergies, and other pre-existing medical conditions included the normal wear and tear on her body at the time of this report. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, one total, administered on 04-MAY-2021 at the right arm for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. The Patient reported that on 04-MAY-2021, after vaccination, she began feeling unwell with a low grade fever, her highest body temperature was 102F. She experienced headache that she initially felt on the right side of her head but could not determine the source for sure. On 14-MAY-2021, she coughed up blood, but she didn't think anything of it and continued her normal routine then on 15-MAY-2021, she coughed up more blood but it had some phlegm in it, so she went to the ER (emergency room) on 18-MAY-2021. She received a Computerized axial tomography (CAT) scan of her chest which showed blood clots in her right lung. She got a secondary CAT scan and blood clots were found in her stomach, brain and in her neck. She was admitted to hospital on 19-MAY-2021. The Patient was reportedly hospitalized for 6 days and was supposedly discharged on 24/May/2021. For treatment, she was receiving an Intravenous (IV) blood thinner but later changed to an oral blood thinner. She was also receiving Tramadol for pain. She was receiving other medications when first admitted but could not recall specific names. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clot in brain, blood clot in right lung, and blood clot in stomach and neck. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210546778-covid-19 vaccine ad26.cov2.s- blood clot in brain, blood clot in right lung, and blood clot in stomach and neck. This events are</p>

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considered unassessable. The events has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events.



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1363784	6/1/2021	NY	65	F	4/6/2021		SUBACUTE PULMONARY EMBOLISM IN LEFT AND RIGHT LUNG; DVT IN LEFT CALF; UNABLE TO DRIVE; EXTREME EXHAUSTION; HEADACHE; SHARP SHOOTING PAIN IN RIGHT LEG; This spontaneous report received from a patient concerned a 65 year old female. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included patient had no known previous medical conditions and had no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 041A21A, expiry: 21-JUN-2021) dose was not reported, once total administered on 06-APR-2021 15:00 in Left Arm for prophylactic vaccination. Concomitant medications included amlodipine, hydrochlorothiazide and losartan for which indication was not provided. On 06-APR-2021, the patient experienced headache while driving back to home and was not sure if it was due to vaccine or traffic conditions. At 18:30, patient got up to walk across the room and felt a strong sharp pain in her right and left leg described as incredible cramping type of pain which her husband had to help sit down to a chair. Patient states that although the pain was in both legs, the left leg felt as though someone had took a knife to her thigh, the pain lasted approximately 15 minutes. On 07-Apr-2021, patient states that she went for a routine doctors visit to her family care physician who wrote her a prescription for routine blood work. On 14-Apr-2021, patient went to get the blood work done and states at this time, she felt extremely exhausted and that due to a bloodwork mix up which required her to drive back to the lab, she was not able to drive back so her husband had to drive her. Around 17-Apr-2021 to 18-Apr-2021 patient had to chase the dog and found that she couldn't catch her breath and that she started coughing. Her daughter who happened to be there asked her why she was coughing and thought that it was not normal and that she should contact her doctor. On 19-Apr-2021, patient called the doctor. On 21-Apr-2021 patient saw the doctor and during examination, patient was instructed to run a D-Dimer test to rule out blood clots. On 22-Apr-2021, doctor stated patient to go to the Emergency Room as the result for the D-Dimer test came positive. The patient was immediately hospitalized where Doppler and CT scan was performed on her and was diagnosed with Deep

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Vein Thrombosis and Pulmonary Embolism on both the lungs. Patient mentioned that she was treated with Heparin drip from 22-Apr-2021 to 24-Apr-2021 and then she was given Xarelto. On 25-Apr-2021, the patient was discharged from the hospital after 4 days of hospitalization. Patient reports that she was still experiencing extreme exhaustion and that the pulmonologist states that this is the normal course of blood clots and it could take anywhere from 60-90 days for the body to clear up the blood clots. She states she still has bouts of shortness of breath but showing signs of improvement. Patient stated that she was scheduled for another Doppler on 19-Jun-2021 which was recommended by her primary care physician. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from sharp shooting pain in right leg on 06-APR-2021, had not recovered from extreme exhaustion, and the outcome of pulmonary embolism in left and right lung, dvt in left calf, headache and unable to drive was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0:20210550248-COVID-19 VACCINE AD26.COV2.S, The case concerns with a Caucasian female. Subacute pulmonary embolism in left and right lung, deep vein thrombosis in left calf. These events are considered unassessable. The events have a compatible/suggestive temporal relationship, are unlabeled, and have unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

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1363787	6/1/2021	MD	73	F		5/13/2021	BLOOD CLOT IN LEG; This spontaneous report received from a consumer concerned a 73 year old female unspecified race and ethnicity. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown, expiry: unknown) dose was not reported, 1 total, administered on 16-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 13- MAY-2021, the patient was taken to the emergency room (ER). On 14-MAY-2021, she was hospitalized with a clot/clots in her leg(s). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot in leg was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0-20210551429 - Covid-19 vaccine ad26.cov2.s-Blood clots in leg. This case concerns with 73 years old female. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

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1363788	6/1/2021	FL		F	4/1/2021		LEGS VIBRATE; MUSCLE FACILITATION; KICKS LEGS ALL NIGHT; SHOOTING NERVE PAIN IN RIGHT FOOT; TEETH GRINDING; THUMBS AND FINGERS TURNING INWARDS IN HANDS; RIGHT FOOT CURVES TO THE SIDE AND TOES CURL INWARDS; GAIT WALK WITH MUSCULOSKELETAL ISSUES; DISTRESS; CYST RIGHT BREAST; TMJ DISORDER; MILD EMPHYSEMA AND NODULES; ARTHRITIC INFLAMMATION; MILD ARTHRITIC INFLAMMATION; ALMOST THREW UP; WHOLE BODY STIFF; WHOLE BODY SPASTIC; SEVERE MIGRAINE; SEVERE LEFT LEG PAIN; MUSCLE STIFFNESS/RIGIDITY; This spontaneous report received from a patient concerned a 43 year old female. The patient's height, and weight were not reported. The patient's past medical history included anxiety and depression, and other pre-existing medical conditions included taking the statin that she was on for 3 years prior. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 205A21A, and expiry: UNKNOWN) dose was not reported, administered on 12-APR-2021 for prophylactic vaccination. Concomitant medications included naproxen for severe left leg pain. On APR-2021, the subject experienced muscle stiffness/rigidity. On 13-APR-2021, the subject experienced severe left leg pain. On 14-APR-2021, Laboratory data included: Diagnostic ultrasound (NR: not provided) Negative for blood clot. On MAY-2021, the subject experienced whole body stiff. On MAY-2021, the subject experienced whole body spastic. On MAY-2021, the subject experienced severe migraine. On 25-MAY-2021, the subject experienced almost threw up. On 26-MAY-2021, Laboratory data included: Ultrasound breast (NR: not provided) Huge Cyst. On an unspecified date, the subject experienced legs vibrate, muscle facilitation, kicks legs all night, shooting nerve pain in right foot, teeth grinding, thumbs and fingers turning inwards in hands, right foot curves to the side and toes curl inwards, gait walk with musculoskeletal issues, distress, cyst right breast, TMJ (Temporomandibular joint) disorder, mild emphysema and nodules, arthritic inflammation, and mild arthritic inflammation. Laboratory data (dates unspecified) included: Blood test (NR: not provided) normal, CT scan abnormal (NR: not provided) Mild emphysema and nodules. She will follow-up with a pulmonologist, Laboratory test abnormal (NR: not

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							provided) All were normal., MRI (NR: not provided) New and mild arthritic inflammation, and Mammogram (NR: not provided) did not have this cyst. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from severe left leg pain, muscle stiffness/rigidity, severe migraine, whole body stiff, whole body spastic, legs vibrate, muscle facilitation, kicks legs all night, shooting nerve pain in right foot, teeth grinding, thumbs and fingers turning inwards in hands, right foot curves to the side and toes curl inwards, gait walk with musculoskeletal issues, distress, cyst right breast, and TMJ disorder, and the outcome of mild emphysema and nodules, arthritic inflammation, almost threw up and mild arthritic inflammation was not reported. This report was non-serious.; Sender's Comments: V0: Medical assessment comments not required as per standard procedure as the case is assessed as non serious
1363797	6/1/2021	CA	24	F	4/1/2021		BLOOD CLOT; This spontaneous report received from a consumer concerned a 24 year old female. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, therapy start date were not reported, with frequency 1 total administered for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date in APR-2021, the patient experienced blood clot and was hospitalized (date unspecified) and it was reported caller said his brother would called to provide more information regarding the patient's case. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210552268-COVID-19 VACCINE AD26.COV2.S-BLOOD CLOT. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1363896	6/1/2021	NY	66	F	5/2/2021		<p>PAIN; PITTING EDEMA; SWELLING; BLOOD CLOT LEFT AND RIGHT LEG; This spontaneous report received from a patient concerned a 66 year old female. The patient's height, and weight were not reported. The patient's past medical history included factor 5 positive. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805022, expiry: UNKNOWN) dose was not reported, administered on 08-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, the patient experienced pain, pitting edema, and swelling. The patient had an Ultrasound done on 02-MAY-2021 at the emergency room that showed a blood clot in her left leg. On 27-MAY-2021 she went to her doctor and had another ultrasound on her right leg that indicated a blood clot. She was started on Zorelto as a treatment for blood clot on 02-May-2021 15 mg BID Three times daily and is now taking 20mg 1 times daily, but that she may not be able to stay on Zorelto because it was not working. Also stated this vaccine had ruined her life and was very sorry that she ever got the vaccine. She was extremely frustrated and unhappy and had pain and swelling that has not allowed her to play tennis and experience inactivity. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clot left and right leg, and the outcome of pain, pitting edema and swelling was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210556299-covid-19 vaccine ad26.cov2.s-Blood clot left and right leg. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY</p>

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1363813	6/1/2021	MI		M		5/14/2021	<p>BLOOD CLOTS IN BOTH LUNGS; LEFT SIDE OF BODY HURTING; GENERALIZED WEAKNESS; TIREDNESS; BLOOD CLOT IN BOTH LEGS; TROUBLE WALKING; This spontaneous report received from a consumer concerned a 77- year old White Not Hispanic or Latino male. The patient's height and weight were not reported. The patient's past medical history included polyp removal on the nose, and concurrent conditions included prostate cancer, asthma, chronic obstructive pulmonary disease, allergic to sulfa drugs, alcohol user (drinks wine 1-2 times a week), and non-smoker, and other pre-existing medical conditions included no drug abuse or illicit drug usage. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 205A21A expiry: UNKNOWN) 1 total, the dose was not reported, administered on right arm on 09-MAY-2021 for prophylactic vaccination. Concomitant medications included prednisone for loss sense of taste, and ascorbic acid/biotin/cyanocobalamin/folic acid/nicotinamide/pantothenic acid/pyridoxine hydrochloride/riboflavin/thiamine hydrochloride, and vitamins and minerals. On 14-MAY-2021, the patient began experiencing symptoms of both legs hurting from hips to knees and generalized body weakness as well as tiredness. a Patient complained about legs that whole week stating was in a lot of pain, having trouble walking. Consumer stated pain level was around at a 7 or 8 and that patient had a lot of difficulties getting out of the car and not being able to walk from kitchen to the bedroom. They were concerned. On, Monday 24-May-2021, the patient stated whole left side of the body was hurting and could not put any pressure or sit on the left side of the body. the Patient also had shortness of breath and chest pain on Monday 24-May-2021. Patient was hospitalized on 25-May- 2021 and found multiple clots in bilateral lungs and both legs. The patient was hospitalized for 2 days. Laboratory data included: Blood test (NR: not provided) blood clots bilateral lungs and both legs, Computerised tomogram scan (NR: not provided) blood clots bilateral lungs and both legs, Venous Doppler (NR: not provided) blood clots in legs, and X-ray (NR: not provided) blood clots bilateral in lungs. On 26-MAY-2021, Laboratory data included: Echocardiogram (NR: not provided) clear. The action taken with covid-19 vaccine</p>

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ad26.cov2.s was not applicable. The patient had not recovered from blood clots in both lungs, blood clot in both legs, trouble walking, left side of body hurting, generalized weakness, and tiredness. This report was serious (Hospitalization Caused / Prolonged ); Sender's Comments: V0:20210554302- blood clots in both lungs, blood clot in both legs, trouble walking, left side of body hurting -This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY, UNDERLYING DISEASE V0:20210554302- generalized weakness, and tiredness.This event(s) is labeled per RSI and is therefore considered potentially related.



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1363983	6/1/2021	PA	34	M	5/13/2021	5/13/2021	Heart Attack; Panic attack; Couldnt breathe; Felt like chest caved in; Chest pain; Blood clot; Arm Pain; This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (Heart Attack), PAIN IN EXTREMITY (Arm Pain), PANIC ATTACK (Panic attack), DYSPNOEA (Couldnt breathe), CHEST DISCOMFORT (Felt like chest caved in), CHEST PAIN (Chest pain) and THROMBOSIS (Blood clot) in a 34-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048B21A) for COVID-19 vaccination. The patient's past medical history included Flu vaccination (received about 5 weeks ago before he got the Covid Shot and had chest pain) and Sinusitis (the patient stated that he violently threw up and he was sick for 2 weeks; the doctors then said that it may have been a stroke or a heart attack but he definitely had sinusitis.). Concurrent medical conditions included Diabetes, Cholesterol high and Blood pressure high. On 13-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-May-2021, the patient experienced PAIN IN EXTREMITY (Arm Pain) (seriousness criterion hospitalization). On 15-May-2021, the patient experienced PANIC ATTACK (Panic attack) (seriousness criterion hospitalization), DYSPNOEA (Couldnt breathe) (seriousness criterion hospitalization), CHEST DISCOMFORT (Felt like chest caved in) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and THROMBOSIS (Blood clot) (seriousness criteria hospitalization and medically significant). On 15-May-2021 at 4:00 PM, the patient experienced MYOCARDIAL INFARCTION (Heart Attack) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 3 days due to CHEST DISCOMFORT, CHEST PAIN, DYSPNOEA, MYOCARDIAL INFARCTION, PAIN IN EXTREMITY, PANIC ATTACK and THROMBOSIS. The patient was treated with ACETYLSALICYLIC ACID (BABY ASPIRIN) ongoing since an unknown date at an unspecified dose and frequency; LISINOPRIL ongoing since an unknown date at a dose of 5 mg; METOPROLOL SUCCINATE ongoing since an unknown date at a dose of 50 mg; NITROGLYCERIN ongoing since an unknown date at a dose of 10 mg as required; PRASUGREL ongoing since

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							<p>an unknown date at a dose of 10 milligram; SPIRONOLACTONE ongoing since an unknown date at a dose of 25 mg and ROSUVASTATIN ongoing since an unknown date at a dose of 80 milligram. At the time of the report, MYOCARDIAL INFARCTION (Heart Attack), PAIN IN EXTREMITY (Arm Pain), PANIC ATTACK (Panic attack), DYSPNOEA (Couldnt breathe), CHEST DISCOMFORT (Felt like chest caved in), CHEST PAIN (Chest pain) and THROMBOSIS (Blood clot) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medications were not reported. The patient reported that he had a heart attack on 15 May 2021, after football practice Patient was in the hospital for 3 days. Treatment also included catheter placement and then a stint in heart. Company Comment : Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>
1364840	6/1/2021	FL	61	F	3/25/2021	3/25/2021	<p>When I got home, I had a headache. I felt tired. I took a nap. When I woke up, I was sick. I was nauseated, my stomach and body hurt all over. The headache was three days long. I felt achy and sore the next day as well. I felt like I had a flu. There were huge blood clot looking blisters, and red dots on both my arms. My left arm was worse than my right arm. I called the doctor and she asked me to come in, but I had to take pictures first of my arms before coming in. Then when I was able to go to the office, I took blood tests and the MRI. Everything came back okay.</p>

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1363851	6/1/2021	PA	46	M		5/19/2021	BLOOD CLOT; STROKE; This spontaneous report received from a patient concerned a 46 year old male. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported and batch number: 202A21A expiry: 23-JUN-2021) dose was not reported, 1 total administered on 07-MAY-2021 for prophylactic vaccination. No concomitant medications were reported. On 19-May-2021, the patient begun to experiencing confusion and could not think straight. On 23-MAY-2021, the symptoms progressed when the patient went to the hospital. The patient was diagnosed with blood clot and had stroke. The patient was hospitalized on 23-MAY-2021 and was discharged on 26-MAY-2021. The patient was hospitalized for 3 days. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the blood clot and stroke was not reported. This report was serious (Hospitalization Caused/Prolonged).; Sender's Comments: V0: 20210554839-covid-19 vaccine ad26.cov2.s-blood clot and stroke. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
1364966	6/1/2021	TX	37	F	4/5/2021	4/5/2021	Heavy and extended period with large and constant blood clots. I was at the end of my period when I got vaccinated and it is still going on. There was about a 24 hour break last Sunday-Monday. It is so heavy there is no point in using a tampon and I have bleed through overnight pads in 1-2 hours at some points.

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1363921	6/1/2021			U			<p>BLOOD CLOTS OF LUNGS; BLOOD CLOTS OF LEGS; This spontaneous report received from a patient via a company representative concerned a patient of unspecified age and sex. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, Expiry: Unknown ) dose, start therapy date were not reported, 1 total for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient ended up getting blood clots of lungs and legs and was wanting to know more information. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the blood clots of lungs and blood clots of legs was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210556674-COVID-19 VACCINE AD26.COV2.S-Blood clots of lungs, blood clots of legs. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1363940	6/1/2021	ME	54	M	4/26/2021		DVT IN LEFT LEG; SORE ARM; This spontaneous report received from a consumer (wife) concerned a 54 year old male. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: unknown) dose was not reported, 1 total, administered on 25-APR-2021 to right arm for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 25-APR-2021, the patient had sore arm. On 17-MAY-2021, the patient noticed that his left leg got bigger and ignored it, he measured his calf which was 2 inch wider and elevated his feet. On 24-MAY-2021, it was really big and then the doctor sent him to urgent care and it was confirmed a case of deep vein thrombosis (DVT) and he was treated with blood thinner. Still his calf, ankle and foot looks bigger. The patient's wife did not have the lot number. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from sore arm on 28-APR-2021, and had not recovered from DVT in left leg. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210556854 -Covid-19 vaccine ad26.cov2.s - DVT IN LEFT LEG . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1363967	6/1/2021	NY	45	F	5/24/2021		HEAVY VAGINAL BLEEDING WITH CLOTS; SPOT; This spontaneous report received from a patient concerned a 45 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included hypertension, and other pre-existing medical conditions included the patient had no known allergies. the patient was not pregnant at the time of reporting. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 206A21A, expiry: UNKNOWN) dose was not reported, administered on 13-MAY-2021 for prophylactic vaccination. No concomitant medications were reported. On 24-MAY-2021, the subject experienced spot. On 29-MAY-2021, the subject experienced heavy vaginal bleeding with clots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from heavy vaginal bleeding with clots, and the outcome of spot was not reported. This report was non-serious.

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1363975	6/1/2021	NJ	83	M	2/6/2021	4/27/2021	<p>Developed blood clot; Sever pain in his stomach; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Developed blood clot) and ABDOMINAL PAIN UPPER (Sever pain in his stomach) in an 83-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 032M20A and 016L20A) for COVID-19 vaccination. Concomitant products included RIVAROXABAN (XARELTO), AMLODIPINE, NEBIVOLOL HYDROCHLORIDE (BYSTOLIC) and AZILSARTAN MEDOXOMIL, CHLORTALIDONE (EDARBYCLOR) for an unknown indication. On 06-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 27-Apr-2021, the patient experienced ABDOMINAL PAIN UPPER (Sever pain in his stomach) (seriousness criterion hospitalization). On an unknown date, the patient experienced THROMBOSIS (Developed blood clot) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 28-Apr-2021 to 04-May-2021 due to ABDOMINAL PAIN UPPER and THROMBOSIS. The patient was treated with Surgery (leading to two and half feet of his small intestine removed) for Thrombosis. At the time of the report, THROMBOSIS (Developed blood clot) and ABDOMINAL PAIN UPPER (Sever pain in his stomach) outcome was unknown. Patient started having severe pain in his stomach on 27-Apr-2021. He was taken to the hospital on 28-Apr-2021, patient's doctor said that he had a clot in his intestine and that caused the pain, was operated removed to two and half feet of his small intestine. Patient was discharged from the hospital on 04-May-2021. The patient received both scheduled doses of mRNA-1273 prior to the events, therefore action taken with the drug in response to the events was not applicable. Company Comment : Very limited information regarding this events has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this events has been provided at this time. Further information has been requested.</p>

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1363977	6/1/2021	CA	50	F	3/6/2021		<p>Clots in left arm after taking 2 shots; Swollen arm after 2 vaccine shots; pain in left arm; 50 days gap between 2 vaccine doses; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Clots in left arm after taking 2 shots) in a 50-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Idiopathic thrombocytopenic purpura, Spina bifida and Psoriasis. On 06-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Clots in left arm after taking 2 shots) (seriousness criterion medically significant), PERIPHERAL SWELLING (Swollen arm after 2 vaccine shots), VACCINATION SITE PAIN (pain in left arm) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (50 days gap between 2 vaccine doses). The patient was treated with APIXABAN (ELIQUIS) at a dose of 25 mg twice a day and APIXABAN (ELIQUIS) at a dose of 5 mg twice a day. At the time of the report, THROMBOSIS (Clots in left arm after taking 2 shots), PERIPHERAL SWELLING (Swollen arm after 2 vaccine shots) and VACCINATION SITE PAIN (pain in left arm) outcome was unknown and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (50 days gap between 2 vaccine doses) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Ultrasound scan: abnormal (abnormal) clot in the left arm. Patient went to emergency after 3 weeks of taking Moderna COVID-19 second Vaccine. No relevant concomitant medications were reported. Reportedly, the treatment with Apixaban (Eliquis) needed to continue for 6 months. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a</p>



*VAERS\_ID RECVDATE STATE AGE\_YRS SEX VAX\_DATE ONSET\_DATE SYMPTOM\_TEXT*

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causal relationship cannot be excluded.

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1363809	6/1/2021	FL	62	F	5/7/2021		<p>BLOOD CLOT FROM GROIN AREA ALL THE WAY TO THE LEG; This spontaneous report received from a patient concerned a 63-year-old female. The patient's height, and weight were not reported. The patient's concurrent conditions included osteoporosis, osteoarthritis, bursitis, rheumatoid arthritis (RA), migraine headache, anxiety, and cholesterol, and other pre-existing medical conditions included patient had no history of blood clots and no prior heart conditions. On 16-Mar-2021 around 09:00, the patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029, expiry: Unknown) dose was not reported, frequency 1 total, administered on left arm for prophylactic vaccination. Concomitant medications included pantoprazole for acid reflux, citalopram for anxiety, simvastatin for cholesterol, and prn 1371 for migraine headache. On an unspecified date in Feb-2021, the patient mentioned (heart doctor) had done some tests on veins making sure the patient's heart was open and does not have any blood clots. Laboratory data included: Diagnostic ultrasound (NR: not provided) Normal, and Doppler ultrasound (NR: not provided) No blood clots. 7 days later the patient was informed everything was fine and she got vaccinated on 16-Mar-2021. On 07-May-2021, the patient reported that her left leg started hurting. On 09-May-2021, the leg started swelling. On 11-May-2021, the patient was admitted to the hospital with a massive blood clot from groin area all the way to the leg. On 14-May-2021, she was discharged from hospital. The patient was hospitalized for 3 days. The patient stated her doctor will let her know if she can move around more next week, the patient is currently in lot of pain. Treatment medications (dates unspecified) included: apixaban, paracetamol, tramadol hydrochloride, gabapentin, and baclofen. The action taken with covid-19 vaccine ad26.cov2. s was not applicable. The patient had not recovered from blood clot from groin area all the way to the leg. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0- 20210500586-COVID-19 VACCINE AD26.COV2.S-This case concerns with 63 year old female – blood clot from groin area all the way to the leg - This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There</p>

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							is no information on any other factors potentially associated with the event(s).
1365073	6/1/2021	MA	19	F	5/20/2021	5/28/2021	deep venous thrombosis of left axillary vein in same arm as vaccine was administered
1365246	6/1/2021	CA	57	F	3/29/2021	4/29/2021	I was scheduled for surgery and had concerns about it following the vaccine, but my doctor said that it should be fine, so I had the surgery. After a few weeks, a blood clot was found in my breast. On May 11, 2021, I had to have another surgery to clean the blood clot from the area.
1365379	6/1/2021	HI	19	F	1/26/2021	1/29/2021	1st day of pain: Extreme Pain in Lower Extremities (Right Leg, Right abdomen, right lower back) Swelling of Right Leg 3rd day: Admitted into the hospital after visiting the ER Acute DVT in R Leg, multiple Pulmonary Embolisms 3rd-5th day in hospital: 2 Surgical Procedures to remove blood clot, on Blood thinners for a year to life
1365501	6/1/2021	NV	37	F	5/18/2021	5/21/2021	on Tuesday 05/18/2021 i take my 2th dose of Vaccine and on 05/19/2021 at around 2100 pm i start to develop high fever at 103-104 with abdominal cramps, same way i was on the 05/20/2021 and on Friday morning 05/21/2021 i start bleeding with large clots and wasn't able to get from the bed, and around noon my waters broke following with a lot of blood and clots,i had to deliver my baby girl at home at 15 weeks, 911 was called, because the placenta didn't come out, so i was rushed to the ER Baby was Delivered at 13:30pm on 05/21/2021
1365729	6/1/2021	NV	34	M	4/1/2021	4/2/2021	Muscle spasms for entire right arm and side, nonstop since both vaccine doses Vaccines were 2 weeks apart 1 week after 2nd dose, visited primary care doc and received muscle relaxers. Did not stop spasms. Uses heating pad, Icy Hot, ibuprofen 3 weeks after 2nd dose, muscle spasms stopped and pain in right arm and shoulder began. Continued regime above. June 1 I went to ER for extreme shoulder pain. They ran blood and ultrasound to check for blood clots, gave morphine and muscle relaxer, and discharged. Visited primary care doc again same day and received cortisone injection in right shoulder to finally relieve pain

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1365741	6/1/2021	OH	40	F	1/30/2021	1/31/2021	After the 1st vaccine, a week later I started my cycle. I thought it was normal. I bled for approximately 5 days, which is normal for me. Less than a week later, I was having weird, long, stringy clots. It reminded me of an abruption since the blood was burgundy in color. It was 3 days, but it still required a tampon. Then a week and 3 days later, I started bleeding again, but that time was for 8 days. At that point, that's when I called my OB and reported it on my V-safe. I didn't have the usual premenstrual symptoms. They did a pregnancy test, an ultrasound, lab work and a speculum pap exam, which including swabbing. The tests revealed nothing, so they told me that I'm getting old and maybe I'm just changing. After that, it didn't happen again and I've had my normal cycle since then. With exception of a sore arm, I didn't have any other side effects from the vaccine.
1365955	6/1/2021	OH	32	F	4/13/2021	4/14/2021	Significant vaginal bleeding and vaginal blood clots. Extremely heavy bleeding during mid-cycle (between periods). No prior history of heavy bleeding nor any vaginal blood clots. Started approx 24 hours after first shot and continued for several days, with bleeding and clots. Scheduled virtual doctors visit immediately and followed up with in-person pelvic exam and ultrasound. Normal ultrasound results. Stopped birth control pills for several days, then restarted, then soon after changed to new birth control.
1366347	6/1/2021	MD	42	M	5/15/2021	5/20/2021	This is not very clear that the Pfizer vaccine is actually the cause of the patient's Cerebral thrombosis, however, we are reporting to VAERS as this is a unique first case where the patient has Dural venous thrombosis within 2 weeks period of getting 2nd dose of Pfizer vaccine. 05/25/2021: CT HEAD/BRAIN W/ IV CONTRAST showed dural venous sinus thrombosis involving the superior sagittal sinus, right transverse, and sigmoid sinuses, extending into the proximal right internal jugular vein.
1364796	6/1/2021	CA	36	F	5/26/2021	5/27/2021	Mild Chest pain shortness of breath 24 hrs after shot. Went way with Tylenol and rest. Returned next day worse. Emergency room tests ruled out heart, lung issues, and blood clot. Following up with primary care.

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1362416	5/31/2021	CT	17	M	5/26/2021	5/27/2021	Thursday started with sore throat, fever, chills, stuffy nose and headache. We gave him Acetaminophen. Fever continued into Friday with the same symptoms. Hives began Saturday morning and gradually got worse. We gave him Benadryl at that time and the fever went up to 102.5 F. Wheezing in his chest began. Sunday morning the hives were worse and we decided to go to the doctor. We went to a walk in clinic who after an EKG wanted us to go to the Emergency room due to a "blip" and a concern for myocarditis. At the ER they administered Prednisone and more Benadryl through an IV. They decided to do a CT Scan to look for blood clots. (the ER doctor mentioned he was glad that we brought him into the ER...) No blood clots were found thankfully and they eventually released him, with a prescription for 4 days for Prednisone, more Benadryl and Pepcid. The hives continue today, the day after, and are barely under control by the Benadryl.
1362428	5/31/2021	PA	40	F	4/12/2021	5/28/2021	On 5/28/2021 I started to develop shortness of breath. It continued to worsen and I went to the hospital on 5/30/2021 and it was discovered that I had a pulmonary embolism and after additional ultrasounds 3 DVT blood clots in my right leg.
1362445	5/31/2021	CA	41	F	4/8/2021	4/8/2021	I had chest pains a few days after receiving the vaccine and went to see my Doctor who referred to the ER to check to see if I had a blood clot.

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1362527	5/31/2021	MD	58	M	4/5/2021	4/15/2021	<p>SHORTLY AFTER TAKING SHOT, HE STARTED COMPLAINING OF LEFT KNEE PAIN. DID NOT TAKE ANY MEDS BUT USED TOPICAL RUBS. PAIN GOT WORST AND MOVE TO LEFT HIP SO HE MADE APPT TO SEE PRIMARY-DR. SHE DID NOT GIVE ANY MEDS BUT REFERRED HIM TO ORTHOPEDIC DR WHO PRESCRIBED NSAID(MELOXICAM) AND PT EXERCISE. BY THEN PAIN HAD MOVED TO RIGHT HIP. HE DID NOT TAKE MELOXICAM-TOOK IBUPROFEN INSTEAD. PAIN GOT WORST AND CONCERNING. ON 5/14/21 PAIN GOT PAIN ENOUGH AND BECAME GENERALIZED AND WAS VERY BAD IN RIB CAGE WITH SHORTNES OF BREATH. MY SON TOOK HIM TO ER AT HOSPITAL WHERE HE WAS ADMITTED. HE WAS WORKED UP AND NOTHING WAS CONCLUSIVE OTHER THAN HE WAS HAVING SICKLE CELL CRISES WHICH HE HAS NEVER HAD IN DECADES. HE WAS GIVEN IV NARCOTICS TO QUELL PAIN WHICH DID NOT WORK. AFTER 2 DAYS PAIN GOT MANAGEBALE AND HE WAS SENT HOME WITH PERCOCET AND BY NOW HE WAS VERY CONSTIPATED. HIS BLOOD PRESSURE WAS HIGH WITH HIGH HEART REATE. HE IMPROVED AND PLANNED ON KEEPING ALL HIS FOLLOWUP APPTS WHEN HE SUDDENLY GOT WEAK IN LEFT HAND AND WAS TAKEN TO ER AGAIN 5/29/21. ONCE AGAIN HE WAS TESTED FOR COVID ALL NEGATIVE AND AGAIN WAS GIVEN CLOT BUSTERS AND OTHET MEDS. THIS TIME MRI SHOWED MINI CLOTS IN HIS BRAIN AND WAS TOLD HE HAD A MINI STROKE. NOW HE WAS SENT HOME ON BLOOD THINNER- ELIQUIS, BABY ASPIRIN, DILTIAZEM, STATIN, AND VITAMINS. HE HAS NEVER TAKEN ANY MEDS AND NEVER HAD HIGH BLOOD PRESSURE UNTIL AFTER VACCINE. NOW HE HAS TO SEE A NEUROLOGIST.</p>

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1362569	5/31/2021	IL	48	F	4/9/2021	4/9/2021	There was extreme pain in the injection site immediately. Twelve hours after the shot, I had terrible chills and flu like symptoms that lasted for several days. I then started getting strange pulsing in my legs that moved around and was more prominent at night. I was somewhat short of breath when exerting myself for about a month. Then I had pain that would travel throughout my legs and in my groin. 2 1/2 weeks later it was so bad that I went to the emergency room to be tested for blood clots, which were negative. The pain in my arm dissipated gradually, but 7 weeks later it still hurts enough to wake me up in the middle of the night. The pulsing in my legs has for the most part finally dissipated, but continues from time to time.

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1362571	5/31/2021	WA	44	M	5/7/2021	5/31/2021	Initially, the patient had dizziness, lightheadedness and a syncopal episode within 5 minutes of the vaccine. He returned to normal fairly quickly and went home by report. He presented to the ER shortly after with palpitations and shortness of breath and required a dose of IM epinephrine. Patient since had intermittent fatigue, dizziness, blurred and vision changes as well as tinnitus. On May 31, 2021, patient presented to the ER with headache, lethargy, weakness, diaphoresis and dizziness. Additionally, noted to have slurred speech by his wife. MRI of the brain done at 4 am on 5/31/21 showed the following "1. Acute bilateral cerebellar infarcts are seen with a right posterior 4.3 mm focus a left middle cerebellar peduncle 3.2 mm focus and a left superior cerebellar 7.9 mm linear focus. 2. Occlusion of the left vertebral artery extending into the basilar artery with reconstitution of the basilar artery via bilateral posterior communicating arteries. Findings are concerning for acute dissection occlusion. Consider further evaluation with MRA head and neck. 3. Question subtle area of restricted diffusion seen within the left dorsal medulla better appreciated on the maps measuring approximately 4.9 mm. Left lateral pontine 7.3 mm focus of restricted diffusion versus artifact. These infarcts are not definite and could be artifactual asymmetry.'. He required admission, heparin drip and neurology consult at that time, as well as permissive hypertension. shortly after 1 pm on May 31, he developed chest pain with ischemic changes on EKG requiring cardiology consult with possible intervention, though this was being coordinated with interventional neurology, as he also required basilar angiogram for his MRI findings. as cardiology and interventional neurology were coordinating taking patient for intervention, he became further unresponsive, though maintained his pulse, and required intubation and transfer to ICU, as well as repeat CT of the head to evaluate for continued thrombosis of his basilar system. Work up is still on going
1362592	5/31/2021	LA	53	F	3/6/2021	3/20/2021	Constant cramps in right calf. I start taking aspirin and natural blood thinners suspecting it may be a blood clot.



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1362381	5/31/2021	FL	64	F	5/10/2021	5/21/2021	5/21 started feeling poorly, fatigue, shortness of breath, evening headaches 5/24 Fatigue, shortness of breath, unable to complete any task, low grade fever 99.8, unable to eat or drink well 5/25 severe heartburn, shortness of breath continued, extreme fatigue 5/28 went to ER with continued extreme shortness of breath and fatigue. CT scan revealed multiple clots in lungs and was admitted for needing oxygen and to start anticoagulation.
1362673	5/31/2021	AZ	18	M	4/5/2021	5/11/2021	Developed clots in both right and left lungs. Wedge shaped infarction in left lung. Extreme headaches. Pulmonary emboli and plural infusion.
1362310	5/31/2021	NJ	45	F	4/9/2021	4/10/2021	I had a completely normal evening after receiving the vaccine. I woke up the next morning and didn't feel quite well. I started washing my hands and I woke to my husband calling an ambulance. I had passed out. I refused to go to the hospital per their request because of worries about COVID. I called my PCP and I discussed the situation with him and he told me to get rest and stay hydrated. I met him a couple days later for a virtual appointment. At this point the vaccine had been paused and I was very concerned about the potential of blood clots. I was still feeling fatigue after my episode, but I was feeling better. He told me to take a baby aspirin, once daily for a month, to help prevent any blood clots. After 5-6 weeks of receiving the vaccine, I started coughing, gagging and choking and had to get my daughter to get my husband. My husband gave me an alavert and I was able to breathe better around 10 minutes later. We think it was a severe reaction to possible pollen, or something in the air, but that has never happened before.

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1362608	5/31/2021	NJ	56	F	1/27/2021	1/30/2021	On 1/27/21, Patient took the 1st Moderna vaccine. She had flu like symptoms after for 3 days and then she broke out in hives. She continued to have flu like symptoms, and she felt very week. On 2/3/21 we took her to Hospital where the doctors indicated that she had a heart attached They released her from the hospital on 2/4/21. When she came home she was very tired and was disoriented. The following morning, she was running a fever and her eyes rolled back in her head. We called the ambulance who took her back to Hospital. The doctors indicated that had a stroke. They indicated that blood clots ?showered? her brain. She has lost her peripheral vision on the right side. She has issues with her memory and executive decision making and reasoning.
1362340	5/31/2021	CA	45	F	4/28/2021	4/29/2021	After my terrible chills and fever were gone I got my period 2 weeks early. It was a normal period however only 5 days later I got ANOTHER period. This was much heavier than normal with done quarter sized blood clots. It lasted 7 days.
1362330	5/31/2021	PA	64	F	1/5/2021	2/15/2021	Spinal fusion on January 12, 2021 one week after first vaccine. Second vaccine on Feb 2, 2021. Developed blood clot in right calf & pulmonary embolism in right lung the week of Feb 15th. May have been post op problem but I had no issue until after the 2nd vaccine. Surgeon felt that post op pts usually get a blood clot within 2 weeks after surgery- that's why I feel it was from the 2nd vaccine.
1362296	5/31/2021	LA	61	M	3/16/2021	4/21/2021	Patient went to Emergency room at local hospital with leg pain. Evaluated and discovered clot in left leg and is being treated with Eloquis

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1362257	5/31/2021	MS	53	M	1/4/2021	1/12/2021	<p>The following is an email the patient wrote to us describing his events: I received Moderna Covid Vaccine on January 4, 2021 and February 1, 2021 at Medical Center in On the evening of January 12, 2021, I arrived home from working as a Pharmacist following a 13 hour shift at Medical Center with no medical complaints. Later that night I experienced a severe coughing, sneezing episode where I was gagging on the mucous. I spit out a bunch of stuff and did a nasal rinse. I took some cold medicine like Certrazine and Mucinex-D. Simultaneously with the coughing episode I developed a tingling sensation on the right side of my body from my neck to my toes. I also noticed that my temperature sensations on my right hand was different from my Left hand. I had gotten a water bottle from my refrigerator that felt room temp to my right hand but was cold when held in the left hand. I was feeling dizzy or drunk and was walking funny. When I tried to walk straight forward I actually drifted to the left as I walked. I was having difficulty swallowing medications, food or liquids. I wondered if was experiencing the onset of Covid Symptoms. I was well enough versed on stroke symptoms to be worried about one sided tingling and altered gait being from a stroke. The flu like nasal symptoms and altered right sided pain and temperature sensations persisted through the night, so I went to the ER at Medical Center the morning of January 13th. The ER worked me over with multiple Covid/Strept/Flu tests, evaluation for possible stroke (with multiple scans and stroke score.) The ERP also evaluated the possibility of Bells Palsy or Guillain Barre secondary to Covid vaccine the week before. The Covid Testing was Negative. The stroke score was low enough NOT to have warranted thrombolytic therapy. The neurological issues did not appear to be Bells palsy or Guillain barre. After the ER Visit I attempted to see a neurologist. May 25, 2021 was the earliest available appointment that I could obtain. The symptoms were not severe enough to prevent me working as a Pharmacist. The altered pain and temperature sensations remain without much improvement even now 4 months later. The Neurologist diagnosed me as having had a stroke, specifically left sided Lateral Medullary Infarct, also known as Wallenburg Syndrome. There have been reports from the other vaccines having caused blood clot issues since my event.</p>

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1362247	5/31/2021	MD	61	M	4/24/2021	5/22/2021	Patient presented 5/22 with acute onset right sided weakness and aphasia, found to have left MCA stroke. He was last normal at 0200 and was found at 0600 when he was found by hi wife. He was not a candidate for tPA as he was outside of the time window once he arrived to ER. He underwent IR thrombectomy with TIC1 2B, residual clot in the left A1 and left M3 vessels. He suffered a large territory stroke with malignant cerebral edema requiring emergent decompressive hemicraniectomy. He has been unable to be extubated thus far, as he is unable to protect his airway. He has severe aphasia and right hemiplegia.
1362194	5/31/2021	PA	52	F	5/17/2021	5/29/2021	Sudden numbness in leg 5:20pm. Went to emergency room via ambulance. Did a CT scan, found blood clot in upper leg. Sent via ambulance to Hospital had Surgery at 10pm to remove clot and save leg.

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1362156	5/31/2021	FL	35	M	5/8/2021	5/8/2021	The night after receiving the vaccine I started to develop a fever and headache. It lasted 3 days for the fever. On Tuesday I felt something different in my body. On Thursday I went to see an Optometrist. While there he found that there was something going on in my eyes. He noticed there was blood clot in the back of my right eye. I did go to the ER because of the blood clot. At the ER I had a CT scan and bloodwork completed. I was told that everything looked normal and I was told to go to a different hospital. I was transferred to Medical Center. While I was there they performed an MRI, CAT scan and Lumbar function test. I was told that everything looked fine from the neurology point of view. I need to follow up with an Ophthalmologist. I have gone completely blind in my right eye and my left eye is not clear anymore. On 05/20 I had an appointment with the ophthalmologist. There was something wrong with my optic nerve as well. There was a test performed 05/21. I went back to the doctor on 05/26 he said that the reports he received are not making sense to him. My next f/u appointment with Dr. is 06/09 because the doctor asked to have 2 weeks to read through my hospital reports. I saw a different doctor instead on 05/27, Dr. , and he said that this can happen from the vaccine. He said that there is a swelling and I need to see a different doctor about my retina. I was told that I need to see another physician. I saw Dr. . on 05/27 and he said that there are fluids there, but no one can confirm that this is because of the vaccine. He gave me the option to take prednisone 10mg and I feel that it is working, but it is very slow. It was moved to 3x per day. I can see objects now even though it's still not clear. I have a f/u with Dr. 06/03.
1362140	5/31/2021	NJ	34	F	4/26/2021	5/26/2021	Acute superficial vein thrombosis. Nodule formed on the back of the right leg which decreased in size after 2 days after initial symptoms. A bruise was formed in the surrounding area the next day. Four days later the bruise became larger so I decided to go to the ER where they did an ultrasound. Deep vein thrombosis was ruled out. I was sent home and recommended to wait for the symptoms to go away, no medications were given. I'm still recovering.

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1362130	5/31/2021	MA	64	F	3/17/2021	4/13/2021	Acute onset stroke symptoms the afternoon of 4/13/21 after returning home from room. EMS transported pt to local hospital. Dx with aortic arch/proximal subclavian artery thrombus, migration into axillary artery. Treated at local hospital with TNK for aortic arch clot & ischemic stroke. Transferred to tertiary medical center. Pt had massive stroke (left & right side) with brain stem herniation. Pt CMO after 16hrs and expired on 4/14, <32 hrs after symptom onset.
1362092	5/31/2021	MA	50	F	5/10/2021	5/12/2021	Acute Horrible abdominal pain, vomiting, went to ER they did a CT scan without contrast and diagnosed me with severe constipation. Sent me home with bowel clear plan. Did not really work and pain continued. Went back to ER on that Friday had another CT scan WITH contrast where they saw a blood clot to the spleen resulting in an infarction as well as a blood clot to the right kidney. Stayed in hospital overnight and placed on blood thinners.
1362334	5/31/2021	CO	48	F	5/9/2021	5/29/2021	Ten minutes after I received the vaccine, my left arm and leg felt very heavy, like I was uneven. I started to feel very dizzy and my left eye became very blurry. I started feeling nauseous, as well. On the car ride home I noticed a rash. We thought it was an allergic reaction. After I got out of the car I noticed it went away. It came back later again, around my neck that evening, but it only lasted 5 minutes. It was a rash with white bumps and then it went away. At night I experienced chills. When I woke up I had a blistering headache with neck pain that lasted a couple days. The nausea and balance picked up and got worse. I spent two weeks being unable to see, walk, read or drive safely. I have had to take time off of work. I cannot view a computer screen without feeling nauseous. Most of the first week I spent on the floor because of the nausea and spinning issues. I sought medical treatment. I had a CAT scan and they ruled out a blood clot. I still have low grade nausea. I have regained peripheral vision in my left eye, which was missing for three weeks. I have been off work for more than 2 weeks. I still cannot work at my normal capacity. I still have a very strong chemical taste in my mouth. It is getting less and less, but I can still taste it. I've have a lot of swelling at the base of my skull, that has not resolved.

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1361911	5/30/2021	AZ	47	F	5/5/2021	5/9/2021	ER visit on 05/09/2021 due to left lower leg pain and swelling. Diagnosis was Superficial thrombophlebitis. Follow-up with primary care on 05/12/2021, then endovascular doctor on 05/19/2021 confirmed diagnosis, no deeper clots found at that time via ultrasound. Received prescription for blood thinner (Xarelto). ER visit on 05/22/2021 due to leg pain higher up the leg. Doctor had recommended ER if pain seemed to move up the leg. Diagnosis via ultrasound of a popliteal vein thrombosis behind the left knee. Follow-up with endovascular doctor, received prescription for blood thinner (Eliquis) instead of Xarelto due to nausea.
1361672	5/30/2021	VA	67	M	2/16/2021	3/7/2021	SYMPTOMS- excessive vomiting, high fever/ chills , back pain; TREATMENT - diagnosed with Idiopathic Necrotizing Acute Pancreatitis Developed blood clots(SMB Thrombosis) , esophageal ulcers/ internal bleeding, internal fluid sacs retention (+25lbs- abdominal and thoracic,) jaundice. Required insulin injections; oxygen nasal cannula; nasogastric tube; TPN Central line and Physical Therapy to regain legs mobility TIME COURCE - One Hospital 8 Days; Another Hospital - 22 Days ED, ICU(20 days), Stepdown; Rehab Center - 9 Days
1362011	5/30/2021	NJ	41	F	4/22/2021	4/24/2021	Shortness of breath, severe headaches, dizziness, fatigue, fever after second dose, went to urgent care 5/30 - doctor called over to ER due to coming in with presented symptoms of blood clot in left calf, ER performed ?standard? testing - and was dismissive to any symptoms I reported and my concern that this was related to vaccination. I felt I was dismissed on my overall health at time of ER visit, and was never seen by an actual doctor.
1361465	5/30/2021	WI	48	F	4/8/2021	5/6/2021	After dose 1 my period for that month was skipped. After dose 2 my period came early and has been unrelenting. I am know on day 22 of bleeding. This duration has NEVER happened in all my life!!!! Not only am I bleeding for an unhealthy length, it is very heavy bleeding with terrible cramping and clot sloughing unlike I have ever seen. THIS IS NOT SAFE FOR A CHRONIC ANEMIC!
1361739	5/30/2021	MN	75	F	4/5/2021	5/22/2021	Development of unexplained Cerebral venous sinus thrombosis

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1361842	5/30/2021		45	F	3/5/2021	5/28/2021	subdural thrombosis
1361440	5/30/2021	WA	43	F	5/15/2021	5/26/2021	Blood clot in right temporal lobe
1361516	5/30/2021	TX	25	F	5/6/2021	5/7/2021	The evening I got my shot I had a very bad migraine. But what concerned me was I took two birth control pills that evening, having accidentally skipped my pill the previous day. I had trouble sleeping all night with a random pains and woke up with a blood pressure of 75/45 and resting heart rate of 50 or less. I am an EMT, so I stayed supine and improved over 30 minutes, but almost went to the ER and would have, had I not been a medical professional. The propensity to clot with the Janssen as well as increased intake of birth control did not cross my mind but I want others to be aware of the potential interference there.
1361562	5/30/2021	OK	70	F	4/1/2021	4/25/2021	3 weeks after shot, numbness and tingling in right hand 3 weeks after that speech problems, trouble swallowing, loss of use of hand, went to the ER on May 18 with a blood clot in brain causing stroke.
1361603	5/30/2021	MD	52	M	5/11/2021	5/18/2021	Stroke .. blood clot.
1361642	5/30/2021	PA	54	M	5/11/2021	5/15/2021	Deep Vein Thrombosis (DVT) in right lower leg. Symptoms initially occurred about two days after feeling sick with a high fever. Initially, the pain in the right calf muscle was thought to be a muscle or tendon strain. On May 22nd, during a campout, there was pain along the entire right leg, but at the time I thought it was just related to lower back pain from sleeping on the ground. On May 27 and 28th there was sharp pain at the bottom of my right foot, then on May 29th I noticed swelling and a hard warm spot just above the inside right ankle. I reported to a local urgent care clinic first then was referred to Medical ER.
1361686	5/30/2021	FL	57	M	4/11/2021	4/21/2021	I had pain in my left leg primarily in my calf that was pretty constant. I went to Urgent Care two weeks later. They were not concerned about a blood clot since the time had passed. I contacted my Doctor and he did not feel that it was necessary to be concerned because I am male which was no cause to worry.



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1361745	5/30/2021	WA	39	F	4/27/2021	5/29/2021	Superficial Thrombosis, right leg
1361434	5/30/2021	NJ	43	F	1/28/2021	3/10/2021	Uterine hemorrhage, severe heavy menstrual with large clots
1361230	5/29/2021	OR	61	F	5/27/2021	5/29/2021	Rash. Red, bumpy and itchy/prickly especially if exposed to sun or heat. The rash was an oval, slightly tear drop shape about 3 inches long by 1 1/2 inch wide. Treatment prescribed was Clotrimazole and Betamethasone Dipropionate.

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1360535	5/29/2021	NC	50	F	4/17/2021	4/1/2021	<p>Her throat was swollen; Bruise under chin/Her throat had bruising; She had an allergic reaction; Strep throat.; She couldn't swallow water; she would jerk if she swallowed water and it was a hurting feeling going down. Her throat was so swollen she could hardly eat; Lip, Jaw and face swollen; Lip, Jaw and face swollen; Throat was going to close; This is a spontaneous report from a contactable consumer reporting for herself. A 50-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EW0150) 17Apr2021 at single dose via an unspecified route of administration on arm left for COVID-19 immunization. Relevant medical history included ongoing hypertension, ongoing from 2016 Blood clot on her right kidney, ongoing from 2016 high cholesterol. The patient received first dose of BNT162B2 (Lot Number: ER8730) on 21Mar2021 around 11:00am on left arm and experienced allergic reaction, Face swollen, she was like the Nutty Professor doing the clump (as reported). Concomitant medications included warfarin for Blood clot on her right kidney and an unspecified product for cholesterol control. Patient reported her lip, jaw, and whole face were swollen around 19Apr2021 or 20Apr2021 until 22Apr2021. She says she went to Urgent Care, they gave her Benadryl, and admitted her to the hospital because they thought her throat was going to close starting from 20Apr2021 or 21Apr2021 until 21Apr2021. Starting from 09May2021 in the afternoon until 10May2021 in the night patient reported she couldn't swallow water; she would jerk if she swallowed water and it was a hurting feeling going down, she thought it was strep throat. Patient also reported under her chin was like a frog out on a log when they inhale and exhale (as such). Starting from Sunday night on 10May2021 her throat was so big and she presented a bruise under chin like someone put their hands up in there and choked her (as reported). Patient informed that her chin was swollen also. Patient went to the hospital where they tested her for strep and released her out of the hospital around 4:00pm. Patient reported she was admitted for one day on 10May2021 and they gave her Benadryl again, another medicine, throughout the day they even did a CAT scan. She says through the day she could start swallowing again. Patient got up Monday (11May2021) and went to the emergency room. She reported that</p>

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							under her chin was swollen where is throat. Her throat had bruising under it and her throat was swollen and she had to go back to the hospital. They gave her Benadryl for her swelling. During call about the Pfizer COVID-19 vaccine, patient reported she had both doses and had an allergic reaction to vaccine, she was assuming it was for BNT162B2. At the time of the reporting outcome for 'Bruise under chin' and 'She had an allergic reaction' was unknown. The patient recovered from Lip, Jaw and face swollen on 2Apr2021, from 'Strep throat' and from 'She couldn't swallow water; she would jerk if she swallowed water and it was a hurting feeling going down. The patient recovered from 'Her throat was so swollen she could hardly eat' and 'Strep throat' on 10May2021, from 'Throat was going to close' on 21Apr2021, while had not yet recovered from other reported events.
1360362	5/29/2021	CT	58	F	3/3/2021	3/3/2021	headache; body aches; Extreme pain/discomfort at the injection site; hazy feeling in brain; Extreme pain/discomfort at the injection site; This is a spontaneous report from a contactable consumer (Patient). A 58-year-old non pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiry date were not reported) via an unspecified route of administration, administered in left arm on 03Mar2021 at 15:00 (at the age of 58-year-old) at a single dose for COVID-19 immunisation at Pharmacy or Drug Store facility. Medical history included seizure disorder, seasonal allergies, depression, low back injury, DVT (Deep vein thrombosis) and obesity. Patient had no allergies. The patient did not receive any other vaccines within four weeks prior to the vaccination. Concomitant medications (in two weeks) included Oxcarbazepine (TRILEPTAL), Sertraline, Acetylsalicylic acid (ASPIRIN LOW DOSE), Colecalciferol (VITAMIN D). Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 03Mar2021 at 15:15, the patient experienced headache, body aches, extreme pain/discomfort at the injection site and hazy feeling in brain. The outcome of the events was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

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1359991	5/29/2021			U			<p>Blood clots under skin; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clots under skin) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clots under skin) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood clots under skin) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. No concomitant medications reported by reporter. No treatment medications provided by the reporter. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p>

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1360502	5/29/2021	GA	57	U	4/9/2021	4/1/2021	right vision got more blurry; stroke on the left side of brain; felt weird; tongue started to go numb; Right side of face went numb; Headache; CBCT scan found nothing but calcification; overall cholesterol was 221; LDL was 124; triglyceride was 156; This is a spontaneous report from a contactable consumer (patient). A 57-year-old patient of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 09Apr2021 (lot number: EW0162), as 1st dose, single dose, at age 57 years old, for COVID-19 immunisation. Medical history included asthma, arthritis, environmental allergies, and allergy to grass ragweed, mold, tree pollen which triggers the asthma. Concomitant medications included celecoxib (CELEBREX) taken for arthritis from an unspecified date and ongoing; nicotinamide (VITAMIN B3); vitamin C; and vitamin b complex, taken for unspecified indications, start and stop dates were not reported. On 19Apr2021, between 19:30 to 20:00, the patient had a stroke on the left side of brain. It was also reported that on an unspecified date in Apr2021, the patient felt weird, tongue started to go numb, right side of face went numb, right vision got more blurry, and had headache. These events resulted to hospitalization on 20Apr2021 for 2 and a half days (as reported). In Apr2021, when the patient was in the hospital, laboratory tests were performed which included activated partial thromboplastin time (APTT), blood thyroid stimulating hormone (TSH), Hemoglobin A1C, lipid panel, basic metabolic panel, comprehensive metabolic panel, CBC platelet with automated differential, prothrombin INR, prothrombin time, i-STAT Troponin and Sonogram of carotid bilateral vascular in neck which were all normal; Triglycerides was 156, High density lipoprotein (HDL) was 53, Low density lipoprotein (LDL) was 124, Total cholesterol (overall cholesterol) was 221. On 10Apr2021, the patient underwent CBCT scan of the whole body which showed no aneurysm, no cancer, found nothing but calcification. The outcome of the events was unknown. Follow-up attempts are needed. Further information is expected.

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1360529	5/29/2021	NC	50	F	3/21/2021		<p>an allergic reaction to the Pfizer; face swelling/She says she was like a actor doing the clump. She says her lip and jaw looked just like that; She says she was like a actor doing the clump. She says her lip and jaw looked just like that.; This is a spontaneous report from a contactable consumer (patient). A 50-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8730), dose 1 via an unspecified route of administration, administered in Arm Left on 21Mar2021 11:00 (at the age of 50-year-old) as 1st dose, single for covid-19 immunisation. Medical history included ongoing high blood pressure, blood clot on her right kidney from 2016, high cholesterol from 2016. Concomitant medications included warfarin; cholesterol. The patient was calling about the Pfizer COVID-19 vaccine. She says she had both of them. She says she had an allergic reaction to the Pfizer; she is assuming it was the Pfizer. She says the 15th through the 19th she was like a actor doing the clump. She says her lip and jaw looked just like that. She says it was at a the pharmacy. She says she went to Urgent Care, they gave her Benadryl, and admitted her to the hospital because they thought her throat was going to close(it started 20Apr2021 or 21Apr2021 and ended on 21Apr2021). The patient stated she was started on a high blood pressure medication after the first time of being in the hospital with face swelling. Prior Vaccinations (within 4 weeks) there is no any other vaccinations within four weeks prior to the first administration date of the suspect vaccine. There is no AE following prior vaccinations. The patient says she has no allergies and was not sick at the time of either vaccination. There is no Family Medical History Relevant to AE. The outcome of the events was unknown.</p>

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1360532	5/29/2021	FL	34	F	5/7/2021	5/12/2021	Blood clots - DVT; This is a spontaneous report from a contactable consumer (patient) reported that a 34-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0171), via an unspecified route of administration, administered in arm left on 07May2021 08:15 (at the age of 34-years-old) as 2nd dose, single dose for covid-19 immunization. The patient was not pregnant at the time of vaccination. The patient medical history included covid-19 prior vaccination. The patient had no known allergies. The patient previously received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EP8737), via an unspecified route of administration, administered in arm left on 16Apr2021 08:00 AM (at the age of 34-years-old) as 1st dose for covid-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included levonorgestrel (PILL 72) taken for birth control, start and stop date were not reported. On 12May2021, the patient experienced blood clots - DVT. The event resulted in emergency room/department or urgent care. Therapeutic measures were taken as a result of blood clots - DVT as patient received blood thinners. The outcome of the event was not recovered. Since the vaccination, the patient has not been tested for COVID-19.

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1360590	5/29/2021	NE	54	F	5/19/2021		DVT and PE; DVT and PE; This is a spontaneous report from a contactable Physician. This Physician reported that a 54-year-old female patient (not pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot No.unknown) at single dose for COVID-19 immunisation on unknown date. Relevant medical history included Migraines, CAD, CKD III, morbid obesity, and allergy to sulfa. Relevant concomitant drugs included escitalopram oxalate (LEXAPRO), levothyroxine sodium (SYNTHROID), topiramate (TOPAMAX), metoprolol succinate (TOPROL-XL). No other vaccine was admitted in four weeks. The patient experienced DVT (deep vein thrombosis) and PE (pulmonary embolism) on 19May2021. Doctor or other healthcare professional office/clinic was visited. Emergency room/department or urgent care required. The patient was hospitalized for 2 days. Treatment therapy included anticoagulation. The outcome of events was resolving. The events were reported as serious (hospitalization and life-threatening). The patient did not have COVID tested post vaccination. Information on the lot/batch number has been requested; Sender's Comments: The reported deep vein thrombosis and pulmonary embolism are considered unrelated to BNT162B2 vaccine. No details on the administration date of vaccine were provided. The presence of morbid obesity and chronic kidney disease (CKD) are considered possible contributory factors for the events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.



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1360642	5/29/2021			U	4/20/2021	5/24/2021	I didn't know if this could be a blood clot forming as result of the vaccination or this just regard could still be a blood clot.; I have too swelling in my lower left leg just below the knee; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot Number: EW0162; NDC / UPC number of COVID Vaccine: Unknown; Expiration Date: 31Jul2021), via an unspecified route of administration on 20Apr2021 as 2nd dose, single for covid-19 immunisation. Medical history included blood clot and stated as I do have blood clot in my past case history. My mother died at blood clot to the heart. Concomitant medications were not reported. Historical vaccine included first dose of BNT162B2 (Lot Number: ER8734; Expiration date: 31Jul2021) for COVID-19 immunisation. On 24May2021, the patient experienced i didn't know if this could be a blood clot forming as result of the vaccination or this just regard could still be a blood clot and i have too swelling in my lower left leg just below the knee. Additional Context was received as, I was calling in regard to my vaccination did I had. The first shot I had on 30Mar2021 and then the second one was on 20Apr2021. Further patient stated, that's what I am really not sure about I am not sure of this, if this is a COVID related vaccine issue or not. I have swelling too in my lower left leg just below the knee. I noticed this first time yesterday and notice this again today few minutes ago looking better and I didn't know if this could be a blood clot forming as result of the vaccination or this just regard could still be a blood clot and I wasn't sure if there was any relation to the vaccine. Patient stated, I am going to try to see my doctor tomorrow, helps to get into see him tomorrow. Like I said I am trying to see my doctor tomorrow. I am trying to see him hopefully he will able to help me. I have concerned about the swelling because I do have blood clot in my past case history. My mother died at blood clot to the heart I had in never and stroke and that is why I concerned. So that's why I go to the doctor tomorrow. Outcome of the events was recovering. Further probing could not be done as consumer was not willing to complete the report. Hence limited information available over the call.

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1361007	5/29/2021	VA	51	M	3/27/2021	4/15/2021	Occlusive deep venous thrombosis in left anterior tibial vein
1361174	5/29/2021	MO	70	F	3/3/2021	4/6/2021	Severe breathing issue. Rattling in chest. urgent care on 4/6 and 4/10; inhalers issued, prednisone taken, shot of antibiotic given, chest x-ray. I flew in to home on 5/1. On 5/3 started having difficulty breathing progressively got worse went to nurse practitioner on Friday, 5/7 sent to diagnostic imaging for ct scan with contrast found bilateral blood clots in lungs. Sent to ER at Hospital. Spent 4 days in hospital. Put on heparin until I was released on Monday. Put on eliquis when I was released on 5/10. See hematologist on June 1.
1361200	5/29/2021	IL	25	F	5/7/2021	5/28/2021	sub clavian vein thrombosis
1361274	5/29/2021	IN	74	F	5/5/2021	5/6/2021	nasuea, vomiting, weakness, passing out twice and could not eat. Removal of large blood clot from left lung on 05/28/21. Released from hospital on 05/29/21. Prescribed oxygen at home until oxygen is maintained above 95.
1360608	5/29/2021	GA		F	5/16/2021	5/1/2021	she said she developed superficial phlebitis; This is a spontaneous report received from a contactable consumer (patient) via a Pfizer sponsored program COVAX US support. A 61-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on 16May2021 as single dose for COVID-19 immunization. Medical history included Blood clots. The patient's concomitant medications were not reported. On May2021, she developed superficial phlebitis. Stated, she received the 1st dose of the Pfizer-BioNTech Covid-19 Vaccine on 16May2021. Afterwards, she said she developed superficial phlebitis. She said she previously had issues with blood clots so when she heard that there were reports of blood clots with the Johnson and Johnson vaccine, she specifically selected the Pfizer Covid vaccine. She wants to know if the reaction she had is a known side effect of the vaccine, what she should do, and if there are any protocols on how to treat it. The outcome of the event was unknown.

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1361194	5/29/2021	MO	65	M	3/23/2021	3/29/2021	Blood clots causing pulmonary embolism on 3/29 . Hospitalized on 4/6-4/8. Clots also caused a mild stroke on 5/5. Hospitalized 5/5-5/6
1360548	5/29/2021	TN	66	M	3/26/2021		3 clots were discovered on the groin area of the left leg; patient has two stunts in the right leg (1 in thigh and 1 in calf) and reported that it had been uncomfortable but not painful; This is a spontaneous report from a contactable pharmacist. A 66-year-old male patient received the second dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, Lot Number: ER8732), via an unspecified route of administration, administered in the right deltoid (reported as right arm) on 26Mar2021 at 03:55 as a single dose for COVID-19 immunization. Medical history included two stunts in the right leg (1 in thigh and 1 in calf) on an unknown date. The patient had no allergies. The patient's concomitant medications were not reported. The patient previously received the first dose of BNT162B2 on 24Feb2021 (lot number:EN6201), intramuscular in the right arm at 65 years of age. The patient went to his vascular doctor on an unspecified date (reported as 05Oct2021) and 3 clots were discovered on the groin area of the left leg. The MD said it did not warrant going to the ER. The patient has two stunts in the right leg (1 in thigh and 1 in calf) and reported that it had been uncomfortable but not painful. The MD placed him on Eliquis 10 mg, BID for 7 days then reduced the dose at 5 mg BID thereafter for about 5 months. The outcome of the events was unknown.; Sender's Comments: "The causal association of the events of 'clots on the groin area of the left leg' and 'leg uncomfortable' with the suspect drug BNT162B2 cannot be excluded due to limited information in the case. The case will be reassessed once new information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.~~

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1357945	5/28/2021	TX	19	F	4/18/2021	5/5/2021	extensive deep vein thrombosis with embolization and massive pulmonary embolism ; patient presented with shortness of breath and severe bilateral leg and back pain unable to move with extensive thrombosis noted. patient had cardiopulmonary arrest was on ecmo now decannulated and extubated , awake, alert oriented in recovery phase
1357318	5/28/2021	CA	51	M	4/22/2021	4/16/2021	a DVT in his left calf after the second vaccine; This is a spontaneous report from a contactable consumer (patient). A 51-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 22Apr2021 18:15 (Batch/Lot Number: ER8735) at the age of 51-years-old as SINGLE DOSE for covid-19 immunization. The patient medical history was not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications was none, patient did not received other medications within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously received the first dose of BNT162B2 (Lot number: ER8733) on 01Apr2021 16:00 at the age of 51-years-old in Left arm for covid-19 immunization and experienced a superficial blood clot in his left calf. The patient experienced a deep vein thrombosis (DVT) in his left calf after the second vaccine on 16Apr2021 6:30 PM. Event resulted in Doctor or other healthcare professional office/clinic visit. Treatment received for the events included had a shot of enoxaparin sodium (LOVENOX) and am taking rivaroxaban (XARELTO). The patient underwent lab tests and procedures which included blood test: negative on 06May2021, Nasal swab covid-19 test: negative on 27Apr2021. The outcome of the event was not recovered.

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1357322	5/28/2021	MA	29	M	1/7/2021	2/17/2021	Breakthrough COVID infection; Breakthrough COVID infection; This is a spontaneous report from a contactable Nurse. This Nurse reported in response to HCP letter. A 29-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Lot number: EH9899 and expiry date: unknown), dose 2 via intramuscular, administered in Deltoid Left on 07Jan2021 as 2nd DOSE, SINGLE for Covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced breakthrough Covid-19 infection on 17Feb2021. The patient underwent lab tests and procedures which included an asymptomatic COVID test (COVID 19 PCR-done of state) prior to visiting elderly family on 17Feb2021 which was positive. The patient was then re-tested using SARS-CoV-2 on 22Feb2021 and 23Feb2021, both of which were negative. The patient was not hospitalized and not admitted to an Intensive Care Unit. The patient did not display clinical signs at rest indicative of severe systemic illness. The patient did not require supplemental oxygen (including high flow or ECMO) or receive mechanical ventilation. The patient did not experience respiratory symptoms like Dyspnea, Tachypnea, Hypoxemia, COVID-pneumonia, Respiratory failure, Acute Respiratory Distress Syndrome (ARDS) and cardiovascular symptoms like Heart failure ,Cardiogenic shock, Acute myocardial infarction, Arrhythmia , Myocarditis and Gastrointestinal/Hepatic symptoms like Vomiting, Diarrhea ,Abdominal pain, Jaundice, Acute liver failure and vascular symptoms like Deep vein thrombosis, Pulmonary embolism, Limb ischemia, Vasculitis and any other thromboembolic events) and renal symptoms like acute kidney injury, Renal failure and Neurological symptoms like Altered consciousness, Convulsions/seizures, Encephalopathy, Meningitis, cerebrovascular accident and Hematological symptoms like thrombocytopenia, Disseminated intravascular coagulation and dermatological symptoms like Chillblains, Erythema multiforme and other symptoms like multisystem inflammatory syndrome. The patient did not receive any additional therapies for COVID-19. On an unknown date in Feb2021 the outcome of the events was recovered. Follow up attempts are needed. Further information has been requested.; Sender's Comments: The efficacy of a drug varies from patient to patient and

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can be affected by different factors; however, a contributory role of the suspect product BNT162B2 or comirnaty to the reported event vaccination failure and covid-19 cannot be ruled out.

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1357347	5/28/2021	MA	74	M	2/23/2021	4/19/2021	<p>Pulmonary embolism; Two massive bilateral clots; This is a spontaneous report received from a contactable physician (patient). A 75 years old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at the age of 74 years old, administered in arm left on 23Feb2021 (Lot Number: EL9204) as single dose for covid-19 immunization. Medical history included, chronic obstructive pulmonary disease (COPD), history of cancers. No known allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient had received other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at the age of 74 years old, administered in arm left on 02Feb2021 (Lot Number: EN6200) as single dose for covid-19 immunisation. The patient experienced pulmonary embolism on 19Apr2021, two massive bilateral clots on 19Apr2021. Events resulted in Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event), Disability or permanent damage. The patient was hospitalized for all events for 6 days. The patient underwent lab tests and procedures which included Nasal swab: negative on 03Feb2021. Therapeutic measures were taken as a result of pulmonary embolism, two massive bilateral clots and included Heparin and Xarelta. The outcome of the events was recovered with Seroquel in 2021.; Sender's Comments: Based on the temporal relation, the association between pulmonary embolism, thrombosis and vaccination with BNT162B2 cannot be completely ruled out. The contribution of patient's age cannot be completely ruled out in the occurrence of the events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.</p>

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1357350	5/28/2021	OH	36	F	4/29/2021	4/30/2021	Blood clots in lung and leg; Blood clots in lung and leg; Dizziness; Weakness; Headache; shortness of breath; This is a spontaneous report from a contactable consumer (patient). A 36-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in the left arm on 29Apr2021 16:00 (Batch/Lot Number: EW0162) as 2nd dose, single dose for COVID-19 immunization. The patient received the first dose of COVID-19 vaccine on 08Apr2021 17:45 left arm for COVID-19 immunization. Medical history included fibromyalgia and had covid-19 prior to vaccination. Concomitant medications included gabapentin; ethinylestradiol, norgestimate (ORTHO-CYCLEN); and diclofenac sodium (DICLOFENAC SODIUM); all taken for an unspecified indication, start and stop date were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 30Apr2021 05:00, the patient had blood clots in lung and leg, dizziness, weakness, headache (still after a month) and shortness of breath. As a result of the events, the patient visited doctor or other healthcare professional and has been to the emergency room. The events required hospitalization and was considered a life-threatening illness (immediate risk of death from the event). The patient was hospitalized for two days. The patient was put on blood thinners as treatment for the events. The patient has not recovered from the events.



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1357365	5/28/2021	IN	37	F	5/7/2021	5/10/2021	<p>bilateral pulmonary embolism; legs were checked and they could not locate any other blood clots - just in lungs.; I experienced extreme shortness of breath/I could not catch my breath; heart was 'resting' at approximately 145 beats per minute./elevated heart rate; This is a spontaneous report from a contactable consumer (patient). A 37-year-old female patient (no pregnancy) received BNT162B2 (Pfizer BioNTech Covid 19 mRNA Vaccine, lot number: EW0182), via an unspecified route of administration, administered in Arm Left on 07May2021 at 10:00 (Batch/Lot Number: EW0182) as unknown, single for COVID-19 immunization. No pregnancy at time of vaccination. Medical history included polycystic ovarian syndrome (Pcos), high cholesterol, and allergies: fish oil. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Other medications the patient received within 2 weeks of vaccination. At 8:00 AM on 10May2021, the patient experienced extreme shortness of breath and an elevated heart rate. She could not catch her breath and her heart was 'resting' at approximately 145 beats per minute. She went to the local emergency room at which time she was taken back for testing, approximately 10 hours later, she was diagnosed with bilateral pulmonary embolism. Her legs were checked, and they could not locate any other blood clots - just in her lungs. Treatments (levofloxacin (LOVENOX) shots and oral blood thinners) received for the adverse events. The events required to visit emergency room/department or urgent care. The events were reported as serious with seriousness criteria of hospitalization (for 2 days) and life threatening (threatening illness, immediate risk of death from the event). Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was recovering.</p>

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1357423	5/28/2021	GA	56	F			<p>BLOOD CLOT IN RIGHT ARM; ARM SWOLLEN; This spontaneous report received from a patient concerned a 56 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included high blood pressure, alcohol use (beer at home), and smoker. The patient experienced drug allergy when treated with acetylsalicylic acid. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown and expiry: unknown) dose was not reported, 1 total, administered on 05-APR-2021 to right arm for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. The patient did not feel sick after vaccination. On an unspecified date in 2021, the patient believed that, she had a blood clot in right arm. In past 2-3 weeks, it had been getting bigger and was moving up in her arm. She probably had the clot for longer but started noticing it more 2-3 weeks ago. Clot was moving from her elbow to the shoulder blade and arm was getting big. Patient did not have any pain but her arm was swollen and due to dark skinned she could not tell if her arm was red. Patient called emergency medical service and told them that she had a blood clot, she could feel and see the blood clot and it was told that she needs to go to the doctor but she did not bother. The blood clot kept moving up. Patient had a regular doctor but she did not inform her doctor. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the blood clot in right arm and arm swollen was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210547027-covid-19 vaccine ad26.cov2.s- blood clot in right arm. This event is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p>

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1358495	5/28/2021	MI	15	M	5/28/2021	5/28/2021	The Jansen vaccine was inadvertently administered to patient. He should have received the Pfizer dose 1. Patient said that his arm was sore for a couple of minutes, but he was fine. Explained to his mother that the Jansen vaccine was temporarily paused due to blood clots in women 18-49 years of age. Explained that the incidence of the blood clots was way less than 1% when compared to the number of patients that have received the vaccine. Told patient that if he experienced fever, chills, or body aches that he could take Tylenol or Ibuprofen. Also explained that if he experienced any type of sudden or intense headache, slurred speech, or one sided weakness to call his PCP right away..
1357862	5/28/2021	MD	43	F	4/12/2021	5/5/2021	Pain in left leg, pit in left leg, swollen left calf. Received care at Patient First. Platelets and white blood cell counts were normal. Received ultrasound of left leg from Progressive Radiology. Results were normal, no sign of clots.
1357269	5/28/2021	IL	35	F	5/11/2021	5/13/2021	I am feeling a clot in my left armpit after 1 day of having 2nd dose of COVID19 Pfizer; This is a spontaneous report from a contactable consumer (patient). A 35-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration and administered in left arm at age of 35-years, on 11May2021 18:00 (Lot Number: EW0179) as single dose for covid-19 immunization. The patient medical history was not reported. The patient was not pregnant at time of vaccination. Concomitant medications were none (the patient did not receive any other medications within 2 weeks of vaccination). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Historical vaccine included the first dose of BNT162B2 on an unknown date for covid-19 immunization. The patient reported that she was feeling a clot in her left armpit at 08:00 on 13May2021 (reported as after 1 day of having 2nd dose of COVID19 Pfizer). The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested for COVID-19 since the vaccination. Event outcome was not recovered. No follow-up attempts needed. No further information expected.

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1357972	5/28/2021	PA	55	M	5/1/2021	5/8/2021	Patient experienced acute pulmonary embolism approximately 8 days after administration of the J&J vaccine. He did not have low platelets. No clear cause of the PE was found. It was thought to be possibly related to superficial thrombosis of his upper extremity secondary to IV that was placed 2 days prior when he was briefly admitted for workup of heavy hematocheiza, at which time he was found to have a mild anemia and discharged. He was treated inpatient at Hospital. I am not sure of the where he obtained the vaccine or the exact date.
1358033	5/28/2021	UT	70	M	4/22/2021	4/24/2021	2 days after second shot blood clot in left arm. Hit while walking in my home. Could not lift my arm. 5 days later heart attack. Pilot with EKG yearly. Last EKG less than one month from my heart attack on April 29, 2021
1358050	5/28/2021	OK	30	M	3/17/2021	3/31/2021	14 days after second vaccination, pt. had dizziness, blurred vision, memory loss; went to hospital x 3 days. Tests were run. Blood clot was never confirmed despite CT scans but was suspected. Pt. is now on ASA 81mg daily maintenance and suffers no ill effects. History was given by mom when her younger son had his vaccine. This patient may have had a VAERS generated by the hospital.
1358106	5/28/2021	MA	17	F	5/18/2021	5/22/2021	Vaccine 5/18. On 5/22 4 days after vaccine, she developed right arm swelling and skin discoloration. On 5/23 she went to the ED. Ultrasound revealed acute, occlusive thrombosis of right subclavian vein. She was admitted to the hospital, started on enoxaparin, achieved therapeutic levels. On 5/25 she underwent thrombolysis and venogram and was confirmed to have findings consistent with Paget-Schroetter syndrome. She was discharged home on 5/25 in good condition. Note: she also has known prothrombin gene mutation G20210A that confers an increased risk of thrombosis. She does have repetitive use of the right arm (lacrosse player).
1358278	5/28/2021	IN	36	F	5/4/2021	5/4/2021	Beginning 2 - 3 days after injection I began noticing easy and severe bruising. I monitored until 5/27 when I went to get blood work, as I was concerned about the effect of another dose. My blood work shows a high prothrombin time and INR. This is a new occurrence. It has not been treated. Course of action is not known at this time.

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1358343	5/28/2021	NC	38	F	5/20/2021	5/26/2021	Patient found unresponsive due to unknown cause on 5/26 (6 days post-vaccination). Transferred, noted to be COVID + by NP swab with high cycle threshold on admission, tracheal aspirate was COVID neg. Patient had prior COVID infection in Nov. 2020. Workup for encephalopathy included MRI (5/27) which revealed thrombosis of left transverse/sigmoid sinuses and proximal jugular vein. However, platelets were normal 245 x 10 <sup>9</sup> /L (5/26).
1358358	5/28/2021	IL	50	F	4/26/2021	5/5/2021	I became dizzy, short of breath and chest tightness on May 5th in the afternoon. I first called my DR who told me to go to the ER. They did the CAT Scan, Blood test. CAT scan showed all clots resolved. I was admitted since the reason for my symptoms could not be identified. They did chemical stress test which came back normal. They sent me home on the following day, the 6th. I followed up with my PCP and pulmonologist. I am also going to follow up with a cardiologist.
1358413	5/28/2021	MD	29	F	4/28/2021	5/22/2021	Patient was found unresponsive at home on 5/22, admitted to another institution, found to be in DKA, multisystem organ failure (renal failure, liver failure), new R femoral DVT, elevation of ferritin, LDH and CRP. Over the course, platelet count continues to drop while on anticoagulation, and continued progression of thrombi, and transferred to our institution for further workup, including hepatic failure, concern for HLH and Castro trophic antiphospholipid syndrome. Based on chart review, patient had non-specific symptoms for a few weeks prior to the presentation, including GI distress, dysphagia and neck/sinus pain. CTH done with cerebral edema but not intracranial venous thrombosis. CT chest and abdomen with no PE, but presence of R popliteal vein thrombus, and portal vein thrombus. Heparin Ab (PF4 -ELISA test) was negative (at both referring hospital and current hospital). Serotonin release assay is pending at the time of report. While the symptoms are not consistent VITT that were reported (Heparin ab negative, received mRNA vaccines), however this possibility cannot be ruled out. IVIG was started on 5/27 - 5/28 to treat empirically for concern for heparin induced thrombocytopenia vs VITT.

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1357434	5/28/2021			U			DEATHS; BLOOD CLOTS; This spontaneous report received from a consumer who reported reading and seeing on the news concerned a patient of unspecified age, race, ethnic origin and sex. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number not reported, expiry not reported) frequency one total, dose, therapy start date were not reported administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the consumer stated that he read and saw on the news that this vaccine causes patient's deaths, and blood clots. On an unspecified date, the patient died from unknown cause of death. It was not reported whether autopsy was performed or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of deaths on an unspecified date, and the outcome of blood clots was not reported. This report was serious (Death, and Other Medically Important Condition).; Sender's Comments: V0: 20210550011-covid-19 vaccine ad26.cov2.s-deaths, blood clots. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

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1357239	5/28/2021			F			blood clot on her left eye; This is a spontaneous report from a contactable consumer (patient). A 25-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, expiry and lot number were not reported), via an unspecified route of administration, administered in the left arm on an unspecified date as 1st dose, single for covid-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient woke up with a blood clot on her left eye on an unspecified date. Outcome of the event was unknown. No follow up attempts are possible. Information about lot/batch number cannot be obtained.

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1357116	5/28/2021	OH	41	M	3/23/2021	3/23/2021	<p>Blood Clots noted all over lungs; Abdominal pain radiating from right side to left side then to collar bone; Abdominal pain-right side; This spontaneous case was reported by a patient and describes the occurrence of PULMONARY EMBOLISM (Blood Clots noted all over lungs) in a 41-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 037421B) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Gallbladder pain. On 23-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, the patient experienced ABDOMINAL PAIN (Abdominal pain-right side). On 30-Apr-2021, the patient experienced PAIN (Abdominal pain radiating from right side to left side then to collar bone). On 04-May-2021, the patient experienced PULMONARY EMBOLISM (Blood Clots noted all over lungs) (seriousness criteria hospitalization and medically significant). On 30-Mar-2021, ABDOMINAL PAIN (Abdominal pain-right side) had resolved. At the time of the report, PULMONARY EMBOLISM (Blood Clots noted all over lungs) and PAIN (Abdominal pain radiating from right side to left side then to collar bone) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-May-2021, Computerised tomogram: Blood clot noted on lungs (all over). The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Patient was given IV and oral blood thinner medication as a treatment. Company comment: Very limited information regarding this event has been provided at this time. It is not clear if abdominal pain was gallbladder pain and surgery was prior to onset of pulmonary embolism. Details of the events and discharge summary is required for further evaluation.; Sender's Comments: Very limited information regarding this event has been provided at this time. It is not clear if abdominal pain was gallbladder pain and surgery was prior to onset of pulmonary embolism. Details of the events and discharge summary is required for further evaluation.</p>



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1357122	5/28/2021	PA	70	F	3/25/2021	4/25/2021	<p>Blood clot in lung diagnosed, worry related to blood thinner use; Chest pains; Chest "didn't feel right"; Blood pressure increased; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY THROMBOSIS (Blood clot in lung diagnosed, worry related to blood thinner use), CHEST PAIN (Chest pains) and CHEST DISCOMFORT (Chest "didn't feel right") in a 70-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 021B21A and 047A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 in November 2020. Concurrent medical conditions included Cholesterol blood excessive, Hypertension and Hyperlipidemia. Concomitant products included APIXABAN (ELIQUIS), CELECOXIB (CELEBREX), METOPROLOL SUCCINATE and LOSARTAN POTASSIUM for an unknown indication. On 25-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 25-Apr-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced CHEST DISCOMFORT (Chest "didn't feel right") (seriousness criterion hospitalization). On 28-Apr-2021, the patient experienced PULMONARY THROMBOSIS (Blood clot in lung diagnosed, worry related to blood thinner use) (seriousness criteria hospitalization, medically significant and life threatening), CHEST PAIN (Chest pains) (seriousness criterion hospitalization) and HYPERTENSION (Blood pressure increased). The patient was hospitalized on 28-Apr-2021 due to CHEST PAIN and PULMONARY THROMBOSIS. At the time of the report, PULMONARY THROMBOSIS (Blood clot in lung diagnosed, worry related to blood thinner use), CHEST PAIN (Chest pains), CHEST DISCOMFORT (Chest "didn't feel right") and HYPERTENSION (Blood pressure increased) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-Apr-2021, Blood pressure measurement: increased (High) Increased. Concomitant medication included high cholesterol drug.</p>

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On 28 Apr 2021, post second dose of vaccination patient experienced chest pains and went to emergency room. Patient reports a chest scan, chest X-ray, bloodwork, EKG, echocardiogram, and various tests were performed at the hospital. Patient was diagnosed with a blood clot in lungs. Patient reports being hospitalized several days and doctors indicated "she dodged a bullet". Patient reports the treating physicians could not determine the cause of the clot, nor determine if it was vaccine related. Patient reports concomitant medication, losartan dose was recently increased from 50mg to 100mg once daily. Patient attributes that the increased blood pressure was the worry related to being placed on blood thinners [Eliquis]. Treatment information included eliquis. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to MOD-2021-138094 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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1357135	5/28/2021	FL	70	M	3/1/2021		<p>Massive stroke; Still trying to get back his mobility; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of CEREBROVASCULAR ACCIDENT (Massive stroke) in a 70-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. In March 2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced CEREBROVASCULAR ACCIDENT (Massive stroke) (seriousness criteria hospitalization, medically significant and life threatening) and MOBILITY DECREASED (Still trying to get back his mobility). At the time of the report, CEREBROVASCULAR ACCIDENT (Massive stroke) and MOBILITY DECREASED (Still trying to get back his mobility) outcome was unknown. Patient had a massive stroke a few weeks after receiving the second shot and was hospitalized. He was still trying to get back his mobility. Patient has had complications with any past surgery, commonly occurring as blood clots in his lungs. Concomitant product use was not provided by the reporter. No treatment information was provided. Very limited information regarding this event has been provided at this time. However subject's history of blood clots in his lungs can be a confounding factor. No further information is expected at this time. This case was linked to US-MODERNATX, INC.-MOD-2021-142295 (E2B Linked Report).; Sender's Comments: Very limited information regarding this event has been provided at this time. However subject's history of blood clots in his lungs can be a confounding factor. No further information is expected at this time. US-MODERNATX, INC.-MOD-2021-142295:crosslinked; niece</p>

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1357190	5/28/2021	IA	64	F	4/6/2021	4/1/2021	Feet are hurting so bad; Chills; Right Ankle is starting to itch on red areas; Left Ankle Swelling; Cramps; Diarrhea; Weakness / she still has no energy whatsoever; Tired; Headache; Chest pain; Swelled Legs / Right Ankle red and swollen; This is a spontaneous report received from a contactable consumer (patient). A 64-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Lot number: EP7533), via an unspecified route of administration in upper left arm on 06Apr2021 as 2nd dose single for COVID-19 immunization. Patient previously received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Lot number: EN6208), via an unspecified route of administration on 13 Mar2021 as 1st dose, single for COVID-19 immunization. Medical history included ongoing fluttering in heart. Concomitant medications were not reported. 07Apr2021, patient experienced, headache. In APR-2021, patient experienced swelled legs. On 07-MAY-2021, patient experienced chills. In May2021, patient experienced, right ankle was starting to itch on red areas. On an unspecified date, patient experienced feet are hurting so bad. Stated she didn't call to report sooner because where she got her vaccine at facility they did not give her any information with Pfizer's number on it. Her husband went and got his vaccine at pharmacy and they gave him the paper with the number on it. Stated her right ankle was really red and swelling (In Apr2021). Says that on 06Apr2021 after her shot, she waited the 15 minutes at the facility and was fine. Stated that around midnight (07Apr2021) she had cramps, diarrhea, weakness, she was tired. A few days later her right ankle began to swell and keeps getting worse. Says now her left ankle is starting to swell. States she also has experienced some chest pain (in Apr2021) and has an appointment the a heart specialist today, 12May2021. Patient stated she reported her symptoms to the Centers for Disease Control and Prevention (CDC). Says it did not seem like they would do anything with her report. Patient stated that she still had no energy whatsoever. She had to really make herself do things that she would normally do. Stated that the diarrhea and cramps that started midnight 07Apr2021 lasted for half that day and then they were gone Patient denies any medications, medical conditions, labs, testing, or treatments relevant to events. Patient

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stated that her husband had Covid 19 on 07Feb2021. He was in Hospital and they gave him antibodies for a day and a half. She states on 08Feb2021 herself and her son got tested for Covid 19 and it was negative. Says they went back on 13Feb 021 to get tested again and it was negative. Patient stated that they wondered if it was false negative tests. Stated that maybe her and her son had Covid 19 and that's why they are having side effects after the vaccine. she had been to the Emergency Room three times to check for blood clots. States her right leg was really red and really bad. She had been to her family doctor and is going to a Neurologist on 27May2021. The outcome of the events cramps, diarrhea was recovered. Outcome of the events feet are hurting so bad, chest pain was unknown and outcome of the other events was not recovered. No follow-up attempts are needed. No further information is expected. Follow-up (26May2021): Follow-up attempts completed. No further information expected.

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1357191	5/28/2021	FL	61	F	2/3/2021	2/3/2021	<p>Tinnitus; hearing loss; Gout; Dry heaves; extreme abdominal cramping; Chills/Fever; Chills/Fever; Body Aches; Slept most of the day; Extreme sore arm; Quarter size hard lump X3weeks;; This is a spontaneous report from a contactable consumer (patient). A non-pregnant 61-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), dose 1 via an unspecified route of administration, administered in the left arm, at age 61 years, on 03Feb2021 (Batch/Lot Number: EL9269) as 1st DOSE, SINGLE for COVID-19 immunisation. Relevant medical history includes hypertension, asthma, glaucoma and cataracts, and blood clot from unspecified dates. Prior to vaccination, the patient was diagnosed with COVID-19 on unspecified date. Concomitant medications included chlorthalidone; apixaban (ELIQUIS); losartan; and verapamil, all taken for an unspecified indication, start and stop date were not reported, received within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient previously received ciprofloxacin (CIPRO) and vancomycin on unspecified dates and experienced known allergies. On 03Feb2021 14:00, the 1st day, patient experienced extreme sore arm; quarter size hard lump X3weeks. On 04Feb2021 14:00, second day, patient experienced chills, fever, body aches, slept most of the day. On 05Feb2021 14:00, third day, patient experienced dry heaves for 2 hours followed by extreme abdominal cramping that required the patient to lay flat for the whole day. On 06Feb2021 14:00, fourth day, patient woke up to gout in his right big toe that lasted for a week. On 08Feb2021 14:00, sixth day, patient had tinnitus in both ears and hearing loss. ENT doctor prescribed oral steroids w/ taper and when that didn't work. Patient went through 4 torturous treatments where ear drum was initially punctured and shot of steroids was inserted through the hole. That didn't work either and around the time of reporting, patient was told that she have permanent hearing loss and the tinnitus has not gone away. She is now looking at needing hearing aids and will not be subjecting herself to the second dose. Hospitalization prolonged was not involved. The adverse event resulted in doctor or other healthcare professional office/clinic visit. Since the vaccination, the patient has not been tested for COVID-19. Facility where the most recent COVID-19 vaccine was administered</p>

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1357202	5/28/2021	CA	38	F	3/19/2021	3/19/2021	<p>was at a doctor's office/urgent care. The outcome of the events was not recovered.</p> <p>BARD Power Port clogged with blood clot; cellulitis; Severe headache; abdominal pain; arm pain; chest pain; dose 1 administered in Leg Left; dose 1 and dose 2 on the same day; dose 1 and dose 2 on the same day; This is a spontaneous report receive from a contactable consumer (patient). A 38 years old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration as single dose, dose 1 administered in Leg Left on 19Mar2021 14:45 (Batch/Lot Number: EP7534), and dose 2 administered in Arm Right on 19Mar2021 (Batch/Lot Number: ER8729) for covid-19 immunisation. Medical history included myasthenia gravis, natural killer cell deficiency, gastroparesis, connective tissue disease, postural orthostatic tachycardia syndrome (POTS), known allergies: Gluten, dairy, xanthan gum, antibiotics, beta blockers, pain medication, latex. No other vaccine received in four weeks. It was unknown if the patient diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient had not been tested for COVID-19. Concomitant medication(s) included escitalopram oxalate (LEXAPRO); montelukast sodium (SINGULAIR); diphenhydramine hydrochloride (BENADRYL); sumatriptan succinate (IMITREX); promethazine (PHENERGAN), all taken for an unspecified indication, start and stop date were not reported. The patient experienced Severe headache 1.5 days, abdominal pain 3 days, arm pain and chest pain 7 days, BARD Power Port clogged with blood clot and subsequent cellulitis from many attempt to flush the clot (22Apr2021 04:00 PM). The adverse event result in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Treatment received for the adverse event: Home nursing visits and admitted to Emergency Room (ER). Outcome of the events was recovering/resolving.</p>

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1357207	5/28/2021			F		5/4/2021	<p>clot in one of the vessels in her brain; severe headaches; Facial pain; This is a spontaneous report from a contactable consumer reporting on behalf of the patient. A female patient (reporter's sister) of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04May2021 (Batch/Lot number was not reported) as 2nd dose, single for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient also received first dose of BNT162B2 on unspecified date (unknown lot number and expiration) for COVID -19 immunization. It was reported that the patient received the second shot of COVID vaccine on 4th of this month (04May2021) and developed severe headaches, facial pain, and other symptoms about a couple of years later. The severity of her headache is so much that they had to get her admitted where medical tests were done in the emergency. CT scan, MRI, ECG, and chest x-rays with unknown results. Everything was done and the doctor is suspecting a clot in one of the vessels in her brain. The reporter further stated, "Can you just guide me about how do I go about it?". The events resulted in emergency room visit. Outcome of the events was unknown. Information on the lot/batch number has been requested.</p>



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1357297	5/28/2021	NJ	48	F	3/17/2021	5/6/2021	5/9/21 diagnosed with thrombus of proximal portal vein and in the splenic vein; 5/9/21 diagnosed with thrombus of proximal portal vein and in the splenic vein; Anemia diagnosed on 5/9/21; This is a spontaneous report from a contactable consumer (the patient). A 48-year-old non-pregnant female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EN6204) via an unspecified route of administration in left arm on 17Mar2021 at age of 48-year-old at single dose for COVID-19 immunisation. Medical history included known allergies: Azythromicine. Concomitant medication (within 2 weeks of vaccination) included ibuprofen (ADVIL 12 HOUR) taken for an unspecified indication from an unspecified date. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EN6202) via an unspecified route of administration in left arm on 24Feb2021 at age of 48-year-old for COVID-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. Nasal swab was negative on 09May2021. On 09May2021, the patient was diagnosed with thrombus of proximal portal vein and in the splenic vein. No prior history of blood disorder or blood clots (the events onset date reported as "06May2021", pending clarification). The events were serious with seriousness criteria of "hospitalized". The events resulted in emergency room/department or urgent care. Treatment received for the events included Heparin. It also reported anemia diagnosed on 09May2021. The outcome of the events was not recovered.

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1357215	5/28/2021	CA	55	F	4/29/2021	5/2/2021	Blood clot in leg and one in each lung. Admitted to hospital on 02May2021; Blood clot in leg and one in each lung. Admitted to hospital on 02May2021; This is a spontaneous report received from a contactable consumer. A 55-year-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 2 via an unspecified route of administration on 29Apr2021 08:30 (at 55 years old, not pregnant) (Batch/Lot number was not reported) as 2ND DOSE, SINGLE for covid-19 immunisation. The patient's medical history was not reported. No concomitant medications. On 02May2021 08:30 patient experienced Blood clot in leg and one in each lung. Admitted to hospital on 02May2021.No other vaccine in four weeks. No other medications in two weeks. Treatment for event was Blood thinners. No covid prior vaccination. Not covid tested post vaccination. The outcome of the events was not recovered. Events resulted in visit to emergency room and physician office. Device Date: 12May2021. Information on the Lot/Batch number has been requested.

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1357288	5/28/2021	CA	51	M	4/1/2021	4/16/2021	had a superficial blood clot in my left calf between the first and second vaccines; This is a spontaneous report from a contactable consumer (Patient). A 51-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 01Apr2021 16:00 (Batch/Lot Number: ER8733) at the age of 51-years-old as SINGLE DOSE for covid-19 immunization. The patient medical history was not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medication was none, patient did not received other medications within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient had a superficial blood clot in his left calf between the first and second vaccines on 16Apr2021. Event resulted in Doctor or other healthcare professional office/clinic visit. Treatment received for the event included had a shot of enoxaparin sodium (LOVENOX) and am taking rivaroxaban (XARELTO). The patient underwent lab tests and procedures which included blood test: negative on 06May2021, Nasal swab covid-19 test: negative on 27Apr2021. The outcome of the event was not recovered.

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1357242	5/28/2021	CA	61	M	4/21/2021	4/28/2021	swollen and red leg; swollen and red leg; blood clot in right leg; Pain in right leg; her husband cannot walk, he is limping; her husband cannot walk, he is limping; This is a spontaneous report from contactable consumers (patient and wife). A 61-year-old male patient received bnt162b2 (BNT162B2 reported as PFIZER COVID-19 VACCINE), dose 2 at vaccination age of 61-year-old via an unspecified route of administration on 21Apr2021 13:00 (Lot Number: ER3732; Expiration Date: 30Nov2022) as 2nd dose, single for covid-19 immunisation. Medical history included ongoing high cholesterol and ongoing prostate [having to go to the bathroom frequently] (prostatic disorder). The patient received the first dose of bnt162b2 (BNT162B2 reported as PFIZER COVID-19 VACCINE) at vaccination age of 61-year-old on 26Mar2021 3:45 pm for covid-19 immunisation. Concomitant medications included (LIPITOR) ongoing since unspecified date (reported as 3 or 4 years ago) for blood cholesterol increased, and tamsulosin on an unspecified therapy dates (reported as he has been taking it for years now) for prostate/having to go to the bathroom frequently (prostatic disorder). The patient did not receive other vaccine in the last four weeks prior to vaccination. The patient received the vaccine from a pharmacy. The patient reported that one week after getting the second vaccine, he had pain in his right leg (28Apr2021). He stated that he did know what was going on, but he continued to work. He added that last Monday (10May2021) it got worse, so he contacted his primary care doctor and he went today (12May2021) because his leg was swollen, red and he had pain. His doctor sent him to the ER (emergency room). The patient mentioned that the ER did a CAT scan on 12May2021 and found that he had a blood clot in his right leg (reported as 10May2021). The patient's wife comes on the line and stated the reason her husband called to report was because it could be from the vaccine, but they are not sure. The wife added that her husband went to the pharmacy to pick up the blood thinner and they told him to report this. She also stated that all the side effects could happen, but he did know the side effects and he just wanted to report because the pharmacy told him to report. She mentioned that her husband started complaining his leg hurt because he has to do yard work. She states that it got worse and worse and she saw his

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1357246	5/28/2021			F	4/1/2021	5/4/2021	leg get swollen and she was like you need to go to the doctor. The wife mentioned that the leg is more swollen and painful, but is the same, her husband cannot walk, he is limping on an unspecified date in 2021. She stated that her husband has just started taking medication, yesterday and today. The outcome of the event thrombosis leg was not recovered while the outcome of the other events was unknown.
							large blood clots during menstruation; irregular menstrual cycle; This is a spontaneous report from a contactable consumer (patient). A 34-year-old female patient received BNT162B2 (Lot Number: er8731), via an unspecified route of administration in Apr2021 as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient experienced irregular menstrual cycle and large blood clots during menstruation, both on 04May2021. The events resulted in Doctor or other healthcare professional office/clinic visit. The outcome of the events was recovering.

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1357247	5/28/2021	WI	68	F	2/4/2021	5/1/2021	Stroke/in her head on her left side; Blockage in her head, there was a blood clot in her head; Arm doesn't work; All she could say was I cant/still needs speech therapy; Really bad headaches; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer (patient) reported that a 68-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EL9269; Expiration date was not reported) on the left arm on 04Feb2021 (13:21) as a 2nd dose, single dose, with route of administration unspecified, for COVID-19 immunization at the public health department (not a military facility). The patient had a family history of five heart bypass surgeries (father); stroke (father); and stents (mother). There were no concomitant medications. The patient had previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EL3249; Expiration date was not reported) on 14Jan2021 (when the patient was 68 years old) for COVID-19 immunization, and had hypersensitivity, rash and cerebrovascular accident. On 07May2021, the patient had a stroke (in her head on the left side). The patient was hospitalized from 07May2021 to 10May2021 due to the stroke. In May2021, the patient had a blockage in her head/there was a blood clot in her head; her arm did not work; all she could say was "I can't", and still needed speech therapy; and had really bad headaches. The events had resulted into an emergency room visit. The patient had received clopidogrel (PLAVIX) as treatment for stroke and blockage in her head/there was a blood clot in her head; and duloxetine ACL as treatment for the really bad headaches. The outcome of the events was recovering for 'stroke' and 'all she could say was "I can't", and still needed speech therapy'; was not recovered for 'really bad headaches'; and was unknown for all the other events. Information on lot/batch number was available. Additional information has been requested.

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1357264	5/28/2021		25	F	5/12/2021	5/12/2021	Red blood clot in left eye; Sore arm; This is a spontaneous report from a contactable consumer (patient). A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE Solution for injection), via an unspecified route of administration, administered in the left arm, on 12May2021 (lot number: EW0182; expiration date: 31Aug2021), as 1st dose, single dose, at age 25 years old, for COVID-19 immunisation. The patient medical history was not reported. Concomitant medication included levothyroxine taken for an unspecified indication, start and stop dates were not reported. On 12May2021, the patient had sore arm. On 13May2021, when the patient woke up, she had a red blood clot in her left eye. Treatment for sore arm included Tylenol. The outcome of the events was unknown. Follow-up attempts are needed. Further information is expected.

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1357265	5/28/2021	TX		U	5/1/2021		<p>I have a blood clot in hurry I have blood clots regularly; Blood is way too thick so he give triple dose; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received bnt162b2 (BNT162B2), via an unspecified route of administration on 01May2021 (batch/lot number and expiration date not reported) as UNKNOWN, SINGLE for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient stated, "I received COVID 19 vaccination on 01May2021 at my Doctor's Office and yesterday (12May2021), I went to see my Oncologist. I am on blood thinners, its Coumadin. I get Warfarin which is you know (incomplete sentence, thus, not clarified and was not captured). Anyway, I take Coumadin, my blood is way too thick, so he gave triple dose and I went back today, and it is still bad, and I am taking another triple dose tonight and going back. What are the safety issues in getting Coumadin and getting that vaccination?" When probed for follow up, consumer stated, "Yes, it be great if they did. I need to find something we need to correct because I have a blood clot in hurry. I have blood clots regularly if I do not keep my blood thin." Patient stated, "Have you heard other people reporting this problem or was it the concern in the beginning or what can be done in other words?" Outcome of the events was unknown. Information on the lot/batch number has been requested.</p>



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1357267	5/28/2021	MA	68	F	1/25/2021		portal vein thrombosis; This is a spontaneous report received from a contactable physician. A 68-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 25Jan2021 (Batch/Lot number was not reported) as unknown single for covid-19 immunisation. Medical history included on hormone replacement therapy (HRT). No known allergies. The patient's concomitant medications were not reported. The patient experienced portal vein thrombosis (seriousness criteria: medically significant) on an unspecified date. The adverse event resulted in doctor or other healthcare professional office/clinic visit. AE treatment including lovenox. No covid prior vaccination. Unknown if covid tested post vaccination. The event outcome was unknown. Information about lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 vaccine can not be excluded for the reported event of portal vein thrombosis due to temporal relationship. Case will be re-assessed upon the additional information provided. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
1358060	5/28/2021	AZ	49	F	4/2/2021	5/24/2021	Patient does not report pain. I am her sister and Legal Guardian and I believe she had symptoms prior to 5/24/21. On 5/24/21, she did not report feeling sick or having a headache and threw up around 11 am. Throwing up was the only way I knew to ask her how she was feeling. She said, I think I threw up because my head hurt. I asked her where it hurt and she said, in the back. I took her to the ED and she had a brain bleed and 5 blood clots in the major veins and sinuses of the left hemisphere of her brain. Her medical team said this is a very rare part of the brain to have blood clots. I would like further investigation into whether this was related to the vaccine.

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1357209	5/28/2021	GA	32	F	4/28/2021	4/29/2021	<p>some chest pain and gas starting on the 10th day; some chest pain and gas starting on the 10th day; got sharp abdominal pain during ovulation on the right side on 11th day after vaccine as well as bleeding during ovulation time on 13th day.; got sharp abdominal pain during ovulation on the right side on 11th day after vaccine as well as bleeding during ovulation time on 13th day.; dizziness; Fever of 102.3; chills; headache; bodyache; weakness; arm pain and swollenness near injection site for 2-3 days.; arm pain and swollenness near injection site for 2-3 days.; A little lymph node swelling in armpits; This is a spontaneous report received from a contactable consumer (patient). A 32-year-old female patient received BNT162B2, via an unspecified route of administration, administered in the left arm on 28Apr2021 17:15 (Batch/Lot number and expiry date were not reported) at 32 years-old as 2nd dose, single for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. No known allergies. The patient previously received BNT162B2, via an unspecified route of administration, administered in the left arm on 07Apr2021 17:45 (Batch/Lot number and expiry date were not reported) at 32 years-old as 1st dose, single for COVID-19 immunisation and experienced local pain and little bit of dizziness right after the vaccine. On 29Apr2021 02:45, the patient experienced got sharp abdominal pain during ovulation on the right side on 11th day after vaccine as well as bleeding during ovulation time on 13th day, dizziness, fever of 102.3, chills, headache, bodyache, weakness, arm pain and swollenness near injection site for 2-3 days, arm pain and swollenness near injection site for 2-3 days, a little lymph node swelling in armpits. In May2021, the patient experienced some chest pain and gas starting on the 10th day. The clinical course was reported as follows: Second dose - dizziness after vaccine, Fever of 102.3, chills, headache, body ache in the middle of the night after vaccine. Fever subsided after next day, headache and weakness persisted. Arm pain and swollenness near injection site for 2-3 days. A little lymph node swelling in armpits for next 5-6 days. Got ok after this. But again, some chest pain and gas starting on the 10th day, perhaps due to ovulation time. However, a striking note is that after almost 2 years got sharp abdominal pain during ovulation on the right side</p>

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							on 11th day after vaccine as well as bleeding during ovulation time on 13th day. Chest pain still lingering. Concerned that it is not a blood clot issue. Or that the vaccine is interfering with the hormonal system. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within four weeks prior to the vaccination and did not received any other medications within 2 weeks of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events weakness, headache and chest pain was not recovered; Fever of 102.3 was recovering. The outcome of the other events was unknown. The following information on the lot/batch number has been requested.
1359309	5/28/2021	CO	47	F	5/8/2021	5/12/2021	left eye stroke (blood clot), Central Retinal Vein Occlusion, no treatment, vision foggy
1358512	5/28/2021	CA	68	M	2/25/2021	2/25/2021	After 4-5 hours of the 2nd dose of Moderna I start to get pain in the arms and legs, feel weir at night time like light headache, dizziness and uncomfortable in breathing that wake me up at the middle of the night. Blood pressure elevated higher than normal. After a week the arm's pain getting better, but the legs' pain gets worse. Since then my legs pain and join pain getting worse and worse, its hurts with activities and no pain at rest while seat or lay down. I've been through many doctors visits including the Urgent Care, ER, Neurology and rheumatology doctors and had many kinds of testing and found nothing wrong with my heart, lung, blood clots in the legs, Both of my legs are just progressively getting worse, both legs are getting more pain and weaker, that make me hard to lift them up for walking. I almost can't work now. I also feel so tired, dizzy and headache for 2-3 days each time that come and go since the 2nd dose of the vaccine. I'll have the MRI tests on 06/05/2021 and 06/06/2021.
1358042	5/28/2021	NC	47	F	4/24/2021	4/27/2021	I got my vaccine while being on my minstrel cycle. My period lasted for 4 weeks and it was very heavy. I experienced blood clots the size of a silver dollar. I had serve headaches.

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1359513	5/28/2021	MI	51	F	5/7/2021	5/7/2021	Patient stated that shortly after getting the Pfizer vaccine she started having unexpected menstrual bleeding which continued for 7 days. She also had abdominal cramping that was 100X worse than her previous menstrual cramps. The cramps went on for 3 days. She discharged clots while bleeding and she also states that she had really bad "medical smelling" gas for about 2 weeks. She did have diarrhea and lasted for about 2 weeks as well.
1359313	5/28/2021	NJ	66	M	1/14/2021	1/25/2021	My husband had a stroke on 01/25/2021, with one large blood clot and many small blood clots. He was put on a ventilator until 02/06/2021 when I asked to have it removed. I died within 5 minutes after it being removed.
1358789	5/28/2021	OH	26	F	4/8/2021	4/9/2021	I woke up at three AM feeling like I had a fever. I had body aches. The next morning when I woke up I felt like I had a tourniquet on my arms and legs. I was also short of breath. I went to the ER and they checked for blood clots. I started to get lower extremity cramps and muscle spasms. Two days after I started to have some shortness of breath and I was out of breath if I walked any length. One week after the vaccine I ended up with an ear infection in my right ear. The muscle spasms continued especially in my right lower legs with twitching which lasted for five weeks. Two weeks after the shot my Asthma, which is normally controlled, got very severe. My inhalers didn't seem to work. Three weeks after the vaccine my Asthma got worse and I was having trouble breathing. I went to the ER again and there were more tests done. I was prescribed Prednisone, and I took one week off work. After multiple treatments I was prescribed antibiotics and switched my inhaler which helped. I have been trying to do some Cardio activity this week and I feel better after six weeks. I don't have to use my Nebulizer as much as I had been.
1358766	5/28/2021	MD	27	M	3/26/2021	5/21/2021	Stroke - Blood Clot in M2 Brain Artery Friday, May 21, 2021 - Air lifted from Hospital to Hospital Admitted to Neuroradiology Dept and immediate Thrombectomy to remove blood clot behind left eye via angiogram through the groin via catheter. Procedure was successful in removing 100% blocked artery and he was transferred to Recovery, observation and follow-on diagnostic testing in ICU for 4 days. Discharged May 24, 2021

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1358748	5/28/2021	CA	39	M	4/9/2021	4/19/2021	April 19 felt like a charlie horse in my leg, I went to the ER on 05/03/2021 and was advised that I had blood clots in my left leg. They did not check my right leg but I also didn't have any pain in that leg. About 2 or 3 years ago I was subject to blood clots because I traveled alot but when I experienced this I was not traveling or anything just staying home
1358720	5/28/2021	CO	37	F	4/9/2021	4/24/2021	Started developing headaches 2 weeks after first dose. On 4/27 patient suffered major stroke as a result of venous sinus clot. ICU for 10 days. Now being treated outpatient w/hematology, speech therapy, neurology. No medical history prior to this event. Hematologist requested this be filed as an adverse event to vaccine at her appointment today.
1358680	5/28/2021	TX	77	M			Blood clots in leg and lung
1358651	5/28/2021	ME	57	M	4/6/2021	4/14/2021	developed dvt/blood clot after first dose. bell's palsy after second dose.
1358538	5/28/2021	NJ	54	M	5/8/2021	5/21/2021	Stroke-like symptoms of headache and left-sided facial droop/paralysis began around 3:30pm on 5/21/2021. Went to Emergency Room. CT scan ruled out blood clot and stroke. Diagnosed with Bells Palsy. 15 day course of treatment of Prednisone is currently underway, starting with 60 mg on days 1-5, followed by 50mg day 6-7, 40 mg day 8-9, 30 mg day 10-11, 20 mg day 13-14, and 10 mg day 14-15. (As of today, 5/28/2021, I am on 50mg day 7). Paralysis has not yet subsided.

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1353019	5/27/2021	NJ	80	F		3/26/2021	LEG CRAMPS; HARD TO WALK; ACHY HIPS; ACHY LEGS; This spontaneous report received from a patient concerned an 81 year old female. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine (suspension for injection, route of admin not reported, batch number: 1805031, expiry: 26-MAY-2021) dose was not reported, administered on 19-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 26-MAR-2021, the subject experienced leg cramps. On 26-MAR-2021, the subject experienced hard to walk. On 26-MAR-2021, the subject experienced achy hips. On 26-MAR-2021, the subject experienced achy legs. Laboratory data (dates unspecified) included: Scan (NR: not provided) No blood clots, and X-ray (NR: not provided) No blood clots. The action taken with covid-19 vaccine was not applicable. The patient was recovering from hard to walk, and had not recovered from achy legs, achy hips, and leg cramps. This report was non-serious.
1354760	5/27/2021	MD	49	F	4/12/2021	4/12/2021	It was really bizarre, I remember feeling like all my senses were heightened , I got my period, it didn't stop for 3 weeks. Called my OBGYN, they said let it run it's coarse and they had they had many similar phone calls. I take a Nuva ring for birth control, I was concerned about estrogen and the blood clots. I did not feel well at all for about a week after my vaccine, everyday around 4pm I would get really bad headaches for about 3-4 weeks. I was nauseated and sweating.

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1354626	5/27/2021	ME	44	F	4/27/2021	4/27/2021	with this 1st of 2 shots I began getting a headache that began within 1 hour after the shot. The headache immediately became intense and stayed. Advil did not do anything for it. That same evening I began having intense abdominal pain on my right side, it became so bad I was scared my appendix was going to burst. I had my son on standby to take me to the hospital. It was so severe I could not stand. The only way that I can describe the pain would be: after natural birth and you begin nursing, the insanely intense contractions of the uterus to shed the afterbirth is how intense the pain was. I then started my menstrual cycle but was not supposed to for another week and 1/2. The pain stayed, but did dull some, it wasn't as sharp but still intense. My flow was extraordinarily heavy and I lost count of how many huge blood clots I passed. Some clots were the size of my palm. This cycle lasted a full 7 days. My normal cycle starts with a little spotting, then 1 or 2 days of medium flow, then a couple days of spotting. I also do not have my cycle every 30 days, more like 38-40. I figure its pre-menopause.

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1353015	5/27/2021	MI		U			<p>BLOOD CLOTS; This spontaneous report received from a consumer via other company (Pfizer, report number: 2021503212) concerned multiple patients of unspecified age and sex. Patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The batch number was not reported. Per procedure, no follow up will be requested for this case. No concomitant medications were reported. On an unspecified date, reporter stated that patients experienced blood clots that scared people all the way around (no further information provided or obtained). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clots was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 : 20210547337 - COVID-19 VACCINE AD26.COV2.S-Blood clots. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>



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1352988	5/27/2021	AR	61	F	4/7/2021		<p>VERTIGO; RUNNY NOSE; FEELING SICK; This spontaneous report received from a patient concerned a 61 year old not Hispanic or Latino, African American female. The patient's height, and weight were not reported. The patient's concurrent conditions included blood pressure, cholesterol, depression, and non smoker, and the patient had no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805025, expiry: unknown) frequency 1 total, dose was not reported, administered on 31-MAR-2021 to right arm for prophylactic vaccination. Concomitant medications included blood pressure pill, cholesterol pill and anti-depressant. One week after vaccination, on 07-APR-2021, the patient was feeling sick and dizzy. She said that the ambulance picked her up that day she felt really dizzy and took her to the hospital. There they performed tests on her and kept her overnight. Doctor of Medicine (MD) diagnosed her with vertigo and told her to take some over the counter medications for it. She reported that her runny nose and sick feeling went away after about a day. One to two weeks after that emergency room (ER) visit, she again went to the ER. This occurred at around 1-2:30 AM she went to the ER and MD said she had vertigo but she just stayed until the morning. MD prescribed her medicine for the vertigo, but the vertigo had not gone away. The MD there, did tests for blood clots but did not find anything but told her to take Aspirin (acetylsalicylic acid). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from runny nose, and feeling sick on 08-APR-2021, and had not recovered from vertigo. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0:20210544583-covid-19 vaccine ad26.cov2-Vertigo, Runny nose. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). V0:20210544583-covid-19 vaccine ad26.cov2-Feeling sick. This event(s) is labeled per RSI and is therefore considered potentially related.</p>

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1352781	5/27/2021	AZ	20	F	4/27/2021	5/23/2021	Headache onset 3-4 days after vaccine on 4/27/21. Subsequently developed visual changes (right homonymous hemianopsia/visual field cut) on 5/23/21 and presented to ED, diagnosed with cerebral venous thrombosis (left transverse, sigmoid and internal jugular thrombosis). On initial labs also had thrombocytopenia and mild leukocytosis.
1354522	5/27/2021	CT	38	F	5/17/2021	5/20/2021	Patient is a 30-year-old previously healthy Mediterranean woman complaining substernal squeezing chest pain for 2 days in the setting of 2nd Pfizer COVID vaccine 2 days ago. The chest pain is pleuritic but otherwise has no exacerbating or relieving factors. It does not radiate. She has never had this pain before. The patient is worried about myocarditis or blood clot as she has heard the can be reactions from the vaccine. The pain is associated with shortness of breath. She denies vomiting, diarrhea. She has had some fever, chills and myalgias over the past few days. She denies cough. She denies history of VTE, hemoptysis, history of immobilization or trauma, estrogen birth control. She denies family history of early cardiac death or MI. 38y/o woman with no significant past medical history who had her second Pfizer vaccine on Monday and later that day developed low grade fever/ diffuse myalgias/ pleuritic and positional central dull 5/10 chest pain. On Tuesday and Wednesday she remained bedridden with same sx. Thursday morning felt improved except had persistent chest pain for which she presented to the ED for evaluation. She had tachycardia, +troponins, and +DDimer. EKG was negative for acute changes. She was admitted to the cardiology service for suspected myocarditis. She was started on colchicine, standing ibuprofen, and metoprolol. Echocardiogram complete on 5/21 was normal with an EF of 60%. She was evaluated again after her echo. She continued to feel significantly improved on medical therapy and was discharged home on 05/21/21. She will continue medical therapy as listed. She will follow-up with as arranged on 5/25/21.

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1354599	5/27/2021	AL	65	M	4/12/2021	4/17/2021	About a week after the shot, I started getting redness, tenderness, discoloration, and swelling of my right arm. The discoloration began to spread and I went to the doctor on the 21st. The doctor said there was inflammation and because it was warm to the touch, was concerned about blood clots. I was sent for an ultrasound and prescribed an anti-inflammatory medication and advised to take aspirin. Everything cleared up about a week later.
1353017	5/27/2021	TX		F			BLOOD CLOTS; HEADACHE; This spontaneous report received from a consumer who reported by seeing a news report concerned a 14 female of unspecified age. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patients received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) 1 total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. It was reported that, on an unspecified date, 14 patients had blood clots, and headaches The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the headache and blood clots was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210540327.; Sender's Comments: V0:20210547453-covid-19 vaccine ad26.cov2.s-This case concerns to 14 female of unspecified age. Blood clots. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1354634	5/27/2021	NY	32	M	3/31/2021	5/7/2021	33 year old healthy man presented with seizure to Hospital ER on 5/7/2021. He required intubation. CT scan and MRI of brain showed dural venous sinus thrombosis along the anterior to mid aspects of the sagittal sinus. CBC was normal at presentation with WBC 13.9, HGB 16.1 and PLT 367k. He was admitted on unfractionated heparin. Repeat platelet count on 5/8/2021 was 153k. HIPA was negative. Patient was extubated and continued to improve. He was put on warfarin and sent home. He has some mild personality change in the immediate weeks of discharge. Hypercoagulable workup had normal Prot S & C activity, normal ATIII activity. The Factor V Leiden and Prothrombin Gene were negative. The homocysteine level was elevated at 16.3.
1354669	5/27/2021	ID	42	F	5/16/2021	5/17/2021	Low grade fever for 5 days. Extreme nausea for 24 hours. Diarrhea for 72 hours. 24 hours after the injection the lymph node under my left arm swelled up to about the size of a baseball, it was extremely hot and painful. It stayed that size for 4 days, and then finally started getting a little smaller each day. It's officially been 10 days and I would say that lymph node is about golf ball sized now. I did see my doctor and she said it can be a normal side effect and as long as it's going down not to worry. I also was having pain in my back and the doctor suspected a possible pe, my d-dimer test came back positive twice but my platelets remained in the normal range. The second d-dimer was only 513 and considered barely out of range so we assume whatever clot I had dissolved on its own.
1354724	5/27/2021	MI	77	M	5/9/2021	5/14/2021	bi-lateral leg pain within 1 week of shot. then severe back pain after 2 weeks. difficulty breathing week 3. Admitted to hospital for multiple blood clots in legs & lungs.
1354733	5/27/2021	FL	53	M	3/15/2021	5/17/2021	on 5/17/2021 pt developed a fever, pain in the left side of his ribs and had SOB. He was brought to Hospital ER. Pt had Chest x-ray, blood work, Doppler on both legs, and CT. His DX was pneumonia, blood clot in left lung and bilateral blood clot in legs. He was admitted and stayed for 5 days.

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1353068	5/27/2021		32	M	3/22/2021	3/31/2021	Passed out multiple times; Blood clots; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out multiple times) and THROMBOSIS (Blood clots) in a 32-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 047a21a) for COVID-19 vaccination. No Medical History information was reported. On 22-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 31-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out multiple times) (seriousness criterion medically significant) and THROMBOSIS (Blood clots) (seriousness criterion medically significant). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out multiple times) and THROMBOSIS (Blood clots) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided. Patient was taken to hospital where it was discovered that he had blood clots that needed to be removed. Very limited information regarding the events has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding the events has been provided at this time. Further information has been requested.
1354759	5/27/2021	NY	49	F	4/3/2021	4/19/2021	Pulmonary embolism. I experienced shortness of breath and rapid heart rate a few days before my second dose. It worsened and I sought treatment on 4/28/2021. I underwent pulmonary arteriogram with mechanical bilateral thromboaspiration to remove the clots and received blood thinners.

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1353521	5/27/2021	TX	73	M	5/8/2021	5/1/2021	developed right upper extremity DVT; 1st dose, 25Feb2021/ 2nd dose, 08May2021; 1st dose, 25Feb2021/ 2nd dose, 08May2021; This is a spontaneous report from a contactable physician. A 73-year-old male patient received bnt162b2, via an unspecified route of administration on 08May2021 (Batch/Lot number was not reported) as 2nd dose, single for covid-19 immunization. Medical history included Chronic A fib, COPD, CVA with residual weakness, Known allergies: erythromycin. The patient's concomitant medications were not reported. The patient previously received the bnt162b2, at the age of 73-year-old, via an unspecified route of administration on 25Feb2021 (Batch/Lot number was not reported) as 1st dose, single for covid-19 immunization and experienced acute respiratory failure due to COVID like pneumonia, small PE and right lower extremity DVT. Within few days (May2021) she developed right upper extremity DVT despite being on Apixaban and being compliant with it. This event resulted in Emergency room/department or urgent care, Hospitalization (4 days). The patient received the Enoxiparin as treatment for this event. The outcome of the event Deep venous thrombosis arm was recovering. Information on the lot/batch number has been requested.; Sender's Comments: As there is limited information in the case provided, the causal association between the Deep vein thrombosis and the vaccine (BNT162B2 )cannot be excluded. The case will be reassessed once new information is available. "The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.~~
1354801	5/27/2021	TX	50	F	4/1/2021	4/7/2021	About 1 week after vaccination. I had pain in my legs and swelling in my feet, it made it difficult to walk. It was like I was carrying around a dead leg. I did have blood clots in leg. I ended up up being hospitalized 3 days to receive blood transfusions due to anemia after taking blood thinners.

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1354849	5/27/2021	IN	44	F	5/19/2021	5/20/2021	Started with chills, fever, body aches, shortness of breath and headache for about 36 hours. The shortness of breath didn't subside so went in to see the NP at my family doctors office. She had me go get some blood work and chest x-ray. My d-dimer was over 2000 so she sent me to the ER where they did a CT Scan and found blood clots in my lungs. They then admitted me for the night on a heparin drip and then discharged me with Eliquis blood thinners. Meeting with my family doctor next week for more information.
1354875	5/27/2021	NY	73	M	5/11/2021	5/13/2021	Acute limb ischemia- with left internal iliac, common femoral, popliteal artery occlusive thrombosis- underwent emergent Fem-Fem bypass with fasciotomy. Patient subsequently developed respiratory failure with shock and encephalopathy- remains undertreatment.
1354901	5/27/2021	NJ	33	M	4/30/2021	5/10/2021	I woke up the morning after my second dose experiencing the common symptoms related to the vaccine -- persistent headache, body ache, fever, cold shivers, and fatigue. These symptoms lasted for approximately 24 hours, and I continued to have a headache for a total of approximately 48 hours. However, I then developed pain in my left calf approximately 10 days after the second dose and on three consecutive evenings at approximately 9pm I developed an all-body itchy rash (big red raised welts) that would disappear by the time I woke up the next morning. The rash only occurred on these three evenings, but the pain in my calf persisted. I went to see my primary care doctor the following Monday (05/17/21) who gave me a referral for an ultrasound to rule out a DVT, although he said that it was not urgent that I go as I didn't have the other regular symptoms of a DVT (swelling, redness, warm to the touch) and I was too young and healthy to be at risk for one. My doctor said that if the pain didn't subside by the end of the week I should go for the ultrasound. The pain got worse and so I went for an ultrasound on Saturday (05/22/2021). I WAS SUBSEQUENTLY DIAGNOSED WITH A BLOOD CLOT (DVT), and sent to the emergency department.
1354753	5/27/2021	KY	51	F	3/25/2021	3/26/2021	Day after second vaccine blood clots in legs and lungs, mesh inserted, started bleeding vaginally and now in intensive care almost on life support.

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1353773	5/27/2021	NJ	68	M	4/6/2021	5/6/2021	Clot; Stroke; Swelling began in the groin / swelling extending up to my upper thigh / swelling extending to the back; Problem with walking; Got mad and walked out of hospital byhimself; Nauseous; Pins and needles sensation; Felt chilly; Dizzy; Whole body(left side) went numb; This spontaneous case was reported by a consumer and describes the occurrence of SWELLING (Swelling began in the groin / swelling extending up to my upper thigh / swelling extending to the back), THROMBOSIS (Clot) and CEREBROVASCULAR ACCIDENT (Stroke) in a 68-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 030A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 06-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 06-May-2021, the patient experienced SWELLING (Swelling began in the groin / swelling extending up to my upper thigh / swelling extending to the back) (seriousness criterion hospitalization), FEELING COLD (Felt chilly), DIZZINESS (Dizzy), HYPOAESTHESIA (Whole body(left side) went numb), PARAESTHESIA (Pins and needles sensation) and NAUSEA (Nauseous). On 07-May-2021, the patient experienced THROMBOSIS (Clot) (seriousness criteria hospitalization and medically significant), CEREBROVASCULAR ACCIDENT (Stroke) (seriousness criteria hospitalization and medically significant), GAIT DISTURBANCE (Problem with walking) and TREATMENT NONCOMPLIANCE (Got mad and walked out of hospital byhimself). The patient was hospitalized on 07-May-2021 due to CEREBROVASCULAR ACCIDENT and THROMBOSIS. At the time of the report, SWELLING (Swelling began in the groin / swelling extending up to my upper thigh / swelling extending to the back), THROMBOSIS (Clot), CEREBROVASCULAR ACCIDENT (Stroke), FEELING COLD (Felt chilly), DIZZINESS (Dizzy), HYPOAESTHESIA (Whole body(left side) went numb), GAIT DISTURBANCE (Problem with walking), PARAESTHESIA (Pins and needles sensation), TREATMENT NONCOMPLIANCE (Got mad and walked out of hospital byhimself) and NAUSEA (Nauseous) outcome was unknown. DIAGNOSTIC RESULTS



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(normal ranges are provided in parenthesis if available):  
 On 07-May-2021, Blood test: unknown (Inconclusive) Unknown. On 07-May-2021, Computerised tomogram: unknown (Inconclusive) Unknown. On 07-May-2021, Magnetic resonance imaging: unknown (Inconclusive) Unknown. On 07-May-2021, X-ray: unknown (Inconclusive) Unknown. Company comment: Although a temporal association exists, provided information is not adequate to assess the causal association between the events of thrombosis, stroke, swelling, hypoesthesia, paresthesia, gait disturbance and mRNA-1273. The detailed medical history and diagnostic report has not been provided. Based on the current available information and temporal association between the use of the product and the start date of the events of dizziness, feeling cold, nausea, a causal relationship cannot be excluded. The causality assessment for the event of Treatment noncompliance remains Not applicable. This case was linked to MOD-2021-133656 (Patient Link).; Sender's Comments: Although a temporal association exists, provided information is not adequate to assess the causal association between the events of thrombosis, stroke, swelling, hypoesthesia, paresthesia, gait disturbance and mRNA-1273. The detailed medical history and diagnostic report has not been provided. Based on the current available information and temporal association between the use of the product and the start date of the events of dizziness, feeling cold, nausea, a causal relationship cannot be excluded. The causality assessment for the event of Treatment noncompliance remains Not applicable.

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1353524	5/27/2021	CA	90	M	2/16/2021	2/16/2021	<p>The pain went down his left shoulder and back/he developed pain down his right side of his shoulder, and down in his hips/His left ankle, right side heel, and shoulders also hurt.; The pain went down his left shoulder and back; he was having problems breathing/difficulty breathing; possibly a swollen lymph node on his trachea; His left ankle, right side heel, and shoulders also hurt.; He has had pains in different parts of his body that last for 2-3 days and then some place else starts to hurt.; chills; His wife took his temperature and it was 100.3./He has weird fevers for one day with no other symptoms.; jaw pain; Dates for COVID vaccine: (Start: 5Feb2021 Stop: 16Feb2021), first dose on 5Feb2021 and second dose on 16Feb2021; Dates for COVID vaccine: (Start: 5Feb2021 Stop: 16Feb2021), first dose on 5Feb2021 and second dose on 16Feb2021; This is a spontaneous report from a contactable consumer (patient). A 90-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Right on 16Feb2021 (Lot Number: EL9267) (at age of 90-year-old) as 2ND DOSE SINGLE for covid-19 immunisation. Medical history included ongoing atrial fibrillation, stent placement from 19Jun2020 and ongoing (successful in the descending aorta), and ongoing Heart problems. The patient's concomitant medications were not reported. The patient received the first dose of BNT162B2, administered in Arm Right on 05Feb2021(Lot: EL9263) (at age of 89-year-old) for covid-19 immunisation. The patient would like to talk to an individual regarding his side effects he has been having since his two COVID vaccinations in Feb 2021. Ten days after the second inoculation on 26Feb2021, he woke in the middle of the night with jaw pain. He was in great pain. The pain went down his left shoulder and back . His wife said that morning that those were signs of heart problems. He does have Atrial Fibrillation, and he had a stent placed 19 Jun 2020. He went to the emergency room where they checked him out for heart problems. He had a clean bill of health. They sent him home, and told him to take Tylenol for the pain. The Tylenol certainly helps. It took whatever number of days for it to subside. It subsided for 2 weeks, but then he developed pain down his right side of his shoulder, and down in his hips. Once again they figured they better</p>

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get back to the ER. They did EKG and a X-ray. There was absolutely nothing wrong with his stent. They told him just to continue with Tylenol to control the pain. He went a third time to the emergency room because he was having problems breathing. The emergency room put him through the COVID entry at Kaiser because of the difficulty breathing. They re did all the previous work, and did a scan of his lung to check for blood clots. He thinks they did that because 6 people died from blood clots from Johnsons and Johnson. They wanted to see if there were blood clots, but there were no blood clots. They told him he needed to make an appointment with his primary who then referred him to a Cardiologist. On 11May2021, he saw his primary doctor who ordered another scan because they found possibly a swollen lymph node on his trachea. The doctor measured that, and said to wait a month to do that again. To see any change in it. On the 26 May 2021, he has his next appointment to get that rechecked. He hasn't had a comfortable day since this started. He has had pains in different parts of his body that last for 2-3 days and then some place else starts to hurt. His left ankle, right side heel, and shoulders also hurt. The pain was under control if he takes ibuprofen, but his doctor advised him against too much of that because of his kidneys. It was very effective. The Tylenol works to some extent, but not like the Ibuprofen. He is just living with it day to day. He can play tennis some days. One day he played tennis and came home with chills. His wife took his temperature and it was 100.3. In the last week and half this has happened two times. After the second shot this has happened probably four times. He has weird fevers for one day with no other symptoms. Ever since 26Feb2021, it has been on a daily basis that some place else hurts. One subsides , but another pain starts up elsewhere. If that is not happening, then his whole demeanor is dead. He is just not comfortable and sitting around he feels like he was wasting what life he has left. He used to be a PE teacher. He has always been in good physical condition. He was 5k and walking 5ks every 4th of Jul. He would compete. He prepared for this 90 birthday/ His goal was to do a 5k in under 60 minutes. He worked out like always , and played tennis 3 days a week to prepare. He also played ball. He likes to walk run 2-3 miles most days. He did his 5k in 52minutes, and he was celebrating. Then ten days

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1354911	5/27/2021	VT	66	F	3/7/2021	5/22/2021	<p>later this all started happening. The patient/caller has been tested for COVID, and it was negative. The aches and pains were moving around. He was still having breathing difficulties. Sometimes he can't talk because of the breathing. It just goes away. If it is something like the tumor or a node on the trachea wouldn't it be happening all the time? Sometimes he can't talk because the breathing is bad. It comes and goes. It is more often recently. It is like all the sudden he can't breath and can't talk. That started right at the beginning. It has gotten progressively worse. He took Tylenol to help the pain in his body. Nothing has helped his breathing. He tried antihistamines to see if maybe it was hay fever or something , but there was no difference. He didn't know where to go from here. He was feeling horrible. He was just waiting on 26 May2021, for the second scan without color of thorax to see those results. The patient said he didn't have questions. The outcome of events was unknown.</p> <p>Patient is a 66 y.o. female with an unknown PMHx admitted with DKA and found to have thrombocytopenia, an intraparenchymal bleed on Head CT 2/2 to dural venous thrombosis. Course also complicated by saddle submassive PE w/ + biomarkers and mild RHS. Given unclear etiology of thrombocytopenia, venous thrombosis, and PE, suspect a precipitating/underlying etiology and cannot rule out possible occult malignancy, autoimmune disorder or alternative hypercoagulable state such as APLS. Possibly bacteremic given GPB and Staph on blood cx, though likely contaminant. DKA resolved, anion gap is closed, continued monitoring of glucose and insulin adjustment .OB/Gyn following for heavy vaginal bleeding and possibly gyn malignancy workup, endometrial biopsy pending. Heme also following.</p>

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1354461	5/27/2021	TN	62	F	12/22/2020	1/23/2021	Had episode of ovarian cyst pain 1/20/21 in am. Went home, rested, pain eased a little. Able to finish work week but still bloated & crampy. No nausea, no diarrhea. 1/23/21 felt like coming down with UTI. Rested, hydrated. Passed 2 small blood clots. Had a telehealth visit. Prescribed Levequin & Flagyl. Told to call PCP, needed a CT to rule out kidney stone. Saw PCP 1/27/21. Drew lab & ordered CT of pelvis. CT done 2/3/21. Consult with Oncology poss. Ovarian Ca. 3/15/21 had Robotic Total Hysterectomy- no cancer.
1354444	5/27/2021	IA	64	F	4/30/2021	5/27/2021	Acute deep vein thrombosis of femoral vein of right lower extremity.
1354412	5/27/2021	TN	43	F	4/9/2021	4/9/2021	The day I received my shot I had a fever and chills 2 hours later. I started my period on Sunday 04/11/2021 and I couldn't stop bleeding . plenty of blood clots and fever. I called my Dr and he called medicine in and after 3 days the symptoms stopped . I had a Dr appointment on 4/27/2021 and my iron was very low and blood pressure was at stroke level. I go back to the Dr. in 3 weeks for blood work.
1354411	5/27/2021	VA	91	M	2/17/2021	2/20/2021	Deep vein thrombosis in left leg requiring hospitalization for 14 days tremors

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1354324	5/27/2021	NJ	28	F	4/3/2021	4/19/2021	On .4/19 I started to feel fatigue in my legs 04/20 it got worse in the legs 04/21 I came to work I worked through out the day with pain in my legs it hurt to walk it hurt to sit down the pain in my leg was getting worse 04/22 the pain got really bad I got up in the middle of the night to use the bathroom and I could feel my legs , my legs got really heavy and it felt like I had Charlie horses from my ankles up to the top of my thigh and I could not stand up. So I went to the ER and I got blood work done and I was told something about my CK levels were extremely high and that's when I was admitted. The day that I got the vaccine I got really dizzy during that 15mins that they make us wait and I felt very sick While I was admitted my CK levels kept going up the doctors told me that I had something rhabdomyositis , the pain got worse and the doctor increased my level of fluids and they did an ultra sound on my legs to check for blood clots and they kept increasing my levels of fluids and once I was let go from the doctor I did have to keep going back to keep getting my blood check. I did continue to feel muscle weakness in my legs while I was home. I did go back to the doctor 05/14 for muscle weakness I was given a bag of fluid.. After that any time I stand too long or I am working out I can no longer work out for as long as I can. I can no longer work out for longer than 15mins because of the pain in my legs. I suffer at night time now with muscle spasms now they happen all throughout the night. I had very low potassium
1354303	5/27/2021	CT	51	M	1/23/2021	4/12/2021	Severe vertigo. ENT determined not inner ear but middle ear was causing it. Imaging done (MRI, CT scan) to rule out structural causes or clot. Severe enough MDs evaluating him though he was having a stroke.

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1353501	5/27/2021			M	4/21/2021	5/3/2021	Patient was diagnosed with blood clots confirmed by Ultrasound; This is a spontaneous report received from a contactable physician. A 48-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EW0164), on 21Apr2021 as 2nd dose, single for COVID-19 immunization. The patient's medical history included colon cancer (patient had a history of colon cancer 2 years removed) from unspecified date. The patient's concomitant medications were not reported. The patient previously received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not reported), on 30Mar2021 as 1st dose, single for COVID-19 immunization. It was reported that patient was diagnosed with blood clots confirmed by ultrasound during the emergency room visit on 03May2021. Patient was placed on apixaban (ELIQUIS) 5 mg, twice a day. Patient had history of colon cancer 2 years removed, and recent colonoscopy on 13Apr2021 was clear. The event was reported as non-serious. The outcome of the event was unknown.; Sender's Comments: The event of blood clot is assessed as possibly related to the suspect BNT162B2 based on temporal association, but medical history of colon cancer was confounder. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Committees, and Investigators, as appropriate.
1354236	5/27/2021	CA	57	F	4/9/2021	4/9/2021	Ran a fever for about 1 week. Had extreme pain in left leg beginning the day after vaccine. Visited emergency room 1 week later based on guidance from physician but little was done- they seemed unsure of what to do. They ran blood tests but since I had no swelling, they assumed no blood clots and did no more testing. Released after about 3 to 4 hours. Pain continued so contacted my doctor a 2nd time. She indicated other patients were reporting the same and suggested continuing aspirin or tylenol. After about 4 weeks pain resolved.

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1353119	5/27/2021	IL	70	M	1/28/2021	2/18/2021	lower leg was swollen and started to get bigger and bigger; blood clot in the right leg; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (blood clot in the right leg) in a 70-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 02AL20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history were reported. Concomitant products included PANTOPRAZOLE for GERD, TRAZODONE for Sleeplessness, SIMVASTATIN and CHLORMEZANONE (RESTORIL [CHLORMEZANONE]) for an unknown indication. On 28-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 18-Feb-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced THROMBOSIS (blood clot in the right leg) (seriousness criterion medically significant). On an unknown date, the patient experienced PERIPHERAL SWELLING (lower leg was swollen and started to get bigger and bigger). The patient was treated with RIVAROXABAN (XARELTO) for Thrombosis, at an unspecified dose and frequency. At the time of the report, THROMBOSIS (blood clot in the right leg) and PERIPHERAL SWELLING (lower leg was swollen and started to get bigger and bigger) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication includes Benapraxine for to simmer down. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.



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1353762	5/27/2021			F			<p>BLOOD CLOT; DISTURBING CHANGES IN MENSTRUAL CYCLES; EARLY PERIODS; UNUSUALLY HEAVY PERIODS; OTHER IRREGULARITIES; This spontaneous report via social media received from a patient concerned multiple patients. The patient's height and weight was not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. The reporter shared from a news article stating that blood clots were not the only vaccine side effects and that women experienced several weird side effects including disturbing changes in menstrual cycles, early and unusually heavy periods and other irregularities. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the other irregularities, early periods, unusually heavy periods, blood clot and disturbing changes in menstrual cycles was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210545709-COVID-19 VACCINE AD26.CO2.S-blood clots. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1353559	5/27/2021	GA	81	U	3/22/2021	3/22/2021	<p>my doctor immediately said you know we want to rule out a blood clot so blood was drawn to the lab; Right ankle was swollen; There is some problem down with the leg not as bad I say but having the same pain I feel a sensation in my feet when I stand; This is a spontaneous report from a contactable consumer (patient). An 81-year-old patient of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 81 years of age), via an unspecified route of administration on 22Mar2021 (Batch/Lot Number: EN6206) as 2ND DOSE, SINGLE for COVID-19 immunisation; amlodipine besilate (manufacturer unknown), via an unspecified route of administration from an unspecified date (Batch/Lot number was not reported) to an unspecified date, at 10 mg, 1x/day for blood pressure management and valsartan via an unspecified route of administration from an unspecified date (Batch/Lot number was not reported) to an unspecified date, at 80 mg, 1x/day at bed time (anywhere between 9 and 10:15 PM) as blood pressure medication. Medical history included glaucoma and hypertension (Blood pressure) from an unknown date and unknown if ongoing; additional medical condition reported as felt at times like he/she want to itch ('felt itching but never scratch myself or anything like that'). Concomitant medication included bimatoprost (LUMIGAN) taken for glaucoma, start and stop date were not reported. Historical vaccine included BNT162B2 dose 1 on 01Mar2021 (at 81 years of age) for COVID-19 immunisation. The patient took the two treatments of the Pfizer vaccine. The patient had a problem from the second vaccination administered on 22Mar2021 with the LOT# EN6206. The patient took the last treatment on 22Mar2021 at the health department, which was the one that had created problems for him/her. The patient mentioned that there was no problem at all with the first treatment. The patient stated that first of all, he/she was on the blood pressure medications and one of the medications was valsartan 80 mg and the other one was amlodipine 10 mg, once a day; the patient take valsartan at bed time (anywhere between 9 and 10:15 [something like] that PM). The patient was taking amlodipine 10 mg for blood pressure, and then from reading what he/she got from the pharmacist on the valsartan, it was supposed to work by relaxing blood vessel so the blood</p>

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can flow more easily lowering high blood pressure to help prevent stroke, heart attack and kidney problems; so the patient had been taking those two. It was reported that after the patient took the second Pfizer vaccine on 22Mar2021, in the evening he/she noticed that his/her right ankle was swollen not in the morning but in the evening say by anywhere from 6 to 7 PM to 8:00 PM, it was swollen occasionally and then it looked like there was some problem down with the leg not as bad he/she said but having the same pain he/she felt a sensation in the feet when he/she stands. So the patient saw his/her doctor, had an appointment with him on 20Apr2021 and at the time of the appointment which was at 2:45 in the afternoon, there was no swelling; the patient did tell him that he/she had this reaction and it started the same day he/she got the treatment but it was in the evening that she/he noticed it, not in the morning, not the afternoon but the evening, late evening. The patient did not take any treatment for these adverse events which the doctor immediately said that they want to rule out a blood clot, so blood was drawn to the lab. The patient saw the doctor on the 20th about a week later and called his office and was told report had not come in and the patient had not heard from his office since that time. The patient was making assumption right or wrong that had there been a blood clot, the office would have called him/her okay. But the doctor said that he wanted to rule that out then he said they might have need to lower the dosage of amlodipine, those were the things he remembered him saying so. But the patient's concern was not it was because the ankle does swell and then when he/she went to bed and lie down of course it stopped it did not swell, when he/she got up in the morning it was normal ankle so but the patient did not know what was going on and did not know if this was the reaction that no one else had; he/she was not sure what to do about it at this point. The patient wondered if the symptoms were direct result of his/her mixed medications that he/she had taken with the Pfizer vaccine and commented that he/she certainly had no problem with the first. The patient added concern whether there was a causal relation between the medication he/she was taking and that second vaccine, he/she does not know what. The patient's main concern was to get his/her ankle un-swollen which what happened since the last dose, no problem with the first

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dose but the last dose that was where it was. The patient did not know what the diagnosis that was causing the problem as he/she said the doctor had taken the had blood drawn to send to the lab to rule out the blood clot. The patient underwent lab tests and procedures which included blood test: unknown results on an unspecified date. The action taken in response to the events for amlodipine besilate and valsartan was unknown. The outcome of the events was unknown. Pfizer is a marketing authorization holder of Amlodipine Besilate in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of Amlodipine Besilate has submitted the same report to the regulatory authorities. No follow-up attempts are needed. No further information is expected.

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1353553	5/27/2021	IA	95	F	3/24/2021	4/1/2021	positive COVID-19 test with symptom; positive COVID-19 test with symptom; This is a spontaneous report from a contactable consumer (patient's daughter) reported that a 95-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: ER8736) via an unspecified route of administration, administered in Arm Right on 24Mar2021 at age of 95-year-old at single dose for COVID-19 immunisation. Medical history included high blood pressure, Alzheimer's disease, depression and blood clot. Concomitant medications included amlodipine taken for high blood pressure from an unspecified date; apixaban (ELIQUIS) taken as blood thinner from an unspecified date; donepezil hcl taken for Alzheimer's disease from an unspecified date; memantine taken for Alzheimer's disease from an unspecified date; escitalopram oxalate (LEXAPRO) taken for depression from an unspecified date; folic acid taken for an unspecified indication from an unspecified date. The reporter was actually calling how to schedule for the second dose since her mother tested positive second week after getting the first dose (Apr2021) and currently she still didn't have the second dose of shot. It also reported about 2 weeks after she got the first vaccine, she got COVID. She just had a fever for couple of days that was it, the reporter asked when she got the second vaccine. No treatment received for the event. No lab work other than COVID that was positive in Apr2021. The outcome of the events was unknown.

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1353535	5/27/2021	MD	56	F	5/6/2021	5/6/2021	Vaginal bleeding in a menopausal woman with blood clots.; Vaginal bleeding in a menopausal woman with blood clots.; Also slept for 13 hours the day following the shot and had a continual headache with nausea; Also slept for 13 hours the day following the shot and had a continual headache with nausea; Also slept for 13 hours the day following the shot and had a continual headache with nausea; This is a spontaneous report from a contactable consumer (patient). A 56-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 06May2021 at 09:45 at single dose in left arm for COVID-19 immunisation at the age of 56-year-old. Lot number EW0183. Medical history included menopausal woman. Concomitant medications were none. Historical vaccine included BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 15Apr2021 at 10:30, Lot number EW0164, dose number: 1, in left arm. On 06May2021, the patient also slept for 13 hours the day following the shot and had a continual headache with nausea. On 10May2021, the patient experienced vaginal bleeding in a menopausal woman with blood clots. It was very concerning; the patient was going to Ob/Gyn soon. The patient underwent ultrasound and biopsy. Prior to vaccination, the patient was not diagnosed with COVID-19; since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was unknown. Follow up needed, further information has been requested

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1353513	5/27/2021	NY	74	F	2/5/2021	4/15/2021	<p>she did not feel good; Migraine after second dose; her heart was pounding; felt palpitations in her chest; potassium was low; dimer test that showed 0.30 clot; slight mitral regurgitation; breathing problems; shingles; This is a spontaneous report received from Pfizer sponsored program. A 74-year old contactable female consumer (patient) reported for herself that she received the second dose of BNT162B2 (Lot No. unknown) at single dose for Covid-19 immunization on 05Feb2021 at 17:30. Relevant history included Shingles when she was 42, Chicken pox. Relevant concomitant drug was unknown. The patient received the first dose of BNT162B2 (Lot No. EL3247) at 0.3 ML single dose for Covid-19 immunization on 15Jan2021, experienced Left arm Pain at injection site. Prior Vaccinations (within 4 weeks): none. The patient went to Urgent care and was diagnosed with Shingles on 15Apr2021, which was started with pain in her side, and on 30Apr2021, she was having breathing problems/ breathing was not well at 15:30-16:00. She said shingles were from the shot. The patient started shrinking before she got the vaccine. It was years before. There was no prescriber. She did not have the pain from the Shingles any longer. The pain was gone for a couple of days now. She had it for 2 1/2 weeks. She was cooking and the next day, she said she did not feel good, her heart was pounding and breathing was difficult. She went to ER and they did dimer test. They took 12 vials of blood. They told her she had .30 clot. She later stated the Dimer result was 0.30. They did chest x-ray and nothing showed. They looked at her legs too. That is why they did the sonogram. They wanted her to stay, but he gave her a sonogram of her heart. It is not enlarged and there is no fluid around it. She thought he gave referral for outpatient. She has been calling ER for an appointment. She then found that the doctor was not able to refer to an Echo cardiogram. She needs to go to the one in her home state and she is still in a different state visiting her daughter. She goes home next week and will get it then. She went for stress test Apr 2019 and emailed results said she had slight mitral regurgitation, so maybe that is where the blood is coming from. Her sister called and she told her she did not feel well. Breathing problem only lasted a day. She was cooking again and was not doing anything strenuous and felt palpitations in her chest and felt breathing issues again.</p>

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It is better, but every now and then she gets palpitations. She had a migraine after second dose at 16:00 (unknown date). She went to bed at 4pm and woke up at 1am. She thought she took an Ibuprofen and did not know if it would affect vaccine or not. When she woke up, she was fine. She had shingles prior. She assumes she must have had COVID and did not know. She had the antibodies present in May 2020, when she was tested. When she googled, the people in another country were getting Shingles. She had the chicken pox when she was young. If you get the Chicken pox and the COVID, you are susceptible to shingles. She does not have any information on those people in other country to report. Her brother and sister both received the Moderna COVID vaccine. Her brother did not have any issues an her sister already reported her issues to them. No further details provided. Separate report completed for her sister. When looking up an address, she stated she needs a magnifying glass. She needed this before the vaccine. She always has her glasses to read with. ER visited on 15Apr2001 and 01May2021. On 15 They gave her ketorolac and ondansetron, potassium chloride. because her potassium was low. The outcome of event shingles, breathing problems was resolving, the outcome of other events was unknown. Follow-up attempts are needed. Information about batch/lot number is expected.



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1353495	5/27/2021	IA	77	F	3/21/2021		<p>getting lightheaded; Excessive hypertension/ 180/88 to 94; This is spontaneous report from a contactable nurse reported for herself. A 77-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in left arm on 21Mar2021 (Batch/Lot Number: ER8727) as 2ND DOSE SINGLE for covid-19 immunisation. Medical history included hypertension, paroxysmal atrial tachycardia, stroke when she was 40, had COVID in Mar2020 (Her cardiologist believes she had COVID too but never did a test) and broke her ankle. Concomitant medication included warfarin sodium (COUMADIN) because she had a stroke and broke her ankle and got a clot from her ankle to her groin; ongoing diltiazem hydrochloride (DILTIAZEM HYDROCHLORIDE) taken for paroxysmal atrial tachycardia and hypertension; Chlorthalidone taken for polyuria and hypertension; verapamil hydrochloride (VERAPAMIL) taken for paroxysmal atrial tachycardia for years. Patient received first dose of bnt162b2 on 28Feb2021 in left upper arm. Patient was a retired nurse and stated about a month after the second dose of the vaccine she started getting lightheaded, she went to Urgent Care because her daughter who is a nurse insisted. Her blood pressure at Urgent Care was really, really high, she was having excessive hypertension. Before the vaccine she was on a blood pressure medication for several years and had no issues. She went to see her cardiologist and they moved her from one medication to 3 medications (then add Losartan, Diltiazem) to get this controlled. In the morning she was lightheaded and her blood pressure is high before her morning medication. Diltiazem is 24 hours. She gets up at 3AM and once she takes the medication it seems to be ok. Her blood pressure is reasonable now. It is not like it was initially when elevated. Initially it was 180/88 to 94 when she first went to see the cardiologist after second COVID19 Vaccine. Currently her blood pressure in the morning is usually 154/ 77. That was when she first takes it when she gets up. Later in the morning it is running 110/77. The event outcome was unknown. She was feeling that it had to do with the second injection. Patient considered it was medically significant for high blood pressure and lightheaded, and considered both events related to COVID19 Vaccine.; Sender's Comments:</p>

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Based on the known drug profile, there is a reasonable possibility of casual relationship between the drug BNT162b2 and the events Dizziness and Hypertension. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

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1353491	5/27/2021	CA	35	M	2/22/2021	2/23/2021	feels like a blood clot; My right calf has felt strange ever since the second dose and it feels like a blood clot/toes also felt strange/My toes also felt strange for a few weeks but that subsided; a tightness in the leg that doesn't want to go away; This is a spontaneous report received from a contactable consumer. This consumer reported for himself that the 35-year-old male patient received second dose of bnt162b2 (BNT162B2, Pfizer COVID 19), via an unspecified route of administration, administered in Arm Left on 22Feb2021 13:00 (Batch/Lot Number: 6203) as 2nd dose, single for covid-19 immunisation. Medical history was none. The patient's concomitant medications were not reported. The patient previously took first dose of bnt162b2 (BNT162B2, Pfizer COVID 19, Lot number=9265) on 01Feb2021,01:00 PM,in Left arm for covid-19 immunisation. The patient experienced feels like a blood clot on 23Feb2021 with outcome of not recovered , my right calf has felt strange ever since the second dose and it feels like a blood clot/toes also felt strange/my toes also felt strange for a few weeks but that subsided on 23Feb2021 with outcome of not recovered , a tightness in the leg that doesn't want to go away on 23Feb2021 with outcome of not recovered. No treatment received for the events. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No List of any other medications the patient received within 2 weeks of vaccination. The clinical course was reported as follows: My right calf has felt strange ever since the second dose and it feels like a blood clot. There is a tightness in the leg that doesn't want to go away. My toes also felt strange for a few weeks but that subsided. The adverse event resulted in Doctor or other healthcare professional office/clinic visit. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. No Known allergies. Follow up letter has been generated for further information.

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1353463	5/27/2021	WI	60	F	5/4/2021	5/1/2021	It was swollen up pretty big/My arm swelled up. It almost looked like I had a big muscle; Feeling really sick; Her arm was hurting/Sore arm; I did have COVID, the virus; Slight headache; Weak; I don't even feel that well right now with the first shot; So I think this was an allergic reaction to the medicine because its not real clear; She was pale and dizzy/kind of dizzy; She was pale and dizzy; Nauseated; She's tired/I just feel tired; I just feel like I am dragging; This is a spontaneous report from a contactable consumer. A 60-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot number: EW0176) dose 1 via an unspecified route of administration in the left arm on 04May2021 (at the age 60 years old), as single dose for COVID-19 immunization. The patient's medical history included patient had a pulled tendon for which she was wearing a boot, hypothyroidism for which the patient was taking Synthroid since 1991, COVID-19 in Dec2020 and was sick from Dec2020 to Jan2021, it took patient a month to get over it. The patient's concomitant medication included Diclofenac Sodium delayed release tablets 75mg, two times a day for 2 pulled tendons in her foot. On 05May2021, patient's arm was hurting/Sore arm. On 06May2021, arm swelled up, it was swollen up pretty big, it almost looked like patient had a big muscle, feeling really sick. On an unspecified date in May2021, patient did have COVID, the virus, patient was pale and dizzy/kind of dizzy, felt nauseated, tired/ just feel tired like patient was dragging, slight headache, weak, patient didn't even feel that well right now with the first shot and patient thought that this was an allergic reaction to the medicine because it was not real clear. Patient was started on Diclofenac Sodium 75mg two tabs daily- started on Tuesday, the same day she got her Pfizer Vaccine. On an unspecified date, patient had ultrasound of the leg to check for clots, but she did not have any. The patient reported that her arm was still really sore, and she was not as nauseous and pale as she was last night but then was tired and slept all night. She just felt tired. The patient did not receive any treatment for the adverse events. Patient wanted to know if this could be a reaction between the medication (Diclofenac Sodium) and the vaccine and also wanted to know if she was allergic to something in the vaccine and how many days side effects might last, patient did not

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							know anyone who got sick after the first dose. Patient was scheduled for the second dose of the vaccine on 26May2021. Outcome of the pale and nauseated was recovering, patient's arm was hurting/sore arm, arm swelled up, it was swollen up pretty big, it almost looked like patient had a big muscle not recovered was not recovered while for the other events was unknown. Patient reported that her 83-years-old mother got Moderna and her arm was a little sore after the first dose and nothing after the second shot. No follow-up attempts are needed. No further information is expected.
1353451	5/27/2021	MD	33	F	3/12/2021	4/15/2021	heavy bleeding clot like; heavy bleeding clot like; extreme low back pain; nausea; sweating; This is a spontaneous report from a contactable consumer (patient). A 33-year-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration, administered in Arm Left on 12Mar2021 (at 33 years old, not pregnant) as unknown, single for covid-19 immunisation. Medical history included allergies: Penicillin, Have not had menstrual cycle in years (Have not had menstrual cycle in years as taking continuous birth control.) all from an unknown date. Concomitant medications included loratadine, pseudoephedrine sulfate (CLARITIN-D); ethinylestradiol, levonorgestrel (LESSINA); sertraline hydrochloride (ZOLOFT). No other vaccine in four weeks. On 15Apr2021, patient experienced heavy bleeding clot like, extreme low back pain, nausea, and sweating. Has been occurring for 3 weeks. Went to doc to rule out serious issues. Everything came back negative. The outcome of the events was not recovered. No treatment for the adverse events. No covid prior vaccination. Not covid tested post vaccination. Information about lot/batch number has been requested.
1354283	5/27/2021	VT	70	M	3/22/2021	5/15/2021	Blood clot in right foot. Swelling. I didn't immediately consider the possible connection to the Pfizer vac. Sorry for the delay.
1355766	5/27/2021	MO	54	F	5/10/2021	5/17/2021	patient claims she developed a blood clot approximately one week after receiving her first dose of the Pfizer Covid-19 vaccine.

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1354961	5/27/2021	CO	56	F	3/16/2021	4/8/2021	Blood clots have developed in both legs. Started with swelling in feet and ankles and went to the doctor. Ultrasound showed clot in artery behind left knee and second clot in right calf.
1353517	5/27/2021	AZ	48	M	4/20/2021	5/1/2021	diagnosed with a Deep Vein Thrombosis since the clot was in his vein/Arm starting swelling specifically in his wrist and forearm; This is a spontaneous report initially directly from a contactable consumer (the patient), and then received from a Pfizer sponsored program. A 48-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EW0164) via an unspecified route of administration, administered in left shoulder on 20Apr2021 at age of 48-year-old at single dose for COVID-19 immunization. The patient had no medical history (including any illness at time of vaccination). No family medical history relevant to AE(s). The patient did not receive any concomitant medications (reported as "the patient did not receive other products"). No relevant tests. No prior vaccinations (within 4 weeks). The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0150) via an unspecified route of administration in his left shoulder on 30Mar2021 at age of 48-year-old for COVID-19 immunization and experienced no adverse event. Caller stated he was calling about the COVID 19 vaccine. Caller stated he got the second dose about 3 weeks ago and about 10 days or 11 days after the second dose (01May2021) his arm starting swelling specifically in his wrist and forearm. Caller stated he went to the emergency room and there was a blood clot found in his left arm. Caller stated he was diagnosed with a deep vein thrombosis since the clot was in his vein. Caller stated everything was going better but the emergency room doctor told him he should probably report this to Pfizer to let Pfizer know. Caller clarified that he was released from the emergency room and was never admitted to the hospital. Treatment received for the event included blood thinner. The event required a visit to emergency room, and the caller stated he went to physician office today. The outcome of the event was recovering.

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1353559	5/27/2021	GA	81	U	3/22/2021	3/22/2021	<p>my doctor immediately said you know we want to rule out a blood clot so blood was drawn to the lab; Right ankle was swollen; There is some problem down with the leg not as bad I say but having the same pain I feel a sensation in my feet when I stand; This is a spontaneous report from a contactable consumer (patient). An 81-year-old patient of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 81 years of age), via an unspecified route of administration on 22Mar2021 (Batch/Lot Number: EN6206) as 2ND DOSE, SINGLE for COVID-19 immunisation; amlodipine besilate (manufacturer unknown), via an unspecified route of administration from an unspecified date (Batch/Lot number was not reported) to an unspecified date, at 10 mg, 1x/day for blood pressure management and valsartan via an unspecified route of administration from an unspecified date (Batch/Lot number was not reported) to an unspecified date, at 80 mg, 1x/day at bed time (anywhere between 9 and 10:15 PM) as blood pressure medication. Medical history included glaucoma and hypertension (Blood pressure) from an unknown date and unknown if ongoing; additional medical condition reported as felt at times like he/she want to itch ('felt itching but never scratch myself or anything like that'). Concomitant medication included bimatoprost (LUMIGAN) taken for glaucoma, start and stop date were not reported. Historical vaccine included BNT162B2 dose 1 on 01Mar2021 (at 81 years of age) for COVID-19 immunisation. The patient took the two treatments of the Pfizer vaccine. The patient had a problem from the second vaccination administered on 22Mar2021 with the LOT# EN6206. The patient took the last treatment on 22Mar2021 at the health department, which was the one that had created problems for him/her. The patient mentioned that there was no problem at all with the first treatment. The patient stated that first of all, he/she was on the blood pressure medications and one of the medications was valsartan 80 mg and the other one was amlodipine 10 mg, once a day; the patient take valsartan at bed time (anywhere between 9 and 10:15 [something like] that PM). The patient was taking amlodipine 10 mg for blood pressure, and then from reading what he/she got from the pharmacist on the valsartan, it was supposed to work by relaxing blood vessel so the blood</p>

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can flow more easily lowering high blood pressure to help prevent stroke, heart attack and kidney problems; so the patient had been taking those two. It was reported that after the patient took the second Pfizer vaccine on 22Mar2021, in the evening he/she noticed that his/her right ankle was swollen not in the morning but in the evening say by anywhere from 6 to 7 PM to 8:00 PM, it was swollen occasionally and then it looked like there was some problem down with the leg not as bad he/she said but having the same pain he/she felt a sensation in the feet when he/she stands. So the patient saw his/her doctor, had an appointment with him on 20Apr2021 and at the time of the appointment which was at 2:45 in the afternoon, there was no swelling; the patient did tell him that he/she had this reaction and it started the same day he/she got the treatment but it was in the evening that she/he noticed it, not in the morning, not the afternoon but the evening, late evening. The patient did not take any treatment for these adverse events which the doctor immediately said that they want to rule out a blood clot, so blood was drawn to the lab. The patient saw the doctor on the 20th about a week later and called his office and was told report had not come in and the patient had not heard from his office since that time. The patient was making assumption right or wrong that had there been a blood clot, the office would have called him/her okay. But the doctor said that he wanted to rule that out then he said they might have need to lower the dosage of amlodipine, those were the things he remembered him saying so. But the patient's concern was not it was because the ankle does swell and then when he/she went to bed and lie down of course it stopped it did not swell, when he/she got up in the morning it was normal ankle so but the patient did not know what was going on and did not know if this was the reaction that no one else had; he/she was not sure what to do about it at this point. The patient wondered if the symptoms were direct result of his/her mixed medications that he/she had taken with the Pfizer vaccine and commented that he/she certainly had no problem with the first. The patient added concern whether there was a causal relation between the medication he/she was taking and that second vaccine, he/she does not know what. The patient's main concern was to get his/her ankle un-swollen which what happened since the last dose, no problem with the first



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1355774	5/27/2021	VA	63	M	5/4/2021	5/9/2021	Already having blood clots in my left leg and
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1355563	5/27/2021	OR	81	F	4/29/2021	4/29/2021	4/29/21: HAD BLURRED VISION (ALL DAY UNTIL MORNING OF NEXT DAY) + PRESSURE IN HEAD (ALL DAY INTO EVENING OF NEXT DAY) ABOUT 40 MINUTES AFTER RECEIVING VACCINE. 4/29/21: EVER SINCE VACCINATION, EXPERIENCING EXCESSIVE THIRST. ONGOING 5/1/21: PATIENT DESCRIBED SYMPTOM AS SKULL BONE PAIN (TENDER SCALP WHEN TOUCHED) UNTIL 5/5/21 5/3/21: ONGLING BLADDER IRRITATION. NO BLOOD IN URINE, BUT SOME SPOTTING (~2TSP) ON PADDING 5/17/21 . NO BLOOD PRESENT SINCE 5/4/21 MORNING: LYMPH NODE SWOLLEN UNDER THE LEFT ARM (INJECTION WAS IN RIGHT ARM). SIZE OF A TENNIS BALL, VERY PAINFUL, AND PAIN RADIATED TO AROUND THE LEFT BREAST AREA. PAIN LASTED UNTIL THE AFTERNOON OF 5/6/21. 5/9/21: BLOOD CLOT IN LEFT LEG REACTIVATED IN THE MORNING, ACCOMPANIED BY EXTREME PAIN, SWELLING, WARM TO THE TOUCH. PAIN AND SWELLING HAS BEEN MINIMAL BEGINNING 5/24/21, AND HAS NOT BEEN AS WARM TO THE TOUCH AS IT HAS BEEN. TREATMENTS: TOOK IBUPROFEN AND TYLENOL AS NEEDED FOR PAIN. USED ARNICA GEL ON THE ARM AT THE INJECTION SITE + MASSAGE+ CONSTANT MOVEMENT FOR PAIN/STIFFNESS. USED ARNICA GEL ALSO ON LYMPH NODE UNDER LEFT ARM ELEVATED CLOTTED LEG AND STAYED ACTIVE TO OPTIMIZE BLOOD FLOW, USED LIGHTLY HEATED PAD TO EASE THE LEG PAIN
1355361	5/27/2021	UT	50	F	5/10/2021	5/11/2021	Menstruation started the next day, May 11 and has continued as of this date, May 27th. It is accompanied with bloating, cramping, bright red blood, spotting, and clots. This is not normal for my cycle.
1355341	5/27/2021	IL	52	F	3/26/2021	3/31/2021	As reported by NP that called with event: Pt has had 3 hospital stays after receiving vaccine. Pt initially went in on 3/31/2021. Stays include: 3/31/21-4/5/21 4/12/21-4/16/21 4/29/21-5/5/21 Symptoms/diagnoses include: IJ thrombosis, PE, esophageal strictures d/t nausea/vomiting

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1355263	5/27/2021	UT	30	F	5/14/2021	5/18/2021	Menstrual cycle started again a week after my normal cycle ended. Abnormal menstrual cycle is still on going (started 18May2021) today is 27May2021, no sign of stopping any time soon. This abnormal menstrual cycle is extremely heavy where it is causing concern. There is a lot of blood clots.
1356050	5/27/2021	UT	34	F	5/6/2021	5/7/2021	pt said the day after she had the covid shot she started seeing an increased amount of bleeding. She said she was about 6 weeks postpartum and she was bleeding normally but increased after shot., no blood clots though just an increased amount. She had as must rest as she could and drank plenty of fluids and water. She talked to md at 6 week appointment, which was shortly thereafter, and he examined her and told her to drink plenty of fluids and rest. He just told her to monitor the bleeding for increased amounts and if need be call him. The doctor said was beneficial to get second shot she seems ok now and said she has what is normal bleeding now. she said she has regularly bleeding to me now when I asked is it back to normal she told me yes. She opted to get another vaccine shot knowing all this.
1355177	5/27/2021	FL	20	M	5/23/2021	5/26/2021	At approximately 12:30 PM on May 26, 2021, Pt. began vomiting while he was at school. Prior to vomiting, school staff reported that he seemed unwell (pt. is severely disabled and has very limited speech). The first episode of vomiting was followed by multiple (4-5) episodes of vomiting blood. School staff including the school nurse report observing clots in the blood, bright red blood, and brown coffee ground type blood in the vomit. The school staff called 911 and pt. was transported to Hospital. In the ambulance pt. vomited again and the paramedic reported observing blood in the vomit. Pt. was observed in the ER and given Zofran and liquids. Blood tests and a CT scan with and without contrast were performed. Neither tests explained the bloody vomiting. Pt has since stopped vomiting and is resting quietly at home and eating normally. The hospital referred Noah to a Gastroenterologist for follow up.
1355317	5/27/2021	OH	47	M	5/20/2021	5/26/2021	Sustained blood clots in left calf area approximately 6 days after receiving 1st dose.

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1355276	5/27/2021	NV	40	M	4/3/2021	4/17/2021	April 17th, felt chest pain and fatigue and shortness of breath. After about two weeks of it, I went to ER on the 26th. I was diagnosed with blood clot on my heart. I spent a week at the hospital Heparin blood thinners and antibiotics - discharged on May 2, 2021. They sent me home with Warfarin regiment. I am still on that. I still have some days where I'm good but some days, I can barely stand and get out of bed due to short of breath, fatigue but not as much chest pain. I think the blood thinners are working. I just have to take it easy and make sure to have some calm days. It could take weeks to months to have the blood clot totally dissolve from the system.
1355286	5/27/2021	FL	68	M	1/24/2021	1/24/2021	He got his vaccine, and had to go from the roof to the parking lot. He was in his car and thought he had put his car in park, but it was in neutral and he hit another car, which he thought he was hit. The gentleman informed him that he was the one that hit him as he had watched him slowly advance to hitting him. He did not know or was aware that he was even moving. He has headaches normally but they have gotten worse since then. He also has motion sickness but has learned to deal with it and get used to the side effects. He also has blurry vision and just not feeling normal. He did go see his PCP and she put him on Meclizine for the dizziness, which works about 50%, but not completely. He did have the 2nd vaccine on 2/22/21 and still had the symptoms, which have stayed since then as well. He then saw his PCP a week ago and she is scheduling for a CT scan to see if he has any blood clots. He did have an aneurysm in his brain 28 years ago and they felt that he would not be able to survive it and deemed that he would be left as a vegetable, but has survived that and does have a little residual headache, but nothing severe. He now is still having these three symptoms that he did not have prior to the vaccine.

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1355297	5/27/2021	TX	43	M	4/30/2021	5/3/2021	Three days after my second shot (on 05/03/2021) I started to feel pain in my left arm, tightness in chest, and I became very light headed. I tried to go to shower but I could not walk and laid down. My ears felt very tingly and I thought I was going to pass out but as far as I know, I did not. I went to my primary care doctor and he has me taking baby aspirin daily (in case blood clot) and wanted to see if it got better I am going to follow up with a cardiologist. I've never had a problem with heart before and get an annual physical at work.
1355298	5/27/2021	VA	76	F	4/7/2021	5/9/2021	Had noises in my ears like a clock ticking. I have titinus but this was not a ringing noise. A couple of weeks later I woke up with my right eyelid all swollen and bruised and went to the ER where there they did a CT scan to make sure I didn't have a blood clot and I did not. Also my platelets were in the normal range. It took a good week for the swelling and bruising to go down and the bruising even went down my face somewhat. I had an appointment with my eye doctor and he didn't know why it happened, but may have had something to do with my taking low dose aspirin. I did not have any contusion to the eye and it was not hit by anything.
1355300	5/27/2021	CT	51	F	4/7/2021	4/7/2021	I was still having chest pain and breathing problems prior to getting it, so they wanted me to get the vaccine because if I got COVID, it would kill me. Over the weeks, my breathing worsened and I had terrible chest pains. They did another CT Scan to make sure I didn't have another embolism. The symptoms of my other conditions flared as well. I got the vaccine 3 or 4 days before the news was released about the blood clots. I'm still experiencing breathing issues, chest pains and dizziness. I'm now on additional meds for my lupus: Cymbalta and Lyrica. They're trying to help with the chest pain and polymyalgia. I was also given a Lidoderm patch to help with my chest pain. It just seems like everything got worse afterwards. I'm not sure if my lungs will ever function at 100% due to everything going on.



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1350522	5/26/2021	PA	54	M	4/22/2021	4/30/2021	ED Discharged 5/5/2021 - 5/6/2021 (3 hours) Last attending ? Treatment team Acute nonintractable headache, unspecified headache type Clinical impression Headache Chief complaint Triage Note: To ED c/o severe HA behind R ear since being dx w COVID 4/30. Denies cough, dyspnea, fevers. Reporting he has had 1 round of COVID vaccines. Has taken "alieve, tylenol, and advil" w/o relief. Last doses all "early this morning." pt awake and alert in triage. History of Present Illness Patient is a 54 y.o. yo male presenting to the ED with severe headache behind the right ear since 4/30. Patient was diagnosed with Covid at that time and has taken 1 round of the Covid vaccine. He has tried Aleve, Tylenol and Advil without relief. He states that his last dose were all early this morning. Denies any numbness or tingling, visual disturbances, ataxia, photophobia. He has no history of strokes, MI or blood clots. He states that prior to his Covid diagnosis he is otherwise healthy. ED Discharged 5/8/2021 (4 hours) Last attending ? Treatment team COVID-19 Clinical impression Fever Chief complaint Medical Decision Making 54-year-old male who presents today due to uncontrolled fever, diagnosed with Covid on April 30. Symptomatic for about 2 weeks now. On exam appears to be uncomfortable, is febrile and tachycardic, however remaining vitals are stable. Physical exam is also reassuring. Patient not complaining of any chest pain, shortness of breath, lightheadedness. Will provide patient with symptomatic relief including fluids and ibuprofen, if able to improve patient's symptomatology will have him discharged home. His labs also show some slight hyponatremia, he will likely improve from fluids as I believe this is secondary to his diarrhea that he has been having over the last few days. CK also slightly elevated, would likely benefit from fluids. After a single liter of fluids, patient symptoms improved, fever and tachycardia also improved, continues to endorse some generalized weakness, will give second liter of fluid and Tylenol at this time as he is due for this. After receiving a second liter, the patient states that his symptoms have greatly improved at this time, comfortable returning home. I advised the patient that she should take ibuprofen and Tylenol on 6-hour cycles very regularly, he can take it in a pattern where he takes Tylenol followed by ibuprofen 3 hours later followed by Tylenol again 3

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1351174	5/26/2021	NJ	36	F	4/8/2021	4/15/2021	<p>hours later, as long as he keeps 6 hours in between doses, explained to him that he should not take this any sooner than this however he should be sure to take these regularly as these will help control his fever. Also encouraged him to hydrate appropriately as this will likely prevent him from feeling poorly. He is agreeable with this plan, I provided him with appropriate return precautions.</p> <p>Over the week after my shot I started to get a headache which isn't abnormal for me but by Sunday April 18 I was having the worst headache I have ever had in my life. I was bed ridden and in tears and unable to function. I went to the ER to make sure I was not having the blood clot issue seen after some j&amp;j shots. I was not having one they said and I was sent home to have further testing done and visit a neurologist. By Tuesday April 20 I began having neurological symptoms such as pain and numbness in my left side. I feared I was having a stroke so I went back to the Er where I was admitted and they ran many tests including multiple brain MRI. They found nothing and said that I was having a complex migraine. I saw a neurologist shortly after my hospital visit and he has been treating my headache with gabapentin and fiorecet for emergency medication. The whole duration of symptoms lasted weeks after my shot and I still struggle with this headache episode today.</p>

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1349749	5/26/2021	TX		F			BLOOD CLOTS; HEADACHES; This spontaneous report received from a consumer who reported by seeing a news report concerned a female of unspecified age. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) 1 total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. It was reported that, on an unspecified date, the patient had blood clots, and headaches. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the headaches and blood clots was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210540314, 20210539987 and 20210547453.; Sender's Comments: V0- 20210540327- Covid-19 vaccine ad26.cov2.s-This case concerns with female of unspecified age.-Blood clot. This event is considered unassessable. The event has an unknown temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

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1349750	5/26/2021			U			<p>GOT A BLOOD CLOT IN LEG; This spontaneous report received from a patient via a company representative concerned a patient of unspecified age and sex. The patient's height and weight were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) frequency one total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient got a blood clot in their leg and our vaccine is not good to compare to mRNA Vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of got a blood clot in leg was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210541027-COVID-19 VACCINE AD26.COV2.S-Got a Blood Clot in Leg. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1350390	5/26/2021	SD	56	M	3/31/2021	4/16/2021	Patient received first dose Moderna vaccine on 3/31/2021. Approximately two weeks after receiving the first Moderna vaccine patient states he started to have pain in the lower leg which was not normal. Pain increased to a point that patient sought care and was evaluated for a blood clot which he was told was "negative" as no clot was initially found. On 4/28/2021 Patient presented to pharmacy to receive second dose. Pharmacist asked how patient tolerated first dose to which he replied he had no issues, so the second dose was administered. AFTER the second dose, patient did state he was seen by a CNP for leg pain but a clot was ruled out. Approximately 3 weeks after the second dose of Moderna vaccine the patients leg pain increased to a point that he presented to the local ER and it was determined at that visit that he did indeed have a large blood clot in the leg and a second smaller clot in the upper thigh. He was sent home on Eliquis. He subsequently presented to another ER approximately one week later for uncontrolled leg pain due to massive size of blood clot in leg. At this point, patient is at home recovering.
1350400	5/26/2021		68	M	3/19/2021	4/30/2021	Patient presented to the ED for bradycardia and dyspnea present for one week prior to admission, he was found to have a second degree AV block. He underwent a procedure to correct atrial lead dislodging/placement of pacemaker. Patient was also started on anticoagulation therapy for a clot in lung. Discharged after 5 days inpatient.

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1350433	5/26/2021	MI	50	F	4/8/2021	5/8/2021	Presented 5/13 to Hospital. Presented to Hospital on 5/13 with one week of symptoms including cough, dyspnea, diarrhea. COVID-19 testing was positive on 5/8. Treatments prior to arrival included remdesivir and dexamethasone, started 5/13. She was also placed on pulse dose steroids 1000 mg/day methylprednisolone given her history of ground glass lung opacities in 2018. Progressed to high-flow nasal cannula, then BiPAP on 5/14, and was intubated on 5/17. Paralysis and proning initiated. Transferred to another hospital for possible VV ECMO candidacy. Patient with severe acute respiratory failure d/t covid who has failed treatment with the ventilator despite paralysis and proning. CTS asked to place patient on VV ECMO. 5/20/21 1135am initiated ECMO Patient is a 50yr old female with past medical history of hypertension, asthma, OSA and obesity BMI 41.5 who presented to hospital on 5/13 with progressive cough and shortness of breath for about a week. Of note, patient also has a history of respiratory failure presenting with ground glass opacities on CT scan in 2018 with unclear etiology despite bronchoscopy and serologic studies which resolved with high dose corticosteroids. Patient recently tested positive for COVID on 5/8 and received johnson and johnson vaccine in April. Patient was admitted on 5/13 and treated with decadron, remdesivir and tocilizumab. Course complicated by progressive respiratory failure requiring HFNC followed by Bipap and ultimately intubation on 5/17. Due to elevated d-dimer, lower extremity dopplers were obtained which were negative, however a heparin gtt was initiated. Course further complicated by cold left lower extremity; arterial duplex demonstrated distal popliteal artery thrombus extending into the peroneal, anterior tibial and dorsalis pedis arteries. therefore heparin was switched to argatroban and a HIT panel was sent. On 5/19 patient continued to decline despite paralytic and proning. Patient transferred to ICU for further level of care and VV ECMO evaluation. On arrival patient was started on velettri; however due to continued respiratory decline a shock call was placed for VV ECMO and patient cannulated for VV @ 1200. Cannulation was difficult and patient was felt to have an IVC thrombus as clot was seen going into the ECMO circuit during cannulation. Post cannulation she developed worsening septic shock and DIC. She received 2uprbc, 1unit cryo, 1

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							platelet, 2 FFP, 5 liters crystalloid and 1L albumin. Blood cultures positive for GPC in clusters. Escalating vasopressors (Epi/NE/vaso) and ongoing hypoxia family opted to change code status to DNR. Patient then continue to have worsening hemodynamic instability and went into PEA and ultimately asystole. She was pronounced deceased at 1815. Family was en route already due to her instability thus will be notified of her passing once they arrive. Dr. was notified of patients death.
1350516	5/26/2021	MI	71	F	3/13/2021	5/11/2021	This is a 71y.o. female hx of HTN, HLD, and breast cancer dx in 2018 with lumpectomy/radiation in 2018 taking Arimidex since presenting secondary to DIB. The patient states she had her covid vaccine Pfizer completed in March. She then decided to go to her timeshare and had flown there last week. She states that they had done multiple driving trips and had only gone to one casino that was low crowds. She states starting on Tuesday prior to flying home she developed shortness of breath with exertion to where she needed a wheelchair for transport. She denies any syncope or chest pain. She denies any history of blood clots. She denies any fever or COVID exposure. In emergency department patient is found to be Covid positive as well as have acute PE. ID consulted and pt on Heparin. seen this morning. No tobacco history, resides with her husband. To check lower extremity venous Doppler studies for completeness. Plan of care discussed with patient. To coordinate outpatient follow-up with her primary care physician, Doctor. Anticipate 6mos of anticoag ID following, on decadron and Remdesivir

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1349623	5/26/2021	TX	66	F	5/9/2021	5/9/2021	get sore arm; Anaphylactic reaction; Shortness of breath; look miserable; This is a spontaneous report from a contactable consumer (patient). A 66-year-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration, administered in Arm Right on 09May2021 (Lot Number: EW0177; Expiration Date: Aug2021) at single dose for COVID-19 immunization. Medical history included asthma since she was 8 years old, when she was a child her asthma was really bad and then she would say after 2004, she would say she went to chemotherapy and then 2005 her asthma got a lot better, didn't have it really bad as she used to, one doctor said he had heard that from patient they go through the chemo and their immune system change, she carried her little inhaler, but she don't have (incomplete sentence), she had asthma but not really bad, she was not like walking around every day with asthma packs but she have asthma and she keep little inhaler, for eg; if there is lot of pollen in air then she will need to take out her inhaler; breast cancer; seizure; hypertension, high cholesterol. Concomitant medications included zonisamide taken for seizure, lacosamide (VIMPAT) taken for seizure, losartan taken for hypertension, atorvastatin taken for high cholesterol, all start and stop date were not reported. Some years ago when she in 2005 when she was on the end like she said its 2005 and she was right on the end of being treated for breast cancer. she was taking, the doctor put her on Tamoxifen and she woke up one morning to really short of her breath and she thought it was her asthma, so the lady she was staying with said you look miserable and she said let her get back on the store and have her take her to the ER she said call now and it turned she had a blood clot in her lungs but 'Dr PRIVACY' (not spelled) who was treating her, he was a cancer specialist he said PRIVACY she was so proud of her, he said that she got to take you off the Tamoxifen, it was that Tamoxifen that caused blood clot in your lung. A blood clot in the lungs was the side effect of the Tamoxifen. Tamoxifen was one of the drug they give women who have had breast cancer and are right at the end of the treatment and put us on Tamoxifen and she ended up with a little bit of blood clot in her lungs. He said that was one of the effects of Tamoxifen. So, that was like in 2008, 2009 it was 12 years ago, could have 11 years ago but this goes to



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show her body may have potency for allergic reaction. The patient stated she had short of her breath because she did have allergic reaction shortness of breath with Pfizer Vaccine first dose at a pharmacy yesterday 09May2021, had been given Prednisone so. She did shortness of breath about 45 minutes after she took it because we had to sit there about she would say we were sitting there about 20 minutes and he finally said well you all can get up and leave and then about say 15 minutes later she start getting shorter and shorter of her breath. " The patient stated, she just needed to Pfizer certainly reporting acting as if this was just a completely safe vaccine there are unsafe reaction to this vaccine so she wanted to get this going okay, she was 66 years old she end up going to the ER, they didn't give her Epipen' (not clarified further) so that's when she started to get sore arm, she had an anaphylactic reaction to this drug. Now if this was the wrong number to report it to then she would call to get to agency she needed to report it to. she was on the Prednisone now. Sometimes it was difficult for she to breathe, so the emergency room they 'have' (not clear) she up with enough medication now, so she had got plenty of medication now." She stated it just happened yesterday, when she saw on the news that they had approved it to be for children and it bothers me that they, this was just a break simple drug no very safe. Yesterday when she first started getting short of her breath she was in denial and didn't want to because she was really started shorter of my breath and the pharmacist that administered he even said he knew that it was the reaction to the drug because she was full animated before he administered the vaccine because she was sitting there talking to the two ladies and you know jabbering and remember the days because of flu shots and how the government used it, they didn't wanted knowledge when people talked about how the flu shot (Unspecified Shot) made them sick and she was just jabbering so he knew it was reaction to the vaccine. Here was this lady 'who was so animated and talking and now she can barely hold her head up' (not clarified further). Patient confirmed Prednisone as treatment. As for the treatment patient stated, "Took the 2 Prednisone and what happened was, if I wasn't even going to go get Prednisone, but the shortness of breath was going transient, what I mean is first of all I talk and I do fine and

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then all of a sudden I get short of my breath again and then looked like I had a good night and then I woke up and my lungs tightened up again and then earlier this evening I called on phone and tell them I have to take Prednisone because my breath was getting short again." Prednisone details were 10 mg 4 tablet by mouth every day for 5 days then 2 tablet every day for 3 days, so 1 every day for 2 days. As for other medications: patient stated she was on seizure medications daily. She was on treatment for asthma, she had a little inhaler she keep in her purse for eg; if there's pollen in the air, when she got out and then maybe get short of her breath if there's pollen in the air yeah she need her little inhaler, but she was on daily treatment for her seizures she was on 800 mg a day for the seizures, Zonisamide and Vimpat. In fact that day she wouldn't take any other medication because she thought well she was not taking any other medication' (not clarified further) to mix it with this vaccine. Normally she take the 25 mg for high blood pressure but she won't take it that day she think it's called Losartan or something. Little bit of high blood pressure they cut that down because her blood pressure had gotten, she had some high blood pressure yes it's called 25 mg of Losartan. Yeah she thought, she won't take it that morning because she though well just lay off all of that stuff that day and so we can take the vaccine, 'mix none of that with vaccine' (not clear), that day the only medication that she was taking was her seizure medication (Zonisamide and Vimpat) because you can't skip medication but the Losartan and Atorvastatin that's for high cholesterol she won't take that either that day. The asthma now, she did have asthma but it's a kind of that's one the things that you have it but you are not on daily medication for it. She do keep her inhaler with because sometimes she go in buildings where they have air condition on really high and it gets to her lungs. In fact when this happened and the guy wanted to call 911 we decide well let's see if new inhaler (Unspecified Medication) worked and it wasn't quite rescuing her lungs like it should." For Vimpat details patient stated, it's a pill (formulation not clarified further), it's 100 mg so she took one in the morning and one in the evening. For Zonisamide details patient stated, Each capsule was 100 mg, so she take two 100 in the morning and two 100 before she go to bed." As for lab Test patient sated, "Just

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							had a MRI but no dye just the plain MRI with no dye or anything. Had MRI without dye, no dye." hen probed for the MRI result, consumer stated, "No because this was the seizure doctor ordering that." As for date of MRI patient stated, "That was on the 4th I think, but what was the MRI have to do with having a reaction to this vaccine, because the MRI. Doctor want specifically had no dyes it was just no dyes but that was the doctors that treat me for seizure he wanted the MRI done, yeah this was the 4th of May." When probed if adverse events are improved, worsened or persisting, consumer stated, "today you know just a short of the breath I am really short of my breath but now when I have taken the Prednisone I am breathing a lot better, breathing so much better yes, you can mark improve (not clarified further)." The outcome of the event shortness of breath was recovering, of other events was not recovered.
1350574	5/26/2021	TN	51	F	3/16/2021	3/30/2021	Both sides of my neck were very swollen. There was extreme pain on my right arm. The pain was severe and numbness in my finger. I went to the ER and they said I have radial thrombus, a clot in the radial artery. Before the shot, my heart was checked multiple times and I was fine. After the shot, my coronary arteries are now very small. There are now luminal changes inside my coronary arteries which are still now very small. I now have been diagnosed with CAD. I had a heart cath on March 29. My arm is still in a lot of pain. My neck is still swollen.
1350684	5/26/2021	NE	58	F	4/22/2021	5/18/2021	Patient seen in ER with pulmonary embolism , (L) lower extremity blood clot

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1350702	5/26/2021	CA	31	F	5/11/2021	5/20/2021	A 31-year-old female received the first dose of mRNA Covid-19 vaccine (EW0179, Pfizer) IM on May 11th, 2021, without any reported clinical problem. Patient has no known medical illness and no previous history of DVT or PE. Patient had negative COVID-19 PCR on April 16th, 2021. She had 3 healthy pregnancies and no miscarriages. She did not have any long flights or car rides for the last several months, except for over 2 months ago. Patient denies any allergic problems, smoking tobacco or use any oral contraceptives. However, patient stated patient's father has a history of unprovoked DVT. On May 20th, 2021 patient experienced worsening of left-sided chest pain and shortness and visit ED on May 22nd, 2021. At the ED, physical examination was unremarkable. Blood tests (renal, hepatic function) were normal and labs resulted in D-dimer 0.86 mcg (FEU)/mL and platelet count 288k (Baseline of 200-250k). CT showed suspected very subtle segmental and subsegmental PE involving the left lower lobe. Duplex did not show evidence of DVT in either lower extremity. Given the family history of DVT, hypercoagulable workup was done with the following results: homocysteine level 5.5, thrombin time 14.9, negative factor II and V mutations, cardiolipin Ab IgG < 1.6 GPL (normal range < 20 GPL), lupus anticoagulant with reflex indeterminate, protein C activity 92 (normal range 70-130%) and protein S activity 67 (normal range 65-140%). Patient was admitted to the hospital. At the ED, enoxaparin 60 mg x 1 and morphine 4 mg x 1 were given. Later, it was switched to apixaban 10 mg BID on the floor and patient was discharged with apixaban 5 mg BID x 7 days and once daily BID. Patient is scheduled to follow up with her PCP in regards to the duration of therapy.
1350784	5/26/2021	NY	40	F	5/26/2021	5/26/2021	High fever of 104.3 Heart Palpitations with chest pain, shaking/chills throughout body and splitting headache (not migraine). Heavy menstrual bleeding with clots for long periods of time

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1350849	5/26/2021	TX	56	F	3/7/2021	3/29/2021	Two weeks after receiving the vaccine my legs started swelling. I went to my PCP and he measured my legs and sent me to hospital because he said that it looked like I had blood clots. While in the ER, they started performing tests, and they found a DVT in the left leg and to PE's, one on each lung. I was under observation because I was given Lovonex to thin my blood. While in the hospital the swelling started to go down and that is when I was discharged. I am now seeing a vein specialist and a pulmonary doctor. I was given Eloquis 5mg 2x per day. I am still having pain and swelling in both legs, but the leg with the DVT is worse. It is very hard to walk around because my left leg will swell a lot.
1350963	5/26/2021	CA	47	F	4/3/2021	4/15/2021	Twelve days after the vaccine I got a severe headache with blurry vision. I was also short of breath and my legs were swollen. I was dizzy and had body aches mostly on my left side. My left kidney was inflamed. The pain went all the way on the left side of my body from my ribs to my legs. My left leg was the most swollen. Many of the symptoms lasted for two and a half weeks. The headache lasted for three days. The first week was the worst. When I went to the ER after a week they did not find any blood clots. The aches pains and swelling in my legs came and went over the course of three weeks. I was very tired when the symptoms were present.
1351071	5/26/2021	FL	54	M	4/5/2021	4/18/2021	Major blood clot in the brain that caused a stroke He is still in hospital
1351118	5/26/2021	IN	23	F	3/31/2021	5/19/2021	She is 11 weeks pregnant. On 5/19/2021 began feeling pain in her left groin area. Didn't think too much about it. 5/20/2021 swelling and pain in left groin area. Went to urgent care. scheduled ultrasound. Blood clot in Left groin detected. Hospitalized and treated for clot with blood thinners.

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1349453	5/26/2021	NC	35	F	4/2/2021	4/1/2021	minor soreness in my arm; This is a spontaneous report from a contactable consumer (patient). This non-pregnant 35-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; lot number EW0150) via an unspecified route of administration in the right arm on 02Apr2021 at 16:30 (at the age 35-years-old) as a single dose for COVID-19 immunisation. Medical history included blood clot from an unknown date and unknown if ongoing. Prior to vaccination the patient had not been diagnosed with COVID-19 and had not received any other vaccines in the four weeks prior to the COVID vaccine. Concomitant medications included apixaban (ELIQUIS) from an unknown date for blood clot. The patient reported experiencing minor soreness in her arm with the first shot on an unspecified date. The patient received the second dose of BNT162B2 (lot number EW0170) in Apr2021. The clinical outcome of minor soreness in arm was unknown. It was also reported that since vaccination the patient had not been tested for COVID-19.
1351106	5/26/2021	MN	30	F	4/29/2021	5/22/2021	Heavy menstrual bleeding (menorrhagia), massive clots followed by bleeding, ongoing 11 days. Abnormally high compared to any menstrual cycle in entire life.

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1349422	5/26/2021	WI	51	F	4/8/2021	4/8/2021	My period came the day of vaccination around 6:00pm. Started with a clot and stopped, 2 days later it came again. I had my period 5 days before vaccination.; This is a spontaneous report from a contactable other Healthcare Professional (patient). A 51-year-old female patient (not pregnant) received bnt162b2 (Pfizer-BioNTech Covid-19 Vaccine), dose 1 via an unspecified route of administration, administered in Arm Right on 08Apr2021 10:15 AM (Lot Number: EW0150) at single dose for covid-19 immunization. Medical history included hypertension, generalized anxiety and Gel nail enamel allergy. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included propranolol (PROPANOLOL) taken for an unspecified indication, start and stop date were not reported; alprazolam taken for an unspecified indication, start and stop date were not reported; cetirizine hydrochloride (CETRIZINE) taken for an unspecified indication, start and stop date were not reported; fish oil taken for an unspecified indication, start and stop date were not reported. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced her period came the day of vaccination around 6:00pm. Started with a clot and stopped, 2 days later it came again. She had her period 5 days before vaccination. The adverse event resulted in doctor or other healthcare professional office/clinic visit. It was unknown if treatment was received for the adverse event. Outcome of event was not recovered. COVID-19 test post vaccination included nasal swab, Negative. Follow-up attempts are completed. No further information is expected.

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1348844	5/26/2021	CA	62	M	4/22/2021	4/23/2021	Day after 2nd dose, discomfort stayed in bed. 2nd day after dose shoulder pain radiating to chest, during night intense chest pain with extremely shallow breathing. By morning chest pain so bad I went to E.R. I was admitted with normal EKG and oxygen levels. Elevated test that indicates blood clot in lung. CT scan done. Diagnosis Pulmonary Embolism. Was admitted to hospital for 2 days while undergoing heparin and warfarin therapy and pain relief. Prescribed blood thinners for 6 mos. After release severe fatigue and low HGB levels limited walking of more than 50' without losing consciousness. It has been 1 month and still can only walk 100' without lightheadedness.
1348878	5/26/2021	GA	38	F	4/13/2021	4/24/2021	I received the first does of the Covid Vaccine on April 13, 2021. Less than two weeks after being vaccinated with the Pfizer brand of vaccine I was hospitalized for an abdominal cyst and whilst in the hospital, I began having difficulty breathing and a CT scan of my chest showed that I had two blood clots [pulmonary embolism] in my right lung. I had to be placed on Heparin and I am currently on Eliquis.



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1349017	5/26/2021	SC	55	M	5/19/2021		<p>MULTIPLE PULMONARY EMBOLISM; MULTIPLE BLOOD CLOTS; SUSPECTED CLINICAL VACCINATION FAILURE; SUSPECTED COVID-19 INFECTION; This spontaneous report received from a health care professional concerned a 55 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, Expiry: Unknown) dose not reported, 1 total, on APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient developed multiple pulmonary embolism included multiple blood clots. On 19-MAY-2021, after 4 week of vaccination, the patient was diagnosed with suspected covid-19 infection (suspected clinical vaccination failure) and was not doing well. The patient got hospitalized. Number of hospitalization days was not reported. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the suspected covid-19 infection, suspected clinical vaccination failure, multiple pulmonary embolism and multiple blood clots was not reported. This report was serious (Hospitalization Caused / Prolonged and Life Threatening). This report was associated with product quality complaint number: 90000180239. The suspected product quality complaint has been confirmed to be not voided based on the PQC evaluation/investigation performed.; Sender's Comments: V0:20210539965-covid-19 vaccine ad26.cov2.s - multiple pulmonary embolism,multiple blood clots,suspected covid 19 infection. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). V0:20210539965 covid-19 vaccine ad26.cov2.s - suspected clinical vaccination failure This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically:SPECIAL SITUATIONS</p>

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1349019	5/26/2021			M		5/1/2021	DEEP VEIN THROMBOSIS; PULMONARY EMBOLISM; This spontaneous report received from a patient via a company representative concerned a male of unspecified age. The patient's height, and weight were not reported. The patient had no family or personal history of clots and no provoking factors. The patient received covid-19 vaccine (suspension for injection, route of admin, and batch number were not reported) dose was not reported, 1 total, administered on 05-APR-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 18-MAY-2021, the patient presented to the emergency department with one week of leg swelling and pain. The patient work up was notable for deep vein thrombosis ultrasound positive for deep venous thrombosis in the left lower extremity in distal femoral and popliteal and PE study showing filling defect in the lobar and interlobar pulmonary arteries extending to segmental and subsegmental pulmonary arteries, right greater than left. On MAY-2021, the subject experienced deep vein thrombosis and pulmonary embolism. The action taken with covid-19 vaccine was not applicable. The outcome of deep vein thrombosis and pulmonary embolism was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: COVID-19 VACCINE deep vein thrombosis, pulmonary embolism. This event(s) is considered unassessable . The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1349025	5/26/2021		30	M	4/1/2021		<p>THROMBOSIS/MORE MILD CLOT ONE IN THE LEG/BLOOD CLOT DISORDER; THROMBOCYTOPENIA; INCREASING LOWER BACK; LEG PAIN; This spontaneous report received from a company representative Via social media concerned a 30 year old male. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total dose was administered on 08-APR-2021 for prophylactic vaccination. The batch number was not reported. The Company was unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On unknown date in APR-2021, the patient experienced increasing low back pain and leg pain (around one week) after vaccination. The patient was hospitalized (date unspecified) and was treated for vaccine-induced thrombotic thrombocytopenia (VITT) (coded as thrombosis and thrombocytopenia). The patient received treatment, which includes intravenous immune globulin, the anticoagulant argatroban and prednisone. Doctors stated, patient was responding well to treatment and should be released soon (discharge details unspecified). It was reported that, patient had more mild clot, and one in the leg. But certainly it was a real clot, and as patient was in his early 30's, so it was likely and could be linked to the vaccine. The action taken with covid-19 vaccine was not applicable. The patient was recovering from thrombocytopenia, thrombosis, low back pain and leg pain. This report was serious (Hospitalization Caused / Prolonged). This is a spontaneous report concerning a 30 year old male, unknown ethnicity, patient who experienced increasing low back pain and leg pain around one week after receiving the Covid-19 vaccine. The patient was hospitalized on an unspecified date and was treated for vaccine-induced thrombotic thrombocytopenia (VITT). The patient was responding well to treatment, which included intravenous immune globulin, an anticoagulant (argatroban) and prednisone. The patient's weight, height, and medical history were not reported. There is mention of patient having vaccine-induced thrombotic thrombocytopenia but information is limited in this case. A relationship with Janssen Covid-19 vaccine cannot be ruled out; thus the relationship is considered</p>

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1349042	5/26/2021	NY		U			<p>indeterminate. Additional information has been requested.</p> <p>DROPPING DEAD; HEART ATTACKS; BLOOD CLOTS; STROKES; BRAIN DAMAGE; HEART CONDITIONS; This spontaneous report received from a consumer who reported reading from many personal social media accounts which concerned multiple patients of unspecified age and sex. No past medical history or concurrent conditions were reported. The patients received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow up will be requested for this case. No concomitant medications were reported. It was reported that, the patients were suffering from blood clots, dropping dead, had strokes, heart attacks, heart conditions and brain damage after vaccination. It was also reported that, the patients were perfectly healthy before and now they would never be the same. On an unspecified date, the patient died from unknown cause of death. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patients died of unknown cause on an unspecified date, and the outcome of blood clots, strokes, heart attacks, heart conditions and brain damage was not reported. This report was serious (Death, and Other Medically Important Condition). This case, from the same reporter is linked to 20210534943.; Sender's Comments: V0: 20210544901-covid-19 vaccine ad26.cov2.s -Dropping dead, brain damage, blood clots, heart attacks and strokes. This event(s) are considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH</p>

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1349111	5/26/2021	SC	49	F	3/27/2021	4/25/2021	Dizziness (After 2nd Vaccine); Labored Breathing (After 2nd Vaccine); Low Blood Pressure (After 2nd Vaccine); Multiple Blood Clots Red area under the injection site, Symptoms were returning (After 2nd Vaccine); Spider Veins going from Arm to Chest (After 2nd Vaccine); Hot to the touch left Arm (After 2nd Vaccine); Protruding Red Veins on Left Arm (After 2nd Vaccine); Purple Swollen entire left arm from under the Injection Site to fingers (After 2nd Vaccine); Red band (3 inches wide and 4-5" long) Below the Injection Site (After 2nd Vaccine); Swollen 1/2 inch below the Injection Site; Fever (After 2nd Vaccine); Chills (After 2nd Vaccine); Left Arm Hurt (After 2nd Vaccine); This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Multiple Blood Clots Red area under the injection site, Symptoms were returning (After 2nd Vaccine)), PERIPHERAL SWELLING (Purple Swollen entire left arm from under the Injection Site to fingers (After 2nd Vaccine)), SPIDER VEIN (Spider Veins going from Arm to Chest (After 2nd Vaccine)), DIZZINESS (Dizziness (After 2nd Vaccine)), DYSPNOEA (Labored Breathing (After 2nd Vaccine)), HYPOTENSION (Low Blood Pressure (After 2nd Vaccine)), SKIN WARM (Hot to the touch left Arm (After 2nd Vaccine)), PAIN IN EXTREMITY (Left Arm Hurt (After 2nd Vaccine)), SUPERFICIAL VEIN PROMINENCE (Protruding Red Veins on Left Arm (After 2nd Vaccine)), VACCINATION SITE ERYTHEMA (Red band (3 inches wide and 4-5" long) Below the Injection Site (After 2nd Vaccine)), VACCINATION SITE SWELLING (Swollen 1/2 inch below the Injection Site), PYREXIA (Fever (After 2nd Vaccine)) and CHILLS (Chills (After 2nd Vaccine)) in a 49-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 045B21A and 017B21A) for COVID-19 vaccination. Concurrent medical conditions included Ulcerative colitis. Concomitant products included MESALAZINE (LIALDA), CETIRIZINE HYDROCHLORIDE (ZYRTEC [CETIRIZINE HYDROCHLORIDE]), MULTIVITAMIN [VITAMINS NOS] and VITAMIN C [ASCORBIC ACID] for an unknown indication. On 27-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 24-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-

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19 Vaccine) (Intramuscular) dosage was changed to 2 dosage form. On 25-Apr-2021, the patient experienced PAIN IN EXTREMITY (Left Arm Hurt (After 2nd Vaccine)), PYREXIA (Fever (After 2nd Vaccine)), and CHILLS (Chills (After 2nd Vaccine)) . On 26-Apr-2021, the patient experienced VACCINATION SITE ERYTHEMA (Red band (3 inches wide and 4-5" long) Below the Injection Site (After 2nd Vaccine), and VACCINATION SITE SWELLING (Swollen 1/2 inch below the Injection Site) .On 27-Apr-2021, the patient experienced PERIPHERAL SWELLING (Purple Swollen entire left arm from under the Injection Site to fingers (After 2nd Vaccine)). On 28-Apr-2021, the patient experienced SPIDER VEIN (Spider Veins going from Arm to Chest (After 2nd Vaccine)), SKIN WARM (Hot to the touch left Arm (After 2nd Vaccine)) and SUPERFICIAL VEIN PROMINENCE (Protruding Red Veins on Left Arm (After 2nd Vaccine)). On 02-May-2021, the patient experienced THROMBOSIS (Multiple Blood Clots Red area under the injection site, Symptoms were returning (After 2nd Vaccine)) (seriousness criteria medically significant), DIZZINESS (Dizziness (After 2nd Vaccine)) DYSPNOEA (Labored Breathing (After 2nd Vaccine)) and HYPOTENSION (Low Blood Pressure (After 2nd Vaccine)). On 02-May-2021, DIZZINESS (Dizziness (After 2nd Vaccine)) and HYPOTENSION (Low Blood Pressure (After 2nd Vaccine)) outcome was unknown, DYSPNOEA (Labored Breathing (After 2nd Vaccine)) had resolved. On 14-May-2021, PYREXIA (Fever (After 2nd Vaccine)) and CHILLS (Chills (After 2nd Vaccine)) had resolved. At the time of the report, THROMBOSIS (Multiple Blood Clots Red area under the injection site, Symptoms were returning (After 2nd Vaccine)), PERIPHERAL SWELLING (Purple Swollen entire left arm from under the Injection Site to fingers (After 2nd Vaccine)), SPIDER VEIN (Spider Veins going from Arm to Chest (After 2nd Vaccine)), SKIN WARM (Hot to the touch left Arm (After 2nd Vaccine)), PAIN IN EXTREMITY (Left Arm Hurt (After 2nd Vaccine)), SUPERFICIAL VEIN PROMINENCE (Protruding Red Veins on Left Arm (After 2nd Vaccine)), VACCINATION SITE ERYTHEMA (Red band (3 inches wide and 4-5" long) Below the Injection Site (After 2nd Vaccine)) and VACCINATION SITE SWELLING (Swollen 1/2 inch below the Injection Site) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges

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are provided in parenthesis if available): On 02-May-2021, Blood pressure measurement: low (Low) low. On 10-May-2021, Full blood count: wbc very high (High) WBC very high. On an unknown date, Full blood count: normal (normal) normal. On an unknown date, Ultrasound scan: multiple blood clots in the red area (abnormal) Multiple Blood Clots in the Red area under the injection site. The patient did not have a medical history of blood clots. On 25APR2021 the patient experienced fever, chills, and her arm hurt. On 26APR2021 her left arm hurt really bad and was swollen 1/2 inch below the injection site (3 inches wide and 4-5" long) and also had a red band wrapped around the left arm below the injection site. On 27Apr2021 the patient's entire arm from under the Injection site to her fingers became swollen and purple. The patient visited the emergency room (ER) and was told to elevate it and place ice on the area and was prescribed Advil. On 28APR2021 the patients veins were protruding, were red and hot to the touch and she experienced spider veins started going to her chest. On 30Apr2021, she went back to the ER. The doctor gave her a steroid and suggested an ultrasound. 02MAY2021 she started experiencing labored breathing, dizziness, and low blood pressure. She visited the ER again. The doctor performed an ultrasound, an EKG, a chest x-ray, and a hot scan of the heart. The ultrasound of the left arm showed multiple blood clots in the red area under the injection site. The doctor started her on Eliquis. On 10May2021 the symptoms were returning. A complete blood count (CBC) showed white blood cells (WBC) were very high but a second blood level showed, on an unknown date showed normal WBC. On 14May2021, the swelling on the arm had come down and her arm was still purple but a lighter color purple with dark protruding veins and spider veins still visible. The patient continued taking Eliquis. Most recent FOLLOW-UP information incorporated above includes: On 14-May-2021: Significant F/U Case & Email ID Add. Conmeds., medical history, Lab data, Product details, iNarrative updated; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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1349508	5/26/2021	CA	71	M	4/14/2021	4/14/2021	This is a spontaneous report from a contactable consumer(patient). A 71-year-old male patient received first dose BNT162B2 (Pfizer BioNTech COVID-19 vaccine, lot number EP7533), via an unspecified route of administration at Arm Left on 14-APR-2021 at the 71 years old at single dose for COVID-19 immunization. The medical history was ongoing Diabetes, he did have the COVID-19 virus in Dec 2020 and not ongoing, pneumonia and not ongoing. The concomitant medications were none. The Historical Vaccine was pneumonia vaccine for pneumonia immunization. There was no Prior Vaccinations within 4 weeks.The patient experienced soreness of arm after getting the dose of the vaccine in Apr2021. It happens every time he moves his arm. He went to Emergency Room last 30Apr2021 due to cough, phlegm, and congestion in Apr 2021. He tested negative for COVID. He wants to know if this is a normal side effect of the vaccine and how long it usually last and 2nd dose would be given on 12May2021.He saw that the other COVID-19 vaccine, the Johnson and Johnson COVID-19 vaccine was taken off the market because of blood clots. He reports that his arm where he received his COVID-19 vaccine injection stayed sore on 15Apr2021. It did get better but came back worse and he cant get rid of the soreness in his left arm. He's tried heating pads and everything. Its his left arm.If he moves a certain way his arm hurts. Is this something to worry about. He's read that some people who received the Johnson and Johnson vaccine had blood clots. The sore arm never actually went away but it was easier for him to put up with. Then all of a sudden it came back worse. It's not affecting him unless he moves a certain way and that's when his arm starts acting up and it started getting worse. He had gone to the emergency department recently because he was having congestion, spitting out phlegm, and a cough in Apr 2021. He was tested for the Covid 19 virus there. The doctor that saw him told him he had some other kind of virus in Apr 2021 and that the virus would take time to go away. He went to the emergency department on 30Apr2021. He received his negative Covid 19 results on 03May2021. In Apr 2021 He started feeling bad a couple days before 30Apr2021. He has had pneumonia in the past and he did not want to get pneumonia because once he gets pneumonia it's bad. The last time he's had pneumonia was about 2



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years ago. He reports he has had the pneumonia vaccine. He still has the cough and it's a little bit congested but it's better. He's not spitting out the phlegm anymore so he figures it's going away. He didn't even go inside the emergency department. He had the COVID-19 virus test outside and the doctor came outside and checked his breathing and stuff and told him he had a virus but the doctor will go ahead and do the COVID-19 virus test just in case. He did not have pneumonia. When probing concomitant medications and medical history, he states he has diabetes. He does not add any medications. He does report he did have the COVID-19 virus in Dec 2020 and he was laid up for a while but his case wasn't severe. The events cough, congestion, spitting out phlegm require a visit to Emergency Room. The patient underwent lab tests and procedures, which included COVID-19 test on 30-APR-2021: Negative (He received his negative COVID-19 results on 03-May-2021). The outcome of the events cough, Phlegm, congestion was recovering, the events Pain in arm, Vaccination site pain was not recovered, the others was unknown. Information on Lot/Batch number was available. Additional information has been requested.

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1349413	5/26/2021	CA	48	F	2/26/2021	2/1/2021	Fever wiped me out; Fatigue for a few weeks; Stroke like headpain; Rapid heart rate; Felt like having stroke then heart racing/stroke like headpain; Heart racing; Chills; Pain; Arm felt like it was beaten with a bat; This is a spontaneous report from a contactable consumer(patient), reported in response to Non-HCP letter sent in cross reference to 2 reports. This is second case of two reports. A 48-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injectio), intramuscularly administered in right arm on 26Feb2021 09:00 am (at an age of 48-year-old during vaccination) as 2nd dose, single dose for covid-19 immunisation. The patient medical history included Hashimotos disease from 2000 and ongoing, high blood pressure from unknown date and ongoing, breast cancer from 2015 underwent lumpectomy on Dec2015, ovarian cyst from 2020 and ongoing, Afib (atrial fibrillation) from Apr2019 to an unknown date, atrial fibrillation event due to too much thyroid medication and heart had extra beat benign. The patient's family history included methylation issues, cardiac issues, cancer, higher BP, medication don't work like they should on many family members. Concomitant medication(s) included levothyroxine sodium (TIROSINT) taken for Hashimotos disease from an unspecified start date and ongoing, levothyroxine (LEVOTHYROXINE) oral taken for Hashimoto's disease from an unspecified start date and ongoing, alprazolam (XANAX) taken for anxiety from an unspecified start date and ongoing; mecobalamin (B12 METHYLCOBALAMIN) methylated B-12 taken for methylenetetrahydrofolate reductase deficiency (MTHFR deficiency) from an unspecified start date and ongoing; vitamin c [ascorbic acid] (VITAMIN C [ASCORBIC ACID]), zinc (ZINC); ergocalciferol (VIT D); calcium, magnesium (CALCIUM MAGNESIUM [CALCIUM;MAGNESIUM]); calcium levomefolate (METHYL FOLATE). The patient previously received of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Batch/Lot number: Not reported), intramuscularly administered in right arm on 28Jan2021 13:30 as 1st dose, single dose for covid-19 immunisation. The vaccination facility was reported as high school for 1st dose and public health clinic for 2nd dose. The patient had not taken any other vaccine 4 weeks prior to Covid-

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19 vaccination. On 31Jan2021, the patient underwent lab test and procedures which include blood work: unknown result, did not show heart attack or blood clot, apple watch as abnormal, heart rate was 144 at rest and x-ray as normal. The patient stated that she had ER trip after vaccination. Doctor though she had an embolism and wanted to do a CT. Because of her breast cancer she wanted to avoid heavy radiation and instead she did her x-ray and blood work. On 31Jan2021, the patient experienced two cardiac events. Heart racing was major, so she went to emergency response center. Her oxygen was 90, her heart rate was 144 at rest. Second time lasted a few minutes. On the same day (31Jan201), the patient stated that both events wake her from sleep and took her breath away and also felt that dermal filling around mouth felt numb right after 1st vaccine around 20 min after which lasted a while ago. On unknown date in Feb2021, the patient experienced stroke like headpain, felt like having stroke then heart racing, fever wiped her out, rapid heart rate, chills, pain, fatigue for a few weeks. She also experienced arm felt it was beaten with a bat. These events were presented for nighttime for 2 days. The seriousness of the events considered as disability and the event arm felt like it was beaten with a bat was assessed as non-serious. Therapeutic measures such as heated blanket was taken to chills and fever. The patient took treatment medication such Tylenol, Xanax to slow heart rate and electrolytes for the resulted events. The outcome of the events was recovered for all events in Feb2021 and unknown for the event arm felt like it was beaten with a bat.

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1349588	5/26/2021	FL	78	M	2/27/2021	3/12/2021	<p>Pulmonary embolism; DVT; This is a spontaneous report from a contactable nurse (patient's wife). A 78-year-old male patient received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EN6201; Expiration Date: 30Jun2021), via an unspecified route of administration on 27Feb2021 (at the age of 78-year-old) as single dose for COVID-19 immunization. Medical history included diabetes mellitus, Liver cirrhosis, thrombocytopenia, kidney stone, sarcoidosis, blood pressure (unspecified condition) and high cholesterol and a pacemaker (cardiac pacemaker insertion). Concomitant medications included insulin (manufacturer unknown), simvastatin (manufacturer unknown), hydrochlorothiazide (manufacturer unknown), carvedilol (COREG) taken for blood pressure, and omeprazole (PROTONIX). On 12Mar2021, the patient developed pulmonary embolism and DVT (deep vein thrombosis) that requiring a hospitalization on 12Mar2021. The nurse reported, "He went into the hospital 12Mar2021 that's when they find out he had pulmonary embolism and DVT. They putted the IVC filter for blood clot." On 12Mar2021, the patient was hospitalized for pulmonary embolism and DVT. Therapeutic measures were taken as a result of pulmonary embolism and DVT. The clinical outcome of the events pulmonary embolism and DVT was unknown. Additional information has been requested and will be provided as it becomes available.; Sender's Comments: Based on available information and known drug profile it is unlikely that the reported pulmonary embolism and DVT (deep vein thrombosis) were causally related to BNT162b2. These are intercurrent medical conditions. Case will be reassessed if additional information is received. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.;Linked Report(s) : US-PFIZER INC-2021528357 same patient/reporter, different vaccine dose with different events separated by time gap.</p>

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1349617	5/26/2021	PA		F	4/19/2021	4/1/2021	Chills; sick; Fever; hard for me to walk; Atrial fibrillation; blood clot in her finger; thumb right now is real cold; the tip of my thumb is numb; tip was numb and real cold- there was no circulation going on; Irregular heartbeat; Blood pressure high; Headache; Muscle ache; This is a spontaneous report from a contactable consumer, the patient, via the Pfizer-sponsored program. A female patient of an unspecified age received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot: Unknown), via an unspecified route of administration on 19Apr2021 as a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient previously received the first dose BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 19Mar2021 for COVID-19 immunization and felt fine (no adverse event). On an unspecified date in Apr2021, four days after the second vaccination, the patient was sick for seven days with chills. On an unspecified date in 2021, the patient had terrible side effects such as muscle ache and fever ("99 something") for 7 days. On an unspecified date in 2021, the patient experienced headache, blood pressure high, irregular heartbeat, atrial fibrillation and the calf was "real bad"- it was hard for the patient to walk. The patient called her doctor and got tested for COVID-19 two weeks after the vaccination, in May2021, with negative results. The doctor stated that the patient got so sick from the shot. On an unspecified date in 2021, the patient's thumb was like a blood clot to the thumb (blood clot in her finger), the tip was numb and real cold- there was no circulation going on. The patient went to the emergency room where an ultrasound was performed on the arm to see if there were any blood clots in there, with unknown results. The patient was treated with an unspecified "pill" for irregular heartbeat. The patient was scheduled for an echocardiogram and heart monitor. The clinical outcome of atrial fibrillation, blood clot in her finger, thumb right now is real cold, the tip of my thumb is numb, "tip was numb and real cold- there was no circulation going on", irregular heartbeat, blood pressure high, headache, muscle ache, chills, sick, fever, "hard for me to walk" was unknown. Information on the lot/batch number has been requested

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1349462	5/26/2021	WV	45	F	4/22/2021	4/23/2021	Late menstrual period by 2 weeks and extreme heavy period (thin, clotty) with lots of cramps; Late menstrual period by 2 weeks and extreme heavy period (thin, clotty) with lots of cramps; Late menstrual period by 2 weeks and extreme heavy period (thin, clotty) with lots of cramps; Fever; chills; nausea; headache; muscle heaviness; metal taste in mouth; sinus swelling; sneezing; extreme fatigue; This is a spontaneous report received from contactable consumers (one of them is the patient). A 45-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: ER8737) via an unspecified route of administration, administered in right arm on 22Apr2021 13:00 (at the age of 45-year-old) as 1st dose, single for COVID-19 immunisation. Medical history included high blood pressure and allergy to sulfa drug. Patient was not pregnant. The patient's concomitant medications were not reported. On 23Apr2021 11:45, patient experienced fever, chills, nausea, headache, muscle heaviness, metal taste in mouth, sinus swelling, sneezing and extreme fatigue. On 03May2021 03:00, patient had late menstrual period by 2 weeks and extreme heavy period (thin, clotty) with lots of cramps on an unspecified date when it did come. The patient did not receive treatment for the events reported. Outcome of events was recovering. No follow-up attempts are needed. No further information is expected.
1351204	5/26/2021	KS	56	F	3/23/2021	4/6/2021	Patient was admitted to the hospital on April 6 with superior mesenteric vein thrombosis. Presented due to periumbilical abdominal pain lasting a week that has gotten worse. Other risk factors for clots include 2 years use of oral contraceptives and the patient having a BMI of 38.

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1349510	5/26/2021	TX	41	F	4/29/2021	5/4/2021	I usually bleed lightly now its heavy and clot as well.; menstruation heavy lasting over week; This is a spontaneous report from a contactable consumer (patient). A 41-year-old female patient (non-pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in arm right on 29Apr2021 11:00 (Lot Number: EW0151) at the age of 41-year-old as single dose for covid-19 immunization. Medical history included none. The patient had known allergies. The patient's concomitant medications were not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient experienced menstruation heavy lasting over week on 04May2021 12:00, it started on 25Apr-28Apr normal 3 day. The patient had shot taken on 29Apr2021. It (menstruation) restarted 30th and continues still of day of 05May2021. She usually bleed lightly now its heavy and clot as well on 04May2021 12:00. No treatment was received for events. Outcome of events was unknown.

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1349543	5/26/2021		49	F	4/29/2021	5/3/2021	acute DVT of left peroneal vein (in the left calf); This is a spontaneous report from a non-contactable consumer (patient). This 49-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number not provided), via an unknown route, on 29Apr2021 11:30 (at the age of 49-year-old) at single dose in the left arm for COVID-19 immunisation. No relevant medical history was provided. No other vaccine was received in four weeks. Relevant concomitant medications included ibuprofen (ADVIL 12 HOUR). From 03May2021, the patient developed sharp, piercing pain in my left calf over several days. The frequency increased the early morning (06:00-09:00) of 09May2021 so she contacted her primary care physician to discuss what she thought might be an indicator of deep vein thrombosis (DVT). She presented to the Emergency Room the morning of 09May2021 and was diagnosed with acute DVT of left peroneal vein (in the left calf). She was given blood thinner. Pre-vaccination and post-vaccination COVID tests were not performed. The patient was recovering from the events. No follow-up attempts are possible; information about lot/batch number cannot be obtained.



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1349560	5/26/2021	IL	66	M	4/20/2021	5/9/2021	Pinched middle finger, got a 1/4 diameter blood clot under skin.; This is a spontaneous report from a contactable consumer (patient). A 66-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in arm left on 20Apr2021 12:00 (Batch/Lot Number: er8735) as single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No other medications the patient received within 2 weeks of vaccination. Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, patient has been tested for COVID-19. The most recent COVID-19 vaccine was administered in facility. The patient experienced pinched middle finger, got a 1/4 diameter blood clot under skin on 09May2021 13:00. Patient was scheduled to go there tomorrow for the second dose. Had an accident yesterday and pinched the right middle finger. Usually when that happens, he gets a boil and it fills with a clear liquid pus. This time, it turned into a giant blood clot, well not giant but about a quarter inch in diameter in the tip of his finger. He has never had that happen before. He may have never damaged his finger in that way before. That is why it turned into a blood clot and not clear fluid. Patient was worried a little with the blood clot because he knew it has been an issue. When he first got a little worried about the blood clot, he thought he would take 2 aspirin and it might thin the blood a little bit. Patient ate some pineapple because he heard that was a blood thinner too. No treatment received for event. The patient underwent lab tests and procedures which included nasal swab: negative on 10Jun2020. Outcome of the event was unknown. Information on lot/batch number was available. Additional information has been requested.

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1349580	5/26/2021	PA	78	F	2/20/2021	4/1/2021	<p>Patient has a blood clot; Pain sent patient to the emergency room; Patient was tired, and was having a hard time breathing. Patient was thinking it was something else; Patient was tired, and was having a hard time breathing. Patient was thinking it was something else; This is a spontaneous report from a contactable consumer. This consumer (patient's daughter) reported for a 79-year-old female patient (reporter's mother) that: Submitted by Call Centre Selected Report Type: Initial Is report related to a study or programme? No Patient Ethnicity: Unknown Is the patient also the reporter? No Reporter type: Consumer or other non-health professional Specify Consumer or other non-health professional: Reporter is patient's daughter Primary / Prescribing Healthcare Professional Info Adverse events: Dates for Patient has a blood clot: (From: Apr2021 To: Ongoing) Reporter seriousness for Patient has a blood clot: Hospitalization Dates when patient was in hospital for Patient has a blood clot: 29Apr2021 to 02May2021 Dates for Pain sent patient to the emergency room: (From: 26Apr2021 To: Ongoing) Reporter seriousness for Pain sent patient to the emergency room: Unspecified Dates for Patient was tired and was having a hard time breathing. Patient was thinking it was something else: (From: Apr2021 To: Ongoing) Reporter seriousness for Patient was tired and was having a hard time breathing. Patient was thinking it was something else: Unspecified Is Pfizer covid vaccine a Pfizer product? Yes Pfizer covid vaccine manufacturer: Unspecified Dates for Pfizer covid vaccine: (Start: 20Feb2021 Stop: Unspecified) NDC number of Pfizer covid vaccine: Unknown Expiry Date of Pfizer covid vaccine: Unknown Why was the patient taking Pfizer covid vaccine (Verbatim): Because of patient's age Other Products: No Patient History: No Investigation Assessment: No Additional Context: Reporter is calling on behalf of someone else. Reporter is calling about the Pfizer covid vaccine. Reporter is hoping for some guidance. It is reporters understanding, that if there is complications after the covid vaccine, there is compensation available. She is asking does she need to go somewhere for that. Reporter is calling about her mother. Reporter's mother is the patient. Reporter's address: Reporter was asked for her mailing address. Reporter stated that she will provide patient's mailing</p>

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address, that it would be easier to provide patient's address. Primary / Prescribing Healthcare Professional Info: Declined. Patient has a blood clot: Patient is now out of the hospital, but she is on a blood thinner for the next six months. She was diagnosed with a blood clot and hospitalized on 29Apr2021. Patient began having adverse reactions two weeks prior, but patient did not realize they were related to her blood clot. Reporter does not know an exact start date. Patient is getting better with the blood thinner, but the blood clot is still there. Pain sent patient to the emergency room: Pain began on 26Apr2021. Patient is still in pain, but it is not as severe. Patient was tired and was having a hard time breathing. Patient was thinking it was something else: Began about two weeks prior to being diagnosed with a blood clot. The problem is, it is a large blood clots, and has done damage to patient's lungs. Reporter states because of the blood thinners that patient is having to take, patient is having complications. The blood thinners are very expensive. The blood thinners are interfering with other medications that patient is on. No further information provided. First dose administered on 20Feb2021 about 12:00PM in left arm. Lot number: EL9266 NDC: Unknown Expiry date: Unknown Second dose administered on 13Mar2021 at 1:30PM in left arm. Lot number: Unknown NDC: Unknown Expiry date: Unknown Patient Age at Time of Vaccination in Years: 79 Vaccination Facility Type: Other, Pop up clinic. Vaccine Administered at Military Facility? Not provided. Additional Vaccines Administered on Same Date of the Pfizer Suspect: None. Did any AE(s) require a visit to: Emergency Room? Yes. If the patient was hospitalized, how many days was the hospital stay? Four days. Physician Office? Yes. Patient has saw an oncologist, primary care physician, neurologist and pneumologist. Prior Vaccinations (within 4 weeks): None. AE(s) following prior vaccinations: Not provided. Patient's Medical History: None. Family Medical History Relevant to AE(s): None. Relevant Tests: None. Reporter is asking what all she needs to submit to Pfizer Legal. Reporter is asking if she needs a lawyer to handle this. PSCC Communication: Caller notified that all requests for compensation will need to be made in writing to Pfizer Legal. Caller was provided with Pfizer Legal Department's address of Pfizer, Inc. Legal Department

*VAERS\_ID RECVDATE STATE AGE\_YRS SEX VAX\_DATE ONSET\_DATE SYMPTOM\_TEXT*

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Follow-up attempts are needed. Additional information is requested

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1349112	5/26/2021		71	F	3/24/2021	3/31/2021	<p>Embolism arterial; Thrombosis; Herpes zoster; Limb discomfort; Pain in extremity; Feeling hot; This case was received via VAERS on 11-May-2021 and was forwarded to Moderna on 11-May-2021. This regulatory authority case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of EMBOLISM ARTERIAL (Embolism arterial), THROMBOSIS (Thrombosis), HERPES ZOSTER (Herpes zoster), LIMB DISCOMFORT (Limb discomfort), PAIN IN EXTREMITY (Pain in extremity) and FEELING HOT (Feeling hot) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 030A21A) for COVID-19 vaccination. Concurrent medical conditions included COPD and Asthma. Concomitant products included ALBUTEROL [SALBUTAMOL], BUDESONIDE, FORMOTEROL FUMARATE (SYMBICORT) and TIOTROPIUM BROMIDE MONOHYDRATE (SPIRIVA) for an unknown indication. On 24-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) at an unspecified dose. On 31-Mar-2021, the patient experienced EMBOLISM ARTERIAL (Embolism arterial) (seriousness criteria hospitalization and medically significant), THROMBOSIS (Thrombosis) (seriousness criteria hospitalization and medically significant), HERPES ZOSTER (Herpes zoster) (seriousness criterion hospitalization), LIMB DISCOMFORT (Limb discomfort) (seriousness criterion hospitalization), PAIN IN EXTREMITY (Pain in extremity) (seriousness criterion hospitalization) and FEELING HOT (Feeling hot) (seriousness criterion hospitalization). At the time of the report, EMBOLISM ARTERIAL (Embolism arterial), THROMBOSIS (Thrombosis), HERPES ZOSTER (Herpes zoster), LIMB DISCOMFORT (Limb discomfort), PAIN IN EXTREMITY (Pain in extremity) and FEELING HOT (Feeling hot) had resolved.</p> <p>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 31-Mar-2021, Full blood count: unknown (Inconclusive) Unknown. On 31-Mar-2021, Ultrasound Doppler: unknown (Inconclusive) Unknown. On 31-Mar-2021, Whole body scan: unknown (Inconclusive) Unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient went to hospital because of blood clots and he had an</p>

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							emergency surgery. It was a huge arterial clot and developed shingles. Action taken with mRNA-1273 in response to the events was not applicable. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
1352139	5/26/2021	CA	74	F	2/17/2021	3/15/2021	Great difficulty breathing, diagnosed with pulmonary embolism and one clot in right leg on May 15. First went to hospital with extreme breathing difficulty on March 15 but no diagnosis was made. this was one month after first Moderna vaccination. Two months later, with same issues (also extremely swollen ankles) and same tests, the embolisms were seen on CT test with contrast.
1351271	5/26/2021	PA	66	M	5/12/2021	5/19/2021	ED to Hosp-Admission Current 5/20/2021 - present (6 days) Last attending ? Treatment team Syncope and collapse Principal problem History of Present Illness a 66 y.o. yo male presenting to the ED with syncope. Patient is diagnosed with COVID-19. He has passed out twice today. He feels lightheaded and nauseous prior to passing out. He wakes up feeling diaphoretic. Denies chest pain. Admits to shortness of breath and the feeling of difficulty getting a deep breath in. Patient denies history of blood clots, recent unilateral leg swelling or edema, hemoptysis.

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1349585	5/26/2021	PA	47	F	4/7/2021	4/12/2021	<p>severe pain when breathing which resulted in bilateral pulmonary embolisms, DVT in right calf, non-occipital; severe pain when breathing which resulted in bilateral pulmonary embolisms, DVT in right calf, non-occipital; severe pain when breathing which resulted in bilateral pulmonary embolisms, DVT in right calf, non-occipital; This is a spontaneous report from a contactable consumer reporting for herself. A 47-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 2 via an unspecified route of administration, administered in the left arm on 07Apr2021 at 08:00 (Batch/Lot Number: EP7533) (at the age of 47 years old) as a single dose for COVID-19 immunisation. The patient previously received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 1 via an unspecified route of administration, administered in the left arm on 17Mar2021 at 08:00 (Batch/Lot Number: EN6204) (at the age of 47 years old) as a single dose for COVID-19 immunisation. Medical history included factor v deficiency from an unknown date and unknown if ongoing, protein c deficiency from an unknown date and unknown if ongoing. The patient did not have any known allergies. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included venlafaxine hydrochloride (EFFEXOR XR) taken for an unspecified indication, start and stop date were not reported; ibuprofen taken for an unspecified indication, start and stop date were not reported; diclofenac potassium (VOLTAREN ACTI) taken for an unspecified indication, start and stop date were not reported; spironolactone (SPIRONOLACTONE) taken for an unspecified indication, start and stop date were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 12Apr2021 at 14:00, the patient experienced severe pain when breathing which resulted in bilateral pulmonary embolisms, deep vein thrombosis (DVT) in right calf, non-occipital. The events severe pain when breathing which resulted in bilateral pulmonary embolisms, deep vein thrombosis (DVT) in right calf, non-occipital required a physician's office visit, emergency room visit and hospitalization for 1 day. The outcome of the events severe pain when breathing which resulted in bilateral pulmonary embolisms, deep vein thrombosis (DVT) in</p>

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							right calf, non-occipital was recovered in Apr2021. Since the vaccination, the patient had not been tested for COVID-19. Follow-up needed, further information has been requested.
1352154	5/26/2021	MD	47	M	4/20/2021	4/28/2021	The Covid vaccine was given April 20 of 21 within eight days of having the vaccine I started to develop shortness of breath fatigue chest pain, I ended up at our local emergency room and was admitted with pulmonary embolism, blood clots in both lungs I stayed a total of three days hospitalized.
1352115	5/26/2021	CA	42	F	5/8/2021	5/10/2021	1 day after shot I had flu symptoms and was basically out of the whole day. 2 days after my fever cleared and I noticed a pain in my left leg calf. I thought it was because of my shot but that it was just body aches. The pain increased and eventually spread to my inside thigh. I went to the urgent care on 5/17/21 and an ultrasound discovered blood clots (Deep Vein Thrombosis) Please note that I also had traveled 5 hours on a flight on 5/6/21 but I was stretching on the flight and have never had a DVT before.



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1351683	5/26/2021	CA	65	F	1/19/2021	1/26/2021	Dose 1 - 1/19/21 - On 1/26/21, I got developed a bad case of SOB. I called my cardiologist and she told me to get tested for COVID. I went to the county facility to get tested and it took 3 days for results, which finally came back negative. During my wait, I went to a Urgent care and they did a Chest Xray, EKG and another COVID test, which was negative and the other tests were normal. I was sent back to cardiologist. She scheduled a stress test on 2/11 and everything was fine. I was also feeling fine by then. Dose 2 - 2/16/21 - The next day, I had a headache, aches, pain, fever and basically felt like I had the flu. I took Tylenol and that lasted about 36 hours. On 2/25, I was doing my 2 mile walk and I start experiencing the SOB again. So, I relaxed and figured it would go away. On 3/1, we drove to a park and back home 3 days later. On 3/3, I was really exhausted, so I took a nap for 3 hours and awakened with calf pain and a low grade fever. That lasted for 3 days, so I went to the ER on 3/6. They did an ultrasound on my leg and found a DVT in my right leg. They did CT Scan of my lung and found several clots (pulmonary emboli). I was in the hospital overnight and put me on a blood thinner, Eliquis 5mg, twice a day. Since then, I've continued to take the Eliquis and I'm following up with a hematologist on June 21. The hematologist has already tested me for two factors came negative and he will test me for the third one at my next visit.
1351668	5/26/2021	NV	46	F	4/20/2021	4/26/2021	Extreme aching in the arm for 5 weeks. So much it's painful. At my second dose, May 11th, I informed the tech that my arm still hurt from the first dose which she replied, "that is odd. we'll just do the injection in your other arm". I went another week in pain before calling my dr to inform him of the pain. They took my information over the phone and asked me to keep them updated. Two days ago was just too much pain to bear so i went to the pharmacy and spoke with the pharmacist. she suggested i get an X-ray. I called my dr and yesterday went it to have it checked out. they did an X-ray and found nothing out of the normal. they also ruled out a blood clot since i didn't have any of the symptoms.

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1351549	5/26/2021	FL	58	M	4/20/2021	5/11/2021	after receiving the vaccine 4/20 and three weeks later I couldn't breath and called 911 and went to hospital and diagnosed with pericarditis. But the day before I felt like I had a fractured rib and it intensified that evening and I took pain medication, then the pain in the left side intensified and I could not breath it felt like a knife piercing and had to breath with very shallow breath into my upper chest and the pain was so intense. I called 911 and they did an EKG, my heart rate went down to 30. One doctor gave me morphine to help me, they did test to check for blood clots and EKG's and blood test. I was also given Oxycodone. Test showed that there was a virus that got into it that caused pericarditis. I'm taking Ibuprofen and anti-inflammatories to help. I'm very active and never had health issues and believe this was a response to the vaccine. First dose was given on 3/23/2021 Lot 047A21A and experienced Molluscum contagion a few days later, and this is a virus. I was prescribe a topical cream, Imiquimod a topical cream to put on it to break down the virus. Triamcinolone Acetonide cream was prescribed later and I'm still taking it now and the site was oozing puss and bleeding.
1351506	5/26/2021	KY	36	F	4/7/2021	4/28/2021	I was taking a shower the night of 04/28/21 and I had a bad pain in my right leg. It felt like it could be a blood clot. The area was swollen and I was in a lot of pain. My blood pressure started getting high and it kept going up. On the way to the hospital, I started getting a headache and shortness of breath. I tried to elevate my leg on the way there. I took an aspirin. I had to sit in the waiting room for 2 1/2 hours and my pain in my leg and headache continued. Once I was taken back, they ran a few tests. I was told that my D-Dimer was elevated which indicates a blood clot. I was checked for a pulmonary embolism and that was negative. I was given a blood thinner because an ultrasound technician was not on duty. I went home at 4 am. I went back for an ultrasound the next day for my entire leg. Everything came back normal. The pain slowly went away.
1351485	5/26/2021	NJ	42	F	4/12/2021	4/25/2021	About two weeks later, I started to get a headache. The pain was massive and it was on one side of my head. I thought I was having a stoke. I took Excedrin and went to sleep and woke up and it was a vain popping out of my head. I had blood clot in my leg.

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1351400	5/26/2021	MN	67	F	5/18/2021	5/25/2021	was at work inside in air conditioning on 5/25/2021 when she noticed she had blurry vision and felt dizzy. called PHN who referred her to call her doctor or go to the emergency room as these could be signs of a blood clot. PHN spoke with on 5/26/2021 and informed PHN that she went home yesterday from work and declined to go to an emergency room or doctor's office, as she has not seen a doctor in the last 10 years. was offered rides from friends and coworkers to a hospital or clinic, but declined. She went home and drank a lot of water, ate some bananas and sat still. She felt better after and that and has not had any reoccurring symptoms. See CONTINUATION PAGE. PHN expressed continued concern for her and recommended considering going to an emergency room or contacting a doctor. PHN reiterated that if she has another episode like that she should go to the hospital or clinic to be checked out.
1351364	5/26/2021	NY	65	F	4/6/2021	4/6/2021	pt stated about 4 hours after taking the vax she had a terrible headache. pt laid down but when she got up she had very sharp pains shooting from her toes up to her legs. pt said she had a stabbing pain in her left mid thigh. This episode lasted about 15 minutes. the next day she went to a routine exam but her PCP did not seem to think there was anything to worry about. pt had to have blood test 10 days later. She stated she was so tired she could barely get to the lab to get the test. The following weekend on 5/17/2021 she started having SOB and a coughing spell. On 5/19/21 she called to make an appt w/ PCP on 5/21/21. She saw a different physician and she was ordered a D-Dimer test. On 5/22/21 the pt got a phone call stating she needed to get to an Emergency Room since the lab test proved she had a blood clot. She went to ER. They did a US Doppler and CT of lungs. She had 2 pulmonary thrombosis. One in left lung and one in right lung. She had one DVT in left calf. Pt was admitted. She was given heparin IV for 3 days. She was then put on Xarelto and discharged on 5/25/2021. she has to take Xarelto for 90 days and scheduled to have another US on 7/19/2021 to see if the clots are dissolved.
1352386	5/26/2021	ME	46	F	4/30/2021	5/25/2021	Extremely heavy bleeding and clots in period

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1347141	5/25/2021	CA	41	F	5/18/2021	5/22/2021	Heavy menstrual cycle bleeding; discharged was gushy and with clots.
1346767	5/25/2021	OH	63	F	4/8/2021	5/17/2021	Patient presents with 7 day history of shortness of breath. Ct angiogram showed multiple pulmonary embolism with ventricular strain. Patient required EKOS procedure for clot dissolution and bridging from Lovenox to warfarin.
1346484	5/25/2021	VA	63	M	5/1/2021	5/8/2021	<p>He got his vaccine, he had no reactions. The next morning he woke up his arm was sore, and it was that was for 2 days. Then his breathing starting getting worse. He started coughing, couldn't lay down, could not sleep due to that. He went to the ER and they told him that there was nothing wrong and that it was just allergies. They told him to go home and take some OTC cold medicine and that everything would be okay. A week later he went to another ER for the same thing as he continued not to be able to breath, they did a bunch of tests and said that nothing was wrong and that it was just a call. He then went to Hospital ER and they released him stating it had just a cold. He then called his cardiologist and they told him to go back to Hospital, was admitted on 5/11/21 and they did more tests and said that he had a blood clot in his left lung and said that it had nothing to do with the vaccine. He was discharged on 5/13/21. They put him on Heparin while in the hospital and sent him home as a disgruntled patient. They also told him that he had fluid around his heart and gave him medicine to get that taken away. They sent him home on Lasix and Eliquis. He then went to another hospital on Friday 5/14/21 as he was going crazy about the blood clot and went there and was kept there for 3 days and discharged on 5/16/21 with the same medications, Lasix and Eliquis. He was also told that he had fluid around his heart again. Before the vaccine he was very healthy, and was able to jog around his neighborhood and now he's not able to do so, and they told him that he was now having heart failure and is having trouble breathing because his heart is swelling up. He went to see his cardiologist last Friday and that's when she told him about his heart failure.</p> <p>ADMISSIONS: ADMITTED 5/11/21 TO 5/13/21; 5/14/21 to 5/16/21.</p>

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1346571	5/25/2021		74	F	3/9/2021	4/22/2021	Patient went to the ED on 5/22/21. She had been having pain and swelling in her R lower extremity for approximately 1 month prior. She was diagnosed with a deep vein thrombosis. She did not have any other known risk factors for DVT.
1346600	5/25/2021	GA	31	F	4/3/2021	4/6/2021	The Tuesday after vaccination, I had physical discomfort and pain inside like period cramps. It felt like there was a tampon inserted weirdly, I tried a yeast infection solution with yogurt on a tampon. Later that week I had pelvic bone pain like I had strained to hard using the bathroom. Friday I got a hyper sensitive spot on upper right thigh, diagnosed as paresthesia, the swelling and discomfort around pelvis was still there. Saturday the swelling and discomfort on the insides started going down, both legs experienced pain, It felt as if I had done a workout and pulled my muscle. I typically have a high threshold for pain, No change on Sunday. Monday the back of right knee stated aching, sensitivity in left thigh. Both muscles on outside of legs felt like I had done a workout and needed stretched, On the 13th the aching traveled from the back of knees to calves I went to the Hospital. Myalgia and paresthesia and acute vaginitis. Shot of Toradol in left arm, which did nothing. Did ultrasound with normal results, no blood clots. The 14th my legs were comfortable as long as I was moving, started having a sharp stinging in left calf. The soles of my feet felt blistered but no visible blisters. Significant headache. I wore compression socks. I got a weird Charlie horse in left foot toes, top of right foot got really sensitive also. Volotal is a topical pain cream that I had I used it on specific areas, of pain. Thursday the 15th the left outside of my foot was still sore, my calves had gotten better, the outside of the calf still had hypersensitivity. The muscles on the back of my knee's and calves were still sore. While driving my Hip and thighs for aching. Ankles are popping a lot. Fri-Sun following I had leg stiffening and muscle soreness mainly in the left side, went for a walk that weekend and while walking they felt ok, until I stopped walking. Mon-tue after I had a headache that felt like my brain was burning near the left temple area.

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1346653	5/25/2021	FL	51	F	4/25/2021	4/27/2021	On and off numbness and tingling in my left arm and hand (primarily) and also in my right hand (a few times) during the day for about 3 weeks. Involuntary movements in my fingers in both hands. My arms and hands still fall asleep at night and this did not happen to me before except on some rare occasion that I slept on my hand or arm. I have been awoken by a limb that is asleep about 4 times since my vaccine. Intermittent headaches for about two week after the vaccine and a very unusual, heavy and somewhat painful period with several large clots the size of a half dollar and lasting much longer than a normal period. I felt dizzy and lightheaded for about a day. I have never had these kinds of periods before.
1346717	5/25/2021	FL	30	F	5/21/2021	5/21/2021	Adverse events experienced and are they still occurring now: Patient called in stating she received the vaccine on Friday 5/21/21 @10:30 am and later she started to experience soreness at the injection site and about the evening time at 6pm she felt nauseous and started throwing up shortly after. She vomited about 5-6 times on Friday night. Saturday morning she woke up with soreness of the body in neck, shoulder body (extreme body aches), fever also started on Saturday. Patient also c/o headache, rash on left wrist (only area), and she also feels fatigued, and chills. **Patient does have a history of blood clots and anemia** She stated as of Monday 5/24/21 @7:26pm she had a fever in the day but that subsided after taking Tylenol. Last time the patient took Tylenol was on 5/24/21 at 2pm.
1346751	5/25/2021	FL	75	F	2/6/2021	2/9/2021	Tues, 2/9, entire upper arm became very red and very swollen, and some itching. Wed. 2/10, Major GI problems. Constipated, PAIN, for several hours, then Difficult multiple BMs with blood, blood clots, & mucus, Thurs, 2/11 BMs with blood clots, mucus, Thurs 2/12 BMs with fewer blood clots

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1346784	5/25/2021	CO	45	F	4/12/2021	4/17/2021	I experienced chest pain/pressure, shortness of breath, rapid/irregular heartbeat approximately 5 days after receiving my first dose of the Moderna shot. I had been exercising outdoors (as I normally do) when it came on. It subsided some and returned in intensity the following day following a long walk. It was mostly mild pain and pressure during the week. However, on 4/24, following exercise, I had pronounced symptoms and acknowledged that I needed to go to the emergency room, as I thought I was having a heart attack. They admitted me and ran various heart tests and ruled out a heart attack or blood clot.
1346790	5/25/2021		24	F	5/11/2021	5/20/2021	I got the second dose of the vaccine on May 11th 2020. I am currently on my second week for completing the vaccine. When it all started I was just laying down on my couch watching Netflix with my laptop on my lap (this was Thursday night, May 20th). My leg fell asleep but I didn't think anything of it because once I started walking around it went back fine. However, On May 21st, Friday morning I was having serious pain in my left thigh. I believed it was a muscle strain. I did a cold compress, warm bath and took Tylenol from Friday to Saturday. I thought it got better but however by May 23rd, Sunday night I was incapable of walking on my own and needed assistance just to go to the bathroom. On May 24th I went to Urgent Care and they stated that I may have a blood clot so I went to the ER. While at the ER they stated I had a massive blood clot that would need a procedure done to remove it and was later admitted into the hospital and scheduled for the procedure. The blood clot travels from my groin to my ankle on my left thigh. They stated the reason for my blood clot would of been because of my birth control. And it's possible reaction to me also taking the Pfizer vaccine. I have been on birth control for over 5 years and have not had any problems until now. I also do not have any history or family history of blood clots. I did not hit my thigh or have done any exercises for this to occur.
1346853	5/25/2021	WA	46	F	5/7/2021	5/23/2021	2 weeks after receiving johnson and johnson vaccine I began a second period in one month. I am very regular with my menstrual cycle so it was weird. And what is very strange it has large clots and not alot of bleeding. I have never had an period like that since I am 11 years old.

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1346862	5/25/2021	CA	41	F	4/15/2021	4/21/2021	On 4/16-4/18 minor soreness and fatigue that temporarily disappeared. Then on 4/21, I experienced High Fever (103.8), Body aches, headache, extreme fatigue that lasted through Monday 4/26. Through that time I went and got a Covid test on Friday 4/23 and it came back negative. On Thursday 4/29, I started having pain on the right upper side of my abdomen. Friday evening, the pain grew even more intense which I could not lay down to sleep and no pain meds were taking it away. Saturday, 4/30 at 6 am ended up in ER at Facility. They were testing me for blood clots due to the chest pain and sever right side pain and the results showed no blood clots and my heart was fine. CT scan showed pneumonia, scarring in my lungs and a nodule growth on my lung. The doctor asked me if I was in the dessert recently if I had ever had valley fever. Valley Fever came back negative, another Covid 19 test came back negative. I completed taking 2 antibiotics and now on 5/25 (day 40) I am still feeling bouts of fatigue, wheezing in my lung and pain in my lung. I was healthy prior to getting the 2nd dose of Moderna and can't help but feel the vaccine triggered something in my system. Reporting this just in case it is an adverse effect from the vaccine.
1346470	5/25/2021	IL	27	F	4/8/2021	4/29/2021	Three weeks after J& J vaccine abnormally heavy vaginal bleeding with large clots.
1347136	5/25/2021	KS	30	F	4/29/2021	5/6/2021	Flu-like symptoms for the first 3 days: fever, chills, body aches, headache, itchy skin, pain in injection site (left arm). A few days later I started my period. It was irregular with severe PMS, panic attacks, anxiety and depression, severe cramping, more bleeding and blood clots than usual, period lasted longer than usual. Every day since I have been having PMS symptoms (anxiety, depression, panic attacks) and cramping. The cramping feels like period cramps but I am no longer on my period. The cramps last all day long and are not going away. I also had severe eye pain in my right eye about 1 week after the injection. The pain lasted for about 2 days, and was a throbbing pain behind my eyeball. I have never experienced any issues with my eyes before. I also had covid January 2021 and did not experience any of these symptoms then.



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1345817	5/25/2021	FL	73	F	4/12/2021	4/16/2021	<p>suspected blood clot; When walking experiences traumatic pain in legs; her legs went numb while at store; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (suspected blood clot) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 12-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 16-Apr-2021, the patient experienced PAIN IN EXTREMITY (When walking experiences traumatic pain in legs) and HYPOAESTHESIA (her legs went numb while at store). On an unknown date, the patient experienced THROMBOSIS (suspected blood clot) (seriousness criterion medically significant). The patient was treated with IBUPROFEN (MOTRIN [IBUPROFEN]) for Pain, at a dose of unknown. On 16-Apr-2021, HYPOAESTHESIA (her legs went numb while at store) had resolved. At the time of the report, THROMBOSIS (suspected blood clot) outcome was unknown and PAIN IN EXTREMITY (When walking experiences traumatic pain in legs) had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. No relevant concomitant medications were reported. Company Comment: Limited information regarding the events has been provided at this time and a causal relationship cannot be excluded.; Sender's Comments: Limited information regarding the events has been provided at this time and a causal relationship cannot be excluded</p>
1347226	5/25/2021	CO	19	F	5/22/2021	5/23/2021	<p>Bleeding from nose and large blood clots from nose, fever, chills</p>
1346923	5/25/2021		34	F	5/15/2021	5/24/2021	<p>prolonged menstrual period, excessive blood clots on menses</p>

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1345811	5/25/2021	FL	51	F	3/31/2021	3/31/2021	blood clots in both lungs; blood clots in left leg; shortness of breath; after the administration her arm hurt really bad; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY THROMBOSIS (blood clots in both lungs) and THROMBOSIS (blood clots in left leg) in a 51-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 037A21B) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 31-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 31-Mar-2021, the patient experienced VACCINATION SITE PAIN (after the administration her arm hurt really bad). On 15-Apr-2021, the patient experienced PULMONARY THROMBOSIS (blood clots in both lungs) (seriousness criteria hospitalization and medically significant) and THROMBOSIS (blood clots in left leg) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced DYSPNOEA (shortness of breath). The patient was hospitalized from 15-Apr-2021 to 18-Apr-2021 due to PULMONARY THROMBOSIS and THROMBOSIS. On 01-Apr-2021, VACCINATION SITE PAIN (after the administration her arm hurt really bad) had resolved. At the time of the report, PULMONARY THROMBOSIS (blood clots in both lungs), THROMBOSIS (blood clots in left leg) and DYSPNOEA (shortness of breath) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. The patient received Apixaban as a treatment medication for blood clots. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Further information has been requested. .

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1345433	5/25/2021	OR	47	M	4/27/2021	5/7/2021	Patient is a 47 y.o. pleasant man with history of diabetes, presented to hospital with intractable vomiting. He was lethargic and unresponsive. He was found to have bilateral transverse and straight sinus thrombosis, multifocal ischemia consistent with venous infarction. He was treated with heparin drip from diagnosis 5/11 and transitioned to apixaban 5/22. His mentation improved. As of today, he is conversant, disoriented, ambulatory, no longer requiring a feeding tube.

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1345674	5/25/2021	NJ	62	F	4/1/2021		<p>COMPUTERISED TOMOGRAM; ELECTROCARDIOGRAM; LABORATORY TEST; PULMONARY EMBOLISM; X-RAY; PAIN ON THE RIGHT-HAND SIDE UNDER MY RIBS; MYALGIA; ULTRASOUND SCAN; LUNG COLLAPSED; FLUID IN THE BOTTOM OF HER LUNG; This spontaneous report received from a patient via Regulatory Authority VAERS (Vaccine Adverse Event Reporting System) and concerned a 62-year-old female patient. The patient's height, and weight were not reported. The patient's concurrent conditions included depression, and penicillin allergy. The patient had no current illness. The patient had no heart problems, no pulmonary problem and diabetes. The patient experienced drug allergy when treated with paracetamol. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 206A21A expiry: UNKNOWN) dose was not reported, 1 total, administered on 11-APR-2021 to left arm for prophylactic vaccination. Concomitant medications included levomilnacipran hydrochloride for depression, and quetiapine fumarate for depression. On an unspecified date in APR/2021, little more than a week after single-dose coronavirus vaccine at hospital facility the patient felt general malaise and minor pain in her right side. The patient had shortness of breath, and she looked anxious and her heart rate was very fast. The vital signs were not stable. The physician suspected that patient had developed pulmonary embolism blood clots in her lungs. When combined with her vitals, the doctor knew it was an emergency. The patient also began to feel mildly ill. She was experienced general malaise, soreness on her right side, and while she was not struggling to breathe, it hurt when she took a deep breath, her right-hand side, like under her ribs, she felt some pain. It was not a bad pain, not enough to take anything for it but just noticed it. The symptoms seemed minor, and at the time. It was reported that by 21-APR-2021, she still was not feeling well and decided to make an appointment at the urgent care center. The patient visited emergency room or department/urgent care facility for treatment of the events. The patient soon learned she had developed blood clots (pulmonary embolism) in both lungs due to the vaccine, a doctor at the hospital told her. One of her lungs also had collapsed. She had developed blood clots in both lungs</p>

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due to the vaccine, she was there for 10 hours (undergoing tests). The patient underwent a computerized tomography scan and an X-ray. They did everything and got the results of the CAT scan, with pulmonary embolism in both lungs. They immediately gave her some blood thinner and was as hospitalized (date unspecified). It was reported that she would spend five days in the hospital. According to the doctors this was from the vaccine. The patient was also experiencing the pain on the right-hand side and also started getting myalgia, muscle aches just in different parts of her body. The patient's legs also felt weird. So they rushed her down and gave a sonogram in her legs to check for deep vein thrombosis. The pain on her right side grew worse for a day or two, and she was treated with morphine. The doctors surmised the patient had fluid in the bottom of her lung, which her body eventually absorbed. The patient was still on a blood thinner and continued to recover. Laboratory data included: Heart rate (NR: not provided) very fast, and Sonogram (NR: not provided) Not provided. On an unspecified date in APR-2021, Laboratory data included: Computerised tomogram (NR: not provided) pulmonary embolisms in both lungs, Electrocardiogram (NR: not provided) Not provided, Laboratory test (NR: not provided) Not provided, Ultrasound scan (NR: not provided) Not provided, and X-ray (NR: not provided) Not provided. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from pulmonary embolism, had not recovered from computerised tomogram, electrocardiogram, laboratory test, ultrasound scan, and x-ray, and the outcome of myalgia, fluid in the bottom of her lung, lung collapsed and pain on the right-hand side under my ribs was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition). Additional information was received from company representative via social media on 18-MAY-2021. The following information was updated and incorporated into the case narrative: patient's city added, events added (pain on the right-hand side under my ribs, myalgia, lung collapsed, fluid in the bottom of her lung), CT scan result updated, lab data updated (Heart rate and Sonogram).; Sender's Comments: V1: The follow up information in this version updates Patient's city, events (pain on the right-hand side under my ribs,

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1345688	5/25/2021	NY					
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myalgia, lung collapsed, fluid in the bottom of her lung), CT scan result updated, lab data updated (Heart rate and Sonogram). The follow up information received in this version does not alter the causality of the previously reported events 20210514298-COVID-19 VACCINE AD26.COV2.S-fluid in the bottom of her lung, pain on the right-hand side under my ribs: These events are considered unassessable. The events have a compatible/suggestive temporal relationship, are unlabeled, and have unknown scientific plausibility. There is no information on any other factors potentially associated with the events. 20210514298- COVID-19 VACCINE AD26.COV2.S-myalgia. This event is labeled per RSI and is therefore considered potentially related. 20210514298-COVID-19 VACCINE AD26.COV2.S-Pulmonary embolism, computerized tomogram, electrocardiogram ,laboratory test, ultrasound scan, X-Ray: These events are considered unassessable. The events have a compatible/suggestive temporal relationship, are unlabeled, and have unknown scientific plausibility. There is no information on any other factors potentially associated with the events.

BLOOD CLOT; This spontaneous report received from a consumer concerned a patient of unspecified age, sex, race and ethnic origin. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported, 1 total administered for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient got blood clot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210534929-covid-19 vaccine ad26.cov2.s-blood clot. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1345692	5/25/2021	NJ	52	M	4/1/2021	LOW PLATLET COUNT; BLACK AND BLUES; This spontaneous report received from a consumer concerned a 52 year old male. The patient's weight was 194 pounds, and height was 180.34 centimeters. The patient's concurrent conditions included non smoker, and other pre-existing medical conditions included blood work clean in september 2020,no drug allergies. The patient did not had any illness at the time of vaccination, no similar event in the past. He never had any adverse event in past for vaccination. The patient did not had family history of any disease or allergy. The patient did not had medical history of blood clots, heart disease. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808978 expiry: Unknown dose was not reported, administered on 12-APR-2021 for prophylactic vaccination on left arm. Concomitant medications included doxycycline for drug used for unknown indication. On APR-2021,he noticed black and blues appearing randomly all over his body for no reason whatsoever. They continued to worsen until he went to primacy doctor who did blood work on 29-APR-2021. On 1-MAY-2021 doctor called about blood work to said that he had dangerously low platelet count and to make sure he did not fall and hurt himself. He was instructed to go to the emergency room where they were waiting for him. He was admitted that day. He was treated with steroids for two days with no response, 2 day plasma treatment with minimal response. On May 7-MAY-2021 he was discharged from hospital and was told to continue Doxycycline 2 weeks treatment course. He later had more blood work and the levels have radically dropped again. He had an appointment with a Hematologist/Oncologist specialist on Friday 12-MAY-2021., Laboratory data included: Blood test (NR: not provided) low platelet count. Laboratory data (dates unspecified) included: Blood test (NR: not provided) levels dropped. Treatment medications (dates unspecified) included: plasma, Steroids. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from low platelet count, and black and blues. This report was serious (Hospitalization Caused / Prolonged). This case, from the same reporter is linked to 20210536558.; Sender's Comments: V0: 20210535373-covid-19 vaccine	

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1345702	5/25/2021	NJ		F			<p>ad26.cov2.s-low platelet count. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> <p>BLOOD CLOT; This spontaneous report received from a patient via a company representative concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The Company is unable to perform follow-up to request batch/lot numbers.No concomitant medications were reported. On an unspecified date, the subject experienced blood clot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0-20210537368-covid-19 vaccine ad26.cov2.s -Blood clot-his event is considered Un assessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p>



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1345734	5/25/2021	TX	54	M	4/1/2021		<p>FEELING HORRIBLE; BLOOD CLOT; BODY ACHES; JOINT PAIN; SPAMS ALL OVER BODY; TOE SWELLING; KNEE SWELLING/ ANKLE SWELLING; This spontaneous report received from a patient concerned a 54 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 042A21A expiry: unknown) dose was not reported, 1 in total administered on 03-APR-2021 to left arm for prophylactic vaccination. No concomitant medications were reported. After getting the vaccine, the patient had immediate joint pain and body aches. He had spasms since day one. After two weeks, he developed swollen toe looked like a bunion, then it moved up to the ankle then it moved up to the knee being swollen. The patient was sent to the imagining center. He had following imaging tests done, bilateral Lower extremity Doppler Exam. On 30-APR-2021, he was recommended to go to the emergency room (ER) and was admitted. He was diagnosed with blood clot and stayed overnight. He was prescribed on Xarelto (rivaroxaban) 15 mg twice a day (BID), titrating to 20 mg once a day. The patient was hospitalised for 2 days. He got another follow up on 14-MAY-2021, gave him another prescription for blood thinner to be on for two months. On 18-MAY-2021, he was given tramadol 7 pills for spasms which had helped with his pain and currently patient was feeling horrible. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from joint pain, body aches, toe swelling, knee swelling/ ankle swelling, spasms all over body, and blood clot, and the outcome of feeling horrible was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210540030- Covid-19 vaccine ad26.cov2.s- A 54 yearold male presents with Blood clot, Body aches, Toe swelling, Knee swelling /Ankle swelling, Spasms all over body, feeling horrible. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). 20210540030- Covid-19 vaccine ad26.cov2.s-Joint pain. This event(s) is labeled per RSI and is therefore considered potentially related.</p>

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1345830	5/25/2021	NY	82	F	4/6/2021	4/6/2021	<p>blood clot was discovered in the left leg; excruciating pain in the left leg below the knee; area is swollen; Area of the left leg below the knee is red; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (blood clot was discovered in the left leg) in an 82-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 026B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 06-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form(s). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 06-Apr-2021, the patient experienced THROMBOSIS (blood clot was discovered in the left leg) (seriousness criterion medically significant), PAIN IN EXTREMITY (excruciating pain in the left leg below the knee), PERIPHERAL SWELLING (area is swollen) and ERYTHEMA (Area of the left leg below the knee is red). At the time of the report, THROMBOSIS (blood clot was discovered in the left leg), PAIN IN EXTREMITY (excruciating pain in the left leg below the knee), PERIPHERAL SWELLING (area is swollen) and ERYTHEMA (Area of the left leg below the knee is red) had not resolved. The patient's concomitant medication was not reported. The information regarding the patient's treatment medication was not provided. Company comment: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. This case was linked to MOD-2021-116642 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.</p>

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1345808	5/25/2021	NY	67	F	2/28/2021		Shortness of breath increasing; lethargy; Hyperkalemia; Acute kidney injury; metabolic encephalopathy; Uremia; metabolic acidosis; protein calorie malnutrition; Hyperuricemia; Hyperphosphatemia; Hyponatremia; Anemia; Substernal chest pain aggravated; increasing abdominal girth; Abdominal Pain; Weakness; Nausea; multiorgan failure; This spontaneous case was reported by a physician assistant (subsequently medically confirmed) and describes the occurrence of MULTIPLE ORGAN DYSFUNCTION SYNDROME (multiorgan failure), DYSPNOEA (Shortness of breath increasing), LETHARGY (lethargy), HYPERKALAEMIA (Hyperkalemia), ACUTE KIDNEY INJURY (Acute kidney injury), METABOLIC ENCEPHALOPATHY (metabolic encephalopathy) and AZOTAEMIA (Uremia) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 001121A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Breast cancer stage IV since March 2019, COPD since an unknown date, GERD since an unknown date, Hypertension since an unknown date, Tobacco user since an unknown date, Transaminases increased since an unknown date, Peritoneal carcinomatosis since an unknown date and Metastatic bone disease prophylaxis (Lumbar spine pelvis and proximal femurs) since an unknown date. Concurrent medical conditions included Acute renal failure (Due to Foley catheter placement) and Pneumonitis. On 28-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced MULTIPLE ORGAN DYSFUNCTION SYNDROME (multiorgan failure) (seriousness criteria death and medically significant), DYSPNOEA (Shortness of breath increasing) (seriousness criterion hospitalization), LETHARGY (lethargy) (seriousness criterion hospitalization), HYPERKALAEMIA (Hyperkalemia) (seriousness criterion medically significant), ACUTE KIDNEY INJURY (Acute kidney injury) (seriousness criterion medically significant), METABOLIC ENCEPHALOPATHY (metabolic encephalopathy) (seriousness criterion medically significant), AZOTAEMIA (Uremia) (seriousness criterion medically significant), METABOLIC ACIDOSIS (metabolic acidosis),

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MALNUTRITION (protein calorie malnutrition), HYPERURICAEMIA (Hyperuricemia), HYPERPHOSPHATAEMIA (Hyperphosphatemia), HYPONATRAEMIA (Hyponatremia), ANAEMIA (Anemia), CHEST PAIN (Substernal chest pain aggravated), WAIST CIRCUMFERENCE INCREASED (increasing abdominal girth), ABDOMINAL PAIN (Abdominal Pain), ASTHENIA (Weakness) and NAUSEA (Nausea). The patient was hospitalized on 09-Mar-2021 due to DYSPNOEA and LETHARGY. The patient died on 13-Mar-2021. The reported cause of death was Multiorgan failure. It is unknown if an autopsy was performed. At the time of death, DYSPNOEA (Shortness of breath increasing), LETHARGY (lethargy), HYPERKALAEMIA (Hyperkalemia), ACUTE KIDNEY INJURY (Acute kidney injury), METABOLIC ENCEPHALOPATHY (metabolic encephalopathy), AZOTAEMIA (Uremia), METABOLIC ACIDOSIS (metabolic acidosis), MALNUTRITION (protein calorie malnutrition), HYPERURICAEMIA (Hyperuricemia), HYPERPHOSPHATAEMIA (Hyperphosphatemia), HYPONATRAEMIA (Hyponatremia), ANAEMIA (Anemia), CHEST PAIN (Substernal chest pain aggravated), WAIST CIRCUMFERENCE INCREASED (increasing abdominal girth), ABDOMINAL PAIN (Abdominal Pain), ASTHENIA (Weakness) and NAUSEA (Nausea) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 12-Mar-2021, Blood culture: negative (Negative) Negative. On 12-Mar-2021, Blood gases: abnormal (abnormal) Compensated mixed respiratory and Metabolic alkalosis. On 12-Mar-2021, Blood pressure measurement: 96/52 (Inconclusive) 96/52 mmHg, 100/50 (Inconclusive) 100/50 mmHg and 88/58 (Inconclusive) 88/58 mmHg. On 12-Mar-2021, Blood test: normal (normal) WBC-2.9 Normal, Hg-Normal, Platelet count-Normal. On 12-Mar-2021, Body temperature: 36.1 (Inconclusive) 36.1degrees Celsius, 35.9 (Inconclusive) 35.9 degrees Celsius and 36.2 (Inconclusive) 36.2degrees Celsius. On 12-Mar-2021, Brain natriuretic peptide: normal (normal) normal. On 12-Mar-2021, Chest X-ray: normal (normal) No acute thoracic pathology. On 12-Mar-2021, Computerised tomogram: abnormal (abnormal) revealed a right sided pleural effusion bony metastatic disease and hepatic metastatic disease, as

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well as small amount of ascites in the upper abdomen. On 12-Mar-2021, Echocardiogram: inconclusive (Inconclusive) Ejection fraction 60-65% and otherwise no significant findings. On 12-Mar-2021, Heart rate: 92 heart beats per minute (Inconclusive) 92, 86 heart beats per minute (Inconclusive) 86 and 90 heart beats per minute (Inconclusive) 90. On 12-Mar-2021, Oxygen saturation: 96 (Inconclusive) 96 percent, 93 (Inconclusive) 93 percent and 98 (Inconclusive) 98 percent. On 12-Mar-2021, Prothrombin time: normal (normal) normal. On 12-Mar-2021, Respiratory rate: 16 (Inconclusive) breaths per minute, 18 (Inconclusive) breaths per minute and 19 (Inconclusive) breaths per minute. On 12-Mar-2021, SARS-CoV-2 test: negative (Negative) Negative. On 12-Mar-2021, Troponin: normal (normal) normal. On 12-Mar-2021, Urine analysis: normal (normal) normal. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter considered MULTIPLE ORGAN DYSFUNCTION SYNDROME (multiorgan failure), DYSPNOEA (Shortness of breath increasing), LETHARGY (lethargy), HYPERKALAEMIA (Hyperkalemia), METABOLIC ENCEPHALOPATHY (metabolic encephalopathy), AZOTAEMIA (Uremia), METABOLIC ACIDOSIS (metabolic acidosis), MALNUTRITION (protein calorie malnutrition), HYPERURICAEMIA (Hyperuricemia), HYPERPHOSPHATAEMIA (Hyperphosphatemia), HYPONATRAEMIA (Hyponatremia), ANAEMIA (Anemia), CHEST PAIN (Substernal chest pain aggravated), WAIST CIRCUMFERENCE INCREASED (increasing abdominal girth), ABDOMINAL PAIN (Abdominal Pain), ASTHENIA (Weakness) and NAUSEA (Nausea) to be possibly related. No further causality assessment was provided for ACUTE KIDNEY INJURY (Acute kidney injury). Concomitant medications were not provided. Treatment for the events included proton pump inhibitors, oxygen, Tylenol, and comfort care. Company comment: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.; Reported Cause(s) of Death: multiorgan failure

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1345947	5/25/2021	NY		U			<p>BLOOD CLOTS; This spontaneous report received from a consumer by a other manufacturer company (Pfizer Inc.) received on14-MAY-2021 and concerned multiple (few) patients. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) frequency 1 total, dose, start therapy date were not reported for prophylactic vaccination. No concomitant medications were reported. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. Reporter stated that Johnson and Johnson vaccine caused blood clots and few people died. It was not reported whether autopsy was performed. On an unspecified date, the patients experienced blood clots. On an unspecified date, the patients died from blood clots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death, and Other Medically Important Condition).; Sender's Comments: V0; 20210545044-covid-19 vaccine ad26.cov2. s Blood clots. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: BLOOD CLOTS</p>

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1345814	5/25/2021	CA	35	M	3/31/2021	5/3/2021	<p>blood clot in left lung, left lung filled with blood; coughing blood; slight headache for 2 days; tightness of chest; night sweats; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of HAEMOPTYSIS (coughing blood) and PULMONARY THROMBOSIS (blood clot in left lung, left lung filled with blood) in a 35-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 039B21A and 019B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Bronchoscopy (left lung filled with blood). Concomitant products included COLECALCIFEROL (VITAMIN D [COLECALCIFEROL]) for an unknown indication. On 31-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 03-May-2021, the patient experienced HAEMOPTYSIS (coughing blood) (seriousness criterion hospitalization), CHEST DISCOMFORT (tightness of chest) and NIGHT SWEATS (night sweats). On an unknown date, the patient experienced PULMONARY THROMBOSIS (blood clot in left lung, left lung filled with blood) (seriousness criteria hospitalization and medically significant). an unknown date, the patient experienced HEADACHE (slight headache for 2 days). The patient was hospitalized on 03-May-2021 due to PULMONARY THROMBOSIS. The patient was treated with HEPARIN (intravenous) on 04-May-2021 for Clot blood, at an unspecified dose and frequency. At the time of the report, HAEMOPTYSIS (coughing blood) and PULMONARY THROMBOSIS (blood clot in left lung, left lung filled with blood) had not resolved, CHEST DISCOMFORT (tightness of chest) and NIGHT SWEATS (night sweats) outcome was unknown and HEADACHE (slight headache for 2 days) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. They did some tests and found there was blood clot in his left lung and put him on blood thinner but he reported that the blood thinner made his bleeding more worse. The patient still in hospital and currently in ICU and the Doctors are unable to determine where the blood is</p>

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coming from and unable to remove the clot. And he is still suffering with blood cough. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested. This case was linked to MOD-2021-116374 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.



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1345815	5/25/2021	MA	62	M	5/1/2021	5/1/2021	<p>Blood clot in urine (black in color) (described it as mucous like and black in color).; Blood in urine (Red in color)(described it as mucous like and black in color).; Always thirsty; This spontaneous case was reported by a consumer and describes the occurrence of HAEMORRHAGE URINARY TRACT (Blood clot in urine (black in color) (described it as mucous like and black in color).) in a 62-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 01-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-May-2021, the patient experienced HAEMORRHAGE URINARY TRACT (Blood clot in urine (black in color) (described it as mucous like and black in color).) (seriousness criterion medically significant), HAEMATURIA (Blood in urine (Red in color)(described it as mucous like and black in color).) and THIRST (Always thirsty). At the time of the report, HAEMORRHAGE URINARY TRACT (Blood clot in urine (black in color) (described it as mucous like and black in color).), HAEMATURIA (Blood in urine (Red in color)(described it as mucous like and black in color).) and THIRST (Always thirsty) had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications was reported.. No allergy reported. No treatment done. Patient did not inform health care provider yet. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1347435	5/25/2021	ID	73	M	2/26/2021	3/7/2021	Feb. 26-2 days after 1st shot, unconscious, blood sepsis, nausea, on a ventilator, severe pneumonia in right lung. In ICU for 3 days, normal ward 3 days, treated with antibiotics Mar. 26-2 days after 2nd shot, unconscious, blood sepsis, blood clot, heart failure, kidney & liver damage, treated with Eliquis and antibiotics. At hospital in ICU for 2 days, normal ward 3 days. Continuing with Eliquis, increased Metoprolol. Follow-up with kidney specialist and Cardiologist PA.

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1345821	5/25/2021	GA		M	4/28/2021	4/28/2021	Blood clots around the heart, 70% blockage; Pneumonia; Can barely walk, need walker or somebody need to hold; Hardly talk; Barely sees; Brain stem stroke; This spontaneous case was reported by a consumer and describes the occurrence of BRAIN STEM STROKE (Brain stem stroke), THROMBOSIS (Blood clots around the heart, 70% blockage) and PNEUMONIA (Pneumonia) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 046B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Stent placement on 29-Apr-2021. On 28-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Apr-2021, the patient experienced BRAIN STEM STROKE (Brain stem stroke) (seriousness criterion medically significant). On 29-Apr-2021, the patient experienced THROMBOSIS (Blood clots around the heart, 70% blockage) (seriousness criterion medically significant), PNEUMONIA (Pneumonia) (seriousness criterion medically significant), GAIT DISTURBANCE (Can barely walk, need walker or somebody need to hold), SPEECH DISORDER (Hardly talk) and VISION BLURRED (Barely sees). At the time of the report, BRAIN STEM STROKE (Brain stem stroke), THROMBOSIS (Blood clots around the heart, 70% blockage), PNEUMONIA (Pneumonia), GAIT DISTURBANCE (Can barely walk, need walker or somebody need to hold), SPEECH DISORDER (Hardly talk) and VISION BLURRED (Barely sees) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication, No treatment information provided. The patient had brain stem stroke after 5 hours of the vaccination. The next day, on 20Apr2021, the doctor found that patient had 70% blockage, blood clot around the heart and they have to put stent. Company comment: The event of pneumonia is of an infective etiology, hence a causal association is unlikely. However, based on strong temporal association between the remaining events and the administration of mRNA-1273, a causal relationship cannot be excluded.; Sender's Comments: The event of

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pneumonia is of an infective etiology, hence a causal association is unlikely. However, based on strong temporal association between the remaining events and the administration of mRNA-1273, a causal relationship cannot be excluded.

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1345839	5/25/2021	FL	75	M	4/24/2021	4/24/2021	Spontaneous blood clots; very swollen leg; Fever; Chills; leg being lightly swollen; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Spontaneous blood clots) in a 75-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 031B21A and 030A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). Concomitant products included DONEPEZIL HYDROCHLORIDE (ARICEPT), EMPAGLIFLOZIN (JARDIANCE), LEVOTHYROXINE, LISINAPRIL, METFORMIN, PRAVASTATIN, METOPROLOL, ARIPIPRAZOLE (ABILIFY), VENLAFAXINE HYDROCHLORIDE (EFFEXOR), FENTANYL, APIXABAN (ELIQUIS) and TESTOSTERONE for an unknown indication, CEFIXIME (FLEXERIL [CEFIXIME]). On 24-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 24-Apr-2021, the patient experienced PERIPHERAL SWELLING (leg being lightly swollen), PYREXIA (Fever) and CHILLS (Chills). On 25-Apr-2021, the patient experienced PERIPHERAL SWELLING (very swollen leg). On an unknown date, the patient experienced THROMBOSIS (Spontaneous blood clots) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Spontaneous blood clots), PYREXIA (Fever) and CHILLS (Chills) outcome was unknown and PERIPHERAL SWELLING (leg being lightly swollen) and PERIPHERAL SWELLING (very swollen leg) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Ultrasound scan: blood clots blood clots. On 25-APR-2021, patient experienced a very swollen leg and was scheduled an ultrasound which revealed blood clots on an unspecified date in 2021. No treatment information was provided. Action taken with mRNA-1273 in response to events was not applicable. Based on the current available information and temporal association between the use of the product and the start date of the events, a

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causal relationship cannot be excluded. For the event Thrombosis concomitant medication interactions are a confounder.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. For the event Thrombosis concomitant medication interactions are a confounder.

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1345936	5/25/2021	FL	71	F	3/1/2021		<p>BLOOD CLOTS IN BOTH ARMS; NUMBNESS IN BILATERAL ARMS; REDNESS ON BOTH LEGS; SWELLING OF BOTH LEGS; PAIN IN BOTH LEGS; This spontaneous report received from a patient concerned a 71 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included breast cancer. The patient experienced drug allergy when treated with hydrocodone, and oxycodone for drug used for unknown indication. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029, and expiry: unknown) dose was not reported, 1 total administered on 20-MAR-2021 on left arm for prophylactic vaccination. No concomitant medications were reported. On an unspecified date in 2021, the patient felt numbness on both arms. Numbness got worse and patient went to emergency room. On an unspecified date in 2021, Laboratory data included: MRI brain results of which were pending. On an unspecified date in MAR-2021, a week after the vaccination patient went to emergency room due to redness, swelling, and pain on both legs. The doctor prescribed antibiotics which relieved those symptoms and was encouraged to get blood circulation assessed once patient returned to home. On 17-MAY-2021, patient got hospitalized, and on same day, ultrasound test showed a blood clot in each arm. Patient underwent chest X-ray and a test with and without contrast for the lungs. It was reported that patient was started on anticoagulants and physical therapy. On 18-MAY-2021, ultrasound of legs was negative for blood clots. On 19-MAY-2021, test in a machine with and without contrast to look at lungs (Lung scan) was within normal limits. On 19-MAY-2021, the patient got discharged from hospital. Patient stated that, consulted two doctors if it may have been the Janssen covid-19 vaccine that caused this and doctors said possibly and recommended that patient should report the information. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from redness on both legs, swelling of both legs, and numbness in bilateral arms, and had not recovered from pain in both legs, and blood clots in both arms. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210540231-COVID-19 VACCINE AD26.COV2.S-BLOOD CLOTS IN BOTH ARMS,</p>

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NUMBNESS IN BILATERAL ARMS. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY



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1345942	5/25/2021	WA	67	F		5/1/2021	LEFT SIDED WEAKNESS; HEART PALPITATIONS; DIZZINESS AND FEELING FAINT; UNABLE TO LIFT LEGS TO GO UPSTAIRS; FATIGUE; WEAKNESS; This spontaneous report received from a patient concerned a 67 year old female. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 205A21A expiry: UNKNOWN) dose was not reported, 1 total, administered on left deltoid 08-MAY-2021 for prophylactic vaccination. No concomitant medications were reported. On 08-MAY-2021, the patient experienced dizziness, heart palpitations during weeding outside, had fatigue and was feeling faint. On 08-MAY-2021, the patient was also unable to lift legs to go upstairs. On 12-MAY-2021, the patient experienced left sided weakness. On 20-MAY-2021, the patient visited the emergency room or department for treatment of the events and this was the second time of weakness. On 20-MAY-2021, Laboratory data included: Blood test (NR: not provided) Not reported, computed tomography scan (NR: not provided) No stroke and no blood clot, Chest X-ray (NR: not provided) Not reported, electrocardiogram 12 lead (ECG) (NR: not provided) Not reported, Investigation (NR: not provided) Not reported, and Magnetic resonance imaging (NR: not provided) No stroke and no blood clot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from fatigue, and had not recovered from left sided weakness, heart palpitations, dizziness and feeling faint, unable to lift legs to go upstairs, and weakness. This report was serious (Other Medically Important Condition). This report was associated with product quality complaint: 90000180437.; Sender's Comments: V0:20210544480-Covid-19 vaccine ad26.cov2.s-Left sided weakness. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

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1345749	5/25/2021	TX		M			BLOOD CLOT; HEADACHES; This spontaneous report received from a consumer via social media/news concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown exp: unknown) frequency 1 total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. Reporter talked about how he saw report in the news about male who got blood clot after receiving Janssen Covid-19 Vaccine. On an unspecified date, the patient experienced blood clot, and headaches. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the headaches and blood clot was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210540327.; Sender's Comments: V0- 20210540314- Covid-19 vaccine ad26.cov2.s-Blood clot. This event is considered unassessable. The event has an unknown temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.
1347829	5/25/2021	HI	43	F	3/23/2021	3/24/2021	Janssen COVID-19 Vaccine EUA I got the vaccine the evening of 03/23/21. Overnight I noticed my body starting to hurt and felt chills. The morning of 03/24/21 I woke up with full body aches, chills, and fever over 100 F. These symptoms lasted all day. Fever went up to 102 F. Recently I have noticed a change in my menses since having the vaccine and I wonder if it is linked. I have been on birth control since last year to control heavy bleeding. It was helping very well. The period I had in April and May were like it was before I started the pill. It was heavy and I had numerous large clots. I will be scheduling an appt with my ob/gyn regarding this change.

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1347505	5/25/2021	PA	50	F	4/9/2021	4/20/2021	4/20/21 5:57 PM Patient contacted RN 4/20/21 6:24 PM Note Developed cough, chest heaviness, and headache today. Midsternal chest heaviness has been present all day. Uses symbicort inhaler daily. Has not relieved Sx. Denies trouble breathing. Will go to ED for evaluation. Reason for Disposition ? SEVERE or constant chest pain or pressure (Exception: mild central chest pain, present only when coughing) Protocols used: CORONAVIRUS (COVID-19) DIAGNOSED OR SUSPECTED-A-AH ED Discharged 4/20/2021 (46 minutes) Treatment team Providers Additional Orders and Documentation Results Meds Orders Flowsheets Encounter Info: History, Allergies, Detailed Report, Vitals Media From this encounter EKG-Encounter - Scan on 4/21/2021 5:06 AM ED Discharged 4/25/2021 (1 hours) Last attending ? Treatment team COVID-19 Clinical impression Shortness of Breath Chief complaint ED Provider Notes (Resident) ? ? Emergency Medicine Cosigned by: DO at 4/25/2021 9:27 PM Expand AllCollapse All ED PROVIDER NOTE Patient: MRN: This note was partially completed using voice recognition technology, and was scanned for gross errors; however some errors may still exist. Please contact the author with any questions or requests for clarification. CC/HPI Patient is a 50 y.o. female presenting to the ED with chief complaint of persistent cough and shortness of breath in the setting of Covid infection. This is a patient with pertinent medical history of asthma. Patient comes in for evaluation today mainly concerned that her asthma medications have not been helping with her breathing ever since being diagnosed with Covid. She was diagnosed about a week ago. She is not having some mild fevers as well as general achiness and fatigue. She is most concerned because she has been having persistent cough and some shortness of breath particularly over the past couple days. She is compliant with her daily Symbicort but has also been using her albuterol inhaler quite frequently. She reports she usually does not have to use her albuterol inhaler nearly as much. She also reports some lightheadedness which is mainly associated with position changes when she gets out of bed too quickly. Patient otherwise denies any previous history of blood clots; she has not had any recent calf swelling/tenderness. She feels that the shortness of breath has been progressively gotten worse

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							over the course of the past week rather than all of a sudden getting worse. Denies any chest pain, even with deep inhalation. ED to Hosp-Admission Discharged 4/27/2021 - 4/30/2021 (3 days) MD Last attending ? Treatment team 2019 novel coronavirus?infected pneumonia (NCIP) Principal problem
1347569	5/25/2021		72	F	3/1/2021	3/2/2021	3/2 MHC, admitted day after covid vaccine with arterial clot. Patient seen for left lower extremity arterial occlusion with critical limb ischemia. The patient was transferred immediately post-operatively to the Progressive Care Unit for observation. The next morning the patient was discharged home with stable vital signs, clean, dry, and intact wounds, good pain control, and vascular exam of +BLE PT and DP doppler signals.
1347697	5/25/2021	NY	40	F	4/17/2021	5/14/2021	Blood Clots (2 PE in right lung) Chills Memory Loss Numbness in limbs Tingling in limbs Muscle weakness Rapid Heart Beat
1347702	5/25/2021	OH	68	F	5/5/2021	5/6/2021	On 05/05/2021 Pt received the Pfizer vaccine. The next day she got chills, headache, muscle aches. These symptoms lasted until 05/08/2021. "I was feeling much better and started working in my garden, suddenly I felt on my right calf, and I noticed a "big knot". Daughter of the patient took her to the ER on 05/08/2020, where she was scheduled to a diagnostic test on 05/12/2021. On May 12, pt also received the phone call of her PCP, who diagnosed her over the phone: "blood clot" and prescribed her with Xarelto (Rivaroxaban), a blood thinner. A doppler test was performed to the patient that day and a blood clot was found. On May 21 Pt had an appt with her PCP, and PCP advised to report this to the CHD. Pt currently walks with a cane. her next appt is with an Hematologist to find out for how long she will be taking blood thinners.

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1347719	5/25/2021	MD	60	F	5/15/2021	5/18/2021	05/15/2021 1300: Received first dose of Moderna COVID vaccine. No issues. 05/16/2021: No issues. 05/17/2021: No issues. 05/18/2021 0800: Some occasional vision blurriness as if my reading/computer glasses were smudged. I kept wiping my glasses all day. That evening, I was anxious and unable to settle down. I did not go to bed until 1:00 AM. 05/19/2021 0500: Brief strange chest sensation (not pain; not pressure; just a strange sensation). 05/19/2021 0800: Dizziness and more noticeable blurred vision which continued throughout the day. 1st BP at home 122/81 2nd BP at home 117/77 05/19/2021 0940: Brief strange chest sensation (not pain; not pressure; just a strange sensation) while driving to doctor's office. 05/19/2021 1015: I happened to have scheduled an annual wellness visit for May 19 at 10:15 AM with a new primary care physician because my previous PCP (in the same practice) has been on a very long medical leave of absence. I was dizzy and having some balance problems walking from the parking lot to the office. 1st BP 143/88 Temperature 97.2 Weight 222.1 EKG good 2nd BP 130/76 Heart: soft murmur Thyroid: symmetrical The blurred vision and dizziness were getting much worse during my appointment. Dr. said he thought the symptoms were likely a side effect of the vaccine but wanted to order an MRI to make sure my brain was OK. Dr. arranged a same day appointment at a Clinic for 3:00 PM. Dr. advised me to rest, stay well hydrated, and not skip meals. My balance was very bad leaving the office and remained bad for about 6 hours. Dr. called me with the results of the MRI and said there was no stroke or clot, and that he thought the symptoms would slowly dissipate. 05/20/2021 0800: I woke up with ringing in my left ear that sounded like a combination of soft static coupled with soft sounds at a higher pitch. The ringing lasted about 1 hour. I had dizziness and blurred vision throughout the day, but it was less severe than the previous day. 05/21/2021 through 05/25/2021: I have had much less dizziness and it usually occurs only in the morning. I still have occasional vision blurriness throughout the day. It is most noticeable when I am working at the computer. I feel as if I have a little brain fog because it takes me longer to figure out how to type some things such as my email address, passwords, etc.

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1347727	5/25/2021	NJ	54	F	3/29/2021	3/30/2021	I have been taking tamoxifen since September 2020 and have not had a menstrual period since then. Prior to that time, I would menstruate regularly, with a very light cycle. Approximately 17 hours after my first Covid 19 vaccination, I started menstruating very heavy with large clots for 3 days. Approximately 60 hours after my second Covid 19 vaccination, I started menstruating very heavy with large clots for 3 days.
1347789	5/25/2021	NC	31	F	4/24/2021	4/29/2021	This individual has a 2 month old infant and was breast feeding at time of administration of both Pfizer covid19 vaccines. Four days after the first vaccine, individual noticed a blood tinged clot-like spit up in infant and then dark stool from infant one day later. Two days after the second vaccine, mom noticed a blood-clot-like drainage from nipple (that individual says looked just like the blood tinged spit-up that was noticed in infant).
1347257	5/25/2021	AZ	44	F	4/29/2021	5/2/2021	Daily bleeding not heavy but enough to have to wear a pad. Have had three half dollar size clots there has been no let up on the bleeding .
1347325	5/25/2021	DC	17	M	5/7/2021	5/23/2021	Patient presented with one week of back, right leg and right groin pain. Right lower extremity swelling and was diagnosed with deep vein thrombosis from right popliteal vein into IVC involving a renal vein. He is on anticoagulation currently and going for catheter-directed thrombolysis today. Patient has been in hospital two days and hospitalization is ongoing at the time of this report.
1345381	5/24/2021	AR	51	F	4/22/2021	5/15/2021	Developed multiple blood clots in both lungs became extremely short of breath with any activity, heart palpitation, tachycardic

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1343673	5/24/2021	TX	41	F	4/8/2021	4/1/2021	The morning after I received the vaccine, I started having chest pressure and acid reflux. There was a hard pressure in my chest and my heart was beating weird. I started to develop a headache. I had low blood pressure a couple days later. I went to the clinic and they said I may have a blood clot. I also went to Hospital and they took some blood and did an X-ray and they told me I was fine. I was told that it may be anxiety or stress. The chest pain started to go away, but now my teeth are hurting and are sensitive. I feel that the adverse event lasted for three weeks.
1343649	5/24/2021	PA	65	M	3/15/2021	5/17/2021	Stroke due to blood clot in artery at the base of the brain
1343624	5/24/2021	WA	84	M	4/23/2021	4/23/2021	could not urinated went to ER had Catheter put in, 24 hours later blood clots in Catheter bag and was in hospital for 10 days
1345270	5/24/2021	GA	20	F	5/15/2021	5/17/2021	Left side numbness. Tests pointed to possible blood clot. Still don't have feeling in left arm. Having to continue to see neurologist.

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1343522	5/24/2021	MO	43	F	4/9/2021	4/9/2021	After the 15 minute waiting period, I felt fine. I did my grocery shopping while I was at the store, went home and worked the rest of the day at my desk. We ran errands in the evening like normal. I hadn't really noticed because we were busy, but my heart rate had been steadily increasing all afternoon and into the evening. My watch tracks my pulse rate and reports on screen. After I took a shower at 9:30, I noticed that my pulse felt high. I laid down, thinking it was just from taking a hot shower and it would go back down to normal. That's when I looked at my watch report and it looked like a stair step, with my heart rate increasing steadily every few hours, starting at 4 p.m. It was currently 110-120 (my normal RHR is 60, and drops into the 50s when I'm asleep). I went to bed, hoping I was just in my own head about this and it would be fine. I woke at 2 a.m. and my heart rate had not dropped below 100 while I was asleep and was at 130. I went to the ER at 2:00 a.m. because it was alarming. There were points where it spiked to 150 while sitting still. The ER ran an EKG, full blood and urine labs, monitored my heart rate and BP - my BP was in the normal range the whole time. The doctor who saw me in the ER was awesome. Her husband is still dealing with lingering neurological damage from having COVID last year. She informed me that I was not in a-fib or any type of cardiac distress and my labs were all normal, but was likely having an immune response to the vaccine. They did a chest x-ray and CT to check for blood clots and both came back negative. My platelet count was well within normal range as well. I returned home about 6 a.m. and my heart rate was still higher than normal, but had already started to work its way down. It stair-stepped down just like it went up and by 4 p.m., my RHR was back down to 70 and it was down in the 50s overnight. Aside from that, I had the typical headache, low-grade temp and overall body aches. Everything had subsided by Sunday afternoon. I did make an appointment see my PCP as instructed by the ER doctor on Tuesday, April 13. She had read all reports from the ER and was pleased with how my heart rate had come back down to normal. This was the same day that the authorities stopped use of the Jannsen shot due to the blood clot concerns. Dr ran another platelet count for my own peace of mind and it was a little higher than it was when I was in the ER, so she was confident that I was not in any danger, but did



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							review the symptoms/warning signs of blood clots with me just in case. I have not had any issues or symptoms since.
1344154	5/24/2021	GA	49	F	2/5/2021	2/22/2021	Deep Vain Thrombosis left leg. Pulmonary embolism. Treatment - Blood thinners.
1343580	5/24/2021	CA	78	M	4/5/2021	4/6/2021	Blood Clot after moderna vaccine
1345049	5/24/2021	CA	77	M	1/1/2021	3/1/2021	Venous thrombosis leading to strokes.
1345025	5/24/2021	CA	47	F	2/16/2021	2/16/2021	Heart Rate and blood pressure increased after 2nd dose within 12 hours. HR did not return to normal since 2nd vaccine. 3 months after 2nd dose, visits to doctor and emergency room for chest pain, increase heart rate and short of breath showed 2 blood clots, one in each lung (bilateral pulmonary embolism)
1344838	5/24/2021	PA	74	M	5/23/2021	5/23/2021	Patient called in and stated that approximately two hours after his vaccination he had "blood clots" in his mouth. Patient didn't know what other words to use to describe it. He said he was not coughing it up, but didn't know where it was coming from. I asked if it could possibly be from his gums and he said yes. It was coming from the upper part of his mouth and it was a thick, dark red blood. It was not bright red. He stated that it would congeal together and then become big enough that he would want to spit it out and this had been occurring throughout the day yesterday and into today. He reports no other loss of blood, dizziness or other symptoms. I requested patient reach out to his physician to discuss this matter.
1343503	5/24/2021	WA	33	M	5/11/2021	5/19/2021	I have blood clots in my left leg and some that have spread to my lungs. Pain started on May 19th shortly after waking up. At this time I can put no weight on my left leg. I went to an urgent care on May 23rd. I received an ultrasound and CT Scan.
1344199	5/24/2021	ID	62	M	3/12/2021	3/16/2021	Blood clot in left thigh

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1343118	5/24/2021	FL	27	F	5/1/2021	5/4/2021	Swollen, painful lumps below right calf. Two weeks no improvement. Ultrasounds done and ruled out blood clots and varicose veins. Still working with my physician to determine the cause. They believe it to be a muscle injury, though I have had no accidents, do not work out or run and no bruising.
1344150	5/24/2021	CT	28	F	4/6/2021	4/6/2021	About 4 pm that afternoon I felt like I had the flu, I got really cold. At 6pm I had a 103 fever. I was completely immobile for 3 days. I started having low-grade fever and severe leg pain for about a week, Went to ER for dehydration. Ruled out blood clots. We back to ER a week later, couldn't find anything wrong. About a month later I still feel off, Dr. diagnosed me with spinal cord inflammation,
1344084	5/24/2021	HI	73	F	5/13/2021	5/15/2021	HISTORY - Had major vein stripping surgery on both legs at age 28 and again at age 57. In between surgeries had sclerotherapy on both legs. Have experienced phlebitis before and know how to manage it. ADVERSE EVENT - The first day after vaccination sore arm and general malaise. The next day inflammation on both legs in multiple locations. (One outbreak is from ankle to knee.) Pain is worse when walking or standing. Legs are hot and sore to touch. Never experienced anything to that extreme degree before. Concern about blood clots. After 10 days it is finally starting to subside.
1344055	5/24/2021	IL	90	F	1/29/2021	2/6/2021	one week after 1st vaccine shot, mom started to feel sick around lunch. Took mom to hospital she had a heart attack. They dissolved the blood clot and found out she also had pneumonia with no symptoms. She died 2 weeks later. She had dementia but health was fine until she received the covid 19 vaccine.
1344020	5/24/2021	FL	50	F	4/12/2021	5/4/2021	had bakers cyst burst and had 3 blood clots

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1344671	5/24/2021	NY	48	F	3/13/2021	4/3/2021	On 4/5, I started with upper stomach pain and then two days later I had a fever and a very rapid pulse. I went the walk-in clinic on 4/7 and they performed COVID (negative), an EKG and CT Scan of abdomen (both were normal). The fever went away, the stomach pain eased but I still had SOB, fatigue and rapid pulse. Three days later, the symptoms remained, so I saw a gastro doctor and he said it could be COVID or blood clots, then sent me to hospital on Monday, 4/12 and 4/13. They did 2 more EKGs, COVID tests and bloodwork. I still had SOB and pain in my upper stomach towards my chest. On 4/14, I woke up with a massive headache and saw the news about the vaccine, so I went back to the ER to get checked for blood clots. They did an EKG, CT Scan of the abdomen and head, along with more bloodwork. Everything was normal, but my bloodwork showed an elevation of something that indicated that I have an infection, but they weren't sure what. They sent me home with no diagnosis. Over the next two days, I rested and I gradually started to get my strength back. I went back to work that Friday for the first time since 4/7.
1343336	5/24/2021	NV	59	M	3/29/2021	4/6/2021	shortness of breath, arrhythmia. Referred to Cardiologist. Recommended scope to check the heart for clots, shocked heart back to normal sinus rhythm.
1343331	5/24/2021	VA	23	F	1/26/2021	2/20/2021	On 2/20/2021 participant went into Urgent Care for routine ultrasound for the liver due to being on Strattera medication. The ultrasound also found a blood clot in the inferior vena cava right above the liver superior hepatic. Participant was sent to the ER for CT scan to confirm the ultrasound findings. Participant was put on blood thinners (Enoxaprin injection twice a day for 1 week). Participant was switch to oral blood thinner Pradaxa 150mg twice a day. Participant is currently still on Pradaxa. She has a CT scan schedule for this Friday to conclude to clot and decide to continue medication.

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1343269	5/24/2021	OH	62	F	5/5/2021	5/5/2021	She got her vaccine in the left arm, and felt fine. She went shopping in the store and noticed that she was short winded when she was leaving, but felt that it was possibly asthma and left. She had a temperature between 102 and 103 for a couple of days and having fever and chills as well. She continued with the shortness windedness, and had company and on 5/9/21 they left and she started having severe pain, felt like it was either on the right side kidney or the lung, and was spasming horribly and knocking her down with the pain. She went to the ER and they did a CAT Scan thinking it was kidney stones, but told her that she had three blood clots in her lungs, lower base right and lower base left and mid right and part of her lung has apparently died due to this. They put her on blood thinners, Xarelto. She was admitted on 5/10 early morning and released on 5/12/21. The doctor in the hospital said that it did not make sense that she had blood clots in her lungs, but nothing in her legs. She told her that she was short winded, and he told her to report her reaction. Since being home she has been coughing a lot due to possibly the blood clots. She was told that she will be on the Xarelto for a very long time. She was also informed that she had lymph node enlargement as well.
1343126	5/24/2021	PA	60	M	5/10/2021	5/18/2021	On 5/18/21 AM, woke to pain in my right side under my shoulder blade. Went to ER. They performed many blood test, chest Xray, Chest CTA. Determined Pulmonary embolism and infarction. I was admitted, more blood tests, Echocardiogram, Venous Doppler study( No evidence of DVT). Released 5/20/21. Prescribed Eliquis to thin blood for easier natural clot dissolve. No Known cause of PE, yet. Follow up scheduled with my PCP.
1343040	5/24/2021	WA	41	F	3/20/2021	3/24/2021	I went in for a scheduled MRI of my foot and the MRI found that I have a 7mm blood clot on my foot. It was found on my left foot plantar region (bottom of my foot). A few days after the vaccine I had swelling on the top and bottom of my left foot. I got two vascular images completed and the MRI was never sent to the vascular department. My podiatrist confirmed the blood clot on an ultrasound. I'm still experiencing swelling.
1342992	5/24/2021	MA	32	F	4/30/2021	5/3/2021	Period clots that resemble miscarriage every 20 minutes for 4+ days

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1343794	5/24/2021	NV	52	M	4/10/2021	4/13/2021	1st day of vaccine; I felt very tired and fatigued and my joints started to hurt and I could not walk due to the pain in my joints. 3rd and 4th day of vaccine; I started to experience numbness sensation to my hands. I also had numbness sensation to my face, right side and lips and also to my head. I went to Urgent Care where lab work was performed as well as a CT scan of the head to check for blood clots and results came back normal. Also an U/S of the right leg to check for any blood clots was performed which came back normal. I then went to see my PCP who performed more tests and exams, again did lab work to check for blood coagulation and still continued with the numbness sensation to my hands and all to my body. After about 10 days of my vaccine, I noticed that my oxygen level was 87, 96, 86, 92 and where my oxygen level has always been around 98 or 99. I will be also having heart studies in a few weeks. I have not recovered from my symptoms and feel very fatigued and tired all the days.
1342589	5/24/2021	OR	23	M	5/7/2021	5/21/2021	Patient presented with chest pain and found to have bilateral pulmonary emboli. He was 2 weeks post 2nd dose of Moderna vaccine. He has personal history of cerebral venous sinus thrombosis and also has positive family history of DVT's (mom had 2 DVT's during pregnancies)

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1343374	5/24/2021	OH	43	M	4/1/2021	4/23/2021	Blood clot in superficial vein behind right knee as well as vertigo and nausea. Currently on 30mg/day of XARELTO blood thinner (I've been taking since diagnosis on 5/5/21). Will continue to take 20mg/day for the next 30 days. Background: I started to notice my right calf get tight and sore approximately ~3 weeks following my vaccination. I had been doing a lot of running and hill training so I assumed it was a muscle strain/aggravation. After approximately 1-2 weeks I noticed the tightness worsen and also noticed significant swelling around my lower calf/ankle. I went to the doctor on 5/4/21 and was given a D Dimer blood test which came back 1.27 mcg/mL FEU (over the recommended 0.5 mcg/mL). The next day I had an ultrasound of my right leg where they discovered the SVT clot behind my right knee in a superficial vein (but near a major/deep vein intersection). I was immediately prescribed XARELTO blood thinner - to be taken for ~51 days. ~21 days of 30mg/day (15mg twice/day) followed by ~30 days of 20mg/day 1x per day. The morning of 5/20/21 around 6:30am I started to feel nausea and vertigo after returning home from walking my dog. I finished a low-intensity exercise routine at my home and around ~7:15am my symptoms worsened. I went upstairs to my bedroom to lay down on my bed and the room started spinning. I then went to the bathroom and vomited clear fluid. I started feeling a little better after vomiting but was still slightly dizzy and light-headed. I made an appointment and went to the doctor around 10:30am. The doctor suggested doing further bloodwork and a CT scan of my head. Both tests came back normal. The doctor suggested the vertigo and nausea were inner ear related and that I should continue taking XARELTO and to also start wearing a compression sock (especially during exercise/activity).
1343212	5/24/2021	IA	33	M	4/24/2021	5/22/2021	He got a COVID vaccine (location unknown to me) and called a few weeks after vaccine to report symptoms of blood clot was diagnosed this past weekend at emergency room.

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1343883	5/24/2021	NC	28	F	5/2/2021	5/17/2021	Adverse Events: I went to the emergency room on 5/18 after experiencing major back pain, sharp pain in ribs, chest pains, difficulty breathing, shortness of breath and chronic coughing. Outcome: After x-rays, EKG, D-Dimer Test and a CT scan the doctor determined that I have Pulmonary Embolism (blood clots in my lungs). I've never had any symptoms prior to receiving the covid vaccine. Today is 5/24 and I am still experiencing most of the same symptoms despite taking my medications as prescribed. The worst symptoms are difficulty breathing and chronic coughing. Treatment: -No longer taking birth control (Azurette) since that can cause blood cots - Xarelto (to treat and prevent blood clots) -Gabapentin 100MG 3x Day (for pain) -Benzonatate 200MG 3x Day (for cough) -Tizanidine 2MG 1X day (for pain) -Albuterol Inhaler Every 4 hours

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1342339	5/23/2021	CA	24	F	2/18/2021	2/18/2021	Epileptic Encephalopathy. Severe increase in seizures (number and intensity). Some of the worse ones she has ever had. Started within 3 hours of receiving her vaccine. For 4 days she had some other weird odd side effects besides significant increase in seizures. Weird reactions and increase in seizures with movement of any kind (in wheelchair, in car, carrying her from chair to bed, etc). Never had this before. Looked odd in her face, glassy eyes for a few days, weird movements. Her doctor called it a cytokine storm type reaction at first but then she never went back down to her baseline for her seizures as they kept getting worse and worse. Finally on March 24th we did a medication infusion via IV to try to break the cycle and then on April 1st we started her on another seizure medication. On April 28 we increased the new seizure medication trying to get her back down to her baseline. She has never gone back down to her baseline, she is still dealing with an increase in seizures. She has days where she is just seizing all day long off and on for no other reason. Her team of doctors and I are 110% (yes 110%) sure this is a reaction to the vaccine. They called off the second dose, considered J&J vaccine but then with the risk of clots and her not 100% stable due to the first vaccine reaction we decided to hold off. This is horrible because for the last year I lived for the day to get her vaccinated to be protected from COVID and now she can't be. I am devastated and so afraid for her life because as you see in her dx she is very high risk for COVID death. We love to travel and just started cruising as she loves it and now we can't because she isn't vaccinated. She can't go back to her life the way she knew it before the pandemic because of the vaccine not being safe for her. :(
1341496	5/23/2021	CA	63	M	4/7/2021	4/10/2021	Leg pain initially, diagnosed with blood clots may 17. receiving treatment currently 15mg xarelto twice daily.



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1341696	5/23/2021	AZ	70	M	5/18/2021	5/19/2021	70yo Male. with no significant PMHX. Presents with LLE swelling. States swelling started 1 day after his first moderna covid vaccination. He was found to have extensive DVT LLE. He denies recent travel or prolonged immobilization, he denies injury to the leg, he denies previous blood clots/blood disorder/cancer. This is sooner than I would expect patient to begin having symptoms after DVT after covid vaccination however I have no other clear etiology at this time.
1341743	5/23/2021	MO	42	F	3/15/2021	3/18/2021	Blood clot in the lining of my stomach- went to urgent care thinking it was gallbladder. They did a CT scan and found blood clot. I was told to get to the ER immediately as it is life-threatening. I was in hospital for 3 days on a blood thinner. Clot was still present when I left. I am still on blood thinners. CT repeated several weeks later and clot is gone.
1341765	5/23/2021	GA	43	F	4/10/2021	4/19/2021	Aortic Thrombosis and Kidney Infart (right)
1342111	5/23/2021	IN	20	F	4/1/2021	4/23/2021	Two days after the vaccine, I developed a rash on my arm and severe pain. Then the day after I was having horrible chest pain and heart palpitations. I was given heparin directly to my heart to treat a possible blood clot.
1341621	5/23/2021	NC	61	F	1/1/2021	5/13/2021	blood clot right lung on xeralto may to november2021
1342231	5/23/2021	WA	33	M	5/11/2021	5/23/2021	Patient developed pain in the left lower leg about 8 days post vaccine, progressively worsening over time, with associated swelling and spread of discomfort to the thigh. Presented to urgent care on 5/23/2021 and was felt to have findings suspicious for deep vein thrombosis. See item 19 for details on test results.

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1342132	5/23/2021	MI	42	F	5/12/2021	5/13/2021	10 Hours after, fever, sweating, very thirsty. 3 Days after vaccination, heaviness in my chest, breathing problems, very tired. Thought it would get better did not. Went to Hospital Emergency Room on May 22, 2021. D-dimer was elevated. Dr was concerned about blood clots. The hospital did a CT Scan of my chest with dye. Did not find any evidence of clots. I was released and told this could be a side effect of the Johnson & Johnson vaccination. I was told to monitor if it doesn't go away or get worse follow-up on further investigation. Was also told to report this side effect. I still have the heaviness and pressure in my chest as well as a bit of breathing problems.
1340421	5/22/2021		52	F	4/30/2021	5/1/2021	transverse sinus thrombosis; This is a spontaneous report from a non-contactable pharmacist. A 52-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 30Apr2021 (Batch/Lot number was not reported) as unknown, single for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced transverse sinus thrombosis on 01May2021 which caused hospitalization. Therapeutic measures were taken as a result of transverse sinus thrombosis. The outcome of the event was unknown. No follow-up attempts are possible, information about lot number cannot be obtained. No further information is expected.
1340811	5/22/2021	MI	30	F	5/5/2021	5/6/2021	Started feeling terrible the day after the vaccine. Very tired, not feeling well, off balance. Symptoms got so back she had to go to the ER. She ended up being transferred to another hospital because they couldn't treat her. She has a blood clot in the carotid artery and acute strokes and brain tissue damage and numbness and loss of strength to right arm and hand

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1340758	5/22/2021	WY	71	M	4/9/2021	5/1/2021	My dad started having breathing problems and heart fluttering shortly after getting his first covid vaccination on April 9, 2021. He had contracted Covid back in October 2020. He never told us he was getting the vaccination until we got a call on his cell phone from Public Health the day after he died of a pulmonary embolism. When he started complaining of symptoms, his doctor referred him to a cardiologist at a Clinic. He had an appointment with them a few days before he died. Apparently, they didn't find any blood clots, possibly because they were looking for heart issues. Either way, I believe that my dad died from side effects of the Moderna vaccine. My dad died on May 1, 2021 of a pulmonary embolism. The coroner and County Sheriff both said it was one of the biggest blood clots they had ever seen. Since he had no history of blood clots, I thought it important that I report it.
1340690	5/22/2021	PA	67	M	4/7/2021	4/11/2021	03/09/21(2:00PM):received dose 1 moderna vaccine - no ill effects; 04/07/21 (10:00AM): received dose 2 Moderna vaccine; 04/11/21 (11:00PM): experienced what seemed muscle cramp in left upper calf muscle; 04/19/21: cramp diminished, some swelling left upper calf, slight swelling left inner ankle; 04/22/21: swelling entire left ankle and top left foot; 04/22/21: visited primary care, diagnosed possible Baker's cyst or venous thrombosis - sent to hospital for ultrasound; 04/22/21: ultrasound revealed deep venous thrombosis, upper left calf vicinity (popliteal vein); 04/22/21: hospital performed blood tests, prescribed Xarelto 15mg (2 daily) for 21 days; 04/26/21: primary care follow up, prescribed Xarelto20mg (once daily) for 90 days. 05/22/21: slight swelling inner left ankle persists, slight fullness upper left calf persists, otherwise no other ill effects; 05/22/21: further blood tests pending (as per primary care physician): cbc with differential, pcrp, ante, esr, 83891, cmbp, tshr, ptp, leid, misc, acab, lupus; NOTE: Moderna dose 1: lot # 048A21A, intramuscular, left arm
1340597	5/22/2021	MI	36	F	5/15/2021	5/17/2021	I had a brain tia-stroke. Blood clots. Paralyzation.loss of vision. Loss of voice

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1340517	5/22/2021	PA	77	F	3/31/2021	5/17/2021	Had a stroke from blood clot; she lost weight; This is a spontaneous report from a contactable consumer (mother) that: A 77-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8272) via an unspecified route of administration on 31Mar2021, as a single for COVID-19 immunization. Previously patient received first dose of BNT162B2 (covid-19 vaccine, Batch/Lot Number: not clear) via an unspecified route of administration on 10Mar2021 as single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Reporter stated, "I don't know so I just was try to find out or who I report or ask about. I convinced my mother to get her Covid vaccine, so she got her second shot on 31Mar we got it together. Yesterday (17May2021 ) my mom had a stroke from blood clot, and I was just asking myself if it could have had anything to do with from Pfizer shot as she never had any problem like that and now, she was in the hospital from the stroke, and I was just wondering if me talking her and getting her vaccine could possibly had to do with this. Reporter further stated, Absolutely, I have question as far as if that was the cause, was there any special treatment that she should be getting maybe I can at least inform the doctor about that anything. I am out of my mind right now because I felt that I talk to her getting the vaccine because I want to her to be safe, she was 77 yrs. old (Not clarified) she never had any medical problem I feel guilty. Height and weight: Reporter stated, She was approximately 5'6. I don't know the weight as she lost weight, she was not obese or anything like that, but I honestly don't know her weight. The outcome for the events was unknown.

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1340506	5/22/2021	GA	46	F	4/14/2021	5/10/2021	I started having shortness of breath and went to the emergency room. It was determined I had blood clots in both lungs based on a CT Scan; This is a spontaneous report from a contactable consumer (patient). A 46-years-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Right on 14Apr2021 (Lot Number: EW0153) as 2ND DOSE, SINGLE for covid-19 immunisation. Medical history included Sleep apnoea. No other vaccine in four weeks. No COVID prior vaccination. Concomitant medication(s) included phentermine hydrochloride (LOMAIRA); fluoxetine; loratadine (CLARITIN); diphenhydramine and Charlotte24 (unspecified). The patient previously took morphine and tetracycline and experienced drug allergy. Patient took the first dose of bnt162b2 (lot number EN6207) in right arm on 17Mar2021 for covid-19 immunisation. The patient started having shortness of breath and went to the emergency room on 10May2021. It was determined she had blood clots in both lungs based on a CT Scan. AE resulted in Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event), Disability or permanent damage. The patient hospitalized for two days. Patient received blood thinners as treatment. The patient had covid test type post vaccination nasal swab on 14May2021 with negative result. The outcome was recovering.

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1340492	5/22/2021	NY	51	M	4/23/2021	5/1/2021	allergic reaction to the Covid 19 vaccine; nerves in his right wrist are bothering him, feels the nerves moving up and down and his arms, and feeling like the nerves in his right arm were jumping; right hand won't relax, can't bend the fingers on his right hand, can't make a fist with his right hand; like he has no control of his arm; right wrist feels like needles and pins; right hand blew up with inflammation; His fingers on his right hand were swollen, right hand looked like it was going to explode; Like his right arm was agitated, right arm was still very uncomfortable; pain in his hand; This is a spontaneous report from a contactable consumer (patient). A 52-year-old male patient received the second dose of BNT162B2 (PFIZER COVID-19 VACCINE, lot number: EW0164), at the age of 51 years old, in right arm at single dose on 23Apr2021 16:30 for covid-19 immunization. Medical history included sleep apnea, congestive heart failure, high blood pressure and type 2 diabetes, seasonal allergy and covid-19 in May2020. The patient reported he had symptoms of the covid-19 virus in May2020. He had a positive covid-19 virus test and did quarantine. The patient reported he's never been allergic to any kind of medication. Concomitant medications included atenolol 50-25 mg at one tablet a day. The patient didn't know the name of the other medication combined with the atenolol. The patient reported one was for the heart and one was for the blood. He also took medication for seasonal allergies but declined to provide the name. The patient previously received a flu vaccine (NDC/Lot/Expiry: unknown) on 2020 that made him feel bad with a head cold. The patient previously received the first dose of BNT162B2 (lot number: EP7534), at the age of 51 years old, in right arm at single dose on 02Apr2021 16:30 for covid-19 immunization. The patient started having some problems maybe a week after that. He started feeling like the nerves in his right arm were jumping. Like his right arm was agitated. His finger on his right hand were swollen. The patient did get his vaccine in the right arm. He thought his arm was going to bother him after he got the vaccine. The nerves in his right wrist are bothering him. Like he felt the nerves moving up and down and his arms, like he had no control of his arm. His right hand blew up with inflammation. His right hand looked like it was going to explode. His right hand won't relax. On 01May2021 was when he noticed his arm acting funny.

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He would say that the swelling had gone down from taking the antibiotics but his right arm was still very uncomfortable and he couldn't bend the fingers on his right hand and he couldn't make a fist with his right hand. His right wrist felt like needle and pins. The patient went to the emergency room at a hospital two nights in a row on 04May2021 and 05May2021. The first time he had x-rays done. The second time he had x-rays and a sonogram of his right arm to check for blood clots and he had some blood work done. All of that came back negative. The emergency room doctor asked him what arm did receive BNT162B2 in, he told the doctor his right arm, the doctor told him he's having an allergic reaction to BNT162B2. The emergency room doctor prescribed him an antibiotic to take. He'd already finished the antibiotic and didn't recall the name, the bottle had been thrown away. The patient followed up with his primary care doctor on 13May2021 and was given a prescription for a muscle relaxer and motrin 600 mg to help bring the swelling and pain down in his hand. In the emergency department he had a right arm and right wrist x-ray. The doctor was trying to figure out why his right hand looked like a balloon. The only conclusion the emergency room doctor came up with was that he was having a reaction to BNT162B2. The outcome of events nerve in wrist bothering, felt nerve moving, feeling nerves jumping, right arm agitated, no control of arm, right hand won't relax and couldn't bend fingers was not recovered. The outcome of events hand blew up with inflammation, fingers on right hand swollen, right hand explode and pain in hand was recovering. The outcome of events wrist felt like needles and pins and allergic reaction to vaccine was unknown. No follow-up attempts are needed. No further information is expected.

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1340487	5/22/2021			F			blood clot in her lungs; bronchial asthma; This is a spontaneous report from a Pfizer-sponsored program. A contactable female consumer (patient) reported for herself that a female patient of an unspecified age received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), dose 2 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as 2ND DOSE, SINGLE for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Patient historically received first dose of BNT162B2 on an unspecified date for COVID-19 immunisation. Patient received second dose of COVID vaccine and has since had a blood clot in her lung and bronchial asthma from unspecified dates. The outcome of the events was unknown. Information about the Lot/batch number has been requested.



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1340479	5/22/2021			F	4/1/2021	4/1/2021	she feels pain in the lungs, in the body,in her head there is blood clot; she feels pain in the lungs, in the body,in her head there is blood clot; she feels pain in the lungs, in the body,in her head there is blood clot; every day she feels different; This is a spontaneous report from a contactable consumer (patient) from a Pfizer-sponsored program. This female patient of an unspecified age received received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Apr2021 (Lot number was not reported) as single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. Previously the patient received the first dose of BNT162B2 on an unspecified date for COVID-19 immunisation. In Apr2021, the patient experienced that she feels pain in the lungs, in the body, in her head there is blood clot, every day she feels different with outcome of unknown. The clinical course was reported as follows: The patient had the 2nd dose of the vaccine 3 or 4 weeks ago, since then she had the symptoms, she feels something's changed, and she feels pain in the lungs, in the body, in her head there is blood clot, every day she feels different. In the hospital they do tests and X-ray but results turn out normal and nothing is wrong. She had never felt this strange in her life, she didn't feel well. Information on the lot/batch number has been requested.

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1340469	5/22/2021	CA	81	F	4/19/2021	4/29/2021	Thrombocytopenia; Blood blisters; This is a spontaneous report from a Pfizer-sponsored program COVAX Support. A contactable Other-HCP reported for a 81-year-old female patient that received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Deltoid Left on 19Apr2021 (Lot Number: ER8737; Expiration Date: Jul2021) as 1ST DOSE, SINGLE for covid-19 immunisation . Medical history included deep vein thrombosis. Concomitant medication included apixaban (ELIQUIS) taken for deep vein thrombosis from 29Apr2021 to 30Apr2021. The patient experienced thrombocytopenia and blood blisters on 29Apr2021. The patient was hospitalized for thrombocytopenia from 29Apr2021 to 02May2021. The patient visited emergency room and physician office due to thrombocytopenia. The patient underwent lab tests and procedures which included platelet count: 3,000/dropped on 29Apr2021, platelet count: 348,000 on 04May2021. Therapeutic measures were taken as a result of thrombocytopenia included platelets. The outcome of events was recovered.; Sender's Comments: As there is limited information in the case provided, the causal association between the event thrombocytopenia and the suspect drug BNT162B2 cannot be excluded. The case will be reassessed once new information is available.

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1340462	5/22/2021	WV	50	M	4/12/2021	4/12/2021	nurse stated it could possibly be blood clots; Patient is afraid he is going to have a stroke or scared he had one after the COVID-19 Vaccines; blurred vision in right eye that comes and goes; ringing in his left ear; Very fatigued throughout the day, sleeping a lot/tired and sleeps a lot; Very fatigued throughout the day, sleeping a lot/tired and sleeps a lot; Date received First dose: Third Friday in Feb2021/Received second dose on 12Apr2021, six weeks after first dose; Date received First dose: Third Friday in Feb2021/Received second dose on 12Apr2021, six weeks after first dose; Fullness in face; Body aches; Brain fog: At times he can't do the simplest things. He will look at the clock on the wall and says he knows what it is, but can't find the words to say. Cannot carry on a conversation intelligently; Brain fog: At times he can't do the simplest things. He will look at the clock on the wall and says he knows what it is, but can't find the words to say. Cannot carry on a conversation intelligently; Brain fog: At times he can't do the simplest things. He will look at the clock on the wall and says he knows what it is, but can't find the words to say. Cannot carry on a conversation intelligently; Brain fog: At times he can't do the simplest things. He will look at the clock on the wall and says he knows what it is, but can't find the words to say. Cannot carry on a conversation intelligently; headache all over the back of his head/Affecting his balance. In back of head, moves around, sometimes the front; headache all over the back of his head/Affecting his balance. In back of head, moves around, sometimes the front; feeling dizziness/had to stop driving; This is a spontaneous report from a contactable consumer (patient's wife). A 50-years-old male patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on 12Apr2021 (may have been in morning) (Batch/Lot Number: Unknown; Pfizer COVID-19 vaccine) as 2ND DOSE, SINGLE for covid-19 immunization, at the age at vaccination of 50 years old. The patient's medical history and concomitant medications were not reported. History and Investigations: Doesn't take any medications. Has no medical conditions, unless age was considered a medical condition. Historical vaccine included first dose of COVID-19 Vaccine reported as on Third Friday in Feb2021 (First dose: between 1430-1530), and experienced AEs: Brain fog; Headache: Thinks in the back of the head, but moved around too, sometimes in the front. Has affected his balance. Dizziness: Had to stop a couple times while driving home from vaccine facility. Aches and pains. All symptoms from the first dose went away within 3-4 days.

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Caller would say patient recovered completely from symptoms associated with first dose. The patient experienced nurse stated it could possibly be blood clots on an unspecified date with outcome of unknown, patient is afraid he is going to have a stroke or scared he had one after the covid-19 vaccines on an unspecified date with outcome of unknown, brain fog: at times he can't do the simplest things. he will look at the clock on the wall and says he knows what it is, but can't find the words to say. cannot carry on a conversation intelligently on 12Apr2021 with outcome of not recovered, headache all over the back of his head/affecting his balance. in back of head, moves around, sometimes the front on 12Apr2021 with outcome of not recovered, feeling dizziness/had to stop driving on 12Apr2021 with outcome of not recovered, blurred vision in right eye that comes and goes on an unspecified date with outcome of not recovered, ringing in his left ear on an unspecified date with outcome of not recovered, fullness in face on 12Apr2021 with outcome of not recovered, body aches on 12Apr2021 with outcome of not recovered, very fatigued throughout the day, sleeping a lot/tired and sleeps a lot on an unspecified date with outcome of not recovered, date received first dose: third friday in feb2021/received second dose on 12apr2021, six weeks after first dose on an unspecified date with outcome of unknown. Patient was caller's husband. Had both doses and had the same problem. His experience is very bad with the second dose and has had it for a month. Within a day after the first dose, had brain fog, headache, and dizziness where he had to stop driving a couple times. This went away within a few days. Patient and caller were concerned about the second dose. They spoke with patient's doctor and the local Health Department, both said it couldn't be from the vaccine. Patient was advised to get the second dose. Had the same symptoms with second dose, but occurred within an hour of received second dose. Symptoms have continued. Also experiencing blurred vision in right eye that comes and goes. Patient had an appointment with his doctor this week, but the doctor basically didn't look at him. Doctor advised patient to see a neurologist. Another nurse stated it could possibly be blood clots. Caller is trying to find help. Caller wanted to add with the second dose, patient experienced ringing in his left ear, fullness in his

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face, and headache all over the back of his head. Was feeling dizziness after second dose and had to stop driving. Patient is afraid he is going to have a stroke or scared he had one after the COVID-19 Vaccines. If the COVID-19 Vaccines woke up some other health issues, patient wants to get it taken care of. Received second dose on 12Apr2021, six weeks after first dose. Got second dose at a different location. Second dose COVID-19 Vaccine AEs: Started experiencing symptoms within an hour. Headache: Affecting his balance. In back of head, moves around, sometimes the front. Comes and goes. Brain fog: At times he can't do the simplest things. He will look at the clock on the wall and says he knows what it is, but can't find the words to say. Cannot carry on a conversation intelligently. Dizziness. Blurred vision in right eye: Doesn't know if this started on 12Apr2021 or a couple days after. States as the day goes on and he gets tired, it will worsen. It comes and goes. Ringing in left ear: Began on 12Apr2021 or a few days after. Fullness in face: Stated this comes and goes, but has stayed the same. Documented as provided. Body aches: Comes and goes. Seems to worsen as the day goes on. Very fatigued throughout the day, sleeping a lot: He's tired and sleeps a lot. It was hard for him to get out of bed. Caller stated patient's symptoms worse as the days goes on. Patient never experienced pain at the injection site. Guesses patient received COVID-19 vaccines in his left arm because the county was doing a drive-thru clinic. Since he didn't get out of his car, she believed patient would have received the vaccines in the left arm. The events REQUIRE A VISIT TO Physician office: Doctor doesn't think anything is wrong. ER: Not yet. Is considering going to the ER today. PRIOR VACCINATIONS WITHIN 4 WEEKS was None. RELEVANT TESTS: None. Events Clot blood and stroke considered medically significant. Follow up attempts are needed. Information of Lot/Batch number has been requested.

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1340455	5/22/2021	IL	61	F	2/2/2021	2/1/2021	BNP just went up and up; Congestive heart failure; She couldn't walk up the stairs; This is a spontaneous report from a contactable nurse (patient). A 61-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration on 02Feb2021 (Lot Number: EL8982) as SINGLE DOSE for covid-19 immunisation, in the afternoon around 4 or 5 o'clock. Vaccination Facility Type was Nursing home/Rehabilitation Center. Medical history included psoriasis from 1986 and ongoing; stent in 2016, the doctor was sure the heart failure was not related to her stent; swollen leg from Jun2020 to an unknown date. She went to her Cardiologist, they said she has no heart failure. The Cardiologist told her the fluid from her knee drained down into her ankle that was why it was swollen, her BNP indicator was 165 at the doctor then. Concomitant medications included atorvastatin (LIPITOR) taken for cholesterol, coronary artery disease, cardiac disorder from 2016 and ongoing; clopidogrel bisulfate (PLAVIX) taken for blood viscosity decreased from 2016 to 14Apr2021, patient reported when she went to the hospital they checked for a PE or Pulmonary Embolism or blood clot, they found nothing, the cardiologist said her blood was flowing beautifully so he discontinued the Plavix; acetylsalicylic acid (BABY ASPIRIN) taken for blood thinner from 2016 and ongoing; ezetimibe (ZETIA) taken for blood thinner, start and stop date were not reported. The patient previously took the first dose of bnt162b2 on 11Jan2021 (lot number: EL0142), also at age of 61 years old, at left deltoid for covid-19 immunization; tremfya injection 100 mg every 60 days for psoriasis. The patient experienced congestive heart failure (CHF) (hospitalization, disability, medically significant) in Feb2021 with outcome of not recovered, she couldn't walk up the stairs (hospitalization) in 2021 with outcome of unknown, bnp just went up and up (hospitalization) in Apr2021 with outcome of unknown. The patient was hospitalized for events from Apr2021 to 16Apr2021. Patient report she got short of breath, which she didn't attribute heart failure, she thought it was something with her lungs. And had a cough. She reported she was so short of breath she couldn't walk up the stairs. At the beginning of the month, she was better, but she couldn't go up the stairs, and she was taking cough syrup and things which didn't

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help. Then she was in the emergency room either on 13Apr2021 or 14Apr2021 and then she was admitted to the hospital, and then she had CHF. This started 2-3 weeks after getting the 2nd vaccine the shortness of breath, heart congestion and wheezing. Her husband said she needs to go pulmonologist to be seen. Patient confirmed she went into the hospital on the 13Apr2021 but, it was midnight and it could have been the next day also, it varies, the time. The shortness of breath and things started in February or March started, they started slowly. She could not breath at all, it started around 2-3 weeks after the vaccine. It was so bad she could not walk around, her husband was worried he went to get the car and she waited on a bench. She could not breath. These things started before 16Mar2021, maybe, between the 15Feb2021 to 21Feb2021. Patient said CHF was heart didn't pump sufficiently anymore. She was now on disability and has a Life-Vest. She was on tons of medications. She wears Life Vest for 3 months then will get echocardiogram or MRI to see what is going on. When she went to the hospital for the CHF, her BNP was 2700 and then it went to 3500. They gave her IV diuretics in the hospital but her BNP just went up and up. This was all on the same day she went to the ER, she spent 13 hours in the emergency room. They drew labs and cardiologics then. Patient got IV diuretics in the hospital, she believed it was Lasix or Furosemide. When she was discharged for the hospital at night on the 16th, her BNP was 518, so they let her go because the diuretics worked. The diuretic was change to oral Torsemide at her discharge. Investigations included chemistry, BNP, a blood count, a metabolic panel.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events, Cardiac failure congestive, gait disturbance, brain natriuretic peptide increased cannot be completely ruled out. The impact of this report on benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethic committees, and Investigators, as appropriate.

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1340812	5/22/2021	AL	58	M	4/6/2021	4/15/2021	Johnson and Johnson Vaccine, shortness of breath, elevated blood pressure, elevated temperature, increased heart rate, decreased kidney functions, blood clots in both arms and jugular vein, slurred speech, severe pain in right side, fluid in right lung and around heart. Admitted to MICU from emergency room. Intubated for 12 days. Chest tubes both sides, central line, Hickman Catheter. Discharged and admitted to hospital. Currently home receiving outpatient therapy.



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1340433	5/22/2021	CA	82	M			<p>This is a spontaneous report from a contactable consumer (patient's wife). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on an unspecified date (Batch/Lot Number: Unknown) as single dose for COVID-19 immunization. Medical history included dementia and he shrunk he is 5'9" or 5'8". Concomitant medication(s) included warfarin sodium (COUMADIN), at 4 mg once daily in the evening 6 days per week, On Fridays he takes 6 mg once in the evening. Patient's wife says her husband had one vaccination, the Pfizer vaccine and a week later her ended up in the hospital. They had to postpone his second dose because he ended up in the hospital but they have the second one coming up on the 14May2021 and she is scared for him to get it, he is adamant he is going to take it. He was taking her to the doctor for a problem she had and he told her he could not go to the bathroom and she was like what, because he has a stoma bag and she looked and it was plugged with a blood clot, he couldn't open it and drain it so she told him to get in the shower and take it off and put a new one on and she was pulling it off, it was full of blood and there was a big huge, like real liver sized clot came out of his stoma bag. She went to get the stoma bag after the thing came off she grabbed it and got it in the bag and took it out. He was taken to the hospital by the paramedics and he spent 3 days in the hospital. He is 83 now but this happened the week before his birthday, he was 82 when they noticed the blood in his stoma bag, he was a week away from 83. She provides his height and says he shrunk he is 5'9" or 5'8". She does not remember the date of the first dose. She says his birthday was 18Apr2021. She thinks he was admitted to the hospital on 12Apr2021 and he got the first dose the week before that. She thinks it was 12Apr2021 that he was admitted because it was just before birthday first dose week prior to that. They never made the connection. She thinks he ended up in the hospital on a Tuesday and she is trying to count from his birthday 18Apr2021, she thinks he got to come home on Thursday, 15Apr2021. She believes he went in on 12Apr2021 and was discharged on 15Apr2021, he was there 3 days. No further information provided. Her husband is not there with her. She does not have his</p>

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vaccine card to provide NDC lot expiration or dose amount. he may not even have his vaccine card because he has dementia. No further information provided. He hardly takes any mediation He takes Coumadin he takes 1 per day except Fridays he takes 2, she thinks it's 4 mg and he takes 2 at night everyday except Friday he takes 3. she was guessing. She has one there called Atorvastatin that says it is for Lipitor, so that is not it. She sees Glipizide. No further information provided. She says she found the Coumadin, they are 2mg tablets and he takes 2 at night. She says the dose is not written on there because they call him every 3 weeks because he has to have a blood draw. He takes 2 tablets at night 6 days per week. She clarifies he takes 4 mg once daily in the evening 6 days per week and on Friday he takes 6 mg once in the evening. They just got report for that and it was 1.8 which is a little bit low but he lost blood and had to have a transfusion while in the hospital. It is in a white plastic bottle they got it from (Name). NDC 0093-1713-01 she does not see anything else. She thinks the pharmacy label is wrapped almost all the way around the bottle but she does not see lot number expiration. She sees they ordered it 11Feb2021 and she has a quantity that is it. Treatment received and outcome was unknown. Information on the lot/batch number has been requested.

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1340403	5/22/2021	KY	82	F	3/4/2021	3/4/2021	leg swelling; ultrasound showed an occlusive clot in her femoral artery; femoral vein clot; had pneumonia; fever; developed chills; then chest pain; shortness of breath; This is a spontaneous report from a contactable physician. An 82-year-old non-pregnant female patient received bnt162b2 (BNT162B2 reported as PFIZER CORONA VIRUS VACCINES-COVID-19), dose 2 intramuscularly administered in the right arm on 04Mar2021 (Batch/Lot number was not reported) as 2nd dose, single for covid-19 immunization. Medical history included hypertension, hypothyroidism and osteoporosis. The patient was not diagnosed with COVID-19 prior to vaccination. The patient received the first dose of bnt162b2 (BNT162B2 reported as PFIZER CORONA VIRUS VACCINES-COVID-19) on an unspecified date for Covid-19 immunisation. Concomitant medications included levothyroxine sodium (SYNTHROID); calcium; acetylcysteine, calcium levomefolate, mecobalamin (METAFOLBIC PLUS); losartan; hydrochlorothiazide; denosumab (PROLIA) and trazodone; all indication, start and stop date were not reported. It was unknown if the patient receive any other vaccines within 4 weeks prior to the COVID vaccine. It was reported that in the evening of the vaccination (04Mar2021), she developed chills and fever, then chest pain and shortness of breath. The physician obtained a CXR (chest x-ray) on the patient on 04Mar2021 and found that she had pneumonia. She was treated with levofloxacin and prednisone. The physician rechecked her in one week and gave her Kenalog injection and Rocephin injection. The physician rechecked her on 22Mar2021 and she was improved, but she returned to the office 12Apr2021 with left leg swelling. The ultrasound on 12Apr2021 showed an occlusive clot in her femoral artery. The patient was admitted to the hospital (Apr2021) for 1 day and placed on heparin, then sent home on Eliquis. The adverse events resulted in doctor or other healthcare professional office/clinic visit and the patient received treatment which included antibiotics and steroids for pneumonia and blood thinners for the femoral vein clot. The patient has not been tested for COVID-19 since the vaccination. The outcome of the events leg swelling, occlusive clot in her femoral artery and femoral vein clot were recovered on Apr2021 while the outcome of the other events was recovered on 22Mar2021. Information about lot/batch

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number has been requested.; Sender's Comments: As there is limited information in the case provided, the causal association between the events peripheral swelling, peripheral artery thrombosis and venous thrombosis limb and the suspect drug BNT162B2 cannot be excluded. The case will be reassessed once new information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Committees, and Investigators, as appropriate.

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1340399	5/22/2021	AZ	35	M	3/31/2021	4/27/2021	<p>This is a spontaneous report from a contactable consumer (patient). A 35-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration administered in left arm on 31Mar2021 09:00 (at the age of 35-year-old) (Batch/Lot Number: ER8730) as 2ND DOSE, SINGLE for COVID-19 immunization. The patient did not receive any other vaccines within four weeks prior to the COVID-19 vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. Medical history included hypertension. Concomitant medication included ascorbic acid, beta carotene, biotin, boron, calcium, calcium pantothenate, chloride, chromium, colesticalferol, copper, cyanocobalamin, folic acid, iodine, iron, lycopene, magnesium, manganese, molybdenum, nickel, nicotinamide, phosphorus, potassium, pyridoxine hydrochloride, retinol, riboflavin, selenium, silicon dioxide, thiamine, tin, tocopheryl acetate, vanadium, vitamin k nos, zinc (CENTRUM MEN). The patient previously took bactrim and experienced allergies. Historical vaccine includes BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EN 6206), administered in left arm on 10Mar2021 at 08:45 AM (at the age of 35-year-old) as 1ST DOSE, SINGLE for COVID-19 immunization. On 27Apr2021 at 08:00 AM, the patient experienced bilateral embolisms (blood clots in lungs) and also had blood clot in left leg. Symptoms before diagnosis included dry cough, coughing up blood, chills, fever, body aches, and body pains. The events caused hospitalization. The events resulted in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. The patient underwent lab tests and procedures which included COVID-19 test via nasal swab post vaccination which was negative on 29Apr2021 and on 07May2021. Therapeutic measures were taken as a result of bilateral pulmonary embolisms and had blood clot in left leg, chills, and body aches/body pains which included Lovenox injection (blood thinner) and Tylenol for pain. The patient was recovering from all events.</p>

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1340371	5/22/2021	CA	75	M		3/1/2021	a blood clot in his left arm; possible sepsis; malnourishment; dehydration.; became so weak he slumped down; health has steadily declined; This is a spontaneous report from a contactable consumer (patient's son). A 75-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in right arm on an unspecified date (batch/lot number was not reported) as 2nd dose, single for covid-19 immunisation. Medical history included Parkinson's disease, essential thrombocythaemia, and chronic kidney disease which were all under control; and allergies to latex and iodine. The patient's concomitant medications were not reported. On 01Mar2021, shortly after second dose, the patient became so weak, he slumped down and had to be lifted by reporter's uncle, after this incident, his health has steadily declined and now he was hospitalized again on an unspecified date with a blood clot in his left arm, possible sepsis, malnourishment and dehydration. He has Parkinson disease, essential thrombocythemia, chronic kidney disease; however, all were under control until he was vaccinated with the second shot. The events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, disability or permanent damage. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had been tested for covid-19. The patient underwent lab tests and procedures which included covid test: negative on an unspecified date. Outcome of events was not recovered. Information about lot/batch number has been requested.

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1340349	5/22/2021	FL	55	M	4/17/2021	4/1/2021	Cellulitis; Chills; scaling; his leg started leaking; redness; sweating; had a crack in his skin; This is a spontaneous report from a contactable consumer (patient) from a Pfizer-sponsored program. A 56-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 intramuscular administered in arm left on 17Apr2021 (Lot Number: ER8737) at the age of 55-year-old as single dose for covid-19 immunisation. He was allergic to milk. He said it gave him sniffles and stuffs his nose but he drinks it anyways. The patient's concomitant medications were not reported. His 2nd shot of the Pfizer COVID Vaccine tomorrow and was asking if the vaccine would just be as effective if he delays the shot a week or 2 later because he was getting treatment for cellulitis on 26Apr2021 and he knew that the side effects of the vaccine and treatment are similar and he does not want to get "double whammed". He has heard that the vaccine would still be effective if delayed for up to 60 days and would like to confirm that. He confirmed that he had cellulitis and chills but said none of that was from the shot. He said that if he got the second shot he was worried about them double teaming his immune system. He said he had athletes foot and had a crack in his skin in Apr2021, and it got into him that way. He said the chills were from the cellulitis. The caller said that the events started shortly after his shot, oddly enough. He said he went to the hospital. He said he was at work. He said he went to the doctor on 29Apr2021 for the chills a week or two before that. He said on 26Apr2021 his leg started leaking. He said he was on antibiotics and it was going down but he still had redness and scaling that he wasn't able to get rid of. He said he got them at the same time, the leaking, the chills started that night. He said he noticed the cellulitis in the morning and he let it go for a couple of days. He went to the doctor on Thursday. He should have gone earlier. He said no more winter coat in the sun. He said his wife and his roommate were sweating and he had a sweater on; he had it bad. He said he didn't remember the days but he was tested for a blood clot which was negative and they checked out his heart. He did not provide the result of them checking out his heart. He says any doctor who knows about cellulitis knows to check these things. He also says they checked his blood pressure and other things: see formal field. He said after the emergency

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room they sent him home and told him to follow up with his primary care provider and a podiatrist, which he has done. He says he saw his primary care provider the following Monday 03MAY2021 and the podiatrist he didn't see until Wednesday 05MAY2021. He says he was supposed to see both of them within 2 days but he couldn't get in. Those events resulted emergency room and physician office. The patient was not hospitalized. He said his family had skin problems like eczema and such but he said it not relevant. The patient underwent lab tests and procedures on 29Apr2021 which included blood pressure: 110/63, temperature: 97.2, pulse: 84, oxygen saturation: 99%, respiration: 16. Outcome of event cellulitis, chills, his leg started leaking, redness was recovering; of sweating was recovered in 2021, of other events was unknown.



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1340343	5/22/2021			F	5/5/2021	5/5/2021	<p>This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number and expiry date unknown), via an unspecified route of administration on 05May2021 as a single dose for COVID-19 immunization. Medical history included lupus, high blood pressure and severe pancreatitis wherein she had surgery all on unknown dates and unknown if ongoing. The patient's concomitant medications were not reported. The patient reported some adverse effects after the first dose of the Pfizer COVID-19 vaccine. The patient reported stomach pain and nausea from an unknown date and fears it may be a blood clot and wants to know if these are common side effects. The patient reported having stomach pain on an unspecified date and she doesn't know if it is normal. At first she thought it was because she was so nauseous, but the nausea went away. Then she thought maybe it was like a bowel thing and she was going to have issues like diarrhea, but that was not the case. The pain is pretty bad. She is wondering if that can be a side effect. She is just wondering if she should follow up with a doctor or go to the hospital, because it hurts pretty bad in 3 different sections of her stomach. Her stomach feels like her arm felt when she got the shot. It feels like she had bruising, not exactly stabbing but it is pretty painful and she is kind of concerned. She doesn't know if her doctor would have information on the vaccine for what to do, and they would probably send her to the hospital. She hopes it's not something serious. She is worried something went wrong. Her entire family got the same shot and were fine. The pain is just like where her pancreas and gallbladder are. Since she had severe pancreatitis last summer, and it hurts where she had surgery. She wants to know if it is related to the shot or something else. The outcome of the event nausea/so nauseous was recovered while the outcome of the other events was unknown. Information on the lot/batch number has been requested. Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported blood clot cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern</p>

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identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities.

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1340294	5/22/2021	MO		M	3/18/2021		<p>Hospitalization involving some serious health conditions; blood clot removed from legs; second dose has passed over 28 days; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of HOSPITALISATION (Hospitalization involving some serious health conditions) and THROMBOSIS (blood clot removed from legs) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. Unknown) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Cardiac transplant in 2004. Concomitant products included TACROLIMUS and MYCOPHENOLATE MOFETIL (MYCOPHENOLATE) for Prophylaxis against heart transplant rejection, APIXABAN (ELIQUIS) for Thrombosis prophylaxis. On 18-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced HOSPITALISATION (Hospitalization involving some serious health conditions) (seriousness criterion hospitalization), THROMBOSIS (blood clot removed from legs) (seriousness criterion medically significant) and PRODUCT DOSE OMISSION ISSUE (second dose has passed over 28 days). The patient was treated with Surgery (blood clot removed) for Thrombosis. At the time of the report, HOSPITALISATION (Hospitalization involving some serious health conditions) and THROMBOSIS (blood clot removed from legs) outcome was unknown and PRODUCT DOSE OMISSION ISSUE (second dose has passed over 28 days) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment information not provided. It was reported that, the patient missed an appointment for his second dose due to hospitalization involving some serious health conditions. The patient was in the hospital for extended period and underwent surgery to get blood clot removed from legs during the hospitalization. Very limited information has been provided for the event at this time. However, details of hospitalization and compliance with anti-coagulant therapy is required for further evaluation. This report also This report refers to a case of product dose omission issue for mRNA-1273, lot # unknown with no associated</p>

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AEs.; Sender's Comments: Very limited information has been provided for the event at this time. However, details of hospitalization and compliance with anti-coagulant therapy is required for further evaluation. This report also This report refers to a case of product dose omission issue for mRNA-1273, lot # unknown with no associated AEs.

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1340277	5/22/2021	IA	60	M	4/5/2021	4/30/2021	Stroke; Patient received his first dose of Moderna COVID19 Vaccine on 05-APR-2021 and second dose on 30-APR-2021; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of CEREBROVASCULAR ACCIDENT (Stroke) in a 60-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 041B21A and 020B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 05-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 30-Apr-2021 at 10:30 AM, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 30-Apr-2021 at 10:30 AM, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Patient received his first dose of Moderna COVID19 Vaccine on 05-APR-2021 and second dose on 30-APR-2021). On 06-May-2021, the patient experienced CEREBROVASCULAR ACCIDENT (Stroke) (seriousness criterion medically significant). The patient was treated with Rehabilitation therapy for Cerebrovascular accident. On 30-Apr-2021 at 10:30 AM, INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Patient received his first dose of Moderna COVID19 Vaccine on 05-APR-2021 and second dose on 30-APR-2021) had resolved. At the time of the report, CEREBROVASCULAR ACCIDENT (Stroke) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-May-2021, Blood test: normal (normal) Normal. On 01-May-2021, Computerised tomogram: normal (normal) Normal. On 01-May-2021, Electrocardiogram: normal (normal) Normal. Concomitant medications were not reported. On 30 Apr 2021, the patient's right arm was numb and he had no feeling in it. He went to the emergency room on 01 May 2021. They thought he had a blood clot. His EKG, blood tests and CAT scan were normal. The patient reported his arm was still numb on 04 May 2021. It's like it was limp; he couldn't coordinate his hand when he tried to mow the law. He stated that he had no feeling in his arm

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and can't control his right hand. The patient was reported to have been diagnosed with a stroke on 06 May 2021 2021 and was to start rehab on 07 May 2021. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 06-May-2021: Stroke added as an event.

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1340276	5/22/2021	NJ	67	M	1/21/2021	2/28/2021	<p>This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (blood clot in each lung) in a 67-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 039K20A and 029L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.</p> <p>Concomitant products included CALCIUM FRUCTOBORATE, CHONDROITIN SULFATE SODIUM, GLUCOSAMINE HYDROCHLORIDE, HYALURONIC ACID (MOVE FREE JOINT HEALTH) for Joint disorder NOS, MINERALS NOS, VITAMINS NOS (ONE A DAY [MINERALS NOS;VITAMINS NOS]) for an unknown indication. On 21-Jan-2021 at 11:00 AM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 18-Feb-2021 at 9:30 AM, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 28-Feb-2021, the patient experienced THROMBOSIS (blood clot in each lung) (seriousness criteria medically significant and life threatening). On 28-Feb-2021 at 6:00 PM, the patient experienced DYSPNOEA (shortness of breath). At the time of the report, THROMBOSIS (blood clot in each lung) outcome was unknown and DYSPNOEA (shortness of breath) had resolved with sequelae. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-Feb-2021, Computerised tomogram: blood clot (abnormal) Blood clot in both lung. On 21Jan2021, patient had received the first dose of Moderna Covid-19 vaccine and about 4-5 days later, he began to noticed that his breathing was labored. At the time of the report, the patient did not think much about the labored breathing since he was older in age and thought it was due to exercise. Patient received second dose of Moderna COVID-19 Vaccine on 18-Feb-2021 and he reported that his breathing became more laboring where he needed to stop walking to catch his breath. He had 2 scan which revealed that he have a blood clot at each lung and he was prescribed Xarelto 15 mg twice a day, then he will begin Xarelto 20mg once a day on 20-MAY-2021. Patient is on Kirkland C 500mg as a concomitant medication as well. Most recent FOLLOW-UP information incorporated above includes: On 13-May-2021: Significant FU- outcome of the event.</p>

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1340229	5/22/2021	TN		M		3/1/2021	<p>CLOTS IN LUNG; BLOOD CLOTS IN BACK; SEVERE ABDOMINAL PAIN; GROIN PAIN; This spontaneous report received from a patient concerned a 52 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown), dose was not reported, 1 total, administered on 16-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. The patient reported that on an unspecified date in MAR-2021, within 5 days of the shot, the adverse reaction began with severe back pain (subsumed under blood clots in back) and abdominal pains. After two additional weeks and four doctor's appointments, the pain was so severe, patient went to the emergency room on 14-APR-2021. A computerised tomogram (CT) scan with contrast revealed clots in lung and back. Patient consulted with his doctor and decided to go to the emergency room. Patient was still suffering from severe abdominal and back pain, especially when sitting or laying down. On 2021, pain had moved to the groin area as well. Laboratory data included: CT scan (NR: not provided) revealed clots in lung and back. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from severe abdominal pain, and groin pain, and the outcome of blood clots in back and clots in lung was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210536709-COVID-19 VACCINE AD26.COV2.S-Clots in lung, Blood clots in back . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>



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1340202	5/22/2021		76	M	4/3/2021		<p>BLOOD CLOT; This spontaneous report received from a consumer concerned a 76 year old male. The patient's weight was 82 kilograms, and height was not reported. The patient's past medical history included angina pectoris, peptic ulcer disease, and tension headache, and concurrent conditions included asthma, atherosclerotic heart disease of native coronary artery, benign hypertension, stage 3 chronic kidney disease, chronic obstructive pulmonary disease with acute exacerbation, cirrhosis of liver, diabetes mellitus type 2, generalized osteoarthritis, morbid obesity, mixed hyperlipidemia, stenosis of bilateral carotid artery, peripheral vascular disease, malignant neoplasm large intestine, carotid artery occlusion, and hepatocellular carcinoma. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose was not reported, administered on 31-MAR-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. Non-company suspect drugs included: cabozantinib s-malate (tablet, oral, batch number was not reported) 40 mg, 4 times every 1 day, from 04-MAR-2021 for hepatocellular/liver cancer. Concomitant medications included apixaban, atorvastatin calcium, carvedilol, ergocalciferol, hydrocodone bitartrate/paracetamol, levothyroxine sodium, losartan potassium, mecobalamin, metformin hydrochloride, salbutamol sulfate, tadalafil, tamsulosin hydrochloride, and vitamin b complex. On 03-APR-2021, the patient experienced blood clot. On an unspecified date in Apr-2021 the patient was hospitalized for one day. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0:20210530464-covid-19 vaccine ad26.cov2.s-Blood clot. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: CONMEDS-OTHER SUSPECT DRUGS, MEDICAL HISTORY</p>

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1340200	5/22/2021			U	4/7/2021		<p>ATRIAL FIBRILLATION; This spontaneous report received from a patient of unspecified age, sex, race and ethnic origin. The patient's weight and height were not reported. The patient's medical history included: On unspecified date, in JAN-2021, the patient's resting heart rate was 61 beats per minute and heart rate variability was 30 milliseconds. On 15-JAN-2021 the patient had last annual physical examination and heart was normal. On unspecified date, in FEB-2021, the patient's resting heart rate was 57 beats per minute and heart rate variability was 32 milliseconds. On unspecified date, in MAR-2021, the patient's resting heart rate was 58 beats per minute and heart rate variability was 33 milliseconds. On 04-APR-2021, the patient's heart rate variability was 25 milliseconds. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown and expiry: Unknown) dose was not reported, 1 total, administered on 05-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 05-APR-2021, the patient's heart rate variability was 36 milliseconds. On 06-APR-2021, the patient's heart rate variability was 40 milliseconds. On 07-APR-2021, EKG (Electrocardiogram) was performed and diagnosed with atrial fibrillation. On the same day, the patient experienced atrial fibrillation (heart rate variability increased) and heart rate variability was 203 milliseconds. On unspecified date, in APR-2021, the patient's resting heart rate was 69 beats per minute and heart rate variability was 185 milliseconds. On unspecified date, in MAY-2021, the patient's resting heart rate was 67 beats per minute and heart rate variability was 184 milliseconds. The patient reported that prior to JANSSEN COVID-19 VACCINE patient had no symptoms of heart condition and the patient's resting heart rate prior to JANSSEN COVID-19 VACCINE was usually below 60 beats per minute. Since 7-APR-2021 the patient's resting heart rate had shown large swings of 30-50 beats per minute change from the day before. The patient reported the adverse event to the Vaccine Adverse Event Reporting System (VAERS) as suggested by patient's cardiologist. The patient concerned about the risk of Blood clot, strokes, stress and other condition including death. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the</p>

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atrial fibrillation was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210529871-covid-19 vaccine ad26.cov2.s-Atrial fibrillation. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1340197	5/22/2021	CA		F			<p>SKIN BREAKDOWN AND RIGHT BREAST IMPLANT EXPOSED; SURGERY TO REMOVE THE RIGHT BREAST IMPLANT; AREA OF ECCHYMOSIS OVER THE RIGHT BREAST; MULTIPLE BRUISES THROUGH OUT BODY; This spontaneous report received from a pharmacist concerned a 64 year old female. The patient's height, and weight were not reported. The patient's past medical history included right breast cancer, right breast removal, removal of TE (tissue expander) with right breast implant, TE (implant), lymphoedema, primary genetic predisposition, and secondary Lyme disease. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: unknown) dose was not reported, 1 total administered on an unknow date in APR-2021 (reported as about 3 weeks ago from the date of reporting) for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date (reported as sometime after receiving the Janssen COVID 19 vaccination), the patient developed multiple bruises though out her body, an area of ecchymosis over the right breast that evolved into skin breakdown and the right breast implant was exposed to this (skin breakdown). The patient was hospitalized on 11-MAY-2021, and she had to have surgery to remove the right breast implant, and the status post washout of redundant skin removal including nipple areola complex. The patient's health care profession was considering Heparin for her post operation for DVT (Deep vein thrombosis) prevention but was concerned about doing that based on the CDC (Centers for Disease Control and Prevention) information. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the multiple bruises through out body, area of ecchymosis over the right breast, skin breakdown and right breast implant exposed and surgery to remove the right breast implant was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0.20210523197-COVID-19 VACCINE AD26.COV2.S –Skin breakdown and right breast implant exposed, surgery to remove the right breast implant, area of ecchymosis over the right breast, multiple bruises</p>

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							through out body. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
1339098	5/22/2021	AZ	72	F	3/22/2021	4/11/2021	Massive stroke from huge clot right of brain. Never regained con..
1339095	5/22/2021	NH	34	F	5/14/2021	5/19/2021	dizziness and vertigo on and off since 5/18; evening of 5/18 had intense digestive issues and diarrhea; period started suddenly at this time as well and extremely heavy with clots, very intense cramping, period will be like this for about 8 hours and then stop and start again about 8-12 hours later; fatigued but can't sleep
1340451	5/22/2021	CA		M	4/14/2021		a blood clot came out on his stoma; This is a spontaneous report from a contactable consumer (patient's wife) from Pfizer-sponsored program . A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 1 via an unspecified route of administration on 14Apr2021 (Batch/Lot number was not reported) as single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Caller (Name) is calling on behalf of her Husband (Name). Her husband got the 1st dose on 14Apr2021 (caller not sure with the date) and after the vaccine he experienced a blood clot came out on his stoma in 2021. Caller asking if this is a reaction of the vaccine. Caller also asked if her husband can get the second dose even if he is a blood thinner. Caller also has a question for herself if she can take the 1st dose because she is allergic to Prednisone and Metformin and had a bad reaction with this medication. Therapeutic measures were taken as a result of event (blood thinner). The outcome of event was unknown. Information on the lot/batch number has been requested.

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1340994	5/22/2021	DC	49	F	3/31/2021	4/9/2021	<p>8 hr post vaccine, typical side fx (fever, headache), but also significant bi-lateral leg cramping and spasms that continued for 6-8 hours. Spasms were prominent in inner thigh/groin and down entire legs. Legs were not movable (heavy), difficult to get out of bed or walk. Very strange and nothing like this ever experienced before shot. Fine next day. Around 4/9, pain began in ball of R foot in the AM, hard to walk. Over next few days, pain extended up to medial posterior calf (very painful), back of knee and groin. Unexplained bruising on lateral calf. 4/20 woke to swelling of R leg (ankle, posterior knee, groin), went to Urgent Care that night and was sent directly to ER for DVT symptoms. ER Ultrasound showed no clot, was sent home. Pain continued to increase, with burning and difficulty walking. Second Ultrasound done 4/22. No clots found. Pain continued to worsen, with swelling/aching on front of calf and severe foot pain. Veins/skin tender. Painful groin spasms happen again, same as night of shot. PCP ordered ABI and spine Xray. ABI was normal. Xray showed same issue as 29 yrs ago (prior known L5S1 anterolisthesis; have not had back pain for many years...when I did, it was localised to spine and sciatic in the L hip, was not at all similar to these current issues in R leg. perhaps related if inflamed, but is vastly different in symptoms and unlike past history). Saw Vascular Surgeon 4/30, ordered abdominal CT Abdomen Pelvis w IV Contrast. results normal. arm bruising at IV and blood draw site. Saw second Vascular Surgeon 5/4 who felt pain related to inflammation response and ordered CBC. Platelets 178. (patient had requested this test starting on 4/20, this was the first doctor to order it). Pain continued but some relief found with compression socks. on 5/10 US Bilateral lower extremity venous duplex with reflux study was done on both legs. No DVTs, but damaged valves and reflux in the external iliac common femoral vein and femoral veins proximal segment (worse in R leg) and great saphenous vein at the sapheno-femoral junction (R only). These areas are where the spasms are happening but doctor not able to conclude relation, wants neuro consult, could be nerves causing spasms. Doctor prescribed compression socks for venous insufficiency concerns, to be rescanned annually for life. Vascular test results don't explain severe pain in calf and foot and referred to Neurologist for 5/28 visit. As of today, 5/22,</p>

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							pain is persistent. Pain/swelling is reduced with use of compression socks but returns without them; walking is difficult in the AM and PM hours; night time spasms. Have also had shooting pains in L calf, both forearms, and ribs (back). These occur mostly in the evening (nerve?). Taking magnesium & extra vitamin D seems to help some. On strict anti-inflammatory diet. I'd really like some guidance for treatment and what to do about boosters - do I switch to an mRNA vaccine? I am a very healthy active 49 yr old woman who felt fine before the shot, and now I've been in a lot of pain, working greatly reduced hours for almost 4 weeks. Please advise on what can be done to help. Concerned about permanent damage and how to handle future vaccines. (also of note: first menstruation period was skipped after the shot, second period came a week late and was very heavy with bright red blood. I am normally extremely regular, mod-heavy flow; also, the J&J shot I had was a "last shot of the day" extra dose. I was offered it while having a routine physical. Could it have been improperly stored, as the last leftover dose? Very unlikely since it was a doctors office, but including this info)
1341216	5/22/2021	NY	70	F	2/22/2021	5/5/2021	Patient received Moderna Covid Vaccine on 01/25/2021 and second Moderna COVID vaccine on 02/22/2021 and was diagnosed with a left lower extremity deep vein thrombosis on 04/22/2021, patient was then subsequently admitted to the hospital on 05/05/2021 with acute on chronic respiratory failure and bilateral pneumonia requiring IV antibiotics and increased supplemental oxygen.
1341471	5/22/2021	NJ	46	F	4/6/2021	4/6/2021	The same day I took vaccine on April 6, 2021, I had pelvic pain and cramping that increase over the next two weeks. I made an appointment with my physician. On 4/29/2021 I was examined by my physician and was told to go to the ER. I had my appendix removed and the pathology report showed that I had a blood clot.

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1340397	5/22/2021	MA	62	F	4/15/2021	4/1/2021	<p>This is a spontaneous report from a contactable Nurse (patient). A 62-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number is either EW0158 or EWD158), intramuscular, administered in Arm Left on 15Apr2021 as 1ST dose, single for COVID-19 immunization. Medical history included Lumpectomy over 20 years ago, High cholesterol over 20 years ago, seasonal allergy and asthma. She gets flu shot every year and has never had any issue with vaccines. No Additional Vaccines Administered on Same Date of the Pfizer Suspect. Prior Vaccinations (within 4 weeks) and AE(s) following prior vaccinations were none. Concomitant products included tocopherol (VITAMIN E); ascorbic acid (VITAMIN C) for the past six months to prevent COVID; colecalciferol (VITAMIN D); and acetylsalicylic acid (BABY ASPIRIN) for the cholesterol thing, takes it every day and has been on it about a year. She uses an inhaler for asthma she has had. Caller had experienced hypertension post first dose. Caller would like to know if she can or should get the second dose of vaccine on 20May2021. Caller has consulted with her PCP and states that she was not able to get answers. She had her first Pfizer COVID19 vaccine on 15Apr2021. That same week she was diagnosed with COVID. She had mild symptoms initially. She started having symptoms that afternoon and didn't know if was related to the vaccine. She had arm soreness, fatigue, foggy memory, and was not feeling right. She went to her internist on that Friday who said she was exhibiting symptoms of COVID. They tested her. She had been tested twice the week before for traveling and was negative. So she was tested a week before she boarded and five days before she left. On the afternoon of 15Apr2021 she had chills and didn't feel well and the symptoms were so similar she didn't know if it was coincidental. She did COVID test on Friday and got the results on Saturday morning. She got sick with fever, chills, malaise, and all of those things. She was in quarantine. Her blood pressure started escalating. She is very fit and an avid walker. She walks 7 to 8 miles per day. She had no issues before the vaccine with blood pressure. Her blood pressure runs 110/60 and heart rate in 60s in Apr 2021, but since the vaccine she has been hypertensive. She ended up in the ER last week because she was having chest tightness probably from COVID</p>



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and shortness of breath. She went to urgent care because the chest tightness got severe. They said her lungs looked good and she had resolving pneumonia. Her blood pressure was almost 170/110 in Apr 2021. It was very up and down and all over the place. They had said maybe it was related to chest tightness and shortness of breath. She is very concerned because of her blood pressure and she is still having some shortness of breath and tightness of chest. They said that could linger a while. All other symptoms are better, but the shortness of breath has not gotten better. Her blood pressure will be better, but if she walks it immediately shoots up. They had made a mistake and scheduled her to get her second vaccine on 05May2021. Callers internist said that they recommend waiting a little longer and there were lots of cases where patients get COVID in between vaccines. They said to wait until 20May2021 to get the second dose of the COVID19 vaccine. Should she get the vaccine if she is still having hypertension? She can't live like this if it is secondary to vaccine. Caller had EKG and all her cardio was good. She was checked for clots because post COVID people get clots. Her dimer was good and all of her results. She had no evidence of clots in the lungs. Caller runs a little high cholesterol. It has always been that way, but her other levels are good. Due to COVID caller cant be on statin. Caller clarified that she had never been on a statin for her cholesterol. The doctor never wanted to start on her a statin because her other levels were good. Her cholesterol is not causing the issue with her blood pressure. She dont know if she should get the second vaccine. She is in her 60's and looks like she is in her 40s. Caller knows the vaccine is directly related to the hypertension. It is not from COVID. The doctor said because she is over the other symptoms except shortness of breath and a little tightness. Her blood pressure is up and down. She knows she can get anxious if she continues to check it. In the morning she has pressure in the neck that she didn't have before. The elevated blood pressure happens all over the day. She didnt check it yesterday. Right now it is 130/80 and that is high for her. Her heart rate is in the 80s currently and usually she has a low pulse. She is getting back to trying to walk a little bit. She is pacing herself. Overall, she feels ok. Her appetite is still not better. She lost 7 to 8 pounds since COVID. She is about

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119 pounds, but feels like it is muscle loss because she is not exercising. Can she safely take the other vaccine that is scheduled for 20May2021? Has it been long enough now? She knows she shouldn't do it before the 14th. Is this going to go away? Are there other reported cases? She did not want to go on blood pressure medication. She is in good health and just turned 63. She never had medical issues. The only issue she had was a lumpectomy over 20 years ago. weight: around 118 pounds. She was in the upper 120s, but since COVID she has not been able to get back to walking 7 to 8 miles per day. Caller was sick, but not as most cases. She didn't end up in the hospital from COVID. She went to hospital because of chest tightness and shortness of breath. Her blood pressure was up when she went to urgent care. All the other symptoms were gone. She is currently still having shortness of breath, chest tightness, and elevated blood pressure. Sometimes the blood pressure will stabilize in the 120s. She is finally sleeping better. She wakes up with a stiff neck, but it is not the bed because she has a nice bed and pillow. As a medical professional and after discussing it with her family that are medical professionals, she feels that it is a result from Pfizer. She just needs to know if it is safe for her to get it. Does she need it since she has antibodies from the first one? Arm soreness: it lasted a week. When she feels her arm now it is tender in the spot. The fatigue and foggy memory were disabling and she couldn't do anything. Hypertensive: Seriousness is hospitalization. She was in the ER for six or seven hours. After they removed her IV the discharge nurse checked her blood pressure again manually and it was 168 over 100. She asked if it was safe to send her home. They said that everything else looked good and that it was related to being cold and being in the hospital. They had ruled the other things out. She was still symptomatic and was still having shortness of breath and chest tightness when she was leaving the ER. The blood pressure hovered a lot in the 140s when she was laying in the bed. Her O2 sats were good, 98 or 99. Her blood pressure would shoot up to the 160s or 170s. The time they have for caller to go back is 05May2021 which is not 30 days. It is completely messed up. First, she went to the Urgent care on 30Apr2021 and they did x-ray. They couldn't check her for clots. She was having shortness of breath, chest

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tightness, and elevated blood pressure. They sent her to the ER on 30Apr2021. Her main question is the hypertension. Blood pressure is related to the vaccine itself and is not from COVID. Does she need the second vaccine since she already had the first one and has antibodies from COVID? Is it safe to do the second vaccine having hypertension from the first? She doesn't want to escalate this more and have it linger for several months. She has to get to work and do her job. With hypertension she gets tightness in chest. They said her lungs look good except for the area of resolving pneumonia. When she gets short of breath it is related to high blood pressure and tightness of chest. Is it safe to get second vaccine? She is very concerned about getting the second vaccine. What will happen with her blood pressure being all over the place? Her blood pressure is not steady and stable. The chest tightness is still there and has not gone away. It has improved some. It wasn't even 30 days. Is it ok to take the second dose with the blood pressure issues? The onset date of events was Apr 2021. The outcome of the events was unknown. The nurse considered the COVID19 Vaccine was related to arm soreness, hypertensive, foggy memory and not feeling right. Information on Lot/Batch number was available. Additional information has been requested.; Sender's Comments: Based on the temporal association, there is a reasonable possibility that the administration of vaccination with BNT162B2 played a contributory role in triggering the onset of the events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities.

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1340983	5/22/2021	CA	34	F	5/2/2021	5/3/2021	Sudden appearance of significant amount of eye floaters, flashes and blurriness in the right eye about 20 hours after the 2nd shot of Pfizer Covid-19 vaccine. First started to notice sporadic floaters and mild blurriness during the 3-week period between the 1st and the 2nd shot of Pfizer vaccine. Diagnosed with Central Retinal Vein Occlusion (CRVO) with macular edema in the right eye within 48 hours of the 2nd shot of the vaccine. Confirmed by second opinion. Right eye vision is currently 20/50. Received Eylea injection in the right eye. Antiphospholipid panel, Protein S, Protein C, Factor V, Homocysteine and Antithrombin all come back normal from lab testing. Blood pressure normal, no diabetes, no known systematic disease. 34 year old female.
1337514	5/21/2021	MO	43	F	4/6/2021	4/6/2021	severe persistent headache developed, went to ER on 4/20/2021, CT/MRI found cerebral vein thrombosis in lower left brain. treatment of blood thinner (warfarin) started. advised to delay second dose.
1338628	5/21/2021	NJ	68	M	4/2/2021	5/14/2021	Although I have heart disease, and had triple bypass surgery three years ago, I consistently take my blood pressure. My blood pressure has been in a normal range since the operation, and following receiving the first dose of the vaccine it became elevated and I needed to go back on an old medication. Even then, my blood pressure was erratic. Two weeks after my 2nd COVID shot I had a heart attack due to a blood clot. This clot was able to be removed by a heart cath-lab. This could be a coincidental flare up due to an old issue, but the timing aligns with both doses of the vaccine.
1337925	5/21/2021	WI	59	M	4/6/2021	4/13/2021	Client was seen by his doctor on April 13th related to severe headaches . He stated that he had headaches prevaccine and was given Tropicort for it which he only took for 2 days as it caused him dizziness. He had CT scan of Head and MRIs on April 13 and 14th and then again on April 27th. The scan on April 27th showed a blood clot with 80% blockage in carotid artery and was dx'd with a blood clot via CT scan. . He was told to get to Hospital where he was admitted to ICU for 4 days Client was also dx'd with Factor 5 Leiden at that time. Per client he has a stroke and is recovering. Per client still unable to work r/t poor balance and dizziness

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1337924	5/21/2021	IL	32	F	3/18/2021	5/14/2021	Patient transferred from outlying hospital for higher level of care. Patient had previously presented to ED with complaint of localized pain in the right calf for 4-5 days. Patient also noticed swelling in R calf. CT chest showed acute pulmonary embolism within distal right pulmonary artery extending into the segmental arteries to both right upper and right lower lobes. Patient was treated with heparin drip. Echo showed EF 68% and hypokinetic free right ventricular wall and apex. Echo also showed reduced right ventricular function. Patient underwent bilateral lower extremity duplex ultrasound which showed acute right femoral, popliteal, posterior tibial and peroneal vein thrombosis. Patient was transitioned and discharged to home. Patient received J&J COVID-19 vaccine in March 2021. Patient denies cigarette smoking/vaping, illicit drug use, ETOH use. Denies recent travels or long distance travels. Denies use of oral contraceptives.
1337830	5/21/2021	CA	55	M	4/29/2021	4/29/2021	Patient presented with on 5/12/21 with headache, nausea and vomiting, malaise, and decreased responsiveness. Headache and malaise had been present on/off since late April after patient had received the second dose of Moderna COVID-19 vaccine. Head CT in ED revealed venous sinus thrombosis. MR venogram with near complete occlusion of the superior sagittal sinus, right transverse and sigmoid sinuses, right internal jugular vein), possible mastoiditis on the right side. Started on heparin drip, unasyn, and transferred to neurosurgical ICU. 5/13/21 underwent mechanical thrombectomy; of the superior sagittal sinus, bilateral transverse and sigmoid sinuses and the right vein of Labbe - flow has been restored. Partial clots remained in right internal jugular vein. Heparin drip was changed to antiXa goal 0.3-0.7. HNS consult - no strong evidence of mastoiditis. 5/14/21 repeat MRI/MRV - thrombus within the right transverse sinus, sigmoid sinus and right jugular bulb, no thrombi in the dominant left transverse sinus or SSS - anticoagulation was changed from heparin to enoxaparin 1 mg/kg every 12 hours 5/15/21 patient was observed in the ICU 5/16/21 discharged home in stable condition

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1337813	5/21/2021	IL	59	F	2/8/2021	5/11/2021	Patient presented to emergency department on 5/11/21 with report of worsening of shortness of breath and chest pain for previous one week. Patient reports that she had COVID-19 3 weeks ago and at that time was diagnosed with community acquired pneumonia. CTA performed in ED noted bilateral pulmonary emboli greater on the right than on the left. There was an embolus in the right main pulmonary artery with some evidence of right heart strain with RV/LV ratio 1.1. Peripheral ground-glass opacity in right lower lobe also noted. Patient treated with heparin. No thrombectomy performed as clot burden had decreased after receiving heparin. Patient was transitioned to Eliquis and discharged to home.
1337718	5/21/2021	IN	21	F	4/28/2021	5/19/2021	patient developed a blood clot
1337708	5/21/2021	NY	39	F	5/20/2021	5/20/2021	The day before she got her vaccine she had started her menstruation cycle. She is not on any medications, everything was normal, went to work and went to get her vaccine. She got her vaccine and around 4:15 she started gushing, which is abnormal for her and having clots the size of a half dollar and covered in blood. This is not normal for her periods, and she is now in the bathroom every hour and a half and looks like a murder scene. Her normal menstrual cycle is heavy for one day and then gradually lessens and only lasts a few days. She does occasionally have small clots with hers, but this are large and bleeding profusely. The only side effect she has is that she is extremely tired. She slept from 4:30 yesterday to 2:00 AM and feels like she could sleep the rest of the day. Her arm is a little bit sore, but otherwise fine from the injection site. Is concerned due to the heavy volume of bleeding, which is extremely abnormal for her. She has taken Tylenol and drinking a lot of fluids.

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1337662	5/21/2021	IA	47	M	5/19/2021	5/19/2021	Patient developed a nose bleed lasting from 7:10pm to 7:40pm on the evening that he received his vaccine. He coughed up a silver dollar sized blood clot around 7:35pm. He was feeling fine the following day, but had another nose bleed that started at bedtime the night after his vaccine. Patient's wife called on call doctor and was told to pinch his nose, which they'd been doing for 35 minutes and to go to ER if needed. Patient saw doctor, who told him to stop using Flonase for a few days.
1337553	5/21/2021	AZ	49	F	4/6/2021	4/12/2021	4/6 vaccination 4/12 HA 4/13 HA turned into migraine, legs started to tingle, achy. Zero sleep due to pain. 4/14 Both extremities very swollen. Rotating between Tylenol and Ibuprofen (started on Tues). I went to my PCM. BP 130/98. Prescribed water pill but only to take on Friday if symptoms got worse, not better. 4/15 Sick all day. By 5pm, I couldn't even focus, my legs were so swollen, my 'head was ready to explode' and I 'didn't feel right. I went to urgent care; 160/98 BP and referred to the ER. I went to the ER, BP was still elevated, legs still swollen. Checked my heart, ultra sound on my legs and x-ray. I was kind of 'out of it'. They did everything to check for blood clots and heart; everything came back clear. They gave me some medicine for my head thru IV. I still left with HA but didn't feel as bad. That helped my BP went down. I was at the ER 2-3 hours, drinking lots of water. The next day the swelling started to go down on the legs and migraine was subsided. By Sat., I felt fine.
1339044	5/21/2021	IN	37	F	5/7/2021	5/10/2021	At 8 AM on 5/10/21 I experienced extreme shortness of breath and an elevated heart rate. I could not catch my breath and my heart was ?resting? at approximately 145 beats per minute. I went to the local ER at which time I was taken back for testing, approximately 10 hours later I was diagnosed with bilateral pulmonary embolism. My legs were checked and they could not locate any other blood clots - just in my lungs.

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1337394	5/21/2021	NC	36	F	4/7/2021	5/10/2021	On 5/10/21 got up with sever pain in my left side neck, shoulder and arm pain. Initially thought it was a muscle pull. Pain was out of control on Tuesday 5/11/21 Night. Took Advil, used equate cool & heat pain relieving liquid. On Wednesday 5/12 discovered I have bruises and blood clots on my back and left side. Took appointment with PCP on 5/14. Prescribed Methylprednisolone 4 MG tables for 6 days. Pain continued with blood clots and bruise marks. Developed left side ear pain, Shivering and mild fever. Visited PCP again on 5/21/21. Prescribed Cyclobenzaprine. Over the past 1 months have lost weight, had a sever pain on left leg, blurry vision.
1337361	5/21/2021	IL	48	M	5/5/2021	5/20/2021	Patient is now hospitalized with the following: VITT, bilateral PE with left lateral lower lob infarct, left superficial femoral vein occlusive deep vein thrombosis, and thrombosis of the posterior tibial vein according to hematologist.



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1337216	5/21/2021	UT	43	F	5/13/2021	5/13/2021	I immediately felt sharp pain and burning in my arm while being injected. The burning in my arm lasted for about 20 minutes. I got a severe migraine about an hour after the vaccine that lasted for about ten hours. I broke out in hives all over my body later that night, the same day as the vaccine. I also had intense heartburn. I never get heartburn so this is not normal for me. The following day, I was still having hives and started also having chest pains. I was consistently taking antihistamines to keep the hives under control. On Saturday morning, 2 days after the vaccine, I was still breaking out in hives. My throat also started to swell and I was having a hard time breathing. My heartburn was also getting more severe. I ended up going to urgent care. There I was prescribed 2 stronger antihistamines and prednisone to help with my reaction. I was also given an epi pen. Later that night, I ended up going to the ER as I was having severe chest pain. I have a history of DVT so I was concerned about blood clots. I had several tests done along with a chest CT scan. Thankfully everything came back clear for blood clots and heart attack. The ER doctor could not explain why I was having chest pain and advised me to monitor it and to come back in if it got worse. The following day, I was still needing antihistamines for hives and difficulty breathing. I woke up in the middle of the night with severe stomach pain and cramping. I had intense vomiting and diarrhea. The diarrhea started to have a lot of blood in it. I went back urgent care and they sent me for a CT scan which showed I now had colitis. The bleeding lasted for about 3 days.
1337043	5/21/2021		18	M	5/8/2021	5/12/2021	Patient received dose 1 of Moderna vaccine on 5/8/2021 and had witnessed seizure 5/12/2021- (first time ever). He was admitted to ICU on 5/12/2021 and discharged 5/15/2021. He states he had one seizure while in the ICU and another seizure 5/16/2021- at home after discharge. He has since been placed on anti-seizure medications and is scheduled for follow up with neurology on 6/2/2021. Patient's mother states ICU doctors told her they found a blood clot in the brain picked up by MRI.
1336997	5/21/2021	MA	32	M	4/12/2021	5/18/2021	Heart attack - Sudden onset chest pressure, shortness of breath, bilateral arm numbness. Found to have clot in LAD requiring stent. No cardiac risk factors.

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1336941	5/21/2021	PA	48	F	3/20/2021	3/24/2021	started out with severe headaches , then started getting out of breathe, which became really intense , admitted to emergency on 5/13/21 released 5/21/21 with mini heart attack and multiple blood clots in the lungs. No blood clots in the legs which would have been from the estrogen pill. Oncologist stated that the clots form in the legs if from the estrogen pill, this formed in both lungs. Been on the tamoxopine for over a year and no side effects at all. Headaches and breathing issues all started after the vaccine
1336852	5/21/2021	OR	78	F	4/7/2021	5/7/2021	Pt found down on 5/7 for unknown period of time. Prodromal dizziness reported, but no additional history or witnesses until pt found down. At ER presentation, noted CHI with subdural hematoma and intracranial hemorrhage. Also noted left cortical vein thrombosis. Follow-up imaging after 24 hours demonstrated persistence of above findings. Pt had concomitant humerus fracture and medical instability after being found down. Now stable but below baseline in rehab facility.

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1336281	5/21/2021	CA	67	F	4/1/2021		SORE THROAT; SHORTNESS OF BREATH; MYALGIA; FATIGUE; HORRIFIC HEADACHE; HORRIBLE PAIN IN CHEST LIKE HEART ATTACK; BONE WRACKING DRY COUGH; METALLIC TASTE IN MOUTH; FELT DIZZY; FELT LIKE HIT BY DUMP TRUCK; BODYACHE; NOT FEELING WELL; AGITATED; URINATING A LOT; BILATERAL EARACHE; WAS TOO SICK; HEART RATE WENT UP TO MORE THAN 80 BPM; This spontaneous report received from a patient concerned a 67 year old female. The patient's weight was 66.7 kilograms, and height was not reported. The patient's past medical history included tachycardia, atrial fibrillation, left periorbital ecchymosis, dry eyes, trouble focusing, headache, nausea on right side of chest, felt like gas bubble and emesis, possible post concussion symptoms, voice hoarse/raspy voice, chronic laryngitis, flare up of hemorrhoid, constipated over a weekend, increased heart rate, nontoxic uninodular thyroid goiter, atherosclerosis of aorta, fatigue, papillary thyroid cancer, right thyroid lobectomy, deep vein thrombosis, gerd, melanoma of skin, dyspnea, deep vein thrombosis, sinus pain, tooth pain, treatment non compliance, pharyngitis, stroke, vertigo, and influenza like illness, and concurrent conditions included non-smoker, no alcohol use, asthma, cerebral palsy, qt prolonged, chest pain when tired, diabetes mellitus, chronic kidney disease stage 3, hypertension, congenital nystagmus, hearing loss, hypothyroidism, and diabetes, and other pre-existing medical conditions included the patient had no history of abuse or illicit drug usage. The patient was previously treated with phenoxymethylpenicillin, guaifenesin for sore throat, calcium carbonate, famotidine, simeticone, promethazine, cefalexin, diphtheria vaccine toxoid/pertussis vaccine acellular/tetanus vaccine toxoid for prophylactic vaccination, salbutamol, ciclesonide, and polymyxin for red eyes; and experienced drug allergy when treated with atenolol, ciprofloxacin, and erythromycin. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 043A21A, and expiry: 21-JUN-2021) dose was not reported, administered on 04-APR-2021 11:15 for prophylactic vaccination. Concomitant medications included disopyramide phosphate. On 10-MAR-2014, Laboratory data included: Factor V Leiden mutation (NR: not provided) negative, and Prothrombin

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mutation G20210A (NR: not provided) HET Abnormal, coagulation. On APR-2021, the subject experienced heart rate went up to more than 80 bpm. On APR-2021, the subject experienced agitated. On APR-2021, the subject experienced urinating a lot. On APR-2021, the subject experienced bilateral earache. On APR-2021, the subject experienced was too sick. On APR-2021, the subject experienced bodyache. On APR-2021, the subject experienced not feeling well. On 04-APR-2021, the subject experienced metallic taste in mouth. On 04-APR-2021, the subject experienced felt dizzy. On 04-APR-2021, the subject experienced felt like hit by dump truck. On 05-APR-2021, the subject experienced horrible pain in chest like heart attack. On 05-APR-2021, the subject experienced bone wracking dry cough. On 05-APR-2021, the subject experienced horrific headache. On 09-APR-2021, the subject experienced fatigue. On 13-APR-2021, Laboratory data included: COVID-19 virus test (NR: not provided) Negative. On 20-APR-2021, the subject experienced sore throat. On 20-APR-2021, the subject experienced shortness of breath. On 20-APR-2021, the subject experienced myalgia. Laboratory data included: Anion gap (NR: not provided) 10 mEq/L, B-type natriuretic peptide (NR: not provided) 64 pg/dL, BUN (NR: not provided) 26 mg/dL, Blood pressure (NR: not provided) 214/91 mm Hg, Body temperature (NR: not provided) 97.8 F, CO2 (NR: not provided) 26 mEq/L, Chloride (NR: not provided) 102 mEq/L, Creatinine (NR: not provided) 0.92 mg/dL, Differential white blood cell count (NR: not provided) Normal, Glomerular filtration rate (NR: not provided) more than 60 mL/min, Glucose (NR: not provided) 328 mg/dL, Hematocrit (NR: not provided) 42.9 %, Hemoglobin (NR: not provided) 14.9 g/dL, Lab test (NR: not provided) Normal (no blood clots/thrombocytopenia), MCV (NR: not provided) 91 fL, Nucleated red cells (NR: not provided) 0 kilo per microliter, Oxygen saturation (NR: not provided) 98 %, Pain scale (NR: not provided) 1 (units unspecified), Platelet count (NR: not provided) 190 kilo per microliter, Potassium (NR: not provided) 4 mEq/L, Pulse rate (NR: not provided) 81 beats per minute, RBC count (NR: not provided) 4.73 million per microliter, Respiratory rate (NR: not provided) 18 (units unspecified), Sodium (NR: not provided) 138 mEq/L, Troponin I (NR: not provided) more than 0.02 ng/dL, WBC count (NR: not provided) 7.3

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kilo per microliter, and X-ray (NR: not provided) Aortic atherosclerosis. Treatment medications included: hydralazine. On 20-APR-2021 17:34, Laboratory data included: Blood pressure (NR: not provided) 190/100 mm Hg, Body temperature (NR: not provided) 36.6 degree celsius, Glasgow coma scale (NR: not provided) Eye opening:4, Verbal response:5, Motor Response: 6, Total Coma Score:15, Oxygen saturation (NR: not provided) 97 %, Pulse rate (NR: not provided) 74 bpm, and Respiratory rate (NR: not provided) 16 (units unspecified). On 28-APR-2021, treatment medications included: prednisone. Additional treatment medications (dates unspecified) included: estradiol, levothyroxine, paracetamol, verapamil hydrochloride, salbutamol, diphenhydramine hydrochloride/lidocaine/nystatin, budesonide/formoterol, guaifenesin, benzonatate, chlorhexidine gluconate, ipratropium, aciclovir, fluticasone, montelukast, hydralazine hydrochloride, fluticasone propionate/salmeterol xinafoate, and famotidine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from metallic taste in mouth on 05-APR-2021, felt dizzy on 20-APR-2021, felt like hit by dump truck on 16-APR-2021, was too sick, and shortness of breath, and horrific headache on 19-APR-2021, had not recovered from bone wracking dry cough, horrible pain in chest like heart attack, sore throat, and bilateral earache, and the outcome of heart rate went up to more than 80 bpm, myalgia, not feeling well, fatigue, urinating a lot, agitated and bodyache was not reported. This report was non-serious.; Sender's Comments: V0: Medical assessment comment not required as per standard procedure as case assessed as non serious

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1336279	5/21/2021	OH		F		4/1/2021	<p>SUSPICION OF FLUID LEAK INTO EARS; DECREASED LUNG FUNCTION; LOSS OF PERIPHERAL VISION; NUMB LEGS; DIFFICULTY WALKING ACROSS THE ROOM/UNSTEADY GAIT; DIARRHEA; SHORTNESS OF BREATH; EXTREME VERTIGO; WEAK LEGS; HEADACHE/OCCIPITAL HEADACHE; ARTHRALGIA; SORE ARMS; MYALGIA; FATIGUE; FOGGY HEADED; ANAPHYLAXIS; FEVER; This spontaneous report received from a physician concerned a 30-year-old patient The patient's height, and weight were not reported. The patient's concurrent conditions included attention deficit hyperactivity disorder (ADHD), asthma, and milk allergy. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration was not reported, batch number and expiry date were unknown) dose was not reported, 1 total, administered on left arm on 10-APR-2021 for prophylactic vaccination. The batch number was not reported has been requested. No concomitant medications were reported. On 10-APR-2021, within 30 minutes of vaccination, the patient developed anaphylaxis with no airway compromise, hives, swelling of limbs, face and administration site. The patient could not get immediate treatment for about an hour and then received Benadryl (diphenhydramine hydrochloride). On an unspecified date, in APR-2021, the patient experienced fever with a temperature of 100s (unit not provided). On 11-APR-2021, the hives started to go down with Benadryl treatment but it was not completely gone. On the same day, the patient experienced headache/occipital headache, arthralgia, sore arms, myalgia, fatigue and was foggy headed. On 12-APR-2021, the patient experienced shortness of breath, difficulty walking across the room (unsteady gait), extreme vertigo, diarrhea, numbness of legs and weakness of legs. It seemed like the patient was exhibiting symptoms of coronavirus disease (COVID-19). On 14-APR-2021, she eventually went to the emergency room (ER). The patient was tested for COVID-19 (swab test) and titres but both were negative. On an unspecified date, in APR-2021 (within 5 days of start of symptoms), a magnetic resonance imaging (MRI) without contrast was done and it did not show any blood clot, and D-dimer test was negative. The physician suspected a fluid leakage into the patient's ear and wanted to know if adenovirus</p>

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							from vaccine could be implicated. The patient was prescribed meclizine, but it did not help. On an unspecified date, a pulmonary function test (PFT) was done which showed decreased lung function. The patient also had steroid (unspecified) for 4 days. On an unspecified date, in MAY-2021 (about 8 days before report), the patient started to lose peripheral vision and her vertigo escalated. It was reported that the patient was due for an MRI on 12-MAY-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the sore arms, fatigue, foggy headed, myalgia, arthralgia, shortness of breath, difficulty walking across the room/unsteady gait, extreme vertigo, diarrhea, weak legs, fever, headache/occipital headache, loss of peripheral vision, anaphylaxis, numb legs, suspicion of fluid leak into ears and decreased lung function was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210520835-COVID-19 VACCINE AD26.COV2.S-Anaphylaxis. This event(s) is labeled and is therefore considered potentially related.
1337640	5/21/2021	AZ	55	F	3/16/2021	3/1/2021	timeline of events: 11/2020 seen by cardiology for atypical chest pain, abnormal ekg, and lower leg edema. lexiscan and echo done, negative. 12/2/2020 vein mapping done BLE, negative for clots. med changes done and venodynes ordered. 3/16/2021 vaccine received. approximately 2 weeks later, developed severe GI virus, increasing back pain, left leg tightness and pain. 3/31 follow up with cardiology, told doctor unable to wear venodynes due to severe pain in knee area. 4/1 phone appt with PCP, treated for GI virus. 5/1 went to PCP for increasing pain and difficulty walking. discovered new swelling in left leg, large area medial calf just below left knee. labs done, normal. 5/12 US left leg done. 5/20 back to PCP; told that US showed large hematoma and surgical consult needed.
1338624	5/21/2021	DE	76	M	3/1/2021	4/3/2021	04/2021 Seen in ED for c/o left sided chest pain increased with deep inspiration. Blood work, chest a-ray and chest CT. DX with 2 blood clots left lung and pneumonia. COVID test done - Negative. Admitted to hospital and anticoagulated with Heparin. Numerous blood tests performed. Followed by Hospitalist and seen by Pulmonologist and Hematologist.

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1333968	5/20/2021	PA	23	M	4/10/2021	5/5/2021	Small blood clot in my left lung. Treatment includes 5 mg dose of Eliquis blood thinner twice a day.
1333360	5/20/2021	IL	63	M	3/10/2021	3/18/2021	5-19-21 Patient self-reported to that 8 days after receiving his first dose of Moderna (3/18/21), he began coughing up blood, was taken to the hospital, transferred to the ICU with thrombosis. He states he was in the ICU for 6 days. He then received second dose on 04/09/21 and was ill for 5 days again. States he currently remains fatigued, short of breath and "just not himself." Patient is concerned that the blood clots were related to his COVID Vaccines.
1333507	5/20/2021	TX	46	M	2/25/2021	3/21/2021	Blood clots in both lungs



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1333638	5/20/2021	CO	44	F	4/14/2021	4/16/2021	pt says she had a hot red swollen right leg that was very painful. On 4/16/21 she went to the Hospital ER. She had blood test and was given an US of the right leg where they found 2 blood clots. She was started on blood thinner. She was discharged and told to FU w/ PCP. On 4/21/21 she saw the doctor. She increased the blood thinner because she found a abdominal hematoma this size of two grapefruits. On 4/25/21 she was having trouble breathing and her leg was red and inflamed. She went back to the Hospital ER they thought she was having a pulmonary embolism. They did more blood work and chest x-ray. She was given Lovenox shots and took her off the blood thinner. She was discharged to go home and give herself these shots. On 4/27/21 she had a reaction to the Lovenox shot so she called her PCP. She saw the doctor on 4/29/21 she was told to continue using the Lovenox. She went back to Dr. on 5/4/21 and she was taken off Lovenox and put back on blood thinner Eliquis with doubled dosage. She was monitored. On 5/8/21 both of her legs were red and swollen and she went to her Doctors office. They did a blood test and was sent home. On 5/10/21 she went back to her PCP. Dr. office where she was sent to Hospital ER for direct admit. They did another US and a CT. They found she had blood clots in both legs. She was given IV fluids, antibiotics, was given heparin and taken off Eliquis. On 5/13/21 she was given warfarin along w/ heparin. She was discharged on 5/16/21. She still has pain and redness in both feet and legs and has been diagnosed w/ Cellulitis. She is now taking Oxycodone and Coumadin. She will see her PCP on 5/21/21.

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1333699	5/20/2021	IL	35	F	4/30/2021	5/2/2021	2 days after vaccination (Sunday May 2) I began to feel slightly chest pain when I would breath on the upper left chest shooting downward to the bottom breast rib area. Every time I would take a deep breath I would feel the pain. Called loyola hotline to discuss and state worries I had. Pain continued the next day. Went to the loyola urgent care center Monday at about noon. Took EKG test there and everything seemed fine however they did mention my birth control and possible side effects. So they sent me to thenhospital for more test. Sent me to the ER. From the ER took several test and blood work. Another eck as well as D-dimer test, lots of blood work and a CT scan. Later that night I was told I had a pulmanary embolism (blood clot in my lung) and I needed to stay overnight. They continued to take addt. Exams the next day and more blood for test. Took a heart echo since pains were happening on my left side. As well as ultrasound on my leg to check for DVT and if more blood clots exist.. Addt. Test done that Tuesday, then was discharged Tuesday at about 5pm.
1333708	5/20/2021	FL	63	M	5/14/2021	5/14/2021	Patient presented to hospital emergency department on 5/19/2021 with complaints of headache, myalgia, nausea, vomiting with hematemesis and severe abdominal pain (rated 8/10) that began on the 5/16. Patient started on argatroban for treatment of mesenteric vein thrombosis. Treatment course pending.
1333734	5/20/2021	TX	74	M	4/9/2021	4/23/2021	Approximately two weeks after vaccination I noticed his left foot and leg swelling. Patient advised me that he needed to go to the hospital because he was not feeling well and his oxygen level was low. We called 911 and was taken to the hospital. After at the hospital I advised a male nurse that I was concerned about his leg being swollen cause he had been given the Jansen Covid vaccine and I was concerned about blood clots. Everyday I would tell someone in the hospital (never saw a doctor I could talk to) about his swollen leg but did not really get anyone interested. Before he was moved to a Veteran?s State Home, I overheard someone saying they were going to give him his anticoagulant. I?m filing this report in case the swollen leg was a result of blood clots due to the vaccine.

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1332971	5/20/2021			U			<p>BLOOD CLOTS; This spontaneous report received from a consumer concerned multiple patients (8 patients) Patients weight, height, and medical history were not reported. Patients received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, 8 patients got blood clots so they stopped using JANSSEN COVID VACCINE. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clots was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210533746-COVID-19 VACCINE AD26.COV2.S-Blood clots. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1333886	5/20/2021	UT	57	F	4/8/2021	4/10/2021	<p>Started out with what I thought were flu like symptoms - chills, then I was warm- extremely tired Then my chest started hurting- I thought this was the vaccine working- then I started getting short of breath- still thinking this is the vaccine working- then my chest started hurting extremely bad- and my ability to breathe became worse- finally I contacted my doctor-because I thought maybe I had gotten bronchitis- so she prescribed an inhaler in the mean time - I ordered a oxygen meter- and my oxygen was registering in the 80s- then my chest was getting more and more painful. And then a few days later, my oxygen started dropping down to the 70s and my body temp dropped to 95.1- I was passing out at home, although I didn't realize that is what was happening, I would just wake up and an hour would have passed and I didn't even realize I was out, and this kept happening especially during the time that my temperature kept dropping below 95. I rushed to the emergency room which after I had been there a long time- they found that I had a *****BLOOD CLOT- MASSIVE***** A SADDLE BLOOD CLOT ***** IN LUNGS They immediately admitted me, and immediately started me on Lovonox and Coumadin I am currently on oxygen and I will have to take Coumadin for the rest of my life. Due to the size of the clot (5-6 inches) they were concerned about my heart, the clot caused a strain on the right side of my heart, so they put me on a different beta blocker Coreg to slow my heart rate down, I will also have to take this medication for the rest of my life</p>

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1332968	5/20/2021	MO		F			BLOOD CLOT IN BRAIN; LOWER LEFT BACK PAIN; This spontaneous report received from a consumer concerned a female of unspecified age. The patient's weight, height, and medical history were not reported The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 08-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. The Company is unable to perform follow-up to request batch/lot numbers. On an unspecified date, she experienced blood clot in brain, and lower left back pain, and was hospitalized (date unspecified) for about 12 days. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the blood clot in brain and lower left back pain was not reported. This report was serious (Hospitalization Caused / Prolonged); Sender's Comments: V0 20210532694-COVID-19 VACCINE AD26.CO2.S-Blood clot in brain, Lower left back pain. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
1333991	5/20/2021	OH	61	M	1/25/2021	4/14/2021	Blot clot followed by fatal aortic thrombosis
1333997	5/20/2021	MO	68	F	3/18/2021	3/19/2021	I have a major history of blood clots Muscle Aches Im never real chill was unable to get warm Rash on half my body Tired When I ate I felt a flushing feeling I felt like a pile of crap But it has lighten up Still dealing with core temperature problem, still cold
1334091	5/20/2021	CA	34	F	4/18/2021	5/16/2021	axillary vein thrombosis (left)

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1334117	5/20/2021	MA	43	F	3/17/2021	3/29/2021	Started with the right arm turning purple or changing colors when elevated above the head. This continued for a few weeks. Then I started to get a tingling sensation in the elbow that went into the right pinky. I visited my primary doctor to see what was going on. She did an evaluation, prescribed Ibuprofen and physical therapy, and had a cervical spine x-ray done. The X-ray looked great when it came back. I could not get an appointment with PT for several weeks so I finally went to the chiropractor on 5/13. He worked on the shoulder area stretching it out. By the morning of 5/15 I was being taken to urgent care and eventually the ER because the arm was swelling and fingers were turning blue. They did blood tests, EKG, chest x-ray, and finally an ultrasound that showed a blood clot. It was DVT in the subclavian vein. I was given a blood thinner and sent home. I had a more thorough ultrasound on 5/17 that sent me back to the ER and with vascular surgeons to discuss immediate surgery with lysis therapy. It was decided that the blood clot had probably been there for weeks and the success rate of the surgery would not be as good.
1334191	5/20/2021	PA	66	M	4/7/2021	4/26/2021	large quantity deep vein thrombosis: R leg extending to mid-IVC, pulmonary emboli, and LLE DVT

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1334195	5/20/2021	PA	78	M	3/29/2021	5/17/2021	ED to Hosp-Admission Discharged 4/16/2021 - 4/19/2021 (3 days) Hospital Doctor Last attending - Treatment team COVID-19 Principal problem Medical Problems Hospital Problems POA * (Principal) COVID-19 Yes Hypercholesterolemia Yes Hypertension Yes Type 2 diabetes mellitus Yes Major depressive disorder Unknown Acute respiratory failure with hypoxia Unknown Hypertensive urgency Unknown Presenting Problem/History of Present Illness/Reason for Admission COVID-19 Hospital Course (Patient) is a 78 y.o. male with medical history of hypertension, type 2 diabetes on insulin, and hyperlipidemia presents with SOB and she was admitted for acute hypoxic respiratory failure with sepsis .Patient was diagnosed with Covid on 4/15 and repeat COVID-19 was positive on admission. Acute hypoxic respiratory failure likely from COVID-19- improving o On admission satting low 90% ,required supplemental oxygen, normal lactic acid & CRP, elevated LDH 263 o CXR (4/16/21): mild basilar atelectasis. o Continue remdesivir (4/16-4/21, Day 4) and dexamethasone (4/16-) since O2 sat <94% on room air, requiring supplemental oxygen o Patient currently satting 95-97% on 2 L nasal cannula. Bedside study does not qualify patient for home oxygen while resting and/or ambulating. PT recommends safe discharge home. Patient clinically stable to be discharged home today. Patient to follow-up with PCP. Sepsis likely from COVID-19 -resolved o On admission HR >90, RR >20 + source of infection COVID= sepsis, procalcitonin neg- antibiotics not indicated Elevated D-dimer likely from SARs-COV-2 o On admission D-dimer elevated 0.59, patient was tachycardic o CTA significant for No pulmonary embolism. No lung consolidation. Hypodense renal lesions. Hypertensive urgency - resolved Essential hypertension o On admission BP >180/120 o Continue home losartan and amlodipine. Diabetes mellitus type 2 o A1c (11/18/20):7.9, repeat A1c 6.7 (4/17) o Home meds metformin 500 BID, Novolin 70-30 : 40 unit AM, 75 unit PM. Home novolin 70-30 = lispro 34 units, glargine 80 unit approximately o Started SSI, lispro TID 5 units, Glargine 10 units BID, confirmed dose with pharmacy based on his home Novolin 70-30 conversion. Patient to continue home medications and follow-up with PCP. MDD-Continue home paroxetine, venlafaxine

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Hyperlipidemia - Continue home statin Treatments: steroids: Dexamethasone 6 mg and remdesivir 100 mg, benzonatate capsule 100 mg Procedures: None Consults: pulmonary/intensive care Pertinent Test Results: CXR: There is mild atelectasis at the lung bases. There is no effusion or pneumothorax. The cardiac silhouette is normal size. The trachea is midline. The osseous mineralization is normal. CTA: IMPRESSION: 1. No pulmonary embolism. 2. No lung consolidation. 3. Hypodense renal lesions as described above. ED to Hosp-Admission Discharged 4/26/2021 - 5/6/2021 (10 days) Hospital Doctor Last attending ? Treatment team Acute pulmonary embolism, unspecified pulmonary embolism type, unspecified whether acute cor pulmonale present Principal problem HPI: (Patient) is a 78 y.o. male with past medical history of T2DM, HTN, HLD, and depression/anxiety who presented to the ED on 4/26 with COVID pneumonia and acute bilateral PE. Orthostatic Hypotension. Improved with IV fluids. No orthostasis this morning. TTE done yesterday showing preserved EF. Acute hypoxemic respiratory failure secondary to Covid 19 Pneumonia with some contribution from PE. Patient now on room air. Patient completed Remdesivir. Completed 10 days of Dexamethasone. He will be transitioned to prednisone 20 mg daily for 7 days, 10 mg daily for 7 days then 5 mg daily for 7 days. He was given Tocilizumab: 8 mg/kg, 4/29. He is not a candidate for convalescent plasma. Acute bilateral PE: Mild clot burden without evidence of RV strain. Was initially started on therapeutic Lovenox, transitioned to Eliquis 4/29. Eliquis priced and affordable to the patient. T2DM: On lantus 23 units nightly and Humalog to 10 units with meals HTN: Continue losartan and amlodipine with holding parameters HLD: Continue statin Depression with anxiety: Continue paroxetine and Effexor BPH: Continue Flomax Suspected OSA: Per his daughter concern for OSA. Will need outpatient sleep study.



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1334510	5/20/2021	MA	41	M	4/23/2021	5/7/2021	After headaches and fatigue following the shot (within 24 hours) I began to notice slight shortness of breath 3-5 days following. I didn't give it much thought, but, roughly two weeks after my dose I began to experience severe intercostal pain and sharp pain in the lower lobe of my right lung upon inhalation. I thought this was musculoskeletal at first but after it didn't abate within days, I went to the hospital and was diagnosed with several distal pulmonary emboli. Luckily I survived and am currently on blood thinners while trying to determine the cause of this, having no history of blood clots personally or in extended family.
1333834	5/20/2021	NM	81	F	3/3/2021	5/5/2021	81 year old female admitted to healthcare facility for deep vein thrombosis and pulmonary emboli. Hospitalized x 14 days; treated by healthcare provider. Patient sought care after Chiropractor noted her right leg was swollen and he told her she should investigate this problem. Patient was then seen by healthcare provider who sent her for diagnostic testing - Doppler of lower extremities, and CT scan of Lungs. Pt was referred to a pulmonary specialist; Pt was hospitalized and treated with Heparin and Coumadin, and Oxygen.

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1332754	5/20/2021	NC	71	M	4/24/2021	4/25/2021	felt unwell; took his oxygen level and it was at 80%; he had swelling; difficulty breathing; tachycardia; allergic reaction; tested Covid-19 positive; blood clots; he got very sick; This is a spontaneous report from a contactable consumer(patient's daughter). A 71-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 24Apr2021 (Batch/Lot number was not reported) at the age of 71-year-old as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient was fine and nothing happened until after the vaccine. The patient took the 1st dose on 24Apr2021 and the next day he got very sick, they thought it was just a reaction from the vaccine, then he was swelling said he was not feeling well. The day after the vaccine, the patient was rushed to the emergency room and confined to the ICU. He felt unwell and it got worse and worse, we took his oxygen level and it was at 80%, he had swelling, difficulty breathing and tachycardia. The reporter thought it was an allergic reaction but this morning the patient tested positive for covid, he didn't go out the only time he went out was to get the vaccine. The reporter asked If he didn't know he had covid and got the vaccine, will he get more sick. In the report they found blood clots and the doctors thought it was from the vaccine. He was diagnosed with blood clots and difficulty breathing and he tested Covid-19 positive. Events seriousness criteria reported as hospitalization. The outcome of the events was unknown. Information on the lot/ batch number has been requested.

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1332671	5/20/2021	IN	28	F	3/24/2021	4/1/2021	Severe calf muscle cramps, possible blood clot; Severe calf muscle cramps, possible blood clot; This is a spontaneous report from a contactable other hcp. A 28-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Right on 24Mar2021 12:00 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunization. Medical history was reported as "none". The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hasn't been tested for COVID-19. the patient previously received the first dose of BNT162B2 on 26Feb2021 at 10:00 administered in the left arm for COVID-19 immunization. The patient's concomitant medications were not reported. The patient experienced severe calf muscle cramps, possible blood clot on 01Apr2021 12:00. The outcome of events was not recovered. Patient did not receive any treatment for the events. Follow up needed, further information has been requested; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation. Case will be reassessed upon receipt of follow-up information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

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1332504	5/20/2021	NY	33	F	4/1/2021	4/30/2021	possibility of a blood clot; Legs were numb; Rash on arm; Whole arm was totally swollen; whole arm Itchy; Fell down; weakness post-vaccination; fever; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (possibility of a blood clot), HYPOAESTHESIA (Legs were numb), RASH (Rash on arm) and PERIPHERAL SWELLING (Whole arm was totally swollen) in a 33-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 3020B1A and 044BZ1A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 01-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 30-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 30-Apr-2021, the patient experienced THROMBOSIS (possibility of a blood clot) (seriousness criteria hospitalization and medically significant), HYPOAESTHESIA (Legs were numb) (seriousness criterion hospitalization), RASH (Rash on arm) (seriousness criterion hospitalization), PERIPHERAL SWELLING (Whole arm was totally swollen) (seriousness criterion hospitalization), PRURITUS (whole arm Itchy), ASTHENIA (weakness post-vaccination) and PYREXIA (fever). 30-Apr-2021, the patient experienced FALL (Fell down). The patient was hospitalized on 30-Apr-2021 due to HYPOAESTHESIA and PERIPHERAL SWELLING. At the time of the report, THROMBOSIS (possibility of a blood clot), HYPOAESTHESIA (Legs were numb), RASH (Rash on arm), PERIPHERAL SWELLING (Whole arm was totally swollen), PRURITUS (whole arm Itchy), FALL (Fell down), ASTHENIA (weakness post-vaccination) and PYREXIA (fever) outcome was unknown. No concomitant medications were reported. Treatment for the events included IV antibiotics, medication to stop itching, oral cephalexin, and Tylenol. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to MOD-2021-121103 (Patient Link).; Sender's Comments: Based on the current available

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information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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1332450	5/20/2021			F			<p>RIGHT EYE BLOODSHOT DUE TO A BLOOD VESSEL BURSTING IN THE EYE; BORDERLINE MIGRAINES; DIARRHEA; EXTREME ILLNESS FOR TWO WHOLE WEEKS; COULD NOT EVEN GET OUT OF BED FOR THE FIRST WEEK; This spontaneous report received from a consumer (daughter) concerned a 58 year old female. The patient's height, and weight were not reported. The patient's past medical history included hip replacement surgery, and concurrent conditions included a little overweight. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) frequency 1 total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. Patient had some alarming symptoms. She was extremely ill for two whole weeks. She was nauseous, vomiting, (subsumed under borderline migraine) had diarrhea and could not even get out of bed for the first week. After those extreme symptoms subsided she had one eye( her right eye) was completely bloodshot due to a blood vessel bursting in her eye. She called her primary care doctor and they told her that they were uncertain if that was even a symptom or not. She also had very painful headaches (subsumed under borderline migraine), borderline migraines and her primary care doctor told her that if it persisted or got any worse to go to the emergency room or possibly go in to the doctor's office. Reporter stated that blood clots were not something that really ran in their family bloodline. Patient hadn't had any real health problems other than having a hip replacement surgery and being a little overweight. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from, diarrhea, extreme illness for two whole weeks, could not even get out of bed for the first week, and the outcome of right eye bloodshot due to a blood vessel bursting in the eye and borderline migraines, was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210532621-JANSSEN COVID-19 VACCINE Ad26.COV2.S- Eye blood shot. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other</p>

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factors potentially associated with the event.

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1332359	5/20/2021	AR	62	M	3/1/2021		CARDIAC ARREST (SEVERE CHEST PAIN); CLOGGED VEIN; LEFT ARM GOES TO SLEEP; This spontaneous report received from a patient concerned a 62 year old white male. The patient's past medical history included blood clot, heart attack, lump in leg, and stents in main arteries, and concurrent conditions included heavy smoker, and heart issues. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808025, expiry: UNKNOWN) dose was not reported, 1 total administered on 12-MAR-2021 to left arm as prophylactic vaccination. The patient was previously treated with clopidogrel bisulfate for blood clot. On an unspecified date in 2021, Laboratory data included: Echocardiogram (NR: not provided) unknown, and Lab test (full workup)(NR: not provided) unknown. On an unspecified date in Mar-2021, a week later vaccination, the patient experienced that left arm went to sleep which felt worse next day, on 25-APR-2021, patient experienced severe pain in chest, called ambulance and was taken to hospital. On same day patient was hospitalized. Patient went to full cardiac arrest twice same day. It was stated that vein that was 60 percent good earlier was 100 percent clogged (clogged vein) in one month after getting the vaccine. They tried to put stent in, clear vein out, and put piece of metal and expanded it, to make alley way for blood flow. Patient stated that patient would not take Plavix this time. According to patient, stent was reacting with Plavix, and decided to take something different. They did same job twice. It was stated that patient was discharged on 05-May-2021 from hospital. On 12-MAY-2021, patient went to consult the health care professional to make sure everything was okay. The patient gave lot number 1808025, then stated that, patient thinks it is 180, and then either 5 or 8, and next it was either D or O, and then after the space it is 25. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the cardiac arrest (severe chest pain), left arm goes to sleep and clogged vein was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210523134-COVID-19 VACCINE AD26.COV2.S-CARDIAC ARREST (SEVERE CHEST PAIN), CLOGGED VEIN. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown



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scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY, UNDERLYING DISEASE

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1332693	5/20/2021	MA	86	F	3/4/2021	3/1/2021	<p>blood clot; Sciatica; She then got sciatica in her leg and couldn't walk; charley horse in her lower leg while walking; soreness in arm / pain in her foot / lower leg/calf still hurt; This is a spontaneous report from a contactable nurse (patient). This 86 years old female patient received the second single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EN6203) on 04Mar2021 at 11:00, in left arm, for COVID-19 immunisation. No other vaccines were administered on the same date. The patient received the first dose of BNT162B2 vaccine intramuscular, on 11Feb2021 at 18:30 (lot EN6201). The patient received some years ago an unspecified pneumonia vaccine and an unspecified tetanus vaccine experiencing after both headache, swollen arm and rash. She didn't react to the flu vaccine. Her body didn't want any more vaccine. Concomitant medications were none. On an unspecified date in Mar2021, maybe a week or two after the second vaccination, early to mid afternoon, the patient had what felt like a charley horse in her lower leg while walking, but didn't pay any attention to it, just put ice on the leg. She then got sciatica in her leg on 24Apr2021 and couldn't walk; that was what sent her to the hospital as it was getting worse and she went to the hospital because of the pain. She just ignored it for at least a week but she was still having pain after the second week and could hardly walk due to the sciatica in that leg. At the hospital they found she had a blood clot in the calf of her leg on 28Apr2021. She was hospitalized from 28Apr2021 to 02May2021. The doctors in the hospital recommended that she should report her experience even though they didn't know if it was due to the COVID vaccine due to the proximity. The hospital doctors took care of her but her primary care provider knew that she had been in the hospital. The doctors gave her medications in the hospital that helped the pain in her foot and the sciatica but her lower leg/calf still hurt so they decided to do an ultrasound and found a blood clot. The patient still had to give herself injections in the belly for blood thinner to treat the blood clot. The patient also experienced soreness in arm on an unspecified date in 2021. Sciatica required ER visit. Blood clot was resolving. The other events outcome was unknown. The doctor said that there was a possibility that the blood clot could be related to the COVID vaccine, but it may not be related at all.;</p>

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Sender's Comments: Based on the information provided by the reporter, including a prolonged onset latency of nearly two months, it appears unlikely that BNT162B2 contributed to the reported events. These are likely intercurrent medical conditions in this elderly patient. This case will be reassessed upon receipt of additional information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. Linked Report(s) : PFIZER INC-2021501847 same patient/drug, different vaccine dose/AE

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1332699	5/20/2021	TX	29	F	4/22/2021	4/26/2021	stroke-like symptoms; not being able to see out of my left eye; the left side of my body was numb; pounding headache on the left side of their head; shooting pain up and down my neck; could barely turn my head with shooting pain down my body; shingles; migraines; This is a spontaneous report from a contactable consumer (patient). A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 29 years of age), via an unspecified route of administration, administered in arm left on 22Apr2021 10:15 (Batch/Lot number was not reported) as 1ST DOSE, SINGLE for COVID-19 immunisation. Medical history included autoimmune disorder from an unknown date and unknown if ongoing. Concomitant medication included levothyroxine taken for an unspecified indication, start and stop date were not reported. The patient was not pregnant. The patient had no known allergies. She was not diagnosed with COVID-19 prior to vaccination. She has not been tested for COVID-19 since the vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. It was reported that the patient had stroke-like symptoms, not being able to see out of her left eye, the left side of her body was numb, and she a pounding headache on the left side of their head. Upon being checked into the ER, she was immediately put on stroke alert. After a CAT-Scan and two MRIs, blood clots were ruled out. She stayed under close watch, and an IV was administered. All her blood work numbers checked out and the doctors were puzzled. After three to four hours, the symptoms reduced. After ten hours, they were almost gone. She went home and didn't have any more complications that day. Fast forward to the 1st, new symptoms. She now has shooting pain up and down her neck. At first, she thought she strained her neck, but the next day she could barely turn her head with shooting pain down her body. This morning they went to their PPC to get checked out. Luckily, a diagnosis was given. She had developed shingles. The events started on 26Apr2021 10:00 AM. The events resulted to Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. The patient was hospitalized for the events. Therapeutic measures were taken as a result of the events. She was given IV for migraines but it did nothing. The outcome of the

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1332703	5/20/2021	TN	55	F	4/15/2021	4/23/2021	<p>events was recovered with lasting effects. Information on the lot/batch number has been requested.</p> <p>My left arm is locked in a paralyzed stage where I haven't been able to lift it no more than a few inches since the second week that I got the Pfizer shot three weeks ago.; muscle spasm; The left side of my shoulder and neck was stiff; This is a spontaneous report from a contactable consumer (patient). A 55-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EL9269), via an unspecified route of administration, administered in arm left on 15Apr2021 at 13:00 (at the age of 55-years-old) as 1st dose, single for COVID-19 immunisation. Medical history included breast cancer, is diabetic and anemic, thyroid disorder, peripheral neuropathy, history of blood clot (reported as 'clog') in leg and pineapple and watermelon allergy, all from an unknown date and unknown if ongoing. On 23Apr2021 at 08:00, the patient's left arm is locked in a paralyzed stage where she hasn't been able to lift it no more than a few inches since the second week that she got the Pfizer shot three weeks ago. The left side of her shoulder and neck was stiff like she had a muscle spasm for about the whole second week. She will not be getting the second shot. The events resulted in doctor or other healthcare professional office/clinic visit. Therapeutic measures [acetaminophen (TYLENOL), heat on areas, move and rotate areas] were taken as a result of all events. The outcome of the events was not recovered.</p>

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1333292	5/20/2021	PA	65	F	3/10/2021	3/26/2021	<p>Sore throat, Fever, unspecified fever cause, Exposure to COVID-19 virus ED to Hosp-Admission Discharged 4/1/2021 - 5/14/2021 (43 days) Hospital MD Last attending o Treatment team COVID-19 Principal problem Discharge Summary MD (Physician) o o Internal Medicine HOSPITAL DISCHARGE SUMMARY HOSPITALIST GROUP .</p> <p>Patient: Date: 5/14/2021 DOB: Admission Date: 4/1/2021 MRN: Length of stay: 43 Days PCP:MD Discharging provider: MD Admission diagnosis: Primary Admission Diagnosis Medical Problems Hospital Problems Hospital Course HPI: Past medical history significant for type 1 diabetes mellitus, essential hypertension, obstructive sleep apnea, peripheral vascular disease status post femoropopliteal bypass 2016, status post multiple toe amputations on left foot, history of right foot osteomyelitis, left foot osteomyelitis in November 2020 who presented to ER on 4/1/2021 with shortness of breath. She was diagnosed with acute hypoxic respiratory insufficiency in the setting of Covid pneumonia with AKI, hyponatremia, troponin elevation, LFT elevation admitted to regular floor on high flow nasal cannula oxygen. Patient was intubated on 4/2/2021 for increased work of breathing and worsening hypoxemia and hypercapnia. Later patient was found to have persistent Candida fungemia. Hospital Course: Persistent Candida fungemia, now improving Blood cultures positive for Candida albicans from 4/12, 4/14 and 4/17/2021. Cardiology was consulted for TEE, done on 04/30 which was negative for vegetations. Ophthalmology was consulted and there was no evidence of fungal endophthalmitis. Blood cultures from 4/23/2021 so far no growth. PICC line has been placed. ID recommendations appreciated. -Currently patient on 6 weeks of IV micafungin, to be continued through 6/7/2021 as per ID recommendations. ID has therapy plan in system Moderate to severe pharyngeal dysphagia Post extubation SLP and modified barium swallow demonstrated aspiration with thin and thickened liquids. S/p PEG tube on 5/7/2021. CT head did not reveal any infarct. Repeat modified barium swallow done today , patient now advanced to level 3 soft diet with thin liquids. -Continue with tube feeds and alter tube feeds based on patient's diet advancement Type I Diabetes</p>

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mellitus: Labile blood sugars in the setting of changes done to tube feeding. Patient currently on tube feeding and diet has been advanced today. Regimen at the time of discharge Lantus twice daily: With sliding scale insulin and standing dose of short-acting insulin with tube feeds bolus. -Patient will need close monitoring of her blood sugars given changes being done to tube feed and diet advancement, will need titration of insulin based on blood sugars. Lower extremity edema, improved Likely dependent lower extremity edema. Echo April 2021 reviewed: Normal EF, no diastolic dysfunction. -Elevate legs while patient is seated -Ace wraps -Restarted home dose of hydrochlorothiazide Acute on chronic anemia Received 1 unit of blood transfusion during this hospitalization Monitor hemoglobin Vitamin B12 and folate level normal. Hb on last check was 8.0 COVID-19 pneumonia Acute hypoxic and hypercapnic respiratory failure -resolved Status post extubation 04/06/2021 Treated with Remdesivir, convalescent plasma, Decadron as well as Tocilizumab. Treated with IV vancomycin, Levaquin and cefepime in the setting of possible secondary bacterial pneumonia. CT chest ruled out PE but showed extensive infiltrates on admission. Patient is off Covid precautions Currently saturating well on room air and stable from respiratory standpoint. Elevated d dimer, POA : Patient had elevated D-dimer on presentation. Lower extremity ultrasound 4/3/2021 was negative for DVT. CT chest ruled out PE. She was initially placed on intermediate dose of anticoagulation. D-dimer eventually trended down. Currently patient is on subcu heparin for prophylaxis. AKI POA now resolved Creatinine stable. -Continue to monitor renal function, electrolytes and urine output. Hypernatremia : resolved Acute Urinary retention, now resolved. Foley catheter was placed on 4/24 after patient had multiple straight cath done. DC'd Foley catheter on 5/3/2021. Patient is currently voiding without any issues. Chronic medical issues : o Essential Hypertension: On amlodipine, Coreg and hydrochlorothiazide. o Peripheral vascular disease status post femoropopliteal bypass: Restarted home aspirin, statin. \_ Admission Current 5/14/2021 - present (6 days) Hospital MD Last attending o Treatment team COVID-19 with multiple comorbidities Principal problem Physical Medicine and Rehabilitation History and Physical Date: 5/14/2021

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Admission Date: (Not on file) PCP: MD DOB: Hospitalist: MD Assessments Patient is a 65 y.o. female on hospital day number 0 Active Problems: No Active Hospital Problems: There are no active hospital problems currently on the Problem List. Please update the Hospital Problem List and refresh. IMPRESSION / PLAN: 1. Covid pneumonia/sepsis with hypoxic respiratory failure Received remdesivir, dexamethasone, convalescent plasma Received IL-6 inhibitor Intubation 4/1/2021—extubated, O2 weaned and now tolerating room air CTA chest 4/22/2021—extensive consolidation in both lungs C/W Covid pneumonia, no PE 2. Diabetes mellitus type 1 Lantus scheduled dose twice daily Humalog every 6 hours scheduled and sliding scale Insulin to be adjusted as PEG feedings decrease 3. Diabetic peripheral neuropathy arterial insufficiency Status post femoropopliteal bypass 2016— Status post right common femoral and mid popliteal bypass 9/28/2020 Dr. —no use of synthetic graft Status post remote history of multiple toe amputations left foot osteomyelitis Acute necrotic areas of feet being treated locally 4. Candida albicans fungemia On 6-week course of IV micafungin Weekly CBC, LFT, sed rate, CRP and BMP 5. Essential hypertension On amlodipine, carvedilol, HCTZ, 6. Dysphagia PEG tube placed 5/7/2021—Dr. Cleared for dysphagia level 3 soft diet thin liquids 5/14/2021 Aspiration precautions Speech and Language Pathology 7. Decreased ambulation and functional mobility and functional ability for activities of daily living Physical therapy, Occupational Therapy Plan Patient is admitted for comprehensive inpatient rehabilitation program consisting of physical therapy, Occupational Therapy, speech and language pathology, rehabilitative nursing, psychology, and case management support. Goals will be aligned with patient family goals and directed to improving functional mobility, functional interaction, and activities of daily living to allow the patient to return home safely and continue his rehabilitation as an outpatient or at a home health basis. Estimated length of stay is 16 days. Patient has a good prognosis History of Present Illness Patient is an 65 y.o. female with history of diabetes mellitus type 1



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hypertension and sleep apnea who became febrile with shortness of breath over several days. Her PCP, Dr, ordered Covid test which was positive. She presented to Hospital on 4/1/2021 for further work-up. On admission she was found to be in hypoxic respiratory failure requiring high flow oxygen which progressed to requiring a nonrebreather and eventually intubation with ICU care. She received remdesivir, dexamethasone, and convalescent plasma. Patient also received IL-6 inhibitor Tocilizumab recommendation of pulmonary critical care. Procalcitonin level was 35.32. Because of concern of superimposed bacterial pneumonia she was also treated with broad-spectrum antibiotics. Patient had a prolonged complicated acute care hospital course. On 4/12/2021 ENT evaluation showed poor phonatory effort but mobile true vocal cord without lesions. Patient was found to have a fungemia from cultures of 4/12/2021 of C albicans with positive blood cultures with C. albicans on 4/17/2021. Patient was placed on IV micafungin for a total of 6-week course. TEE showed no evidence of acute valve pathology. Ophthalmology was consulted and there was no evidence of fungal endophthalmitis. Repeat blood cultures from 4/23/2021 showed no growth. Patient had PEG tube placed by Dr of GI on 5/7/2021. Repeat modified barium swallow on 5/14/2021 showed improvement of swallowing and the patient was upgraded to a dysphagia level 3 soft diet with double swallows and thin liquids via cup or straw with aspiration precautions. Patient was evaluated by therapies while at Hospital acute care. She requires supervision to rise from sit to stand using a rolling walker and contact-guard ambulate 45 feet using a rolling walker with wheelchair follow and verbal cues for walker management. She continues to have some knee buckling. She needs minimal assistance for bathing and min mod assistance for lower body dressing. She is able to perform toileting with contact-guard. Acute inpatient rehabilitation was recommended. Patient is being transferred to the Hospital for comprehensive inpatient rehabilitation program. Additional information for Item 19: Updated Procedure 04/01/21 1217 Respiratory virus detection panel Collected: 04/01/21 0917 | Final result | Specimen: Swab from Nasopharynx Adenovirus Not Detected Mycoplasma pneumoniae Not Detected Chlamydia pneumoniae Not Detected Parainfluenza

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Not Detected COVID-19 SARS-CoV-2 Overall Result  
 DetectedCritical Enterovirus/Rhinovirus Not Detected  
 Coronavirus Not Detected Respiratory Syncytial Virus Not  
 Detected Influenza A Not Detected Bordetella pertussis  
 Not Detected Influenza B Not Detected Bordetella  
 parapertussis Not Detected Metapneumovirus Not  
 Detected 03/27/21 1807 COVID-19 (SARS CoV-  
 2,RNA Molecular Amplification) Collected: 03/27/21  
 0859 | Final result | Specimen: Swab COVID-19 SARS-  
 CoV-2 Overall Result DetectedCritical Labs/Imaging  
 LABORATORY: CBC: Results from last 7 days Lab  
 Units 05/13/21 0557 05/10/21 0614 05/09/21 0724 WBC  
 AUTO K/mcL 5.4 5.0 4.7 HEMOGLOBIN g/dL 8.0\* 8.0\*  
 8.5\* HEMATOCRIT % 24.7\* 25.3\* 26.4\* PLATELETS  
 K/mcL 201 197 196 NEUTROS PCT AUTO % 67 -- --  
 LYMPHS PCT AUTO % 21 -- -- MONOS PCT AUTO  
 % 8 -- -- EOS PCT AUTO % 4 -- -- CHEMISTRY:  
 Results from last 7 days Lab Units 05/14/21 0609  
 05/13/21 0557 05/10/21 0614 SODIUM mmol/L 137 134\*  
 136 POTASSIUM mmol/L 4.2 4.2 3.9 CHLORIDE mmol/L  
 103 101 104 CO2 mmol/L 28 25 26 BUN mg/dL 23 21 16  
 CREATININE mg/dL 0.86 0.78 0.82 CALCIUM mg/dL 9.0  
 8.8 8.6 Results from last 7 days Lab Units 05/14/21  
 0609 05/13/21 0557 05/10/21 0614 MAGNESIUM mg/dL  
 2.0 1.9 1.7 COAGULATION: OTHER TESTS: 0  
 Lab Value Date/Time TROPONINI 0.10 (H) 04/06/2021  
 0412 TROPONINI 0.17 (H) 04/03/2021 0436  
 TROPONINI 0.29 (H) 04/02/2021 1655 TROPONINI  
 0.28 (H) 04/02/2021 1323 TROPONINI 0.29 (H)  
 04/02/2021 1107 TROPONINI 0.28 (H) 04/02/2021  
 0546 TROPONINI 0.38 (H) 04/01/2021 1248  
 TROPONINI 0.15 (H) 04/01/2021 0857 TROPONINI  
 0.01 11/27/2012 0522 TROPONINI 0.08 (H) 11/26/2012  
 1104 TROPONINI 0.04 11/26/2012 0626 TROPONINI  
 0.04 11/25/2012 2304 IMAGING: Gastrostomy tube,  
 place Result Date: 5/7/2021 Gastrostomy tube, place  
 Procedure Note Surgical Pre-Operative Patient  
 Identification Yes, after the patient was placed on the  
 operating room/procedure table, I confirmed the patient's  
 identity. Impression Overall Impression: Normal EGD up  
 to second part of duodenum. 20 French PEG placed  
 without any immediate complications. Recommendation  
 There is no recommended follow-up for this procedure.  
 Okay to use back for medications and water flushes.  
 Start feeding via PEG tomorrow after GI evaluation.

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Indication Pre-procedure diagnosis: Pharyngeal dysphagia Post-procedure diagnosis: See impression Preprocedure A history and physical has been performed, and patient medication allergies have been reviewed. The patient's tolerance of previous anesthesia has been reviewed. The risks and benefits of the procedure and the sedation options and risks were discussed with the patient. All questions were answered and informed consent obtained. Details of the Procedure The patient underwent monitored anesthesia care, which was administered by an anesthesia professional. The patient's blood pressure, heart rate, level of consciousness, oxygen, respirations, ETCO2 and ECG were monitored throughout the procedure. The scope was introduced through the mouth and advanced to the second part of the duodenum. Retroflexion was performed in the cardia, fundus and incisura. The patient experienced no blood loss. The procedure was not difficult. The patient tolerated the procedure well. There were no apparent complications. See anesthesia record for more information regarding anesthesia administered. Specimens \* No specimens in log \* Implants No implants documented in log. I attest the accuracy of any implant/graft nursing documentation. Findings The cricopharynx, upper third of the esophagus, middle third of the esophagus, lower third of the esophagus, GE junction, Z-line, cardia, fundus of the stomach, body of the stomach, greater curve of the stomach, lesser curve of the stomach, incisura, antrum, prepyloric region, pylorus, duodenal bulb, 1st part of the duodenum and 2nd part of the duodenum appeared normal. PEG-G tube successfully placed in the body of the stomach using a deformable internal bolster via the pull technique after the site was identified via transillumination, visualized indentation and needle passed through abdominal wall; distance from external bolster to external end of tube: 3 cm; scope reinserted to confirm placement Staff/Assistant(s) Staff Role RN Other CRNA Other Other MD Other Disposition: PACU - hemodynamically stable. Condition: stable Attending Attestation: I performed the entire procedure. CT abdomen pelvis without contrast Result Date: 4/15/2021 PROCEDURE INFORMATION: Exam: CT Abdomen And Pelvis Without Contrast Exam date and time: 4/15/2021 12:00 AM Age: 65 years old Clinical indication: Other: Na; Additional

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info: Distention, fungemia workup. TECHNIQUE: Imaging protocol: Computed tomography of the abdomen and pelvis without contrast. Radiation optimization: All CT scans at this facility use at least one of these dose optimization techniques: automated exposure control; mA and/or kV adjustment per patient size (includes targeted exams where dose is matched to clinical indication); or iterative reconstruction. COMPARISON: No relevant prior studies available. FINDINGS: Tubes, catheters and devices: Small bowel feeding tube noted. Lungs: Bibasilar patchy nodular airspace disease with ground-glass opacity. Liver: Normal. No mass. Gallbladder and bile ducts: Multiple gallstones. Pancreas: Normal. No ductal dilation. Spleen: Normal. No splenomegaly. Adrenal glands: Normal. No mass. Kidneys and ureters: Bilateral renal vascular calcifications. Stomach and bowel: Visualized bowels demonstrated a generalized constipation. Appendix: Not well seen. Intraperitoneal space: Unremarkable. No free air. No significant fluid collection. Vasculature: Moderate atherosclerotic changes. Lymph nodes: Unremarkable. No enlarged lymph nodes. Urinary bladder: Unremarkable as visualized. Reproductive: Unremarkable as visualized. Bones/joints: Degenerative changes within the lumbar spine. Soft tissues: Unremarkable. IMPRESSION: Bibasilar nodular airspace disease with ground-glass opacity. No other acute inflammatory process or obstructive uropathy within the abdomen and pelvis. THIS DOCUMENT HAS BEEN ELECTRONICALLY SIGNED BY MD X-ray abdomen 1 view Result Date: 5/4/2021 XR ABDOMEN 1 VW PORT IMPRESSION: Weighted enteric tube with the tip in the gastric antrum. Residual oral contrast throughout a nondilated colon. END OF IMPRESSION: INDICATION: ng tube placement ng tube placement. TECHNIQUE: AP supine portable projection of the abdomen was acquired. COMPARISON: AP abdomen on 4/15/2021. FINDINGS: The gas pattern is unremarkable. There is residual oral contrast equally distributed throughout a nondilated colon. There is a new weighted enteric tube with the tip in the gastric antrum. Small right lung base pleural effusion is present. No abnormal mass effect is noted. No significant radiopaque calculus is identified. There are no significant bony findings. This report was created using Voice Recognition software. Thank you for allowing us to

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participate in the care of your patient. X-ray abdomen 1 view Result Date: 4/15/2021 XR ABDOMEN 1 VW  
 PORT IMPRESSION: Orogastric tube is in the stomach. Nonspecific bowel gas pattern. END OF IMPRESSION:  
 INDICATION: Feeding tube placement. TECHNIQUE: Single view of the abdomen. COMPARISON: Prior examination of April 15, 2020. FINDINGS: Orogastric tube is in the stomach. Nonspecific bowel gas pattern is noted. Osseous skeleton is grossly intact. This report was created using Voice Recognition software. Thank you for allowing us to participate in the care of your patient. CT head without contrast Result Date: 4/21/2021 CT HEAD WO CONTRAST IMPRESSION: No acute intracranial pathology. Mucoperiosteal thickening in the ethmoid sinuses as well as some opacification of the bilateral mastoid air cells consistent with chronic sinus disease and mastoiditis. END OF IMPRESSION: INDICATION: DYSPHAGIA DYSPHAGIA. TECHNIQUE: Spiral CT scan through the head from the skull base through the vertex was performed with 5 mm axial reconstructions. Images obtained without contrast. CONTRAST: No contrast was administered. COMPARISON: April 13, 2021 FINDINGS: No acute hemorrhage, mass, or mass effect. No abnormal extra-axial fluid collections are identified. There is preservation the gray-white differentiation. No evidence to suggest large vascular distribution infarct. The ventricles, cisterns, and other CSF containing spaces demonstrate normal size, shape, and configuration. The basal cisterns are patent and symmetric. Stable focal area of gliosis in the right frontal white matter. The calvarium is intact. The visualized portions the aerated paranasal sinuses mastoid air cells demonstrate bilateral ethmoid sinus mucoperiosteal thickening. Additionally there is scattered opacification of some mastoid air cells bilaterally. This report was created using Voice Recognition software. Thank you for allowing us to participate in the care of your patient. Fluoroscopy video swallow with speech therapy Result Date: 4/19/2021 FL VIDEO SWALLOW WITH SPEECH THERAPY MBSS IMPRESSION: Aspiration of thin and nectar thick liquid. Please refer to speech therapy report. END OF IMPRESSION: INDICATION: Dysphagia. Concern for aspiration. Covid 19. SUPERVISION: Procedure was performed by RRA under direct supervision by MD TECHNIQUE:

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Fluoroscopy assistance was provided to the speech pathology department. Multiple consistencies of barium and food products were administered to the patient. Fluoroscopy of the oral and pharyngeal region was performed. FLUOROSCOPY TIME: 1.1 minutes  
COMPARISON: Modified barium swallow of 4/12/2021.  
FINDINGS: Aspiration of thin and nectar thick fluid. Hypopharyngeal residue with all trials provided. Significant dry secretions in the oral cavity and pharynx. Please see speech pathologist's report for further details and recommendations. This report was created using Voice Recognition software. Thank you for allowing us to participate in the care of your patient. Fluoro NG long tube placement Result Date: 4/30/2021 FL NG LONG TUBE PLACEMENT IMPRESSION: Successful fluoroscopically guided Dobbhoff placement. END OF IMPRESSION: INDICATION: Dobbhoff placement. SUPERVISION: Procedure was performed by staff member under personal supervision by Dr..  
TECHNIQUE: Fluoroscopic guidance for nasogastric tube placement. FLUOROSCOPY TIME: 2.2 minutes  
COMPARISON: None available. FINDINGS: Using fluoroscopic guidance, a nasogastric tube was placed from the left nares into the stomach. Upon placement of the nasogastric tube, 10 cc of Omnipaque contrast material was injected to confirm placement. Opacification within the stomach was visualized confirming appropriate NG tube placement. There were no intraprocedural complications and the procedure was well tolerated by the patient. The patient was discharged from the imaging department in satisfactory condition. This report was created using Voice Recognition software. Thank you for allowing us to participate in the care of your patient. X-ray chest 1 view Result Date: 4/26/2021 XR CHEST 1 VW PORT IMPRESSION: NG tube in the fundus of stomach left upper abdomen. END OF IMPRESSION: INDICATION: SOB evaluate NGT placement following advancement.. TECHNIQUE: AP projection of the chest is acquired. COMPARISON: 4/26/2021 FINDINGS: NG tube in the fundus of stomach left upper abdomen. Stable diffuse patchy infiltrates both lungs in the upper, mid to lower zones and left effusion. No pneumothorax. The heart size is normal. Rib cage is unremarkable. This report was created using Voice Recognition software. Thank you for allowing us to participate in the care of

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your patient. X-ray chest 1 view - portable Result Date: 4/26/2021 XR CHEST 1 VW PORT IMPRESSION: 1. Interval increase in diffuse airspace opacity and effusions from prior. 2. NG tube tip in the region of the GE junction. Consider further advancement. END OF IMPRESSION: INDICATION: Hypoxia, acute shortness of breath. TECHNIQUE: Portable AP view of the chest is acquired. COMPARISON: 4/22/2021. FINDINGS: Diffuse airspace opacity and effusions appear mildly increased from prior. The NG tube tip is in the region of GE junction. Recommend further advancement. No pneumothorax is identified. This report was created using Voice Recognition software. Thank you for allowing us to participate in the care of your patient. X-ray chest 1 view Result Date: 4/22/2021 XR CHEST 1 VW PORT IMPRESSION: Persistent diffuse patchy infiltrates bilaterally, consistent with Covid infection. END OF IMPRESSION: INDICATION: hypoxia. Covid 19. TECHNIQUE: AP upright projection of the chest is acquired. COMPARISON: Radiographs of 4/18/2021. FINDINGS: The cardiomeastinal silhouette is unchanged. Persistent diffuse patchy infiltrates bilaterally, consistent with Covid infection. No evidence of pleural effusion or pneumothorax. No significant change compared to prior radiographs. This report was created using Voice Recognition software. Thank you for allowing us to participate in the care of your patient. X-ray chest 1 view, Portable Result Date: 4/18/2021 XR CHEST 1 VW PORT IMPRESSION: Enteric tube extends into the stomach. Tip collimated from view. Multifocal airspace disease, increased slightly since 4/13/2021. END OF IMPRESSION: INDICATION: Verify placement of NG tube. TECHNIQUE: AP upright portable projection of the chest is acquired. COMPARISON: 4/13/2021 FINDINGS: An enteric tube extends into the stomach; the tip is collimated from view. The lungs are symmetrically aerated. Multifocal airspace opacities are slightly increased since 4/13/2021. No pneumothorax or pleural effusion. Cardiomeastinal silhouette is stable. This report was created using Voice Recognition software. Thank you for allowing us to participate in the care of your patient. Transthoracic echo (TTE) limited Result Date: 4/21/2021 FINALIZED REPORT TWO-DIMENSIONAL ECHOCARDIOGRAPHIC FINDINGS LEFT VENTRICLE: Normal size and function RIGHT

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VENTRICLE: Normal size and function AORTIC VALVE: Trileaflet sclerotic MITRAL VALVE: Mitral annular calcification TRICUSPID VALVE: Normal PULMONIC VALVE: Not well seen LEFT ATRIUM: Normal size RIGHT ATRIUM: Normal size INTERATRIAL SEPTUM: Intact AORTIC ROOT: Normal size PERICARDIUM: No effusion IVC: Normal size and normal collapse AORTIC ARCH: Not well seen COLOR AND SPECTRAL DOPPLER: PA systolic pressure in the range of 30 mmHg FINAL IMPRESSIONS: This is a technically limited study with poor acoustic windows and poor endocardial border definition. Normal LV size with normal wall thickness. No clear-cut regional wall motion abnormalities. EF 55 to 60% Normal RV size and function Aortic sclerosis Mitral annular calcification No vegetations or a source of fungemia noted Transesophageal echo (TEE) Result Date: 4/30/2021 FINALIZED REPORT TWO-DIMENSIONAL ECHOCARDIOGRAPHIC FINDINGS: INTUBATION: Anesthesia airway management provided by the anesthesiologist. I intubated esophagus myself without difficulty LEFT VENTRICLE: LV cavity size mild LVH normal function EF 55-60 RIGHT VENTRICLE: Normal RV size function AORTIC VALVE: Leaflet no vegetation MITRAL VALVE: Appears normal no vegetation TRICUSPID VALVE: Appears normal no vegetation PULMONIC VALVE: Appears normal no vegetation LEFT ATRIUM: Appears normal RIGHT ATRIUM: Appears normal INTERATRIAL SEPTUM: Intact SVC: Appears normal IVC: Appears normal PERICARDIUM no effusion LEFT ATRIAL APPENDAGE: Appears normal PULMONARY VEINS: Not well seen AORTIC ROOT: Appears normal ASCENDING THORACIC AORTA: Appears normal AORTIC ARCH: Appears normal DESCENDING AORTA: Appears normal COLOR AND SPECTRAL DOPPLER: No stenotic regurgitant lesions noted FINAL IMPRESSIONS: No vegetations noted Normal LV cavity size wall thickness function EF 55-60 Normal RV size function No valve abnormalities Ultrasound upper extremity venous right Result Date: 4/24/2021 US UPPER EXTREMITY VENOUS RIGHT IMPRESSION: No DVT identified. Superficial thrombosis identified in the cephalic vein. END OF IMPRESSION: INDICATION: Concern for DVT. TECHNIQUE: Real-time two-dimensional ultrasound of the right upper extremity



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was performed with grayscale, color and duplex Doppler imaging. Compression and augmentation were performed where possible. Permanently recorded images were obtained and stored. FINDINGS: The internal jugular vein, subclavian vein, axillary vein, brachial veins, basilic vein are normal. They demonstrate normal flow and compressibility. There is a thrombus identified in the right cephalic vein at the mid arm through distal forearm. This report was created using Voice Recognition software. Thank you for allowing us to participate in the care of your patient. CT angiogram chest pulmonary embolism with and without contrast Result Date: 4/22/2021 CTA CHEST PULMONARY EMBOLISM W WO CONTRAST IMPRESSION: No evidence of pulmonary embolus or right heart strain. Extensive parenchymal consolidation in both lungs, left greater than right consistent with severe pneumonia such as Covid 19 pneumonia. Moderate left-sided small to moderate right sided pleural effusions are seen with associated compressive atelectasis. Enlarged main pulmonary artery which can be seen in the setting of chronic pulmonary hypertension. Interval development of large mediastinal adenopathy particularly in the right paratracheal region and subcarinal region. These may be reactive in nature in the setting of as diffuse pneumonia. Enterogastric tube with the tip extending to just within the stomach. END OF IMPRESSION: INDICATION: pneumonia. Assess for pulmonary artery embolism. TECHNIQUE: Enhanced helical CT scan of the chest was performed from the lung apices to below the diaphragm. 2mm axial reconstruction with MPR coronal, oblique and sagittal images were created. 3D shaded surface images also created on a separate workstation and permanently stored. CONTRAST: 100mL of IOHEXOL 350 MG IODINE/ML INTRAVENOUS SOLUTION administered INTRAVENOUS. Quality of contrast opacification was adequate. COMPARISON: July 22, 2013 FINDINGS: Lung windows demonstrate extensive consolidation involving the lungs, left greater than right. There is a moderate left-sided effusion and a small to moderate right sided effusion with associated compressive atelectasis. The trachea and bronchi are grossly unremarkable. No endobronchial lesions are seen. Soft tissue windows demonstrate a grossly unremarkable thoracic inlet. The thyroid is unremarkable. Moderate

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bilateral axillary lymph nodes are seen with extensive bulky adenopathy in the mediastinum to include the right paratracheal region as well as the subcarinal region and to a lesser extent the hila. The largest lymph nodes are seen in the paratracheal chain demonstrating short axis of approximately 15 mm. Smaller lymph nodes are seen in the aortopulmonary window. These may be reactive in nature. The heart demonstrates a normal configuration. No right heart enlargement is seen. No pericardial effusion is seen. The thoracic aorta and great vessels demonstrate normal branching pattern. Normal course and caliber is seen. The pulmonary arteries demonstrate normal course. There is moderate dilation of the main pulmonary artery up to 3.2 cm. This can be seen in the setting of chronic pulmonary arterial hypertension. No filling defects are seen. Enterogastric tube is seen with the distal tip extending to just within the proximal stomach. The visualized portions of the upper abdomen are grossly unremarkable. The surrounding osseous structures demonstrate mild degenerative changes of the thoracic spine. This report was created using Voice Recognition software. Thank you for allowing us to participate in the care of your patient.

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1332730	5/20/2021	NC	62	F	3/31/2021	3/1/2021	severe arm pain; Nausea; Dizziness; klebsiella pneumoniae, 50,000 to 100,000 cfu; Headache; Urine retention; blood and blood clots in her urine; blood and blood clots in her urine; tore or messed up a ligament in her hand; This is a spontaneous report received via a Pfizer-sponsored program, from a contactable nurse (patient). A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number not reported), via an unspecified route of administration, administered in arm right on 31Mar2021 (at the age of 62-years-old) as 2nd dose, single for COVID-19 immunisation. Medical history included fibromyalgia from 1996 and ongoing, allergies from 1981 and ongoing, hypothyroidism and is pre-diabetic from 2012 and ongoing, Lyme disease from an unknown date and unknown if ongoing, concussion from Sep2019 to an unknown date, post-concussion syndrome from Sep2019 and ongoing , seasonal, food and chemical allergies from an unknown date and unknown if ongoing and had wisdom teeth extracted on an unknown date. The patient's concomitant medications were not reported. The patient previously took nalbuphine hydrochloride (NUBAIN) and experienced anaphylaxis. The patient previously received the first dose of BNT162B2 (Batch/Lot Number: EN6206), administered in right arm on 10Mar2021 for COVID-19 immunisation and experienced Face and ears became very flushed, red, and itchy, Headache, headache was more like a migraine/felt like a migraine, but worse, Post concussion syndrome was retriggered, not eating well and had lost some weight, feeling more worn out, she is allergic to alcohol and thought maybe it was the glycol in the COVID-19 vaccine that caused the reaction, flu like symptoms, achiness all over, pelvic pain and pressure, some burning during urination, did not have the energy level and stamina that she used to, blood in her urine and clots, she was not able to release the urine (urine retention), Nausea and Dizziness. About a week after receiving the second dose of the Covid-19 vaccine on 31Mar2021, she noticed the feeling again of retaining the urine. She was not swollen or anything and immediately went with increased fluids. The urine retention was not as severe at that point. It really showed up and intensified quickly with groin pain, pelvic pain, abdominal pain, and some back pain. She woke up the next morning after

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being doubled over in pain the night before and there was so much blood in her urine that she couldn't see any urine. Her urine was the darkest burgundy and the color of the darkest wine. She did not have anything in her urine the night before when she was doubled over in pain. She was increasing fluids and even drinking Propel for the electrolytes to make sure she was not making things worse. She woke up around 5 AM and felt so sick to her stomach. She had nausea the night before, but she was really nauseated the morning that she discovered blood in her urine. She woke up with severe nausea last Friday, 30Apr2021. Her doctor performed a urine culture. The urine culture returned positive for Klebsiella Pneumoniae with 50,000 to 100,000 CFU/mL on 30Apr2021. She does not have the urine culture results from her first doctor visit. Her friend is an RN that is administering the Covid-19 vaccine, was talking to company representatives and told the caller that she needed to call company to make a report and see if anyone else has experienced the same adverse events. Urinary retention came back in Apr2021 following her second dose of the Covid-19 vaccine on 31Mar2021. She can really go to the bathroom, but she is still feeling the abdominal and pelvic pressure as well as some burning and pain. Her symptoms are improving but not enough. It feels like she always has a full bladder still. She tore or messed up a ligament in her hand and she has been going to occupational therapy. She can't seem to be able to handle a pain level like she used to. It seems like pain is triggering her feelings of nausea and dizziness. Her body is not doing things well right now. The day before, of, and after getting the Covid-19 vaccine, someone suggested taking electrolytes before the second dose of the Covid-19 vaccine, so she drank Powerade. She was expecting the symptoms following the second dose of the Covid-19 vaccine to be a lot worse and they were a walk in the park in comparison. She had a mild headache the first day, 31Mar2021. She woke up in the morning of 01Apr2021 and her headache was gone. Following the second dose of the Covid-19 vaccine, she had severe arm pain. It felt like she was walking around with someone constantly punching her. She was moving her arm all around trying to get it to stop hurting. She saw blood and blood clots in her urine for over 24 hours. The blood and clots were lessening over

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the 24-hour time period. She probably saw in a 2-hour period at least 60 clots about the size of a quarter to a half dollar. The pain was excruciating. She was taking Phenazopyridine but is still feeling a sense of urgency, burning, and sometimes pain during urination. Her doctor did give her a prescription for phenazopyridine, but it was cheaper for her to buy over the counter and take the same dosage. She has been taking generic Macrobid, Nitrofurantoin Mono, 100 mg twice daily. It was dispensed in a pharmacy bottle. She is seeing a urogynecologist tomorrow, 06May2021. The patient underwent lab tests and procedures which included culture urine: unknown cfu on 26Mar2021 and culture urine: klebsiella pneumoniae, 50,000 to 100,000 cfu on 30Apr2021. The outcome of the event Headache was recovered on 01Apr2021 while of the rest was unknown. No follow-up attempts are possible. No further information is expected. Information on lot number already obtained.; Sender's Comments: Based on the compatible temporal association, there was a reasonable possibility that the vaccination with BNT162B2 played a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1332677	5/20/2021	CA	51	F	4/7/2021	4/30/2021	she had developed a blood clot in her lungs; coughing up blood; This is a spontaneous report from a contactable consumer (patient). A 51-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration (at the age of 51-years-old), administered in Deltoid Right (reported as "right upper arm shoulder") on 07Apr2021 09:45 (Lot Number: EW0150) as 2nd dose, single for COVID-19 immunization. Medical history included eosinophilic granulomatosis with polyangiitis (Churg Strauss syndrome) and asthma. The patient's concomitant medications were not reported. The patient previously received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Right upper arm shoulder on 17Mar2021 (Lot Number: EN6208) as 1st dose, single for COVID-19 immunization. The second dose of the vaccine the patient received on 07Apr2021 and she had a great experience with it and nothing happened. Then on 30Apr2021, patient experienced coughing up blood, which required a visit to the Emergency Room. She was admitted in the hospital on 30Apr2021, and they discovered a clot in her lung she is surprised to find out because she is very healthy individual. She had got out of the hospital yesterday (03May2021) for a blood clot in her lungs where the hospital did a bronchoscopy, they cut it out. The blood clot was big and deep. They did a test to see if the blood clot is from her rare disease which it was not so the doctors have no idea what caused the blood clot. She did her research and the only thing that had changed was she got the vaccine and then she also just switched to a different inhaler for her asthma but she has taken it before. The doctors do not think it is any of the two things. The doctor does not know what caused the blood clot and she saw there has been 35 cases reported of a rare blood clot and according to her findings. She was hospitalized for 3 nights (when discovered a clot in her lung) from 30Apr2021 to 03May2021. The blood clot was removed Sunday 02May2021. She had blood work done prior to the vaccine and her count was excellent. The patient underwent lab tests and procedures which included blood test: her count was excellent prior to the vaccine, blood test: it was not (from her rare disease), bronchoscopy: blood clot, electrocardiogram: well, full

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1334526	5/20/2021	MI	37	M	5/3/2021	5/12/2021	<p>blood count: well, liver function test: well, thyroid function test: it need to be adjusted: all on unspecified dates. The patient reported that, "hospital where my blood drawn, oh actual testing too many to mention, CBC (complete blood count), ECG (electrocardiogram), Liver function lot of different test. Everything was well except my thyroid it need to be adjusted am taking care of it. It was Saturday prior to the second shot maybe I don't know."</p> <p>Therapeutic measures were taken as a result of the events which included bronchoscopy, they cut it out, they did a catheter in upper part of left lung. The outcome of the events was recovered on 02May2021. There were no prior vaccinations (within 4 weeks). No adverse events following prior vaccinations.</p> <p>(1) Wed, May 12th - I woke up around 7:30am with pain in my right side near the rib cage/beneath my chest. The pain was also in my upper right shoulder and trap/neck area. (2) Sat, May 15th - in the evening time around 7:30pm I was riding passenger seat in a car and started having shortness of breath (constricted breathing) and immense pain in my right side near my rib cage/beneath my chest. The pain felt like the worst muscle spasm I've ever encountered. The pain was gripping and persistent. It was hard to breathe and even harder to utter out a word or two. This intense pain last for 45 minutes until I got home. I admitted myself into the ER around 8:30pm. Around 7 hours later and after a series of multiple tests I was told I have PE-blood clot in my lungs. (3) Sun, May 16th - I was admitted in the hospital around 5:30am. (4) Tue, May 17th - I was discharged around 4:30pm</p>

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1332784	5/20/2021	CO	66	M	3/29/2021	4/1/2021	<p>Blood clot in leg; This is a spontaneous report from a contactable consumer (patient). A 66 year old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 2 via an unspecified route of administration on 29Mar2021 at 12:45 (Batch/Lot Number: EN6198) as a single dose for COVID-19 immunisation. Medical history included COVID-19 from Nov2020 to an unknown date: came down with COVID virus in November and it felt like mild flu symptoms. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 1 via an unspecified route of administration on 08Mar2021 at 12:45 (Batch/Lot Number: EN6198) as a single dose in the right shoulder for COVID-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not have any adverse events following prior vaccinations. The patient's medical history included: father had a blood clot in his 50s. Concomitant medication (other medications taken in two weeks) were none. On an unspecified date in Apr2021, the patient experienced blood clot in leg. Relevant test included: ultrasound on 15Apr2021 showed blood clot. The clinical course was as follows: On 04Apr2021 or 05Apr2021 he started to notice a problem on his right leg. He went to see the doctor and it was determined he has a vascular problem. This problem got worse and ended up in the emergency room and was informed he had a blood clot in his leg. The clot started down by his ankle and had moved up towards half way to knee. Then moved up higher. He went to the emergency room on 15Apr2021 and was diagnosed with a blood clot with an ultrasound scan that was done. He was then prescribed a blood thinner. He was informed it is a superficial thrombosis. The patient clarified the problem he started to notice with his right leg as it was like a bump, and sore. He was not sure what it was. He thought at first he may have banged his leg. Then he noticed it was sore and getting higher. He went to see his physician who referred him to a vascular surgeon. It took a while to get in to be seen by the vascular surgeon because so busy. A few days after that he went to the hospital, the emergency room because he was not getting better. That is when he found out he had a blood clot. Treatment for the blood clot in leg included, patient was prescribed</p>



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1332963	5/20/2021	IL	52	F	4/1/2021		<p>rivaroxaban (XARELTO) 10mg once a day. The patient confirmed the blood clot was getting better. The outcome of the event blood clot was recovering. No follow-up attempts are needed. No further information is expected.</p> <p>COVID SHOULDER; WHITE BLOOD CELLS ELEVATED; This spontaneous report received from a patient concerned a 52 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included high cholesterol, and other pre-existing medical conditions included the patient had no allergies to medication, food or other products. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 206A21A, and expiry: UNKNOWN) dose was not reported, administered on 12-APR-2021 00:40 for prophylactic vaccination. Concomitant medications included ethinylestradiol/norethisterone acetate for drug used for unknown indication, rosuvastatin for drug used for unknown indication, and venlafaxine hydrochloride for drug used for unknown indication. On APR-2021, the subject experienced white blood cells elevated. Laboratory data included: Blood test (NR: not provided) White blood cells elevated, Diagnostic ultrasound (NR: not provided) Negative for blood clots, and X-ray (NR: not provided) Negative for bone abnormalities. On 25-APR-2021, the subject experienced covid shoulder. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from covid shoulder, and white blood cells elevated. This report was non-serious.; Sender's Comments: V0: Medical Assessment comment not required per standard procedure as the case is assessed as non-serious.</p>

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1332799	5/20/2021	KY		F	1/1/2021	2/6/2021	some problem with her left leg and her left arm; stroke; This is a spontaneous report from a contactable consumer (patient herself). A 72-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration on an unspecified date in Jan2021 (Batch/Lot number was not reported) as the 1st dose, single for COVID-19 immunization. The patient got her vaccine at the hospital. Relevant medical history included arthritis and had half of thyroid (not clarified further); both from an unknown date and unknown if ongoing. Concomitant medications included levothyroxine sodium (SYNTHROID) taken for an unspecified indication and tramadol taken for pain when she had arthritis; both start and stop date were not reported. The patient had her shots in Jan2021 and had been visiting her doctor's place since then. On 06Feb2021, the patient had a stroke. On an unspecified date, the patient had some problem with her left leg and her left arm, which she thought had improved. The patient underwent lab tests and procedures, which included brain scanning and magnetic resonance imaging (MRI's), both with unknown results on an unspecified date in 2021. Therapeutic measures were taken as a result of stroke, which included a clot buster medicine. The patient was recovering from the event "some problem with her left leg and her left arm," while the outcome of the event "stroke" was unknown. Information on the batch/lot number has been requested.

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1332800	5/20/2021	GA		U			large saddle blood clot in the patient's lungs; putting a strain on the patient's heart; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number and expiry date unknown), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunization. Medical history included blood clot from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. It was reported that on an unspecified date, 20 days after receiving the first dose of the COVID vaccine, the patient admitted in the hospital with a large saddle blood clot in the patient's lungs putting a strain on the patient's heart. The patient stated that there should be more warnings for people that have had previous blood clots. The patient stated that he/she could have died. The outcome of the events was unknown. Information about lot/batch number has been requested.

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1332836	5/20/2021	MD	59	M	4/16/2021	5/2/2021	blood clots in both lungs along with lung inflammation; blood clots in both lungs along with lung inflammation; This is a spontaneous report from a contactable consumer (patient). A 59-year-old male patient received the second dose (reported as dose 1) of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: ER2613), via an unspecified route of administration, administered in the right arm on 16Apr2021 at 08:45 AM as single dose for COVID-19 immunisation. Medical history included cholestoral, blood pressure, indigestion. No known allergies. No covid prior vaccination. Concomitant medications included losartan, atorvastatin, omeprazole. The patient previously took the first dose (reported as dose 2) of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: ER2613), via an unspecified route of administration, administered in the left arm on 22Mar2021 at 08:45 AM as single dose for COVID-19 immunization. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 02May2021 at 16:00, patient experienced blood clots in both lungs along with lung inflammation. Events caused a call to the emergency responders and a 2-day hospital stay from 02May2021 to 04May2021. Events resulted in Emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event). Lab data included covid test on 02May2021 was negative (Nasal swab). Lots treatment received for the events. The outcome of events was resolved with sequel on unspecified date.

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1332964	5/20/2021	NJ	55	F	4/16/2021		<p>BLOOD CLOTS GALORE; FEELING SICK (NOT FEELING WELL); FEELING OF WOULD NOT MAKE IT AND SAYING GOODBYE TOMORROW; MUSCLE ACHES; TIRED; LETHARGIC; BODY ACHES; This spontaneous report received from a consumer concerned a 55 year old female of unknown race and ethnicity. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, expiry date: UNKNOWN) dose was not reported, 1 total, administered on 16-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 16-APR-2021 after vaccination, the patient got tired, lethargic, was not "feeling well" and body and muscles started to ache and progressed further. The consumer reported that on 08-MAY-2021, the patient was feeling sick and drove herself into the hospital. On 11-MAY-2021, the patient had blood clots galore and was on dialysis. On 12-MAY-2021, the consumer had one note stating the patient was holding steady and during night the consumer stated there's no change in patient's condition. On 13-MAY-2021, patient was going through with computerised tomography scan and told later that patient would not make it and would be saying goodbye tomorrow. On 13-MAY-2021, Laboratory data included: CT scan (NR: not provided) unknown. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clots galore, and the outcome of tired, lethargic, body aches, feeling sick (not feeling well) and muscle aches was not reported. This report was serious (Other Medically Important Condition).;</p> <p>Sender's Comments: V0. 20210529809 - Covid-19 vaccine ad26.cov2.s- blood clots galore. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1332727	5/20/2021	NC	62	F	3/10/2021	3/1/2021	<p>This is a spontaneous report received from a contactable nurse (patient) via a Pfizer-sponsored program. A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6206), via an unspecified route of administration in the right arm, on 10Mar2021, as 1st dose, single, for COVID-19 immunisation. Medical history included ongoing fibromyalgia (diagnosed in 1996), ongoing allergies from 1981, ongoing food allergies and chemical allergies, ongoing allergy to alcohol, ongoing hypothyroidism from 2012, ongoing pre-diabetic from 2012, Lyme disease for 11 years before being correctly diagnosed and treated, concussion in Sep2019, and post concussion syndrome in Sep2019. The patient previously took nalbuphine hydrochloride (NUBAIN) in 1981 and experienced anaphylaxis; and paracetamol (TYLENOL) and was very sensitive, had rash and high blood pressure. Within the first 15 to 20 minutes following the administration of the first dose of the Covid-19 vaccine, on 10Mar2021, the patient's face and ears got very red, flushed, and itchy. The patient reported that she is allergic to alcohol and thought maybe it was the glycol in the COVID-19 vaccine that caused the reaction. She reported that she has had glycol before and has never reacted quite like that. The flushing, redness, and itchiness of her face and ears subsided within an hour and were gone by 4 hours. Her allergist instructed her to take 2 Zyrtec before getting the second dose of the Covid-19 vaccine. After her face and ears became flushed, red, and itchy, she ended up having a really bad headache that continued until the next day. Her headache was severe for about 12 hours and continued for a total of a day and a half. She stated that her headache was more like a migraine during the 12 hours when it was severe. It felt like a migraine, but worse. On 10Mar2021, the patient reported that she experienced flu-like symptoms like being nauseous, had dizziness, achiness all over, and was not feeling well, her post-concussion syndrome was triggered and had more headaches, dizziness, nausea. She reported that things have been going awry in her body since she had the COVID-19 vaccine. She reported that the increase in headaches seemed to have improved, but the nausea and dizziness have in some ways improved and then some days it feels like "here we go again" when it hits. About a week after she received the first dose of the</p>

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Covid-19 vaccine, in Mar2021, the patient noticed a change in her urination. It wasn't severe or anything at that point, she just felt like she was not able to release the urine (urine retention). She thought to increase her intake to see if it would help her urinate and it didn't seem to help much. She received a prescription on 26Mar2021, and during that week, she noticed that she was having more issues with some burning during urination and was developing pelvic pain and pressure. The patient stated that the scent and color of her urine looked fine. She reported that the frequency started to increase with not much urine coming out. When she finished her antibiotics about 7 days later, the urine retention had really improved and went away at the end of March. In the morning of 26Mar2021, when the patient woke up, she had blood in her urine and clots. The clots were about the size of a pea and a couple were about the size of a dime. The blood and blood clots in her urine were what made her go to the doctor. She reported she has never had blood in her urine that she remembers. She was put on Macrobid for 5 days. She reported that Macrobid wasn't relieving enough of her symptoms and her provider ended up adding a couple more days. The patient reported feeling more worn out in Mar2021, since she received the first dose of the COVID-19 vaccine. This did not improve and some days it was worse. The patient did not have the energy level and stamina that she used to (Mar2021). She reported that whether it's combined with the retriggering of her post-concussion syndrome, it is significant for her life. She was also not eating well and had lost some weight (Mar2021). She reported that her appetite is improving but it is still not normal for her. She mentioned it was harder for her to want to eat something because of feeling nauseated. The patient assessed the events "face and ears became very flushed, red, and itchy", headache, "headache was more like a migraine/felt like a migraine, but worse", "post concussion syndrome was retriggered", "blood in her urine and clots", "not eating well and had lost some weight" and "feeling more worn out" as serious (medically significant). The patient recovered from "face and ears became very flushed, red, and itchy" and "she is allergic to alcohol and thought maybe it was the glycol in the COVID-19 vaccine that caused the reaction" on 10Mar2021; headache, "headache was more like a

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migraine/felt like a migraine, but worse", "she was not able to release the urine (urine retention)", "blood in her urine and clots", "flu like symptoms", dizziness, "achiness all over", "pelvic pain and pressure", and "some burning during urination" in Mar2021; and was recovering from "not eating well and had lost some weight". The outcome of the remaining events was unknown. The patient assessed the causality of events headache, flu like symptoms, nausea, "face and ears became very flushed, red, and itchy", dizziness, "post concussion syndrome was retriggered", and "not eating well and had lost some weight" as related to BNT162B2.; Sender's Comments: Based on the information in the case report and a plausible temporal association, A possible causal relationship between urinary retention, hemorrhage urinary tract and suspect drug BNT162B2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.



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1334818	5/20/2021	MD	78	M	2/21/2021	2/27/2021	<p>Blood Clot Left Lung; Has not received 2nd dose; ow 90's and high 50s oxygen levels; Feeling bad; This spontaneous case was reported by a consumer and describes the occurrence of PULMONARY EMBOLISM (Blood Clot Left Lung) in a 78-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was provided by the reporter. The patient's past medical history included Chronic kidney disease, Thrombus and Cancer. Concomitant products included SODIUM BICARBONATE (SODIUM BICARB.PED), HYDRALAZINE, Folic Acid, SEVELAMER CARBONATE (RENVELA), AMLODIPINE BESILATE (AMLODIPINE (ALS BESILAT) SANDOZ), FUROSEMIDE, POTASSIUM CHLORIDE (LASIX + K), PRAVASTATIN and MONTELUKAST for an unknown indication. On 21-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 27-Feb-2021, the patient experienced PULMONARY EMBOLISM (Blood Clot Left Lung) (seriousness criteria hospitalization and medically significant), OXYGEN SATURATION ABNORMAL (ow 90's and high 50s oxygen levels) and FEELING ABNORMAL (Feeling bad). On an unknown date, the patient experienced PRODUCT DOSE OMISSION ISSUE (Has not received 2nd dose). At the time of the report, PULMONARY EMBOLISM (Blood Clot Left Lung), OXYGEN SATURATION ABNORMAL (ow 90's and high 50s oxygen levels), FEELING ABNORMAL (Feeling bad) and PRODUCT DOSE OMISSION ISSUE (Has not received 2nd dose) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment with warfarin to treat the blood clot as provided by the patient. Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded. This case was linked to MOD21-087825, US-MODERNATX, INC.-MOD-2021-114702 (E2B Linked Report).; Sender's Comments: Based on current available information and the temporal</p>

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							association between product use and the start date of the events a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-114702:Case for husband
1334551	5/20/2021	NH	67	F	3/6/2021	5/18/2021	I was going in for a heart ablation on 5/20/2021, had a CT scan on 5/18/21 and a blood clot was found in my heart. I am a pharmacy Technician and they wanted me to stay on eliquis and added plavix to that to help dissolve clot. I spoke to the pharmacist as I had concerns about taking both and in speaking with him he asked if I had had my covid shot, I said I had, he asked which one and told him the moderna. He then stated his brother had the moderna and developed a blood clot in his lung two wks after. So I thought I should report this, I was very surprised that I had a clot as I faithfully take my eliquis daily and never miss a dose. We don't know how long this clot has been in my heart so there is no way of knowing for sure. But I has noticed in April 2021, a heaviness in my chest, and just assumed it was the Afib.
1332801	5/20/2021			M			blood clots in his nose; White Spots on the Palm of Hand; allergic reaction; This is a spontaneous report from a contactable consumer (patient). A male patient of unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as 1st single dose for covid-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient was having allergic reaction he did have blood clots in his nose that did go after some days but now he did have white spots on the palms of his hands and he wanted to know if it was like common allergic reaction. Outcome of the events was unknown. No follow-up attempts are needed; information about lot/batch number cannot be obtained.

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1334947	5/20/2021	WA	48	F	5/7/2021	5/10/2021	<p>huge blood clot in her neck and a huge one in her left arm; her arm had swollen up at the elbow and was red, painful and warm to the touch; her arm had swollen up at the elbow and was red, painful and warm to the touch; her arm had swollen up at the elbow; her arm had swollen up at the elbow and was red, painful and warm to the touch; her arm had swollen up at the elbow; This is a spontaneous report from a contactable consumer (patient). A 48-year-old female patient received the second dose bnt162b2 (BNT162B2, Solution for injection, Lot Number: ER2613), via an unspecified route of administration, administered in Arm Left on 07May2021 (received at 48-years-old) as 2ND DOSE, SINGLE for COVID-19 immunisation. Medical history included fibromyalgia, colon cancer/postchemo from 2018, APS (antiphospholipid syndrome), arthritis and allergy to sulfa drugs. The patient was not diagnosed with COVID-19 prior to vaccination and was not tested for COVID-19 post vaccination. She was not pregnant. Concomitant medication(s) included pregabalin (LYRICA) taken for an unspecified indication, start and stop date were not reported; omeprazole (OMEPRAZOLE) taken for an unspecified indication, start and stop date were not reported; oxybutynin (OXYBUTYNIN) taken for an unspecified indication, start and stop date were not reported; ergocalciferol (VIT D) taken for an unspecified indication, start and stop date were not reported; cyanocobalamin (VIT B12) taken for an unspecified indication, start and stop date were not reported. Past drug history included known allergies to naproxen and oxycodone. The patient previously received the first dose of bnt162b2 (BNT162B2, Lot Number: EW0161), administered in Arm Right on 16Apr2021 12:00 for COVID-19 immunisation. The patient got her second dose of the Pfizer vaccine on Friday, 07May2021. By Monday evening, 10May2021, her arm had swollen up at the elbow and was red, painful and warm to the touch. After appointment she had on Tuesday, 11May2021, she went to the ER (emergency room) as it had gotten worse and confirmed she has a huge blood clot in her neck and a huge one in her left arm. She was put on permanent blood thinners after following up with my PCP (primary care physician). The adverse events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Life</p>

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threatening illness (immediate risk of death from the event). As corrective treatment, the patient received Lovenox, Warfarin, Zarelto. Outcome of the events was recovered with sequelae on an unspecified date in May2021. The adverse events were assessed as life-threatening.

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1334787	5/20/2021			F			<p>THROMBOTIC THROMBOCYTOPENIC PURPURA; ALTERED MENTAL STATUS; ACUTE KIDNEY INJURY; LIVER FUNCTION TEST ABNORMAL; EMESIS; This spontaneous report was received from literature dated 2021 May 02; 11-2. This report concerned a 62 year old female. The patient's height and weight were not reported. The patient's concurrent conditions included hypertension, hyperlipidemia, hypothyroidism and gastroesophageal reflux disease. On an unspecified date, the patient received COVID-19 vaccine Ad26.CoV2.S (suspension for injection, intramuscular, batch number unknown), dose, vaccination date and site of administration not reported, for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date (37 days post vaccination), the patient experienced thrombotic thrombocytopenic purpura (TTP), altered mental status, acute kidney injury, liver function test abnormal, and emesis, and was hospitalized (date unspecified). It was reported by emergency medical services that the patient was found altered in her bathroom combative and covered in faeces. The patient was unable to converse or provide any history. The patient's family reported she was last seen normal around 21:00 hours on an unspecified date and around midnight they heard a loud sound upstairs and went up to find the patient's room covered in emesis, faeces on the floor and she had torn her room apart and ripped things off the walls. It was reported that before going upstairs for bed she was in her normal state of good health and had eaten dinner with her family. The patient appeared altered, unwell and was spontaneously moving all extremities. Physical examination revealed temperature of 36.6 degrees Celsius, blood pressure of 154/131 mmHg, a pulse rate of 87 beats per minute, a respiratory rate of 32 breaths per minute, and pulse oximetry of 96% on room air. There were no signs of trauma; her pupils were 3 mm, equal and reactive. She had a full passive range of motion of her neck, normal heart sounds, tachypnoea with a few scattered wheezes, Glasgow Coma Scale of 12 and skin revealed scattered petechiae. Laboratory workup revealed the following abnormal results: elevated white blood cell count 19.25 k/mcL, absolute neutrophils 15.59 k/mcL, lactate 4 mmol/L, procalcitonin 13.21 ng/mL, and C-reactive</p>

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protein 6.4 mg/dL. Low fibrinogen 120 mg/dL and platelets 29 k/mL. Urinalysis revealed large haemoglobin and 11 - 25 red blood cells per high powered field. Other tests that included COVID-19 testing, drug screen, haptoglobin, prothrombin time and international normalized ratio were all normal. A complete metabolic was not able to be collected in the emergency department (ED) due to persistently haemolyzed specimens even from the central venous catheter. Computerized tomography (CT) of the brain and cervical spine revealed no acute abnormalities. Chest and pelvis x-ray were normal. The patient had an episode of emesis and there was a concern for aspiration. She was intubated for airway protection and admitted to the medical intensive care unit (ICU). During admission, haematology, neurology and infectious disease were consulted. She was found in the ICU to have acute kidney injury with a blood urea nitrogen of 26 mg/dL and creatinine of 2.19 mg/dL (NR not provided). On an unspecified date, (day 1 of the hospital) haptoglobin became low at below 10 mg/dL. On hospital day 2, her platelet count was reported as "11,000 k/uL", blood urea (BUN) was 66 mg/dL and creatinine was 6 mg/dL. The patient's liver function tests were abnormal with aspartate aminotransferase (AST) of 982 U/L and alanine aminotransferase (ALT) of 231 U/L. Her fibrinogen increased to 619 mg/dL, lactate hydrogenase was greater than 2500 U/L, and her high-sensitivity troponin was found to be 2408 ng/L. Haemoglobin had also dropped from 14 g/dL upon admission to 8.2 g/dL on day 2 of her hospitalisation (NR not provided for all). Her anti-platelet factor 4 test, double-stranded DNA antibody test, and "complement component 3" were normal. Direct coombs was negative and the patient was platelet factor 4 negative. "Compliment component 4" was slightly low at 12 mg/dL and "ADAMTS13" activity was less than 12%. Once in the medical ICU, plasma exchange and high dose steroids were initiated due to worsening platelets. When her haptoglobin and "ADAMTS13" results were abnormal, the diagnosis of TTP was confirmed. While hospitalized the patient required hemodialysis, packed red blood cells for anaemia, plasma exchange, and 10,000 mg of methylprednisolone daily. The action taken with COVID-19 vaccine Ad26.CoV2.S was not applicable. The outcomes of the

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thrombotic thrombocytopenic purpura, liver function test abnormal, emesis and acute kidney injury were not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: This report from the literature describes a 62-year-old female who developed thrombotic thrombocytopenic purpura (TTP) 37 days after receiving the Janssen COVID-19 vaccine. She suddenly developed emesis and severe mental status changes; physical examination was significant for a blood pressure of 154/31, tachypnea, and scattered petechiae. Initial laboratory evaluation was significant for a platelet count of 29 k/mcl, hemoglobinuria, a BUN of 26 mg/dl and creatinine of 2.19 mg/dl. Computerized tomography of the brain revealed no abnormalities. She was intubated for airway protection and admitted to the intensive care unit. Follow-up labs included: haptoglobin low at 10 mg/dl, BUN 66 mg/dl, creatinine 6 mg/dl, elevated hepatic enzymes, anti-platelet factor 4 negative, and ADAMTS13 activity less than 12% (abnormal). Based on the low haptoglobin and ADAMTS13 activity level, a diagnosis of TTP was made. She underwent hemodialysis, plasma exchange, red blood cell transfusions, and daily methylprednisolone administration. The outcome was not reported. Thrombotic thrombocytopenic purpura is not a labeled event for the Janssen COVID-19 vaccine; however, based on the temporal relationship of the events to vaccination, a relationship with the vaccine cannot be ruled out. The relationship is considered indeterminate

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1334771	5/20/2021	MI	70	M	5/17/2021		BLOOD CLOT IN LEG; SWEATING; This spontaneous report received from a consumer concerned a 70 year old male of unspecified ethnicity. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date in 2021, the patient experienced sweating which lasted about one day. It was stated that patient received vaccine around 18-APR-2021. It was also reported that actual date of vaccination may have been prior to 18-APR-2021 but definitely in April. On 17-MAY-2021, patient visited hospital and got diagnosed with blood clot in leg. The patient was on unspecified medications to dissolve clots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from sweating on 2021, and had not recovered from blood clot in leg. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0- 20210534558-Covid 19 Vaccine- This case concerns a 70 yr old male. Blood clot in leg, Sweating. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).



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1334759	5/20/2021	TX		M		5/1/2021	<p>BLOOD CLOTS IN THE LEFT LUNG; SHORT IN BREATH/ BARELY BREATHING; MOVEMENT DISORDER (COULD NOT GET OUT OF THE CAR); CONFUSED; ZERO APPETITE; WEAKNESS AND ZERO ENERGY; This spontaneous report received from a parent (mother) concerned a 49 year old male. Initial information was processed with additional information received on 17-MAY-2021. The patient's weight was 200 pounds, and height was not reported. The patient's past medical history included asthma. He did not experience something like that for thirty years. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) frequency 1 total, dose was not reported, administered on 02-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. Patient got the Janssen Covid 19 vaccine on 02-APR-2021, nothing happened no side effects at all ,he didn't experience anything abnormal. On 06-MAY-2021 (four weeks later),patient drove for 22 miles, he didn't get enough drinks, short in breath, he could not get out of the car (coded as movement disorder), he was in the car since 11.30 am in the morning, remained in the car till 12 PM at night, leaning against the kitchen sink, he was barely breathing. The reporter called the ambulance, they came and transported the patient to the medical center, they admitted him on 07-MAY-2021, and they did tests, and x-rays, they confirmed that he had blood clots in the left lung. The hospital was full, they couldn't find a room for patient then they admitted him in to a room on second floor. The patient had no medical issues or problem before the vaccine The patient got out of the hospital on 12-MAY-2021 (Wednesday). Patient was hospitalized for 6 days. During follow-up, reporter mentioned that on an unspecified date in MAY-2021, her son was weak and confused ,zero appetite ,zero energy, he was not the same person he was two weeks ago, he was going to take medications indefinitely its like a life sentence for him, and she also did not have an email address. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from movement disorder (could not get out of the car), had not recovered from blood clots in the left lung, and short in breath/ barely breathing, and the outcome of weakness and zero</p>

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energy, confused and zero appetite was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0.20210531244-covid-19 vaccine ad26.cov2.s -blood clots in the left lung, and short in breath ,weakness and zero energy, confused and zero appetite. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1334756	5/20/2021	NY	56	F	3/25/2021		POSSIBLE CVA; HIGH BLOOD PRESSURE; HEADACHE; POTENTIAL BLOOD CLOT; STOMACH PAIN; LEG PAIN; This spontaneous report received from a patient concerned a 56 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included polycythemia, and Meniere's disease, and other pre-existing medical conditions included no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805022, expiry: 25-MAY-2021) dose was not reported,1 total administered on 10-MAR-2021 to right arm for prophylactic vaccination. No concomitant medications were reported. On 10-MAR-2021, the patient had no side effects right after the vaccination. On 25-MAR-2021, the patient felt a really bad leg pain in left leg behind the knee which had lasted for five days until 31-MAR-2021 or 01-APR-2021. On 31-MAR-2021, the patient had very bad stomach pain and felt if somebody was stabbing her until 11-APR-2021. On 23-APR-2021, the patient had pain in head, it woke the patient up in her sleep; the patient had no control over the right side of body and was not able to see, walk or talk. The patient did not know how long it lasted. On 24-APR-2021, the patient was lying in bed and felt that somebody taken the bottom of the bed and flipped her out; she also had blurred vision. On 26-APR-2021, patient went to the hospital. The patient underwent a CT (computed tomography) scan and found no bleeding in brain but a possible CVA (cerebrovascular accident-stroke). The patient was asked to admit in the hospital but the patient wanted to go back home. The patient's blood pressure was really high although she had a perfect blood pressure and never took medication before. The patient was scared to take the pill and left the hospital. On an unspecified date, after coming back home, the patient suddenly lost control over left side of the body while taking bath and had blurred vision. The patient was taken to the hospital and found no bleeding in her brain. On an unspecified date in MAY-2021, a week prior to this report, the patient undergone phlebotomy and had to draw 500 ml of blood because patient had polycythemia and her blood was super thick. The patient also had a CT (computed tomography) scan and the results were unknown. On 13-May-2021, the patient had MRI (magnetic resonance imaging) and all

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were normal. On 14-MAY-2021, patient would be taking CT (computed tomography) angiography for finding out blood clot in brain. The patient was concerned about all events and was scared to find out if there would be blood clots in her brain. The PCP (primary care physician) of two hospitals she visited told her that she should not have taken the vaccine shot because of her polycythemia. On 14-MAY-2021, the patient's blood pressure was 175/112 (unit unspecified) and in the morning it was 156/117(unit unspecified). The patient was started with unspecified blood pressure medication and also acetylsalicylic acid (Aspirin) to thin her blood. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from stomach pain on 11-APR-2021, and leg pain on 31-MAR-2021, had not recovered from high blood pressure, and the outcome of headache, possible cva and potential blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210530382-COVID-19 VACCINE AD26.COV2.S- Cerebrovascular accident, Thrombosis, Hypertension. This event(s) is considered not related. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY

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1334745	5/20/2021	NC	42	F		4/1/2021	BODY ACHES; CHILLS; FEVER; DEEP VEIN THROMBOSIS; This spontaneous report received from a patient concerned a 42 year old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 043A21A, and expiry: 21-JUN-2021) 1 total, dose was not reported, administered on 10-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 10-APR-2021, the patient had body aches, chills and fever. In APR-2021 (a week after vaccination), the patient experienced right leg pain and felt heavy and visited her primary care physician who recommended ultrasound scan of the leg. On 10-MAY-2021, the patient's ultrasound scan revealed deep vein thrombosis and she was treated with unspecified blood thinners. The patient was also put on Xarelto (rivaroxaban) therapy 15 milligram for 21 days. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from body aches, chills, and fever on 11-APR-2021, and the outcome of deep vein thrombosis was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0;20210520235-covid-19 vaccine ad26.cov2.s -Deep vein thrombosis. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.
1334635	5/20/2021	FL	55	F	4/8/2021	4/8/2021	15 mins after getting the 2nd shot, I had a burning in my throat & lips. Also my ears clotted, vision got blurry& my face got numb. A pain on my left arm & my whole right side of face swollen. After being hospitalized the Dr. said I got Bell's palsy
1334558	5/20/2021	IA	68	M	4/27/2021	5/13/2021	had redness and tightening of the legs, went to ER, found very small blood clot in right calf. Gave rx blood thinner elouis along with current plavix and asa

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1334555	5/20/2021	TX	40	M	4/8/2021	4/8/2021	I experienced ringing in my left ear , non stop since the J&J vaccine about 5 minutes. I also have ringing in my right ear also have had a pressure headache since the moment of vaccine. I seen doctors, had ears cleaned, hearing tests, have seen an ENT specialist and also have had an MRI. MRI was to make sure there was no tumors in my ears, my results were negative. Lab work done for blood clots which were also negative. Today I still continue to experience these symptoms.
1335964	5/20/2021	MI	45	M	3/1/2021		pain in his leg that felt like a clot; pain in his leg; This is a spontaneous report from a contactable consumer, the patient. A 45-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the right arm on Mar2021 at 11:15 (at the age of 45-years-old) as a single dose for COVID-19 immunization. Medical history included ongoing venous insufficiency since 2019. Concomitant medications were none. The patient did not receive any other vaccinations within 4 weeks of the vaccine. The patient stated that he received his first dose on 30Mar2021 or 31Mar2021. On an unspecified date, the next day after the first vaccination, the patient experienced pain in his leg that felt like a clot for the first week and a half to two weeks. Then, the patient got a little bit better, even though he had almost gone to the emergency room, but he got better after a couple weeks. The clinical outcome of "pain in his leg that felt like a clot " was resolved on Apr2021. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021507016 Same patient/drug, different dose/event

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1330065	5/19/2021	MD	68	M	4/13/2021	4/23/2021	I had the Moderna COVID-19 vaccine shot one on March 16, 2021 and shot two April 13, 2021. I am not sure when the headaches started, but I estimated about two weeks, or about April 9, 2021. The headache on April 23, 2021 was bad enough that my wife called our PCP. My PCP asked me a lot of questions and said for me to get a blood draw and an MRI without contrast STAT. The report dated April 23, 2021 was ?a Large 1.5 cm thick right frontoparietal subdural hematoma with transfalcine right to left herniation measuring 1.0 cm. Tiny parafalcine and left frontoparietal subdural hematomas. Given recent vaccination, consider contrast enhanced MRV to rule out venous sinus thrombosis.? I was ordered to go to the ER where I was admitted the same day. A neurosurgery team performed an operation on April 27 to drain the internal bleeding that had occurred (possibly for over a month). As I was about to be released on April 28, 2021, my heart monitor recorded a ventricular tachycardia (vtac); I exhibited 17 beats of vtac where no Potassium and magnesium levels were present. A cardiology team then got involved. An EKG and ultrasound were taken April 29, 2021. Since there were no recurring issues, I was released on April 29, 2021. I do not know if the spontaneous subdural hematoma or the ventricular tachycardia could have been an adverse reaction to the COVID-19 vaccine, but I thought I should report it.

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1329659	5/19/2021	LA	47	F	3/19/2021		<p>LEFT ANKLE STARTED SWELLING, LEFT ANKLE SWELLING INCREASED AND REACHED LEFT THIGH, WENT ULTRASOUND WHICH RESULT BLOOD CLOT; This spontaneous report received from a patient concerned a 47 year old female. The patient's weight was 95.70 kilogram, and height was 167 centimeter. The patient's concurrent condition included Cholesterol. Patient was non alcohol user and non smoker.. Patient had no known allergies and no history of drug abuse or illicit drug use. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number and expiry date were unknown) dose was not reported, administered on 11-MAR-2021 in right arm for prophylactic vaccination. The batch number was not reported and has been requested. Concomitant medications included pravastatin for cholesterol. Around 19-MAR-2021 (approximately 1 week after the vaccine), the patient experienced left ankle swelling (as per patient, she did not think much of it, and just elevated her leg and applied hot-cold compress). Around 26-Apr-2021 the patient experienced increased left ankle swelling and had reached her left thigh. On 26-April-2021 patient went to the hospital and was hospitalized, was given an ultrasound procedure which result stated that she had blood clot. Patient was given Eliquis right away, while in the hospital. On an unspecified date patient was discharged and upon discharge she was prescribed Eliquis 5 mg for 2 times per day. Patient stated that she will go back to the doctor will be doing another ultrasound. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clot. Patient stated her left leg swelling was not yet completely resolved, but not as worse, whenever she elevates her leg, the pain and swelling gets better, but once she gets up and move around, the swelling starts again. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0:20210529680-covid-19 vaccine ad26.cov2.s ,LEFT ANKLE STARTED SWELLING, LEFT ANKLE SWELLING INCREASED AND REACHED LEFT THIGH, WENT ULTRASOUND WHICH RESULT BLOOD CLOT. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially</p>



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associated with the event(s).

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1329527	5/19/2021			M			<p>Had some blood clot in his urine; This is a spontaneous report received from a contactable consumer. A male patient with age reported as 52 (unknown unit) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number unknown), via unspecified route of administration on unspecified date in 2021 (reported as Monday or Tuesday) as 1st dose, single for COVID-19 immunisation. The patient's medical history included diabetic. The patient had not had COVID in the past. The patient's concomitant medications were not reported. Reporter stated that she had some questions. Her husband and she got the Pfizer shot and they didn't have anything, everything was fine. They had one family member and he was 52 and diabetic (history) and he worked in an area where he was out of range at the time of this report, so they could not talk to him for about like next half an hour. So, this week, he had the Pfizer shot and he was also put on two new medications (unspecified medications) right after that. He woke and he went to his work today and then he called, and he had some blood clot in his urine. The first thing they thought of was the company which they didn't had (further clarification unknown). So, they just need to know that new medication, also he was diabetic (history) and he had been on the same medication forever and there was no problem but the two new medication that he was put on (sentence incomplete). About lot number reporter stated that she did not have all that. They were just concerned, and reporter was kind of like, reporter asked if he should go to emergency room with the blood clot showed up in the urine or could that just be a urinary tract infection (UTI). It was his first COVID shot and he had not had COVID in the past. Reporter further stated, the two new drugs that he started, they just wanted to know if they need to worry about blood clot like if it could from the shot or it could be from the two drugs that he was taking. Reporter further asked if this was something that he should go to the emergency room. Reporter also asked if blood clot was possible due to Pfizer vaccine or it could be a urinary tract infection. She just wanted to know if Pfizer vaccine did cause blood clot like the Johnson and Johnson did (further clarification unknown). About vaccination date of second shot reporter stated in two weeks or something she did not know. The outcome of the event was unknown. Information about the</p>

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1329533	5/19/2021	NY		U			<p>lot/batch number has been requested.</p> <p>Blood clot; This is a spontaneous report from a contactable healthcare professional and a physician. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number/expiration date not reported), via an unspecified route of administration on an unspecified date as unknown, single for COVID-19 immunization. Medical history and concomitant medications were not reported. The reporter had a patient who may have had a possible side effect. It was reported that the patient may be experiencing a blood clot on an unspecified date. The reporter wanted further direction on whether or not an anticoagulant can be given. Anatomical location of blood clot is unknown. The outcome of the event was unknown. Information on the batch/lot number has been requested.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 vaccine can not be excluded for the reported event of blood clot due to temporal relationship. Case will be re-assessed upon the additional information provided. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.</p>

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1329544	5/19/2021	WV		U			<p>Blood Clot; right leg was red &amp; hot; right leg was red &amp; hot; itching; Pain; This is a spontaneous report from a contactable consumer. A 63-year-old patient of an unspecified gender received second dose of BNT162B2 (BNT162B2), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunization. Medical history included covid-19 from 28Mar2021 to an unknown date. The patient's concomitant medications were not reported. The patient experienced blood clot, right leg was red &amp; hot, itching and pain all on unspecified date. On 28Mar2021 I caught covid-19. The staff next at united states penitentiary put me in quarantine until 14Apr2021. They did not do anything for me what so ever while I had covid-19. Shorty after I became better (on my own) I took the exist shot of the vaccine Pfizer. 3 weeks later in the end of this month I took the second vaccine shot. My right leg in my blood vein started burning me up. My right leg was red &amp; hot so I went to commissary to purchase ORAJEL to put my leg to kill the pain and itching. I then put a sick call in to the prison nurse, she came the next day and said you have a blood clot and if it moves to let her know. 3 days later or more she was back in the housing unit and I ask her what she was going to do about my blood clot. She said oh you found have a blood clot you just have the big viens. Outcome of the events was unknown. Information on the lot/batch number has been requested.</p>

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1329555	5/19/2021	WA	33	F	3/31/2021	4/19/2021	blood clot; Also have had neck pain since the first vaccine that will not go away; extreme pain in my left leg; unable to walk; This is a spontaneous report from a contactable consumer (patient) who reported events after first and second dose of the vaccine. This case is for events after the second dose. A 33-year-old female patient (not pregnant) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number was not reported), via an unspecified route of administration in Arm Left on 31Mar2021 at 13:00 (at 33 years) for covid-19 immunization. Medical history included asthma. Concomitant medication included methylphenidate taken for an unspecified indication, start and stop date were not reported. The patient previously took the first dose of the vaccine on 03Mar2021 at 13:00 in Left arm for covid-19 immunization and had neck pain. On 19Apr2021 at 12:00 (also reported as 3 weeks after the final vaccination) the patient experienced suddenly extreme pain in her left leg and was unable to walk on it. Doctors found a superficial blood clot. Also had neck pain since the first vaccine that will not go away. Events required Doctor or other healthcare professional office/clinic visit and treatment (unspecified) was given. The final outcome of all the events was reported as recovering. Information on the batch number has been requested; Sender's Comments: Linked Report(s) : - PFIZER INC-2021523861 same patient/drug, different dose/event

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1329556	5/19/2021	TN	67	F	4/9/2021	4/1/2021	<p>Sciatica with pain going down the back of her leg; This is a spontaneous report from a contactable Nurse (patient). A 68-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: ER8731), an unspecified route of administration, in right arm on 09Apr2021 (at 67 years) at single dose for covid-19 immunisation. Medical history included ongoing rheumatoid arthritis (diagnosed about a year ago; an overlap with rheumatoid arthritis a year ago; she has been in remission from her rheumatoid arthritis and off medication since Aug2020), ongoing hypothyroidism (diagnosed 2 years before in 2019), ongoing osteoarthritis (for years) and ongoing Sjogren's disease (for years). Previously patient took methylprednisolone (MEDROL) that worked before. The patient's concomitant medications were not reported. The patient developed sciatica with pain going down the back of her leg in Apr2021, serious as medically significant and described as follows: patient had the first dose of the vaccine on 09Apr2021 and her symptoms started two weeks later in Apr2021; she went to her internist on 22Apr2021 because she was in such pain. Internist doctor said she had developed sciatica. Patient reported the pain was going down the back of her leg and knee was hurting, it was very painful, her foot was tingling, like when the foot was waking up from being asleep, has had this feeling before when she first got rheumatoid arthritis, stated behind her knee hurt so bad. Patient had a doppler done on an unknown date in 2021, that was negative for blood clots. Patient was put on a methylprednisolone (MEDROL) dose pack but it did not help at all, did nothing and made no difference whatsoever. Final outcome of the event was not recovered. Patient asked if there was any report of the first dose of the covid 19 vaccine that caused a flare or bring a person out of remission for persons with autoimmune disorders. Patient stated she was not sure if this sciatica was due to the vaccine revving up her autoimmune issues or if it was unrelated. Patient delayed the second dose by one week per the doctor's recommendation and second dose was administered on 07May2021 (at 68 years, lot ER8736) in right arm.; Sender's Comments: Based on available information, the contributory role of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: ER8731), to the</p>

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1329575	5/19/2021	KY		M	4/19/2021		<p>reported event sciatica cannot be excluded.</p> <p>Pulmonary emboli and DVT bilateral; Pulmonary emboli and DVT bilateral; This is a spontaneous report from a contactable nurse. A 75-year-old male patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on an unspecified date (Lot Number: EN6204) as single dose for covid-19 immunisation. Medical history included prediabetes, hypertension (HTN), gastroesophageal reflux disease (GERD), atherosclerotic heart disease, ophthalmoplegic migraine, vitamin D deficiency. No known allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had been tested for COVID-19. Concomitant medications included butalbital, paracetamol (BUPAP); atorvastatin; doxepin; esomeprazole sodium (NEXIUM); minocycline; carvedilol; montelukast sodium (SINGULAIR); topiramate (TOPAMAX). The patient previously received first dose of bnt162b2 (lot number: EL9267) via intramuscular on 19Feb2021 for covid-19 immunisation. The patient experienced pulmonary emboli and deep vein thrombosis (DVT) bilateral on 19Apr2021. The events resulted in doctor or other healthcare professional office/clinic visit. The patient was hospitalized for 1 day. And anticoagulation treatment received for the events. The events were reported as serious, serious criteria included life threatening, caused/prolonged hospitalization. The patient underwent lab tests and procedures which included nasal swab: negative on 23Apr2021. The outcome of events was recovering.; Sender's Comments: Based on current information available, the events pulmonary emboli and DVT mostly represented intercurrent condition in this patient with advanced age and relevant medical history, unrelated to Bnt162b2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.</p>
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1329660	5/19/2021	NY	86	M	5/11/2021		<p>BLOOD CLOTS IN URINE; VISUAL BLOOD CLOTS IN PENILE DISCHARGE; DISCOLOURATION OF URINE; BLOOD DISCHARGE AND CLOTS IN STOOL (CLOTS WOULD FALL OUT WHEN WENT FROM SITTING TO STANDING); This spontaneous report received from a consumer concerned an 86 year old white, not Hispanic or Latino male. The patient's weight, height and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: 206A21A, expiry: 23-JUN-2021) frequency one total, dose was not reported, administered on 10-MAY-2021 at 10:00 a.m. in left arm for prophylactic vaccination. No concomitant medications were reported. On 11-MAY-2021, the patient experienced clots in stool which would fall out when patient went from sitting to standing. They are about 3 inches in diameter. He also experienced blood discharge. On 12-MAY-2021, he experienced discoloration of urine with unknown origin. From the night of 13-MAY-2021 to the morning to 14-MAY-2021, he experienced clots in urine and visual of blood clots in penile discharge. The patient was hospitalized on 14-MAY-2021 and the duration of hospitalization was not reported. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from discoloration of urine, blood discharge and clots in stool (clots would fall out when went from sitting to standing), blood clots in urine, and visual blood clots in penile discharge. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210529768 -JANSSEN COVID-19 VACCINE Ad26.COV2.S- Blood in stool, Discoloration of urine, Blood clots in urine and Penile bleeding. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>



<i>VAERS_ID</i>	<i>RECVDATE</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1329661	5/19/2021			U			<p>BLOOD CLOT IN LEFT LEG; This spontaneous report received from a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced blood clot in left leg from the vaccine. Patient stated that never in life had a blood clot before The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot in left leg was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210529802-Covid-19 vaccine ad26.cov2.s-Blood clot in left leg. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1329662	5/19/2021	FL		F			BLOOD CLOTS; This spontaneous report received from a consumer concerned 3 women with unknown race and ethnicity . The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number and expiry was unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date,3 women died from blood clots after getting (Janssen) covid 19 vaccine. It was unknown whether autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0 : 20210530454-COVID-19 VACCINE AD26.COV2.S-Blood clots . This event is considered unassessable. The event has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: BLOOD CLOT

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1329664	5/19/2021			F			<p>BLOOD CLOTS; This spontaneous report received from a patient concerned multiple patients. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose 1 total ,start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 2021, the subject experienced blood clots, and was hospitalized (date unspecified). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clots leading to hospitalization was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: v0-20210530971-covid-19 vaccine ad26.cov2.s-Blood Clots. This event(s) is considered Un assessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

<u>VAERS_ID</u>	<u>RECVD</u>	<u>STATE</u>	<u>AGE_YRS</u>	<u>SEX</u>	<u>VAX_DATE</u>	<u>ONSET_DATE</u>	<u>SYMPTOM_TEXT</u>
1329665	5/19/2021	NJ	62	F	4/1/2021		<p>BLOOD CLOTS IN BOTH LUNGS; LUNG COLLAPSED; PAIN, SORENESS ON RIGHT SIDE; HURT WHEN TOOK A DEEP BREATH; CONCERN CREEP IN (ANXIOUS); HEART RATE FAST; RIGHT HAND SIDE UNDER RIBS FELT SOME PAIN; GENERAL MALAISE, FELT MILDLY ILL; This spontaneous report received from a patient via a company representative concerned a 62 year old female of an unknown ethnicity and race. The patient's height, and weight were not reported. The patient had no heart problems, pulmonary problems and diabetes. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown and expiry date: Unknown) dose was not reported, 1 total administered on 11-APR-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date in APR-2021, about a week later of vaccination patient felt mildly ill and experienced general malaise, soreness on right side, and while patient wasn't struggling to breathe, it hurt when took a deep breath. Patient stated that right-hand side, like under ribs, felt some pain; not a bad pain, not enough to took anything for it but just noticed it. The symptoms seemed minor, and at the time, no reports had linked the Johnson vaccine and blood clots. But the following week, when symptoms began cases started to emerge. The patient hadn't panic by reading the reports, but concern did creep in (anxious) and heart rate fast. The patient had never battled serious illness, certainly nothing related to blood clots. Patient thought, might have a reaction. On 21-APR-2021, patient still wasn't feeling well and decided to make an appointment at the urgent care center. Patient soon learned that she had developed blood clots in both lungs due to the vaccine, physician told one of the lungs also had collapsed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the general malaise, felt mildly ill, pain, soreness on right side, hurt when took a deep breath, concern creep in (anxious), heart rate fast, blood clots in both lungs, lung collapsed and right hand side under ribs felt some pain was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210531023-Covid-19 vaccine ad26.cov2.s.Blood clots</p>

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in both lungs and lung collapsed . These events are considered unassessable. The events has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events.

1329869	5/19/2021	MA	43	F	5/2/2021	5/7/2021	Bloody noses lasting more than one hour with clots
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1329452	5/19/2021	TX	68	F	4/16/2021	4/27/2021	Had headaches and felt nauseated; Had headaches and felt nauseated; Had a blood clot in her lungs; she had tripped and fallen; This is a spontaneous report from a contactable consumer (patient). A 68-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection; Lot Number: EN6206) via an unspecified route of administration on 16Apr2021 at 10:00 ("around 10:00 or so"; at the age of 68-years-old) as a single dose in the left arm for COVID-19 immunisation (the patient was "fearful of the new variants and wanted to be extra protected against those variants.") Medical history included COVID in Dec2020 and uses oxygen (normally used oxygen, but not all the time), from an unspecified date and unspecified if ongoing. Medical history was also reported as none. Relevant family history related to the adverse event was reported as none. Concomitant medications (other products) were reported as none. The patient did not receive prior vaccinations, within 4 weeks prior, or on the same date as the COVID-19 vaccine. The patient previously received iodine contrast dye on an unspecified date for an unspecified indication and experienced anaphylactic shock. The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection; Lot Number: EN6207) via an unspecified route of administration on (at the age of 68-years-old) as a single dose in the left arm for COVID-19 immunisation and experienced did not feel well, felt achy and nauseated (captured in AER: 2021495492). On 27Apr2021 the patient experienced had a blood clot in her lungs and she had tripped and fallen and on unspecified dates the patient experienced had headaches and felt nauseated. The course of events was reported as follows: "After the second dose of the vaccine the patient felt fine, she felt pretty much okay. She attributed that to her having had COVID back in Dec2020 based on her biological knowledge. She ran this idea past a pharmacist that said that generally people might take the first dose of the COVID vaccine and be fine and then be worse on the second dose. But since she had COVID in Dec2020 her second dose of the COVID vaccine was the problem like how people's antibodies were already built up and had that reaction so that is why she was fine. She was walking out of the hospital on 27Apr2021, there were people that had

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crossed in front of them very quickly and her foot had hit the foot of a lady that was pushing a gurney. The patient tripped and fell down and she was taken to the emergency room. In the emergency room, a doctor did some tests and shockingly the doctor said that the patient had a blood clot in her lungs. A physician's assistant told the patient that she needed to have a computerized tomography (CT) scan done. The patient needed to go home to take care of responsibilities there, so she walked out of the hospital. She did not know if she had a blood clot in her lungs or not. Her doctor said that the blood clot in her lungs was based off of two blood values. One was the d-dimer that had a reference value of < 500 and her level was 1,079 and the other blood work was troponin-I but it looked like it should be in the normal range because her level was less than 0.03 and the reference range was 0-0.04, so she would think that she would fall into the normal range. The d-dimer one was kind of scary. She had other tests done. They did a regular complete blood count (CBC) on her, another kind of test and another set of blood values but from looking at the results she was only a little low on a couple of things. They did not do the test with the contrast, but they did take an x-ray of her lung. The technician had found out that she had not had a Computed axial tomography (CAT) scan in a while, since she apparently needed them periodically, and she felt uneasy because that technician was urging her to get a CAT scan. The patient she did not know if these results were relevant or from the COVID vaccine. She did not understand this but when she was looking at the lab notice there was a note that the patient should be monitored for B Type Natriuretic Peptide (b/np) levels. It had the reference range on that one but when she read it, it looked like hers lied within the normal range. After the second dose she just had a headache but did not feel sick, but a week later they were telling her that she had a possible blood clot in her lungs. The patient was concerned at this point because she had no reason as to why she would have a possible blood clot. When she gets exhausted her oxygen drops and sometimes it will without her being exhausted. She was scared to go back to that one hospital. She was thinking about going to another hospital that was 60 miles away. If they would need to keep her overnight, she would need to make arrangements for her animals. She has had

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							headaches, but they may be due to stress. She did not feel sick, other than she had been nauseated. The patient stated that she was not saying that what was reported on report 1 of 2 was due to the Pfizer COVID vaccine but why would they say that she had a blood clot too." The clinical outcomes of the events had a blood clot in her lungs, she had tripped and fallen, had headaches, and felt nauseated were all unknown.
1330193	5/19/2021	UT	63	F	3/6/2021	3/16/2021	I experienced usual side effects, fever and chills but the entire reason is that I have swelling and edema in both feet and ankles enough so to concern doctors. I went to clinic on 03-26-2021 for evaluation. They put me on 3 day steroids. I went back to First med which they put me on a 6 day course of medication of steroids. I then went to my podiatrist, of my right ankle, I was scanned for blood clots but no blood clots were found. My exams only identify swelling and edema. I can only take NSAID'S. I have to get up wait a few hours to move. My ankle swelling and edema nerve decreases and my feet hurt so bad when I apply pressure. I had an MRI done as well and I am very upset that they cant find why I can not walk without pain and swelling. My doctors at this point do not what to do for me and I would like some answers. To this day, I am still having swelling and edema to both of my feet and ankles.
1330199	5/19/2021	IL	29	M	5/6/2021	5/6/2021	Patient with PMH of Aspergers, ADD and obesity brought to ED in status epilepticus. Headaches and nausea/vomiting started day of vaccine and progressively worsened. Was observed to have 2-3 seizures before arriving to ED (possibly over a 2 hour period) on 5/18. Found to have Superior sagittal sinus thrombosis and thrombocytopenia with elevated D-Dimer and PF4 and low fibrinogen. Patient suffered irreverisble brain injury. Decision made with family to withdraw care



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1329666	5/19/2021			U			<p>BLOOD CLOT; This spontaneous report received from a patient concerned a patient of unspecified ethnicity, age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown and expiry: Unknown) dose was not reported, 1 total, administered on 06-APR-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 2021, the patient developed a blood clot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210531990-COVID-19 VACCINE AD26.COV2.S-Blood clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1329410	5/19/2021	FL		F			<p>may have blood clots; since she took the first COVID vaccine, she did have some symptoms. Her face flushed, like she had a temperature and experienced fatigue; since she took the first COVID vaccine, she did have some symptoms. Her face flushed, like she had a temperature and experienced fatigue; since she took the first COVID vaccine, she did have some symptoms. Her face flushed, like she had a temperature and experienced fatigue; This is a spontaneous report from a contactable consumer received from a non-Pfizer sponsored program,, received from a contactable consumer, based on information received by Pfizer. This case is split for a 80 year old patient taking COVID vaccine and experienced face flushed, fatigue. This 80-year-old female patient received first dose of (PFIZER BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Lot number and Expiration date: unknown), dose 1 via an unspecified route of administration on an unspecified date as 1st dose, single for COVID-19 immunization. Medical history included high frequency ablation (vein), breast cancer from 2015 to an unknown date (34 radiation treatment to left breast and no recurrence of the cancer), radiotherapy (breast cancer), atrial fibrillation from Jan2016 to an unknown date, surgery (she had 6 veins removed from her legs). Concomitant medication(s) included apixaban (ELIQUIS) taken for cerebrovascular accident prophylaxis (batch no. 1745824) (oral, 5 milligram, twice a day) in 2017 or 2018, losartan taken for blood pressure (50 mg once daily), paracetamol (TYLENOL) taken for pain (as needed (but not every day)), vitamin b nos, ascorbic acid, zinc, colecalciferol and cyanocobalamin (VITAMIN B12 [CYANOCOBALAMIN]). The patient experienced since she took the first COVID vaccine, she did have some symptoms, her face flushed, like she had a temperature and experienced fatigue, and may have blood clots. The patient reported that she may have blood clots but was unsure because she did not underwent any tests to confirm. The patient was due for her second COVID-19 vaccination. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.</p>

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1328996	5/19/2021	TN	52	M	3/16/2021	3/20/2021	abdominal pain. The pain was so severe that my knees would buckle and several times if I was holding anything, it caused me to drop it. After about a week, I had an appointment at 4:30 and was scheduled for the next morning at 8:30 to meet with a back and spine doctor for xrays. Xrays were negative. I was then schedule with a neck and hand specialist a few days later. This appointment could not provide a diagnosis. Back and abdominal pain increase and soreness had spread to the stomach and groin. After the news broke of the cerebral blood clots in 6 women. See attached Continuation Page.

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1329018	5/19/2021			F		2/1/2021	<p>now was dealing with low iron count and getting infusions.; now was dealing with low iron count and getting infusions.; superficial blood clot to left lower leg found last week at dr office/blood clots pt no longer having issues with clots; This is a solicited report from a non-Pfizer sponsored program (marketing program name not available) from a contactable consumer, based on information received by Pfizer. This serious solicited report was reported to Amgen on 26/FEB/2021 by a consumer from a commercial program and involves a 72 year old female patient who had superficial blood clot to left lower leg [PT: thrombosis] while receiving Enbrel, Single Dose Prefilled Autoinjector. No historical medical condition was reported. The patient's current medical condition included rheumatoid arthritis. No concomitant medications were provided. No co-suspect medications were reported. The patient began Enbrel, Single Dose Prefilled Autoinjector on an unknown date. Last week on an unknown date in FEB/2021, the patient noticed a superficial blood clot to left lower leg at physician's office. The patient was treated with unspecified medications. The outcome of the event thrombosis was reported as unknown. Action taken with Enbrel and Single Dose Prefilled Autoinjector was reported as unknown for the event thrombosis. The causal relationship between the event thrombosis and Enbrel with Single Dose Prefilled Autoinjector was not provided by the consumer. The reporter declined to provide the lot number. The reporter declined consent for follow up. No follow up attempts are possible. No further information is expected Amgen comment: This individual case report does not change the safety profile of the product. Amgen Causality Assessment: The event thrombosis leg was assessed as related to etanercept by Amgen. The reporter's assessment of thrombosis leg with the suspect product was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment. Follow-up (06May2021): This is a follow-up solicited report from a non-Pfizer sponsored program from a contactable consumer, based on information received by Pfizer from Amgen, license party for etanercept (ENBREL). ADDITIONAL INFORMATION RECEIVED ON 06/MAY/2021: In this follow up, it was reported that the patient experienced blood clots pt no longer having</p>

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issues with clots [PT: thrombosis] while receiving Enbrel, Single Dose Prefilled Autoinjector. The patient's current medical condition included low iron. The patient's concomitant medications included covid-19 (corona virus disease -2019) vaccine. On an unknown date, the patient received covid-19 (corona virus disease -2019) vaccine. On an unknown date in FEB/2021, the patient had blood clot (previously reported). Then on an unknown date in 2021, the patient stated that she had no longer having issues with clots. The patient stated that they thought it might be related to covid or covid vaccine. The patient stated that she now was dealing with low iron count and getting infusions. The patient stated she had low iron as a kid. The outcome of the event thrombosis was reported as recovered/resolved. The event thrombosis was resolved on an unknown date in 2021. The reporter declined consent for follow up. No follow up attempts are possible. No further information is expected. Amgen comment: This individual case report does not change the safety profile of the product. Amgen Causality Assessment Thrombosis leg is serious and related to etanercept. The reporter's assessment of thrombosis leg with the suspect product was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment.; Sender's Comments: Based on the information currently available and the safety profile of the drug there is a reasonable possibility that suspect product etanercept contributed to the occurrence of the event, thrombosis leg. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

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1329071	5/19/2021	CA	40	F		5/10/2021	ANAPHYLAXIS; HOT AND BRUISED SHOULDER; FLUSHING; BODY ACHES; LOSS OF FEELING IN FACE; LOSS OF APPETITE; VOMITING; CAN NOT SLEEP; CAN NOT DRINK WATER; STOMACH FEELS LIKE SODA; SWOLLEN ARM AND SHOULDER; COULD NOT MOVE FINGER; VERY HOT LEFT ARM; LEFT ARM SENSITIVE TO TOUCH; HOT SHOULDER; LOWER BACK PAIN; DEHYDRATED; SORE ARM; RASH; HIVES AND BUMPS AROUND THE INJECTION SITE; WEAKNESS; INJECTION SITE PAIN; HEADACHE; VERY TENDER ARM AND SHOULDER; TERRIBLE NAUSEA; FEVER; LOSS OF TASTE; LOSS OF SMELL; BRUISE ON LEFT WRIST; PALMS TURNED BLUE FROM CLAPPING; This spontaneous report received from a patient concerned a 40 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included smoker, non-alcoholic, crohn's disease, heart murmur, chronic vertigo, panic attack disorder, depression, drug allergy, fish allergy, and perimenopause, anxiety and other pre-existing medical conditions included patient had no drug abuse or illicit drug, patient is allergic to all the narcotics, passes large clots of blood during menstruation. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 043A21A, and expiry: unknown) dose was not reported, administered on 06-MAY-2021 13:15 for prophylactic vaccination. Concomitant medication included meclizine for vertigo. After receiving vaccination the first thing she felt like there was hot lava going down her left arm ( where she got injected) and she could not move her finger then that went away after 10-15 minutes later. they told her that symptom was normal and everyone experience the same kind of symptom. She completely lost her appetite, the smell of food made her sick ever since she got the shot. Patient stated her left arm was very hot, sensitive to the touch, bumpy around the injection site and sore. all these symptoms were the same day of her shot (on 6-MAY-2021). since the injection she had the headache and it wont go away and she still has the headache today. her relative was telling her that her shoulder was hot. she had body aches ( lower back pain and everywhere, the pain was moving though her body). the second day everything got worse; her arm where she received the

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injection her whole shoulder was black it looks like if someone threw brick at her, she had hives and bumps around the injection site. she cannot sleep, she cannot eat and she cannot drink water. she was tired and she was not feeling good. she had anaphylaxis 30 hours, dizziness, loss of feeling in her face, her heart was racing. she took two tablets of antihistamine to manage the anaphylaxis reaction. 30 hours after the vaccination she has dizziness, wheezing, she had flushing , rapid pulse, she was throwing up for hours then she had to take the antihistamine. On an unspecified date patient had weakness. Patient said that her fever gets worse every day. On the day of vaccination (on 6-MAY-2021) her temperature was 99.4, and has checked it 5 to 6 times with the same reading. on 7-MAY-2021 it was 99.6 and on 8-MAY-2021 it was 100.3. she said it felt like both sides of her throat were touching. Patient had barely been able to eat since 6-MAY-2021, but has been able to drink small amounts of water. Patient stated her saliva makes her nauseated. On 10-MAY-2021 she clapped her hands and they turned blue and also developed an egg shaped bump/hematoma on her left wrist after bumping it. She went to urgent care where she was instructed to use ice pack for bump, which gave her no relief. There, she was stuck with a needle 4 times to get blood work because she was dehydrated. Patient stated that her whole body felt like a walking pin cushion and skin was hypersensitive. Urgent care checked platelets and hemoglobin which came back normal. Patient stated her menstrual cycle started on 10-MAY-2021 was different than usual with super heavy, red flow, no clots, and soaked pad in an hour, it was slowed down since but flow was heavy. Urgent care advised this may be normal due to change of hormone during perimenopause. As of today, patient could not smell or taste anything. Patient was taking antihistamines 2 a day. Temperature was normal. Patient stated nausea and vomiting were better but would definitely come back if she stopped taking meclizine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from could not move finger, had not recovered from sore arm, headache, loss of appetite, vomiting, injection site pain, stomach feels like soda, terrible nausea, swollen arm and shoulder, feels like both sides of throat are touching, weakness, bruise on left wrist, loss of taste,

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and loss of smell, and the outcome of sore body, hot and bruised shoulder, rash, anaphylaxis, flushing, body aches, not feeling good, dizziness, loss of feeling in face, wheezing, rapid pulse, hives and bumps around the injection site, can not sleep, can not drink water, fever, very tender arm and shoulder, very hot left arm, left arm sensitive to touch, hot shoulder, lower back pain, palms turned blue from clapping and dehydrated was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 20210516682-COVID-19 VACCINE AD26.COV2.S-Anaphylaxis. This event(s) is labeled per RSI and is therefore considered potentially related.



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1329073	5/19/2021	SC	78	M	4/1/2021		STROKE; SHORT WINDED; This spontaneous report received from a patient concerned a 78 year old White and not Hispanic or Latino male. The patient's height, and weight were not reported. The patient's past medical history included blood clot in leg around 10 year ago, and concurrent conditions included high blood pressure, social drinker, hole in heart from birth, and non-smoker, and other pre-existing medical conditions included the patient had no known allergies. the patient did not have any drug abuse/illicit drug use. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total, administered on left arm on 11-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. Concomitant medications included acetylsalicylic acid, atorvastatin, clopidogrel bisulfate, colecalciferol, escitalopram, finasteride, gabapentin, hydroxychloroquine sulfate, levothyroxine, lisinopril, thioctic acid, ticagrelor and verapamil hydrochloride were drug used for unknown indication. On 12-APR-2021, the patient experienced headaches, which lasted 1 week. On 18-APR-2021, the patient had CT scan (computerized tomography) result was not reported. Patient was sent home for tension headache. On same day, patient had also experienced no energy. On 19-APR-2021, the patient was Hospitalized for MRI (Magnetic resonance imaging) which showed patient had stroke within 5 days and also had plaque around the brain. Patient was started on Plavix and aspirin. On 21-APR-2021, the patient discharged from hospital. On same date, the patient went to cardiologist to have monitor placed where patient had another stroke and patient was readmitted to the hospital. patient was taken off Plavix and started on Lisinopril and placed on heart monitor. On 23-APR-2021, the patient was discharged from hospital. Patient was hospitalized for 5 days. On APR-2021 patient had experienced down hill, short winded and voice was gone. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from stroke, and had not recovered from short winded. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0. 20210518146-COVID-19 VACCINE AD26.COV2.S-Stroke. This event(s) is considered not related. The event(s) has a

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compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY

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1329076	5/19/2021	MI	40	F	4/10/2021		<p>MULTIPLE BLOOD CLOTS ON BOTH SIDES OF THE LUNGS/NAUSEA(THREW UP BLOOD TWICE)/BLACK STOOL (WAS LIKE DIARRHEA)/FEVER/OXYGEN WAS ON 80S/; WEIRD TASTE (AWFUL); BONE PAIN/BONE PAIN AS BONES FELT LIKE A GLASS/PAINFUL (ANYTHING THAT TOUCHED WAS HURTING); SORE ARM; POSITIVE COVID TEST (RAPID TEST)/CAME POSITIVE BOTH TIMES; HEADACHE; This spontaneous report received from a patient concerned a 40 year old White and Non Hispanic or Latino female. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, expiry: unknown) dose was not reported,1 total dose administered on 10-APR-2021 on left arm as prophylactic vaccination. Batch/Lot number was not reported and has been requested. No concomitant medications were reported. The patient was not pregnant at the time of reporting. On 10-APR-2021, 5 hours after the vaccination, the patient started experiencing headache. On an unknown date the patient experienced sore arm for about a week. On an unknown date the patient experienced bone pain as felt like a glass, painful and anything that touched was hurting. On an unknown date the patient experienced weird taste that was awful. On 16-APR-2021 the patient tested positive for covid-19 (rapid test) (coded as: suspected covid-19). On 17-APR-2021 the patient was again tested positive for covid-19 (rapid test) on both time tested as positive. On 17-APR-2021 the patient experienced 2 episodes nausea (threw up blood twice) before visiting hospital and at the hospital. On an unknown date the patient experienced black stool (was like diarrhea). On 18-APR-2021 the patient had body temperature 100.8 to 100.9 and went to hospital again there diagnosed with multiple blood clots on both sides of the lungs. On an unspecified date the patient was taken with tums and pedialyte for an unknown indication. The patient was treated with tylenol (for an unknown indication), nausea medicine, steroids, blood thinner and oxygen (for oxygen level in 80s). On 21-APR-2021 the patient was discharged from hospital. The patient was hospitalized for 4 days. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. On 26-APR-2021 the patient was recovered from headache. On an</p>

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unknown date the patient was recovered from sore arm and not recovered from multiple blood clots on both sides of the lungs/nausea(threw up blood twice)/black stool (was like diarrhea)/fever/oxygen was on 80s/, and the outcome of positive covid test (rapid test)/came positive both times, weird taste (awful) and bone pain/bone pain as bones felt like a glass/painful (anything that touched was hurting) was not reported. This report was serious (Hospitalization Caused / Prolonged). This report was associated with product quality complaint: 90000179162 The suspected product quality complaint has been confirmed to be voided (did not meet PQC criteria) based on the PQC evaluation/investigation performed. This case, involving the same patient is linked to 20210521944.; Sender's Comments: V0: 20210520244-Covid-19 vaccine ad26.cov2.s-multiple blood clots on both sides of the lungs. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1329088	5/19/2021	PA	56	M	4/3/2021		<p>BLOOD IN THE STOOL; SHORTNESS OF BREATHE; TINGLING IN THE FINGERTIPS AND THE TOES; SORENESS IN THE RIBCAGE NEAR THE HEART/LEFT CALF SORENESS; PUMPING SENSATION IN RIGHT SIDE OF HEAD; TIREDNESS; RIGHT ARM SORENESS; COUGHING; LIGHT HEADEDNESS SENSATION; HEMORRHOIDS; This spontaneous report received from a patient concerned a 56 year old male. The patient's height, and weight were not reported. The patient had no relevant medical history and was not on regular medication. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805022, and expiry: UNKNOWN) dose was not reported, once total administered on 01-APR-2021 on left arm for prophylactic vaccination. No concomitant medications were reported. Patient reported that, he received the vaccine on 01-APR-2021. Approximately 2 days after he coughed and felt lightheaded and noticed some lights around his eyes. Approximately 7 days after patient noticed a list of symptoms including a pumping sensation in the right side of his head, left calf soreness, soreness in the ribcage near the heart, a tingling sensation in the fingertips and toes (but not at the center), sense of tiredness, shortness of breath, blood in stool that he referred to repeatedly as clots, right arm soreness (although the injection was given in the left arm). Patient called his doctor twice and was told to go to the hospital. Patient went to the hospital on 04-MAY-2021. Arrived at 12 PM and discharged at 11 PM approximately. Conducted a chest x-ray, took a blood sample twice, and put some stuff on patient's chest. Patient was discharged on 04-MAY-2021 and given a prescription for Motrin 800 mg taken three times per day as needed, and for cyclobenzaprine 10 mg taken twice a day as needed for spasms. Patient decided not to take these medications as he was unsure if they were pain medications and felt apprehensive. He main concerns seemed to be the pumping sensation in the right side of his head and the blood in his stool which he repeatedly referred to as a clot. His family doctor is aware of the situation and says he thinks its hemorrhoids. He refers to the clot as darker red in colour and also mentions that there is regular red blood in stool alongside the darker clot. Patient notices this about 3 times per week. The action taken with covid-</p>

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19 vaccine ad26.cov2.s was not applicable. The patient recovered from coughing, and light headedness sensation on 03-APR-2021, was recovering from right arm soreness, and had not recovered from pumping sensation in right side of head, soreness in the ribcage near the heart/left calf soreness, tingling in the fingertips and the toes, tiredness, shortness of breathe, blood in the stool, and hemorrhoids. This report was serious (Other Medically Important Condition).; Sender's Comments: V0.20210526242-covid-19 vaccine ad26.cov2.s -blood in stool . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1329170	5/19/2021	NH	45	F	4/18/2021	4/22/2021	Small Pulmonary Embolism; blood clots in upper arm, arm pit, neck, across right side of chest; Opposite arm blew up like a balloon; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Small Pulmonary Embolism) and THROMBOSIS (blood clots in upper arm, arm pit, neck, across right side of chest) in a 45-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 18-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Apr-2021, the patient experienced PULMONARY EMBOLISM (Small Pulmonary Embolism) (seriousness criteria medically significant and life threatening), THROMBOSIS (blood clots in upper arm, arm pit, neck, across right side of chest) (seriousness criteria medically significant and life threatening) and PERIPHERAL SWELLING (Opposite arm blew up like a balloon). At the time of the report, PULMONARY EMBOLISM (Small Pulmonary Embolism), THROMBOSIS (blood clots in upper arm, arm pit, neck, across right side of chest) and PERIPHERAL SWELLING (Opposite arm blew up like a balloon) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medication information was provided by the reporter. Treatment medications for the events included Xarelto (rivaroxaban). Reporter states patient went to Urgent Care on 22-Apr-2021 due to the events and was then told to go to the Emergency Room. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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1329459	5/19/2021	TX	72	M	4/16/2021	4/16/2021	unresponsive; had a stroke in his temporal, frontal and parietal regions of his brain and he has even had prior strokes too; feverish; they all fell down, her brother, her and the rollator; rapid heartbeat/ his normal heartrate is in the 60s and it was going from 110 to 140s and it wasn't coming down; had some blood clots that were thrown into the frontal, temporal and parietal region in his brain; agonal breathing; stopped breathing but then he came back so that's when he was intubated; felt very bad/ malaise/ feeling ill; vomiting in the trash can/ had stuff that looked like had came out of his mouth and he had vomit on legs; he just said that he hurt; nauseated; fatigue; his head hurt; having no appetite/ he ate one bowl of soup that the caller had made for him but he wasn't really eating; This is a spontaneous report from a contactable consumer (patient's sister) via a Pfizer-sponsored program. A 72-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in the right arm on 16Apr2021 10:00 (batch/lot number: unknown) as 2nd dose, single for COVID-19 immunisation. Medical history included blood clot years ago, ongoing leukemia (in remission), coma, gout (he takes a gout medicine), neuropathic pain, pain, high blood pressure, thyroid (disorder), varicose veins and uses rollator (his wheelchair with a seat). Concomitant medications included metoprolol taken for high blood pressure from an unspecified start date and ongoing; levothyroxine sodium (THYROXINE) taken for thyroid from an unspecified start date and ongoing; hydrocodone taken for pain from an unspecified start date and ongoing; imatinib taken for leukemia in remission from an unspecified start date and ongoing; gabapentin taken for neuropathic pain from an unspecified start date and ongoing; iron taken for an unspecified indication, start and stop date were not reported; folic acid (FOLATE) taken for an unspecified indication, start and stop date were not reported; vitamin d nos (VITAMIN D) taken for an unspecified indication, start and stop date were not reported; and ongoing unspecified gout medicine. The patient previously took morphine; he had a shot of morphine in the emergency room sometime before his COVID vaccine. Historical vaccine included BNT162B2 on 25Mar2021 (batch/lot number: unknown) as 1st dose, single for COVID-19 immunisation. Vaccination facility



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was PRIVACY she thinks. Prior vaccination (4 weeks prior) were none. The patient's sister reported that they both had their second dose and she forgot to tell the other woman she spoke to about herself because the caller's focus was on her elderly brother who was 72-years-old. They both received their COVID vaccines in the morning of 16Apr2021, a Friday, and within hours her brother felt very bad. She went downstairs and saw her brother vomiting in the trash can and he just said that he hurt and that he felt nauseated. This continued for a few days, in fact it continued for 4 days. He was beginning to feel better on Monday, but he was still not up to par. Then Tuesday she guesses her brother was feeling better. On Wednesday night she went downstairs and heard him around 2300 to midnight talking to the dogs and then the next morning she found him unresponsive (22Apr2021). Her first thought was that maybe her brother had a stroke so she called 911. In the emergency room he had a CAT (computerized tomography) scan and at first they said that he didn't have a stroke. But something very unusual was that her brother had a rapid heartbeat and his normal was around 60 but in the emergency room his heartrate was upwards to 120 to 130 to 140. He was then transferred to another hospital where they said the next evening that in fact he did have a stroke even though that first doctor said that he didn't have a stroke. The doctor didn't find any further information until 2 days later when the doctor thought her brother already had some blood clots that were thrown into the frontal, temporal and parietal region in his brain. She was a biologist so she can't say that the COVID vaccine caused this but she thought that Pfizer should be aware of his situation and then she was so focused on her brother that she forgot to tell the other woman the really bizarre things. She had asked certain questions to the doctor based on what her sister was telling her to ask. The caller asked the doctor if her brother was going to be seen by a neurologist and the doctor gave a rambling evasive answer and then turned on his heels and walked out and kicked her out of the hospital. They both had their COVID vaccines in the morning around 1000 or so and she doesn't know if he was vomiting still the next day or not but her brother felt really bad. He has chronic conditions and he generally just felt bad and he had thought that something was wrong with him. He felt

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malaise, fatigue, his head hurt and he was nauseated. He ate one bowl of soup that the caller had made for him but he wasn't really eating. That lasted for about 4 days and then he started to feel better on Tuesday, confirmed to 20Apr2021, and then he felt even better on Wednesday, confirmed to 21Apr2021, because the caller did take him on some trips. He doesn't drive. Her brother said that he felt feverish and the caller says that he felt feverish to the touch as well but the thermometer said that he didn't have a fever because it had an error sign when she took his temperature. Unresponsive: Her brother was fine Wednesday night around 2300, maybe midnight, she had heard him downstairs talking to the dogs and she knew that he was okay. Then the next morning, 22Apr2021, she found him slumped into his rollator (his wheelchair with a seat) and he was slumped over and had stuff that looked like had came out of his mouth and he had vomit on legs. He was unresponsive so she called 911 and said that she thought her brother had a stroke. The operator said to lay him flat and the caller was finally able to get him up and then his arm got hung up and the operator said again to get her brother on the floor and get him flat. She understands that this was important and she was able to do it but they all fell down, her brother, her and the rollator. Shortly after this the ambulance had shown up. The ambulance took her brother to the emergency room in town and they said that her brother's heartrate was fast. She gave them all of the relevant information but she didn't think to tell them about the COVID vaccine. They said that her brother's heart was acting erradicate and it was very fast. Again, his normal heartrate is in the 60s and it was going from 110 to 140s and it wasn't coming down. She told them that when he was unresponsive that she thought he was having agonal breathing. In the emergency room, her brother's breathing was still not very good and she heard the doctor say that her brother had stopped breathing but then he came back so that's when he was intubated in the emergency room. They did a CAT scan of his head and his neck and the doctor comes back and said that her brother didn't have a stroke. But that was not the case according to a different doctor's later assessment. Approximately around 1430 to 1445 on that Thursday, 22Apr2021, they transferred him to PRIVACY, where he was in the ICU (Intensive Care Unit). His heartrate

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conditioned to being very fast. He went from the emergency room to the ICU. Thursday when he got transferred to the ICU they didn't do any diagnostic tests that day, he was still intubated and his heartrate was still up into the next day, Friday, 23Apr2021. It wasn't until late in the afternoon that a doctor came in and said that her brother did have a stroke he has even had prior strokes too. They had done an MRI (Magnetic resonance imaging) on Friday of his brain, which was not what they did in the first emergency room, that showed that he had a stroke in his temporal, frontal and parietal regions of his brain. At first caller states that on Saturday, he opened his eyes but he was still unresponsive essentially but then she says that this statement was wrong because he actually didn't respond that quickly. He has gone into a coma once before and when he had came out of it a very unpleasant thing happened that was very personal so she was not going to tell it. On Saturday and Sunday the doctor didn't want to answer the callers questions, this was a different doctor than the first ICU doctor and this one didn't have good bedside manner. Finally on Monday, 26Apr2021, her brother started responding. He was moving his legs with purpose, he had tried to kick the nurse, and he had made some words. The day before this, on Sunday the caller had brought the priest in to bless her brother and he sort of nodded and he seemed to make movements but he was still not able to talk. Monday he said what sounded like words and then Tuesday he made, what seemed to her like, meaningful statements. She was told that he had an ultrasound of his neck to see if he had any clogged arteries or veins and the nurse said that the test results came back good that their were no clogs. But this was where the whole story just becomes awful. Caller discusses how there were issues with a cousin having power of attorney from 2015 that was supposedly no longer valid according to the caller and she had spoke with administration and then she got kicked out of the hospital on Tuesday because of a question she had asked the doctor about her brother seeing a neurologist. The doctor said that the neurologist makes his own schedule and it might be 10 days or more if he even decided he wanted to see her brother. When the doctor asked the caller how would she like her brother's care to be she mentioned that he was in a coma before and was being treated for similar circumstances

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from PRIVACY and that he was seen by a neurologist and she said that maybe her brother should be seen by PRIVACY and the doctor walked out and within minutes she was being escorted out of the hospital for belittling the doctor and calling administration. Now they won't even let flowers be delivered to her brother. Unfortunately the person who has been involved with him the most, the caller, was now barred from him. She was not saying that this was all due to the Pfizer COVID vaccine but why were they saying that she has a blood clot too. She has had headaches but they may be due to stress. She didn't feel sick like her brother. She has a question and she was really scared about the answer. She was just now reading that if you're on immunosuppressant drugs then you're not supposed to have the COVID vaccine. She asked was that true. Well her brother was in remission for leukemia and he was on a cancer medication called imatinib. Caller declined to speak to medical information about this and says it was already too late because he was already taking it and she doesn't know why he didn't stop them. Her brother's friends have tried to call and they were all getting the same statement, which she believes the hospital was stone walling, but the hospital says that they don't have a patient by his name and they have even told the florist the same thing. So caller was unsure if her brother has been discharged or not. He didn't seem to be in the shape to be shipped to a care facility but she doesn't know. It was hard for her to piece it all together. The hospital wasn't feeding her brother enough before she left so for all she knows they could be starving him to death and holding nutrition from him. History/ Investigations: His medications were ones that he has been taking for years and she doesn't know exact start dates for any and if she needs to she can get the dosage information from the pharmacy. Her brother has hid his pills before and he puts them in different bottles, it was a nightmare. He takes a gout medicine and she doesn't know the name of it. Those were the main ones that he takes other than the cancer medicine she said earlier. And he also takes gabapentin for some of his neuropathic pain and he takes something at night and a few others she thinks. For medical conditions the only thing that she knows was that many years ago he had a blood clot but she can't really say what year it was. She does know that her brother wasn't on any blood thinners

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to he knowledge and not long ago he had an ultrasound of his legs to determine if he had a blood clot but she was not 100 % sure if he had that but she thinks he did. Her brother told her that years ago he had blood clots that were due to weight lifting causing varicose veins and later they collateralized and they found out that the other secondary vessels took over for pumping his blood so it wasn't a problem. Her concern was can someone from Pfizer talk to her about what's going on with her brother, she knows Pfizer doesn't have his records but how will Pfizer be able to determine if this was from the COVID vaccine. She guesses that she was curious about what may of caused the blood clots. She mentioned the COVID vaccine to one doctor and he didn't seem like she respected her knowledge. She asked was there anything that can be done to help her brother if it was a blood clot. She was upset that the hospital and her wanting her brother to see a neurologist and beginning with a claim that he didn't have a stroke and then a claim that he did. She thinks that they were not doing enough for her brother and they were just saying oh well, it was all due to a fast heart rate which can happen as a result of the COVID vaccine. She was going to be honest, she was exhausted and she can't keep talking for a long time. She asked if she can call medical information back later when she was more refreshed. Consumer further stated that her brother had complaints of feeling ill, feverish and having no appetite. Caller stated that the next Thursday she found her brother unconscious, heart rate was elevated 120 to140 beats per minute and that her brother had a stroke. The outcome was recovered on 21Apr2021 for the events Malaise, Nauseated, Fatigue, Headache and Appetite absent; recovering for the event Vomiting; and unknown for the rest of the events. Information on lot/batch number has been requested.

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1329329	5/19/2021		41	F	1/11/2021	1/1/2021	Blood clot in neck; Shortness of breath (dyspnea); Pressure on her chest; Edema to her feet; Weight gain of 2 pounds overnight; Rash on chest; Rash on chest, possibly due to tape (dermatitis contact); Heart palpitations; Oxygen saturations dropped to 85% on room air; Diarrhea; This is a solicited report based on information received by Pfizer. A contactable consumer reported that a 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date: unknown), via an unspecified route of administration on 11Jan2021 at a single dose for COVID-19 immunization; treprostinil sodium (REMODULIN), intravenous from 03Mar2020 to an unspecified date at 0.041 ug/kg, then at 0.045 ug/kg with therapy dates unspecified, and then at 0.049 ug/kg with therapy dates unspecified, for primary pulmonary arterial hypertension; and macitentan (OPSUMIT) on 11Jan2021, orally from 11Jan2021 at 10 mg, 1x/day for primary pulmonary hypertension. Medical history included ongoing primary pulmonary arterial hypertension. Concomitant medication included sildenafil citrate. On 15Jan2021, the patient had a blood clot in neck. The patient was hospitalized from 15Jan2021 to 16Jan2021 due to the blood clot in neck. It was reported that on 15Jan2021, which is 10 months 13 days after initiating IV Remodulin, the patient was hospitalized due to blood clot in her neck. The patient went to the emergency room on 15Jan2021 and she was planned to be admitted to change her catheter, later she was hospitalized on the same day and her Remodulin central line was changed as per the prior plans of getting the catheter changed. The patient was discharged on 16Jan2021. The patient then had a rash to her chest (dermatitis contact previously reported) that started on 20Jan2021. The patient believed it was from the original dressing that was placed after her catheter was replaced. The rash to left chest around her Remodulin catheter line (dermatitis contact previously reported) was also reportedly itchy at night. On an unknown date in 2021, the patient's oxygen saturations dropped to 85% on room air (oxygen saturation decreased). The patient continued to have rash on her chest (dermatitis contact previously reported). On 29Jan2021, 10 months 27 days after initiating IV Remodulin, the patient was in the emergency room due to increased shortness of breath, pressure on

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her chest, edema in her feet and a weight gain of 2 pounds overnight. All the tests were negative but during walking test, the patient's oxygen saturation dropped to 85% on room air. The patient was advised to wear mask continuously. 2 weeks after receiving the first COVID-19 vaccine, the patient had heart palpitations, shortness of breath, and chest pressure 2 weeks after receiving the first COVID-19 vaccine (dyspnoea and chest discomfort previously reported). The patient went to the ER (emergency room), had worked up and was seen by a pulmonologist, nothing was found, and the patient was released home. The prescribing physician's practice ordered her to wear oxygen (O2) continuously. The patient said that she only wears it when she leaves the house and at night and was fine. She felt this episode was related to the COVID-19 vaccine and was not receiving the second dose. The patient stated that her physician had took her off the Opsumit due to shortness of breath (dyspnoea previously reported). The events 'blood clot in neck', 'shortness of breath (dyspnea)', 'pressure on her chest', 'edema to her feet', 'weight gain of two pounds overnight' and 'heart palpitations', resulted in emergency room visit. The event, 'diarrhea', was controlled with diphenoxylate and atropine (LOMOTIL). The patient had a walking distance test on an unspecified date in 2021 (results were not provided) and weight was 209 lbs on an unspecified date in 2021. The events, shortness of breath (dyspnea)', 'pressure on her chest' and 'heart palpitations', was reported as serious (medically significant). The events rash on chest, and rash on chest possibly due to tape (dermatitis contact) had not resolved while the outcome of the rest of the events was unknown. The reporter's assessment of the causal relationship of the events with the suspect product was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment. Follow-up (12Mar2021): This is a follow-up solicited report based on the information received by Pfizer. Additional information included medical history, suspect drug data, reaction details and clinical course details. Information on the batch/lot number has been requested. Follow-up (04May2021): This follow-up is being submitted to notify that the batch number is not available despite the follow-up attempts made. Follow-up attempts have been

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completed and no further information is expected.;  
 Sender's Comments: Based on the available information the events are most likely related to an intercurrent or underlying condition which is not related to the subject drug. There is a reasonable possibility that the drug contributed to occurrence of the event rash. The follow-up information received does not alter the previous company clinical evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

1329511 5/19/2021 PA

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4/15/2021

4/1/2021

blood clot in right leg; This is a spontaneous report from a contactable consumer (patient). A female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 15Apr2021 (Batch/Lot number was not reported) as 1st dose, single for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient received the first COVID vaccine on 15Apr2021, a week later (in Apr2021), the patient experienced a blood clot in right leg. The patient is currently on blood thinners and was scheduled to receive the 2nd vaccine on 06Mar2021. Outcome of the event was unknown. Information on the lot/batch number has been requested.



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1329437	5/19/2021	PA	34	F	2/7/2021	3/13/2021	<p>endometriosis; fibroids; I recently received my Covid vaccine and about a month later had a hospitalization due to abnormal uterine bleeding; This is a spontaneous report from a contactable consumer (patient). A 35-year-old female patient received her second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; lot number: EN5318, expiration date not reported), via an unspecified route of administration on 07Feb2021 09:00 (at the age of 34-years-old) at 2nd dose, single in the left arm for COVID-19 immunisation. Medical history included two C-sections (patient was over a year post-partum from having her last child). Concomitant medication included citalopram hydrobromide (CELEXA) for anxiety from Apr2020 to an unspecified date at 10mg, daily, and from Apr2020 and ongoing at 20mg, daily. Historical vaccine included first dose of BNT162B2 on 17Jan2021 09:30 given intramuscularly for COVID-19 immunisation. The patient reported that recently, she received her COVID vaccine and about a month later, on 13Mar2021, she was hospitalized due to abnormal uterine bleeding. The patient has no significant medical history gynecologically, so she wanted to see if there was any correlation with receiving the vaccine and her abnormal uterine bleeding. The patient further stated that she was bleeding heavier than normal and was hospitalized because she had a heavy uncontrollable bleeding that started on 16Mar2021, and also had larger than normal clots, started on 15Mar2021, which presented like fibroids or endometriosis, however, she does not have any of these. The patient had three episodes. On 16Mar2021, the patient went to the emergency room due to bleeding. The patient was there most of the day and was sent home later on. On 17Mar2021, she went to the emergency room by ambulance and was admitted to the hospital. The patient lost so much blood that she had to have five transfusions. The patient was also treated with blood pressure medications because everything was coming out. While in the hospital, the patient had a uterine artery embolization. After discharge, she followed up with the gynecologist who followed her through the hospital. She had no gynecological history of any kind prior to this. The doctors were unable to give a definite explanation as to why this happened. It may have been hormonal at this time in the patient's cycle. She was over a year post-</p>

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partum from having her last child and she had two C-sections with no issues. The patient stated that this could be completely coincidental. At the hospital on Mar2021, the patient had labs and an ultrasound. The results were in her patient portal online. She had blood work drawn a few days after hospital discharge ordered by the gynecologist and another blood work several weeks later, ordered by her primary care provider. The patient was placed on Iron 325mg by mouth twice daily and was prescribed pain medication, but the patient never took it. The patient was currently taking doxycycline 100mg tablets every 12 hours for inflammation response from the uterine artery embolization procedure that she had. The patient was unsure if this was coincidence or related. The vaccine was the only thing she can think of that may have been a contributing factor. The patient went to emergency room and was hospitalized due to the events. The patient was discharged from the hospital on 21Mar2021. Outcome of the events abnormal uterine bleeding, and bleeding was recovered on 19Mar2021, for event clot blood was recovered on 18Mar2021, and for other events was unknown.

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1329441	5/19/2021			M	2/24/2021		immune complex mediated response due to vaccine; portal vein thrombosis; experienced a 30 pound weight loss (over the past two months); night sweats; intermittent fever of unknown origin; chills; This is a spontaneous report from a contactable health care profession and follow up report from a contactable consumer via Pfizer-sponsored program. A 74-years-old male patient received the second dose bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; ), via an unspecified route of administration on 24Feb2021 (Batch/Lot Number: Not provided) as 2nd dose, single for covid-19 immunisation . Medical history included coronary artery, chronic obstructive pulmonary disease, chronic kidney disease, type II diabetes mellitus, hyperlipidaemia, hypertension. The patient's concomitant medications were not reported. The patient experienced immune complex mediated response due to vaccine, portal vein thrombosis, night sweats, intermittent fever, chills, experienced a 30 pound weight loss (over the past two months) on an unspecified date. The patient underwent lab tests and procedures which included ESR: 101 (elevated), CRP: 225 (elevated), White blood cell count elevated (18 today), Procalcitonin: 1.89 (elevated), Haptoglobin: 380, Quantitative IgG: 1.664 (elevated), Antinuclear Factor 1:320 ANA (at first came out negative then positive), Beta-2glycoprotein IgG: 33.4, Antiphospholipid panel: positive, Tumor marker CA 19-9: 46 (Mildly elevated) all on an unspecified date. Negative Lab results: Negative Cultures, Covid-19, RVP, TB, Hepatitis panel, dsDNA, EBV antigen, CMV, Lyme titers, quantitative IgA and IgM, beta 2 glyco IgA, venous duplex, white cell scan, nuclear scan of bone marrow, PNH panel all on an unspecified date. Reporter inquired Are there any reports on portal vein thrombosis after receiving both doses of the Pfizer Covid-19 vaccine? The clinical course was reported as follows Medical assistant stated that she has been treating a 74 year old male patient who received the first dose of the Pfizer Covid-19 vaccine on 02FEB2021 and the second dose on 24FEB2021 and after two weeks of receiving the second dose the patient started experiencing night sweats (2-3 times a night), intermittent fever of unknown origin and chills, he experienced a 30 pound weight loss (over the past two months) and portal vein thrombosis, at this point the differential includes an immune complex mediated

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response due to vaccine. He has been admitted for two weeks (admitted on 20APR2021) and performed rheumatology, oncology, hematology panels and ruled out infectious causes. It was also reported They did a full work up but nothing came up except that PRIVACY has a portal vein thrombosis. They are wondering if it is related to the vaccine and if there are some reports regarding this side effects. First dose of the vaccine was given 02Feb or 03Feb (reporter is not sure). Second dose of the vaccine was given 24Feb2021. The clinical outcome of the events was unknown

1329517 5/19/2021 NY

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4/9/2021

4/28/2021

This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date: unknown), via an unspecified route of administration on 09Apr2021 as 1st dose, single; via an unspecified route of administration on 30Apr2021 as 2nd dose, single for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced first signs of blood clot on 28Apr2021 and ended up in hospital from 30Apr2021 to 02May2021, getting blood thinner. The patient thought he/she should report this in case it is possibly connected to vaccine. The outcome of the event was unknown. Information on the lot/batch number has been requested.

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1329453	5/19/2021	PA	64	M	4/2/2021	4/2/2021	fainted; fell and hit his head; fell and hit his head; felt lightheaded/Dizziness; blood clots in his lungs; he has a spot on his lung that they are monitoring; hypoacusis and has a new hearing aid; This is a spontaneous report from a contactable consumer (patient's wife). A 64-years-old male patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; ), via an unspecified route of administration, administered in Arm Left on 02Apr2021 (at the age of 64 years old) (Batch/Lot Number: ER8733) as 1st SINGLE DOSE for covid-19 immunisation. Medical history included severe sleep apnea from 18Mar2021 (received a machine not long after), gout (diagnosed about four years ago) , ex-tobacco user from an unknown date to an unknown date (two pack a day smoker over thirty years). Concomitant medication included colchicine (COLCHICINE) 0.6 mg, 1x/day taken for gout, start date was not reported to Apr2021. The patient experienced blood clots in his lungs (hospitalization, medically significant) on 02Apr2021 (also reported as 02May2021). , fainted, fell and hit his head, felt lightheaded/dizziness on 02Apr2021, The patient was hospitalized from 2Apr2021 to 4Apr202. It was reported the patient experienced hypoacusis and has a new hearing aid on an unspecified date. Caller says her husband has new hearing aids, which is why he is not doing the report himself. Patient has a spot on his lung that they are monitoring on an unspecified date. The patient underwent lab tests and procedures which included blood test: results unavailable on an unspecified date , 'they did a couple tests' (details not provided) results unavailable on 02Apr2021, urine analysis: results unavailable on an unspecified date. Therapeutic measures were taken as a result of blood clots in his lungs included Thrombectomy on 02Apr2021. The clinical course was reported as follows on April 2nd her husband received his first dose of the Pfizer COVID-19 vaccine. Approximately an hour later they went to the market and he felt lightheaded, so instead of getting out of the car they sat there 20 minutes. He started to get out again then halfway out the door he fainted and fell down on the ground. She says he was out for, 5-10 minutes, clarified to not even a minute. Since he hit his head she called an ambulance, and they took him to PRIVACY in PRIVACY. They did a couple tests and said since it was so soon after getting the vaccine that they did not think

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1330328	5/19/2021	PA	52	M	5/4/2021	5/13/2021	<p>the vaccine had to do with his blood clots. Caller also stated he fainted because that was one of the side effects of the vaccine, but they were glad he got there since he had several blood clots in his lungs. On the same day (02Apr2021) he had a thrombectomy to remove the blood clots and put him on a blood thinner. Patient was admitted to the hospital April 2nd and was discharged April 4th. He is doing better, he is on a blood thinner now. She says there were a few doctors that had to weigh in on whether he should get the second dose, they decided it wouldn't affect it since the vaccine goes into his muscle. No other vaccinations on the same days as his Pfizer COVID-19 vaccinations or during the four weeks prior. Once they placed him on a blood thinner, they took him off Colchicine 0.6mg. He stopped taking Colchicine because they said the blood thinner doesn't work with that particular medication. It was also reported The patient is to schedule an appointment with a rheumatologist and a hematologist, they did blood work and a urine test and said he has a spot on his lung that they are monitoring. The clinical outcome of the event blood clots in his lungs was Recovered/Resolved with Sequel while the remaining events was unknown. The second dose bnt162b2 was administered on April 29th. LOT: ER8751, caller hopes that is a 5, the writing is very bad on there. The patient had no side effects from his second dose of the Pfizer COVID-19 vaccine.</p> <p>On 5-13-21 the patient began complaining of dizziness, weakness, and left side chest pain. The patient was sent to a hospital via 911 ambulance and admitted to the hospital from 5-13-21 to 5-18-21. He was diagnosed with a Pulmonary Embolism, Acute Venous Thrombosis, and a Pulmonary Embolism.</p>

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1329475	5/19/2021	NJ	59	M	4/7/2021	4/22/2021	pulmonary embolism; Blood Clot; This is a spontaneous report from a contactable consumer (patient). A 59-yearold male patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in Arm Left on 07Apr2021 (Batch/Lot Number: ew0153) as 1st dose, single (at the age of 59 years) for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient has not had covid-19 prior to vaccination. The patient experienced pulmonary embolism on an unspecified date and blood clot on 22Apr2021 with outcome of not recovered. The patient was hospitalized for blood clot for 2 days. The patient underwent lab tests and procedures which included blood test: negative on 26Apr2021. Therapeutic measures were taken as a result of the events includes blood thinner. The outcome of the event blood clot was not recovered and unknown outcome for the event pulmonary embolism. The patient was tested negative for Covid-19 on 23Apr2021 (post vaccination). No follow-up attempts are possible; information about batch number already obtained.

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1329495	5/19/2021	OK	78	F	2/24/2021	2/28/2021	<p>numerous blood clots below the knee; left leg swelling/ It got so swollen/left foot swelling; pain with walking left leg; This is a spontaneous report from a contactable nurse reporting for herself. A 78-years-old female patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in Right Arm on 24Feb2021 (Batch/Lot Number: EN6202) as single dose for covid-19 immunisation (Age at vaccination 78 years). The patient medical history was not reported. On 04Feb2021 the patient received the first dose of BNT162B2 and experienced sore arm. The patient's concomitant medications were not reported. The patient experienced pain with walking left leg on 28Feb2021 with outcome of recovering , left leg swelling/ it got so swollen/left foot swelling on 03Mar2021 with outcome of not recovered , numerous blood clots below the knee on 04Apr2021 with outcome of not recovered. The patient underwent lab tests and procedures which included blood test: unknown results, ultrasound joint: numerous blood clots below the knee on 04Apr2021 , vital signs measurement: unknown results. Course of the event: The patient waited for the timeframe after the second dose and had no problems. 4 days after, she experienced pain with walking in her left leg. She took Aleve for a few days. It got so swollen, she should have gone then to her Primary Medical Doctor, but she did not go until 25Mar2021. She was sent to Hospital for an Ultrasound of her leg on 04Apr2021. After the Ultrasound, she was taken to the Emergency Department at the hospital. The doctor told her she had numerous blood clots below the knee. Was prescribed Eliquis 5mg. She was instructed to take 2 tablets or 10mg twice a day, 8hrs apart for 1 week and then 1 tablet twice a day for the remainder of the 74 tablets. She completed that. She was out of them and got a refill of Eliquis 5mg on 26Apr2021. She received 60 tablets and can refill for 5 times. She is really concerned. The swelling is still so bad and so that could that mean blood clots are still in there. The ER doctor told her that the medication is dangerous. It thins the blood and can cause bleeding and the blood clot can go to her heart. Follow up information has been requested.; Sender's Comments: The causality has been assessed as related to bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in Right Arm on 24Feb2021</p>



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1329172	5/19/2021			M			(Batch/Lot Number: EN6202) as single dose for covid-19 immunization, based on temporal association and profile of the product.,Linked Report(s) : 2021499984 same patient/drug, diff dose/event
							multiple subsegmental pulmonary emboli; blood clot; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (multiple subsegmental pulmonary emboli) and THROMBOSIS (blood clot) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced PULMONARY EMBOLISM (multiple subsegmental pulmonary emboli) (seriousness criterion medically significant) and THROMBOSIS (blood clot) (seriousness criterion medically significant). At the time of the report, PULMONARY EMBOLISM (multiple subsegmental pulmonary emboli) and THROMBOSIS (blood clot) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant and treatment medications were provided. Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.
1331012	5/19/2021	NC	72	M	3/19/2021	3/20/2021	Per client, "I received the second dose of Moderna in my right arm on 03/19/2021. The next morning on 03/20/2021 around 9:00 AM, I noticed my left arm swelling. I got to feeling real bad. On 03/25/2021, I was feeling so bad that I went to Family Medicine to see my doctor, MD. He sent me straight to the Emergency room. They gave me the clot buster for my left arm. I was in there for 3 or 4 days. I was discharged. I have blood clots in my lungs. I had a follow up appointment. I also started seeing a new doctor, a pulmonologist, for the blood clots in my lungs. I lost a lot of weight, 32 pounds.

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1329329	5/19/2021		41	F	1/11/2021	1/1/2021	Blood clot in neck; Shortness of breath (dyspnea); Pressure on her chest; Edema to her feet; Weight gain of 2 pounds overnight; Rash on chest; Rash on chest, possibly due to tape (dermatitis contact); Heart palpitations; Oxygen saturations dropped to 85% on room air; Diarrhea; This is a solicited report based on information received by Pfizer. A contactable consumer reported that a 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date: unknown), via an unspecified route of administration on 11Jan2021 at a single dose for COVID-19 immunization; treprostinil sodium (REMODULIN), intravenous from 03Mar2020 to an unspecified date at 0.041 ug/kg, then at 0.045 ug/kg with therapy dates unspecified, and then at 0.049 ug/kg with therapy dates unspecified, for primary pulmonary arterial hypertension; and macitentan (OPSUMIT) on 11Jan2021, orally from 11Jan2021 at 10 mg, 1x/day for primary pulmonary hypertension. Medical history included ongoing primary pulmonary arterial hypertension. Concomitant medication included sildenafil citrate. On 15Jan2021, the patient had a blood clot in neck. The patient was hospitalized from 15Jan2021 to 16Jan2021 due to the blood clot in neck. It was reported that on 15Jan2021, which is 10 months 13 days after initiating IV Remodulin, the patient was hospitalized due to blood clot in her neck. The patient went to the emergency room on 15Jan2021 and she was planned to be admitted to change her catheter, later she was hospitalized on the same day and her Remodulin central line was changed as per the prior plans of getting the catheter changed. The patient was discharged on 16Jan2021. The patient then had a rash to her chest (dermatitis contact previously reported) that started on 20Jan2021. The patient believed it was from the original dressing that was placed after her catheter was replaced. The rash to left chest around her Remodulin catheter line (dermatitis contact previously reported) was also reportedly itchy at night. On an unknown date in 2021, the patient's oxygen saturations dropped to 85% on room air (oxygen saturation decreased). The patient continued to have rash on her chest (dermatitis contact previously reported). On 29Jan2021, 10 months 27 days after initiating IV Remodulin, the patient was in the emergency room due to increased shortness of breath, pressure on

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her chest, edema in her feet and a weight gain of 2 pounds overnight. All the tests were negative but during walking test, the patient's oxygen saturation dropped to 85% on room air. The patient was advised to wear mask continuously. 2 weeks after receiving the first COVID-19 vaccine, the patient had heart palpitations, shortness of breath, and chest pressure 2 weeks after receiving the first COVID-19 vaccine (dyspnoea and chest discomfort previously reported). The patient went to the ER (emergency room), had worked up and was seen by a pulmonologist, nothing was found, and the patient was released home. The prescribing physician's practice ordered her to wear oxygen (O2) continuously. The patient said that she only wears it when she leaves the house and at night and was fine. She felt this episode was related to the COVID-19 vaccine and was not receiving the second dose. The patient stated that her physician had took her off the Opsumit due to shortness of breath (dyspnoea previously reported). The events 'blood clot in neck', 'shortness of breath (dyspnea)', 'pressure on her chest', 'edema to her feet', 'weight gain of two pounds overnight' and 'heart palpitations', resulted in emergency room visit. The event, 'diarrhea', was controlled with diphenoxylate and atropine (LOMOTIL). The patient had a walking distance test on an unspecified date in 2021 (results were not provided) and weight was 209 lbs on an unspecified date in 2021. The events, shortness of breath (dyspnea)', 'pressure on her chest' and 'heart palpitations', was reported as serious (medically significant). The events rash on chest, and rash on chest possibly due to tape (dermatitis contact) had not resolved while the outcome of the rest of the events was unknown. The reporter's assessment of the causal relationship of the events with the suspect product was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment. Follow-up (12Mar2021): This is a follow-up solicited report based on the information received by Pfizer. Additional information included medical history, suspect drug data, reaction details and clinical course details. Information on the batch/lot number has been requested. Follow-up (04May2021): This follow-up is being submitted to notify that the batch number is not available despite the follow-up attempts made. Follow-up attempts have been

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completed and no further information is expected.;  
 Sender's Comments: Based on the available information the events are most likely related to an intercurrent or underlying condition which is not related to the subject drug. There is a reasonable possibility that the drug contributed to occurrence of the event rash. The follow-up information received does not alter the previous company clinical evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

1329497 5/19/2021 MN

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5/3/2021

5/3/2021

I have barely hit my hands on something and they start bleeding on my knuckles; This is a spontaneous report from a contactable consumer (patient). This 39-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in the left arm on 03May2021 (at the age of 39-year-old) (Lot Number: EW0176) as single dose for COVID-19 immunisation. Relevant medical history and concomitant medications were not reported. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date for COVID-19 immunisation and experienced heavy menstrual bleeding for 3 weeks following the first dose; very large clots. On 03May2021 at 15:00, after the second dose, the patient had barely hit her hands on something and they started bleeding on her knuckles. The patient had not recovered from the event. Prior to vaccination, the patient was not diagnosed with COVID-19; since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021498328 same patient/drug, different vaccine dose/AE

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1330329	5/19/2021	FL	17	F	5/13/2021	5/14/2021	- Pain/tenderness at injection sight for ~72hrs after vaccination -Small red bump (size of quart) at injection site( was gone after 72hrs.) ***- Abnormal vaginal bleeding, heavy bleeding occured, o clots within blood, cramping*** - General malaise

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1329329	5/19/2021		41	F	1/11/2021	1/1/2021	Blood clot in neck; Shortness of breath (dyspnea); Pressure on her chest; Edema to her feet; Weight gain of 2 pounds overnight; Rash on chest; Rash on chest, possibly due to tape (dermatitis contact); Heart palpitations; Oxygen saturations dropped to 85% on room air; Diarrhea; This is a solicited report based on information received by Pfizer. A contactable consumer reported that a 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date: unknown), via an unspecified route of administration on 11Jan2021 at a single dose for COVID-19 immunization; treprostinil sodium (REMODULIN), intravenous from 03Mar2020 to an unspecified date at 0.041 ug/kg, then at 0.045 ug/kg with therapy dates unspecified, and then at 0.049 ug/kg with therapy dates unspecified, for primary pulmonary arterial hypertension; and macitentan (OPSUMIT) on 11Jan2021, orally from 11Jan2021 at 10 mg, 1x/day for primary pulmonary hypertension. Medical history included ongoing primary pulmonary arterial hypertension. Concomitant medication included sildenafil citrate. On 15Jan2021, the patient had a blood clot in neck. The patient was hospitalized from 15Jan2021 to 16Jan2021 due to the blood clot in neck. It was reported that on 15Jan2021, which is 10 months 13 days after initiating IV Remodulin, the patient was hospitalized due to blood clot in her neck. The patient went to the emergency room on 15Jan2021 and she was planned to be admitted to change her catheter, later she was hospitalized on the same day and her Remodulin central line was changed as per the prior plans of getting the catheter changed. The patient was discharged on 16Jan2021. The patient then had a rash to her chest (dermatitis contact previously reported) that started on 20Jan2021. The patient believed it was from the original dressing that was placed after her catheter was replaced. The rash to left chest around her Remodulin catheter line (dermatitis contact previously reported) was also reportedly itchy at night. On an unknown date in 2021, the patient's oxygen saturations dropped to 85% on room air (oxygen saturation decreased). The patient continued to have rash on her chest (dermatitis contact previously reported). On 29Jan2021, 10 months 27 days after initiating IV Remodulin, the patient was in the emergency room due to increased shortness of breath, pressure on

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her chest, edema in her feet and a weight gain of 2 pounds overnight. All the tests were negative but during walking test, the patient's oxygen saturation dropped to 85% on room air. The patient was advised to wear mask continuously. 2 weeks after receiving the first COVID-19 vaccine, the patient had heart palpitations, shortness of breath, and chest pressure 2 weeks after receiving the first COVID-19 vaccine (dyspnoea and chest discomfort previously reported). The patient went to the ER (emergency room), had worked up and was seen by a pulmonologist, nothing was found, and the patient was released home. The prescribing physician's practice ordered her to wear oxygen (O2) continuously. The patient said that she only wears it when she leaves the house and at night and was fine. She felt this episode was related to the COVID-19 vaccine and was not receiving the second dose. The patient stated that her physician had took her off the Opsumit due to shortness of breath (dyspnoea previously reported). The events 'blood clot in neck', 'shortness of breath (dyspnea)', 'pressure on her chest', 'edema to her feet', 'weight gain of two pounds overnight' and 'heart palpitations', resulted in emergency room visit. The event, 'diarrhea', was controlled with diphenoxylate and atropine (LOMOTIL). The patient had a walking distance test on an unspecified date in 2021 (results were not provided) and weight was 209 lbs on an unspecified date in 2021. The events, shortness of breath (dyspnea)', 'pressure on her chest' and 'heart palpitations', was reported as serious (medically significant). The events rash on chest, and rash on chest possibly due to tape (dermatitis contact) had not resolved while the outcome of the rest of the events was unknown. The reporter's assessment of the causal relationship of the events with the suspect product was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment. Follow-up (12Mar2021): This is a follow-up solicited report based on the information received by Pfizer. Additional information included medical history, suspect drug data, reaction details and clinical course details. Information on the batch/lot number has been requested. Follow-up (04May2021): This follow-up is being submitted to notify that the batch number is not available despite the follow-up attempts made. Follow-up attempts have been

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completed and no further information is expected.;  
 Sender's Comments: Based on the available information the events are most likely related to an intercurrent or underlying condition which is not related to the subject drug. There is a reasonable possibility that the drug contributed to occurrence of the event rash. The follow-up information received does not alter the previous company clinical evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

1331063	5/19/2021	LA	60	F	3/8/2021	3/10/2021	I woke up Wednesday and I felt like I was hit by a train. I felt like a wet dish rag hanging on the sink. Everything hurt, even taking a step, I just felt bad, tired like the flu but no respiratory issues. By the 14th I started getting short of breath, couldn't walk without SOB, my legs started to swell, joints were sore, I felt tired. Went to the doctor and my blood pressure was high, I was prescribed medication for my blood pressure and fluid pills. It hurt just to brush against the skin on my calf. An ultrasound revealed 4 blood clots in my left calf. Went to the ER at . Hospital in and sent to hematologist Dr. and there were no findings.
1330905	5/19/2021	WA	39	F	4/30/2021	5/5/2021	Wheezing in my chest and bad cough started on 5/5. Pain in my left calf began on 5/14. I went to the Emergency Room on 5/16 and was diagnosed pulmonary embolism in both lungs and deep vein thrombosis in my left leg.
1330734	5/19/2021	NE	78	M	3/3/2021	5/6/2021	Pulmonary Embolism, blood clot left lung. Put on Eliquis 10 mgs a day.



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1330709	5/19/2021	IA	38	M	4/7/2021	4/7/2021	After my vaccine I experienced sweats, fever body aches and had stomach pain for three days. I had arm pain for about three weeks as well. On Monday afternoon, I still had stomach pains, fever and leg cramps. I went to see my doctor and he performed exams on me and was told I had swelling of my intestine. My digestive tract has been profusely slow since receiving the J&J vaccine. They also ran some tests to check if I had any blood clots. I still experiencing full digestive tract issues and slowness.

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1330701	5/19/2021	PA	75	M	3/5/2021	3/15/2021	<p>COUGH 3/15/2021 - 3/19/2021 (4 days) Last attending ? Treatment team Pneumonia due to COVID-19 virus</p> <p>Principal problem Discharge Summary INPATIENT DISCHARGE SUMMARY HOSPITALIST GROUP .</p> <p>Admission diagnosis: Primary Admission Diagnosis</p> <p>Hospital Problems * (Principal) Pneumonia due to COVID-19 virus Yes Hyperlipidemia Yes</p> <p>HYPERLIPIDEMIA NEC/NOS; Hypertension Yes Obstructive sleep apnea Yes Sick sinus syndrome (CMS/HCC) Yes S/p atrial pacing</p> <p>History of placement of stent in LAD coronary artery Not Applicable Acute deep vein thrombosis (DVT) of popliteal vein of left lower extremity (CMS/HCC) Yes Hypoxia Yes Disposition: discharge to home with home health care CODE STATUS (LOI): Full Code</p> <p>Consulted Services: none Operative Procedures Performed _ Active Issues Requiring Follow-up</p> <p>COVID19 pneumonia with acute respiratory insufficiency-Home O2 evaluation completed and the patient requires 1 L of oxygen with rest and 3 L with exertion. He will be discharged with 5 more days of Decadron to complete a 10-day course. He received convalescent plasma while hospitalized. He completed a 5-day course of remdesivir. He already received his first Covid vaccine. His second Covid vaccine was rescheduled for April 9 at 1245 at the Hospital. Acute DVT of the left popliteal vein-started on Eliquis. Patient will complete 7 days of 10 mg p.o. twice daily then start on 5 mg p.o. twice daily</p> <p>Coronary artery disease-aspirin was decreased to 81 mg since he was started on Eliquis Iron deficiency anemia-started on iron replacement. Recommend further work-up as indicated as an outpatient. The patient does report he had a colonoscopy 2 years ago which was normal. He has had intentional weight loss over the past year of 35 pounds so this could be from his dietary changes but discussed outpatient monitoring through his family doctor.</p>
1330614	5/19/2021			U			<p>Patient diagnosed with dural sinus thrombosis, our stroke team believes this to be an incidental finding, as this was ordered for initial work-up of new onset headache. However, symptoms had resolved completely by time of COVID vaccination on 3/14/21.</p>

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1330554	5/19/2021	CA	63	F	3/31/2021	5/18/2021	Upon speaking with patient here at the hospital she reports having vaccine on March 31, 2021 and reports experiencing clot that had been previously reported to CDC and she asked that this hospitalization be reported to hospitalization as concerns that it may be related. Patient admitted for possible stroke/TIA symptoms resolving
1330552	5/19/2021	IA	45	F	1/11/2021	1/29/2021	Blood clot in brain causing stroke then death
1330508	5/19/2021	NY	26	M	5/17/2021	5/18/2021	patient stated he ended up in the hospital with blood clot in the lungs
1331237	5/19/2021	TX	56	M	3/13/2021	3/1/2021	Pain in right lower leg lead to hospitalization for a blood clot. Patient discharged on Eliquis.

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1327562	5/18/2021	AK	38	F	1/20/2021	1/20/2021	Right after injection, I got really hot and flushed. I thought I am not a fan of needles - so I thought it was anxiety. My throat got really dry. They gave me a Dixie cup of water and I asked for more. After I had finished the one cup, I was clearing my throat and it felt like I couldn't swallow and my tongue had swollen up and I couldn't swallow any water from next Dixie cup. I couldn't swallow - it felt like it would get stuck at the back of my throat. The nurse said she was going to stab me with the epi-pen but had me lay down first and my face started to feel slightly numb and I told her that and she stabbed me in right hip with the epi-pen. They called the ambulance to take me to hospital and after the epi-pen was given they had me sit up and put a mask on my face and I was in a state of panic. I wore an oxygen full face mask and was breathing into it. The paramedics came in and put me on stretcher - monitored for six hours. Because of the adrenaline from the epi- pen - I had high blood pressure and heart rates - everything was really high. After a few hours, she told me that my tongue was looking better and there was better color in my tongue. I was sitting there every six hours - I was monitoring as how to I was doing. They gave me Benadryl and I think they gave me something else but I can't remember what it was. I came home and it was late at night - 11:00 or 11:30 and from there until February 1st, I was extremely sick. I went back to ER on 23rd; and did telehealth visits - with my doctor (right after ER visit from Injection was first one; and then I went to the hospital on the 23rd; Telehealth on 24th or 25th and I - I was running fevers of 104, 103 and went up to 105 almost- on 23rd of January - 3 days after injection - I'm weak, I can't move - everything hurt. From head to toe. I couldn't sleep or do anything. I was so weak, I couldn't even move. It was difficult just to use the bathroom. I had the fevers that was causing my chills and my body aches were bad. I had been trying to alternate Tylenol and Ibuprofen; I was finally prescribed Hydro Codone just to sleep. I was told to take this during the day and the Tylenol and Ibuprofen combo at night. Shoulder surgery was about a month after the vaccine - 18th of February - And on the 22nd of February I went to the hospital again for left side chest pains. - I couldn't breathe - I was discharged February 25th - I was on blood thinners for three months. - the surgeon said that I developed clots and I developed these shortly after surgery and ended up

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							in the hospital for three days. The clots are unknown - blood clots started in the legs and then developed the fluid/clot issue in the lungs - I had a pulmonary embolism in my left lung. Surgeon said it could have been caused by vaccine as he did not work on the lower part of my body.
1326742	5/18/2021	VA	61	M	3/8/2021	3/9/2021	The day after the vaccine I was working and later in the day I started to feel dizzy. Within an hour and a half I could not stand up and I was very dizzy. My coworkers said my eyes rolled back in my head. The ambulance transported me to the ER and my Blood Pressure was at 80 Systolic. I was given fluids and I was discharged after five hours. I still couldn't work the next day and I was still really tired for the rest of the week. It seemed to take a couple of weeks to feel normal but the fatigue was extreme for the first week after the episode of dizziness. I have two autoimmune diseases and a history of blood clots so I might not have gotten the Janssen vaccine if the risk was known. The blood thinner I was taking at the time might have helped but my blood pressure on discharge was still only 110/60.
1326764	5/18/2021	WA	57	M	4/20/2021	5/8/2021	First vaccine dose administered on 4/20/21. Patient was admitted on 4/29/21 with shortness of breath and pleuritic chest pain. CT scan revealed pulmonary embolism and doppler showed vascular access (Hero graft) thrombosis. Patient was treated with heparin and warfarin, and was discharged on 5/5/2021 after being converted to apixaban. Patient missed scheduled dialysis treatment (no call/no show) on 5/8/21 and 5/11/21. Subsequent welfare check found the patient expired at home.
1326824	5/18/2021	FL	47	F	4/9/2021	5/1/2021	3 weeks plus 1 day following vaccine, i developed pain in my left calf. After having an ultrasound, two blood clots were discovered in my left leg (one DTV and one superficial). I was sent to the ER, a CT was performed, blood work was taken, and I was sent home with a prescription for Xarelto blood thinner. I have to be on this for 3 months, and we will evaluate to make sure I'm no longer at risk. My medical bills for the date of 5/3/21 were over \$11,000, and my portion so far is over \$3300 after insurance.

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1326951	5/18/2021	FL	66	F	4/6/2021	4/7/2021	She been feels ill slightly ill ever since the shot. Always short of breathe. Now she died of a blood clot / heart attack while at night in her chair.
1327032	5/18/2021	NC	60	M	3/17/2021	3/17/2021	Coughing started right away and has gotten progressively worse. I saw a specialist about three weeks ago and I'm not bad enough to have COPD but close. Treatments with inhalers with steroids and I have been on those for two weeks. I started feeling pain in back of my left leg. I thought it was a blood clot and went to ER but it wasn't a blood clot. No treatment for that. I still feel the pain occasionally at this time. I have been taking Tylenol for it.
1327305	5/18/2021	PA	89	F	5/3/2021	5/13/2021	Patient presented to the ED 5/18/21 with voice slurring, headache, leg swelling. Patient with symptoms starting on Friday 5/14/21. Patient with profound weakness of her lower extremities, unable to ambulate around the house which is new. Patient also reporting she feels "different/wrong." While here in the Emergency department, patient fell onto her rear while at ultrasound, did not hit her head. Unable to stand on her own after. Patient was found to have an acute left lower extremity DVT on 5/17/21: Acute deep venous thrombosis throughout the left lower extremity with most proximal extension of thrombus into the common femoral vein noting that the external iliac vein could not be visualized
1327350	5/18/2021	MI	70	M	4/5/2021	5/18/2021	Blood Clot right leg after flight.
1327369	5/18/2021	WY	68	F	3/18/2021	3/19/2021	Pt said that on the day following the vaccine she felt very dizzy and kept blacking out. Her husband said that she was also mumbling nonsensical things, and started drooling. Today when she called, she had trouble with speaking and she is still drooling. Client suspects that she might have had a stroke or a blood clot, but she have not gone to the doctor because she does not have health insurance.

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1327469	5/18/2021	OH	49	F	5/5/2021	5/9/2021	Patient, 5/8 for anemia/iron deficiency readmit 5/9 for stroke symptoms and transferred to Hospital after receiving tPA. The patient received a J&J COVID vaccine 5/5. Patient found to have a right MCA stroke and went to IR for thrombectomy with partial recanalization. Patient with hemorrhagic conversion 5/11 leading to right hemicranectomy for mass effect. Patient with risk factors for stroke of HTN and obesity. Cannot confirm or rule out relationship to COVID J&J vaccine. This was not a case of the stroke type that has been associated rarely with the J&J vaccine (cerebral venous sinus thrombosis) but shall report to the FDA VAERS program.
1326571	5/18/2021	FL	61	F	3/20/2021	3/20/2021	3/20/2021 @ 1:00 vaccination I sat in a chair for 5 minutes. After, I felt warm, I was flushed. Fifteen minutes later I walked out, driving down road with friend and I said 'something is wrong'; really bad 'metal taste' in mouth, blurred vision, grabbed her arm and said I am going to throw up, I was so dizzy and I said I can't think. My face was drooping, I couldn't say my A,B,C's, and by the time I got to the ER they got me on an IV. I couldn't talk, think, and had the metal taste for a few hours. The dr. said we are going to give you fluids, my BP was elevated for 6 hours 198/130, no clots. BP went down to 178/98, taste started to go down, I was drinking fluids, I was able to talk a little bit. I felt like in a 'bubble', I couldn't think. When I was discharged I had no temp, my BP was normal. *my body reacted to the vaccination. *6 hours my body reacted *body had felt like I was recovering from the flu for 2 weeks *Never ran a temperature

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1327493	5/18/2021	CO	48	M	4/13/2021	4/17/2021	Strong shoulder pain started on Sat 4/17 in the early morning that woke me up. Went away by 10a after taking tylenol and having a coffee. Sun 4/18: pain again woke me up and was more severe. Had to get out of bed to move around as pain was pretty bad. Went to urgent care. Found nothing serious (not a heart attack or clots, etc). Referred me to go see my PCP if it did not resolve in a few days. Thu 4/22: went to PCP. Pain had subsided for the most part, but started having reduced range of motion when lifting arm straight forward...could not get past 90 degrees (straight out) without pain and a feeling of physical binding in the joint. Suspected bursitis. Prescribed a steroid pack and muscle relaxer. Sat: 4/24: my son noticed my shoulder blade sticking out when attempting to reach for a glass of water while seated. Decided to make appt with an orthopedic. Fri 4/30: went to orthopedic. Took xray. Found no physical damage, trauma, etc. Noticed winged scapula as reason for lack of range of motion. Prescribed physical therapy. Fir 5/14: still same lack of range of motion and no pain. Went to first PT appt. They took range of motion measurements and agreed I was limited. Tested for other pain or signs of trauma and found none. Prescribed a PT regimen. After my own research combined with symptoms, and no physical trauma as the source. My suspicion is Parsonage Turner Syndrome brought on by the vaccination.



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1326170	5/18/2021	LA	63	F	4/14/2021	4/28/2021	D Dimer was high; Chest tightness; blood clots in the lungs; This is a spontaneous report from a contactable consumer. A 63-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Right on 14Apr2021 10:30 (Lot Number: ER2613) as SINGLE DOSE for covid-19 immunization. Medical history included ongoing retinal tear from an unknown date (long ago, maybe 2005), Blood pressure, anxiety, reflux, irritable bowel syndrome, eye care. Three years ago, patient had a blood clot on the portal vein. She was treated with Eliquis, referring to Apixaban, for six months. Then they went into the D Dimer and found out she only had one gene for the blood clots, so they discontinued Eliquis, referring to Apixaban. The doctor said the protocol didn't call for it because she only had one gene. Eliquis, referring to Apixaban, was discontinued a year and half ago. The reporter mentioned the specifically didn't get the Johnson and Johnson shot due to blood clots. Family History included that her mother and sister had blood clots in the past unrelated to the vaccine, anxiety which her mom has. Concomitant medications included ramipril taken for blood pressure from an unspecified start date (for five to ten years) and ongoing; ongoing omeprazole taken for reflux; fluoxetine taken for anxiety (for what her mom has) taking for three years and ongoing; linaclotide (LINZESS) taken for irritable bowel syndrome taking for 3 year and ongoing; magnesium sulfate taken for eye care taking for 3 year and ongoing; latanoprost taken for retinal tear from 2005 and ongoing. Prior Vaccinations (within 4 weeks) was none. The patient previously received the first dose of the Pfizer COVID 19 vaccine on 26MAR2021 at 1000AM in the right upper arm (Lot number for first dose is ER8732; expiration date 31Jul2021). Last Wednesday she started to have tightness in her chest so they called an ambulance. She was admitted to the hospital 28Apr2021 and was discharged Saturday 01May2021. In the hospital they did a CT and it came out that she had bilateral blood clots in the lungs; the doctor said it was a shower of blood clots in the lungs, small enough not to occlude anything. They treated with a 72 hour heparin drip. They didn't do any more CT but they did put her on Eliquis, referring to Apixaban, for the rest of her life. For the Eliquis he

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							mentioned the generic Apixaban; unknown manufacturer; caller did not see NDC, lot, or expiration date on product dispensed in a pharmacy vial. Last time she was also on the Apixaban, not the brand Eliquis but they have discarded all the old product. The patient also did an X Ray; EKG (Electrocardiogram) was normal sinus; all the blood work including the CBC (Full blood count) was normal on an unknown date; her D Dimer was high on 01May2021. The events required a visit to Emergency Room. The outcome of the event chest pain was recovered with sequelae, of blood clots in the lungs was not recovered, of other events was unknown. Batch/Lot number had been obtained. Further information has been requested
1327483	5/18/2021	MO	32	F	4/8/2021	4/19/2021	I experienced chest pains, felt like hard time breathing, little cough that felt like an asthma attack but not quite. I've had PE blood clots I went to urgent care on 04-23-2021, where they did CT scans of the chest and upper abdomen and lab work and my exams were negative. I can say today that I have recovered from my symptoms.

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1326142	5/18/2021	NM	76	M	3/10/2021		<p>developed a thrombosis on the left arm; varicose veins on the arm; whole arm is swollen; veins are swollen; burning pain in left lung, and it goes up to the breast and lymph nodes/ discomfort on left side Lung; burning pain in left lung, and it goes up to the breast and lymph nodes, it is sensitive there; burning pain in left lung, and it goes up to the breast and lymph nodes, it is sensitive there; has tenderness near the wrist and elbow, clarifying the inside of the elbow; felt numbness in the left arm; hot flashes; This is a spontaneous report from a contactable consumer (patient) and physician. A 76-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose via an unspecified route of administration, administered in left arm on 10Mar2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included heart conditions, he has had 2 heart attacks in the past, the first one was 21 years ago, and the second was 2 years ago. Concomitant medications included all his regular medications, nothing new; (also reported as No other products). Patient previously received BNT162B2 first dose on 13Feb2021 administered in left arm for COVID-19 immunization. Patient developed varicose veins a month after he received both his shots for Pfizer's COVID vaccine. Caller stated veins are swollen. It's coming down some, but patient need to know what medications could take or not take. On the left arm right inside of his elbow, he started getting some pattern of varicose veins. It was tender to some degree and people told him to massage it and put a warm pad on it. Seems like the veins were going to pop out. Patient stated he received his vaccine at a hospital. On 03May2021, reported patient was calling in regards to a covid vaccine. He developed a thrombosis on the left arm, it was varicose veins on the arm and the whole arm is swollen, it was still swollen but it was coming down. He had been using a heat pad. Initially after 2 weeks from when he got the shot he wasn't concerned, he went to the doctor and they gave him Cat scan, Ultra sound, and blood test and did not find a blood clot. He added that he had discomfort on left side Lung, but he had discomfort several years ago, an MRI in the past that showed he has a spot in the lungs, but they didn't think it was progressing. With this thing in the past 3-5 weeks he has burning pain in left lung, and it went up to the breast and lymph nodes, it is</p>

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sensitive there, he has no idea what it is. Caller was asked to clarify since he stated that he had a thrombosis but all tests show no blood clot. Caller stated that he thought Thrombosis meant when the veins are popping out and gives impression of varicose veins. He had tenderness near the wrist and elbow, clarifying the inside of the elbow. If looking at the arm from the elbow up little, it looked like worms coming out, it was veins or arteries showing. The varicose veins appearance was more pronounced close to surface initially but is now minimizing. First dose date on 13Feb2021. He was not concerned after the first dose, he was fine, he thought it was a good product and it still is. Second dose date on 10Mar2021. After the second dose he felt numbness in the left arm and hot flashes, he looked down and saw the varicose veins. He did go see the primary care doctor. He also saw his heart doctor but that was an already scheduled appointment, he did not schedule it because of this situation. the heart doctor said to put a warm pad on the arm and lift the arm up over the head every so often. Caller did not have his covid vaccine card, caller stated that he has miss placed it. He found some paper but it only has his ID number and "LHDSER" on it. He received the vaccine in the left arm both times. All symptoms occurred on the left side. He recieved the vaccine in a hospital. Patient asked to refer to his primary care doctor as he has all the results for the tests. Investigation included CAT scan normal; Ultrasound normal; Blood test normal and MRI abnormal which showed spots in the lungs on unspecified date. The event outcome for all events was unknown. Information for batch/ lot number has been requested.

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1325834	5/18/2021			M			<p>LOW PLATELET COUNT; INFLAMED LIVER; BLOOD CLOTS; HEADACHES; This spontaneous report received from a patient, via social media, via a company representative concerned a 33 year old male. The patient's weight, height, and medical history were not reported. The patient received COVID-19 VACCINE AD26.COV2.S (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, two weeks after vaccination, the patient experienced headaches, low platelet count, inflamed liver, and blood clots. It was stated the patient had an inflamed liver because of all the blood clots found; the patient is now on blood thinners for a minimum of 6 months. Laboratory data (dates unspecified) included: Low platelets (NR: not provided) 26K. The action taken with COVID-19 VACCINE AD26.COV2.S was not applicable. The outcome of the headaches, inflamed liver, blood clots and low platelet count was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This spontaneous report received from a patient, via social media, via a company representative concerned a 33-year-old man who experienced blood clots and low platelet (26,000) count two weeks after vaccine. Medical history, concomitant medications, and other details were not reported. It was stated the patient had an "inflamed liver because of all the blood clots found"; the patient is now on blood thinners for a minimum of 6 months. Information is limited in this case, and the occurrence of blood clots and low platelet count could represent background incidence of such events in the general population. However, a relationship with Janssen Covid-19 vaccine cannot be ruled out and thus the relationship is considered indeterminate (Brighton Collaboration Criteria level 5).</p>

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1325835	5/18/2021	OH		F	4/1/2021		<p>BLOOD CLOTS IN BOTH LEGS; PLATELET COUNT DECREASED; ABDOMINAL PAIN; LEG CRAMPS; SEVERE CHILLS; SEVERE HEADACHE; FEVER OF UP TO 102 DEGREES; SEEING LINES; DIFFICULTY IN WALKING; LEG PAIN; This spontaneous report received from a patient concerned a 40 year old female. The patient's weight was 155 pounds, and height was 67 inches. The patient's past medical history included back surgery, and kidney stone removal, and concurrent conditions included alcohol use (one drink once or twice a month), and non smoker, and other pre-existing medical conditions included patient had no drug abuse or illicit drug usage. January 2021, she had a procedure and her platelet count was 300 (unit unspecified). The patient experienced drug allergy when treated with amitriptyline hydrochloride, heparin, oxybutynin, tramadol hydrochloride, and hydrocodone bitartrate/paracetamol. The patient was not pregnant at the time of report. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808980, expiry: 20-JUN-2021) frequency 1 total, dose was not reported, administered to left deltoid on 07-APR-2021 for prophylactic vaccination. No concomitant medications were reported. One week later, on 14-APR-2021, patient began experiencing a severe headache, severe chills, abdominal pain, leg cramps, and a fever of up to 102 degrees. She reported no history of headache or migraines, yet along with the headache, she said she was seeing lines. She said that she called her doctor on 15-APR-2021 (the next day) who advised her to go to the hospital. On 16-APR-2021, patient went to the Hospital, where she was admitted for vaccine induced blood clots in both legs. After receiving the Janssen COVID vaccine, on 16-APR-2021, her platelet count was 27 (coded as platelet count decreased). While in the hospital, she was placed on a blood thinner drip, and her platelet count went as low as 9 (units unspecified). On 19-APR-2021, she was flown to another hospital. She remained in that hospital until 27-APR-2021 when she was discharged. Patient was hospitalized for a total of 11 days. She was currently taking Eliquis 5mg twice a day. She was still having leg pain, and could barely walk (coded as difficulty in walking). She was also concerned about her medical bills. She said that before getting the Janssen COVID vaccine, she was a healthy</p>

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individual and had not taken any birth control or estrogen. She was continuing to follow up with her physician. Treatment medications (dates unspecified) included: apixaban. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from severe chills on 27-APR-2021, was recovering from severe headache, and fever of up to 102 degrees, had not recovered from abdominal pain, leg cramps, and leg pain, and the outcome of blood clots in both legs, seeing lines, difficulty in walking and platelet count decreased was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: This spontaneous report received from a patient concerned a 40-year-old female (BMI 24.3 kg/m2), who experienced "blood clots in both legs" and platelet count decreased 9 days after vaccine. Past medical history included back surgery and kidney stone removal. Her baseline platelet count was 300,000 last checked 4 months before vaccine. The patient was not pregnant at the time of report. No concomitant medications were reported but she denied taking oral contraceptives or other forms of estrogen. Seven days after vaccine, the patient began experiencing a severe headache, severe chills, abdominal pain, leg cramps, and a fever of up to 102 degrees. She said that she called her doctor on day 8 who advised her to go to the hospital. On day 9, patient went to the hospital, where she was admitted for vaccine induced blood clots in both legs. No specific imaging modality or results were reported. Nine days after vaccine, her platelet count was 27,000. While in the hospital, she was placed on an unspecified blood thinner drip, and her platelet count went as low as 9,000. On day 12, she was flown to another hospital. She remained in that hospital until day 20 when she was discharged. She was started on Eliquis 5mg twice a day. As of this report, she was still having leg pain and difficulty walking. She was continuing to follow up with her physician. Based on evolving knowledge of Thrombosis with Thrombocytopenia Syndrome (TTS, per definition from Brighton Collaboration-BC), the low platelet count and temporal relationship to vaccination (BC Criteria level 5), the events are assessed to have a plausible relationship with vaccination.

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1325853	5/18/2021	CA	31	F	4/9/2021		<p>BLOOD CLOTS IN LUNGS; COMPLICATED MIGRAINE; ANEMIA; INJECTION SITE PAIN; BODY PAIN; This spontaneous report received from a patient concerned a 31 year old African American and not Hispanic or Latino female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported and batch number: 043A21A expiry: 20-JUN-2021) dose was not reported, 1 total administered on 09-APR-2021 to left arm for prophylactic vaccination. Concomitant medications included escitalopram oxalate. On 09-APR-2021, the patient experienced body pain, injection site pain on left arm as it had been injected incorrectly that lasted for 4 days. On 17-APR-2021, the patient experienced experienced chest pain, complicated migraine, shortness of breath, left arm numbness, anxiety and weakness. The patient took tylenol (paracetamol) to sleep at night. The patient went to the hospital on 18-APR-2021 and was hospitalized for 3 days. It was found that she had blood clots in her lungs. The patient was discharged on 20-APR-2021 and was put on treatment medications, 2 tablets of xarelto 15 milligram once daily for 3 weeks and it was decreased to 1 tablet 20 milligram daily for 6 months. The patient was put on topiramate 50 milligram daily for migraine, ferrous gluconate 195 milligram for anemia, hydroxyzine 50 milligram for anxiety due to chest pain and 2 tablets of tylenol (extra strength) for chest pain. The patient had no relevant medical history. The patient had a nuvaring for birth control. On 26- MAR-2021, she was also started on lexapro 10 milligram. The symptoms were not resolved except injection site pain and the doctor thought the left arm numbness was due to migraine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from injection site pain on 12-APR-2021, was recovering from body pain, complicated migraine (left arm numbness and weakness) and the outcome blood clots in lungs (chest pain, shortness of breath and anxiety) and anemia was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210523268-JANSSEN COVID-19 VACCINE Ad26.COV2.S- Blood clots in lungs, Complicated migraine. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown</p>



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1325857	5/18/2021	CA		F			<p>scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> <p>BLOOD CLOT; MULTIPLE RED SPOTS ON NECK/RASH; This spontaneous report received from a patient concerned a 19 year old Asian and not Hispanic or Latino female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 203A21A, and expiry: UNKNOWN) dose was not reported, 1 total administered on 11-MAY-2021 14:30 to left arm for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, the patient experienced symptoms of blood clot and multiple red spots on neck. Patient reported that the red spots on neck might be a rash. The patient's father wanted to know about treatment of rash. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from multiple red spots on neck/rash and the outcome of blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210524274- Covid-19 vaccine ad26.cov2.s- A 19- year old Asian and not Hispanic or Latino female presents with Blood clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1325860	5/18/2021	FL		F			CENTRAL VEIN THROMBOSIS; This spontaneous report received from a patient concerned 14 female patients. The patient's weight, height, and medical history were not reported. The patients received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the 14 out of 15 patients experienced central vein thrombosis. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of central vein thrombosis was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0; 20210524749-covid-19 vaccine ad26.cov2.s-Venous thrombosis. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
1325868	5/18/2021	CA		F			BLOOD CLOTS; This spontaneous report received from a consumer concerned multiple 6 female patients. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported), frequency once total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the consumer stated that 6 patients experienced blood clots from the vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clots was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0-20210526046-Covid 19 vaccine- blood clots. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

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1326254	5/18/2021			F			blood clot in her lung; lung problems; bronchial asthma; may have damaged her immune system; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer (patient, self report) A female consumer of unspecified age, reported that she received the second dose of BNT162B2 (Pfizer-BioNTech Covid-19 Vaccine, Solution for injection, Batch/Lot Number and Expiration date: UNKNOWN), via an unspecified route of administration on an unknown date as single dose for COVID-19 immunisation. Patient reported that after she received the 2nd dose of the Pfizer-BioNTech Covid-19 Vaccine, she developed lung problems. She also said she had blood clot in her lung, and had bronchial asthma. Patient wants to know if there have been many reports of this nature after vaccination. She said the vaccine may have damaged her immune system, and wants to know what Pfizer can do for her. She also said the vaccine was dangerous. Information on the lot/batch number has been requested.
1326136	5/18/2021	TX	37	F	3/30/2021	4/5/2021	thrombosis in left ovary vein; blood in her legs was not circulating well; pain; This is a spontaneous report from a contactable consumer (patient). A 37-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in arm left on 30Mar2021 (Batch/Lot Number: EN6204) as 2nd dose, single for covid-19 immunisation. The first dose was received on 10Mar2021 (lot number: EN6204). Medical history included allergy to cherry. Patient was not pregnant. The patient's concomitant medications were not reported. No other vaccines were received within 4 weeks prior. The patient previously took cortisone and experienced allergy. On 05Apr2021, patient was admitted to hospital with thrombosis in left ovary vein. Moreover, blood in her legs was not circulating well, causing her so much pain. The event resulted in emergency care. Patient was given anticoagulants as treatment for 6 months. Patient was discharged on 08Apr2021. Patient had not been diagnosed with COVID prior to vaccination and had been tested post vaccination on an unspecified date with negative results. Outcome of the events was not recovered. No follow-up attempts are needed. No further information is expected.

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1326500	5/18/2021	NC	32	F	4/1/2021	4/24/2021	Two weeks after vaccine woke up with tingling running up and down left leg and being based in the left foot. Throughout the day tingling turned to numbness as if leg were asleep, and feeling in foot turned to strong pain. Had ultrasound in the leg to check for clots (although they did not check foot) and nothing was discovered. After this pain escalated and a week after I was unable to keep my foot still for more than a minute without the intense pain rushing back - the feeling was as if my foot were cramping to an extreme. Elevating helped somewhat but for the most part if I wasn't moving I was crying in pain. The numb feeling is still there as of over a month later but I'm able to hold still without feeling as if my foot is rapidly atrophying.

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1326161	5/18/2021	FL		M	4/1/2021	4/5/2021	felt like my body was hit by a truck; felt like my head was exploding; exhausted; arm pain; hardness and swollen in my other arm like a blood clot; brain fog; suicidal thoughts; I got sick for ten days; Migraine; severe body aches; chills; shakes; dehydrated; saw weird lights when I closed my eyes; hard to breathe; earache; This is a spontaneous report from a contactable consumer reporting for himself. A 47-years-old male patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in Left Arm on Apr2021 (Batch/Lot Number: ER8734; Expiration Date: Apr2021) as single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. The patient experienced suicidal thoughts on 05Apr2021 04:00 with outcome of recovering , i got sick for ten days on 05Apr2021 04:00 with outcome of recovering , migraine on 05Apr2021 04:00 with outcome of recovering , severe body aches on 05Apr2021 04:00 with outcome of recovering , chills on 05Apr2021 04:00 with outcome of recovering , shakes on 05Apr2021 04:00 with outcome of recovering , dehydrated on 05Apr2021 04:00 with outcome of recovering , saw weird lights when i closed my eyes on 05Apr2021 04:00 with outcome of recovering , hard to breathe on 05Apr2021 04:00 with outcome of recovering , earache on 05Apr2021 04:00 with outcome of recovering , felt like my body was hit by a truck on 05Apr2021 04:00 with outcome of recovering , felt like my head was exploding on 05Apr2021 04:00 with outcome of recovering , exhausted on 05Apr2021 04:00 with outcome of recovering , arm pain on 05Apr2021 04:00 with outcome of recovering , hardness and swollen in my other arm like a blood clot on 05Apr2021 04:00 with outcome of recovering , brain fog on 05Apr2021 04:00 with outcome of recovering. Suicidal thoughts was considered an Important Medical Event. The patient was not diagnosed with COVID-19 prior to vaccination. The patient has not been tested for COVID-19 since the vaccination. Follow up information has been requested.

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1327735	5/18/2021	SC	82	M	2/15/2021	5/3/2021	The patient, began suffering from extreme fatigue about 4 weeks ago and has now been admitted on an emergency basis to Hospital. He has blood clots in his lungs and his heart rate is sustained at approximately 140 beats per minute. No cause for the clots has been determined as of yet and the possibility of the COVID 19 vaccine causing the clots as an adverse effect can not be ruled out. This case needs to be investigated. Patient is still in the hospital as of 5/18/2021.
1326236	5/18/2021	DE	55	F	4/24/2021	4/27/2021	week later diagnosed with blood clot in right leg; 102 degree fever; This is a spontaneous report from a contactable consumer (patient). This 55-year-old female patient received BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, dose 2 via an unspecified route of administration, administered in left arm on 24Apr2021 15:30 (Batch/Lot Number: EW0161) (age at vaccination: 55 years) as single dose for COVID-19 immunisation. The patient medical history was not reported. The patient was not pregnant. The patient had received first dose of BNT162b2 on 03Apr2021 (Batch/lot number: ER8733) for COVID-19 immunisation and experienced headache, joint pain and muscle aches. Prior to vaccination, the patient was not diagnosed with COVID-19. She had not been tested for COVID-19 since the vaccination. No other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication(s) included zolpidem tartrate (AMBIEN) taken for an unspecified indication, start and stop date were not reported. Week later after the second dose, the patient was diagnosed with blood clot in right leg on 27Apr2021 and developed 102 degree fever on 27Apr2021. The patient received treatment (unspecified) for the events. The events resulted in emergency room/department or urgent care. The events were not resolved.

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1326264	5/18/2021	MN	48	F	5/5/2021		<p>headache; fatigue; dyspnea; chest pain; RV infarction; a large amount of clot in the RCA; This is a spontaneous report from a contactable physician. A 48-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 05May2021 as single dose for COVID-19 immunization. Medical history included chronic smoker 2 packs per day. Patient was not pregnant at the time of vaccination. Concomitant medications within 2 weeks of vaccination included paracetamol (TYLENOL) and ibuprofen. Patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) as single dose for COVID-19 immunization. It was unknown if the patient received any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, it was unknown if the patient was diagnosed with COVID-19. Patient developed headache, fatigue, dyspnea, and chest pain for 3 days. She was admitted to hospital on 08May2021 with a completed right ventricular (RV) infarction. Angio in May2021 showed clean coronaries with the exception of a large amount of clot in the right coronary artery(RCA). Given correlation to vaccine administration, unclear if this was related (as reported). Device Date: 11May2021 (as reported). The adverse events resulted in emergency room/department or urgent care. The events were assessed as serious, hospitalization and life-threatening. Since the vaccination, the patient had not been tested for COVID-19. Outcome of events at the time of last observation was recovering. Information on Lot/Batch number has been requested.; Sender's Comments: As a cautionary measure and considering the drug-event temporal relationship of three days, the company cannot completely exclude a causal association between the administration of the PFIZER-BIONTECH COVID-19 VACCINE BNT162B2 and the onset of all the reported events. Medical history of chronic smoker (2 packs per day) cannot be also excluded as contributing factor and additional information of medical history and concomitant medications concerning possible risk factors for cardiovascular diseases, should be also useful for an overall assessment of the case. The impacts of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern</p>

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							identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
1326270	5/18/2021	VA	38	F	4/23/2021	4/25/2021	I had thrombosis.; I felt sick; This is a spontaneous report from a contactable consumer (patient). A 38-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 1 via an unspecified route of administration on 23Apr2021 (Batch/Lot number was not reported) age at vaccination of 38-years-old, as single dose, for covid-19 immunisation. The patient medical history and concomitant medications were not reported. On 25Apr2021 the patient felt sick and went to the hospital where she was told she had thrombosis. The patient didn't have any risks for this disease. The patient received blood thinners as therapeutic measure of the event thrombosis and the doctor told her not to combine them with other medications. Outcome of the events was unknown. Information on the lot/batch number has been requested.
1326471	5/18/2021	IA	68	F	4/1/2021	4/4/2021	Bladder irritation two days after first shot. Some blood tinge. Resolved in a few days. Significant bladder pain, bleeding, incl clots two days after second shot. Resolved with cranberry pills after a few days. Thought maybe was due to eating jalapena peppers in my chicken nachoes. Both weekends. Then heard that women are reporting bizarre bleeding after vaccination so re evaluated and considered the bleeding could have been an adverse reaction to vaccine and decided to report my experience.



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1326123	5/18/2021	CA	74	M	1/28/2021	1/29/2021	PE lower lobs of my lung; diagnosis of sever DVT left leg (ankle to groin); This is a spontaneous report from a contactable consumer reported for himself. A 74-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EL9262) dose 1 via an unspecified route of administration, administered in left arm on 28Jan2021 12:45 PM (74-year-old at vaccination) at a single dose for COVID-19 immunisation. Medical history was not reported. No known allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No other medications the patient received within 2 weeks of vaccination. On Friday, 29Jan2021, the day after his 1st shot he began having pain in the lower left leg. Adverse event start date was on 29Jan2021 11:00 AM. The pain intensified through Sunday. On Thursday 02Feb2021 went to emergency room (ER) Confirmed diagnosis of sever deep vein thrombosis (DVT) left leg (ankle to groin) and pulmonary embolism (PE) lower lobs of his lung; on 04Feb2021. Now on apixaban (ELIQUIS) for 6 months. The adverse event result in doctor or other healthcare professional office/clinic visit, and emergency room/department or urgent care. Treatment received for the adverse event included apixaban. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of events was not resolved. Information on batch/lot number has been requested.
1327847	5/18/2021	KS	38	F	4/7/2021	4/8/2021	pt called reporting arm pain, swelling, heat and redness for the last 5 days after injection on 04/07. pt was asked to see MD. When she saw urgent care MD, they ruled out blood clot and diagnosed cellulitis. MD prescribed antibiotics to treat the cellulitis.
1327968	5/18/2021	MD	57	M	4/12/2021	4/17/2021	5 days after dose had pain in left calf. On May 8th went to the hospital with pain under my left rib cage. It was determined by testing that I had a blood clot in left leg and one in each lung. There was also heart arrhythmia. I was given blood thinners for the clots which I am still taking. I was also given medication to help with high blood pressure and to help with heart beat.

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1328018	5/18/2021	CA	48	F	3/18/2021	3/24/2021	Pain in left leg... progressive. Called doctor weeks later to verify if clot. I still have pain in my leg. Dr sent for X-rays and made a referral to orthopedic dr. Also extremely tired, and occasional pain in left breast area/chest. Also locking jaw and headache that does not go away
1328729	5/18/2021	FL	55	M	3/21/2021	4/25/2021	Very strong headaches and high blood pressure for two weeks. Went to the hospital twice in that span of time. Monday May 10, he couldn't see through his right eyes. He went to the ER and they found a blood clot in his artery(thrombosis) and that night had a stroke in the brain. Still at hospital.
1328733	5/18/2021	IA	57	M	3/10/2021	3/25/2021	Stroke due to blood clot in right side of brain. Severely affected speech, mildly affected left hand. Is currently going through speech therapy.
1327655	5/18/2021	KY	57	F	4/14/2021	4/24/2021	4/24-4/28/2021 pain in left leg hurts to walk or put weight on it 4/29/2021 swelling begins in left lower leg and foot 4/30/2021- 5/4/2021 swelling continues to worsen left leg, can't walk, can't move or feel toes, purple discoloration of foot 5/5/2021 go to Emergency Room Admitted into hospital due to extensive blood clot in left leg 5/6/2021 Surgery for removal of blood clot with Dr. 3 hour procedure 70 percent removed 5/7/2021 Released with blood thinner med 5/7/2021 revisit emergency room due to pain swelling and numbness moving into left upper leg and thigh 5/8-5/12/2021 swelling continues to progress 5/13/2021 follow up at vascular Dr. Readmitted into hospital 5/13 surgery for removal of clot Not all removed 5/16/2021 released from hospital on blood thinner
1327567	5/18/2021	TX	57	F	4/8/2021	4/20/2021	Day 12 post-injection had a sharp pain in lower part of torso, then immediately passed a large clot from my vagina, bright blood accompanied. Then no post-period or anything with it. I'm post-menopausal and have no women health issues at all and haven't had a period in about one year.

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1324020	5/17/2021	CA	30	F	4/19/2021	4/28/2021	About ten days after the vaccine I started to have intense cramping and I lost a blood clot. My belly was tightening up and I started to feel downward pressure. I also had back pain. I was checked out at the hospital, and they did not find anything wrong. I was 23 weeks pregnant at the time. I have not had any more cramping. I am also breast feeding my toddler and she was cranky and out of sorts after each dose of the vaccine. She was really irritable and she was running a low grade fever. My daughter is 22 months old. Pregnancy-second
1323625	5/17/2021	KY	65	M	5/4/2021	5/4/2021	Patient received vaccine on tuesday 5/4. Patient developed a rash surrounding both ankles. Patient and wife dismissed this as possible side effect of vaccine. The patient had difficulty breathing and dismissed it as a panic attack on 5/10. Symptoms continued for several days, went to walk-in clinic on Wednesday 5/12 for tests and inconclusive. Thursday 5/13 the patient continued to experience these symptoms and elevated pain, tightness and cramping in legs and went to the ER where he was diagnosed with bilateral pulmonary emboli. Patient was admitted for 2 days and treated for clots. Upon discharge the patient was instructed to discontinue meloxicam, carbidopa/levodopa and started on eliquis for 6 months. After 6 months the patient will follow-up with a hematologist.

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1323709	5/17/2021	NC	17	M	5/5/2021	5/8/2021	<p>Pt was seen at ED on 5/8 for L sided weakness in the setting of a headache. Pt's mother reports that these symptoms began 2 days after receiving second dose of Pfizer COVID-19 vaccination in R deltoid. She says that on 5/6, pt complained of L arm weakness during cooking class at school, which was followed by a mild L sided headache later in the day. Symptoms resolved without intervention but recurred on 5/8 with associated L sided facial droop, slurred speech, L arm spasms, and L foot drag. Pt was seen at ED for this and had a HA (5/10 in severity) at that time -- workup was unremarkable with a normal head CT, laboratory workup, and resolution of symptoms. Pediatric Neurology evaluated the pt, deemed no further workup necessary, and advised outpatient follow up. Pt presented again to the ED on 5/10 with concern for full tonic/clonic seizure, witnessed by pt's mother. Mother reports that she heard pt fall and went upstairs to find pt seizing on his bed -- says that pt had shaking of bilateral upper extremities (in flexed position close to chest) and symmetric lower extremity shaking; eyes were closed without clear focality or eye deviation. Also some drooling, though no incontinence or tongue biting. Episode lasted for approximately 2 minutes; pt was confused and did not recall what happened immediately afterwards but improved within the next 8 minutes. He was taken to the ED by EMS. By the time he arrived in the ED, he had left sided weakness again. He was given Keppra 1g, placed on EEG, and was admitted. EEG overnight was read "normal" and additional workup was unremarkable. Pt had MRI brain completed showing cortical abnormalities in the R parietal lobe, suspected to be related to recent seizure. MRA showed patent intracranial cerebral vasculature. MRV showed no evidence of dural venous sinus thrombosis. Weakness resolved by the morning and pt was back to baseline on morning of 5/11/21. However, around 9 AM, L sided weakness (face, arm&gt;leg) with associated headache recurred. Mom says that this event was captured on EEG. He was then transferred to our facility. He was placed on pEEG and had repeat labs, imaging completed. Pt did have L sided facial droop, L arm weakness, and slurred speech on arrival, but this resolved within 24 hours. Pt had one additional episode of "wave" of L sided weakness including L sided facial droop and slurred speech at one other time during the</p>

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							hospitalization, but no additional seizure like activity. He was discharged on 5/14 with a normal neuro exam--some labs (including labs of Rheum and Id workup were pending at time of discharge.) Primary and consulting teams elected to forgo steroids but reconsider should symptoms worsen or return. Pt was readmitted on 5/16--had an episode of expressive aphasia + headache while at a social gathering; states that he became overwhelmed by the noise. No additional seizure like activity.
1323725	5/17/2021	CA	36	F	4/11/2021	4/11/2021	The day of the vaccine I was told that my arm might be sore. I felt sore right away and as soon as I got in the car to drive home I was extremely tired and I slept for the entire six hour car ride home. I was very fatigued that night and then I got a bad headache, fever and it lasted for 48 hours. After that, the headache was less intense and they were intermittent but my arm still hurt and I couldn't lay on it. I was still fatigued for a week. On the fourth day I started to get a weird feeling of vibrations and twitching all over my body. It is especially worse in my temple. It has been a month but I still get the twitching in different parts of my body. My face, arms, legs and temples. It is in different places. It happens less often now, it is not all day but it is still daily and mostly in my head and my legs. I had it happen in my temples last night. I had my menstrual cycle since the vaccine and it was about three days later than expected. I had a lot of blood clots which was unusual for me. I have had flu like symptoms this week and I have a cough, runny nose and headaches but I am planning on trying to go to the doctor this week.
1323746	5/17/2021	CA	43	F	4/6/2021	4/6/2021	By 7:30, I felt drunk. My brain was not functioning normally and had a fever all night. By 7:15 I felt fine, with the exception for random joint pain. The following Friday, April 9th, I had bloodwork done. It felt like I had hit my funny bone. I had shooting pain up my arm and into my neck and down my spine. I thought it was just the blood draw, so I suffered all weekend. My husband made me go to the doctor on Monday. My doctor said I had the same symptoms of a blood clot. They sent me to the hospital for an ultrasound and blood tests recommended, but everything was negative. She told me to just watch out for any changes and it went away after a few days.

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1323820	5/17/2021	CA	45	F	3/5/2021	3/5/2021	Vaccine in L deltoid. Quickly, pt developed L hand/fingers numbness, coolness. Subsequent pain. Pt referred to hematologist ultimately 5/5/21. Later started on eliquis. Subsequent imaging confirmed arterial thrombosis in brachial/radial arteries. Symptoms markedly better with eliquis.
1322563	5/17/2021	CA		M			BLOOD CLOTS; This spontaneous report received from a consumer who reported hearing a news report concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number not reported, expiry not reported frequency one total, dose, therapy start date were not reported administered for prophylactic vaccination. The batch number was not reported and has been requested.No concomitant medications were reported. On an unspecified date, the patient had blood clots. On an unspecified date in 2021, the patient was died due to blood clots. it was not reported whether autopsy was performed or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died due to blood clot on an unspecified date in 2021. This report was serious (Death). This case, from the same reporter is linked to 20210523500.; Sender's Comments: V0. 20210522533-COVID-19 VACCINE AD26.COV2.S-Blood clots. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: BLOOD CLOTS
1323977	5/17/2021	OH	16	F	5/17/2021	5/17/2021	Presented with acute onset chest pain, found to have right lower extremity DVT and bilateral PEs. Required short stay in ICU for close monitoring given clot burden in her lungs. Required heparin infusion and then transitioned to lovenox for home-going therapy.
1323477	5/17/2021	GA	46	F	4/14/2021	5/10/2021	I started having shortness of breath and went to the emergency room. It was determined I had blood clots in both lungs and I was prescribed blood thinners for the next 3-6 months

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1325242	5/17/2021	AZ	91	F	3/1/2021	3/26/2021	J&J vaccine, extremely dizzy, fainting spells, vertigo started on March 26, 2021. Went to ER after reaction becoming worse on April 8, resulting in falling outside in yard. Dr advised going to ER after visit on April 13. Symptoms were stroke and or blood clots. At hospital they took multiple tests but inconclusive if she had a stroke or blood clots. Took CT scan of brain looking for bleeding on the brain. They have all test results. Today still has vertigo, weakness, and fainting spells.
1324507	5/17/2021	CA	86	F	5/12/2021	5/13/2021	Pulmonary blood clot
1324137	5/17/2021	TX	41	F	3/8/2021	3/10/2021	I did have leg injury in April - and ever since the vaccine, I now have an issue with swelling that won't stop - still have swelling. I was checked with blood clots - and it was elevated so they gave me an ultrasound in leg - no blood clot. Swelling on right leg was enlarged after the vaccine. Two missed menstrual cycles; now I have had the cycle but it's a longer cycle than I normally would have. It's abnormal - the length and flow is off. Spotted for a week before I started bleeding. I had slightly elevated blood pressure after the vaccine - 117/83 usual but it was elevated 141/95 - and it's never high ever like that before. So they had thought I had a potential blood clot. Have an upcoming doctor's appt scheduled.
1323958	5/17/2021	ND	46	F	3/31/2021	4/15/2021	Patient presented to the ED and was subsequently hospitalized within 6 weeks of receiving COVID vaccination. Diagnosis was thrombosis of AV fistula.

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1322564	5/17/2021	WI	26	F			<p>BLOOD CLOT; This spontaneous report received from a pharmacist concerned a 26 year old female of unknown ethnicity. The patient's height, and weight were not reported. The patient had no known drug allergies. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 043A21A expiry: unknown) dose was not reported, 1 total dose, administered on 07-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On an unspecified date (after vaccination), the patient experienced blood clot. The pharmacist thought, that she has been treated, and at the time of this report she was at home, but he was not 100% sure. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210522731-Covid-19 vaccine ad26.cov2.s-blood clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>



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1324058	5/17/2021	CA	55	M	3/15/2021	3/28/2021	On March 28th, started noticing symptoms. There was pain in my entire right leg, shin swelling; calf- swelling and skin discoloration; and right foot - swelling. On 4/1, I went to Urgent Care where I was seen, evaluated and treated by Dr. She ordered blood tests and an ultrasound within 20 minutes. I had 4 blood clots in 3 veins in my right leg/DVT. My blood platelet value was 267 and the standard range is 130 to 400. They didn't consider it low, but it's still an issue. I was given an injection of Enoxaparin Sodium Injection--1 ml injection twice a day for 5 days, which was started in the ER. I then switched to Pradaxa 150mg pill twice a day. I took that until around the 6th of this month when I noticed my right leg had gotten worse. I was instructed to go back to the urgent care. Another ultrasound was ordered and it showed I still had the 4 blood clots in 3 veins that seems to have worsened, so the meds were not working. He consulted with a vascular surgeon and they put me back on the injection once a day, which I am currently still on. I was told to follow up with my PCP in two weeks and that appt is on Thursday with Dr.
1322566	5/17/2021	NJ		U			BLOOD CLOTS; This spontaneous report received from a consumer via social media (internet) concerned a patient of unspecified age and sex. The patient's height, weight and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown expiry: UNKNOWN) dose, 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the consumer reported that he heard about issues of blood clot associated with the Janssen Covid 19 vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clots was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210523657-covid-19 vaccine ad26.cov2.s-Blood clots. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

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1322526	5/17/2021	NJ	41	F	4/29/2021	5/3/2021	Transient moderate headaches and nose bleeds 3-7 days post-injection, including sneezing out blood clot Menstruation lasted longer than normal Mild fatigue 1-5 days post-injection
1322586	5/17/2021			U			LEG CLOT; SICK; This spontaneous report received from a consumer concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported , 1 in total administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient experienced leg clot and sick. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of leg clot and sick was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210526445 and 20210525676.; Sender's Comments: V0:20210526416 -Covid-19 vaccine ad26.cov2.s- Thrombosis - This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
1323565	5/17/2021	WA	54	F	4/9/2021	4/22/2021	Thirteen days after the vaccine I got a sudden sharp pain in my right leg after the vaccine. I am predisposed to blood clots and the staff could not find pulses in my foot. The pain started in my groin area where the femoral artery is located. I have been diagnosed with Raynaud's Syndrome which could have caused the lack of pulse. I was observed for six hours and all tests were negative. The pain did not happens again since then and no other side effects besides initial flu like reaction.

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1322616	5/17/2021	RI	43	F	1/16/2021	1/21/2021	Vaginal hemorrhage 5 days after 2nd Pfizer dose on 1/16/21. Very heavy menstruation on 1/21/21 with large clots one week prior to anticipated cycle date. Prior to event, menstrual cycle regular at 29 days and lasted 7 days from date on onset. After event, cycle shortened and then became irregular. Second menses after 2nd Pfizer began at 23 days 2/12/21, next cycle at 24 days 3/7/21, next 34 days on 4/9/21, next to 22 days 4/30/21, next to 14 days 5/12/21.
1322819	5/17/2021	OK	34	F	2/1/2021	3/8/2021	Fatigue and pain in left arm continues 3 months post vaccination. Chronic menstrual clots larger than a golf ball.
1322955	5/17/2021	NJ	66	M	2/9/2021	2/24/2021	2 weeks later developed DVT (leg pain, also found to have ACL tear of unknown duration), loss of appetite, and bilateral stiffness in hands. Hospitalized for DVT on blood thinners since Diagnosis: Acute embolism and thrombosis of unspecified deep veins of right lower extremity ; Unspecified abdominal pain ; Nausea with vomiting, unspecified ; Strain of muscle, fascia and tendon of the posterior muscle group at thigh level, left thigh, initial encounter ; Essential (primary) hypertension
1323193	5/17/2021	KY	66	M	4/19/2021	5/8/2021	Blood clots
1323239	5/17/2021	NC	59	M	3/12/2021	3/23/2021	a severe pain in my left leg inside thigh. A bright red dot was there. My arch of my foot was burning and then the burning moved up my shin. Pain is not continuous, but moves to my calf and back to my thigh. I had a ultra sound done, my doctor told me I have a blood clot and put me on Eliquis on 4-21-21.
1323286	5/17/2021	DC	49	M	5/5/2021	5/14/2021	Patient had minor car accident with no evidence of severe trauma. Found to have Cerebral venous thrombosis, sagittal and transverse sinuses .
1323318	5/17/2021	TX	24	M	4/8/2021	4/28/2021	Portal Vein Thrombosis
1323476	5/17/2021	OH	49	F	4/1/2021	4/3/2021	Saturday April 3,2021 shortness of breath went to hospital on April 12th with multiple unprovoked PE's Stayed in hospital 6 days and released without oxygen Given blood thinners to take for life Right side of heart damaged due to blood clots

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1322565	5/17/2021			F		4/1/2021	BLOOD CLOTS IN LEFT LEG; BLOOD CLOTS IN BOTH LUNGS; This spontaneous report received from a patient via social media concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: UNKNOWN) dose was not reported, 1 total administered on 19-MAR-2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. The patient reports that 3 weeks later(after vaccination) on an unspecified date APR-2021, the patient was in urgent care with blood clots in left leg and blood clots in both lungs. The patient also reports that she was literally headed to her 1 week follow up when it was flashed on the news about blood clots. And reports that since month she was on very expensive unspecified medication, injection and pills and also undergone unspecified labs and diagnostics. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the blood clots in left leg and blood clots in both lungs was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0;20210523088-covid-19 vaccine ad26.cov2.s-Blood clots in left leg, blood clots in both lungs. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
1321620	5/16/2021	OR	63	F	5/15/2021	5/15/2021	that night, work from sleep with rapid heart beat, headache, sweating, nausea, took aspirin, drank more water, work just feeling off, slight headache and nausea, and left arm pain, concern of blood clots.
1321678	5/16/2021	FL	81	F	4/5/2021	4/8/2021	blood clot, stroke
1321745	5/16/2021	VA	91	M	5/6/2021	5/11/2021	He suffered a blot clot on may 11th and a stroke.
1321774	5/16/2021	NY	49	F	4/16/2021	4/22/2021	Multiple small blood clots in lungs. Put on blood thinners and is now home. Symptoms began as pain and trouble taking deep breaths on left side of upper side/back.

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1321826	5/16/2021	NJ	46	M	5/6/2021	5/9/2021	Blood Clot in my lower right leg. Which can be life threatening if it were to dislodge and travel to the lungs and or Heart. Treatment: 30 day starter pack Eliquis 5mg tabs blood thinner, Methylprednisone 4mg dospak 21s, Acetaminophen 325mg 2@-6hrs or as needed

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1321852	5/16/2021	MA	80	F	3/12/2021	4/10/2021	<p>Patient is an 80 y/o right handed female who is totally independent at baseline who received her Pfizer vaccine out of the country (1st dose 2/19/21, 2nd dose 3/12/21). She was reactive to both shots, reporting arthralgias, headache, low grade fever, chills. She had a rise in blood pressure later during the day of her shot as well as the next day (up to 180/70, from baseline of 130/70). She also had an episode of epistaxis several days after her first shot. She traveled independently out of the country on 3/31/21 to visit her son on a leisure trip. On 4/5/21 she had headache, dizziness/lightheadedness, and did not feel well, and her systolic BP was 198, after which she took additional 40 mg of lisinopril. Her BP subsequently decreased to systolic BP of 130 mm Hg on 4/5/21, but over the next few days she had labile BP with a range of BP of 125 to 171/ 58 - 68. She was meticulous in checking and recording her BP several times a day, and she increased her lisinopril dose to 40 mg po qd from 20 mg po qd given the higher than usual blood pressure range. On 4/10/21 her BP was as follows: 6:30 am, 148/60 (she took her daily lisinopril 20 mg po); 11:30 am: 132/52; 3 pm: 171/69 (she took additional lisinopril 20 mg po) after which her systolic BP decreased to 130. Then around 6:20 pm the same day (4/10/21), she had acute onset of headache, vomiting, left sided weakness, SBP 220, and was witnessed to have rapid change in mental status. There was no antecedent trauma to the head. EMTs were called immediately and she had loss of consciousness during the ambulance ride to the ED, after about 20 minutes of symptom onset, with agonal breathing and bradycardia to the 40s, but never lost her pulse. Upon arrival to the ED out of the country, her Glasgow Coma Scale (GCS) was 6, she was rapidly intubated and stabilized. Head CT demonstrated massive intraparenchymal hemorrhage (140 cc) within the R temporal parietal and occipital lobes, with cerebral edema and 14 mm midline shift, associated with small subdural hematoma and small intraventricular hemorrhage within the temporal horn and body of the R lateral ventricle. They reported hyperdense "spot sign" within the intraparenchymal hematoma compatible with active hemorrhage, no evidence of venous thrombosis, no masses, no arteriovenous malformations. She had 2.5 mm aneurysm right that was thought to be incidental finding unrelated to her event. She was taken emergently</p>

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							to the OR on 4/10/2021 for decompressive R hemicraniectomy, which she underwent successfully with minimal blood loss. She had no coagulopathy and her platelets and hemoglobin were normal. She remained in the Neuro ICU for 3 weeks. She received a tracheostomy two weeks after her presentation, and was weaned off the ventilator. She is breathing spontaneously after 5 weeks from presentation. She remains in coma or minimally conscious state, with GCS score of 5-6 as of 5/13/2021.
1322020	5/16/2021	NC	63	M	4/17/2021	4/19/2021	Patient was admitted 2 days after 2nd dose of Pfizer vaccine with right-sided facial weakness, numbness in addition to headache and found on imaging to have central venous thrombosis, he was started on OAC and got better and discharged home.
1322184	5/16/2021	SC	59	F	4/10/2021	4/13/2021	Patient reported heart attack due to blood clot. Patient report catheterization with stent placement.
1322179	5/16/2021	NY	23	F	4/26/2021	5/2/2021	Lost feeling on right side of body, have minimal feeling in left leg. I've developed non epileptic seizures. Developed a superficial blood clot in my right arm. Muscles spasms so bad that my jaw/eyes clenches and I'm unable to swallow my spit. Occasionally I have apnea from the spasming. I cannot walk unassisted due to right side partial paralysis. I have developed a stutter. I cannot lift my right arm above my head nor can i pick up the right leg. I've developed foot drop of both feet.
1322178	5/16/2021	IA	61	F	4/24/2021	5/10/2021	2/22/21 Had Nuc scan to eval for blood clots/ there was no evidence 5/12/21 ct scan finds PE post vaccine. in with cough and SOB
1322043	5/16/2021	CA	69	F	2/12/2021	2/13/2021	2/12/21 2nd round; 2/13/21: Woke up with chills, then sweats, fever of 102 fluctuated, aches and pains, stayed in bed for 4 days. It took a week to become active again. Called my doctor's office several times. I was told it was normal, part of the vaccine reaction. Worse reaction was my leg bones feeling like metal strips of a toy erector set. The taste of metal in my mouth lasted 4 days. Difficulty walking because of leg weakness and dizziness. Loss of appetite. 5/1/21 - 5/3/21 Hospitalization for diagnosis of Acute Pulmonary Embolism and Deep Vein Thrombosis

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1320281	5/15/2021	FL	61	F	4/9/2021	4/30/2021	Numerous blood clots in both lungs; This is a spontaneous report from a contactable consumer (patient reported for herself). A 61-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Solution for injection, Lot Number: ER8730, expiry date not reported), via an unspecified route of administration, administered in left arm on 09Apr2021 09:00 AM as 2ND DOSE, SINGLE for covid-19 immunization. Medical history included degenerative disc disease, fibromyalgia, hypothyroidism, migraines, known allergies to tape and anise allergy. The patient had negative nasal swab on 07Nov2020. The patient had no covid prior to vaccination. Concomitant medications included morphine at 15 mg, twice a day; oxycodone (XTAMPZA ER) at 36 mg; and heparin; all taken for an unspecified indication, start and stop date were not reported. The patient received the first dose of BNT162B2 as COVID-19 immunization on 19Mar2021 09:00 AM (at the age of 61 years old) (brand Pfizer, lot en6208) administered on the left arm. The patient had no other vaccine in four weeks. On 30Apr2021 09:00 AM, patient had numerous blood clots in both lungs. On 01May2021 to May2021, she was admitted to the hospital for 2 days with numerous blood clots in both lungs. After several tests (May2021), they could not find any reason for getting these clots. So, thinking the only other thing patient did different was get the covid vaccine. The event was reported as serious medically significant, life threatening, and had caused hospitalization from 01May2021 to an unspecified date in May2021. It resulted to emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event). Therapeutic measures were taken as a result of the event which included Heparin IV. The patient had not recovered from the event numerous blood clots in both lungs.



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1320186	5/15/2021			M			<p>Blood clot; He was peeing a lot of blood; all of the joints went wondering in one another that was swelling up and it just so painful. Rheumatoid Arthritis layered up; leg swells up twice the size of the other leg; This is a spontaneous report from a contactable consumer reporting for his father. A male patient of an unspecified age received BNT162b2 (BNT162B2), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for Covid-19 immunisation. Medical history included rheumatoid arthritis. The patient's concomitant medications were not reported. The patient experienced blood clot on an unspecified date with outcome of unknown, he was peeing a lot of blood on an unspecified date with outcome of unknown, all of the joints went wondering in one another that was swelling up and it just so painful/ he is just swelling up, leg swells up twice the size of the other leg on an unspecified date with outcome of unknown. The patient underwent lab tests and procedures which included ultrasound scan: clot blood. The event thrombosis and hematuria were considered Important Medical Events. Course of the events: Reporter stated, "My father got the Pfizer Covid vaccine couple of weeks ago and it caused I think Rheumatoid Arthritis layered up in his joints one of the times started swelling up. He got a blood clot, his legs swelled up like twice the size of the other leg and they did ultrasound on it and got a blood clot. They put him up on blood thinners (Unspecified Medication) now today he had an appointment with the doctor in the room and when he was there he went to the bathroom and then he was peeing a lot of blood. Doctor told him that It should be okay if stop taking the blood thinners and she cleared up and that's it and I am like freaking out that why would they not got him to the hospital. He went to the hospital because it's the other blood clot. People saying this is on the blood thinner. I don't know why is they rolling up a lot. Nobody wants to say its from the vaccine but it is happen in half an hour within the vaccine, its started."</p> <p>Information about Lot number has been requested.</p>

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1320189	5/15/2021	NY	66	F	2/25/2021	2/25/2021	visual and neurological issues; She says she got her phone and it affected her brain; her fever went down; She gives her height and says that she shrunk; hoarse was reported as worsened; hoarse; slept a lot; 12 to 16 hours for the next 5 days; trouble walking; trouble seeing; This is a spontaneous report from a contactable other nurse (patient). This nurse reported 2 reports for same patient, this is first of 2 reports. A 66-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose via an unspecified route of administration, administered in left arm on 25Feb2021 11:00 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included ongoing asthma, she says she has been having respiratory problems and asthma since she was a teen; covid-19 from 06Feb2020 to 18Feb2021, She says she didn't see her doctor until the day she got better. She says she realized she was in big trouble and need help. She says she got her phone and it affected her brain. She says she she 5 sons and she flipped around her phone having trouble. She says he has had the same phone for 4 years. She says she was fine that day, 18FEB2021, that she had half of the symptoms, and her fever went down. She says the headache lasted a while; allergies; No thyroid gland, clots; thyroid cancer; tremors that started 7 years ago in one hand. She says she has no thyroid gland. She says she has been taking this since her surgery; she was around 33 years old, and she is 66 now, so for 33 years. She says she had clots. History: She says she takes a lot of medications, a lot of neurological medications. She says the only other pertinent thing is she does have tremors that started 7 years ago in the one hand. She says just before she got the COVID virus, a week before, tremors started in the other hand and progressed rapidly. It is remarked that she thinks she was infected when this started. She says the other one took 7 years to be once a day while this one progressed to be daily. She says she does not take anything for that, she is just trying to increase her activity levels. She says when she was 30 or 40 she was very active. She says the doctors think there is something wrong with her immune system. She says they are trying her on diff medications for asthma; they changed it, added more. She says Advair work beautifully and she doesn't use a breakthrough inhaler. She says ever since

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COVID in 2020, the first week of FEB2020 she thought it was the flu. She says she didn't get any medical help, she was in severe shape, and her headache was severe. She says she crawled to the bathroom once a day, she had a high fever and it felt like a snake effect of a cobra all over, squeezing. She says her pulmonologist gave her Spiriva and that has opened her up, once a day. Caller had gotten to the point she couldn't take 5 or 6 steps and couldn't breath. She gained a ton of weight cause she couldn't move related to this breathing issue. She thought she wouldn't recover, he gave samples once a month. She says she saw him a week ago, 10 days ago maybe. She says she had shortness of breath and couldn't walk. She clarifies she is talking about when she had COVID last year, not this current shot report. She says she didn't consider these current side effects a problem, she expected some side effects and they went away. She says the shortness of breath walking problem was due to shortness of breath; that was what happened with COVID. She says her hoarseness is related to spring allergies and is due to the climate and it is usually from 10APR to 16JUN. She says she gets a sinus drip and congestion and that she is on 5 different medications for that. She says she has more trouble with inhouse allergies. She says she gets trouble as soon as the trees pop. She has had hoarseness for about a year and the allergies have really started around 10Mar2021 for this year. Concomitant medication included ongoing levothyroxine sodium (SYNTHROID) taken for thyroid cancer. She says something new was 8 weeks out she got the flu shot. She says she has a lethal allergy to egg white so she has never had a flu shot her entire life. She says she asked her doctor why they didn't get the one without egg whites. She says they made one without egg white in the 1990's. She says 08DEC2020 was her first flu shot. She says everyone wants her to take more shots but she won't take any more. She says COVID and the flu shot are enough for one year. She says if they have the COVID booster then she will take that one but not any other. She says no but she was told don't ever have anything with egg white in it so she never had the flu shot, she refused. The patient took first dose of BNT162B2 on 04Feb2021 for COVID-19 immunisation and experienced headache. The patient experienced trouble walking (Disabling) on 25Feb2021 19:00 (about

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7:00pm in the evening) with outcome of recovered on 25Feb2021, trouble seeing (Disabling) on 25Feb2021 19:00 (about 7:00pm in the evening) with outcome of recovered on 25Feb2021, hoarse was reported as worsened (medically significant) on Mar2021 with outcome of not recovered, hoarse (medically significant) on Mar2021 with outcome of not recovered, slept a lot; 12 to 16 hours for the next 5 days on 25Feb2021 22:00 (10:00pm at night) with outcome of recovered on 2Mar2021. The caller is calling about the COVID 19 vaccine. She says she had side effects but she would consider them mild. She says the shot was wonderful. She says she has put off reporting this. Caller remarks she has shrunk, when providing her height. Caller apologizing when clearing her throat, says sorry she is so hoarse today. She says the second dose they came and went away. She says the second shot was at 11:00 am. She says the second shot was on 25FEB2021. She says she had a lot of water to drink then 7 hours after the second shot, about 7:00pm in the evening, she had 45 minutes of visual and neurological issues. She says she had trouble walking, she was stumbling with her feet, she had trouble with eyesight, different sections of her vision was together. She says this was like when she had 5 children. She says her pregnancy during the first 3 months she had neurological visual experiences of shadows put together and at the end of the pregnancy, 2 months after delivery, it would go away. She says she is in an apartment and she sat down then it was 45 minutes total for both occurrences at the same time. She also reports that she slept a lot; 12 to 16 hours for the next 5 days. She says on the 6th day she was fine, no symptoms and no sleepiness. She says it occurred the evening at 10:00pm at night, then it went up through the 5th day afterwards. When asked seriousness of the sleeping event she says none of the above. She says she lives in a senior housing area, they all got it at the same time, that there was only one person who declines. She says almost everyone had sleepiness for at least 3 days afterwards. She says she is still battling the COVID after effects, it was disrupting her breathing. She says she was glad she got the shot, she is glad she was able to do it. She says her second dose seemed to be around 11:00am. For the second dose lot number she reads GL92 then AA or 00. She does not see an

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expiration date or NDC number for the first or second dose. She says her second dose was in her left arm up high near the shoulder, upper arm high. She says she didn't feel either of them. She says that she was put on BREZTRI Expiration date, lot number, and NDC number not provided. She says her doctors thought she had COPD but she didn't; it doesn't work for people over 70. She says the cardiac problem was with a respiratory medication. She says it was Trelegy. She does not have an expiration date, lot number, or NDC number for Trelegy. She says she is not sure where she put the container but she does have it somewhere. She says it affects the QRS. She says when she had COVID she was sneezing and in August her hair fell out. She says she had a fever for 4 days that week then she went away. She says she wondered if she had the long haul COVID. She says the doctor gave her something to make her lungs spring open. She says she is currently hoarse due to spring allergies, not because of the shot. A medication called Breeze didn't work for her. She says that she was put on BREZTRI Expiration date, lot number, and NDC number not provided. She says her doctors thought she had COPD but she didn't; it doesn't work for people over 70. No additional vaccines administered on same date of the Pfizer suspect. All events did not require a visit to Emergency Room or Physician Office. No family medical history relevant to AE. No relevant Tests. The reporter considered events trouble walking, trouble seeing, slept a lot; 12 to 16 hours for the next 5 days were related to covid 19 vaccine, event hoarse was unrelated to covid 19 vaccine. The outcome of other events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the available information there is not a reasonable possibility that the drug contributed to occurrence of the events, a possible contribution of the drug to the event pyrexia cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate –data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021493623 same patient/drug, different

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vaccine dose/event.

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1320198	5/15/2021	NY	84	F	3/26/2021	4/1/2021	<p>This is a spontaneous report from a contactable nurse (patient). An 84-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8730), via an unspecified route of administration, administered in Deltoid Left on 26Mar2021 as 2nd dose, single for covid-19 immunisation. Medical history included cholesterol abnormal. Concomitant medications included cholesterol medication. The patient previously received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6202), administered in left arm on 26Feb2021 for COVID-19 Immunization. The patient states she had no immediate side effects. She states that two weeks, after the second dose (in Apr2021), she developed unbearable body aches, specifically in her arms and legs. The patient states she was unable to pick up her right leg and put it over her left leg. She states she is not getting better. The patient is asking if this is a side effect of the Covid vaccine, or is it from something else? She states she was healthy, she walked and was active, before the vaccine. The patient answers as there is very minimal improvement. She states that maybe there is some improvement because she has been taking Ibuprofen and Tylenol. The patient states her event has improved with the medications but they start to come back once the medications wear off. The patient stated she received her Pfizer Covid vaccine first dose in Feb and second dose in march. She stated 2 weeks after the second dose (in Apr2021) she is having terrible muscle aches in her arm and leg (calf muscle) she has to take ibuprofen to get through the day. The patient wanted to know about reports of it. She stated she has seen her doctor and done some tests. She has gone off her cholesterol medication and got checked for clots (no clots). The patient stated, "I got the vaccine in couple of week, I had no problem when I got the vaccine not even a sore arm. couple of weeks later I have developed excruciating pain and aching in my leg and my left arm. I went to the doctor and had whole panel of test and they ruled everything out I don't have Lyme, they took me of my cholesterol medication, I bought a new mattress, I am not sleeping in new mattress. I only take one medication cholesterol medication which I stopped and I am in agony and I wanted to know, if this is possibly connected to the COVID vaccine because I was really really healthy</p>

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							individual before they started." There is no additional Vaccines Administered on Same Date of the Pfizer Suspect, no prior Vaccinations (within 4 weeks), no AE following prior vaccinations, no patient's Medical History (including any illness at time of vaccination). The patient states she feels her medications are not relevant to the report. The outcome of the events was unknown.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events. There is limited information provided in this report. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
1320205	5/15/2021	MO		F	4/27/2021	4/1/2021	she has a blood clot; had a blood clot and it looked like dark red bruises on the left side of her chest; This is a spontaneous report from a Pfizer sponsored program COVAX US support from a contactable consumer (patient). A female patient of unknown age received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 27Apr2021 at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient previously received first dose of BNT162B2 on 06Apr2021. The patient had a blood clot and it looked like dark red bruises on the left side of her chest. She just noticed it after she received her 2nd dose on 27Apr2021. The outcome of the events was unknown. Information on the lot/batch number has been requested.



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1320242	5/15/2021	NV		F	4/6/2021	4/16/2021	deathly ill after the vaccine; blood clots in stool; This is a spontaneous report from a contactable pharmacist. An adult female patient received COVID-19 vaccine (UNSPECIFIED TRADE NAME), via an unspecified route of administration on 06Apr2021 (Batch/Lot Number: Unknown) as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. Facility where the most recent COVID-19 vaccine was administered: Pharmacy or Drug Store. The patient experienced deathly ill after the vaccine and blood clots in stool on 16Apr2021 with outcome of recovering. Patient stated they had blood clots in stool 2 weeks after the vaccination but was deathly ill after the vaccine. The adverse event result in Doctor or other healthcare professional office/clinic visit. Information on the lot/batch number has been requested.; Sender's Comments: Based on the temporal relationship, the association between the events "deathly ill" and "blood clots in stool" with COVID-19 vaccine can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
1320251	5/15/2021	CA		M			blood clot; heart attack; This is a spontaneous report from a contactable consumer. This consumer reported for his father. A male patient of an unspecified age received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced blood clot and had an heart attack on an unspecified date with outcome of unknown. Information on the lot/batch number has been requested.

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1320263	5/15/2021	NC	63	M	3/23/2021		dvt; diarrhea; okay for him to get the second dose outside of the recommended 3 weeks ( 6 weeks and 2 days ); This is a spontaneous report from a contactable consumer. This male consumer reported for himself. A 63-years-old male patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Batch/Lot number was not reported) via an unspecified route of administration on 23Mar2021 as 1ST DOSE, SINGLE for covid-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. On unspecified date patient experienced side effects such as diarrhea and DVT on their left leg. As second dose scheduled on 06May2021 wanted to know if it is okay for him to get the second dose outside of the recommended 3 weeks (6 weeks and 2 days). He would like to know if Diarrhea and Blood Clots are side effects of the vaccine as he is currently experiencing these adverse events. The Outcome of the events were unknown. Follow-up (05May2021): This is a Follow-up spontaneous report from a Pfizer-sponsored program. This contactable male consumer reported side effect from the first dose, second dose scheduled on 06May2021. Medical Information: Were any unaddressed medical questions referred or forwarded to Medical Information: Yes: Customer and/or medical inquiry forwarded or referred to MI. Information about lot/ batch number has been requested.

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1320357	5/15/2021		73	F	2/1/2021	3/1/2021	cough; chest hurts; clots on both legs and stomach; hemorrhage; Blood sugar decreased; Oxygen saturation low; Blood pressure low; Skin discoloration; vein on her right leg was torn; Difficulty breathing; Tiredness; Breast pain; blockage all over the heart; This is a solicited report from A contactable consumer (patient) based on the information received by Pfizer from AbbVie (Manufacturer Control No: 21K-163-3840719-00). A 73-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 intramuscular on 27Feb2021 (Batch/Lot number was not reported) as 2ND DOSE, SINGLE for COVID-19 immunization; adalimumab (HUMIRA), subcutaneous from 2005 (Batch/Lot number was not reported) to Feb2021, at 40 mg/0.4 ml, then subcutaneous from 21Apr2021 (Batch/Lot number was not reported) and ongoing, at 40 mg 1 in 2 week for moderate to severe rheumatoid arthritis psoriatic arthritis. Medical history included patient consumed a pack of cigarette a day from 1967 to 2019, heart attack from 2003 to 2003, abstains from alcohol, and high blood pressure. Concomitant medication included metoprolol taken for high blood pressure. The patient previously took metformin to manage blood sugar. On an unspecified date, the patient experienced cough, chest hurts, clots on both legs and stomach. In 2010, the patient experienced breast pain and blockage all over the heart. She first tried to do the balloon and had three stents on her heart due to blockage sometime in 2010. In Jan2021, the patient had bypass surgery as treatment heart blockage as well. On 18Feb2021, echocardiogram/ECHO showed blockage all over the heart again. In 2021, the patient had difficulty breathing and experienced tiredness easily. In Mar2021, she was told to have an outpatient diagnostic heart catheter procedure and they had to take her by ambulance to be admitted in a hospital, when she moved during the procedure, a vein on her right leg was torn and also had hemorrhage, blood sugar decreased, oxygen saturation low, blood pressure low, skin discoloration. She experienced a recurring pain in between the breast bone after the triple bypass surgery that was done last 09Mar2021 while in the hospital. She also had blood transfusions while hospitalized as treatment for hemorrhage. The patient was hospitalized for the events for 28 days (also reported as 4 weeks). The event vein

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on her right leg was torn was considered life threatening. The events breast pain, blockage all over the heart, difficulty breathing, tiredness, hemorrhage, blood sugar decreased, oxygen saturation low, blood pressure low, and skin discoloration were also considered medically significant. The patient underwent lab tests and procedures which included stress test and echocardiogram/ECHO with unknown result in Jan2021; echocardiogram/ECHO showed blockage all over the heart on 18Feb2021; blood sugar: decreased, blood pressure: low, and oxygen saturation: low, all in Mar2021. The action taken in response to the events for adalimumab was dose not changed. The outcome of vein on her right leg was torn was recovered in Apr2021; hemorrhage and skin discoloration were recovered in Mar2021; clots on both legs and stomach, difficulty breathing, tiredness, blood sugar decreased, oxygen saturation low, blood pressure low was recovering; breast pain, blockage all over the heart was recovered on an unspecified date, while other events was unknown. Causality: Drug : Humira 1.Vein on her right leg was torn Causality as per reporter (Drug/Vaccine) : Not Related Causality as per Mfr.(Drug/Vaccine) : No reasonable possibility 2.Clots on both legs and stomach Causality as per reporter (Drug/Vaccine) : Not Reported Causality as per Mfr.(Drug/Vaccine) : No reasonable possibility 3.Blockage all over the heart Causality as per reporter (Drug/Vaccine) : Not Related Causality as per Mfr.(Drug/Vaccine) : No reasonable possibility 4.Difficulty breathing (Dyspnoea) Causality as per reporter (Drug/Vaccine) : Not Related Causality as per Mfr.(Drug/Vaccine) : No reasonable possibility 5.Hemorrhage Causality as per reporter (Drug/Vaccine) : Not Related Causality as per Mfr.(Drug/Vaccine) : No reasonable possibility 6.Breast pain Causality as per reporter (Drug/Vaccine) : Not Related Causality as per Mfr.(Drug/Vaccine) : No reasonable possibility 7.Skin discoloration Causality as per reporter (Drug/ Dose Not Changed) : Not Related Causality as per Mfr.(Drug/Vaccine) : No reasonable possibility 8.Blood pressure low Causality as per reporter (Drug/Vaccine) : Not Related Causality as per Mfr.(Drug/Vaccine) : No reasonable possibility 9.Cough Causality as per reporter (Drug/Vaccine) : Not Reported Causality as per Mfr.(Drug/Vaccine) : No reasonable possibility

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10.Oxygen saturation low Causality as per reporter (Drug/Vaccine) : Not Related Causality as per Mfr.(Drug/Vaccine) : No reasonable possibility 11.Blood sugar decreased Causality as per reporter (Drug/Vaccine) : Not Related Causality as per Mfr.(Drug/Vaccine) : No reasonable possibility 12.Chest pain Causality as per reporter (Drug/Vaccine) : Not Reported Causality as per Mfr.(Drug/Vaccine) : No reasonable possibility 13.Tiredness Causality as per reporter (Drug/Vaccine) : Not Related Causality as per Mfr.(Drug/Vaccine) : No reasonable possibility Causality: Covid-19 Vaccine 1.Vein on her right leg was torn Causality as per reporter (Drug/Vaccine) : Not Related 2.Clots on both legs and stomach Causality as per reporter (Drug/Vaccine) : Not Reported 3.Difficulty breathing Causality as per reporter (Drug/Vaccine) : Not Related 4.Hemorrhage Causality as per reporter (Drug/Vaccine) : Not Related 5.Breast pain Causality as per reporter (Drug/Vaccine) : Not Related 6.Skin discoloration Causality as per reporter (Drug/Vaccine): Not Related 7.Blood pressure low Causality as per reporter (Drug/Vaccine) : Not Related 8.Cough Causality as per reporter (Drug/Vaccine) : Not Reported 9.Oxygen saturation low Causality as per reporter (Drug/Vaccine) : Not Related 10.Blood sugar decreased Causality as per reporter (Drug/Vaccine) : Not Related 11.Chest pain Causality as per reporter (Drug/Vaccine) : Not Reported 12.Tiredness Causality as per reporter (Drug/Vaccine) : Not Related 13.Blockage all over the heart Causality as per reporter (Drug/Vaccine) : Not Related Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information, the reported events are most likely related to an intercurrent or underlying condition which is not related to the suspected drug. The case will be reassessed if additional information becomes available.

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1320270	5/15/2021	TX		F	3/4/2021	3/1/2021	Patient reported clot developed in calf 1 week following first dose; Confusion; This is a spontaneous report from a contactable consumer (reporting for herself). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Mar2021 (Batch/Lot number was not reported) as 1ST DOSE, SINGLE for COVID-19 immunization; and sarilumab (KEVZARA), via an unspecified route of administration from 05Mar2021 (Batch/Lot number was not reported) at an unknown dose and frequency for an unspecified indication. The patient medical history was not reported. Concomitant medication included enoxaparin sodium (LOVENOX [ENOXAPARIN SODIUM]) taken for an unspecified indication, start and stop date were not reported. In Mar2021, the patient reported that clot developed in calf 1 week following first dose of Pfizer covid-19 vaccine. Also, with a lot of confusion. She stated that she was driving and got lost in her 1 stoplight/1-mile small town. The outcome of the events was unknown. The action taken in response to the event for sarilumab was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

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1320172	5/15/2021	SC	57	F	4/14/2021	4/24/2021	Blood clot; Random bruise on knuckle; Joint pain; Rash; This is a spontaneous report received from a contactable consumer (patient). A 57-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, LOT/Batch number and expiration date unknown) via an unspecified route of administration on 14Apr2021 at 04:00 PM at age of 57-year-old at single dose, unknown dose number for COVID-19 immunization. Patient was not pregnant at time of vaccination and at time of events onset. Medical history included known allergies (unspecified). Compound heft (pending clarification) was reported as other medical history. Prior to vaccination, it was unknown if patient was diagnosed with COVID-19. Since the vaccination, the patient wasn't tested for COVID-19. Concomitant medications included supplements in two weeks. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient had rash on day 10 on 24Apr2021 at 03:00 PM, joint pain on day 11 (25Apr2021), day 12 (26Apr2021), day 13 (27Apr2021) and a blood clot and random bruise on knuckle on day 14 (28Apr2021). Events didn't result in emergency room visit or physician office visit. No treatment received for the events. Outcome of events was recovering. Information about Lot/Batch number has been requested.

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1320283	5/15/2021	ID	36	F	5/4/2021	5/5/2021	found a blood clot in right lung (pulmonary embolism) with no prior blood clot issues; Chest pressure and pain, found a blood clot in right lung (pulmonary embolism) with no prior blood clot issues; Chest pressure and pain, found a blood clot in right lung (pulmonary embolism) with no prior blood clot issues; This is a spontaneous report from a contactable consumer (patient). A 36-year-old female patient (not pregnant) received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date unknown), via an unspecified route of administration, administered in Left arm on 04May2021 at 09:00 AM (at the age of 36-year-old) at single dose for COVID-19 immunisation. Medical history included Hypothyroidism, previous experience with WPW (wolff-parkinson-white) syndrome and SVT (Supraventricular tachycardia), known allergies with Penicillin and latex. No COVID prior vaccination. Concomitant medication included levothyroxine sodium (SYNTHROID, strength: 88 ug). The patient previously received first does of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiration date unknown) administered in Left arm on 13Apr2021 at 07:45 PM (at the age of 36-year-old) at single dose for COVID-19 immunisation. No other vaccine received in four weeks. The patient experienced chest pressure and pain, found a blood clot in right lung (pulmonary embolism) with no prior blood clot issues on 05May2021 at 02:30 AM. Events were resulted in emergency room/department or urgent care, life threatening illness (immediate risk of death from the event). Therapeutic measures were taken as a result of all events included began taking apixoban immediately. No COVID tested post vaccination. The outcome of the events was not recovered. Information on the lot/batch number has been requested.



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1320289	5/15/2021	KS		M	3/25/2021		<p>it is weird clot it is not that area where I got the shot; feeling like I was having heart pain; His left upper chest area has swelling and when he touches it he feels something hard. Pain when he touches; His left upper chest area has swelling and when he touches it he feels something hard. Pain when he touches; His left upper chest area has swelling and when he touches it he feels something hard. Pain when he touches; He feels pressure on his chest; It feels like pain on the heart. It's a sharp needle like pain in some spots; my left arm and also my back there is going to pain seems like needle anything from the back; my left arm and also my back there is going to pain seems like needle anything from the back; This is a spontaneous report from a contactable consumer (Patient) via a Pfizer sponsored program. A male patient of an unspecified age received second dose of BNT162B2 (solution for injection, Lot number: ER8735) via an unspecified route of administration on 25Mar2020, as 2nd dose, single for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient received first dose of BNT162B2 (solution for injection, Lot number: CVS8601) via an unspecified route of administration on an unspecified date, as 1st dose, single for COVID-19 immunization. It was stated that everything was fine on the first day after second dose and then from the second and third day the patient had a pain which was weird clot, and it was not that area where he got the shot. It was like between shoulder and neck, left shoulder, and neck. A kind of in deeper area there was lot of bone and just like where neck was connected to shoulder but it was in front of right. Patient had pain when he touched there in like size of the corn was like he could feel something hard inside and then just started day prior to this report further on the evening and started having chest pain like whole that spot felt like he was having heart pain and his left arm and his back there was going to pain seemed like needle anything from the back. The pain was constant. It was not on chest, it was not like that would come and go, would say it was bearable thing, but it was constant and breath that goes inside his body it was still there when touched, it was still paining. Patient upper left chest area had swelling and when touched it, he felt something hard. It would pain when touched. Patient felt pressure on his chest. It feels like pain on the</p>

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heart. It was a sharp needle like pain in some spots. Patient took aspirin on the day and a day prior to this report. The outcome of the event of all the events was unknown. Additional information about batch/lot has been requested.

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1320314	5/15/2021	MA	52	M	4/21/2021	4/21/2021	<p>Blood Clot in right leg; Severe pain in leg; cry; This is a spontaneous legal report (Marketing Program) from a contactable consumer (patient himself). A 52-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE solution for injection) dose 2 (Batch/Lot Number: EW0770) via an unspecified route of administration, on 21Apr2021 11:30, as single dose for covid-19 immunization. Medical history included Asthma ongoing, Diabetes had been on and off since 2018, Covid-19 in an unspecified date in Jan2021. The patient received dose 1 (Batch no/Lot Number: ER8732) via an unspecified route of administration, on 29 Mar 2021, as single dose for covid-19 immunization. The patient's concomitant medications were not reported. On 21Apr2021 around 11:30-12:00 in the night the patient experienced Blood clot in his right leg, had a severe pain and cannot walk, feels like he's being stabbed in the leg every time he gets up. He had to keep his legs up all the time and not put them down. He stated that his life was going to be upside down for 6 months because of the Covid vaccination. Stated that was unacceptable. Reporter also said that if the blood clot breaks off it could be dangerous. Said it was substantial; it was all the way up to his groin, not its down almost to his knee and goes all the way down to his ankle. Patient went to the hospital last Saturday due to pain in the back of his leg. The pain started 12 hours after the second Covid vaccine. He wanted to cry he was in so much pain. He could not take anything for it. Patient stated that if the clot breaks off, he was dead. So, he had to put everything on hold because he did the right thing which ended up being the wrong thing. Patient stated that the pain in his leg was a 13 or 14 on a scale of 1-10. Patient took Tylenol and Pain patches did not work on a blood clot. Patient stated that when he was in the hospital, 4 different doctors, told him the event was at least 50 if not 100 percent caused by the Covid dose of vaccine. Patient stated that after the first dose of vaccine he was sick as a dog and he said that the clot may have started with the first dose of vaccine, stated that he had a 102 degree fever a few minutes after the vaccination, felt dizzy and thought he was going to fall over. Patient stated that he got the vaccination dose to get his life back and now he could not, that what about in 6 months if he had to get a booster vaccine and probably go through it all over again;</p>

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or to be on quarantine. Patient stated that he went with his 84-year-old mother to get the vaccine. Patient said that the only reason she didn't get a blood clot was because she was already on blood thinners and said that he is the one who takes care of his mom and now he cannot walk barely, he had Covid in January and that people who had Covid shouldn't be taking these vaccinations because they have immunity, he talked to a doctor and a woman yesterday who still have their antibodies a year after having Covid. He said that the vaccine was injuring people. He was hospitalized related to his leg pain and diagnosed with the blood clot from 24 Apr 2021 to 27 Apr 2021. In the hospital he was told to him take Oxycontin or Morphine. He said that he did not want to take those and end up addicted. He said after a motor vehicle accident he had in 2002 he took Naprosyn and it helped, he said could not take that now because he was on a blood thinner. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient had tested COVID-19 positive prior to vaccination. This is to notify that potential legal action from a reporter in the attached source document booked into AER 2021506757 and 2021506972. The outcome of the event Blood Clot in right leg and Severe pain in leg was not recovered, feels like he's being stabbed in the leg was recovered and cry was not recovered. Information on Lot/Batch number was available. Additional information has been requested.

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1320341	5/15/2021	MI		U			<p>I am bleeding heavily because I am getting blood clots and stuff like that; I am bleeding heavily because I am getting blood clots and stuff like that; Lot of pain in my joints and in my bones; Lot of pain in my joints and in my bones; Right side of face, my tongue inside is very swollen and irritated; Right side of face, my tongue inside is very swollen and irritated; Right side of face, my tongue inside is very swollen and irritated; Right side of face, my tongue inside is very swollen and irritated; This is a spontaneous report from two contactable consumers (one was the patient). A patient of unspecified age and gender received the second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: FN6200), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunisation; axitinib (INLYTA), via an unspecified route of administration from an unspecified date (Batch/Lot number was not reported) at 2 pills once a day for clear cell renal cancer; pembrolizumab (KEYTRUDA), route of administration, start and stop date, batch/lot number and dose were not reported for clear cell renal cancer; zoledronic acid (ZOMETA), route of administration, start and stop date, batch/lot number and dose were not reported for the bones. The patient received the first dose of BNT162B2 on unknown date (Lot Number: CL9265) for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was getting terrible side effects from either the axitinib or the pembrolizumab. The patient was bleeding very heavily and the right side of face and tongue inside was very swollen and irritated. The patient was getting a lot of pain in the joints and bones. The patient was bleeding heavily because was getting blood clots and "stuff like that" (as reported). The actions taken with axitinib, pzoledronic acid, and embolizumab were unknown." The outcome of the events was unknown. Follow up (23Apr2021): New information received from a contactable consumer includes reporter details. No Follow-up attempts are needed. No further information is expected. Follow-up (07May2021): This is a follow-up report to notify that the case 2021406450 and case 2021513212 are duplicates. All subsequent follow-up information will be reported under Manufacturer report number 2021513212.</p>

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1320345	5/15/2021	VA	53	F	4/18/2021	4/19/2021	got acute deep vein thrombosis of right lower extremities; inflammation and blood clot in vein; inflammation and blood clot in vein; This is a spontaneous report from a contactable consumer (patient). A 53-years-old female patient reported for herself that received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 18Apr2021 (Batch/Lot number was not reported) at the age of 53-years-old, as single dose for covid-19 immunisation. The patient had no medical history. The patient's concomitant medications were not reported. The patient reported: I got acute Deep Vein Thrombosis of right lower extremities, inflammation and blood clot in vein on 19Apr2021 01:00 AM. The patient was visited by physician in Emergency Room. The reported events were deep vein thrombosis, thrombosis and inflammation, all considered life-threatening. Clinical outcome of the events was not recovered. Lab tests: CBC with auto diff CBC/ ETC. Unspecified therapeutic measures were taken as a result of the events. The patient was not diagnosed with COVID-19 prior to vaccination and since the patient was not vaccinated. Information on the lot/batch number has been requested.

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1320346	5/15/2021	RI	75	M	3/11/2021	4/1/2021	<p>diagnosed with a pulmonary embolism; dry cough; This is a spontaneous report received from a contactable consumer (patient). A 75-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 11Mar2021 10:45 (Lot number: EN620A) as 2nd dose, single (at age of 75-year-old) for covid-19 immunization. Medical history included diabetes mellitus and cholesterol. Concomitant medications in two weeks prior to the vaccination included acetylsalicylic acid (ASPIRIN 81), cyanocobalamin (VITAMIN B-12) and metformin. First vaccine dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), was administered on 18Feb2021 in Left arm (at age of 75-year-old) for COVID-19 immunization, lot number: EL9262. Patient did not receive other vaccine in four weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. It was reported that on 11Mar2021 patient received his second (2nd) shot. Late in Mar2021 or early Apr2021 he developed a dry cough and on 21Apr2021 was diagnosed with a pulmonary embolism. Events resulted in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Onset date of the events was reported as 01Apr2021. Event pulmonary embolism required admission to hospital for one day (dates unknown) event also considered serious as life-threatening. Patient was treated for the events with blood thinner infusion with (w/) Eliquis follow up. It was reported that since the vaccination, the patient has been tested for COVID-19. As of 10May2021, it was reported that the patient had a blood clot in his lung; he has pulmonary embolism in his left lung. The patient had the last shot on 11Mar2021 and he started experiencing a clot two weeks after that and then, he was not diagnosed with the blood clot in 21Apr2021 he believed; he was experiencing coughing system two or three weeks before when he was actually diagnosed with the blood clot. The patient has been treated for blood clot for long, he doesn't know what is that, he was on Eliquis (treatment for blood clot) to break up the clot or still in his blood or whatever the process is, it takes like three months. When he was hospitalized for this, he had been on Heparin drip for about 12 hours heparin blood DNA they had been intravenous. The patient underwent laboratory tests and</p>

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							procedures which included sars-cov-2 test: negative on 21Apr2021. Patient was recovering from the events. Information on the lot/batch number has been requested. Follow-up (10May2021): New information reported from a contactable consumer includes: medical history, concomitant medication and clinical course details.
1320352	5/15/2021	TX	54	M	4/19/2021	4/29/2021	coma; Basilar artery thrombosis; This is a spontaneous report from a contactable consumer. A 54-year-old male patient received bnt162b2 (Pfizer-BioNTech COVID-19 vaccine), dose 1 via an unspecified route of administration, administered in Arm Left on 19Apr2021 10:00 (Batch/Lot Number: EP6955) as 1ST DOSE, SINGLE for covid-19 immunisation. Medical history included psoriatic arthritis from an unknown date and unknown if ongoing. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, the patient has not been tested for COVID-19. Concomitant medications included metronidazole; sulfasalazine; lamotrigine and trazodone all taken for an unspecified indication, start and stop date were not reported. On 29Apr2021 06:00, 10 days after the first shot, the patient experienced come due to a basilar artery thrombosis. The event required emergency room/department or urgent care visit where the patient was subsequently brought to the ICU. The patient received unspecified treatment for the events. The outcome of the event was not recovered. Follow up attempts needed. Further information is expected.



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1320266	5/15/2021	PA		M	2/14/2021	3/18/2021	Acute Deep Vein Thrombosis of the Right Subclavian Vein; Swelling of his right arm; This is a spontaneous report received from a contactable Physician. A 59-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose via intramuscular, administered in right arm on 14Feb2021 (Lot Number: el9269) at single dose for COVID-19 immunization in workplace clinic. Medical history included hypertension, hyperlipidemia, lyme, osteoarthritis. There was no known allergies. Concomitant medications included lisinopril; pravastatin; pantoprazole sodium sesquihydrate (PROTONIX). It was unknown if the patient receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously took first dose of bnt162b2 via intramuscular, administered in left arm on 24Jan2021 (Lot Number: en5318) at single dose for COVID-19 immunization. The patient evaluated in the emergency room on 18Mar2021 for swelling of his right arm. Patient had a venous doppler right ext, which showed acute deep vein thrombosis of the right subclavian vein. The events result in doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care, and serious for life threatening illness. Treatment for the events included rivaroxaban (XARELTO) and referral to hematologist. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was not resolved.; Sender's Comments: Based on the information currently available, causality between reported events Subclavian vein thrombosis and Peripheral swelling and BNT162B2 vaccine cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1320081	5/15/2021			F	4/1/2021	4/25/2021	blood clots, Clots were going down the back of her throat; currently feels very weak; nose bleed; This is a spontaneous report from a non-contactable consumer. This report was received via a sales representative. A 70-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: unknown), single dose via an unspecified route of administration in Apr2021 for covid-19 immunization. The patient's medical history was not reported. The patient has been on icosapent ethyl (VESCEPA) and ibuprofen for years and currently feels very weak on 25Apr2021. Concomitant medications were unknown. The patient experienced nose bleed blood clots throughout the week on 25Apr2021. Clots were going down the back of her throat. The patient had to seek medical attention. and currently feels very weak on 25Apr2021, two weeks after vaccination. The outcome of nose bleed blood clots and weak was unknown. No follow-up attempts are possible. No further information expected.
1319733	5/15/2021	TX	41	F	2/23/2021	3/1/2021	Early and irregular menstrual cycle. After receiving the 2nd moderna vaccine my menstrual cycle was almost 2 weeks early, it was also very heavy flow with lots of blood clots, and was very painful. Every period I have had since receiving the COVID vaccine has been uncomfortable and abnormal for me. Before I had a clockwork period that would start every 28th day, flow was heaviest on day 1 and 2(never more than 3 Menstrual cups full) and then tapered off on day 3 and 4 and no cramps. My periods( hemorrhaging, clots and cramps) are much longer than 4-5 days per-vaccine, they are now lasting up to 2 weeks.

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1319774	5/15/2021	NC		F			<p>BLOOD CLOT IN LEFT LEG/MUSCLE IN LEG TIGHTENED UP/CHARLEY HORSE LIKE/LEFT THIGH STILL HURT; FATTY LIVER; This spontaneous report received from a patient concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company was unable to perform follow-up to request batch/lot numbers. Concomitant medications included ustekinumab used for unknown indication. On an unspecified date, the patient experienced blood clot in left leg/muscle in leg tightened up/charley horse like/left thigh still hurt, and had a fatty liver a few weeks ago and was hospitalized. The patient stated that she took the vaccine of covid-19 three weeks ago and developed a left leg blood clot and had muscle in leg tightened up (real tight) like charley horse. Then, she went to the PCP (primary care physician) who told her for the valley imaging an ultrasound laboratory test which discovered the clot. On 30-APR-2021, the patient got admitted to the hospital and was discharged on 02-MAY-2021. The patient was hospitalized for two days. Treatment medications (dates unspecified) included: apixaban and she was doubled up on eliquis (apixaban) for blood clot in left leg. On the day of report, she stated that left thigh hurt still ongoing. (The patient have a colonoscopy laboratory test on 09-JUN-2021). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the blood clot in left leg/muscle in leg tightened up/charley horse like/left thigh still hurt and fatty liver was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0 20210506567 -COVID-19 VACCINE AD26.COV2.S- Blood clot in left leg/Muscle in leg tightened up/Charley horse like/Left thigh still hurt, Fatty liver. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1319775	5/15/2021	MI	38	F	3/23/2021		<p>TUMMY TUCK; BREAST IMPLANT; FLU LIKE SYMPTOMS; SORE ARM; This spontaneous report received from a patient concerned a 38-year-old female. The patient's height, and weight were not reported. The patient's concurrent conditions included mild asthma. Patient was non-alcoholic, and non-smoker. From an unknown date, the patient was taking birth control (unspecified). The patient had no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808609, and expiry: 09-JUN-2021) dose was not reported, administered on 22-MAR-2021 at 12:26 for prophylactic vaccination to left arm. No concomitant medications were reported. On 23-MAR-2021, the next day after vaccination, she had Flu like symptoms like fever (not too high, body feels warm), chills, light cough, arm was sore and body aches for the whole next day. On 23-MAR-2021, she had a COVID 19 test because she was travelling to other country and the test came back negative. On 16-APR-2021, about 3 weeks later, she had major surgeries including Tummy Tuck and Breast Implant. She thought she was taking a big risk especially after hearing on the news about blood clots. Her surgeries went well with no complications. She didn't have any symptoms of blood clots. She was now recovering from the surgeries and was doing great so far. She wanted her case to be useful for Janssen to help with research. She was willing to share the documents and reports from her surgeries if needed. Patient does not have a PCP (primary care physician) at that time. Laboratory data included: COVID-19 virus test (NR: not provided) as negative. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from flu like symptoms, and sore arm on 24-MAR-2021, and was recovering from breast implant, and tummy tuck. This report was serious (Other Medically Important Condition).; Sender's Comments: V0-20210506581-Covid 19 Vaccine- Tummy Tuck and Breast Implant. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1319778	5/15/2021	VA	66	F	4/28/2021	DEATH; BLOOD CLOT; This spontaneous report received from a health care professional concerned a 66 year old White and not Hispanic or Latino female. Initial information received from the health care professional on 05-MAY-2021 was processed with additional information obtained from live follow up with health care professional on 06-MAY-2021. The patient's height, and weight were not reported. The patient's concurrent conditions included high blood pressure, diabetes, high cholesterol, non smoker, non alcohol user and other pre-existing medical conditions included no known allergies, no drug abuse or illicit drug use. Lab work was done 3-4 months ago, the results of which were unavailable. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 202A21A, and expiry: Unknown) dose was not reported, 1 total, administered on 10-APR-2021 possibly left arm for prophylactic vaccination. Unspecified concomitant medications were reported. On 28-APR-2021, the patient developed right leg pain and right leg swelling also began around this time as well. On 04-MAY-2021, the patient died from blood clot. An autopsy was not performed. The reporter stated that the patient's death was related to Janssen covid-19 vaccination and blood clots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of blood clot on 04-MAY-2021. This report was serious (Death).; Sender's Comments: V0:20210509157-JANSSEN COVID-19 VACCINE- Death, blood clot - These events are considered unassessable. The events have a compatible/suggestive temporal relationship, are unlabeled, and have unknown scientific plausibility. There is no information on any other factors potentially associated with the events.; Reported Cause(s) of Death: BLOOD CLOT	

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1319782	5/15/2021	WA	38	F	4/12/2021		LEG PAIN, ONE WORSE THAN THE OTHER; HEART BEATING FAST; COLD SWEAT; THROAT CLOSING UP; HANDS AND FEET SWOLLEN; BLOOD PRESSURE UP A LOT; BODY ACHE; DIZZY; FELT VERY BAD; This spontaneous report received from a patient concerned a 38 year old female. The patient's height, and weight were not reported. The patient had no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, batch number: 202A21A, and expiry: 31-DEC-2069) dose was not reported, 1 total, administered on 12-APR-2021 for prophylactic vaccination on left arm. No concomitant medications were reported. On 12-APR-2021, the patient experienced heart beating fast, cold sweat, throat closing up, hands and feet swollen, blood pressure up a lot, body ache, dizzy and felt very bad shortly after vaccination approximately within 5 to 10 minutes. In the 15 minutes of post vaccine observation, emergency services were called and the ambulance/EMTs came and helped stabilize the patient. The patient conveyed when she had arrived home that day after receiving emergency services she did not felt well at all and felt very bad. The patient was still had same symptoms at home that experienced shortly after vaccination, the symptoms did not resolve. The symptoms had lasted for two weeks. On 19-APR-2021, the only symptom patient had was strong leg pain in both legs, one worse than the other and was hospitalized (date unspecified). The patient's legs get swollen still and the pain remained to be intense. The patient's HCP was aware and was monitoring the patient. On 04-MAY-2021, Laboratory data included: Diagnostic ultrasound (NR: not provided) Results pending to rule out blood clots in the leg. Laboratory data (dates unspecified) included: Blood test (NR: not provided) Cleared, CT scan (NR: not provided) Cyst, but she complained no pain there and Urinalysis (NR: not provided) Cleared. The patient was told to go to clinic and the patient had followed up with clinic, then the patient was told to visit hospital as no appointment. The patient needed to be seen at a hospital and that was when she returned back to hospital a couple days after. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from heart beating fast, cold sweat, throat closing up, blood pressure up a lot, and dizzy on 19-APR-2021, and body ache on APR-2021, had not

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1319803	5/15/2021			U			<p>recovered from leg pain, one worse than the other, and hands and feet swollen, and the outcome of felt very bad was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210513962 -covid-19 vaccine ad26.cov2.s-Pain in extremity. This event(s) is labeled per RSI and is therefore considered potentially related.</p> <p>BLOOD CLOTS; HEART ATTACK; This spontaneous report received from a social media via a company representative concerned a patient of unspecified age and sex with unknown ethnicity. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number and expiry were unknown) 1 total dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient experienced heart attack due to blood clots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the heart attack and blood clots was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210522101-Covid-19 vaccine ad26.cov2.s-Blood clots, Heart attack. This event(s) is considered un-assessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1320023	5/15/2021	NY	29	F	4/15/2021	4/22/2021	A retinal vein occlusion, and I noticed right away; I scheduled an appointment with a retina specialist, and I was told I had a small blood clot in my right away; Exactly seven days after, something happened to my right eye that caused me issues with my vision.; This is a spontaneous report from a contactable consumer (patient). A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in arm left on 15Apr2021 18:15 (Batch/Lot Number: EW0162) as single dose for COVID-19 immunisation. Medical history included type 1 diabetes and thyroid issues, allergic to shellfish and to fluconazole. Concomitant medications included insulin and thyroid medication. Exactly seven days after (on 22Apr2021), something happened to patient's right eye that caused issues with her vision. Patient scheduled an appointment with a retina specialist and was told patient had a small blood clot in right away. A retinal vein occlusion and patient noticed right away because it was right in the middle of vision field/where the light enters through in the eye. Patient was type 1 diabetic with perfect control and patient had never had issues with vision (even got checked last year before COVID and no problems). Her endocrinologist did not think it was diabetes related either. The only different thing was the vaccine. Now patient was not sure if she should take the second dose and also her retina doctor wanted her to get checked for further blood clots to make sure she was okay. No treatment was received for the events. The events resulted in physician office visit and disability. Outcome of the events was not resolved.



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1320179	5/15/2021	CA	76	F	2/23/2021	2/25/2021	<p>Left distal artery thrombus 2 days after receiving covid vaccination in left arm; This is a spontaneous report from a contactable physician. A 76-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), intramuscularly, administered in the left arm on 23Feb2021 (batch/lot number and expiration date were unknown) as an unknown dose number, single for COVID-19 immunization. Relevant medical history included chronic kidney disease (CKD), vitamin (vit) b12 deficiency, vit d deficiency, and hypertension (htn); all from an unknown date and unknown if ongoing. The patient received other unspecified medications for hormone replacement therapy within 2 weeks of vaccination. The patient previously took tramadol and gentamicin, from which the patient experienced known allergies. The facility where the most recent COVID-19 vaccine was administered was unknown. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 25Feb2021, the patient experienced left distal artery thrombus 2 days after receiving COVID vaccination in left arm. The adverse event (AE) resulted in a doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care, as well as hospitalization for 6 days. Therapeutic measures were taken as a result of left distal artery thrombus 2 days after receiving COVID vaccination in left arm, which included embolectomy and anticoagulation. The patient recovered from the event on an unspecified date. Information on the batch/lot number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event peripheral artery thrombosis cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as</p>

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any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

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1320074	5/15/2021	CA	61	F	1/30/2021	1/30/2021	<p>Second blood clot that traveled to her brain which caused her to have a stroke; Blood clot in her right leg; Weight Loss from 258 pounds, down to 208 pounds, back up to 214 pounds.; She has to learn how to walk again, she is in a wheelchair now; Having Problems Swallowing from the Stoke; Speech went down to 25% and now she is at 50%, because of the Stroke; high blood pressure; slept five days; Arm was Sore; Body was Sore; Diarrhea; Slept and was Totally Exhausted; This is a spontaneous report received from a contactable consumer (husband of the patient) and a contactable other healthcare professional. This consumer reported similar events with different doses of the same product; this case refers to dose 2; only this case is serious. A 61-year-old adult female received the second dose of BNT162B2 (solution for injection, Lot EL3246 expiry information not provided) as a single dose via an unspecified route on 30Jan2021 at 13:45 (at 61-years-old) for COVID-19 immunization. Relevant medical history included ongoing seizures (1964; began at 5 years old, minor seizures; under control in 1984, possibility configuration it is the right cocktail), and wound on her left leg (that was being treated by a wound doctor for the last 7 years). Concomitant medications included gabapentin; 300mg three times a day by mouth (6am, 2pm and bedtime) ongoing from 2014 for nerves; valproate semisodium (DIVALPROEX; 500mg two tablets in the morning and one tablet at 6pm ongoing from 2010 for seizures furosemide 20mg every 48 hours (odd days); States she takes it to reduce swelling (diuresis) on the leg wound leg; states he gives it to her on the odd day of the month from an unspecified date; metoprolol (50mg) one tablet twice a day (6am and 6pm), for Blood pressure management; ascorbic acid, zinc (VITAMIN C WITH ZINC; 500mg/50mg) once daily from an unspecified date for an unspecified indication; acetylsalicylic acid (ASPIRIN) 81mg once daily from an unspecified date for an unspecified indication; and pramipexole 0.5mg once daily at 6pm ongoing from an unspecified date for seizures. The patient previously received COVID-19 immunization with the first dose of BNT162B2 (solution for injection; Lot EL1284) on 09Jan2021 (at 61-years-old) and experienced arm was sore, slept for two to three-days, body was sore, and diarrhea. The consumer reported that on 30Jan2021, the patient experienced her arm was</p>

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sore, her whole body was sore for about five days, she had diarrhea for five days, and she for slept five days and was totally exhausted. The consumer then reported that on 22Feb2021, she developed a blood clot in her right leg. The reporter explained that her leg swelled up and turned dark blue, almost black. The consumer reported that the patient was immediately rushed to the hospital. Caller states they did all sorts of tests and confirmed she had a blood clot in her right leg. States she was hospitalized from 22Feb2021 through 26Feb2021, so for five days. Caller states the leg went back to normal color, the swelling went down and she felt good. Caller states they came home on 26Feb2021, and she was up moving around, and everything was wonderful. On an unspecified date in Feb2021, around the time of the first blood clot, the patient was diagnosed with high blood pressure. Caller states on 12Mar2021 she had a second blood clot that traveled to her brain which caused her to have a stroke. Caller states when they got to the hospital they said she had a stroke from a blood clot that was somewhere in her system and it traveled to her brain. Caller states she was hospitalized from 12Mar2021 through 16Mar2021 when she was released from the hospital. Caller states she was too sick to go home so she was transferred to Rehab Center. She was there from 16Mar2021-27Apr2021. Caller states on 27Apr2021, she was transferred for rehab. Caller states at the center they only give rehab once a day for 30 minutes and he only works five days a week. Now she gets three hours of physical therapy a day and it is seven days a week. States they are working to get her to walk again and she is receiving speech therapy. States she has to learn how to walk again. Caller states her lowest weight was 208lbs, and they weighed her in yesterday and she was at 214lbs. Caller states with the stroke when she was at the hospital, they put her on baby food because she was having problems swallowing. While at rehab center she went from baby food to mechanical food. On 27Apr2021 she went to regular food. Speech because of the stroke went down to 25% and now she is at 50% and she is also getting one hour of speech therapy at hospital. Caller states they recognized it is important to get as much therapy as possible in the first 90 days, they call it a boot camp and patients are limited to 90 days to repair the damage. After 90 days, that is it.

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States that is why it was important to transfer her to hospital to heal and get back to normal. Caller states she is in a wheelchair and they are trying to get her to stand up. Caller states at the hospital they were able to get her to take 2 steps. At Hospital they were able to get her to do special training and he was able to get her to take 4 steps. Caller states he has no idea where she is with the walking right now. States she did not do anything on the 27Apr2021, because that was arrival date. Therapy started yesterday on 28Apr2021 at Hospital. The consumer also reported that the patient's current weight is 214 pounds, from 258 when she took the shot and down to 208 pounds on an unspecified date in 2021. Treatment for the events included occupational, physical and speech therapies, as well as apixaban (ELIQUIS), rivaroxaban (XARELTO), and spironolactone 25mg once a day; takes in the evening at 6:00p.m. ongoing from 12Mar2021 for hypertension. The outcome of the events arm was sore, body was sore, diarrhea, and slept and was totally exhausted and slept five days was recovered on 04Feb2021. The outcome of the event blood clot in right leg was recovered on 26Feb2021. The outcome of the event second blood clot that traveled to her brain which caused her to have a stroke was recovered with sequelae on an unspecified date in 2021. The outcome of the event Having Problems Swallowing from the Stoke was recovered on 27Apr2021. The outcome of the events speech went down to 25%, back up to 50%, and weight loss from 258 pounds, down to 208 pounds, back up to 214 pounds was recovering. The outcome of the event high blood pressure was unknown.; Sender's Comments: Linked Report(s) : PFIZER INC-2021484454 PFIZER (Same reporter/patient/different doses/events)

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1320173	5/15/2021	NY	37	F	4/22/2021	4/29/2021	<p>her chest didn't feel normal/ she had shooting "things" in her chest, and she felt weird; really bad chest pain; when the chest pain first started, she couldn't move or breath; when the chest pain first started, she couldn't move or breath; she had shooting pains in her left breast area. She said after an hour, the shooting pains moved from her left breast area to the center of her chest; This is a spontaneous report received from a contactable consumer (patient). A 37-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, LOT number: EW0169, expiration date unknown) via an unspecified route of administration at arm left on 22Apr2021 between 07:00-07:30 at age of 37-year-old at single dose for COVID-19 immunization. Medical history was reported as none. Patient had no history of all previous immunization with the Pfizer vaccine considered as suspect and no additional vaccines administered on same date of the Pfizer suspect. The events required a visit to emergency room. Physician Office visit was not required. There was no prior vaccinations (within 4 weeks). Concomitant medications included acetylsalicylic acid (ASPIRIN (E.C.)), paracetamol (TYLENOL 8 HOUR). Patient had her first COVID-19 Vaccine dose one week and one day ago on 22Apr2021. She said she was rushed to the hospital last night on 29Apr2021 (at around 11:00 PM) because she thought she was having a heart attack. She said she had really bad chest pain that lasted about 30 minutes. She clarified when the chest pain first started, she couldn't move or breath. She said she took an aspirin before she went to the hospital. She said she still had a shooting pain in her chest, today on 30Apr2021. She said she wanted to know what was going on. She said while she was at the hospital (Emergency Room), she had blood work done on 29Apr2021, and she had no blood clots. She said she had a (chest) x-ray done on 29Apr2021, and the (chest) x-ray was fine. She said her heart was monitored, and her heart was fine, but her left chest still had pain. She said she was a healthy 37 year old, who had no types of problems. She said the only thing she had recently was the COVID-19 Vaccine. She said she wanted to know if she should get the second COVID-19 Vaccine, or if the second COVID-19 Vaccine would kill her. The caller was advised she would be transferred to Pfizer Medical Information for further</p>

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assistance. Patient reported she liked to Google, and was not sure if anybody had called Pfizer to go and report if they experienced chest pain after getting the COVID-19 Vaccine. She said she was not sure if the hospital was going to report what happened to her. She said she asked the (emergency room) doctor last night about people experiencing chest pain after getting the COVID-19 Vaccine. She said the doctor told her people with COVID complain about chest pain. She said what the doctor said didn't mean anything because he was talking about the COVID-19 Virus, and not the COVID-19 Vaccine. She stated she took 1 Bayer brand Aspirin 81mg (Lot Number: N8A94D0 or O, Expiration Date: Sep2022) before she went to the hospital for chest pain. She stated the hospital gave her Ketorolac to treat her chest pain. She said the Ketorolac was given to her in an IV form through an IV access in her arm. She said she did not have the Ketorolac dose, NDC, Lot, and Expiration Date. She reported that on 29Apr2021, the hospital took some urine and blood tests, a chest x-ray, and an EKG which was normal. She said beside the Ketorolac that was all the hospital (emergency room) did. Patient reported she took Tylenol 500mg caplet (Lot Number: AAA103, Expiration Date: Sep2024) if she had a headache, but usually didn't take medication. Reported while waiting for the doctor to see her at the hospital (emergency room) on 29Apr2021, she had chest pain for about 5-10 minutes. She said the chest pain calmed down, but she had shooting pains in her left breast area. She said after an hour, the shooting pain moved from her left breast area to the center of her chest. She said the chest pain was not as bad today (30Apr2021), as it was last night. She said her chest didn't feel normal on 30Apr2021, and she still had the shooting pains. She said after she had been talking with the Pfizer agent, she had shooting "things" in her chest, and she felt weird. No further details provided. Events were serious as hospitalized. Outcome of chest pain was recovering, of the other events was unknown. Communication: The caller was provided with phone number of option 3, and hours of operation of Monday through Friday, 8AM to 8PM ET & Saturday and Sunday 9AM-3PM, prior to warm transfer. Follow-up attempts are needed. Further information is expected.

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1320089	5/15/2021	NJ	68	F	12/29/2020	3/15/2021	DVT to right popliteal vein; This is a spontaneous report from a contactable physician (patient). A 68-year-old female patient received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EL0140), intramuscularly, administered in left arm, on 29Dec2020 (at the age of 68-years-old) at 1st dose, single for COVID-19 immunisation. Medical history included type II diabetes and hypertension. The patient was not pregnant. No COVID prior vaccination and no COVID tested post vaccination. The patient had no known allergies. Other medications in two weeks included metoprolol, ramipril and metformin. No other vaccines were received in four weeks. The patient experienced deep vein thrombosis (DVT) to right popliteal vein on 15Mar2021. The event resulted in doctor or other healthcare professional office/clinic visit. Treatments were administered as a result of the event and included ELIQUIS, bed rest, legs elevated. The patient was recovering from the event.; Sender's Comments: Based on the temporal relationship, the association between the event deep vein thrombosis with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.



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1320109	5/15/2021	NY	69	M	3/11/2021	3/1/2021	Blood clots; Delirious; Oxygen was down to 80%; Sepsis; E. coli/sepsis with cultures of E. coli; C-diff; sick; Shaking uncontrollably; Achy; Extremely high fever/a high fever of 103 F; Chills; Aneurysm in his leg; Bleeding from somewhere; weak; missed his second dose of the Pfizer COVID-19 vaccine; Caller says her husband's kidney was failing too while he was in the hospital; This is a spontaneous report from a contactable consumer reported for her husband. A 69-years-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in arm on 11Mar2021 18:00 (Lot Number: EV6206) as single dose for covid-19 immunization. Medical history included Kidney transplant from 1998, same kidney all these years, on immune medication, polycystic kidney disease from 1998, the transplant saved him in 1998, blood pressure high went along with the polycystic kidney disease, had it for a while, Type 2 diabetes mellitus this was diagnosed probably about four years ago and immunocompromised. There were no concomitant medications. The patient had the first dose of the Pfizer vaccine on 11Mar2021, "he felt okay first evening, Friday was okay, Saturday 13Mar2021 achy, Sunday running a high fever of 103 F, he started to get chills. Then Around 3am (Early Monday on the 15Mar2021) called the ambulance, oxygen was down to 80% he was shaking uncontrollably, temperature was still 103 F when they took it and even at the hospital was the same temperature. He was delirious on 15Mar2021. When he got to Emergency Room he was in critical section, had to put on BiPAP with 100% oxygen, When in the ambulance they tested for covid and was negative each time he was tested for covid he was negative. He was in the hospital from 15Mar2021 to 24Mar2021, in critical care unit. He Turned out having sepsis, E.coli, had to put him on strong antibiotics. He developed CDIFF on 15Mar2021, and an aneurysm in his leg in Mar2021 and needed a blood transfusion. They were trying to rule out blood clots and did sonogram and found it. His blood was going down, he was bleeding from somewhere and had to have a transfusion. They did a procedure on the leg to break up the aneurysm twice. On BiPAP for a few days and then did the medium one and then able to take off oxygen when he went home. He came home on antibiotics and tons of medication. Should he get the

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second vaccine? Is it related? Is it to late to get the second vaccine? following Sunday he had an extremely high fever and was shaking uncontrollably on 14Mar2021. He was told to get the shot by his provider. She had to call an ambulance, he almost died, and she didn't know if it is related to her husband getting the vaccine. They put her husband on a BiPAP with 100% O2 when he went to the hospital by ambulance and was admitted on 15Mar2021, which he was on the BiPAP a couple days then went on to the second level, then right before he came home he was weaned off of oxygen. They kept testing him for COVID every day, because the symptoms were similar but they tests kept coming up negative. On 15Mar2021, the patient had sepsis, with cultures of E. Coli, and very contagious C-diff, he was sick from the 15th to the 24th for all those things. She didn't know if the vaccine brought it on if it was brewing in him before that, or if it had to nothing to do with vaccine. He also had an aneurysm in his leg and had a medical procedure where they had to go in and take care of it to break up the aneurysm. The patient's kidney was failing too while he was in the hospital. The patient missed his second dose of the Pfizer COVID-19 vaccine due to his hospitalization from 15Mar2021 to 24Mar2021. She would like to know if it would still be recommended for the patient to get the second shot of his COVID-19 vaccination since he is past the deadline to get it, is it going to be too late for him to get the second dose to be fully vaccinated and effective to get it after waiting this long? His first dose was injected about 06:00PM in unknown arm. The patient had a fever Saturday evening, clarified to being 13Mar2021, which was higher the next day on 14Mar2021 and reached 103 degrees Fahrenheit, and he went to the hospital by ambulance at 03:00AM 15Mar2021. His fever started getting higher late Saturday to Sunday and he got progressively worse. The patient had had serious complications before related to his health problems, but she had never had to call an ambulance before this. The patient had chills on Saturday 13Mar2021 and then Sunday evening he was shaking and it wouldn't stop so she gave him Tylenol, then she called the ambulance Monday morning. The patient can't take anything more than Tylenol, and he never usually takes anything. The patient's kidney function was getting bad while he was in the hospital, his

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Creatinine went high and was 3.8, which is high for someone with a transplant. The patient was doing better, he was still very weak, he was under a doctor's care, he was on very strong antibiotics for a month, Vancomycin and other medications which also make him weak. The patient was on IV antibiotics at the hospital and then came home on oral. The 3.8 for the Creatinine was probably at the beginning when he went into the hospital. The outcome of the event Sepsis was Resolved with Sequel and the outcome of the other events was unknown.

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1320114	5/15/2021	WI	49	M	4/21/2021	4/23/2021	<p>23Apr2021 at 4pm sudden onset severe dizziness 4:15pm SEVERE Vertigo, Nausea, Vomiting until 7pm.;</p> <p>23Apr2021 at 4pm sudden onset severe dizziness 4:15pm SEVERE Vertigo, Nausea, Vomiting until 7pm;</p> <p>23Apr2021 at 4pm sudden onset severe dizziness 4:15pm SEVERE Vertigo, Nausea, Vomiting until 7pm.;</p> <p>diagnosed Vestibular Neuritis; 23Apr2021 at 4pm sudden onset severe dizziness 4:15pm SEVERE Vertigo, Nausea, Vomiting until 7pm.; unable to work for more than a few minutes without nystagmus; extreme fatigue and continued vertigo; This is a spontaneous report received from a contactable consumer, the patient. A 49-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EW0172) via an unspecified route of administration, administered in the arm right on 21Apr2021 at 10:45 (at the age of 49-years-old) as a single dose for COVID-19 immunisation. Medical history included asthma from an unknown date and unknown if ongoing , hypertension from an unknown date and unknown if ongoing , sarcoidosis from an unknown date and unknown if ongoing , obesity from an unknown date and unknown if ongoing , seasonal allergy from an unknown date and unknown if ongoing , allergy to horse and cat dander from an unknown date and unknown if ongoing. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient's concomitant medications were not reported. The patient previously received the first dose of BNT162b2 on 31Mar2021 at 10:45 (Lot Number: EW0150) via an unspecified route of administration in the right arm for COVID-19 immunisation. The patient had not received any other vaccines within 4 weeks prior to the COVID-19 vaccine. On 23Apr2021 at 16:00, the patient experienced vestibular neuritis (medically significant), 23apr2021 at 4pm sudden onset severe dizziness, 4:15pm severe vertigo, nausea, vomiting until 7pm, unable to work for more than a few minutes without nystagmus, and extreme fatigue. Clinical course: on 23Apr2021 at 4pm sudden onset severe dizziness. At 4:15pm severe vertigo, nausea, vomiting until 7pm. At 7pm, wife took patient to ER and received a CT and MRI to rule out a blood clot. Vomiting has resolved with medication. On 26Apr2021, patient was diagnosed vestibular neuritis.</p>

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							<p>Symptoms are slightly better but patient have been unable to drive, walk without increase in symptoms, unable to work for more than a few minutes without nystagmus, extreme fatigue and continued vertigo. Treatment received for the events included diphenhydramine (BENADRYL), droperidol, meclizine, and methylprednisone. The patient recovered from the event, vomiting. The patient had not recovered from the events, vestibular neuritis, 23apr2021 at 4pm sudden onset severe dizziness, 4:15pm severe vertigo, nausea until 7pm, unable to work for more than a few minutes without nystagmus, and extreme fatigue. No follow-up attempts are needed. No further information is expected.</p>
1320124	5/15/2021	SC	59	F	4/1/2021	4/7/2021	<p>Developed Deep Vein Thrombosis. Diagnosed 30Apr2021; This is a spontaneous report from a contactable consumer (patient). A 59-year-old female non-pregnant patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 01Apr2021 14:30 (Batch/lot number: EN8207) as 2nd dose, single for COVID-19 immunisation. Medical history included Diabetes, High Blood Pressure and High Cholesterol, all from an unknown date. There no concomitant medications. The patient previously received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) in Arm Left on 11Mar2021 11:45 AM (Batch/lot number: EP7533) at the age of 59-year-old for COVID-19 immunisation. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient developed deep vein thrombosis since 07Apr2021, which was diagnosed on 30Apr2021. Therapeutic measures were taken as a result of deep vein thrombosis which included Prescribed Xarelto. The adverse event result in Doctor or other healthcare professional office/clinic visit. The outcome of event was not recovered. Since the vaccination, the patient has not been tested for COVID-19.</p>

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1320143	5/15/2021	MI	37	F	3/25/2021	4/28/2021	Heavy bleeding including passing a blood clot with my first cycle after my second dose.; Heavy bleeding including passing a blood clot with my first cycle after my second dose.; This is a spontaneous report from a contactable consumer (reporting for herself). A 37-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 25Mar2021 at 13:00 (Batch/Lot Number: ER2613) as 2ND DOSE, SINGLE for COVID-19 immunization. Medical history included hypothyroidism from an unknown date and unknown if ongoing. Concomitant medication included etonogestrel (NEXPLANON); levothyroxine sodium (LEVOTHYROXIN); cetirizine hydrochloride (ZYRTEC ALLERGY); fluticasone propionate (FLONASE ALLERGY RELIEF), all taken for an unspecified indication, start and stop date were not reported. The patient previously took first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Left Arm on 04Mar2021 at 13:00 (Batch/Lot number: EN6206) for COVID-19 immunization. On 28Apr2021 at 14:30, the patient experienced heavy bleeding including passing a blood clot with her first cycle after my second dose. The have NEVER bleed like this except for when she was having a miscarriage or postpartum after giving birth to her daughters. She usually can go all day with the same pad and soaked through a pad and her underwear was completely bloody in 3 hours (it was so bad I discarded the underwear). When she got on the toilet it kept gushing out and that was when she passed a clot. After that the bleeding slowed down. The outcome of the events was unknown. The patient did not received any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and has not been tested for COVID-19 since the vaccination.

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1320149	5/15/2021	CT	63	M	3/23/2021	4/3/2021	Diagnosed with a blood clot; Diagnosed with stroke; not feeling well; wakes up at night; Numbness of left hand and mouth; Numbness of left hand and mouth; Constipation; severe headache, described as he felt his eyes were exploding out of his head.; Temperature of 100.2; Could not sleep; This is a spontaneous report from a contactable consumer (spouse reporting on behalf of husband). A 63-years-old male patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, administered in Arm Left on 23Mar2021 09:00 (Batch/Lot Number: ER2613) as SINGLE DOSE for covid-19 immunization. Medical history included ongoing rheumatoid arthritis started few years ago, ongoing back pain (for many years), ongoing pain (for many years) (patient is a farmer 'seeing another doctor' for back pain/pain, testis cancer from 1986 and ongoing. Concomitant medication(s) included adalimumab (HUMIRA) taken for rheumatoid arthritis from an unspecified start date 'a few years ago.' and ongoing; tramadol (TRAMADOL) taken for back pain from an unspecified start date 'for years' and ongoing. Vaccine was not Administered at Military Facility. No other vaccines were given within 4 weeks. No additional vaccines were administered on the same date of the Pfizer suspect product. The patient experienced diagnosed with a blood clot, diagnosed with stroke, numbness of left hand and mouth on 12Apr2021, severe headache, described as he felt his eyes were exploding out of his head, temperature of 100.2 (in the evening.) , could not sleep on 03Apr2021, constipation on 05Apr2021, not feeling well and wakes up at night on an unspecified date. The patient was hospitalized for stroke and blood clot from 12Apr2021 to 14Apr2021. The patient underwent lab tests and procedures which included body temperature increased: 100.2 on 03Apr2021; computerized tomogram: first cat scan, a blood clot was diagnosed on unspecified date., computerised tomogram head: unknown result on an unspecified date, electrocardiogram: unknown results (husband was not having a heart attack) on 12Apr2021 , laboratory test: unknown results an unknown date , sars-cov-2 test: negative on 12Apr2021, computerised tomogram: negative on an unspecified date. Treatment was given thrombosis, Stroke, Headache, Insomnia. On

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an unspecified date patient contacted his primary care doctor and was told to take some extra Motrin, twice a day but Motrin was not effective for his headache. The patient was not feeling well he went to his primary care doctor. Caller states her husband was at his doctor on 07Apr2021, and he went to radiology for a Cat Scan on an unspecified date and the results was negative. He had lab work drawn and a CT of the head. Her husband was given a medication to help him sleep, medication not specified. Caller mentioned she rescheduled her husband's second vaccine. On 12Apr2021, in the evening when he was getting out of the shower, he developed numbness in his left hand, and added later in the report, numbness of his mouth. Patient went to the emergency room, where they performed several tests, Multiple Cat Scans. Results of the first Cat Scan, a blood clot was diagnosed, and an EKG because they thought he may be having a heart attack but it was confirmed he was not having a heart attack.. When her husband was in the emergency room, they did a Covid test and it was negative. The patient was diagnosed with a blood clot and got Tissue plasminogen activator. At 7:33 pm, when he was given tissue plasminogen activator. After the treatment, the headache went away, but she is not sure if he has lasting effects. He was admitted to the Intensive Care Unit and was in the hospital for two days and diagnosed with a stroke, but he was able to walk out of the hospital. The patient still gets an ache in his head, and it comes and goes. Caller states it seems that these events were not coincidental, as they all happened after he got the vaccine. Since her husband has been home from the hospital, he is sleeping better but normally does not get a full night of sleep, and he usually wakes up at night and husband gets constipated when he takes Motrin. Caller mentioned that her husband is not fully constipated anymore, but he feels that his system is not back to normal. Caller assumed the stroke has cleared up, but is not sure. Caller rescheduled her husband's second vaccine, and she is not sure her husband should get the second vaccine. Caller states if these events were caused from the Covid vaccine, what will happen in the future? The clinical outcome of the events Clot blood, Stroke, malaise and wakes up at night was unknown; Numbness of left hand and mouth was recovered on 12Apr2021, Fever was recovered on 04Apr2021, while



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1320077	5/15/2021	MO	41	F	4/1/2021	4/1/2021	<p>headache and Constipation was recovering. Follow up attempts are needed. Further information has been requested.</p> <p>Left calf pain started around 4/12; went to Total Access Urgent Care on 4/28 as pain had increased with minor swelling and Ultrasound showed DVT.; swelling; Ultrasound showed DVT; This is a spontaneous report from a contactable other healthcare professional (patient). A 41-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Right on 01Apr2021 (Lot Number: er8733, at age of 41 years old) as single dose for COVID-19 immunisation. The patient was diagnosed with COVID-19 prior to vaccination. Concomitant medications included: Levonorgestrel; Pravastatin. The patient previously received Penicillin, dairy products. Left calf pain started around 12Apr2021; went to Total Access Urgent Care on 28Apr2021 as pain had increased with minor swelling and Ultrasound showed DVT (Deep vein thrombosis) in Apr2021. The adverse event result in Emergency room/department or urgent care. The patient received treatment for the adverse event: On Eliquis blood thinner for 3 months. The outcome of events was unknown. No follow-up attempts are needed. No further information is expected.; Sender's Comments: Based on the information currently available, a possible contribution of the suspect drug administration to the event deep vein thrombosis cannot be excluded, due to a plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>

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1320025	5/15/2021	CO		M		4/22/2021	Superficial blood clots in my right leg; This is a spontaneous report from a contactable consumer. A 55-years-old male patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in Arm Left on an unspecified date (Batch/Lot Number: EW0164) as SINGLE DOSE for covid-19 immunisation. Medical history included Alfa 1 Antitrypsin (hereditary), Sulfa allergies. Patient previously received the first dose of bnt162b2 on 27Mar2021 for covid-19 immunization (lot number=ER8734,vaccine location=Left arm). Patient was not diagnosed as COVID-19 prior vaccination. No covid tested post vaccination.The patient's concomitant medications were not reported. The patient experienced superficial blood clots in his right leg 5 days after his second COVID 19 vaccination shot on 22Apr2021 04:00 with outcome of unknown. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Treatment received for the adverse event included Rest and pain relievers. Case was reported as non-serious. Information on Lot/Batch number was available. Additional information has been requested.
1321357	5/15/2021	TX	79	F	4/9/2021	4/9/2021	after getting the vaccine in morning, later that same evening patient felt sluggish, nauseaus, tired. Daughter finally convinced patient to see a doctor. Md prescribed her a cough medication. She still felt bad for another 2-3 weeks, so she finally went to the emergency room where she diagnosed with blood clots in the legs and the lungs. She staying in hospital approx. 4-5 days before being released.

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1320270	5/15/2021	TX		F	3/4/2021	3/1/2021	Patient reported clot developed in calf 1 week following first dose; Confusion; This is a spontaneous report from a contactable consumer (reporting for herself). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Mar2021 (Batch/Lot number was not reported) as 1ST DOSE, SINGLE for COVID-19 immunization; and sarilumab (KEVZARA), via an unspecified route of administration from 05Mar2021 (Batch/Lot number was not reported) at an unknown dose and frequency for an unspecified indication. The patient medical history was not reported. Concomitant medication included enoxaparin sodium (LOVENOX [ENOXAPARIN SODIUM]) taken for an unspecified indication, start and stop date were not reported. In Mar2021, the patient reported that clot developed in calf 1 week following first dose of Pfizer covid-19 vaccine. Also, with a lot of confusion. She stated that she was driving and got lost in her 1 stoplight/1-mile small town. The outcome of the events was unknown. The action taken in response to the event for sarilumab was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

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1320048	5/15/2021	IL		M	4/24/2021	4/25/2021	AFib; has no appetite; all he wanted to do was sleep; felt like he was getting the flu; felt faint; lethargy; This is a spontaneous report from a contactable consumer. A 79-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EP6955 or GP6955), via an unspecified route of administration on 24Apr2021 as single dose for covid-19 immunization. Medical history included atrial fibrillation from an unknown date for 20 years. Concomitant medication included warfarin (MANUFACTURER UNKNOWN), taken for an unspecified indication, start and stop date were not reported. No prior vaccinations within 4 weeks were noted. The patient experienced AFib on an unspecified date with outcome of unknown; felt faint on 25Apr2021 with outcome of recovered on 25Apr2021 (elaborated as felt faint when his head was down by his knees, in which he had to quickly jerk himself up and go sit down), lethargy on 25Apr2021 with outcome of recovering (elaborated as lethargy/he was so lethargic, he could hardly keep his eyes open); has no appetite on an unspecified date with outcome of not recovered; all he wanted to do was sleep (elaborated as that he laid down and his eyes were so heavy in which all he wanted to do was sleep) on an unspecified date with outcome of unknown; felt like he was getting the flu on an unspecified date with outcome of unknown. The patient underwent lab tests and procedures which included body height: 180 (180 cm /5'11"), weight: 72.57 kg (160 lbs) on an unspecified date. Details were as follows: Details were as follows: patient got his first COVID-19 vaccine shot on 24Apr2021. He said he was fine on Saturday. He said on 25Apr2021, he was so lethargic, he could hardly keep his eyes open. He said he got faint, and had to lay down. He said on Sunday, he thought the lethargy and faintness were a side effect of the COVID-19 vaccine, but the lethargy was continuing through to 29Apr2021. He said he also had no appetite, saying his appetite was waning. He said he did not feel like eating anything on 29Apr2021. No emergency room or physician office visit was required. He had AFIB, and that was why he had to worry about blood clots, and the reason he took Warfarin. Lethargic treatment was declined. The lethargy had improved some. He first felt faint around 10:00 an on Sunday. Faint Treatment included cat naps during the day on Sunday, and didn't move around much. The

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1320081	5/15/2021			F	4/1/2021	4/25/2021	<p>patient noted that the faint feeling was better by Sunday night. Reported for the last year his appetite had not been good, but he made it a habit to eat every day as a matter of his health. He said he kept asking himself what was he going to eat, and he said nothing appealed to him; he declined appetite suppressed treatment, but had taken Centrum every day for 10 years to supplement his diet, no further details provided.</p> <p>blood clots, Clots were going down the back of her throat; currently feels very weak; nose bleed; This is a spontaneous report from a non-contactable consumer. This report was received via a sales representative. A 70-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: unknown), single dose via an unspecified route of administration in Apr2021 for covid-19 immunization. The patient's medical history was not reported. The patient has been on icosapent ethyl (VESCEPA) and ibuprofen for years and currently feels very weak on 25Apr2021. Concomitant medications were unknown. The patient experienced nose bleed blood clots throughout the week on 25Apr2021. Clots were going down the back of her throat. The patient had to seek medical attention. and currently feels very weak on 25Apr2021, two weeks after vaccination. The outcome of nose bleed blood clots and weak was unknown. No follow-up attempts are possible. No further information expected.</p>

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1320081	5/15/2021			F	4/1/2021	4/25/2021	blood clots, Clots were going down the back of her throat; currently feels very weak; nose bleed; This is a spontaneous report from a non-contactable consumer. This report was received via a sales representative. A 70-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: unknown), single dose via an unspecified route of administration in Apr2021 for covid-19 immunization. The patient's medical history was not reported. The patient has been on icosapent ethyl (VESCEPA) and ibuprofen for years and currently feels very weak on 25Apr2021. Concomitant medications were unknown. The patient experienced nose bleed blood clots throughout the week on 25Apr2021. Clots were going down the back of her throat. The patient had to seek medical attention. and currently feels very weak on 25Apr2021, two weeks after vaccination. The outcome of nose bleed blood clots and weak was unknown. No follow-up attempts are possible. No further information expected.
1321460	5/15/2021	CA	60	M	5/6/2021	5/6/2021	05/06/21 PATIENT RECEIVED 2ND DOSE OF MODERNA COVID 19 VACCINE AT JOBSITE CLINIC . PATIENT FELT FINE AFTER THE CLINIC BUT LATER AT HOME STARTED FEELING SICK. PATIENT WAITED UNTIL SUNDAY 5/9/21 TO SEEK MEDICAL ATTENTION AT THE HOSPITAL AND WAS ADMITTED FOR STROKE. PATIENT REPORTED LOSS OF VISION IN ONE EYE. THE HOSPITAL NEUROLOGIST TOLD PATIENT THAT IT WAS DUE TO CLOTS IN HIS EYE. PATIENT IS WATING TO SEE AN OPHTHALMALOGIST ABOUT THE EYE CLOTS. PATIENT HAS NOT BEEN BACK TO WORK SINCE FEELING SICK. EMPLOYER STATES HAS NOT RECEIVED ANY NOTICE FROM DOCTOR STATING ANY CAUSE OR RELATION TO VACCINE

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1321418	5/15/2021	NC	48	F	3/10/2021	4/10/2021	On Saturday, April 10, 2021, I had started having pain and swelling in my right calf that lasted for several days on and Tuesday, April 13th, I started having pain on the left side of my chest. On Thursday, April 15th, I went to the ER due to pain and swelling in my leg and it was discovered that I had 2 clots in my leg (on at my calf and a second one on the right side of my knee). Not realizing my chest pain was related, I discussed with my primary care at a follow up visit on Monday, April 19th, and a CT scan was performed confirming I have an pulmonary embolism (extensive pulmonary emboli in both lungs). I was immediately put on Xarelto blood thinner and sent home.
1320362	5/15/2021	MS	70	M	5/6/2021	5/7/2021	patient passed away, due to what was being told as possible blood clot in lungs; This is a spontaneous report from a contactable consumer. A 70-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 06May2021 (Lot Number: ER8633) (at the age of 70-year-old) as single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient did not experienced COVID-19 prior or post vaccination. The patient passed away, due to what was being told as possible blood clot in lungs (on 07May2021). The event was serious (fatal) and required emergency room visit. It was not reported if an autopsy was performed.; Reported Cause(s) of Death: blood clot in his lungs
1321295	5/15/2021	FL	88	F	4/17/2021	4/21/2021	patient said 4 to 5 days after the vaccine, she went to the hospital and had blood clots in the lungs and legs. she said she's ok now and dr told her to get her second vaccine today. she is now on Eliquis.
1320860	5/15/2021	WA	48	F	5/7/2021	5/10/2021	Got my second Pfizer Covid shot Friday, by Monday I had a huge blood clot in my neck and also a huge one in my left arm. I am now permanently on a blood thinner because of this.

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1320834	5/15/2021	CO	63	F	3/6/2021	3/7/2021	Fever night of getting the shot. Severe abdominal pain for weeks. GI Dr. visit on April 7, 2021 and the PA ordered an abdominal CT with contrast. CT exam on April 13, 2021 which showed total occlusion of the superior mesenteric artery (SMA) and a clot in the thoracic aorta. Went to emergency room on April 14, 2021. Doctor determined that a SMA embolectomy is needed via exploratory laparotomy. Post operation had an event and returned to the ER but was released with all normal blood and heart values.
1320793	5/15/2021	UT	17	M	4/16/2021	4/27/2021	After 1st shot; Patient developed multiple blood clots (lungs and legs) about 10-11 days afterwards. All tests for cause of clots were inconclusive. Patient received his second dose and with in 48 hours was hospitalized for appendicitis. If it was a reaction after just one shot, I would normally think it was a coincidence. With him have severe reactions after both shots, it seems very suspicious!
1320700	5/15/2021	WA	31	M	5/4/2021	5/8/2021	The patient had first dose of Moderna COVID-19 vaccine on 05/04/2021. On 05/08/2021 the patient began having cramping abdominal pain. He was seen in his primary office and the ED once before ultimately being admitted with a portal vein thrombosis and mesenteric vein thrombus. His only risk factors for blood clots are obesity. He has no family history of significant blood clots (except for father who had PE in setting of COVID infection). He has no history of malignancy or family history of malignancy at a young age. He is now being admitted for anticoagulation.
1320522	5/15/2021	SC	46	F	2/1/2021	5/1/2021	Chills, fever , body aches the first few days. Next two periods not normal. Having extremely heavy menses with large blood clots that are not usual for me. Extreme fatigue due to blood loss. Still have not stopped bleeding
1320430	5/15/2021	MA	61	M	4/7/2021	4/8/2021	Chills at 12 hours after shot. Abdominal aches around the rib cage and gut starting 48 hours after shot. Aches were severe for 14 days, moderate for 12 additional days, mild for 10 additional days. Treated abdominal pain with Advil. Shortness of breath after mild exertion - like walking the dogs around the block. Shortness of breath still persists today after 5 weeks. I am concerned the shortness of breath may be due to a PE blood clot.



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1320413	5/15/2021	PA	39	F	5/6/2021	5/8/2021	Heavy menstrual bleeding, large and excessive menstrual blood clots

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1320378	5/15/2021	FL	78	M	3/20/2021	3/1/2021	DVT was twice as bad; death/natural process; This is a spontaneous report from a contactable Nurse reporting for reporter's husband. A 78-year-old male patient received bnt162b2 (reported as COVID vaccine), dose 2 via an unspecified route of administration on 20Mar2021 (Lot Number: EN6201; Expiration Date: 30Jun2021) as 2nd dose, single (at the age of 78-year-old) for COVID-19 immunisation. Medical history included diabetes, Liver cirrhosis, thrombocytopenia, Kidney stone, sarcoidosis, blood pressure abnormal, high cholesterol, pacemaker and they putted the IVC filter for blood clot. Concomitant medications included insulin, simvastatin, hydrochlorothiazide and omeprazole (PROTONIX), all taken for an unspecified indication, start and stop date were not reported; and carvedilol (COREG) taken for blood pressure, start and stop date were not reported. The patient previously received the first dose of bnt162b2 (Lot Number: EN6201; Expiration Date: 30Jun2021) on 27Feb2021 at the age of 78-year-old for COVID-19 immunization and experienced pulmonary embolism and deep vein thrombosis (DVT) on 12Mar2021, and went into the hospital 12Mar2021. Then the patient had the second COVID shot on 20Mar2021 and the reporter had taken him right back into the hospital couple days later because the DVT got twice as worst. The patient experienced DVT was twice as bad on an unspecified date in Mar2021, which required hospitalization on 22Mar2021. The patient underwent lab tests, he had lab tests on 22Mar2021 when he went in and he probably had them on 23rd and 24th of Mar2021. The reporter didn't know what all the lab tests were done in the hospital. The patient died on 12Apr2021. The reporter stated they put Reason of death as natural process because she sent him in the Hospice. An autopsy was not performed. The outcome of event DVT was unknown. The reporter considered there was a causal relationship, when he got his second COVID shot on 20Mar2021 and then he went back in the hospital on 22Mar2021 and the DVT was twice as bad.; Sender's Comments: Based on a positive temporal association, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported DVT. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse

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							events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: death/natural process
1321426	5/15/2021	NY	69	M	4/23/2021	5/11/2021	blood clots in both legs were detected on 5/11/2021, 18 days after receiving the 2nd dose of Moderna vaccine.
1316948	5/14/2021	OR	60	F	4/12/2021	4/26/2021	Patient's husband reported that his wife had gone to the ED with s/s of blood clot.
1316620	5/14/2021	TX	84	M	3/16/2021	3/17/2021	Hospital admission on 03/22/2021, dx COVID+ with acute respiratory failure, acute embolism and thrombosis of unspecified deep veins of unspecified lower extremity.

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1316639	5/14/2021	MI	51	F	4/12/2021	4/12/2021	<p>She got her vaccine, she felt the burning sensation all the way down to her fingers and her wrist. I proceeded to go forward and wait the 15 minutes. She then started to have pain in the side of her neck on the right side, discomfort and pain in her arm. Within the hour she started to have headaches (has had COVID in the past). She went home and it was a nagging pain in her arm, not at the site but the whole arm was sore and limited using the arm due to the discomfort. That night is when she came on the news and started that the vaccine was being pulled from administration. That night it was like a pulling sensation right in her upper arm, up near the armpit and the fatty tissue from the breast and where you raise your arm. When she started noticing the discoloration started in her skin. Her hands started getting black, under both arms were black, the back of her legs was black, and she started feeling worsening fatigue. She started getting worried and was looking at how her veins turned purple blue/green just in the one arm. She was trying to figure out why she had limited use of her arm, and was holding it as if she had a sling on it as when it hung to her side it had the pulling sensation and a crawling sensation in her veins (that night and going into the next day). The next morning she was so exhausted and tired, as was her mother who had the vaccine at the same time, and was not feeling well. She was feeling that possibly due to the fibromyalgia she was have worsening symptoms than her mother. She then started bruises on her body, on the arm itself as if somebody grabbed and squeezed her arm, purplish/black bruising. It had her forearm develop 3 large pockets of swollen, almost as if the medicine was sitting in her arm. She was slowly getting the pulling sensation down to her hand, and she called the UC first and due to the high volume of COVID she wanted to know how long of a wait she would have. They instructed her to go to the ER due to the development of the blood clots on the news. There was no change in her symptoms, and got to the point that she could not move her arm, and the knots stayed in there and there was a reddish discoloration around them. Now she was having a pulling sensation in her chest and palpitations of pain near her heart. She was having soreness in her legs to the point that she was not able to walk, and felt it was in her nerves 3 days after the vaccine. She stayed in the bed the entire week just due to the exhaustion and</p>

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							effects. Every time she would go to reach for something she would have the pulling sensation down to her hand, and the entire arm was swollen with the bruising all over. Her body started having purple and blue knots and also in the left leg. Her arm and fingers were swollen as well. She then started having itching of her arm, and her lips started swelling and got up and went to Hospital and was able to be seen. She was having problems with her stomach as well, having a knot in the stomach where it was protruding and started losing weight since the vaccine. The ER doctor told her she had a reaction to the vaccine, and did a Doppler to see if she had blood clots. They did not give her the results and didn't feel that she didn't have problems. She also went to the UC and back and forth to the ER, and still had the knots and finally looked at the knots and her jaw was swollen, and her arm was still swollen. The UC told her that she was having a fibromyalgia flare. She is still having the same symptoms green/blue and have started protruding. Due to the fatigue she has mainly just stayed in bed and knew that she was to have COVID symptoms, but knows that the crawling sensation and the knots sitting in her arm, and now her arm looks disfigured and the swelling is not going down. They told her that the test was negative for the blood clots. She had made an appointment with her neurologist and has an APT on Tuesday 5/25/21. She continues to lose weight no matter how much she consumes and still continues to have the knots and pain in the arm.
1316667	5/14/2021	PA	85	F	3/16/2021	4/16/2021	Pt was hospitalized at facility from 4/20/2021 -4/25/2021 had RLE DVT and PE. Venous Dopplers (4/20/2021) demonstrated significant clot burden in R lower and upper legs as well as CTA (4/20/2021) which showed B significant pulmonary emboli and evidence of R heart strain. Prior to sudden onset of symptoms pt has led a very active lifestyle.
1317002	5/14/2021	NJ	61	M	4/29/2021	5/2/2021	A blood clot ( DVT)

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1317005	5/14/2021	VA	41	M	5/7/2021	5/8/2021	Patient is 41 year old who presented with right sided upper and lower extremities weakness with facial drip , call as code stroke level 1 -CTbrain, CTA showed right basilar ganglia hemorrhage with small volume subarachnoid hemorrhage, left middle cerebral artery thrombosis with left basilar ganglia infarct and right basilar ganglia infarcts. TEE was negative for LV thrombus /vegetation .
1317043	5/14/2021	AL	65	F	3/18/2021	5/3/2021	Spontaneous Cortical Non aneurysmal subarachnoid hemorrhage with diagnostic suspicion but not confirmation of cortical venous thrombosis, and spontaneous ventricular tachycardia.
1317052	5/14/2021	UT	46	M	3/3/2021	3/26/2021	Deep vein thrombosis
1317065	5/14/2021	VA	56	F	4/28/2021	5/1/2021	blood clots in lungs
1316583	5/14/2021	NC	77	M	3/1/2021	3/22/2021	Couldn't Breath, Died due to Blood Clots on Lungs, Bilateral Pulmonary Embolism, Bleeding on the Brain.
1317146	5/14/2021	CA	77	M	2/12/2021	3/6/2021	Severe clots on right thigh rushed to urgent care and urgent care referred me to emergency Hospital. Was hospitalized for 5 nights with severe swelling on right thigh. The swelling has since abated but has still not subsided. Feel still very heavy on right thigh.

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1316167	5/14/2021		22	F	4/7/2021	4/20/2021	My period started two weeks early. This was already strange because my periods are very regular. I was bleeding very heavily; My period started two weeks early. This was already strange because my periods are very regular.; lightheaded; My period started two weeks early. This was already strange because my periods are very regular. I was bleeding very heavilynoticed several blood clots; This is a spontaneous report from a contactable consume (patient). A 22-years-old non pregnant female patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 07Apr2021 (at the age of 22 years old) (Batch/Lot Number: ER8734) as SINGLE DOSE for covid-19 immunisation. The patients medical history and concomitant medications were not reported. No other vaccines were given within 4 weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination the patient had not been tested for COVID-19. On 20Apr2021 the patient experienced period started two weeks early, bleeding very heavily (medically significant), noticed several blood clots as well and lightheaded. The clinical course was reported as follows ' My period started two weeks early. This was already strange because my periods are very regular. I was bleeding very heavily and I considered going to urgent care but I was light headed and decided against driving. I noticed several blood clots as well. No Treatment was given for the events. The clinical outcome of the events was recovered. The patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), Single dose, Lot number EW0170 on 28Apr2021 No follow-up attempts are needed. No further information is expected.
1317215	5/14/2021	MD	45	M	5/2/2021	5/9/2021	Patient presented with seizures, found to have an Intracranial hemorrhage. On further investigation patient noted to have cerebral venous thrombosis of his superior sagittal sinus. No other obvious etiologies for venous thrombosis noted patient. Which included an extensive hypercoagulable workup..

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1317095	5/14/2021	NC	76	F	3/29/2021	3/30/2021	Chills (no fever) within 24 hours of the Janssen vaccination, lethargic, no appetite. Very dizzy and lightheaded on day 5 and day 6 after the Janssen vaccination with continued lethargy and loss of appetite for approximately 3 weeks. Heavy nosebleed in left side of nostril with large blood clots for 1.5 hours approximately 3 weeks after the Janssen vaccination



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1316160	5/14/2021	PA	67	F	3/3/2021	3/4/2021	<p>left hand was edematous and cold; left hand was edematous and cold; left hand pain; blood clot; swollen submandibular gland that got bigger/could feel her mouth getting bigger; ill with something not related to the vaccine; This is a spontaneous report from a contactable nurse (patient) via Medical information team. A 67-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 intramuscular, administered in Arm Left on 03Mar2021 15:00 (Lot Number: EN6201) as 1ST DOSE, SINGLE for COVID-19 immunization. Medical history included stroke on 2007, COVID-19 from an unknown date and unknown if ongoing. Concomitant medications included clopidogrel bisulfate (PLAVIX) taken for stroke from 2007 to an unspecified stop date; and acetylsalicylic acid (ASPIRIN (E.C.)) taken for stroke from 2007 to an unspecified stop date. The next day on 04Mar2021, the patient had a swollen submandibular gland that got bigger. She could feel her mouth getting bigger. The patient was admitted into the hospital on 07Mar2021 and released on 09Mar2021. She was readmitted to the hospital on 11Mar2021 until 18Mar2021. The patient went back into the hospital on 21Mar2021 and released 20Apr2021. The gland was removed on 13Apr2021. She developed a blood clot. She went to the emergency room and was sent home on Xarelto. The patient mentioned that she received the 1st dose of the vaccine on 03Mar2021 and came down ill with something not related to the vaccine. She was hospitalized for 4 weeks and ended up missing her 2nd dose appointment on 24/Mar/2021. She would like to get her 2nd dose but she is now 5 weeks overdue for it. She mentioned the hospital is recommending that she restart her vaccination. She is looking for guidance from Pfizer. The facility where the most recent COVID-19 vaccine was administered was in the hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient underwent had CT and MRI of left arm/wrist which she does not have results to provide. Event relatedness to vaccine was unknown for events, swollen submandibular gland that got bigger, left hand was edematous and cold, left hand pain and blood clot. The outcome of the event blood clot swollen</p>

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submandibular gland was recovered with sequel on unspecified date, the outcome of ill feeling was unknown and the outcome of the rest of the events was recovering.; Sender's Comments: The 67-year-old female patient had medical history of stroke. Based on information available, the reported thrombosis and other events were unlikely related to the vaccine of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE). This case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1315911	5/14/2021	MI	66	F	1/21/2021	1/23/2021	Aching on left side of her chest/ achy on the left side of her chest; Shortness of breath where it was hard to get a deep breath; This is a spontaneous report from a contactable consumer or other non hcp (the patient reported for herself). A 66-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: solution for injection, Batch/ lot number: EL9261. Expiry date: UNKNOWN) via an unspecified route of administration, in the region of left arm on 21Jan2021 at 12:20 (At the age of 66-years-old) as 0.3 mL, single for COVID-19 immunisation (reported as virus protection). Medical history was not reported. History of all previous immunization with the Pfizer vaccine considered as suspect and any additional Vaccines Administered on Same Date of the Pfizer Suspect was reported as none. No Prior vaccination within 4 weeks of the vaccination. On 23JAN2021, the patient experienced aching on left side of her chest, shortness of breath where it was hard to get a deep breath. Patient was advised by her doctor to call and report the side effects that she has experienced since receiving the first dose of the Covid-19 vaccine. Patient went to the emergency room on 27Jan2021 due to the events, Aching on left side, shortness of breath. They were unable to find anything wrong with her heart. She did not have any blood clots. She also had an X-ray of her lungs. Because of these symptoms she had a COVID test on 23Jan2021 at the urgent care. The test was negative. She may have been exposed to COVID on 01Jan2021. Her next dose is 11Feb2021. She wants to get the second dose. Her doctor said she needs to speak with Pfizer for recommendations about the next dose. Both the events were reported as ongoing. The outcome of the events was reported as not recovered. Follow-up attempts are completed. No further information is expected.

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1316143	5/14/2021	NJ	58	F	3/14/2021	4/17/2021	they packed my nose to stop it from bleeding, clots were coming out, clots coming both ways,; nose bleed; my blood pressure went up; This is a spontaneous report from a contactable consumer (patient). A 58-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration on 14Mar2021 10:00 as 2nd dose ,single for covid-19 immunisation. The patient medical history was not reported. Concomitant medication included acetylsalicylic acid (ASPIRIN BAYER). The patient previously received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) on 28Feb2021 for COVID-19 Immunization. The patient received the Second dose of Pfizer on 14Mar2021, states, "On 17Apr2021, Saturday, nose bleed started, and my blood pressure went up. I Called ambulance took blood pressure and it was 210/107. I didn't go to hospital, nose bleed had stopped while they were there, I stayed in ambulance until blood pressure came down. Sunday I went to ER (emergency room) because my nose started bleeding again, it stopped Sunday, but they checked the nose, nothing was there. I stayed in the hotel, Monday morning I blood again, Tuesday I bled even more starting at 7am and it didn't stop. Went to the hospital to ER (emergency room), they packed my nose to stop it from bleeding, clots were coming out, clots coming both ways, they checked blood, not anemic, everything okay with blood. on 23rd they removed the pack from nose, ENT told me no vessels were broken, he said I was fine. That is when I received a phone call about someone else having this problem. A week later a class mate said her sister had the same reaction after getting the Pfizer vaccine." She was calling about the Covid 19 vaccine. She received her second vaccine on 14Mar2021 and had no problems during that time. On 17Apr2021 she called an ambulance because she had a nosebleed. Her blood pressure was also high at that time around 210/107mmHg. Her nosebleed stopped with emergency management technicians and her blood pressure came back down. She did not go to the emergency room at this time. On 18Apr2021 at around 3:00AM, she had another nosebleed and she did go to the emergency department at about 10:00AM. She has never had a nosebleed before. When she was examined in the emergency room on 18Apr2021, she had no blood in her nose that the

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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doctor could see. On 19Apr2021 around 7:00AM she had another nosebleed but the nosebleed stopped and she did not go back to the emergency room. On 20Apr2021, her nose started bleeding around 5:00AM and it didn't stop so she went back to the emergency room around 7:00AM and the doctor in the emergency room packed her left nostril and the blood was coming out of the right nostril and out of her mouth. She was bleeding for a few more minutes and then the bleeding stopped. Her blood pressure was fine. Her bloodwork was checked and everything was fine. She wasn't anemic or anything like that. She didn't have any bad effects from the nosebleeds. The emergency room told her to follow up with her primary care doctor on Thursday, 22Apr2021, but her primary care doctor no longer takes her insurance. She did go see an Ear, Nose, and Throat doctor on Friday, 23Apr2021. The Ear, Nose, and Throat doctor removed the nasal packing and examined the inside of her nose and told her that he could not see any broken vessels or any cause as to why she would be having nosebleeds. The patient's apartment is being renovated and she thought she might be having a reaction to the hotel she's staying in. She moved out of her apartment on 12Apr2021 and her nosebleeds started 17Apr2021. She has missed work because of her nosebleeds and she started back to work this week. When probing for her Covid 19 vaccine information she reports she does not have the vaccine record card with her. She received the second Covid 19 vaccine on 17Mar2021. NDC/Lot/Expiry not known. First Covid 19 vaccine date is in the suspect product field. She does not have the NDC/Lot/Expiry for the first date either. She reports she had a regular physical with her doctor in Nov2020. She received a tetanus vaccine at that visit. She reported she sometimes takes 2-3 regular Bayer Aspirin for minor pain. She took the Bayer Aspirin on Saturday, 17Apr2021, because she was going somewhere and she knew she would be sitting for a while at that place. She would like to report she experienced no discomfort, or aches or pains or headaches with her Covid 19 vaccine. There is no prior Vaccinations (within 4 weeks). The outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021476976 same reporter/drug/event, different patient

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1316147	5/14/2021		28	M	4/19/2021	4/25/2021	<p>he had an episode which he states is similar to a TIA (transient ischemic attack); Reports experiencing something similar last may except for 'the paralysis'; numbness, pain and tightness in his lower half of his body which was more prominently felt on his left side.; numbness, pain and tightness in his lower half of his body which was more prominently felt on his left side.; numbness, pain and tightness in his lower half of his body which was more prominently felt on his left side.; States he felt as though his knee had a tear in it- it felt it was on fire; tightness in left knee; shortness of breath; feeling foggy; headache; balance issue; coordination off; having a hard time to get a sentence out (felt like his motor skills were affected); having a hard time to get a sentence out (felt like his motor skills were affected); confusion; blurred vision; impending sense of doom; post fatigue; his energy doesnt feel up to par; This is a spontaneous report from a contactable consumer (patient) reported for himself. A 28-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 19Apr2021 at 28 years old (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. Patient stated that on 19Apr, he had the first shot of pfizer covid vaccine. This past sunday (25Apr2021), he had an episode which he stated was similar to a TIA (transient ischemic attack). Reported numbness, pain and tightness in his lower half of his body which was more prominently felt on his left side. Stated he felt as though his knee had a tear in it- it felt it was on fire; he experienced burning and tightness in left knee. He also reported having shortness of breath, headache, feeling foggy, balance issue, coordination off, having a hard time to get a sentence out (felt like his motor skills were affected), confusion, blurred vision and an impending sense of doom. Stated this episode persisted for 15 min and then it resolved. Currently he was experiencing a 'post fatigue' and his energy didn't feel up to par. Reported experiencing something similar last may except for 'the paralysis'. Had not followed up with his provider. Patient was scheduled for second shot of Pfizer covid vaccine on 10May, he was asking for information if he decided to delay his second shot past may 10th. He was asking for</p>

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1316152	5/14/2021	NJ					
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1316152	5/14/2021	NJ		F			
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information on getting the second shot given his recent experience possibly related to the vaccine shot. Was not sure if he should get the second shot. He was asking about side effects for the second shot- if it would be worse. Asking if there were any reports of blood clots with Pfizer covid vaccine. The outcome of the events 'post fatigue' and "his energy didn't feel up to par" was unknown, of other events was recovered on 25Apr2021. Information about lot/batch number has been requested.

clots were coming out; nose bleed; blood pressure went up; This is a spontaneous report from a contactable consumer (classmate's sister). This is the second of two reports. A 62-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection) via an unspecified route of administration on an unspecified date (at an unspecified age) as a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection) via an unspecified route of administration on an unspecified date (at an unspecified age) as a single dose for COVID-19 immunization. On an unspecified date (almost a month after receiving the second COVID-19 vaccine) the patient experienced clots were coming out, nosebleed and blood pressure went up. The reporter called to report that she had received a phone call from an old classmate, who had a sister, who experienced the same reaction after getting the Pfizer vaccine. This patient experienced the same nosebleeds after the COVID-19 vaccine. This person's nosebleeds started almost a month after she received the second dose of the COVID-19 vaccine. That was when the reporter started trying to figure out where these nosebleeds were coming from. She did not have any further information on the person that she mentioned. The clinical outcomes of the events clots were coming out, nosebleed and blood pressure went up were unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021476256 same reporter/drug/event, different patient

<i>VAERS_ID</i>	<i>RECVDATE</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1316154	5/14/2021	IL	51	F	4/8/2021	4/23/2021	bleeding heavily with small clots; has not had menstrual cycle since 2018; started spotting; bleeding heavily with small clots; This is a spontaneous report from a contactable consumer, the patient. This 51-year-old (non-pregnant) female patient received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: ER8727), via an unspecified route of administration in the right arm on 08Apr2021 11:30 (at the age of 51-year-old) as a single dose for COVID-19 immunization. Medical history included endometriosis diagnosed in 1993 and subsequently she had laparoscopy twice by the age of 26-year-old; and ongoing menopause since 2018. History of Parity 1: the patient was pregnant with her daughter and have her naturally at 27 years old and never had another pregnancy again. The patient's concomitant medications were only women multi-vitamins. Prior to the vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient reported that she has not had menstrual cycle since 2018. On 23Apr2021, the patient started spotting. Since 26Apr2021, she has been bleeding heavily with small clots. All day today (on 28Apr2021) she has been bleeding very very heavy with clots. She was planning to go to her doctor by morning, but she was following through with her second dose tomorrow (29Apr2021). The clinical outcome of the events "have not had menstrual cycle since 2018; started spotting; bleeding heavily with small clots" were not resolved. The lot number for the vaccine, BNT162b2, was not provided and will be requested during follow-up.



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1316155	5/14/2021	MI		F			This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer (Patient's relative) reported for a female patient of an unspecified age received BNT162B2 (PFIZER COVID 19 VACCINE, Lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at unknown dose number, single for COVID-19 immunization. The patient's medical history and concomitant medication were not reported. The patient received the Pfizer Covid vaccine. The patient was fine and healthy after the shot. Subsequently she fell down, hurt her hip and broke her wrist. Last Monday, she went for a steroid shot that was given in her wrist. On Tuesday, she was flushed and threw up. They took her to the hospital, and she was diagnosed with blood clots in her brain. She has been in the hospital since that Tuesday (unspecified date) due to the reported events. She has since been admitted to the hospital with a swelling of her brain, and confusion. The events happened on unspecified dates. She is scheduled for a magnetic resonance imaging (MRI). The outcome of the events was unknown. Information on the batch number has been requested.
1316156	5/14/2021	PA		M	1/22/2021		resulted into blood clots in his throat and left side of his body; This is a spontaneous report from a contactable consumer via a Pfizer sponsored program. A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose on 22Jan2021 (Batch/Lot Number: EL1283) as 1st dose, single, second dose on 16Feb2021 (Batch/Lot Number: EL9264) as 2nd dose, single; both via an unspecified route of administration for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient reported that he ended up in the hospital after receiving both covid vaccines which resulted into blood clots in his throat and left side of his body from the waist down on an unspecified date. The patient was hospitalized due to the event from 25Apr2021 to 27Apr2021. The outcome of the event was unknown.

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1316174	5/14/2021	MI	77	M	3/30/2021		<p>Blood clot in leg - first dose; This is a spontaneous report received from a contactable consumer, the patient. A 77-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot: CR2613), via an unspecified route of administration in the left arm on 30Mar2021 (at the age of 77-years-old) as a single dose for COVID-19 immunization. Medical history included broke femur of right leg on 09Nov2020 and hospitalized from 09Nov2020 until 15Nov2020 or 16Nov2020, surgery to repair broken right femur on 12Nov2020, rehabilitation following hospital discharge and got out of the rehab facility on 14Dec2020, been in either a walker or a wheelchair and still not fully recovered (ongoing); chronic obstructive pulmonary disease (COPD), asthma diagnosed at least 13-14 years ago, bronchitis, all ongoing from an unspecified date diagnosed at least 13-14 years ago. Concomitant medications were not reported. There were no other vaccinations within 4 weeks of the vaccine. On an unspecified date, the patient experienced a blood clot in the leg. The clinical course was follows: After he was discharged from rehab, the patient went to his own family doctor on 30Mar2021 because his ankle and leg were still swollen. The physician sent him to have a vascular done, on an unspecified date after 30Mar2021, with unknown results. The patient reported that the physician determined that he had blood clots in his leg. The patient was sent to the emergency room and started "that stuff" for about a week until he went to a regular vascular doctor and the physician determined what the patient should be doing. The patient reported that he was diagnosed with the blood clots after he got out of rehab. The patient received apixaban (ELIQUIS) from Apr2021 for blood clot in leg. The clinical outcome of blood clot in leg was unknown.; Sender's Comments: Linked Report(s) : PFIZER INC-2021478767 same patient, different dose/event</p>

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1316159	5/14/2021	FL	36	M	4/6/2021	4/6/2021	Cellulitis; immune system being weakened; fevers which came and went; chills; sweats; nausea; loss of appetite; light headedness; lack of energy; This is a spontaneous report from a contactable consumer (the patient). A 36-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EW0151) via an unspecified route of administration in left arm on 06Apr2021 12:30 at age of 36-year-old at single dose for COVID-19 immunisation. The patient had no relevant medical history. No known allergies. The patient's concomitant medications were not reported. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EN6205) via an unspecified route of administration in left arm from 16Mar2021 12:30 at age of 36-year-old for COVID-19 immunization. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No other medications the patient received within 2 weeks of vaccination. The patient did not diagnose with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The patient was very sick for 4 days: fevers which came and went, chills, sweats, nausea, loss of appetite, light headedness, lack of energy. As a result of his immune system being weakened, he wound up with Cellulitis which he was still fighting over 3 weeks after the shot. As the patient was normally a healthy male, it was strange that he would wind up with a bacterial infection. The patient also stated that after the second dose he experienced cellulitis in his left leg to thigh area. He went to emergency room for scan and to rule out clot. He thought he was immunocompromised and that was why he got the cellulitis in the leg. Caller wanted to get the compensation information to help with the bills. The events onset date was 06Apr2021 17:00. 2 rounds of antibiotics was received for the events. The events result in doctor or other healthcare professional office/clinic visit and emergency room/departement or urgent care. The patient underwent lab tests and procedures which included ultrasound with unknown result. The outcome of the events was recovering.
1316521	5/14/2021	NY	66	M	1/30/2021	4/1/2021	I developed a severe blood clot in my left calf. I needed to be admitted in the hospital. I was there for 4 days.

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1317316	5/14/2021	CO	60	M	12/17/2020	12/21/2020	About 1 week following first Pfizer vaccination, I began having achiness in left leg and thought this was possibly from sitting in a chair without enough cushion. I simply could not get leg comfortable. Over a couple days duration the leg continued to be achy and slightly swollen. On December 23rd at night I awoke due to such discomfort in leg and could not get comfortable enough to go to sleep. I went to ED where I was examined and found to be mildly short of breath and in pain. Ultrasound of leg showed large upper leg DVT. CT of chest showed submassive Pulmonary Horseshoe Embolus. I was placed on Heparin and anticoagulated. Hospitalized for several days while anticoagulated and observed for any clot progression or respiratory distress and discharged home on Xarelto for anticoagulation and follow up with PCP, Hematology, Pulmonary medicine.

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1316170	5/14/2021	NC	55	M	4/19/2021	4/20/2021	<p>Pulmonary embolism in his left lung; Chills; Hard to breathe; shaking a lot; This is a spontaneous report received from a contactable consumer (patient). A 55-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection; Lot Number: EW0164) via an unspecified route of administration on 19Apr2021 at 12:00 (at the age of 55-years-old) as a single dose in the left shoulder for COVID-19 immunisation. Medical history included chronic obstructive pulmonary disease (COPD) from an unspecified date and ongoing and urinary tract infection (UTI) from an unspecified date and unspecified if ongoing. Concomitant medications were reported as none. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection; Lot Number: first letter is either a G or O but he thought it was OE8732) via an unspecified route of administration on 29Mar2021 at 11:45 (at the age of 55-years-old) as a single dose in the left shoulder for COVID-19 immunisation. Illness at vaccination was UTI. On 20Apr2021 the patient experienced pulmonary embolism in his left lung, chills, hard to breathe and shaking a lot. The patient was hospitalized for pulmonary embolism in his left lung (blood clot) from 20Apr2021 to 26Apr2021. The clinical course was reported as follows: The patient stated that he had the second Pfizer shot on 19Apr2021 and on the 20Apr2021 he had a really bad reaction to it. He had chills, it was hard to breathe, he was shaking a lot and had a UTI and COPD and had to call an ambulance to come get him. When he went to the emergency room, they did a CT (computerized tomography) scan of his chest and found a pulmonary embolism in his left lung and he was put on a Heparin drip for 7 days and stayed in the hospital for 7 days. The event hard to breathe ended shortly after he got to the emergency room since he was on oxygen. The patient had a history of COPD, so sometimes he had trouble breathing, but right now he did not. The event shaking a lot ended a little after he got to the emergency room. The patient also stated that he had a history of UTI in the past and had a UTI during the vaccine but was not treated for the UTI until he was at the hospital. The clinical outcomes of the event pulmonary embolism in his left lung was unknown; chills, hard to breathe and shaking a lot were all</p>

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							recovered/resolved on 20Apr2021.
1316237	5/14/2021	GA	45	F	4/17/2021	4/17/2021	breakthrough bleeding/Bleeding heavily with large clots; period started 1 day later with breakthrough bleeding; nausea; headache; lethargic; This is a spontaneous report from a contactable consumer (patient). A 45-year-old female patient (not pregnant) received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: ew0169), via an unspecified route of administration, administered in Left arm on 17Apr2021 at 13:45 (at the age of 45-year-old) at single dose for COVID-19 immunisation. Medical history reported as no. Prior to vaccination, patient was not diagnosed with COVID-19. Concomitant medications included probiotic (probiotics nos); daily vitamins; birth control pills. The patient previously received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: er8730), administered in left arm on 27Mar2021 at 10:00 AM (at the age of 45-year-old) at single dose for COVID-19 immunisation. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced nausea, headache and lethargic, all on 17Apr2021; and period started 1 day later (18Apr2021) with breakthrough bleeding. Bleeding heavily with large clots beginning 25Apr2021 and still happening 4 days later. Normal period lasts 6 days with 2 heavy days, 3 regular days and one light day. Since the vaccination, patient had not been tested for COVID-19. The outcome of the events was not recovered.
1316300	5/14/2021		30	F	4/29/2021	5/11/2021	Patient found to have asymptomatic intracranial sinus vein thrombosis in the transverse/sigmoid sinus on the left side

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1316349	5/14/2021			F			<p>This spontaneous report received from a consumer via a company representative concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown and expiry: Unknown) dose, start therapy date were not reported, 1 total administered for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient died from blood clot. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0. 20210514012-COVID-19 VACCINE AD26.COV2.S-Blood clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: BLOOD CLOT</p>

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1316350	5/14/2021			U			BLOOD CLOTS IN LEGS; This spontaneous report received from a patient via a company representative concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported 1 total for prophylactic vaccination. The batch number was not reported and had been requested. No concomitant medications were reported. On an unspecified date, on 2021, the patient experienced blood clots in legs. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clots in legs. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210515265-covid-19 vaccine ad26.cov2.s-thrombosis. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).



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1316351	5/14/2021	FL	38	F	5/1/2021		THROMBOSIS IN RIGHT HAND MIDDLE FINGER KNUCKLE; RIGHT ARM AND HAND COLD; RIGHT ARM AND HAND NUMB, LEFT HAND NUMB; WEAK LEFT HAND AND WEAK LEGS; CRAMP IN INNER MIDDLE FOOT LEFT FOOT; PAIN ALL OVER BODY; CHILLS; FEVER; HAND AND LEG STIFFNESS, STIFF NECK; RED/BLEU BRUISE; This spontaneous report received from a patient concerned a 38 year old white and Hispanic or Latino female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported and batch number: 205A21A expiry: UNKNOWN) dose was not reported, 1 total administered on 03-MAY-2021 to left arm for prophylactic vaccination. No concomitant medications were reported. On MAY-2021, the patient experienced red/blue bruise. On 03-MAY-2021, the patient experienced pain all over body, hand and leg stiffness for 10 minutes, stiff neck, chills and fever. On 04-MAY-2021, the patient experienced cramp in inner middle foot left foot. On 09-MAY-2021, the patient experienced thrombosis in right hand middle finger knuckle, right arm and hand cold, right arm and hand numb, left hand numb and weak left hand and weak legs. Treatment medications (dates unspecified) included: acetylsalicylic acid. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from cramp in inner middle foot left foot on 04-MAY-2021, pain all over body on MAY-2021, and chills, and fever on 03-MAY-2021, was recovering from right arm and hand cold, right arm and hand numb, left hand numb, and weak left hand and weak legs, had not recovered from thrombosis in right hand middle finger knuckle, and hand and leg stiffness, stiff neck, and the outcome of red/blue bruise was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210516231-covid-19 vaccine ad26.cov2.s - thrombosis in right hand middle finger in Hispanic or Latino patient. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1316157	5/14/2021			F			they were concerned about blood clot; shaking uncontrollably; pouring sweat; sheet white with no color to skin at all; blood pressure 68/30; not particularly coherent; This is a spontaneous report received from a contactable consumer (patient's husband). A female patient of unspecified age received BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: UNKNOWN) via an unspecified route on an unspecified date as a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The reporter stated his wife had adverse event to the COVID vaccine last week. He stated that they both got the vaccine. At 3 AM on unspecified date, the reporter woke up because his wife (patient) was shaking uncontrollably, pouring sweat, sheet white no color to skin at all, not particularly coherent and had blood pressure 68/30. They had to call an ambulance and she was brought to the hospital. They were able to get her blood pressure up and stabilized her after 8 hours. They were concerned about blood clot and did other scans. Lab data included blood pressure 68/30 (units unspecified) and scans with unknown results; both on unspecified date. The clinical outcomes of shaking uncontrollably, pouring sweat, sheet white no color to skin at all, not particularly coherent and blood clot were unknown, while of blood pressure 68/30 was recovering. The lot number for the vaccine, BNT162b2, was not provided and will be requested during follow up.
1318527	5/14/2021	TX	71	M	4/28/2021	5/11/2021	PATIENT WAS ADMITTED TO ICU ON 5-11-2021. CHIEF COMPLAINT BEING BLOOD CLOTS.
1317301	5/14/2021	CA	42	M	4/23/2021	4/25/2021	Blood clots in lungs (PE).

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1317257	5/14/2021	NV	62	M	3/15/2021	3/22/2021	I started to get a weird feeling in my chest a week after the vaccine. It was a burning sensation and I thought it was vaping at first. It started to get worse and worse. A week later I went to the ER and they ran some tests. After testing it was confirmed that I was having a heart attack. I had blot clot in my OM1 discovered on 04/07/2021. I had had an angiogram in 2019 and there were no problems then. I was hospitalized for four days and I was given a Stent which ended up getting a blood clot. The original Stent was removed and a larger one was put in. I am now taking some blood thinners, Aspirin, Atorvastatin, Carvedilol 6mg, Prasugrel 10mg, and I am scheduled to see a cardiologist because I still have a little chest pain.
1318546	5/14/2021	AZ	42	M	4/23/2021	5/1/2021	Blood clot formed.
1317800	5/14/2021	PA	92	F	5/13/2021	5/14/2021	pt presented at store today with a bruise on her upper left calf. she did not remember hitting her leg. she noticed it after her janssen covid vaccine. I advised pt to seek medical attention due to the risk of low platelets/blood clots- under advisement of the EUA. Pt was going to get looked at Med Express.
1317621	5/14/2021	NY	58	F	4/21/2021	4/30/2021	58F w/o significant PMHx presenting to ER with arteriolar thrombosis. Two weeks prior, pt developed swelling and pain in left foot (~1 week post vaccine #2). She went to urgent care and was prescribed ketoconazole cream. She then developed multiple ulcers on her left foot. She presented to ED on 5/12/21. Arterial duplex reviewed complete occlusion of mid-distal SFA into the popliteal and posterior tibial arteries. Pt now returned and ready to be admitted. Of note, pt is a 20 year smoker, half pack a day. Denies any personal or family hx of previous clots. Arterial duplex reviewed complete occlusion of mid-distal SFA into the popliteal and posterior tibial arteries
1317607	5/14/2021	NC	36	F	4/7/2021	5/9/2021	Patient describes muscle pain and bruising/"blood clots" on left side. The onset was 5/9/2021. Describes as severe pain that increased till seen at healthcare provider's office by healthcare provider.

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1317532	5/14/2021	ME	58	F	1/14/2021	5/13/2021	PULMONARY EMBOLISM in patient with no history of VTE or hypercoagulable state. Patient complaint of exertional dyspnea on exertion over past 2 weeks. She saw her PCP, D-dimer=3424, CT angiography with fairly extensive clot burden of pulmonary emboli throughout all lobes, beginning just distal to the main pulmonary arteries. Flattening of intraventricular septum is concerning for right heart strain. admitted with IV heparin for further studies. Dyspnea has significantly improved with anticoagulation and bed rest.
1317525	5/14/2021	CA	49	F	4/2/2021	4/23/2021	(4/23/21) Symptoms included intermittent (R) lower leg pain. After 3days, started myself on Aspirin which seemed to improve Sx somewhat. Stopped the Aspirin. Then learned of the link of J&J Vaccines to blood clots. Called my primary physician (5/6/21) who suggested testing to r/o DVT. (5/7) Venous ultrasound confirmed a DVT/ blood clot in (R) lower leg. Was then sent directly to ER for further exam and initiation of anti-coagulation therapy. Started on Eliquis starter pack: Initially 10mg BID, then 5mg BID.
1317434	5/14/2021	KY	45	F	4/3/2021	4/6/2021	Pt is a 45 y/o F who presents w/ epigastric pain and intermittent L arm numbness. She was found to have extensive clots in descending thoracic aorta with additional clot in L subclavian and axillary arteries. She denies any birth control and does not smoke. We have a hypercoaguable workup pending. Transthoracic echo 5/13 did not reveal a cardiac source nor PFO. She developed sx and saw PCP 4/6/21 which was 3d after second dose COVID vaccine, Moderna (administered 4/3/21). At the PCP 4/6 pt complained of some left arm numbness and a decreased pulse and the doctor noted that it was a little bit cooler to touch and ordered a arterial ultrasound and MRI of the brain. However, the patient did not feel like she needed it therefor did not have either test done. During her admission the pt has been evaluated by vascular surgery and cardiothoracic surgery. Surgically the patient is to have 5/14/21 Penumbra thrombectomy of L axillary and L subclavian artery. Then she will have 5/17/21 removal of thrombus in descending thoracic aorta via L thoracotomy/L heart bypass.

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1317380	5/14/2021	TX	35	M	12/17/2020	5/7/2021	May 11th had the worse headache of my life. Went to ED. CT scan showed SAH in right frontal/parietal regions. MRA showed multifocal venous sinus thrombosis. Partial thrombosis of superior sagittal. Heparin gtt and sent home on Lovenox BID
1314584	5/13/2021	VA	58	F	3/3/2021	4/10/2021	On the day after my second Covid vaccine (03/26/2021) I had headache and fatigue. On 04/10/2021, I started noticing a lot of bruising all over my body (petechiae and a lot of other areas of bruising) and I had a lump and pain behind my left calf. I had some fatigue, but otherwise felt fine. I went to the Emergency Department on April 11th thinking that my INR was too high since I'm on a blood thinner medication. The ER did an ultrasound of my legs and no blood clots were found. They did a CBC and I had a platelet count of 6,000. They admitted me, gave me a platelet transfusion and a steroid injection. They discharged me from the hospital on 04/12/2021 on 60 mg of Prednisone and to follow up with my hematologist, MD. My platelet count has since returned to normal. I am having a CBC once a week and tapering off the Prednisone. Both Dr. and my Rheumatologist, MD believe that my severe drop in platelets were due to the Covid vaccine causing my Lupus to become very active and attack my platelets. Please feel free to contact me if you have any additional questions. Thanks you,
1314289	5/13/2021	CO	29	F	4/6/2021	4/27/2021	nonocclusive dural venous sinus thrombosis
1313691	5/13/2021	NV	58	F	4/26/2021	5/1/2021	Following the vaccination patient didn't feel well. Fever, chills, cold symptoms, incredibly irritable. 5/1 she awake with a terrible headache which continued all day. Around 9:30 pm she laid down and shortly after was unable to move her body. 5/4/21 at 4:19pm her time of death was called. Cause; brain death due to aneurysm and stroke due to passing blood clot in brain.

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1313900	5/13/2021		80	M	3/4/2021	3/5/2021	Altered mental status, confusion, subdural hematoma. Was lifeflighted to Clinic and remained there about 5 weeks, developed a stage IV pressure ulcer on buttock. Diagnosed with multi organ failure. Went to a SNF for rehab after being discharged. Wife said then patient received 2nd dose of vaccine about 2 weeks ago and is currently at Hosptial in town for a GI bleed, passing frank blood and clots. He was admitted 5/9/21. Patient is still confused and lethargic. Before the vaccine, he was taking care of his farm and home. Now he doesn?t even know his wife or what is going on.
1314221	5/13/2021	OR	70	F	4/9/2021	4/27/2021	Patient got small blood clot show on skin 4 days after shot, it went away lighter red in 1.2 week, blood pressure went up and down suddently. Sunday was fine, Monday the 26 was fine, went to bed at 9:00 PM. Was not able to wake up, went to ER around 8:30 AM on 4/27 AM by daughter call 911. In ER for 28 hour and found out she got stroke. Pnewnewmia. ER gave antibootic around 3:00 PM, transfer to intensive care, MRI around 7:00 PM 4/27/2021 due to CT scan shown stroke. Lost Vision on right side and parcial on left side due to stroke.
1314231	5/13/2021	NC	41	M	3/25/2021	4/30/2021	April 30th began to notice dull ache in calf. At first assumed it was a muscle cramp. The pain began to increase through the weekend and into the following week. I went to urgent care on May 6th. They sent me to the ER to get an ultra sound as their preliminary evaluation was that it could be a blood clot. The ER ultrasound confirmed the presence of a superficial thrombosis in my left calf. No blood work was performed. I was told to take ibuprofen and use a heated compress and to wear compression stockings. If the pain grew worse, I was to return to the ER. I scheduled a follow-up with my Primary the next day. Blood tests show all values to be in normal range. I have no history of blood clots and perform cardiovascular exercise on a daily basis.

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1314279	5/13/2021	KY	38	F	4/7/2021	4/12/2021	About a week after being vaccinated I started experiencing bad headaches, chest pains and pains in my leg. I went to the emergency department at Hospital to get checked out. They took blood and I had a high d dimer test result. They did an Ultrasound of both legs, and a CT with contrast of the lungs and a CT of the head. No blood clots were evident at the time. Over the next couple of weeks my left leg has continued to swell and hold fluid. On 5-11-2021 I had another ultrasound of the left leg again to rule out a possible blood clot. Again they did not find anything. After reviewing blood work from a coag profile all results were elevated but not worrisome per the dr. I continue to have more swelling in the left lower extremity, muscle aches and pains in that leg along with more busted blood vessels. I have experienced pains in places that I have never had before. Example a sharp pain started around my left pelvic area and shot up to the left shoulder and then burned for several minutes.
1313667	5/13/2021	FL	67	F	4/22/2021	5/6/2021	Before vaccine went for sonogram, no signs of blood clot Vein doctor did more advanced sonogram and was negative again for clots. A few days later clots started appearing on varicose veins. First clot started inside of knee, thought it was a boil, it was a big red figure with a dark center, doctor diagnosed with superficial blood clots (about 10 days after vaccine) On the 10th when seeing doctor blood pressure shot up, had to double lisinopril. Patient reports history of smoking.
1314349	5/13/2021	PA	49	M	4/9/2021	4/21/2021	Blood clot developed in the leg 10 days after the injection
1314351	5/13/2021	FL	43	F	5/12/2021	5/13/2021	PATIENT CAME TO THE PHARMACY WITH SWOLLEN LIPS AND END UP HAVING ANAPHYLATIC REACTION AND BLOOD CLOT
1314360	5/13/2021	IL	78	F	2/28/2021	4/26/2021	Patient stated she developed clots during hospital admission with the complaint of chest pain. Patient stated at hospital admission, they discovered blood clot in her right leg and right lung. Patient was treated with oxygen and medication. Patient was inpatient for two nights and sent home lovenox injections for one week and continuing with Eliquis. Patient is currently on Eliquis for unknown duration. Patient will see cardiologist in three weeks and reevaluate.

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1313623	5/13/2021	OH	42	M	3/19/2021	3/29/2021	STEMI with 100% blockage in LAD with clot. Emergency cath lab with stents. Symptoms started at 330am on 3-29-21. Came to ED shortly after. Initial testing and labs were negative. Began to have severe symptoms shortly after. Multiple doses of nitro and morphine given for chest pain with no relief. Taken for emergency heart cath by 7am.
1314436	5/13/2021	RI	75	M	3/11/2021	4/19/2021	3/11/2021-- received dose of Pfizer vaccine. Soon after vaccination, had B/L anterior rib pain that he could not otherwise explain. No trauma, dyspnea, dizziness, fever, headache, N/V, falls, personal or family history of blood clots or autoimmune disease, recent smoking (quit 38 yrs ago), prolonged immobility or travel, history of bleeding, red/hot joints, known cancer, or cough/hemoptysis (and patient has outpatient medical follow-up including preventive measures like screening colonoscopy). 4/19/2021-- B/L rib pain got worse with new scant hemoptysis. Went to Urgent Care and diagnosed with "pneumonia"-- prescribed azithromycin, Augmentin; of which he took 2 doses the next two days. Due to persistent symptoms, he presented to the ER 4/21/2021 and was found to have B/L segmental and subsegmental PE's without R heart strain. He had a mild troponin elevation in the setting of known vascular disease. He was not hypoxemic or hemodynamically unstable. No residual DVT noted on imaging. He was transitioned to Eliquis on was discharged home after 1 day (4/22/2021) with outpatient follow-up with outpatient physicians (plus hematology referral) for pending hypercoaguable workup. His medications were adjusted accordingly (e.g. ASA dose decreased given his new DOAC use).



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1313030	5/13/2021	MD	73	M	4/8/2021	4/27/2021	two blood clots in his right calf; It is painful; This is a spontaneous report from a contactable nurse. A 73-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 1 via an unspecified route of administration, administered in arm left at 10 am on 16Mar2021 (Batch/Lot number was not reported) as 1st dose, single; dose 2 via an unspecified route of administration, administered in arm left at 10 am on 08Apr2021 (Batch/Lot number was not reported) as 2nd dose, single, both for covid-19 immunisation. Medical history included ongoing varicose vein (for years, barely noticeable). No history of all previous immunization with the Pfizer vaccine considered as suspect. No additional vaccines administered on same date of the Pfizer suspect. No prior vaccinations received within 4 weeks. The patient's concomitant medications were not reported. The patient experienced two blood clots in his right calf on 27Apr2021, it is painful. The event 'two blood clots in his right calf' was reported as serious and seriousness criteria were medically significant and disability. He said it is better today once he started apixaban (ELIQUIS). He did not know if that was physical or mental. The adverse event required a visit to physician office. The patient underwent lab tests and procedures which included sonogram on leg: unknown results. The outcome of events was recovering.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

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1314655	5/13/2021	MD	48	F	3/28/2021	4/8/2021	April 8 - during normal exercise heart rate monitor registered at 177bpm (102%) for 4.5 minutes. Typically heart rate during same exercise is not higher than 90%, 158bpm. April 11 - winded after going up half a flight of stairs April 12 - low throbbing pain under right arm April 13 - low throbbing pain in right calf and top of right quad April 13 - contact PCP with symptoms and concern over J&J pause April 14 - PCP suggested a ECG and a d-dimer blood test April 15 - ECG showed abnormal (normal in August 2020) April 16 - blood test d-dimer results were 0.78 (no prior test to reference). PCP suggested Ultrasound for right leg. Oncologist recommended stopping tamoxifen April 19 - Ultrasound of right leg showed no clo Ultrasound showed no clots. April 22 - PCP recommended retesting D-Dimer in a few weeks to see if the value changed. May 7 - retested D-Dimer. Test score was 0.40 within normal limits.
1312642	5/13/2021	NC	84	F	3/1/2021	3/10/2021	My mother had her first Moderna COVID-19 vaccination on March 1st. On March 10th, she suffered a blood clot in her eye that caused the eye to lose vision. Her eye doctor said she is now permanently legally blind in that eye.... I do not know if the blood clot was caused by the vaccine, but I am reporting it in case there is a correlation.

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1314691	5/13/2021	WI	57	M	4/27/2021	5/8/2021	History of Present Illness: Patient has a history of sinus problems. He was scheduled for sinuplasty and had preoperative evaluation on 04/21/2021 with WBC 5.8, Hb 15.5, PLT 193,000. He had J&J covid vaccination on 04/27/2021. He underwent sinuplasty on 05/05/2021. Subsequent to his surgery he was having headache. He had some nasal discharge with blood. He took tramadol but had persistent pain. His symptoms were worsening up with some weakness of his right upper extremity. Was having generalized fatigue and weakness. He states he was getting short of breath with a flight of stairs. He had decreased appetite. He was given Vicodin for his headache with some improvement. He noted discoloration and bruising with pain in his left internal thigh area. Was noticing some changes in his vision but no loss of vision. He presented to the ED on 05/11/2021 and laboratory showed WBC 8.7 Hb15.2, PLT 6,000, segs 77%, lymphs 9%. He had no dark colored urine. INR 1.4 PTT 33, immature platelets 30.2. His bili was 2.1. He was treated with dexamethasone 40 mg. There is tiny focus of restricted diffusion in the both cerebellar hemispheres measuring up to 0.4 cm white matter left cerebellar hemisphere of left parietal junction measuring 0.5 cm compatible small lacunar infarcts. Chronic paranasal sinusitis. Patient described minimal blood with flushing his sinuses. Patient was ultimately transferred to Hospital after 3 days (on 5/11) for further acute care management given the multiple clots and bleeds associated with severe thrombocytopenia.
1314427	5/13/2021	TX	55	M	2/4/2021	4/9/2021	2/4/2021 - Vaccine 2/26/2021 - Left Ankle surgery 4/9/2021 - Left leg swelling 4/22/2021 - Ultrasound found clots in left leg from groin to ankle

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1312860	5/13/2021	TN	33	F	3/3/2021	4/9/2021	thought she was suffering from a stroke; anemia; double vertigo; blood clots, thick blood; dissociated; liver spazzed; slurring words; could not speak; possible underlying autoimmune disorder where genetic composition may have triggered this; malabsorption; looked very pale; heart disease; blood pressure was elevated, blood pressure was 190/130, uncontrolled and unspecified hypertension; severe vasculitis on the right side of brain; Thyroid calcification/thyroid had a lot of calcium build up; interstitial markings on lungs/doctor stated looked like COVID lungs; hands were so swollen that could not clench it; face was swollen; electrical shooting pain from the right brain stem of the neck; vision was blurry; stuttering; paranoid; confused; not able to recognize her daughter; hands were very stiff; stomach was bloated/looked 6 months pregnant; lethargic; bile dumps which then leads to inflammation of her intestines; clots the size of golf balls/soaked through a 24 count box of super tampons in 24 hours/period was very bright red; stomach was inflamed; period started 10 days early, which is completely abnormal for her menstrual cycle; severe ovarian pain that was up very high; could feel her hormones whooshing through her veins/foggy head/feeling funky/ felt stoned/ daydream dazes; irritable; migraine; stabbing pain; kidney pain; period pain; lightheaded; pimple in the back of her head; headache; chills; fatigue, tired; fever of 102.6F/fever which lasted another 12 hours; nausea; body aches, muscles started to ache; diarrhea; significant abdominal pain from the cramping due to heaving from the nausea; cramping/lot of cramping in the groin and thigh area; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of CEREBROVASCULAR ACCIDENT (thought she was suffering from a stroke), HYPERTENSION (blood pressure was elevated, blood pressure was 190/130, uncontrolled and unspecified hypertension), CENTRAL NERVOUS SYSTEM VASCULITIS (severe vasculitis on the right side of brain), AUTOIMMUNE DISORDER (possible underlying autoimmune disorder where genetic composition may have triggered this), THROMBOSIS (blood clots, thick blood) and INTERSTITIAL LUNG DISEASE (interstitial markings on lungs/doctor stated looked like COVID lungs) in a 33-year-old female patient who received

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mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 030B21A and 010A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Gallbladder removal. On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 09-Apr-2021, the patient experienced MUSCLE SPASMS (cramping/lot of cramping in the groin and thigh area), ABDOMINAL PAIN (significant abdominal pain from the cramping due to heaving from the nausea), DIARRHOEA (diarrhea), PYREXIA (fever of 102.6F/fever which lasted another 12 hours), NAUSEA (nausea), MYALGIA (body aches, muscles started to ache), CHILLS (chills) and FATIGUE (fatigue, tired). On 10-Apr-2021, the patient experienced HEADACHE (headache). On 12-Apr-2021, the patient experienced ACNE (pimple in the back of her head). On 13-Apr-2021, the patient experienced MENSTRUAL DISORDER (period started 10 days early, which is completely abnormal for her menstrual cycle), ADNEXA UTERI PAIN (severe ovarian pain that was up very high), FEELING ABNORMAL (could feel her hormones whooshing through her veins/foggy head/feeling funky/felt stoned/ daydream dazes), IRRITABILITY (irritable), MIGRAINE (migraine), PAIN (stabbing pain), RENAL PAIN (kidney pain), DYSMENORRHOEA (period pain), DIZZINESS (lightheaded), GASTRITIS (stomach was inflamed), GASTROINTESTINAL INFLAMMATION (bile dumps which then leads to inflammation of her intestines) and HEAVY MENSTRUAL BLEEDING (clots the size of golf balls/soaked through a 24 count box of super tampons in 24 hours/period was very bright red). On 14-Apr-2021, the patient experienced LETHARGY (lethargic). On 15-Apr-2021, the patient experienced MUSCULOSKELETAL STIFFNESS (hands were very stiff), ABDOMINAL DISTENSION (stomach was bloated/looked 6 months pregnant), PERIPHERAL SWELLING (hands were so swollen that could not clench it), SWELLING FACE (face was swollen), NECK PAIN (electrical shooting pain from the right brain stem of the neck), VISION BLURRED (vision was blurry), DYSPEMIA (stuttering), PARANOIA (paranoid),

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CONFUSIONAL STATE (confused) and MEMORY IMPAIRMENT (not able to recognize her daughter). On 16-Apr-2021, the patient experienced CEREBROVASCULAR ACCIDENT (thought she was suffering from a stroke) (seriousness criterion hospitalization), HYPERTENSION (blood pressure was elevated, blood pressure was 190/130, uncontrolled and unspecified hypertension) (seriousness criterion hospitalization prolonged), CENTRAL NERVOUS SYSTEM VASCULITIS (severe vasculitis on the right side of brain) (seriousness criterion medically significant), INTERSTITIAL LUNG DISEASE (interstitial markings on lungs/doctor stated looked like COVID lungs) (seriousness criterion medically significant), PALLOR (looked very pale), CARDIAC DISORDER (heart disease) and THYROID CALCIFICATION (Thyroid calcification/thyroid had a lot of calcium build up). On 19-Apr-2021, the patient experienced AUTOIMMUNE DISORDER (possible underlying autoimmune disorder where genetic composition may have triggered this) (seriousness criterion medically significant) and MALABSORPTION (malabsorption). On an unknown date, the patient experienced THROMBOSIS (blood clots, thick blood) (seriousness criteria disability and medically significant), ANAEMIA (anemia), VERTIGO (double vertigo), DISSOCIATION (dissociated), LIVER DISORDER (liver spazzed), DYSARTHRIA (slurring words) and APHASIA (could not speak). The patient was hospitalized from 16-Apr-2021 to 17-Apr-2021 due to CEREBROVASCULAR ACCIDENT and HYPERTENSION. On 10-Apr-2021, PYREXIA (fever of 102.6F/fever which lasted another 12 hours) and CHILLS (chills) had resolved. On 12-Apr-2021, MUSCLE SPASMS (cramping/lot of cramping in the groin and thigh area), MYALGIA (body aches, muscles started to ache) and FATIGUE (fatigue, tired) had resolved. At the time of the report, CEREBROVASCULAR ACCIDENT (thought she was suffering from a stroke), CENTRAL NERVOUS SYSTEM VASCULITIS (severe vasculitis on the right side of brain), AUTOIMMUNE DISORDER (possible underlying autoimmune disorder where genetic composition may have triggered this), THROMBOSIS (blood clots, thick blood), INTERSTITIAL LUNG DISEASE (interstitial markings on lungs/doctor stated looked like COVID lungs), IRRITABILITY (irritable), PAIN

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(stabbing pain), DIZZINESS (lightheaded), MUSCULOSKELETAL STIFFNESS (hands were very stiff), ABDOMINAL DISTENSION (stomach was bloated/looked 6 months pregnant), GASTRITIS (stomach was inflamed), PERIPHERAL SWELLING (hands were so swollen that could not clench it), SWELLING FACE (face was swollen), NECK PAIN (electrical shooting pain from the right brain stem of the neck), VISION BLURRED (vision was blurry), DYSPHEMIA (stuttering), PARANOIA (paranoid), CONFUSIONAL STATE (confused), MEMORY IMPAIRMENT (not able to recognize her daughter), PALLOR (looked very pale), CARDIAC DISORDER (heart disease), MALABSORPTION (malabsorption), ANAEMIA (anemia), VERTIGO (double vertigo), THYROID CALCIFICATION (Thyroid calcification/thyroid had a lot of calcium build up), GASTROINTESTINAL INFLAMMATION (bile dumps which then leads to inflammation of her intestines), LETHARGY (lethargic), ACNE (pimple in the back of her head), DIARRHOEA (diarrhea), DISSOCIATION (dissociated), LIVER DISORDER (liver spazzed), DYSARTHRIA (slurring words), APHASIA (could not speak), NAUSEA (nausea) and HEADACHE (headache) outcome was unknown, HYPERTENSION (blood pressure was elevated, blood pressure was 190/130, uncontrolled and unspecified hypertension) and FEELING ABNORMAL (could feel her hormones whooshing through her veins/foggy head/feeling funky/ felt stoned/ daydream dazes) had not resolved, MENSTRUAL DISORDER (period started 10 days early, which is completely abnormal for her menstrual cycle), ADNEXA UTERI PAIN (severe ovarian pain that was up very high), RENAL PAIN (kidney pain), DYSMENORRHOEA (period pain), HEAVY MENSTRUAL BLEEDING (clots the size of golf balls/soaked through a 24 count box of super tampons in 24 hours/period was very bright red) and ABDOMINAL PAIN (significant abdominal pain from the cramping due to heaving from the nausea) had resolved and MIGRAINE (migraine) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Apr-2021, Body temperature: 102.6 (High) fever of 102.6F. In April 2021, Neurological examination: abnormal (abnormal) neurological damage to the hippocampus of the central cranial. On 16-Apr-

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1312663	5/13/2021	CA	45	M	3/26/2021	3/27/2021	<p>2021, Blood pressure measurement: 190/130 (abnormal) 190/130 and 175/99 (abnormal) 175/99 after treatment with Metoprolol. On 16-Apr-2021, Chest X-ray: interstitial markings of her lungs (abnormal) interstitial markings of her lungs. On 16-Apr-2021, Computerised tomogram: interstitial markings of her lungs (abnormal) interstitial markings of her lungs. On 16-Apr-2021, Magnetic resonance imaging: severe vasculitis on the right side of her brain (abnormal) severe vasculitis on the right side of her brain. On 16-Apr-2021, Neurological examination: 3/5 tests failed (abnormal) 3/5 tests failed. On 19-Apr-2021, Stool analysis: abnormal (abnormal) showed she was putting out too much potassium, magnesium. On 28-Apr-2021, Blood pressure measurement: 145/90 (abnormal) 145/90. On 28-Apr-2021, Heart rate: 90 (High) was not coming under 90 bpm. On 28-Apr-2021, Magnetic resonance imaging: blood clots, thick blood, anemia (abnormal) blood clots, thick blood, anemia. Action taken with mRNA-1273 in response to the events was not Applicable. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to MOD-2021-095842 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> <p>Several hours after Covid vaccine pt developed his classic sickle cell crisis symptoms of severe pain and was hospitalized 3/ 27 to 3/ 31 with sickle cell crisis. No clinical evidence of thrombosis, treated with IV hydration and oxygen and improved in several days. Had a previous h/o sickle cell crisis and hospitalization while taking oral typhoid vaccine in 2017. After discharge, 5 days later had onset of chest pain, returned to ER, Chest CT negative for embolus, D- Dimer &gt; 18,000. No clinical evidence of clot. pt hydrated again / O2 but was able to go home. Covid negative by PCR during both episodes.</p>



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1312761	5/13/2021	MS	64	F	3/24/2021		<p>BOTH LEG PAIN; HIVES / WORSENING HIVES; GASTROESOPHAGEAL REFLUX DISEASE; FELT LIKE HAVING HEART ATTACK; SLEEP INTERRUPTIONS; FLU-LIKE SYMPTOMS; ACES; NAUSEA; This spontaneous report received from a patient concerned a 64 year old female. The patient's height, and weight were not reported. The patient's past medical history included neuropathy. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805022, expiry: UNKNOWN) dose was not reported, administered on 06-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 2021, Laboratory data included: Investigation (NR: not provided) blood clots which were negative. On 24-MAR-2021, the subject experienced flu-like symptoms. On 24-MAR-2021, the subject experienced aches. On 24-MAR-2021, the subject experienced sleep interruptions. On 24-MAR-2021, the subject experienced nausea. On 27-MAR-2021, the subject experienced felt like having heart attack. On 27-MAR-2021, the subject experienced gastroesophageal reflux disease. On 30-MAR-2021, the subject experienced hives / worsening hives. On 04-APR-2021, the subject experienced both leg pain. Treatment medications (dates unspecified) included: diphenhydramine hydrochloride, and famotidine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from flu-like symptoms, aches, felt like having heart attack, sleep interruptions, gastroesophageal reflux disease, hives / worsening hives, and nausea on 2021, and both leg pain on APR-2021. This report was non-serious.; Sender's Comments: V0: Medical assessment comment not required as per standard procedure as case assessed as non-serious.</p>

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1312763	5/13/2021	IL	48	F	3/16/2021		<p>COVID-19 PNEUMONIA; ALLERGY TO VACCINE; STOOLS HARD; STOMACH SWELL UP; MUSCLE SPASMS/ CRAMPS; BREAST SWELLING; PAIN FROM BACK OF SPINE TO TOP OF THE HEAD; NUMBNESS IN THE FINGERS; ABDOMINAL TENDERNESS; BLANKED OUT; RINGING IN THE EAR; FACIAL SWELLING; PAINFUL BLISTER; DIFFICULTY EATING; This spontaneous report received from a patient concerned a 48 year old (Indian or Native/aboriginal) female. The patient's weight was 272 pounds, and height was 66 inches. The patient's past medical history included partial tubal ligation, and part of colon removed, and concurrent conditions included asthma, bronchitis, bleeding disorder (irregular period), cyst on ovary, gerd, high blood pressure, adhd, dysmenorrhea, tingling of extremities, asa allergy, narcotics allergy, soap residue allergy, lactose intolerance, tramadol allergy, sulfa antibiotics allergy, strawberry extract allergy, penicillin allergy, metronidazole allergy, nalbuphine allergy, oxybutynin allergy, bees wax allergy, haloperidol allergy, fluoxetine allergy, medroxy progesterone allergy, gabapentin allergy, and latex allergy. The patient had a blood test with her MD prior to and was told did not have Covid and could get the shot. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805018, expiry: unknown) dose was not reported, administered to right arm on 16-MAR-2021, around 16:00 for prophylactic vaccination. No concomitant medications were reported. The patient was treated with injections to prevent blood clots (they did injection in the stomach area). On 16-MAR-2021, around 09:00 PM, patient experienced facial swelling and blister on the right side of her lip was burst and formed a scab and that made it difficult to eat. On next morning, 17-MAR-2021, patient had excruciating pain from top of her head to nostrils, it caused being weak and blanked out. On the day after, 18-MAR-2021, patient had a different taste and a different smell, also had ringing in the ear and was nauseous. On the 5th day, 20-MAR-2021, patient's stomach was swelled and was really tender and breast was also swelled. The patient had a lot of headache, cramps, muscle spasms, body ache and was cold and hot. The patient had diarrhoea and had to lay down and had to crawl to bathroom with throwing up. The patient had high fever and could not</p>

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keep anything down. On 20-MAR-2021, the patient experienced pain from back of spine to top of the head, numbness in the fingers. On 22-APR-2021, the patient experienced hard stools. On 27-MAR-2021, patient was hospitalized as she was coughing blood. On an unknown date, patient had patches on the x-ray and was diagnosed with pneumonia and her Covid (unknown) test was positive. Patient reported that she was given injections to prevent blood clots in the stomach area. The patient had pain back from spine to top of the head, was weak, had numbness in the fingers. She had headache, had lost appetite. The patient reported that as per her healthcare providers, was allergic to the vaccine as they noted shortness of breath, nausea and diarrhea. Laboratory data included: Body temperature (NR: not provided) High. On 27-MAR-2021, COVID-19 virus test positive (NR: not provided) positive, and X-ray (NR: not provided) blood patched, pneumonia. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from covid-19 pneumonia, and ringing in the ear, was recovering from facial swelling, painful blister, difficulty eating, stomach swell up, muscle spasms/ cramps, blanked out, and abdominal tenderness, had not recovered from pain from back of spine to top of the head, numbness in the fingers, and stools hard, and the outcome of allergy to vaccine and breast swelling was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0:20210507603-covid-19 vaccine ad26.cov2.s -covid-19 pneumonia. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: UNDERLYING DISEASE

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1312771	5/13/2021	VA		U			<p>FEMALE ISSUES; BLOOD CLOTS; This spontaneous report received from a consumer concerned multiple patients. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. No concomitant medications were reported. The batch number was not reported and has been requested. On an unspecified date, the consumer called and reported that he had read in newspaper that women had gotten blood clots and 3 passed away with female issues. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of female issues on an unspecified date, and the outcome of blood clots was not reported. This report was serious (Death, and Other Medically Important Condition).; Sender's Comments: V0. 20210510294 - COVID-19 VACCINE AD26.COV2.S- Female issues, Blood clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH</p>

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1312782	5/13/2021	NM		F		4/9/2021	BLOOD CLOT IN BRAIN; BODYACHES; HORRIBLE NAUSEA; SLIGHT FEVER; This spontaneous report received from social media/news via a company representative concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose was not reported, 1 total administered on 08-APR-2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On 09-APR-2021, the patient developed blood clot in brain and it was discovered by computed tomography (CT) scan (date unspecified), went to emergency room (ER). He was admitted in the hospital (date unspecified) for blood clot in brain. On the same day, the patient also experienced body aches, horrible nausea and horrible headache, slight fever. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the blood clot in brain, horrible nausea, body aches and slight fever was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210514154-covid-19 vaccine ad26.cov2.s-blood clot in brain. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
1314742	5/13/2021	CA	68	M	3/22/2021	3/23/2021	Patient's body was found on May 1st. Since the shot , he was complaining of tinnitus, sore legs, dizziness (passed out several times), loss of bowel control, and unable to maintain a stream of thought, which are stroke symptoms. He has had surgery for blood clots in the past. He seemed to get worse in the weeks following the Jansen shot.

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1313046	5/13/2021	KY	36	F	4/26/2021	4/27/2021	<p>began having severe cramping and heavy bleeding with clots the next day; Started menstrual cycle a week early a day after getting second dose; began having severe cramping; heavy bleeding with clots the next day; This is a spontaneous report from a contactable consumer (patient). A 36-year-old female patient received bnt162b2 (BNT162B2, Pfizer COVID 19), dose 2 via an unspecified route of administration, administered in left arm on 26Apr2021 08:45 (Lot Number: unknown) as single dose for covid-19 immunization. Medical history included Anemia, ulcerative colitis, intracranial hypertension. None allergies reported. Concomitant medications included iron taken for anaemia. The patient received dose 1 on 01Apr2021 07:45 in right arm for covid-19 immunization. The patient started menstrual cycle a week early a day after getting second dose. The patient began having severe cramping and heavy bleeding with clots the next day 27Apr2021. No treatment received. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, patient was not diagnosed with COVID-19, Since the vaccination, patient has not been tested for COVID-19. The outcome was recovering. Follow up attempts are needed. Further information has been requested.</p>

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1315709	5/13/2021	NY	33	M	4/1/2021		<p>BLOOD CLOT IN LOWER CALF MUSCLES IN RIGHT LEG (DVT); NAUSEA (AFTER VACCINATION); EXTREMELY BAD HEADACHES; MUSCLES ACHE; BODY ACHE; LEG PAIN; This spontaneous report received from a patient concerned a 33 year old hispanic or latino male. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included the patient had no known drug allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 041A21A, expiry: 21-JUN-2021) dose was not reported, 1 total administered on 02-APR-2021 on left arm for prophylactic vaccination. No concomitant medications were reported. On 03-APR-2021, the patient experienced post vaccine nausea, extremely bad headaches, muscles aches. On 28-APR-2021, the patient experienced blood clot in lower calf muscles in right leg DVT (deep vein thrombosis). At around 2 weeks ago on 28-Apr-2021 or 29-Apr-2021, he started to feel throbbing pain and tightness in calf area. On an unspecified date in APR-2021, the patient experienced body aches specially in leg, back and arms and felt like it was a strain calf muscles or achilles pain, tightness in calf. At around 1-May-2021 to 2-May-2021, he felt the pain was extremely worse although he did not have any trauma and he did not run that may have caused a muscles strain. He went to emergent care on 5-May-2021, as he does not have a medical insurance. The doctor ordered an ultrasound as the pain he was experiencing was unlikely due to muscles strains as he did not do anything that may have caused it. On same day, laboratory data included: blood test (NR: not provided) all results are normal and diagnostic ultrasound showed DVT in lower right calf muscles in right leg. It was reported that, he was asked if he reporting those side effect to Janssen would affect him by anyway if he want to proceed into any legal action against Janssen as he experienced a blood clot. he was also asking if Janssen can provide him for the cost. On 08-May-2021, treatment medications included rivaroxaban. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from nausea (after vaccination), extremely bad headaches, and muscles aches, had not recovered from blood clot in lower calf muscles in right leg (DVT), and the outcome of body</p>

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ache and leg pain was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210515729 -Covid-19 vaccine ad26.cov2.s-BLOOD CLOT IN LOWER CALF MUSCLES IN RIGHT LEG (DVT). This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).





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1312890	5/13/2021	PA	68	F	2/17/2021	2/19/2021	<p>She is bleeding behind retina so she can't see properly; Clot in retinal branch; She can't see properly; She sees blurry; Light nose bleed; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of RETINAL HAEMORRHAGE (She is bleeding behind retina so she can't see properly) and RETINAL VASCULAR OCCLUSION (Clot in retinal branch) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 016M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was provided by the reporter. On 17-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 19-Feb-2021, the patient experienced EPISTAXIS (Light nose bleed). On 22-Apr-2021, the patient experienced VISION BLURRED (She sees blurry). On 29-Apr-2021, the patient experienced RETINAL HAEMORRHAGE (She is bleeding behind retina so she can't see properly) (seriousness criterion medically significant), RETINAL VASCULAR OCCLUSION (Clot in retinal branch) (seriousness criterion medically significant) and VISUAL IMPAIRMENT (She can't see properly). At the time of the report, RETINAL HAEMORRHAGE (She is bleeding behind retina so she can't see properly), RETINAL VASCULAR OCCLUSION (Clot in retinal branch), VISUAL IMPAIRMENT (She can't see properly), VISION BLURRED (She sees blurry) and EPISTAXIS (Light nose bleed) outcome was unknown. Patient started with light nose bleed 2 days after receiving vaccine. Then 2 weeks ago, she developed problem with her eyes. She mentions that she sees blurry. She went to doctor on 29Apr2021 and doctor said that there was a clot in retinal branch and she is bleeding behind retina so she can't see properly. Treatment medication includes: Vastin Injection for the eyes Concomitant medication includes: BP medicine Company comment Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information</p>

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and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

1313014 5/13/2021 ND

46 M

2/17/2021

4/18/2021

Blood clot in left leg; This is a spontaneous report from a contactable consumer (patient). A 47-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), on 25Jan2021 10:30 (lot: EL3302) as 1ST DOSE, SINGLE then on 17Feb2021 10:30 (lot: EL9264) as 2ND DOSE, SINGLE; both via an unspecified route of administration in left arm (at the age of 46-years-old) for covid-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, the patient was not tested for COVID-19. Medical history included covid-19 (prior to vaccination, diagnosed with COVID) and no past drug event. The patient's concomitant medications were not reported. The reported event was blood clot in left leg on 18Apr2021 at 22:00. The event resulted in doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Treatment received for the adverse event was an unspecified medication. The outcome of the event was not recovered. No follow-up attempts are needed. No further information is expected.

1313019 5/13/2021 IL

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blood clot; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as unknown, single for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that this patient who is a physician, experienced blood clot on an unspecified date. The outcome of the event was unknown. Information on batch number has been requested

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1313038	5/13/2021	WA	53	M	4/20/2021	4/20/2021	possible thrombosis reaction; Unexpected bruising near injection site.; Bruise was purple and red splotches and has now progressed to mostly yellow/discoloration; Bruise was purple and red splotches and has now progressed to mostly yellow/discoloration; minimal pain/stiffness following the shot; minimal pain/stiffness following the shot; This is a spontaneous report from a contactable consumer (patient). A 53-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), at the age of 53-year-old via an unspecified route of administration, administered in Arm Left on 20Apr2021 11:15 (Lot Number: EW0153) at 1st dose, single for covid-19 immunisation. The patient medical history was not reported. The patient received no other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Concomitant medication included famotidine (PEPCID AC). The patient previously took flu shot in Oct2020, prilosec [omeprazole magnesium] for seasonal allergy and experienced drug hypersensitivity. The patient experienced unexpected bruising near injection site. Bruise was the size of the bandaaid, approximately 1" x 2". Bruising had persisted for more than a week now. The patient had never experienced bruising like this with other vaccines. He would like to rule out possible thrombosis reaction before second shot. He did not have bruising at any other locations other than the injection site. Bruise was purple and red splotches and has now progressed to mostly yellow. He believed the discoloration was a reaction to the vaccine and not the result of the needle. The shot itself was painful but patient felt minimal pain/stiffness following the shot. The event start date was on 20Apr2021. No treatment was received. The outcome was unknown.

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1313057	5/13/2021	TX	63	F	2/28/2021	3/11/2021	a blot clot discovered in lung within 2 weeks of first shot.; This is a spontaneous report from a contactable consumer (patient). A 63-year-old patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number En6202, on 28Feb2021 10:45 at single dose in right arm for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient had no known allergies. The patient had no covid prior vaccination. The patient had not tested covid post vaccination. The patient had not received any other vaccines within 4 weeks prior to the COVID vaccine. The patient had a blot clot discovered in lung within 2 weeks of first shot on 11Mar2021. The event resulted in Physician Office Visit. Treatment included blood thinner for blood clot. The outcome of the event was unknown. The event is serious with hospitalization and disability. Follow-up attempts are needed. Further information is expected.

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1313062	5/13/2021	NV	68	F	4/8/2021	4/1/2021	<p>passing blood clots from her rectum; blood clots; deathly ill; the lymph nodes underneath the arm swell up / She swelled up on her right side; kind of in the breast/chest area, up a little higher than the breast and it was very uncomfortable; This is a spontaneous report received a contactable consumer, the patient. A 68-year-old elderly female received the first dose of intramuscular BNT162b2 (solution for injection; Lot ER8737 and expiry information not provided) as a single dose in the left arm on 08Apr2021 at 11:00 (at 68-years-old) for COVID-19 immunisation. Relevant medical history included ongoing back problems for which she takes medication. Concomitant medications included unspecified medication for back problems. The patient denied any other vaccines within four weeks prior to this vaccine. The patient reported that she generally gets the flu shot every year and has never had any adverse reactions. The patient also mentioned that she previously tramadol (for an unspecified indication) in the past but has not taken it for years. The patient reported that she received her first dose on 08Apr2021 at (Privacy). The patient explained that within six hours she was deathly ill. The patient reported that stayed very ill for quite a few days. The patient stated when she gets up in the morning, she gets up early and she always goes to the bathroom. The patient stated that on 13Apr2021, when she went to the bathroom, she started passing blood clots from her rectum which went on until 16Apr2021. When describing the blood clots, the patient stated 'envision sunny side up eggs, between six to eight of them, and in between that was all this webbing holding the clots together'. The patient stated while she was urinating, the clots were just pouring out of her rectum. The patient clarified that there was not blood in her stool. The patient explained that she took the opportunity to get some plastic gloves and look through her stool for blood and there was not any. The patient stated that her underwear and the toilet paper was stained. The patient also stated that she was reading that whichever arm you get the vaccine, the lymph nodes underneath the arm swell up. The patient explained that her lymph nodes did not swell up underneath her left arm where she got the shot. She swelled up on her right side. She clarifies she was swollen underneath her arm, kind of in the breast area and chest area, up a little higher than the breast. It was very uncomfortable. The patient</p>

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1313235	5/13/2021		26	M	5/2/2021		<p>denied any visits to the emergency room or doctor's office for the events. The outcome of the event passing blood clots from her rectum was recovered on 16Apr2021. The outcome of the events deathly ill, the lymph nodes underneath the arm swell up / She swelled up on her right side, and was very uncomfortable was unknown.</p> <p>SUSPECTED URETHRAL MUCOSITIS; CLOT; PENIS TIP GOT RED; PENIS PAIN; SAW ANGELS AND DEMONS IN BED; TERRIBLE MALAISE; HEADACHE; FEVER 40 DEGREE; This spontaneous report received from a patient concerned a 26-year-old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 204A21A, and expiry: UNKNOWN) dose was not reported, 1 total, administered on 02-MAY-2021 for prophylactic vaccination. No concomitant medications were reported. On 02-MAY-2021 at night, the patient experienced some symptoms after vaccination including Fever of 40 degrees Celsius, headache, and a terrible malaise. The patient also reported seeing angels and demons in bed; Also, the patient noticed that the penis tip got red and experienced pain. On 05-MAY-2021, the patient continued with the symptoms, and it seemed as if a clot was generated. On 06-MAY-2021, the patient had an appointment with general physician who informed that he never saw an adverse reaction like this after vaccination and that it could be a urethral mucositis. On 10-May-2021, the patient would have an appointment with the urologist to inform the symptoms. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the fever 40 degree Celsius, saw angels and demons in bed, headache, terrible malaise, penis tip got red, penis pain, clot and urethral mucositis was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0.20210513944-covid-19 vaccine ad26.cov2.s -thrombosis. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>



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1312847	5/13/2021	NC	21	F	4/7/2021		LEG PAIN; FATIGUE; FEVER; DIZZY; This spontaneous report received from a parent concerned a 21 year old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 043A21A expiry: UNKNOWN) dose was not reported, administered on 07-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, the subject experienced dizzy. On 07-APR-2021, the subject experienced fatigue. On 07-APR-2021, the subject experienced fever. On 08-APR-2021, the subject experienced leg pain. On 16-APR-2021, Laboratory data included: Diagnostic ultrasound (NR: not provided) Not had clots. Treatment medications (dates unspecified) included: ibuprofen. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from dizzy, fatigue, and fever on 08-APR-2021, and leg pain. This report was non-serious.

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1315704	5/13/2021	MD	64	M		3/16/2021	BLOOD CLOTS BOTH LEGS; POSSIBLE HEARTBURN; SWELLING AT INJECTION SITE; This spontaneous report received from a patient concerned a 64 year old male. The patients weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805022, and expiry: UNKNOWN) dose was not reported, frequency 1 total, administered on 16-MAR-2021 at left arm for prophylactic vaccination. No concomitant medications were reported. On 16-MAR-2021, the patient experienced swelling at injection site. On 19-APR-2021, patient had blood clots (1 in each leg), Hematologist put him on xarelto 10mg, in hospital for few days for blood clots. Patient initially went to hospital ER on 19-APR-2021 because he thought having chest pains or heartburn. Emergency Room ran tests and heart was normal, but found blood clots in his both legs. Lab test (NR: not provided) Heart normal. Treatment medications (dates unspecified) included: rivaroxaban. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from thought having chest pains/heartburn on 22-APR-2021, had not recovered from blood clots both legs, and the outcome of swelling at injection site was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210504455-COVID-19 VACCINE AD26.COV2.S-Blood clot both legs. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
1314916	5/13/2021	CO	26	F		4/7/2021	4/7/2021 My symptoms starting the night I got the vaccine and lasted for 2 weeks after. I had a fever, chills, severe headache, nausea, shortness of breath, muscle aches, fatigue, and pain in my left leg. We ended up going to the emergency room the week after because of fear of blood clots.

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1315855	5/13/2021	CO	48	F	3/31/2021	3/31/2021	Went hiking and got a blood clot; beyond 36 days since first dose without receiving second dose; Interfered with work; Glands got super swollen; Trunk Rash; Excruciating headaches for three days; Extremely fatigued; High temperature; Nauseous; Ringing in ears; Taste buds changed; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Went hiking and got a blood clot) in a 48-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 017B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Grover's disease. Concurrent medical conditions included Allergy NOS (allergies for which she has an epi pen) and Premenopausal symptoms (Rashes with premenopausal condition). On 31-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 31-Mar-2021, the patient experienced TINNITUS (Ringing in ears), TASTE DISORDER (Taste buds changed), LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (Interfered with work), LYMPHADENOPATHY (Glands got super swollen), RASH (Trunk Rash), HEADACHE (Excruciating headaches for three days), FATIGUE (Extremely fatigued), PYREXIA (High temperature) and NAUSEA (Nauseous). On 30-Apr-2021, the patient experienced INTENTIONAL PRODUCT USE ISSUE (beyond 36 days since first dose without receiving second dose). On 01-May-2021, the patient experienced THROMBOSIS (Went hiking and got a blood clot) (seriousness criterion medically significant). On 30-Apr-2021, INTENTIONAL PRODUCT USE ISSUE (beyond 36 days since first dose without receiving second dose) had resolved. At the time of the report, THROMBOSIS (Went hiking and got a blood clot), TINNITUS (Ringing in ears), TASTE DISORDER (Taste buds changed), LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (Interfered with work), LYMPHADENOPATHY (Glands got super swollen), RASH (Trunk Rash), HEADACHE (Excruciating headaches for three days), FATIGUE (Extremely fatigued), PYREXIA (High temperature) and NAUSEA (Nauseous) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test:

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							negative (Negative) Negative. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not reported. Treatment information was not provided. Company Comment Very limited information regarding these events has been provided at this time. The events are probably related to the patient's comorbidities. A causal relationship cannot be excluded for the events of rash, fatigue, pyrexia, lymphadenopathy and headache.
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1315815	5/13/2021	NY	74	M	9/18/2020	1/27/2021	Dysphonia; Intentional product use issue; dyspnea on exertion; pulmonary edema; immune mediated pneumonitis; right ventricular failure; atrial fibrillation; hyperdynamic left ventricle; mitral valve incompetence; Interstitial lung disease; Tricuspid valve incompetence; Pulmonary fibrosis; Hypoxia; Hypotension; Unevaluable event; Headache; Therapeutic product effect incomplete; Drug ineffective; Vomiting; Asthenia; Diarrhoea; Nausea; pneumonia; Right atrial dilatation; Aortic valve sclerosis; Coronary artery disease; Malaise; Muscular weakness; Fatigue; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of HYPOXIA (Hypoxia), DYSPNOEA EXERTIONAL (dyspnea on exertion), PULMONARY OEDEMA (pulmonary edema), IMMUNE-MEDIATED LUNG DISEASE (immune mediated pneumonitis), RIGHT VENTRICULAR FAILURE (right ventricular failure), ATRIAL FIBRILLATION (atrial fibrillation), HYPERDYNAMIC LEFT VENTRICLE (hyperdynamic left ventricle), MITRAL VALVE INCOMPETENCE (mitral valve incompetence), INTERSTITIAL LUNG DISEASE (Interstitial lung disease), TRICUSPID VALVE INCOMPETENCE (Tricuspid valve incompetence), PULMONARY FIBROSIS (Pulmonary fibrosis), INTENTIONAL PRODUCT USE ISSUE (Intentional product use issue), DYSPHONIA (Dysphonia) and HYPOTENSION (Hypotension) in a 74-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product AMIFAMPRIDINE PHOSPHATE (FIRDAPSE) for Myasthenic syndrome. The patient's past medical history included Pulmonary arterial pressure abnormal on 03-Jul-2018, Migraine (Ever since he was a kid), Headache, Small cell lung cancer metastatic (In liver and lymph nodes; brain metastases; right-sided pulmonary nodules), Metastases to liver, Metastases to lymph nodes (One measurable mediastinal lymph node; lymphadenopathy), Gait disturbance, Metastases to central nervous system, Muscular weakness and Radiotherapy (of his head and lung for his cancer). Concurrent medical conditions included Myasthenic syndrome (Cannot walk without FIRDAPSE). Concomitant products included PANTOPRAZOLE,

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ACETYLSALICYLIC ACID (ASPIRIN 81) and FUROSEMIDE for an unknown indication. On 18-Sep-2020, the patient started AMIFAMPRIDINE PHOSPHATE (FIRDAPSE) (Oral) 10 milligram three times a day. In January 2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 27-Jan-2021, the patient experienced HYPOXIA (Hypoxia) (seriousness criteria death, hospitalization and medically significant), PULMONARY OEDEMA (pulmonary edema) (seriousness criteria death and hospitalization), IMMUNE-MEDIATED LUNG DISEASE (immune mediated pneumonitis) (seriousness criteria death and hospitalization), RIGHT VENTRICULAR FAILURE (right ventricular failure) (seriousness criteria death, hospitalization and medically significant), ATRIAL FIBRILLATION (atrial fibrillation) (seriousness criteria death, hospitalization and medically significant), HYPERDYNAMIC LEFT VENTRICLE (hyperdynamic left ventricle) (seriousness criteria death, hospitalization and medically significant), MITRAL VALVE INCOMPETENCE (mitral valve incompetence) (seriousness criteria death, hospitalization and medically significant), INTERSTITIAL LUNG DISEASE (Interstitial lung disease) (seriousness criteria death and hospitalization), TRICUSPID VALVE INCOMPETENCE (Tricuspid valve incompetence) (seriousness criteria death, hospitalization and medically significant), PULMONARY FIBROSIS (Pulmonary fibrosis) (seriousness criteria death, hospitalization and medically significant), DYSPHONIA (Dysphonia) (seriousness criteria death and hospitalization), HYPOTENSION (Hypotension) (seriousness criteria death and hospitalization), PNEUMONIA (pneumonia), RIGHT ATRIAL DILATATION (Right atrial dilatation), AORTIC VALVE SCLEROSIS (Aortic valve sclerosis), CORONARY ARTERY DISEASE (Coronary artery disease), MALAISE (Malaise), MUSCULAR WEAKNESS (Muscular weakness) and FATIGUE (Fatigue). On 31-Jan-2021, the patient experienced DYSPNOEA EXERTIONAL (dyspnea on exertion) (seriousness criteria death and hospitalization), ASTHENIA (Asthenia), DIARRHOEA (Diarrhoea), NAUSEA (Nausea) and VOMITING (Vomiting). On an unknown date, the patient experienced INTENTIONAL PRODUCT USE ISSUE (Intentional product use issue) (seriousness criteria death

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and hospitalization), UNEVALUABLE EVENT (Unevaluable event), THERAPEUTIC PRODUCT EFFECT INCOMPLETE (Therapeutic product effect incomplete), DRUG INEFFECTIVE (Drug ineffective) and HEADACHE (Headache). The patient was hospitalized from 27-Jan-2021 to 15-Feb-2021 due to DYSPHONIA, then from 31-Jan-2021 to 15-Feb-2021 due to ATRIAL FIBRILLATION, DYSPNOEA EXERTIONAL, HYPERDYNAMIC LEFT VENTRICLE, HYPOTENSION, HYPOXIA, IMMUNE-MEDIATED LUNG DISEASE, INTENTIONAL PRODUCT USE ISSUE, INTERSTITIAL LUNG DISEASE, MITRAL VALVE INCOMPETENCE, PULMONARY FIBROSIS, PULMONARY OEDEMA, RIGHT VENTRICULAR FAILURE and TRICUSPID VALVE INCOMPETENCE. The last dose administered for AMIFAMPRIDINE PHOSPHATE (FIRDAPSE) was on 18-Feb-2021. The patient died on 19-Feb-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, PNEUMONIA (pneumonia), UNEVALUABLE EVENT (Unevaluable event), ASTHENIA (Asthenia), DIARRHOEA (Diarrhoea), THERAPEUTIC PRODUCT EFFECT INCOMPLETE (Therapeutic product effect incomplete), DRUG INEFFECTIVE (Drug ineffective), RIGHT ATRIAL DILATATION (Right atrial dilatation), AORTIC VALVE SCLEROSIS (Aortic valve sclerosis), CORONARY ARTERY DISEASE (Coronary artery disease), MALAISE (Malaise), MUSCULAR WEAKNESS (Muscular weakness), FATIGUE (Fatigue), NAUSEA (Nausea), HEADACHE (Headache) and VOMITING (Vomiting) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Jul-2018, Pulmonary arterial pressure: pulmonary arterial pressure elevated (High) Pulmonary arterial pressure elevated. In 2021, Angiogram: no evidence for central pulmonary embolus. (Inconclusive) No evidence for central pulmonary embolus. Slight interval decrease in the patient's 2 previously identified right sided pulmonary nodules. Slight decrease in the one measurable mediastinal lymph node. The patient's other lymphadenopathy is probably also improved but difficult to measure due to the technique. Worsening airspace disease in a somewhat interstitial pattern. Pulmonary edema would be the first consideration. Infection would be the second consideration. Severe

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centrilobar and paraseptal emphysema with basilar predominately peripheral reticular opacities consistent with fibrotic lung disease.. In 2021, Chest X-ray: no infiltrate (Inconclusive) no infiltrate. In 2021, Echocardiogram: severe right atrial ventricular dilatation with... (abnormal) Severe right atrial ventricular dilatation with reduced RV systolic function ("D" sign). Small and under-filled left ventricle with hyperdynamic systolic function, estimated LVEF is 75%. Minimal aortic valve sclerosis with no stenosis. Moderate mitral and tricuspid valve regurgitation. Estimated PA systolic pressure is severely elevated (68.6 mmHg). Compared to the prior report dated 7/3/2018; there is a worsening right heart dilatation and function. There is increased mitral and tricuspid valve regurgitation. No significant change in estimated PA pressure.. In 2021, Heart rate: abnormal (abnormal) abnormal. In 2021, Pulmonary arterial pressure: 68.6 mmhg (High) Severely elevated. In 2021, Ultrasound scan: no evidence of deep venous thrombosis in the... (Inconclusive) No evidence of deep venous thrombosis in the bilateral lower extremities. In 2021, White blood cell count: no leukocytosis (Inconclusive) No leukocytosis. Concomitant medications included unknown statins. On 02-OCT-2020, Co- suspect drug chemotherapy is given to the patient to treat small cell lung cancer metastatic, Metastases to liver and Metastases to lymph nodes. On an unspecified date(s) in 2021, the patient had radiation of his head and lung for his cancer. Initially on 18-SEP-2020, the patient started with 10mg of firdapse, On 02-OCT-2020, the dose increased to 20mg. On 22-SEP-2020, while in the hospital the patient experienced blood pressure fluctuations. the patient experienced a headache that was "4/10. Treatment medications included acetaminophen; aspirin; caffeine and ibuprofen for headache, treated with prednisone 60mg and methyl prednisolone for immune mediated pneumonitis, On an unspecified date, the patient was treated with midodrine, patient was cautiously diuresed with IV furosemide bolus dosing followed by gtt (drip) given "soft pressures. the patient was treated with low dose diltiazem For paroxysmal a-fib (atrial fibrillation) and MAT (medication-assisted treatment). patient was initially given amiodarone 400mg daily x 7 days for blood pressure, then the dose reduced to 200mg, On an unspecified



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date, patient was treated with low dose metoprolol (12.5 mg), patient was treated with Xarelto (rivaroxaban) 15 mg daily for stroke risk reduction. On an unspecified date, the patient's diuretic (presumed IV Lasix drip) was transitioned to torsemide 5 mg, orally daily. patient received atovaquone for PJP (Pneumocystis jiroveci pneumonia) prophylaxis and treated with empiric antibiotics for CAP (community acquired pneumonia). On unspecified date, steroid regimen was increased. On an unspecified date, the patient's respiratory symptoms improved and was weaned to 2 liters of oxygen. While hospitalized, the patient received non drug treatment like PT (physical therapy) and OT (occupational therapy), the patient was treated with supplemental O2 (oxygen) and IVF (intravenous fluids). Company Comment: Limited information regarding the events and the vaccination date has been provided at this time. A contributory role of the concurrent medical conditions and medical history is considerable. A causal relationship cannot be excluded. Further information has been requested.; Sender's Comments: Limited information regarding the events and the vaccination date has been provided at this time. A contributory role of the concurrent medical conditions and medical history is considerable. A causal relationship cannot be excluded. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

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1315776	5/13/2021	WI		M		5/12/2021	CLOT IN LUNGS; This spontaneous report received from a pharmacist concerned a 58 year old male. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included unknown. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported and batch number: 043A21A expiry: UNKNOWN) dose was not reported, administered on 06-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 12-MAY-2021, the patient experienced clot in lungs, and was hospitalized (date unspecified). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from clot in lungs. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0 : 20210522762 - Covid-19 vaccine ad26.cov2.s - CLOT IN LUNGS . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1315751	5/13/2021	OH	79	F	4/2/2021		<p>BLOOD CLOT IN LEFT CALF; PAIN IN ANKLE; PAIN SLOWLY MOVING UP TO THE CALF; SLIGHT HEADACHE; This spontaneous report received from a patient concerned a 79 year old female of unknown race and ethnicity. The patient's height, and weight were not reported. The patient's concurrent conditions included high blood pressure, and penicillin allergy. The patient experienced drug allergy when treated with ciprofloxacin, and pethidine hydrochloride. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808980, and expiry: 21-JUN-2021) dose was not reported, 1 total administered on 02-APR-2021 to left arm for prophylactic vaccination. Concomitant medications included blood-pressure pills, water pills and Omega-3. On 02-APR-2021, the patient experienced a slight headache for about 2 days. On 29-APR-2021, the patient felt some pain in ankle, which was slowly moving up to the calf (left leg). The patient was brought to the emergency room, where an ultrasound and blood work was performed. Ultrasound detected a blood clot in her left calf and prescribed with Xarelto daily for 3 months. Patient stated that pain reached its most intense status on 01-MAY-2021 and is slowly getting better. Treatment medications (dates unspecified) included: rivaroxaban. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from headache on 04-APR-2021, was recovering from pain in ankle, and pain moving up to the calf, and had not recovered from blood clot in left calf. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210520686 -JANSSEN COVID-19 VACCINE Ad26.COV2.S-Thrombosis. The event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1315738	5/13/2021			M			<p>BLOOD CLOT IN LUNG; This spontaneous report received from a patient concerned a male of unspecified age. The reporter obtained the information from news/media. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient had blood clot in lung. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot in lung was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210519715- covid-19 vaccine ad26.cov2.s - blood clot in lung . This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1315728	5/13/2021	NC	58	M	4/12/2021		<p>BLOOD CLOTS IN LUNGS; NUMBNESS IN HANDS AND FEET; SWELLING IN HANDS AND FEET; This spontaneous report received from a patient concerned a 58 year old white male. Initial information was processed along with the additional information received on 11-MAY-2021. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included the patient had no history of blood clots. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 207A21A expiry: UNKNOWN) dose was not reported, 1 total administered to right deltoid on 09-APR-2021 around 13:00 for prophylactic vaccination. No concomitant medications were reported. After receiving the vaccination on 09-APR-2021, the patient went home and slept for 6 hours. One week after vaccination, on 12-APR-2021 the patient experienced swelling in hands and feet. Two weeks after, on 19-APR-2021 the patient experienced numbness in hands and feet. On 21-APR-2021, the patient went to the emergency room (ER) and was given the tests, laboratory data included: Blood test (NR: not provided) unknown, CAT scan (NR: not provided) blood clots in lungs, and EKG (NR: not provided) unknown. The patient experienced blood clots in lungs and was hospitalized. On 22-APR-2021, laboratory data included: Sonogram (NR: not provided) results awaiting and will get records on wednesday. As of 22-APR-2021 the patient was started on blood thinner. Treatment medications included: apixaban (Eliquis) 2 a day. On an unspecified date in APR-2021 while in the hospital the patient was on oxygen (unspecified indication). The patient was discharged on 22-APR-2021 and the duration of hospitalization was 1 day. The patient was released with a prescription of Eliquis for 3 months. Laboratory data (dates unspecified) included: COVID-19 virus test (NR: not provided) negative. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from swelling in hands and feet, numbness in hands and feet, and blood clots in lungs. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0 20210518013 - COVID-19 VACCINE AD26.COV2.S- Blood Clots in lungs . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific</p>

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1315725	5/13/2021			U			<p>plausibility. There is no information on any other factors potentially associated with the event(s).</p> <p>PASSED AWAY BECAUSE OF CLOT; This spontaneous report received from a consumer concerned a patient of Unspecified Race, ethnic origin, age and sex. The patient's weight, height and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, expiry: unknown) dose, start therapy date were not reported for prophylactic vaccination. No concomitant medications were reported. The batch number was not reported and has been requested. On an unspecified date, the patient passed away because of clot. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0: 20210517449- covid-19 vaccine ad26.cov2.s-thrombosis. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: CLOT</p>

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1315724	5/13/2021			U			DEEP VEIN THROMBOSIS LEG; This spontaneous report received from a patient concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total administered on MAR-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient developed deep vein thrombosis (DVT) on leg. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The outcome of deep vein thrombosis leg was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210517421- COVID-19 VACCINE AD26.COV2.S – Deep vein thrombosis leg. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

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1315710	5/13/2021	TX	48	F		5/9/2021	BLOOD CLOT IN LEFT LEG; This spontaneous report received from a patient concerned a 48 year old, White and Hispanic or Latino female. The patient's height, weight and medical history were not reported. The patient had no blood clots in the past or no recent trauma and surgery. The patient was not on any medications. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1802072 and expiry: UNKNOWN) dose was not reported, 1 total, administered to the left arm, on 06-MAY-2021 for prophylactic vaccination. No concomitant medications were reported. On 09-MAY-2021, the patient came into the hospital with swelling in left leg, a lot of heat and a lot of pain. In emergency room (ER) they did scans and tests and it was found that the patient had a blood clot in left leg. The patient has to stay in the hospital for 24 hours until the blood clot was resolved. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clot in left leg. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0;20210516127- covid-19 vaccine ad26.cov2.s-Blood Clot in left leg. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).



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1315707	5/13/2021	FL		F		5/6/2021	UNABLE TO WALK AND WAS ON WHEELCHAIR; FELT SMALL TIRED; This spontaneous report received from a patient concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included tibial plateau fracture surgery, and concurrent conditions included allergic to penicillin, allergic to sulfas, allergy to macrolide, and deep vein thrombosis. The patient experienced allergy when treated with codeine, glyclazide, and diazepam. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 206A21A, expiry: UNKNOWN) dose was not reported, administered on 06-MAY-2021 for prophylactic vaccination. Concomitant medications included cannabis sativa, celecoxib, gabapentin, and paracetamol. On 06-MAY-2021, the subject experienced unable to walk and was on wheelchair. On 06-MAY-2021, the subject experienced felt small tired. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from unable to walk and was on wheelchair, and the outcome of felt small tired was not reported. This report was non-serious.

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1315700	5/13/2021	MI		F			<p>NUMBNESS ON FOOT; LEG PAIN; This spontaneous report received from a consumer concerned a female of unspecified age (race and ethnicity not reported). The patient's height, and weight were not reported. The patient's concurrent conditions included low platelet count. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, ) dose, 1 total, administered ,start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. The reporter mentioned of blood clots in the news and was concerned due to having leg pain and numbness on her foot with history of low platelet count. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the events leg pain and numbness on foot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: The case concerned a female patient of unspecified age (race and ethnicity not reported) who developed important medical events of a leg pain and numbness of foot unspecified time after receiving the Janssen Covid-19 vaccine, for prophylaxis of symptomatic SARS.CO2 S infection. The patient's height, and weight were not reported. The patient's concurrent condition included low platelet count. The outcome of the events leg pain and numbness on foot was not reported. Additional information (e.g. height, weight, full medical history, social history, family history, concomitant medications, specific platelet levels, peripheral smear, D-dimer, fibrinogen, anti-platelet factor 4 antibodies, radiologic diagnostic test results such as ultrasound, CT, MRI, angiogram, or venogram) was not provided. Based on evolving knowledge of Thrombosis with Thrombocytopenia Syndrome (TTS, per definition from Brighton Collaboration-BC), the relationship of leg pain and numbness of foot to vaccination is considered unclassifiable (BC Criteria level 5) due to insufficient information. Additional information has been requested for further assessment.</p>

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1315726	5/13/2021			M			BLOOD CLOT IN LEFT CALF; This spontaneous report received from a patient via a company representative through social media concerned a male of unspecified age and ethnicity. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown and expiry: Unknown) dose, start therapy date were not reported, 1 total, administered for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, the subject experienced blood clot in left calf. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot in left calf was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0;0210517568-covid-19 vaccine ad26.cov2.-Blood clot in left calf. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.
1315015	5/13/2021	AZ	40	F	3/22/2021	3/22/2021	I noticed right away after the vaccine, I noticed nerve pain through my body. I noticed a headache. I had some weird stomach pain (kind of sharp, nerve pain) that was on my right side. It felt sudden and it startled me. It ended up going away - that happened four or five times the first day. The next day, I woke up with migraine headache - told doctor experienced nausea, vomiting, sweating. That migraine lasted three or four days. I was taking Imitrex (I take it as needed - 2 a day) and that was not helping. It was a horrible headache. I saw the PCP and the rheumatologist and they did a nerve block which helped. The nerve block was about a month ago. And that worked for about a month but now I'm having migraines again. I am still having a lot of the nerve pain. The doctor said that I have pre-anti-fossid lipid - syndrome (APS) - and was concerned about clots.

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1310703	5/12/2021	MA	38	M	4/28/2021	5/1/2021	description from patient: 1.. On Wed, Apr 28, I got the JnJ vaccine. Other than fatigue the following day no major issues. 2. On Sat, May 1, I had an afib episode in the morning. Reset to sinus rhythm the next morning around 2:30am. I spoke with you during the episode. 3. On Mon, May 3, I had brain fog. I?m usually tired after an afib episode. But this seemed different. I?ve never experienced something like this before. But I chalked it out to the after effects of the afib and moved on. 4. On Fri, May 7, I started having the stiffness in my right calf. I checked in with you that weekend to make sure it wasn?t a clot. After we spoke I think we ruled out a clot. 5. In addition, I?ve developed some added symptoms since then: (i) Sweaty feet. (ii) Pins and needles sensation in feet. (iii) Tightness in the arch of the right foot. (iv) Feet and hands feel sensitive to cold. (v) Burning sensation in feet and left hand. (vi) Mild headache mostly felt in the left temple. (vii) A pulling feeling on the left side of the face. (viii) A feeling that if I close my eyes, I may faint.
1309754	5/12/2021	WV	56	M	5/10/2021	5/11/2021	Patient received Moderna on 05/10/2021. Patient stated that approximately 2 am on 05/11/2021 he started to experience pain in left calf. When patient awoke that morning left calf was red and swollen. Patient was sent to medical facility for US to rule out DVT. Blood clot noted and patient was sent to ER> Patient was sent home. Appt made with Dr., vascular, for 05/12/2021 at 10:30 am.

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1310063	5/12/2021	IL	40	F	3/26/2021	4/29/2021	March 26th, 2021 I received the Moderna vaccine. After the Moderna vaccine, my arm felt very sore. I was dizzy and tired. On March 29,2021 I got a heavy menstrual cycle. It was the heaviest on March 31-April 2. (March 14th, 2021 I put in a new nuva ring, I should not have gotten my period) On March 29th, 2020 I went to the chiropractor. My lower back was hurting and I felt awful. On April 8th I woke up to bloody blisters in my mouth. The right side kept bleeding and wouldn't clot. On April 9th, I developed inflamed blood vessels all throughout my body from my head to my feet called purpura and petechiae. I called doctor immediately because bruises and red dots were spreading quickly. He sent to me immediately to get labs drawn at the hospital. My platelets were critically low and I was told to head to the ER. From there I was admitted. On April 9th, 2021, my blood platelets were 2,000. They are supposed to be 150,000-450,000 Prior to the vaccine, a full physical with labs were done by physician on March 22. My platelets were 210,000. Everything in my labs were perfect. Currently I am battling kidney stones. I had surgery on May 10th. I've never had a kidney stone in my life.

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1310114	5/12/2021	NY	23	F	5/7/2021	5/9/2021	Central Venous Sinus Thrombosis in Superior Sagittal Sinus I arrived home at 12:38 on Sunday, 5/9, and opened the door to see my sister with facial droop, slurred speech and a contracted right hand/fingers. She was crying and immediately knew she was having a stroke. She had been trying to clasp some jewelry while getting ready for Mother's Day. She was able to walk down to the car with me no problem (no extremity involvement other than right hand/fingers). We arrived at the hospital within 10 minutes and she was a Code Stroke. A CT scan showed the clots as well as a tiny Subarachnoid bleed and she was admitted to NeuroICU. The symptoms waxed and waned for a few hours and at one point she developed the droop again, had headache and heartburn and vomited. A CT scan was repeated after some Heparin had entered her system and it was stable/not worse; subarach bleed was not changed and Heparin was continued. She has now been admitted for 3 days and the Heparin is complete. She is now being transitioned to oral Xaralto. She has no deficits whatsoever and has made a full recovery so far. We are still pending the results of her coagulation studies to see if she has a hereditary condition. The doctors believe the clot is due to her Nuvaring Estrogen, which is most likely. However, I would still like to report this event just in case.
1310142	5/12/2021	MD	68	F	4/1/2021	4/15/2021	On April 15 developed a rash on left arm that traveled to the elbow over three days. At that time the Stills disease flared up, this has been under control of over 15 years. I developed a pain in the right calf and had a scan to make sure it wasn't a blood clot. It was not a blood clot but continues to be a problem with undiagnosed pain. It was decided it would be better to hold off on the second shot. It feels like my body is now fighting itself again.

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1310149	5/12/2021	NY	83	M	4/20/2021	5/4/2021	TWO EVENTS; #1 retinal occlusion, #2 disability and pain at left side Details #1 L I VITREO RETINAL, DIAGNOSE RETINAL OCCLUSION, SMALL BLOOD CLOT BACK OF RT EYE. CAUSED LOSS OF VISION ON TUE 5/4/21 AT 2AM, VISION CONSISTED OF BLACK CLOUDS AND PATTERNS WITH HOLES. NO TREATMENT OBSERVATION AND REPORT TO DR. PRESENT CONDITION IS OF CONSTANT THIN PATTERNS WITH HOLES DISTURBING ANY CLOSE READING OR COMPUTER WORK. DISTANCE WITH BOTH EYES HAVE THE PATTERNS BUT MUCH LESS NOTICABLE. #2 ORTHOPEDIC DR. 5/8/2021 6AM SAT 5/8/2021 SEVERE PAIN L SIDE
1310585	5/12/2021	CT	78	F	2/23/2021	4/4/2021	Deep vein thrombosis occurring 12 days after 2nd vaccine. No previous DVT in lifetime.

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1309751	5/12/2021	NV		M	4/1/2021		<p>PAIN IN UPPER BACK; CLOT IN LUNG; CLOT IN CALF; DIZZINESS; FLU LIKE SYMPTOMS; JOINT PAIN; STOMACH ACHES; SWELLING IN CALF; This spontaneous report was received from a patient and concerned a 55 year old male. The patient's height and weight were not reported. The patient's past medical history included fractured ribs and T6, and concurrent conditions included drug allergy to Vicodin (causes rash). The patient was healthy before the vaccine. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 042A21A expiry: 21-JUN-2021) dose was not reported, administered on and unknown date in APR-2021 (approximately "middle of April") in the left arm for prophylactic vaccination. There were no concomitant medications. The day after receiving the vaccine the patient started experiencing fever (no actual temp given), stomach aches, chills, joint pain, "flu-like symptoms" which lasted "4 to 5 days after getting the vaccine" (no actual dates given). He stated those symptoms went away. On the "10th day after getting the vaccine" he experienced pain in his calf and had a hard swollen spot which he assumed was cramps. This lasted until Sunday, 02-MAY-2021. On Monday, 03-MAY-2021 (also reported as 02-MAY-2021), the patient started experiencing pain in upper back which he felt "in his lungs". On Tuesday 04-MAY-2021, the pain was still present. On Wednesday, 05-MAY-2021, he started experiencing difficulty breathing, dizziness, and shortness of breath and went to the emergency room (ER). This pain was unlike anything he had ever experienced. While at the hospital, they performed an ultrasound and found a clot in his calf. They also performed a CAT scan and found a clot in his lungs. The patient was treated with heparin, but after he expressed concern with heparin, the hematologist changed it to Eliquis (apixaban). The patient was discharged on 05-MAY-2021 with Eliquis 20 mg, one tablet by mouth twice a day for two weeks. He will be on it for the next 6 months. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from flu like symptoms, and stomach aches on APR-2021, and joint pain on an unspecified date, and the outcome of pain in upper back, dizziness, clot in calf, clot in lung and swelling in calf was not reported. This report was serious (Hospitalization Caused / Prolonged).;</p>



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							Sender's Comments: V0:20210511212-covid-19 vaccine ad26.cov2.s-Pulmonary thrombosis, Thrombosis, Pain in upper back. This events are considered unassessable. The events has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events.
1310621	5/12/2021	AZ	67	F	2/12/2021	5/9/2021	Renal Infarct (blood clots to both kidneys)
1309558	5/12/2021			M			developed 2 DVTs post Pfizer COVID vaccine; This is a spontaneous report from a non-contactable physician communicated to a Pfizer sales representative. A 40-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) unknown dose number, via an unspecified route of administration on an unspecified date (Lot number was not reported) as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient developed 2 DVTs post Pfizer COVID vaccine. Patient was put on apixaban (ELIQUIS). Event took place after use of product. Outcome of the event was unknown. No follow-up attempts are possible, information about batch number cannot be obtained. No further information expected.; Sender's Comments: The causal relationship between BNT162B2 and the reported deep vein thrombosis cannot be completely excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

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1310732	5/12/2021		72	M	3/1/2021	5/1/2021	Patient received both doses of the Astra Zeneca COVID-19 while in another country. Exact administration dates are unknown. First dose late March/early April, 2nd dose early May. Patient reports that leg swelling happened while he was in another country about 1 week following 2nd dose of Astra Zeneca covid vaccine. Went to doctor in other country and prescribed Xarelto 10mg/day, no imaging at that time. Sent for imaging after presenting to our clinic on 05/11/21. Doppler ultrasound confirmed blood clot in left leg. Patient currently being treated with xarelto 15mg twice daily x 3 weeks, then continuing at 20mg once daily.
1310737	5/12/2021	OH	18	F	4/7/2021	5/3/2021	Deep venous thrombosis involving the common femoral vein and central portions of both superficial and deep femoral veins. Thrombus is also present within the saphenous vein. symptoms- leg swelling and pain since 5/2/21
1310788	5/12/2021	PA	53	M	3/1/2021	5/11/2021	Multiple blood clots Right lung
1310620	5/12/2021	WA	77	F	4/6/2021	4/7/2021	After receiving the J&J vaccine 6 weeks ago and started getting stomach cramps that lasted a week, after that it subsided but has never stopped, now I can hardly eat anything. I went to the ER two weeks ago but there was no concern because there were no blood clots. Now my bowel is restricted and I've had auto-immune issue about a year and a half ago. Now just cramps and bloating. I also have a tooth that's come loose and I have a strange taste in my mouth since having the vaccine. I saw the doctor and they just called and the doctor stated that I've continue to have problems I should consider having an ultrasound of my stomach. Also, in the past, I went to Hospital.

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1309626	5/12/2021	PA	40	M	4/28/2021	4/28/2021	part of my left kidney was no longer receiving blood; blood clot; placed on stroke protocols.; I developed severe abdominal pain in my left side during the evening; lack of appetite; bouts of severe discomfort; This is a spontaneous report from a contactable consumer (patient). A 40-years-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot Number: EW0167) via an unspecified route of administration, administered in Arm Left on 28Apr2021 12:15 (40-years-old) as 2nd dose, single for COVID-19 immunization. The patient medical history was not reported. Vaccination Facility Type was clinic. Concomitant medications included ibuprofen (ADVIL); desloratadine (CLARINEX). The patient previously took first dose of BNT162B2 (lot number=EN6208) on 07Apr2021 01:15 PM (40-years-old) on Left arm for COVID-19 immunization. It was reported that the patient developed severe abdominal pain in my left side during the evening of Wednesday, 28Apr2021 19:00. The pain appeared sporadically throughout the evening and continued through Friday, April 30. During this time, he experienced a lack of appetite and bouts of severe discomfort. Tried treating with GasX and Tylenol. Duration of Hospitalization reported as 3 days. On Saturday, 01May2021, starting around 10:30 a.m., the pain in his left-side abdominal area intensified and did not diminish. After 6 hours, he visited the ER at hospital. After being admitted to the ER, a series of blood, urine and imaging tests were performed on me. The doctor on duty reported that a CT scan showed that part of my left kidney was no longer receiving blood (disability). He was placed on Heparin and admitted to the hospital. He was diagnosed with a blood clot and placed on stroke protocols. The adverse event result in Emergency room/department or urgent care. Treatment received for the adverse events was Heparin, fluids, blood work, urine analysis. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events abdominal pain, lack of appetite, and bouts of severe discomfort was recovering; while other events was unknown. Events reported as serious due to hospitalization and life threatening.

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1309594	5/12/2021	TX		F			Sudden pulsatile tinnitus and loss of hearing in left ear within a week or so after 2nd shot.; Sudden pulsatile tinnitus and loss of hearing in left ear within a week or so after 2nd shot.; This is a spontaneous report from a contactable consumer (patient). A 63-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number Er8727, on unknown date at single dose in right arm for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient had no known allergies. The patient had no covid prior vaccination. The patient had not tested covid post vaccination. The patient had not received any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously received first dose of BNT162B2 Lot number En6202, on 28Feb2021 and had a blot clot discovered in lung within 2 weeks of first shot. The patient had sudden pulsatile tinnitus and loss of hearing in left ear within a week or so after 2nd shot. The patient went for ENT Dr for hear. Treatment was received for the events. The outcome of the event was unknown. The event is serious with hospitalization and disability.

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1309553	5/12/2021	NY	73	M	4/23/2021	4/24/2021	blood clot in one of his leg; leg became red; This is a spontaneous report from a contactable consumer (patient). A 73-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in left arm on 23Apr2021 (at the age of 73 years old) (Lot Number: EW0169, unknown expiration) as 1st dose, single for COVID-19 immunization. Medical history and concomitant medications were reported as none. The patient received his first dose of COVID-19 vaccine on 23Apr2021. In the night of 24Apr2021, his leg became red and he spoke to his doctor. The experienced a blood clot in one of his leg on 25Apr2021. The patient received Eliquis for the events to be taken for 45 days. He would like to consult if he should receive the second dose after the side effect from the first dose. Patient would like to know if there have been reports of blood clots after receiving the COVID-19 vaccine. The patient is scheduled to receive his second dose on 14May2021. The patient underwent lab tests and procedures which included blood test and ultrasound on leg: unknown results on 26Apr2021. Outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.

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1309570	5/12/2021	PA	44	F	4/15/2021	4/23/2021	<p>unprovoked DVT of Right lower leg; This is a spontaneous report from a contactable physician. A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) intramuscular, administered in Arm Left on 15Apr2021 14:00 (Batch/Lot Number: ER873I) as 1st dose, single for covid-19 immunization. Medical history included Crohn's, HTN and ADHD. Concomitant medications included spironolactone and alfetamine aspartate, alfetamine sulfate, dexamphetamine saccharate, dexamphetamine sulfate (ADDERALL).CHLORPERAZINE EDISYLATE)) and experienced allergies. The The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously took prochlorperazine (COMPAZINE [PROpatient experienced unprovoked DVT of right lower leg on 23Apr2021 08:00. The event resulted in Doctor or other healthcare professional office/clinic visit. The patient was not diagnosed with COVID-19 prior to vaccination and has not been tested for COVID-19 since the vaccination. Therapeutic measures were taken as a result of unprovoked DVT of right lower leg including Xarelto 15 mg bid. The outcome of the event was not recovered.; Sender's Comments: The reported deep vein thrombosis leg was more likely an intercurrent disease, and less likely related to BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE). The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.</p>

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1309557	5/12/2021			F	2/24/2021		blood clot in her left calf; This is a spontaneous report from a contactable consumer, the patient. A female patient of unspecified age received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 24Feb2021 as a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot: EN6203) on 02Feb2021 for COVID-19 immunization. On an unspecified date, the patient experienced pain and on 15Mar2021 it was confirmed that the patient had a blood clot in her left calf via ultrasound performed on 15Mar2021 with positive results. The patient was treated for the blood clot. The clinical outcome of "blood clot in her left calf" was unknown. Information on the lot/batch number has been requested.
1310873	5/12/2021	MD	45	M	4/30/2021	5/9/2021	Pt developed a spontaneous superior sagittal venous thrombosis with resultant subarachnoid hemorrhage and Frontal IPH and seizure. Pt had a sudden seizure at home and CTA/MRI showed Superior sagittal sinus thrombosis. Pt required intubation secondary to altered mental status. Pt underwent diagnostic cerebral angiogram which confirmed cerebral sagittal sinus thrombosis. Pt tolerated extubation on 5/11.

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1309554	5/12/2021		29	F	4/21/2021	4/24/2021	Calf muscle pain since 1 week. Clots upto 1 inch near the knee area. Observed on both legs; Calf muscle pain since 1 week. Clots upto 1 inch near the knee area. Observed on both legs; This is a spontaneous report from a contactable consumer. A 29-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in Arm Left on 21Apr2021 16:00 (Batch/Lot number was not reported) as 2ND DOSE, SINGLE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient received BNT162B2 for COVID-19 immunization on 31Mar2021 (Lot unknown=True, Lot unknown reason=Unable to locate or read the details, Administration date=31Mar2021, Administration time=02:00 PM, Dose number=1, Vaccine location=Left arm, No reaction.) On 24Apr2021, Calf muscle pain since 1 week. Clots upto 1 inch near the knee area. Observed on both legs. The patient did not receive treatment for the events. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.



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1309527	5/12/2021	AR	49	M	2/3/2021	2/3/2021	have some clots; Neuropathy; autoimmune disorder; Fell and hit elbow and 3 ribs on left side; lost 6 (lbs) pounds/Within 2 months, he has lost 47 lbs and eats all the time and is still losing weight; falling; felt super strong; dizziness; failed all the tests for motor skills for his arms and legs; Fell and hit elbow and 3 ribs on left side; Fell and hit head; Sensory nerves are all gone; Fatigue; scabs; delusional; tore tendons in between ribs; They are tender(ribs); hurting all over; Cannot walk or lift anything; chest pain; his arm was sore a little; Left arm injection site pain; Disoriented; This is a spontaneous report from a contactable consumer (patient). A 49-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 intramuscular, administered in left arm on 03Feb2021 (batch/lot number and expiration date not reported) at the age of 49 years old, as 1ST DOSE, SINGLE for COVID-19 immunisation. Medical history included COVID-19 from Dec2020 to an unknown date, vascular disease, bilateral stents placement, cataracts since he was born. Concomitant medication included gabapentin taken for an unspecified indication from an unspecified start date and ongoing. On 04Feb2021, the patient experienced left arm injection site pain. The patient experienced dizziness, falling, and couldn't go to work on unspecified date. He was treated by his (MD) physician, was given a CT scan, echocardiogram, and found to have some clots. He stated he has a history of vascular disease and had bilateral stents placed a year ago. He was placed back on an aspirin/Plavix regimen and referred to a neurologist because he has no motor skills anymore. He stated he failed all the tests for motor skills for his arms and legs. He was advised not to take the second dose of the vaccine and was diagnosed with neuropathy and autoimmune disorder (caller does not specify which disorder). He reported being positive for Covid-19 in Dec2020. He wanted to know what else he can do for his symptoms and is offering to be tested by Pfizer for treatment. The symptoms come in really hard seven days later. He actually had to go to the (ER) emergency and they worked on him and a whole string of doctors. He went to the emergency room and something was going on and wanted him to go to a family practitioner. They sent him to vascular, neurological and now they want to send him to a research center. It was a

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whole week after receiving vaccine before he began having symptoms. With the neuropathy and autoimmune, he cannot work like he did. He can hardly walk. Unspecified autoimmune was diagnosed last week. He can't remember the name of it. They told him not to take second one because the first one did what it did to him. It hurt a little and it was quick. The next day (04Feb2021), he said his arm was sore a little. He is only taking 4 medications and they looked it up. He did not think they were relevant. He was disoriented and fell and hit his head a couple of times. They ran an MRI on his head trying to figure that part out. That was done last week. He doesn't know the date and said it may have been on Friday. Results were good. The date he was disoriented was Wednesday 03Feb2021, when he took the shot. He has been disoriented and has been that way ever since. They kept him for 15 minutes to make sure no one passed out. He has been disoriented since then. He could not think clearly, and he could not do his job. He tore tendons in between ribs. He first thought he actually broke his ribs, but did not. There were two different falls. He cannot feel feet or anything. His motor skills are OK but when they did neuropathy test, they put needles in and shocked him to make his motor fire. His reflexes were really bad. He fell and hit elbow to keep from falling on face and twisted going down hitting 3-4 ribs on left side. It has been over 3 weeks now for his ribs. They are tender but they are not like the initial blow. It feels like they are healing. He fell and hit head a week ago. He was unsure of the exact date. He did not go to the emergency room with this one because the bed caught him. He fell and hit his head. All he has left is scabs. He cannot walk or lift anything (11Feb2021). That next Wednesday, he got ready to go to work and was so delusional and could not go in. He slept from 5:30 all that day and all that night. Then Thursday, he gets up and goes to work and goes slower, just to see what happened on Wednesday. He had fatigue and was disoriented. He did not provide start date or outcome for fatigue. He walked in and said either call an ambulance or he would go home. He went home and that was the last day of work. He then stated he laid in the car for 30 minutes and he said he is going to the emergency room. He went straight there that day. He had stents put in lower part of his body a year before. The neuropathy and

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the autoimmune kicked in 7 days later after the shot. The reason he went to the ER is because he thought it was his stent. He had bilateral, 4 of them. He was having chest pain and hurting all over on 11Feb2021. He thought he was having a heart attack. He was seen in the emergency room and released. It depends on how far he goes, how the chest pain worsens. Right now, he is ok, but when he gets up and moves around, it does the same thing. Within 2 months, he has lost 47 lbs and eats all the time and is still losing weight. He was about 200 something and was kind of built and now is skin and bones. He lost 6 (lbs) pounds within a week and is eating like crazy. Sensory nerves are all gone. If hit with a baseball bat and he would not feel it. It came on slowly almost that he did not know it was happening. That is why they want to send him to Privacy for a research center and he does not want to go. He never had this happen before. ER or physician's office required: 1st date was on Thursday, 11Feb2021, when he went to Privacy. He was having chest pain and hurting all over. He thought he was having a heart attack. He was released. The patient stated he wanted to change the information he had provided since he was not in his right mind since he had taken the wrong medication dose than the doctor had given him. He stated the medication dosage he wanted to change was for Amiripyin. He stated he wanted to say he told the representative the symptoms he had experienced was enhanced which they were yesterday because he was trying to fight everything and stay awake. COVID 19 vaccine: he stated the doctor did not want him to take the second dose of the vaccine. He stated one of the symptoms he had experienced after the vaccine that he wanted to change the outcome for is the neuropathy. He stated he is back to where he used to be and yesterday it was bad he could hardly walk or talk. He stated also the other symptoms he wanted to change the outcome for is the autoimmune. The patient has not recovered from neuropathy, autoimmune disorder, disoriented, can't walk or lift anything, chest pain, and sensory nerves all gone; while outcome of the remaining events was unknown. Information on the lot/batch number has been requested.

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1309286	5/12/2021	CA	61	M	2/16/2021	2/28/2021	vertigo; Migraine type headaches; Flu like symptoms; Fever; Blood clot in right upper arm; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of VERTIGO (vertigo) and THROMBOSIS (Blood clot in right upper arm) in a 61-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 022M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 16-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Feb-2021, the patient experienced VERTIGO (vertigo) (seriousness criterion hospitalization). On an unknown date, the patient experienced THROMBOSIS (Blood clot in right upper arm) (seriousness criterion medically significant), MIGRAINE (Migraine type headaches), INFLUENZA LIKE ILLNESS (Flu like symptoms) and PYREXIA (Fever). The patient was hospitalized on 28-Feb-2021 due to VERTIGO. At the time of the report, VERTIGO (vertigo), THROMBOSIS (Blood clot in right upper arm), MIGRAINE (Migraine type headaches), INFLUENZA LIKE ILLNESS (Flu like symptoms) and PYREXIA (Fever) outcome was unknown. No concomitant medications were reported. No corrective treatment was provided. 28-Feb-2021, he was hospitalized for vertigo for 3 days. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Very limited information regarding these events have been provided at this time. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Very limited information regarding these events have been provided at this time. Further information has been requested.

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1309242	5/12/2021	NY	51	F			<p>THERAPEUTIC RESPONSE DECREASED; ACHY; SHIVERING; CHILLS; HEADACHE; FEVER; This spontaneous report received from a patient concerned a 51 year old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808978, and expiry: 13/JUN/2021) dose was not reported, administered on 31-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 16-APR-2021, Laboratory data included: Antibody test (NR: not provided) no antibodies. On 30-APR-2021, Laboratory data included: Antibody test (NR: not provided) no antibodies. On an unspecified date, the subject experienced therapeutic response decreased, achy, shivering, chills, headache, and fever. Laboratory data (dates unspecified) included: Body temperature (NR: not provided) 101 F, 103 F, and MRI (NR: not provided) no blood clots. Treatment medications (dates unspecified) included: ibuprofen. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the achy, fever, shivering, chills, headache and therapeutic response decreased was not reported. This report was non-serious.</p>

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1309190	5/12/2021	CA	58	F	3/18/2021		BLOOD CLOTS IN BOTH LOWER LEGS; LEG CRAMPS; This spontaneous report received from a patient concerned a 58 year old white non-Hispanic or Latino female. The patients weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805020, expiry: 25-MAY-2021) dose was not reported, frequency 1 total, administered on 18-MAR-2021 to left deltoid for prophylactic vaccination. No concomitant medications were reported. On 18-MAR-2021, the patient started experienced leg cramps. On 22-MAR-2021, the patient diagnosed with blood clots in both lower legs by ultrasound. Patient was put on unspecified blood thinner and started RX on 23-Mar-2021 Laboratory data included: Diagnostic ultrasound (NR: not provided) Positive for bilateral blood clots in lower legs. On 04-Apr-2021 patient went to ER for severe leg cramps, Patient got RX for Soma and started taking on 05-Apr-2021. Treatment medications (dates unspecified) included: carisoprodol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clots, lower extremities, and leg cramps. This report was serious (Other Medically Important Condition).; Sender's Comments: V0-20210506805 - Covid-19 vaccine ad26.cov2.s-Blood clots in both lower legs. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

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1309181	5/12/2021	TN	63	F	4/1/2021		DEEP VEIN THROMBOSIS; NON-ST-ELEVATION MYOCARDIAL INFARCTION.; This spontaneous report received from a patient concerned a 63 year white (Not Hispanic or Latino) old female. The patient's height, and weight were not reported. The patient's past medical history included coronary artery bypass grafting (CABG), and concurrent conditions included chronic coronary artery disease (CAD). The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, 1 total dose administered on 23-APR-2021 for prophylactic vaccination in right arm. Concomitant medications included valsartan for unknown indication. On 30-APR-2021, the patient developed deep vein thrombosis and was admitted in the hospital. On APR-2021, she also had developed possible non-ST-elevation myocardial infarction (NSTEMI). She was prescribed with ticagrelor (Brillinta) 60 bid and acetylsalicylic acid (Aspirin) The action taken with COVID-19 VACCINE AD26.COV2.S was not applicable. The patient recovered from deep vein thrombosis on 30-APR-2021, and the outcome of non-st-elevation myocardial infarction. was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0 20210502029-covid-19 vaccine ad26.cov2.s- Deep vein thrombosis - This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event. V0- 20210502029-covid-19 vaccine ad26.cov2.s- Non-ST-elevation myocardial infarction-. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY - chronic coronary artery disease (CAD)

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1309178	5/12/2021	MO	38	F	3/17/2021		COMPUTERISED TOMOGRAM HEAD ABNORMAL; VENOUS SINUS THROMBOSIS; INTRACEREBRAL HAEMATOMA; THROMBOCYTOPENIA; EXPERIENCING HEADACHES 1 WEEK AGO; This spontaneous report received from a healthcare professional via VAERS (Vaccine Adverse Event Reporting System) (VAERS reference number 1133212) and concerned a 38 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included amoxicillin allergy. The patient, age 38, received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805029) dose was not reported, administered on 08-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 17-MAR-2021, the patient was "experiencing headaches 1 week ago", and also had aphasia later in the week. On 24-MAR-2021, the patient went to an outside hospital and was found to have intraparenchymal hemorrhage in addition to venous sinus thrombosis and developed intracerebral haematoma. On 25-MAR-2021, Computerized tomography (CT) of the head without contrast showed parenchymal hemorrhage and persistent hyperdensity in the left transverse sinus, consistent with known venous sinus thrombosis. The patient was being treated for the venous sinus thrombosis with heparin. On an unknown date, platelet count was 78,000 (thrombocytopenia). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of events thrombocytopenia, intracerebral haematoma, venous sinus thrombosis, experiencing headaches 1 week ago, and computerized tomogram head abnormal was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition). Version 3 was created on 26-APR-2021 for the purpose of quality improvement. The following corrections were made: platelet count was added as the event of thrombocytopenia.; Sender's Comments: V2: Follow up added additional laboratory information. This report received via VAERs database (ID# 1133212) concerned a 38-year-old female patient who experienced intraparenchymal hemorrhage and venous sinus thrombosis 16 days after vaccination. Diagnosis was confirmed on computerized tomography (CT) of the head. Platelet count was 78,000. Medical history and



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concomitant medications were not reported. Presenting symptoms included headache and aphasia. Treatment included heparin. Outcome was not reported. Based on evolving knowledge of Thrombosis with Thrombocytopenia Syndrome (TTS), the low platelet count and temporal relationship to vaccination (Criteria level 2), the events are assessed to have a plausible relationship with vaccination.

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1309578	5/12/2021	NY	62	F	3/31/2021	4/3/2021	To check if it was blood clot; Intermittent long-lasting palpitations; Lymph discomfort in one leg; Severe pain of bones in chest; Joint pains; Severe shooting intermittent head pain; Cold sweat; Felt like she was going to faint; COVID arm popped out; Severe nerve pain behind ear same side as vaccine; Exacerbated back pain; Bad menstrual cramps; This is spontaneous report from contactable consumer (patient). A non-pregnant 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: ER8727), via an unspecified route of administration in left arm, on 31Mar2021 at 01:00 PM (13:00), as first dose, single, for COVID-19 immunization. The patient's medical history included fibromyalgia, complex regional pain syndrome (CRPS), lymphedema (previously resolved), mild asthma, osteoporosis, herniated discs, allergies, and menopause. The patient's concomitant medications included unspecified vitamins. The patient had no other vaccine in four weeks (however, it was also reported that other vaccine was administered in same date, 31Mar2021; pending clarification). The patient was not diagnosed with COVID-19 prior vaccination. On 03Apr2021 at 02:00 AM, the patient experienced intermittent long-lasting palpitations, lymph discomfort in one leg for which they went to check if it was blood clot. On 03Apr2021 at 02:00 AM, the patient also had severe pain of bones in chest, joint pains, severe shooting intermittent head pain, cold sweat, felt like she was going to faint, COVID arm popped out (nite 8; as reported), severe nerve pain behind ear same side as vaccine, exacerbated back pain, and bad menstrual cramps for 2 mornings 11 years post-menopause. The adverse events resulted in doctor or other healthcare professional office or clinic visit. No treatment was received for the adverse events. The events were considered non-serious. The patient has not been tested for COVID-19 post-vaccination. The patient had not recovered from the events. No follow-up attempts are needed. No further information is expected.
1312174	5/12/2021	OH	37	F	3/11/2021	5/10/2021	Dural sinus thrombosis postpartum diagnosed postpartum day 6 after uncomplicated vaginal delivery

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1310883	5/12/2021	PA	52	M	5/2/2021	5/5/2021	Patient stated he didn't feel well 2 days after receiving the vaccine and he went to hospital next day. He was diagnosed for blood clot in lung, treated in the hospital and discharged home. Patient stated the doctor was not sure what has caused the blood clot in lung.
1309550	5/12/2021	TX		F	3/23/2021	3/24/2021	leg formed a blood clot above knee; Severe pain; Numbing in arm and leg; This is a spontaneous report from a contactable other healthcare professional (patient). A 52-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 23Mar2021 10:00 (Batch/Lot Number: unknown) as 1ST DOSE, SINGLE for Covid-19 immunization. The patient was not pregnant at the time of vaccination. Medical history included complications from bladder mesh and mitral valve prolapse. The patient's concomitant medications included Vitamins (unspecified). The patient was not diagnosed with COVID-19 prior to vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 24Mar2021 06:00, the patient experienced severe pain followed by numbing in arm and leg, and leg formed a blood clot above knee. The patient tried to make doctor appointment but 40 days out. The patient took aspirin daily for clot and will see doctor in 2 weeks. No treatment was received for severe pain and numbing in arm and leg. The patient has not been tested for COVID-19 since the vaccination. The outcome of events severe pain and numbing in arm and leg was recovering; outcome of event leg formed a blood clot above knee was recovered on an unspecified date. Information on the lot/batch number has been requested.
1311728	5/12/2021	FL	81	F	2/19/2021	2/20/2021	Syncope leading to fall 24 hours post vaccine Deep venous thrombosis 2 weeks post vaccine

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1311716	5/12/2021	IL	46	F	3/7/2021	3/7/2021	Reported feeling fatigue and contractions early on after the second vaccine dose. Then the next day had pain and welts at heparin injection sites as well as increased contractions. Two days after vaccine went in for weekly fetal ultrasound and a large subamniotic hematoma [up to 7 cm in the greatest diameter] was found that was not present on ultrasound the week prior. There was mild thrombocytopenia on testing. Because of the hematoma providers did not want to continue anticoagulation. However due to an elevated risk of thrombosis due to a compound thrombophilia and pregnancy prolonged pregnancy without anticoagulation would also have a high risk for adverse outcomes. The decision was made for preterm delivery at 35 weeks. The postpartum course was complicated by postpartum hypertension. The newborn required an intensive care unit admission due to hypoxia within the first day of life and was found to have neonatal pneumonia.
1311511	5/12/2021	MD	21	F	4/8/2021	4/19/2021	For thirty-six hours after the vaccine. I had body aches and chills and my eye sockets were sore and it hurt to look up. Ten days after the vaccine I was in the shower and a large blood clot came out of my nose. It was a large clot about the size of a quarter and there was no other blood with it. The clot came out of my left nostril but it was not like a nose bleed. I went to the Urgent Care but they did not do tests.

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1311212	5/12/2021	WA	53	F	4/5/2021	4/6/2021	I had a severe case of Covid-19 in December of 2020 and was hospitalized for twenty days. The day after the vaccine I got swelling in my left leg which was severe and painful. Testing revealed that there were blood clots in my legs. I have been having problems with blood clots since having Covid-19. My blood Sugar was over 500 the day after the shot and my blood pressure was very high. My blood sugar has been under control for a long time, and it is never this high. I also started to get headaches daily which I am still getting but they are not as often. I now only get headaches two to three times a week especially toward the end of the work week. Before the vaccine I was getting the occasional headache, but they were controlled with Excedrin. The new headaches are only controlled with prescription medication. The swelling in my left leg is still happening on occasion. I had been experiencing Long Covid-19 symptoms before the vaccine but they were much improved and the vaccine seemed to cause all of the symptoms to regress.
1311083	5/12/2021	NY	28	F	4/10/2021	4/15/2021	persistent headache. mild headache ~7 days after vaccine. increased severity leading to two emergency room visits to check blood and have cat scan in order to rule out blood clot.
1310885	5/12/2021	IL	83	F	4/16/2021	4/27/2021	Pt suffered diarrhea for two days prior to collapsing . she could not move that morning to get out of bed and could barely talk. She mentioned chest pain and an ambulance was called. Following her vaccinations she was very confused and had fallen in the kitchen the Thursday (22nd) prior to her heart attack. They took her to ER noted she was in shock and had very low blood pressure enroute to hospital. Her pulse was very low. She was life flighted to the medical center. It was determined a blood clot had blocked a major artery into the right side of her heart and it was removed and a stent was placed. She remained at hospital 3 nights and was transferred to nursing home for recovery and therapy where she currently is being assessed for mental issues and is on 4 different heart medications to control blood pressure and prevent future heart attacks. There is not a family history of heart issues. Pt was very healthy in spite of being 83 years old.

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1307067	5/11/2021	WA	49	F	5/6/2021	5/6/2021	I received the shot at 11:00 am May 6th, by 1:35 pm I was in full respiratory arrest. Spent two days in ICU where a blood clot was found in my lung. Followed up with PCP and suggested I NOT take second dose.
1306815	5/11/2021		84	F	3/2/2021	3/16/2021	patient reports development of peroneal vein thrombosis about 1-2 weeks after J&J vaccine. patient was on a flight at this time. she saw her PCP for swollen legs are was diagnosed with superficial thrombophlebitis. patient started asprin 325mg BID. after an ultrasound was done, it was revealed that the patient had right peroneal vein thrombosis as well as superficial thrombophlebitis of the medial right thigh. she was started on Xarelto 10mg daily. since taking Xarelto "tender lumpy spot on right upper thigh has gotten much better". patient has been referred to hematology to follow up.
1306313	5/11/2021			U			THROMBOSIS; This spontaneous report received from a health care professional concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced thrombosis. Treatment medications (dates unspecified) included: apixaban for thrombosis. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The outcome of thrombosis was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210516823-Covid-19 vaccine ad26.cov2.s - Thrombosis. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

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1306326	5/11/2021	TX	63	F	4/19/2021	4/30/2021	<p>epiploic appendages; nausea; dizziness; blood clot; pain on left side of abdomen; This spontaneous case was reported by a nurse (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (blood clot) in a 63-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. D17B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 19-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 30-Apr-2021, the patient experienced THROMBOSIS (blood clot) (seriousness criterion medically significant) and ABDOMINAL PAIN (pain on left side of abdomen). On 03-May-2021, the patient experienced DIZZINESS (dizziness) and NAUSEA (nausea). On an unknown date, the patient experienced EPIPLOIC APPENDAGITIS (epiploic appendages). At the time of the report, THROMBOSIS (blood clot), ABDOMINAL PAIN (pain on left side of abdomen), DIZZINESS (dizziness), EPIPLOIC APPENDAGITIS (epiploic appendages) and NAUSEA (nausea) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In April 2021, Computerised tomogram: epiploic appendagitis Epiploic Appendagitis. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment given included antibiotic amoxicillin/clavulanic acid. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, Very limited information regarding this events has been provided at this time. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, Very limited information regarding this events has been provided at this time. Further information has been requested.</p>

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1306594	5/11/2021	NY	30	F	4/2/2021	4/8/2021	7 days after first vaccine I started feeling like I pulled a muscle in my right bicep (shot was in right arm) I waited a few days and the pain got worse and spread to my forearm. It was extremely painful and swollen. I could not straighten my arm. Where the pain was in my forearm red blotchiness appeared and got bigger over a day. I did have an endoscopy the day before and had an IV in for a short time. I don't want this to be disregarded because both Birth control and having an IV can contribute to blood clots, I think it needs to be warned before getting the vaccine that those things can increase the risk of blood clots. So just avoid IVs around the time of the vaccine and maybe pause Birth Control.
1306670	5/11/2021	PA	75	F	3/17/2021	3/23/2021	On 3/23/21 pt had SOB so went to the Hospital ER. She had lab work, CT, Chest Xray, ECG 12 lead. DX is pneumonia of right lower lobe of the lung. She was given Augmentin and released after 7 hours and told to FU w/ PCP. On 3/31/21 pt went to see her PCP due to having SOB. She was given a Covid Test which was negative. She was sent home and told to breathe deeply and hopefully this symptom would go away. On 4/18/21 she went back to the Hospital ER for SOB. Pt was admitted with acute DVT and other blood clots as well as pleural effusion of the right lung. They did US on legs and Chest X-Rays. They found fluid around her right lung which they drained. She was prescribed Eliquis. Pt was discharged on 4/21/2021 and was told to FU w/ PCP. On 4/24/21 pt went back to the Hospital ER, because she had a bruising/blood clots in the groin area. She had 3 blood clots on the left side and one on the right side. They told her the bruising was from the Eliquis and they did a US. She was told she had the same blood clots that she had during her hospital stay and they were right where they were before. She was discharged. On 4/29/2021 she went back to her PCP due to SOB. She told her PCP about the DVT that was bothering her. She was sent to another Hospital. She had a stat Chest X-Ray- results were that her lungs were stable with inflammation around the right lung. She was told to FU w/ PCP in July 2021 and go back to ER if she had another episode w/ SOB.



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1306312	5/11/2021			F			EXTENSIVE DEEP VEIN THROMBOSIS; This spontaneous report received from a consumer concerned a 59 year old female. The patient's height, and weight were not reported. The patient's past medical history included coronary artery disease. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced extensive deep vein thrombosis after the vaccine was released to the public. She began feeling symptoms seven days after getting the shot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of extensive deep vein thrombosis was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 : 20210514131- COVID-19 VACCINE AD26.COV2.S -Extensive Deep Vein Thrombosis. This event is considered not related. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event than the drug. Specifically: MEDICAL HISTORY.

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1306864	5/11/2021	VA	85	F	4/9/2021	4/21/2021	<p>S/p pfizer vaccine 4/9/21. S/p fall. She presented last wk to the hospital in cardiogenic shock, anemia, acute RLE DVTs, AKI, and rib fractures. She was found to have a n intramuscular hematoma along her posterior right thigh and with an acute DVT in her leg - see imaging reports below. Her INR was in the 7 range. She was also found to be in cardiogenic shock as mentioned above, requiring pressors. Pressors were eventually weaned off. S/p PRBCs. Imaging studies were obtained. Findings are listed below. Her AKI resolved by day of discharge. Since hospital discharge: The swelling is improving along her right leg. She is not checking her weight on a daily basis. She has access to a scale. She needs a refill on iron and Fosamax. No bleeding. On day of discharge, her hemoglobin was 8.8. Her MCV was elevated at 100. Her platelet count was 132. Her INR was 1.4. Her calcium is mildly low at 8.3. Her coumadin is on hold at this time. 106/56 was her BP today. She's been resting well. She's doing some house chores. She has yet to schedule a follow-up visit with for an INR check and in office checkup apt since hospital discharge. 4/23/21 RLE CT: Postop changes from ACDF for right femoral neck fracture again noted with good alignment. Early healing process of the fracture noted. No acute osseous fracture or hardware fracture. Extensive muscular and subcutaneous edema in right thigh. Two elongated intramuscular hematomas also noted at the medial posterior right thigh as above. 4/23/21 CXR: Patchy bibasilar pleural parenchymal opacities and enlarged cardiac silhouette without interval change. Multiple thoracic compression deformities better characterize on recent CT. Postoperative changes as discussed. Stable hiatal hernia. 4/23/21 RUQ Ultrasound: Mild gallbladder prominence, nonspecific. Findings similar to reference CT. No gallbladder wall thickening. Negative sonographic Murphy sign. Trace ascites. Partially evaluated right pleural effusion. Increased renal echogenicity. Correlate for medical renal disease. -1.1 cm right renal cyst. 4/22/21 PVL Study: Acute non-occlusive deep vein thrombosis in the mid and distal femoral vein within the right lower extremity. Acute non-occlusive deep vein thrombosis in the distal femoral vein within the left lower extremity. 4/21/21 Chest/Abdomen/Pelvis CT: Age-indeterminate T1, T3, T8, and T9 compression deformities. Subacute or chronic right posterior 12th,</p>

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							11th, and 10th rib fractures. Intramuscular hematoma in the posterior right thigh, partially visualized. Subcutaneous contusion in the right posterior hip region. Small volume of free fluid which appears minimally complex. No convincing solid organ injury, but assessment is limited without administration of intravenous contrast. Mild biliary dilatation of uncertain etiology. Possible 1.8 cm peripherally calcified splenic artery aneurysm. Nonspecific bilateral perinephric stranding. Trace pleural effusions. Moderate sliding-type hiatal hernia. Additional incidentals as above. 4/21/21 C Spine CT: Age-indeterminate T1 compression fracture, new from March 2019. No other acute fracture or subluxation
1306915	5/11/2021	NJ	55	F	4/9/2021	4/23/2021	Client rec'd her vaccination on 04/09/2021. Approximately 2 weeks later, family states client started to not "feel well." Patient had leg pains and fatigue, as per family. On Saturday, May 8th, client drove her self to the ER, due to worsening symptoms of cough, leg pain, and shortness of breath. Client was evaluated in the ER and evaluation showed clots in bi-lateral lungs and lower legs. Surgery was performed to remove clots in lungs. Client was admitted. On 5/9/2021 client was intubated, and had an ECMO procedure. Client i remains in the hospital.
1307005	5/11/2021		47	F	4/5/2021	4/16/2021	possible adverse reaction of blood clot following J&J CoVid vaccine. J&J Vaccine received: 4/5/21 Fracture of 5th proximal phalanx: 4/16/21 Pt wearing constrictive device at location of DVT after 4/16/21 Pt taking OCP daily for years

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1306309	5/11/2021	NJ		M		4/10/2021	VERTIGO; CLOGGED AND HOLLOW EARS; SUPERFICIAL THROMBOSIS OF LEG; This spontaneous report received from a patient concerned a 77 year old male. The patient's height, and weight were not reported. The patient's past medical history included right leg amputated below the knee, and concurrent conditions included varicose veins in legs. The patient was previously treated with acetylsalicylic acid for right leg amputated below the knee. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 041A21A, expiry: UNKNOWN) dose was not reported, administered on 07-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 10-APR-2021, the subject experienced superficial thrombosis of leg. On 12-APR-2021, Laboratory data included: Ultrasonography (NR: not provided) no deep vein thrombosis. had a "superficial thrombosis. On 13-APR-2021, the subject experienced vertigo. On 13-APR-2021, the subject experienced clogged and hollow ears. Treatment medications (dates unspecified) included: meclozine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from vertigo on 04-MAY-2021, and had not recovered from superficial thrombosis of leg, and clogged and hollow ears. This report was non-serious.; Sender's Comments: V0: Medical assessment comment not required as per standard procedure as the case is assessed as non serious
1307066	5/11/2021	MI	29	M	2/27/2021	4/29/2021	Blood clot in right calf and part of the thigh

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1305836	5/11/2021	NY	65	F	4/20/2021	4/1/2021	Whole Leg Pain after second dose of Covid Vaccine; Lower back sore intermittently; This also occurred after both vaccines.; Leg pain making it hard to sleep; This is a spontaneous report from PPDi. A contactable nurse reported herself that a 65-years-old female patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in Deltoid Right on 20Apr2021 10:15 (Batch/Lot Number: ER8731) as 2ND DOSE, SINGLE for covid-19 immunization, with Age at Time of Vaccination at 65 years old. Medical history included ongoing blood cholesterol increased (Verbatim: High cholesterol. Stated she was diagnosed about 30 years ago. Said it was hereditary), ongoing autoimmune thyroiditis (Verbatim: Hashimoto's thyroiditis. Stated she was diagnosed about 20 years ago). Historical vaccine included first dose of Covid Vaccine (Batch/lot number: ER8727) on 29Mar2021 given at 1030, at Left Deltoid and experienced whole leg pain (about 2 weeks after the first vaccine she started having leg pain). Concomitant medications included rosuvastatin taken for blood cholesterol from an unspecified start date to Apr2021 (reported as Started medication about 3 years ago. Stopped a few weeks after the first dose of the vaccine, was not on any cholesterol medication at this time); levothyroxine sodium (UNITHROID) taken for autoimmune thyroiditis from an unspecified start date and ongoing. The patient experienced whole leg pain after second dose of covid vaccine (medically significant) on Apr2021 with outcome of not recovered, lower back sore intermittently (non-serious) on Apr2021 with outcome of not recovered, leg pain making it hard to sleep (non-serious) on Apr2021 with outcome of unknown. The patient underwent lab tests which included ultrasound doppler: no blood clots on Apr2021. Reported she went for her second vaccine and about 5 days later the leg pain came back. Said she took Tylenol and Motrin, nothing helps the pain. Said her legs have been hurting for about 4 days now. Stated that her pain seems unusual because it goes all the way down into her ankles and travels back and forth. Caller stated that she was a hiker and was in amazing shape. She had not done anything different, nothing that would have exacerbated this. Caller states she retired after being a Licensed Practical Nurse for 30 years in 2019. Caller stated that

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the leg pain after her first vaccine started about 2 weeks after the vaccine and lasted for about a week. Said it ended a few days before she got the second vaccine. Caller stated that her leg pain after the second vaccine was ongoing. Said that she got the vaccine on a Tuesday and her legs started to hurt again around Friday. Said that was effecting her life. Her legs hurt in every position. It was making it hard for her to sleep. Stated she believed her symptoms were medically significant as she did not know for sure what was causing them. Later in the call the caller mentioned that she had issues with her back. Said she noticed something new. Her lower back was sometimes sore. It comes and goes intermittently; unlike the leg pain that was constant. Stated the back pain fluctuates from a pressure and mild ache to soreness. This also occurred after both vaccines. Treatment received included: Tylenol and Motrin that did not offer any relief for her leg pains: Tylenol Extra Strength 500mg; P121876; Expiration Date: Sep 2023. Stated she took 2 tablets at a time. Motrin 200mg; 0GE2545A; Expiration Date: Mar 2022. Stated she took 2 tablets at a time. Causality: Stated she was uncertain if her symptoms have been caused by the Covid Vaccine. Follow-up attempts have been completed.; Sender's Comments: Based on the temporal association, there is a reasonable possibility that the administration of vaccination BNT162B2 played a contributory role in triggering the onset of the event pain in extremity. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Committees and Investigators, as appropriate.,Linked Report(s) : 2021467913 same patient/drug, different vaccine dose/AE

1307124 5/11/2021 NY

80 F

3/31/2021

4/2/2021

Headache, blood clot and was operated twice. Subdural Hematoma.

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1307428	5/11/2021	CA	56	F	4/1/2021	4/2/2021	I experienced had recurrent headaches 04-02-2021 lasting to 04-22-2021. I did not work 04-02-2021, 04-03-2021, 04-04-2021 and also on 04-14-21 and 04-15-2021. I also had some nausea that came and went in the time I experienced the headaches. n 04-08-2021 had a telehealth visits about my headaches and recommended I take two Benadryl tablets to break the cycle of the headaches and try it for 3 days. On 04-13-2021, went to urgent care, they gave me tramadol and more migraine medicine and I got sick for the next couple of days and could not hold any water or food. I also had a CT scan which did not demonstrate blood clots. I also had lab work performed. I take Furenell which I take for my migraines.
1307025	5/11/2021	DE	65	F	4/10/2021	4/10/2021	Saturday 30 minutes after administration patient felt nausea lethargy and stiff neck and back. Next morning Sunday patient woke with a fever of 99.6 and large blood clot in mouth. Two days post vaccine Monday patient work with large blood clot on pillow. That evening patient had 2 more blood clots spontaneously coming from teeth. Tuesday morning upon arising from chair pt experienced an intense metallic taste. Patient then experienced several 8 mouth fulls of blood on 3 occasion in same evening. Patient states it was pushing out from gums.

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1305769	5/11/2021	NY	56	F	4/22/2021	4/22/2021	she thinks may be blood clot or a muscle but not really sure; passed out; very anxious and nervous; her heart is beating fast and she is nervous.; burning sensation in her ear; tiredness; headache; heaviness on her back and chest on the left side; heaviness on her back and chest on the left side; no appetite; nauseous; diarrhea; throbbing is almost like a band-aid is too tight. If she rubbed her hand across her thigh she could feel crushing and throbbing; her heart is beating fast and she is nervous.; sharp pain in her thigh/pinching sensation on inner thigh; sick; throbbing; muscle pain; weird sensation; throbbing sensation to the left side of her belly button/It was like at her stomach; fever of 100.3F; had a feeling of heat on her neck, face, and ears; redness and itchiness at the injection site; redness and itchiness at the injection site; the injection was large, red, hot, and itchy; the injection was large/ the swelling went down; dizzy; This is a spontaneous report from a contactable consumer reported herself. A 56-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Apr2021 (Batch/Lot number was not reported) as 1st dose, single for covid-19 immunisation. Medical history included disability, obese, covid-19 when she was sick with COVID last year, she has never been that sick. she thinks she made it through because she owns a nebulizer and can say her lungs have never felt like they were full of fluid. If anything, they felt heavy. It was heavy in her back and chest. She also had a fever. She guesses she would be considered obese. Concomitant medications included paracetamol (TYLENOL). The patient received the first dose of the Pfizer COVID vaccine last week and she has experienced several side effects and is very anxious and nervous. She experienced redness and itchiness at the injection site, pinching sensation on inner thigh that she thinks may be blood clot or a muscle but not really sure, fever of 100.3F from 24Apr2021, burning sensation in her ear, tiredness, headache, heaviness on her back and chest on the left side, no appetite, nauseous, diarrhea, had a feeling of heat on her neck, face, and ears, throbbing sensation to the left side of her belly button from 26Apr2021 and she felt dizzy from 22Apr2021. The patient stated there was a bad connection and she was having difficulty hearing. The patient was a little nervous. Maybe this was a



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psychosomatic issue and she was thinking of things too much. She was sick for 5 weeks. She was never in the hospital or intubated. The site where she had the injection was large, red, hot, and itchy. It was from 22Apr2021 (Thursday) for the next maybe 3 days. Now the color is diminishing, the color is going down more like to pink and smaller and it not itching anymore. Once in a while she got a pinching sensation on her inner thigh ever since she had the injection. In the last couple days, she has been feeling a that a little more. She wanted to make sure it was not a symptom of a blood clot. She doesn't feel short of breath. She was nervous talking the call handler so that is why she is talking fast. She doesn't want to feel so sick like she did last year when she had it in March or April. She wanted to know that it's not a symptom of a blood clot. It was a throbbing pinching pain that goes and doesn't come back for a little bit, but it might come back a little bit later. It happened when she woke up. She has no swelling in her legs or thighs or anything else. She says she would not be talking this fast, but her heart was beating fast and she was nervous. She tended to be an anxious and nervous person. The patient never had blood clot issues. She wanted to make sure with everything that she has heard about Pfizer she hasn't heard of anyone having blood clot issues. She had to read to calm herself down a bit. It is a sharp pain with throbbing that comes and goes. She didn't read where it could be a blot clot, she just wanted to know. She is horrible at running to the hospital when she feels something because she gets so nervous and she thinks knowing is better because she's a realist. It takes her a minute to go to the hospital to figure it out. If she continues to feel like this she and her daughter will go to the emergency room. It is 5 blocks away. It is a small little hospital and they will be able to ease her mind. It could be her nerves getting to her too. Her fever got up to 100.3 and that was only on Saturday, 48 hours after the vaccine. Once she took Tylenol it was gone and didn't return again. She took her temperature; it was a beeping one. She always says she would take like 2 out of 3, and every time she took it went up. She felt a weird sensation of burning in her ears, the same as when she first had Covid, feeling like a fever. It brought her back to a bad place and it freaked her out. She is on disability and has people go to the store for her. She did that for 3 to 4

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months. She is not agoraphobic, but she hadn't gone out until she got the vaccine. It took her all day to get back home because she loves the outdoors. It is kind of sad, and she knows she is not the only one who experienced that. She was able to actually stay at home, and when she went out, she wanted to stay. She still has her second dose to take, not everyone in has this and she doesn't want to feel that sick again. Eventually she will perish away one day, from God knows what but a slow death of not being able to breathe she cannot picture for herself or anybody else. She tries not to watch the news, it was depressing, because it is all over the news, she tries to stay in the loop. She was tired and had a headache. She took Tylenol and slept for an hour or hour and half. When she woke up she felt heaviness on her back and chest on the left side, and as she moved around more it was on her back and less on her chest. It was the same as she felt when she had Covid. She didn't have any aches or pains. The other thing was she had no appetite for the next 3 days. Every time she woke up, she felt extremely nauseous but had nothing to vomit. For the next 3 days or 72 hours, she had diarrhea. If she ate anything, she was in the bathroom. On 24Apr2021 (Saturday) after 48 hours she started to feel the heat in her neck and face and ears like right on her ears. She was talking to her daughter and her daughter said these are normal. Where she got the injection was itchy and a little more red. She told herself not to scratch it in her sleep, she is one of those people if something itches, she scratches. What she would do is rub her arm up and down on the site. It was almost the size of an 8 ounce tomato sauce can or maybe the size of a baseball. Then the third day it got redder. In her sleep she was rubbing her arm because it got itchy. Today the swelling went down, the color is like a light pink, and the size is also minimized. The fever lasted that night. She took her temperature again the next day and it was 97.9. That is usually what it is when she wakes up. She is not just tired; she is exhausted and feels like she has to go to sleep. Her daughter came with her granddaughter who is a baby, and she didn't know how to tell them. She was happy to see them but so exhausted. She worries about the sharp pain in her thigh. The other thing is she started getting pain in the middle of her thigh, her inner thigh. A sharp pain with like a throbbing is almost like a band-aid

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is too tight. If she rubbed her hand across her thigh, she could feel crushing and throbbing. She can feel it from touching the area. She had this before like when she is stretching. It started maybe 3 months ago and went away but then after she took the injection and heard about thing, she worried about a blood clot with Johnson & Johnson, not that she would know because she has never had a blood clot. It could be psychosomatic and all working in her head. It started the last 2 days when she woke up, she felt fine and as she was lying in bed, she started feeling a sharp throbbing pain that eventually goes away. She has no swelling of her legs or thighs, and her daughter said it looks fine. She is semi-terrified of hearing bad news. It takes her longer to go to the hospital. If she starts feeling worse, she will be there in no time. She does not want to wait until it is worse, but she does not want to spook herself into going. She suffers from anxiety. She definitely had the fever not like she was just tired it was like she was exhausted. She got up early and would take a little nap because she was doing a bunch of stuff. That hasn't happened, but that's her. It will be 2300 when she goes to sleep. She was doing a bunch of stuff and felt like she just needed to take a nap. Maybe it is part of that too, but usually she doesn't feel tired like this. After her daughter left, she read something on her phone and passed out. When she woke up, she saw she actually dropped her phone. Her thigh is now not a pinch but more a little bit of a muscle pain. Now it is not like the inner thigh, it is more behind the thigh now, but not below the knee, right behind the thigh, closest to the knee but not on the knee. It is the same thing as if the middle had gone behind her thigh a bit. The little pillow on her chair is not helping anything either. It feels like it maybe muscular, its deep feeling. It feels like it could be muscle, if she rubs it, she can feel it. When asked has it improved persisted or worsened, caller states it is there, but it is dull. She can say there is pain, but it is a little duller just because it is more in the muscle. It is hard to explain, it was not the same throbbing pain but there is a dull pain, it goes around the chunkier part of her thigh, like the inner thigh. When she rubs it there is pain but a dull pain. When she rubs it, it feels better but she can still feel the site where it hurts. When she rubs it, it is still located right in the lower middle going toward her knee but not at the knee, maybe

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3 to 4 inches away from the fold of her knee, almost at the center of her thigh almost. Almost like a dull muscle ache, there is a bit of throbbing with it. She will go to the doctor if something weird happens and will call back when they have an idea of what happened to her. This will sound crazy. The next thing she felt was a light throbbing where her belly button is but more to the left side, but not at the belly button. It was like at her stomach, not right at the belly button but right on the same line as her belly button but more at her waist. It was a small throbbing started today about an hour ago. She is hoping it is gas. Her fever went away pretty fast. She was on the phone and took her temperature to tell what it was. The woman said to take some Tylenol. It went from 99.9 to 100 to 100.3. She thought oh no. That was the highest she saw. Then eventually it started going down to 99.4, and then by morning it was back to normal. She only took Tylenol the one time. She is thinking maybe it is from being nervous and causing her body to heat up. She doesn't know she is just thinking. She thinks the fever went away the same day within an hour to 2 hours. She also wasn't drinking enough water. When asked if her fever has recovered completely or with last effects, caller states that is fine now, her temperature today was 99.4 without the fan on, she says she thinks that was pretty normal. When she first wakes up it is 97.9 usually. There was also a 98.4. The redness and itching at the injection site started 3 hours after the injection. She took her 2 sons with her. She took it and then her son took it. They said to wait 15 minutes. As soon as she stepped out, she looked up and felt so dizzy. It looks like when in summer and it seems to be boiling hot, that is how it got for her. Things got blurry. It was not like she was going to black out, but she had to close her eyes because the room was going to spin. She knocked back on the door and took a seat, so she sat down because she was not feeling right. When she gets nervous, she chews gum as a coping mechanism. Her son got some gum for her. She felt better but kind of nervous waiting for 15 minutes to go by, what if she felt dizzy again. She let 20 minutes go by and she got up and was fine. She wanted to be out of there and in the cool air outside. That is the first reaction that she had. She is one of those people that feel so nervous she is sure that happens that they feel like, oh they are so nervous, and they read so

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much, and it is in our faces everyday no matter what. Maybe it had nothing to do with the injection, maybe more that she was so nervous, but it was a weird sensation after. She knows when people first started getting the COVID vaccine, people were just like falling to the ground, she was like that would be terrible. She went with high expectations and was also nervous. Her heart was beating, and she could hear her own heartbeat. She still feels tired and like she can go take a nap now. She asks if that is normal. She would rather talk to Medical Information now. She is over this statistics part of it. She doesn't feel a release, she is just giving her information and she doesn't feel any better. Outcome of the event throbbing sensation to the left side of her belly button/it was like at her stomach was not recovered; of the event dizzy was recovered; of the events the injection was large, red, hot, and itchy/ the swelling went down, tiredness was recovering; of the other events was unknown. Information about lot/batch number has been requested.

1304849      5/11/2021    WA

32 F

5/6/2021

5/9/2021

Lost use of my right arm so I went to the hospital they checked for a clot I teated slightly positive with the blood test then the did an ultrasound and couldn't find one. The only explication for my Paralysis is a mini stroke.a Also besides the numbness and loss of use I have hyperreflexia.

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1304956	5/11/2021		42	M			BLOOD CLOT; This spontaneous report received from a company representative concerned a 42 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number and expiry were unknown) dose, 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, between three to ten days later after vaccination the patient died due to blood clots. It was unknown, whether autopsy was performed or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0;20210510772-covid-19 vaccine ad26.cov2.s-Thrombosis. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: BLOOD CLOT
1304971	5/11/2021			M			BLOOD CLOT; This spontaneous report received from a traditional media article concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, start therapy date were not reported, 1 total, administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient had blood clot after vaccination. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210514145 -Blood clot (PT-Thrombosis). This event is considered unassessable. The event has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

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1305011	5/11/2021	GA	89	F	1/16/2021	2/17/2021	<p>This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of ATRIAL FIBRILLATION (atrial fibrillation), PULMONARY EMBOLISM (blood clots in her lungs) and THROMBOSIS (blood clots everywhere) in an 89-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was provided by the reporter. Concomitant products included VITAMINS NOS for an unknown indication. On 16-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 17-Feb-2021, the patient experienced INFLUENZA LIKE ILLNESS (felt like she was getting the flu), DIARRHOEA (diarrhea), BLOOD PRESSURE ABNORMAL (no blood pressure), VACCINATION SITE PAIN (arm still hurts from time to time) and FATIGUE (felt tired). On 03-Mar-2021, the patient experienced ATRIAL FIBRILLATION (atrial fibrillation) (seriousness criterion hospitalization), PULMONARY EMBOLISM (blood clots in her lungs) (seriousness criterion hospitalization) and THROMBOSIS (blood clots everywhere) (seriousness criterion hospitalization). At the time of the report, ATRIAL FIBRILLATION (atrial fibrillation), PULMONARY EMBOLISM (blood clots in her lungs), THROMBOSIS (blood clots everywhere), INFLUENZA LIKE ILLNESS (felt like she was getting the flu), BLOOD PRESSURE ABNORMAL (no blood pressure) and FATIGUE (felt tired) outcome was unknown and DIARRHOEA (diarrhea) and VACCINATION SITE PAIN (arm still hurts from time to time) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Computerised tomogram: normal (normal) haven't found anything. On an unknown date, Endoscopy: normal (normal) haven't found anything. Treatment medication included apixaban. Action taken with mRNA-1273 in response to the events was not Applicable. The patient had an endoscopy and CAT scan where they haven't found anything at when she was at the clinic. Consumer was vaccinated with first dose on 16JAN2021 (was not able to</p>

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locate lot/expiration on vaccination card). She got her second dose on 17FEB2021 (was not able to locate lot/expiration on vaccination card) and she felt like she was getting the flu, felt tired and on 3MAR2021, she was rushed to the hospital because she had "no blood pressure" and presented atrial fibrillation and blood clots in her lungs and everywhere. Her arm still hurts from time to time and continues to have diarrhea. She states she is a fairly healthy person does not take any medications, only Centrum vitamins. Since then she has gone to the clinic, had an endoscopy and CAT scan where they haven't found anything. She is now on Eliquis. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to MOD-2021-101609 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.



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1305039	5/11/2021	AL	43	F	2/1/2021	2/1/2021	high blood pressure/blood pressure 167/93/Blood pressure 144/95; Racing pulse/pulse was 177/pulse was 163/Pulse 116/ rapid pulse; Her heart was pounding; she couldn't catch her breath; This is a spontaneous report from a contactable consumer (patient herself). A 43-year-old non-pregnant female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: EL8983, Expiration date: Unknown), via an unspecified route of administration in left arm on 01Feb2021 at 08:45 AM (at the age of 43-year-old) as a single dose for COVID-19 immunization. The patient's medical history included mitral valve prolapse (diagnosed at the age of 18). No known allergies. Concomitant medication included medroxyprogesterone acetate (DEPO PROVERA) from an unspecified date in 2020 and ongoing, received in two weeks within the vaccination. She took a Depo Provera shot on Saturday 30Jan2021, but she has been on this medication for a year now since either Feb2020 or Mar2020. The lot number and expiration date was unknown, since she has discarded the packaging. She usually picks up the drug, and her neighbour was a nurse, she usually just gives her the injection, since COVID has started. The patient previously received flu vaccine on an unspecified date in 2020 for immunisation and experienced feeling bad, didn't feel good. The patient previously received flu vaccine on an unspecified date for immunisation and experienced thrown up, chills, fever, body was sensitive. Caller was queried she if she had had any issues with vaccine in the past, caller states that she takes the flu vaccine every year, her body was sensitive to the flu vaccine, this year she had no issue, but last year (on an unspecified date in 2020) after the flu vaccine she started feeling bad, didn't feel good, years before she has thrown up and had chills and fever. Her body must be sensitive. However she has never had the heart issues. The patient did not receive other vaccine in four weeks. The patient was not diagnosed with COVID-19 prior vaccination. The patient has not been tested with COVID-19 post vaccination. It was reported that, she was calling about the COVID-19 vaccine. She received the vaccine yesterday at 8:45 AM, then at 12:30 PM she began to have a rapid pulse and high blood pressure. She went to the ER because of her pulse and blood pressure. In the

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ER, she received an IV to calm the heart, she doesn't know what was in the IV. They did blood work and told her the blood work was fine, and the chest X-ray was fine. She went to a Cardiologist today, she does have a valve prolapse, but she has had no issues with that for many years. She states that her body had a weird response to the covid vaccine. Caller states that she need Pfizer to know what happened because it was real scary. She has her first dose on 01Feb2021 at 8:45 AM. The rapid pulse began while she was sitting at the computer working. Her heart was pounding on 01Feb2021, she couldn't catch her breath on 01Feb2021, and so she was a school teacher, so then she went to find the nurse, and even in that she was having trouble catching her breath to be able to even talk. The nurse took her into the office, and she put a pulse ox monitor on her finger. At 12:25 PM her pulse was 177, at 12:30 PM her pulse was 163 with blood pressure 167/93, at 12:40 PM pulse 116, blood pressure 144/95. The nurse then called the ambulance because it was alarming. Caller states that doesn't know what her readings were in the ambulance. She went to the ER at (institute name withheld) and they did an EKG, 2 of them. The regular ER doctor was not super helpful, he said that she was okay to take the second vaccine. Caller did not agree with him thinking that the 1st covid vaccine sent her to the ER. HCP: He was at (institute name withheld) Cardiology. He did an EKG today (on an unspecified date in Feb2021), she doesn't know results at the moment. He didn't say if it was normal or abnormal. They did an echocardiogram, she was also assuming nothing was alarming or she would have been told the results. He listened to the heart and said it sounded fine, there was nothing he could detect. She did have a rapid heart rate at the cardiologist office, both pulse and blood pressure were elevated. He said that she was going to do a stress test in a week, the doctor was also going to see what the blood work from the ER yesterday looks like, he would also check the thyroid. He told her that next week she would also wear a heart monitor. She was at the doctor's office today at 10:30 AM. Her biggest concern was which she talked to the cardiologist today about was the 2nd dose of the vaccine. She doesn't want a repeat of this event. The cardiologist said that she was supposed to get the second dose in 3 weeks, let's do testing and see

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where we stand. Her 2nd dose was scheduled for 22Feb2021. She was concerned this happened. She doesn't know what could be done. This was bizarre. In the ER, the doctor said this wouldn't be considered an allergic reaction. Caller wonders what this was considered then. The ER doctors thing was that this didn't happen in first 15 to 30 minutes of receiving the vaccine, and that would be considered an allergic reaction if it did. She wants to know if this was an allergic reaction. Enquired was this allergic reaction. The adverse events resulted in emergency room/department or urgent care. She has no results for the tests that were performed at the ER, she was just told the chest X-ray was normal and so was the blood work, but she doesn't know what the blood work involved. They were looking for blood clots at the ER. She was not admitted into the hospital, she was sent home the same day. She has had no positive COVID test prior to the vaccine. She also has had no symptoms, and therefore no reason to get tested either. On 01Feb2021, the patient underwent lab tests and procedure which included chest X-ray: Normal, pulse rapid: 177 (at 12:25 PM), pulse rapid: 163 (at 12:30 PM), blood pressure: 167/93 (at 12:30 PM), pulse rapid: 116 (at 12:40 PM), blood pressure: 144/95 (at 12:40 PM). On an unspecified date in Feb2021, the patient underwent lab tests and procedures which included blood work: Unknown results (the doctor was also going to see what the blood work from the ER yesterday looks like. They were looking for blood clots at the ER), EKG: Unknown results, EKG: Unknown results, Echocardiogram: Unknown results. The patient was treated with IV for the adverse events. The outcome of the events she couldn't catch her breath, her heart was pounding was unknown and not recovered for the other events.

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1305064	5/11/2021	IA	80	F	2/9/2021	2/1/2021	hands are tingly; My hands are tingly and so cold.; felt terrible everyday; Nauseated; Arms felt like they were asleep; so sick; Hurt all over; not moving too fast; I do not want food; I have not eaten, taken a shower or anything; This is a spontaneous report from a contactable consumer (Patient, self-reported). A 80-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Batch/Lot number was not reported), dose 1 via an unspecified route of administration on 09Feb2021 09:45 (at the age of 80-years-old) as SINGLE DOSE for covid-19 immunisation. Medical history included immunodeficiency, atrial fibrillation. The patient got her shot last Tuesday morning at 9:45 and had been real sick after this. The patient had a bad reaction to it. Well after patient got the shot it was in the. And it said if she was on blood thinner (Unspecified Medications) or 'immune disorder' (not clarified further) she know and she was both of those and was just wondering what to expect and today from elbow. On unspecified date of Feb2021 , her arms felt like they were asleep and then now it was from elbow bit down and her hands got real cold. Now she had not ran a fever and she had not vomited, but she did not want food. She had hurt all over and she had been nauseated (on unspecified date of Feb2021) but not vomited. She had not eaten, taken a shower or anything, and she had been so sick (on unspecified date of Feb2021). Well let her see if she could see a pen that writes. She was not moving too fast (on unspecified date of Feb2021). She wanted to know if this was going to affect her blood, the thickness or the firmness. Since Tuesday, 09Feb2021, patient hands were tingly and so cold. The patient had felt terrible everyday. She had other relatives that got some aches and fatigue , but nothing like what she had. The patient was not currently not taking any immunosuppressant drugs. Patient was enquiring that was it ok to get her 2nd Pfizer vaccine vaccine dose in 4 weeks. The patient also enquiring about was it a problem, with getting the vaccine, if she take Blood thinners, she had atrial Fib and used to get a lot of blood clots. And was there any problem with being immunocompromised and getting the vaccine. Outcome of the events was unknown. Information on batch/lot number has been requested. Follow-up attempts are completed. No further information is expected.

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1306045	5/11/2021	NY	81	F	3/9/2021		Deep vein thrombosis leg; This is a spontaneous report from a contactable consumer, based on information received by Pfizer. This case is split from master case for a 81 year old patient taking BNT162B2 and experienced Deep vein thrombosis leg. This is a spontaneous report from a contactable consumer. An 81-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 09Mar2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included exposed to toxins from 911, patient stated that she is 911 survivor. The patient's concomitant medications were not reported. The patient experienced deep vein thrombosis leg on an unspecified date. The event outcome was unknown.
1305754	5/11/2021	AL	42	F	4/11/2021	4/15/2021	Blood clot in right calf; This is a spontaneous report received from contactable consumer for herself. A 42-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) dose 2 via an unspecified route of administration, administered in Arm Left on 11Apr2021 17:15 (Batch/Lot Number: EW0151) as 2nd dose, single for covid-19 immunisation. No pregnancy at time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient medical history allergy to penicillin. The patient's concomitant medications were not reported. Historical Vaccine included the first dose of BNT162B2 on 21Mar2021 05:15 PM in Left Arm (Batch/lot number: Ep6955) as 1st dose, single for COVID-19 Immunization. The patient experienced blood clot in right calf on 15Apr2021 03:00 AM. The adverse event result in doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Therapeutic measures were taken as a result of blood clot in right calf included Blood thinners. No Hospitalization Prolonged. Prior to vaccination, the patient did not diagnose with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Outcome of the events was recovering.

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1306306	5/11/2021	NY		F		4/1/2021	DEEP VEIN THROMBOSIS; This spontaneous report was received from 66-year-old, White, not Hispanic or Latino female patient. The patient's height, and weight were not reported. The patient's past medical history included Factor 5 Leiden positive (no clot issues since 1998 and did not take any standard medication for it as per guidelines), and anaphylaxis due to drug and shellfish allergies. The patient underwent a surgery (unspecified) and was immobilized and developed multiple clots in her right leg. Concurrent condition included shellfish allergy. The patient drinks alcohol socially (rarely), does not smoke and had no drug abuse or illicit drug use. The patient experienced drug allergy when treated with Aspirin (acetylsalicylic acid), and ibuprofen. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration was not reported, batch number: 1805022 and expiry: unknown) dose was not reported, 1 total, administered on left arm on 08-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 15-APR-2021 (approximate date), the patient experienced persistent leg pains. On 29-APR-2021, the patient developed pitting edema, experienced ankle redness and ankle pain. On 01-May-2021, the patient saw a retired orthopedic surgeon who advised the patient to go to a doctor immediately. On 02-May-2021, the patient went to the primary care office, saw a nurse practitioner and was immediately sent to the Emergency room (ER). On the same day, many blood tests were done (including differential, routine chemistry and coagulation), all of which showed normal results and a computed tomography (CT) scan showed thrombus in left posterior tibial vein below the knee (blood clot in left calf) following which a diagnosis of deep vein thrombosis (DVT) was made. On 02-May-2021, the patient started with Xarelto (rivaroxaban) 15 mg twice daily for 21 days then decrease to once daily as part of treatment for DVT. The patient completed 6 doses of Xarelto at the time of report. Both the ER doctor and the primary care doctor stated that the cause of DVT was the vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of deep vein thrombosis was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210509051- covid-19 vaccine ad26.cov2.s - Deep

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Vein Thrombosis. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY, UNDERLYING DISEASE.

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1305777	5/11/2021	WA	38	M	4/15/2021	4/17/2021	chest pains; short of breath; troponin at 4.6/Went up to 5.0/troponin peaked at 9.9; Echo shows decreased blood flow (50%); This is a spontaneous report from a contactable consumer (patient). A 38-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), at same age, via an unspecified route of administration, administered in arm left on 15Apr2021 12:45 (Batch/Lot Number: EW0162) as single dose for covid-19 immunisation. The patient medical history was not reported. Concomitant medication included loratadine/ pseudoephedrine (CLARIDIN-D). The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), at same age, administered in arm left on 25Mar2021 04:30 PM (Batch/Lot Number: ER8730) for covid-19 immunisation. The patient experienced chest pains, and short of breath both on 17Apr2021 22:00. Tried to sleep it off. 24 hours, didn't get better. On 17Apr2021, went to local ER, troponin at 4.6 ng/L. Doctors didn't believe it, did another blood draw. Went up to 5.0 ng/L. Ambulance to nearby hospital, troponin peaked at 9.9 ng/L. Echo showed decreased blood flow (50%) and EKG was irregular. Angiogram and CT scan show no blood clots or blockages. Patient was a healthy 38 male who was a distance runner. No history of chest pain or heart issues. Doctors determined incident almost certainly related to vaccine. The serious criteria for all events were hospitalization and duration were 2 days. The adverse events result in doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Colchicine received as treatment for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID 19. Since the vaccination, the patient has been tested for COVID 19. The patient underwent lab tests and procedures which included COVID test (COVID antibody blood test): negative on 20Apr2021, Covid test (Nasal Swab): negative on 18Apr2021. The outcomes of events were recovering.



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1305784	5/11/2021	MA	36	M	4/24/2021	4/24/2021	Thrombosis; Vericose veins; Swollen, bulged nerves around left hand palm and fingers/The same symptoms noticed on right foot; Nerves are in black darkened color and the palm fingers, knuckle areas; the palm, fingers, knuckle areas had moderate pain. The same symptoms noticed on right foot.; the palm, fingers, knuckle areas had moderate pain; sensitive to touch; This is a spontaneous report from a contactable consumer(patient). The 36-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in arm left on 24Apr2021 14:45 (Lot Number: EN6205) as first dose, single for covid-19 immunization. Medical history included none. He had not known allergies to food or medications, no illness history. Concomitant medications included minerals nos, vitamins nos (CENTRUM A TO ZINC) adutls vitamin, miconazole nitrate (LOTRIMIN AF ANTIFUNGAL) topical cream. The patient experienced one hour after first dose of vaccine shot at left arm shoulder, he saw swollen, bulged nerves around left hand palm and fingers. Nerves were in black darkened color and the palm, fingers, knuckle areas had moderate pain. The same symptoms noticed on right foot. The affected areas on both palm, fingers, foot area have dark patch areas with moderate pain. After 32 hours, he saw swollen nerve back of left leg thigh area with deep pain. It was sensitive to touch. It looked like thrombosis or vericose veins not sure about it. He reached out to doctor office and they said to wait for another day to see if he can recover. whereas he still have the darkened black nerve with pain in the affected areas. Events occurred on 24Apr2021 16:00 which was resulted in doctor or other healthcare professional office/clinic visit. There was unknown if treatment received. Outcome of events was not recovered. There was no covid prior vaccination and post vaccination.

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1305834	5/11/2021	NY	65	F	3/29/2021	4/1/2021	Whole Leg Pain after first dose of Covid Vaccine/hurt in her thighs, knees, calves, and down into her ankles; Lower back sore intermittently/The back pain fluctuates from a pressure and mild ache to soreness; This is a spontaneous report from a contactable other nurse (patient). A 65-year-old female patient received bnt162b2 (Pfizer-BioNTech Covid-19 Vaccine), via an unspecified route of administration, administered in Deltoid Left on 29Mar2021 10:30 (Batch/Lot Number: ER8727) as First Dose; Left Deltoid for covid-19 immunization. Vaccination facility type was in pharmacy. No vaccines administered on same date of the Pfizer suspect. None prior vaccinations within 4 weeks. Family medical history relevant to AE was none. Medical history included ongoing high cholesterol diagnosed about 30 years ago (it was hereditary), ongoing Hashimoto's thyroiditis diagnosed about 20 years ago. Concomitant medications included rosuvastatin taken for blood cholesterol from about 3 years ago in 2018 to Apr2021 (a few weeks after the first dose of the vaccine); levothyroxine sodium (UNITHROID) taken for Hashimotos thyroiditis and ongoing. Patient was not on any other cholesterol medication currently. About 2 weeks after the first vaccine she started having leg pain. It was whole leg pain. It hurt in her thighs, knees, calves, and down into her ankles. She went to her doctor who did doppler studies and found no blood clots in Apr2021. Thought maybe it was the cholesterol medications that she had been on for years; so she stopped taking it. The pain in legs subsided a few days later and ended a few days before she got the second vaccine. She was a hiker and was in amazing shape. She had not done anything different, nothing that would have exacerbated this. She believed her symptoms are medically significant as she did not know for sure what was causing them. She was uncertain if her symptoms have been caused by the Covid Vaccine. The event whole leg pain after first dose of Covid Vaccine required a visit to physician office. No emergency room visited. She had issues with her back. She noticed something new. Her lower back was sometimes sore. It came and went intermittently; unlike the leg pain that was constant. The back pain fluctuates from a pressure and mild ache to soreness. This also occurred after both vaccines. The outcome of back pain was not recovered, of other event was recovered in

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							Apr2021. The reporter (patient) was uncertain if her symptoms have been caused by the Covid Vaccine.; Sender's Comments: Based on the information currently available,The casual association between the reported event "Pain in extremity","Back pain" and suspected vaccine BNT162B2 cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021467940 same patient/drug, different vaccine dose/AE
1307444	5/11/2021	KY	43	F	4/3/2021	4/7/2021	she?s had blood clots and has had surgery 3 times, she is unconscious at the moment. the whole left side of her brain has been removed and she is paralyzed on the left side. this is definitely from the shot.
1305902	5/11/2021	CA		M			blood clots in his lungs; shortness of breath; This is a spontaneous report from a Pfizer- sponsored program from a contactable consumer reported for self. This male patient of unspecified age received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose on an unspecified date for COVID-19 immunization. Medical history and concomitant medication were not reported. Patient felt so out of it after receiving second dose. He went to the hospital a week after second dose and was diagnosed with blood clots in his lungs. He had shortness of breath as well. He was on a blood thinner now. The outcome of events was unknown. The information on the lot/batch number has been requested.

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1306200	5/11/2021	CT	53	M	2/3/2021	2/24/2021	DVT causing Muscle cramps; DVT causing Muscle cramps; fever; chest pain; This is a spontaneous report received from a contactable healthcare professional (patient). A 53-year-old male patient received the second dose of BNT162B2 (lot number: EL9261), intramuscularly in left arm on 03Feb2021 13:00 at single dose for COVID-19 immunisation. Medical history included gout. The patient's concomitant medications were not reported. The patient previously received the first dose of BNT162B2 (lot number: EL0142), intramuscularly in left arm on 06Jan2021 13:00 for COVID-19 immunisation. The patient experienced deep vein thrombosis (DVT) causing muscle cramps, chest pain, fever, etc 2-3 weeks after the second dose on 24Feb2021 12:00. Patient did not receive any treatment for the adverse events. Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Outcome of the events was not resolved.; Sender's Comments: Considering a positive temporal association, a causal relationship between the event deep vein thrombosis and suspect drug bnt162b2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate

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1306215	5/11/2021	MI	77	F	2/12/2021	2/23/2021	<p>Legs swelled up really bad ; it left blotches in my leg; Legs swelled up really bad ; it left blotches in my leg; Fever; Bladder infection; UTI; He gave me some medications and it is helping the rash; stomach even swelled up; This is a spontaneous report from a contactable consumer (patient). A 77-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration on 12Feb2021 (Batch/Lot number was not reported) as SINGLE DOSE (at the age of 77 years old) for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. Historical vaccine information included BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, for COVID-19 immunization, dose 1 on 17Jan2021 at age of 77 years old. On 23Feb2021, the patient experienced legs swelled up really bad it left blotches in my leg and she went to the doctor, she had fever, bladder infection and Urinary tract infection (UTI). The legs swelled up real bad, her thighs from the waist, she just swelled up everywhere. Her stomach even swelled up but the right leg mostly. She experienced the blotching, it looks like a birth mark on my right leg and the left leg. It is blotchy, looks like a birth mark on the legs. The right one got really big. She did go to doctor and he said it was not a blood clot. He said people are getting swelled up with rash, some people are having rashes and swelling. Treatment included the physician gave her some medications and it is helping the rash and "cephalexin 500 mg, 3 times a day" for the UTI. Outcome of the events was unknown. No follow-up attempts are needed; information about lot/batch number cannot be obtained.</p>

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1305114	5/11/2021	MT	56	F	2/14/2021	4/14/2021	Dear Sir or Madam: Writing to you to please refer me to VAERS for possible CVST s/p dose 2 of Moderna I am a retired APRN and just reviewed your article HPI: 57 y/o female (not obese, no hypothyroidism) H/O travel (February1-March 1 2021) with possible SARS Cov2 exposure; possible long COVID Big supporter of public health and COVID19 vaccine campaign with Moderna dose one 2/14/21 and dose 2 on 3/14/21 Mild to moderate sx after both doses Routine ophthalmology exam 4/8/21 Approximately 4/13/21 left sided facial pain, HA and swelling-self treated for blepharitis with warm compresses 4/15/21 returned to ophthalmologist: forceful lower lid compression applied and diagnosed with pre-septal cellulitis-Rxd Augmentin 875 and steroid dose pack-on return to home experienced severe projectile vomiting x2 and awakened with massive facial edema and ecchymosis-petechial hemorrhages-terrible sinus pain Went back to ophthalmology-they said I had a chalazion and black eye-referred back to PCP for r/o temporal arteritis. ESR and CRP neg Symptoms progressed to severe headache in left temporal lobe since 4/15/21-severe nausea, changes in speech, problems with word finding photophobia, global malaise, fatigue (seems like migraine) Went to see PCP 5/6/21 and transported via ambulance to ER for severe HA; HTN; neuro deficits, r/o stroke CBC CMP Etc wnl with CT of Head showing no stroke or aneurysm. Physician did state there may have been Micro thrombi not detected on CT. Neurology consult with plan to treat intractable HA and rxd Zofran and Sumatriptan -I do not recall anyone asking me about COVID19 vaccine timing or side effects. No PL4 As an APRN I would say I have never had migraines-now experience left sided head pain radiating from temporal lobe to jaw; this waxes and wanes; nausea; overall rapid onset of persistent speech deficit and organizational problems also noted by spouse (since dose 2 Moderna)-symptoms poorly controlled with migraine medication I think this needs further investigation as potential vaccine side effect

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1307924	5/11/2021	WI	16	M	4/29/2021	5/10/2021	<p>HPI: Patient is a 16-year-old male who was upgraded to our emergency department after blood work showed a significant thrombocytopenia. Please see walk-in clinic provider NP for presenting history and physical exam. Patient reports to me development of sore throat as well as blood from the throat last Thursday. Patient also began to notice development of bruising to his legs without any injury approximately a week ago. Denies any pain. Denies any blood in the urine or stool. No other medical complaints at this time. Chief Complaint Patient presents with ? Sore Throat was seen a few weeks ago for ear infection, also had sore throat at that time that never went away. School nurse wanted him swabbed for strep and covid PCR ? Bleeding/Bruising has large bruising to right leg for about a week, no injury. also states bruise to upper left thigh and right shoulder and scattered small bruises. School nurse wants his platelets checked. Denies pain. States mild bleeding in gums and states notices blood in back of throat ROS: See HPI above. All other 12 review systems negative otherwise specified in HPI above. ROS PMH: Past Medical History Past Medical History: Diagnosis Date ? Asthma ? GI symptoms 10/2018 with pharyngitis ? Headache ? Strep throat ? Tonsillar and adenoid hypertrophy nasal scope Past Surgical History Past Surgical History: Procedure Laterality Date ? COLONOSCOPY 12/07/2018 with biopsies ? ESOPHAGOGASTRODUODENOSCOPY 12/07/2018 with biopsies ? TONSILLECTOMY &amp; ADENOIDECTOMY 2011 Family History Family History Problem Relation Age of Onset ? Hypertension Father ? Diabetes Mellitus Father Social History Tobacco Use ? Smoking status: Never Smoker ? Smokeless tobacco: Never Used ? Tobacco comment: no second hand smoke exposure Substance Use Topics ? Alcohol use: No Allergies: No Known Allergies Meds: No current facility-administered medications on file prior to encounter. Current Outpatient Medications on File Prior to Encounter Medication Sig Dispense Refill ? albuterol HFA 108 (90 Base) MCG/ACT inhaler Inhale 2 puffs every 4 hours as needed. 1 inhaler 1 ? Aspirin-Acetaminophen-Caffeine (EXCEDRIN PO) ? acetaminophen (TYLENOL) 325 MG tablet Take 975 mg by mouth every 6 hours as needed for Pain. ? naproxen (NAPROSYN) 220 MG tablet Take 440 mg by</p>

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mouth twice daily - with breakfast and supper.  
 Physical Exam: Blood pressure (!) 148/93, pulse 107, temperature 98.6 °F (37 °C), resp. rate 20, height 6' 5" (1.956 m), weight (!) 348 lb 8 oz (158.1 kg), SpO2 96 %.  
 O2 flow: Physical Exam Constitutional: He is well-developed, well-nourished, and in no distress. No distress. HENT: Head: Normocephalic. Right Ear: External ear normal. Nose: Nose normal. Mouth/Throat: Oropharynx is clear and moist. No oropharyngeal exudate. Mild erythema in the posterior pharynx with some bleeding. No posterior pharynx edema. Eyes: Conjunctivae are normal. Right eye exhibits no discharge. Left eye exhibits no discharge. No scleral icterus. Cardiovascular: Exam reveals no gallop and no friction rub. No murmur heard. Pulmonary/Chest: Effort normal. No stridor. No respiratory distress. He has no wheezes. He has no rales. Abdominal: Soft. Left upper quadrant tenderness. Musculoskeletal: General: No tenderness, deformity or edema. Cervical back: Normal range of motion. Neurological: He is alert. Gait normal. GCS score is 15. Skin: Skin is warm. He is not diaphoretic. Multiple baseball to softball size bruises to the bilateral lower extremities worse on the right than left. Mild petechiae. Psychiatric: Mood, memory, affect and judgment normal. Diagnostics: Results for orders placed or performed during the hospital encounter of 05/10/21 CBC WITH DIFFERENTIAL Result Value Ref Range White Blood Cells 7.72 4.0 - 13.0 K/uL Red Blood Cells 3.48 (L) 4.15 - 5.30 M/uL Hemoglobin 10.8 (L) 11.8 - 15.4 g/dL Hematocrit 30.5 (L) 35.5 - 46.5 % MCV 87.7 77 - 94 fL MCH 31.0 25.0 - 32.3 pg MCHC 35.4 31.9 - 35.9 g/dL RDW 16.2 (H) 11.5 - 14.8 % Platelet Count 9 (LL) 160 - 424 K/uL MPV 11.4 (H) 6.8 - 10.5 fL Neutrophil % Pending % Lymphocyte % Pending % Monocyte % Pending % Eosinophil % Pending % Basophil % Pending % Absolute Neutrophils Pending 1.6 - 7.5 K/uL Absolute Lymphocytes Pending 1.2 - 4.9 K/uL Absolute Monocytes Pending 0.1 - 0.9 K/uL Absolute Eosinophils Pending 0.0 - 0.6 K/uL Absolute Basophils Pending 0.0 - 0.2 K/uL COMPREHENSIVE METABOLIC PANEL Result Value Ref Range Sodium 138 133 - 144 mEq/L Potassium 4.4 3.5 - 5.0 mEq/L Chloride 101 95 - 107 mEq/L Carbon Dioxide 22 22 - 32 mEq/L Anion Gap 15 6 - 15 mEq/L BUN 14 8 - 24 mg/dL Creatinine 0.81



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0.69 - 1.20 mg/dL Glomerular Filtration Rate NOT CALCULATED due to age less than 18 years. mL/min  
 Glucose 110 (H) 70 - 100 mg/dL Albumin 4.9 3.5 - 5.2 g/dL Calcium 10.0 8.6 - 10.4 mg/dL AST 23 11 - 41 IU/L ALT 28 (H) 0 - 19 IU/L Alkaline Phosphatase 142 90 - 366 IU/L Bilirubin, Total 0.4 <1.5 mg/dL Total Protein 7.7 5.9 - 7.8 g/dL Globulin 2.8 1.8 - 3.7 g/dL A:G Ratio 1.8 1.2 - 2.7 PROTHROMBIN TIME Result Value Ref Range Prothrombin Time 18.4 (H) 12.0 - 14.6 sec INR 1.5 (H) 0.9 - 1.1 PTT, PARTIAL THROMBOPLASTIN Result Value Ref Range PTT 32 23 - 36 sec CRITICAL VALUE HEME Result Value Ref Range Critical Value ED Course: Patient was upgraded to the emergency department after he was noted to have significant thrombocytopenia. Patient is pleasant he has no active complaints other than some throat irritation bleeding in the throat and bruising that was nontraumatic to the legs. My physical examination reveals multiple rather large bruises to the bilateral lower extremities up to softball size worse on the right than left. Patient had some mild left upper quadrant discomfort. Very minimal bleeding in the posterior pharynx. I personally reviewed the labs and CBC revealed an anemia at 10.830.5 hemoglobin hematocrit respectively. Most notably a 9000 thrombocytopenia. CMP essentially unremarkable. INR 1.5 PTT normal. I added on Lyme disease and tick-borne illness as well as a Monospot type and screen. Patient did receive his 1st visor vaccine for COVID-19 on April 29, 2021. IV was established in the emergency department in consultation made to Pediatric Oncology. I spoke with pediatric oncology in regards to patient's history and present illness. He does agree that the patient should in fact be transferred under the pediatric care but recommended under the general hospitalist service. He did not advise to proceed with any active treatment in our emergency department such as gamma globulin, platelets or steroids. Awaited call back from pediatric hospitalist and spoke with Dr. She has agreed to accept the patient in transfer. Patient and family are comfortable disposition plan no further questions at this time. Impression: 1. ITP Disposition: Transfer ED on 5/10/2021  
 Revision History Detailed Report Note shared with patient Note filed date Mon May 10, 2021 12:24 PM

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1307388	5/11/2021	CA	90	F	3/3/2021	3/3/2021	Patient had a stroke with clot on right MCA
1307481	5/11/2021	MI	48	M	4/3/2021	4/29/2021	Patient is a 48-year-old male with patient history significant for CAD, CHF, ICD, HTN, hyperlipidemia, and smoking who presented to the ED yesterday morning with 1 day history of chest pain. Patient described the CP as moderate aching in the substernal area that did not radiate. The pain was intermittent, with each episode lasting 1-2 minutes. The CP was associated with LUE numbness and SOB on exertion. The chest pain and LUE numbness have now resolved. Patient also reports a three week history of RUE swelling. The swelling gradually worsened and is now associated with pain and proximal RUE bruising. RUE pain is rated 5/10. In the ED, patient was found to have NSTEMI and small right lower lobe segmental pulmonary artery embolus. Venous Doppler was positive for occlusive thrombosis in the R subclavian, basilic, and cephalic veins. Patient was started on IV heparin. Patient is scheduled for cardiac cath today. Hematology is consulted regarding PE and RUE DVT. Patient denies personal or family history of blood clots or recent travel. Reports receiving COVID vaccine in LUE approximately three weeks ago. Also admits to being more sedentary recently due to being unemployed. Denies nausea, vomiting, bleeding, bowel changes, fever, or chills. Significant PE findings: RUE edema, firm and tender to palpation, ecchymosis on proximal RUE, distal sensation and active ROM intact
1308488	5/11/2021	IL	61	F	3/29/2021	5/11/2021	Patient called 5/11/21 stating today she blew a blood clot from her nose

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1308074	5/11/2021	NC	40	F	4/6/2021	4/26/2021	Was diagnosed with a DVT 3.5 weeks after vaccination. Started experiencing symptoms of DVT 20 days after the vaccine. Symptoms were not atypical and were almost not checked for DVT at ER. Started with twinges in my right leg for several days. Then pain in my back right behind my heart. Then developed sporadic chest pain and heart palpitations. I was afraid to go to the ER because of COVID because my 12-year-old daughter has a heart condition. Then on April 30 mid-day my right thigh began to hurt like a pulled muscle although I had not injured it or pulled it. I couldn't walk on my leg the pain was so intense. My family was very worried about a blood clot because of the Johnson and Johnson vaccine. That night I had really sharp chest pains and my thigh pain was no better by the next morning. I went to the ER told them my symptoms. After the ER doctor examined me he said he was 99% sure I didn't have a blood clot because my pain was in my thigh and there was no redness or swelling. He told me my chest pain was probably due to anxiety. I asked if he would check my leg anyway. Once the ultrasound of my leg was done the DR came back and said I had a DVT. Then I had to have an MRI of my chest which he told me was a lot of radiation. I did not have a PE. They did not prescribe Heparin because they felt the DVT was from the vaccine. So I was giving Eliquis. Since then my family DR has run more tests and I do not have any genetic reason to have the DVT. I do not and have not taken birth control in the past 20 years. I am now on a blood thinner for at least 90 days if not longer and I am continuing to have twinges and chest pain twinges.
1309367	5/11/2021	CA	61	F	4/7/2021	4/12/2021	right leg pain started 5 days after vaccination. Went to the ER on 5-1-2021 x-rays, ultrasound and blood work done. Diagnosed with a deep vein thrombosis blood clot in the right leg. given Eliquis starter pack 2 tabs 10 mg each twice a day for 7 days, 1 5mg each tabs twice a day, ongoing Tramadol 50mg 1 every 6 hours for severe pain Acetaminophen 500mg 1 every 4 hours for pain Ondansetron 4mg as needed for nausea/vomiting

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1307905	5/11/2021	TX	71	M	1/1/2021	2/1/2021	My name is patient, 71 year old. On 5/5/21 my Cardiologist told me to go to the ER to get a Chest CT. I was diagnosed with PE (Pulmonary Embolism). I was put in ICU under blood thinner Heparin drip treatment. On 5/09/21, I was discharged to go home to continue treatment with blood thinner Eliquis. I have always been an active healthy person with no major issues other than one Stent put in my Left Descending Artery by doctor in June of 2013. I've been playing Tennis (mostly singles) on weekends till last November and I've been playing Ping Pong on weekdays till end of April. Never expected to getting this PE. Could this blood clots be the result of Pfizer Covid Vaccine ?
1307839	5/11/2021	HI	33	F	5/6/2021	5/6/2021	Healthy 33-year-old female who denies any illness except for cord prolapse during her NSVD delivery. She got her first Pfizer COVID-19 vaccine today afterwards she felt dizzy, lightheaded, and some chest tightness. Also some air hunger. Symptoms have improved. She was advised to go to the nearest emergency department. She arrived to hospital w temperature 98.6 already 146 bpm. She received 2 L of saline 0.5 mg Ativan. Pt has never formally been diagnosed with anxiety but says she is an anxious person. She has received prior needle punctures without reaction. She is concerned about blood clots as the media has reported this with the Johnson and Johnson vaccine. Pt was admitted for observation overnight. Bilateral LE duplex US negative for DVT. Pt stable and discharged to home.
1307708	5/11/2021	DC	37	M	4/7/2021	5/10/2021	Two weeks of abdominal discomfort, followed by onset of extreme abdominal pain Followed by diagnosis of blood clot at kidney artery

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1307658	5/11/2021	PA	53	F	4/9/2021	4/22/2021	4/29/2021 1. Localized edema 2. H/O factor V Leiden mutation 3. History of deep vein thrombosis (DVT) of lower extremity - patient had Johnson and John vaccine on 4/9/2021. She then developed bilateral leg pain with calf swelling, redness, and warmth about 1 week ago. Patient has a history of DVT and factor V Leiden mutation. She has previously been treated with Eliquis for DVT. Patient concerned for repeat DVT. Recommended bilateral venous dopplers. - VAS US Doppler Venous Lower Extremity Left; Future - VAS US Doppler Venous Lower Extremity Right; Future . Acute deep vein thrombosis (DVT) of calf muscle vein of left lower extremity (HCC) 5. H/O factor V Leiden mutation - patient diagnosed with a new DVT on 4/29/2021. She is currently anticoagulated with Eliquis 5mg 1 tablet BID with plan to continue anticoagulation for at least 6 months. Patient follows with hematology
1307592	5/11/2021	OH	72	M	4/20/2021	4/22/2021	Symptoms lasted 2-3 days. 10 days after shot, for the first time in my life I experienced chest pain. I thought I was experiencing possible blood clots. I went to the hospital. EKG and blood results were negative. The next day after a stress test, I was transferred to another hospital for a heart cath. I have an artery clogged and will have open heart surgery on 5-13-2021.
1307585	5/11/2021	NY	68	F	3/7/2021	3/28/2021	Patient reported knee pain at the end of march 3/28/2021 she was seen by a doctor on 4/14 and thought to have arthritis prescribed NSAIDS. Patient had no history of arthritis or chronic prescription use or chronic health conditions. She was referred to an orthopedic and when no arthritis was found she was referred to ER to check for a blood clot on 5/10/2021. Patient was diagnosed with a DVT on 5/10/2021 with no previous history of clots or other risk factors known.
1308259	5/11/2021	MN	59	F	4/6/2021	4/8/2021	Recurrence of PE blood clots in left lung.

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1303947	5/10/2021	CA	26	F		5/3/2021	BACK ACHE; MUSCLE SPASM; HEAVY DARK CLOTTY PERIOD; PARALYSIS; PINS AND NEEDLES SENSATION; NUMBING; SWEATS; SORENESS; NAUSEA; This spontaneous report received from a consumer concerned a 26 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included birth control implanted in arm that is old and needs to be taken out, alcohol user, and non smoker, and other pre-existing medical conditions included the patient had no drug allergies nor illicit drug use. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808982, and batch number: 1808982 expiry: UNKNOWN) dose was not reported, 1 total, administered on 03-MAY-2021 at 09:00 on left arm for prophylactic vaccination. No concomitant medications were reported. On 3-May-2021 at 09:00, the patient was vaccinated. At 17:00, the patient had pain, nausea, sweats, and soreness. At 18:00, she had pins and needles sensation, numbing, and paralysis. Later, she had sweats. Paramedics had checked the patient blood pressure and heart rate and they were within normal limits. The patient was still experiencing backache, muscle spasm, pain and heavy dark clotty period which was unusual. The patient had birth control implanted in arm that was old and needed to be taken out. Laboratory data included: Blood pressure and Heart rate was found normal. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from soreness, back ache, muscle spasm, and heavy dark clotty period, and the outcome of nausea, sweats, pins and needles sensation, numbing and paralysis was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 20210511206-COVID-19 VACCINE AD26.COV2.S- Paralysis. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
1301803	5/10/2021	AZ	36	F	4/14/2021	4/15/2021	Almost instantaneous ovary pains, blood clots passing vaginally, abnormal vaginal bleeding for two weeks

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1304689	5/10/2021	PA	50	M	4/1/2021	4/14/2021	Blood clot
1304151	5/10/2021	IL	47	M	5/7/2021	5/9/2021	Patient was found at home Saturday afternoon passed out. Patient was rushed to the hospital where it was discovered he had a blood clot. He is going to hospitalized for a few days per patients mother.
1303797	5/10/2021	GA	44	M	3/1/2021	5/7/2021	Bilateral blood clots in my lungs
1303476	5/10/2021	WI	82	M	3/29/2021	4/12/2021	Central retinal vein thrombosis with associated retinal hemorrhage. Started the week after vaccination. Identified by ophthalmology on 4/12/21
1303446	5/10/2021	TX	61	F	5/4/2021	5/6/2021	pain in side, blood clots in lung
1303206	5/10/2021	IL	87	M	4/1/2021	4/15/2021	The days after the shot the patient was sleeping 12-14 hours a day which was not normal. On 04/15 pt started to feel dizzy and signs of blurry vision began. They went their general physician ruled out stroke & clot, then recommended they see an eye dr since the vision was the worst symptom. By 04/21/2021 the pt lost 100% of their eye sight. They eye dr after doing a scan discovered the pt had temporal arteritis. They believe the vaccine could had caused the body to lose the fight against the temporal arteritis and pt eyesight was lost.
1302795	5/10/2021	MN	60	F	4/20/2021	4/22/2021	patient with unprovoked large left lower extremity DVT and bilateral PE with moderate/high clot burden. Platelet count was normal. Hemoglobin was still low at 9 but improving with iron supplementation over the last month. She does not have a previous history of blood clot or family history of blood clot or hypercoagulable state.

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1301964	5/10/2021			F			BRAIN BLOOD CLOTS; This spontaneous report received via social media from a consumer via a company representative concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company does not perform follow-up in this scenario to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient experienced brain blood clots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of brain blood clots was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210504075.; Sender's Comments: V0. 20210505140-COVID-19 VACCINE AD26.COV2.S-Brain blood clot. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
1303074	5/10/2021	WV	64	M	4/8/2021	4/10/2021	1st dose in series on 03-18-2021; 2nd dose in series on 04-08-2021 2 days after 2nd dose, he developed severe pain in both legs. He was taken to the hospital where clots were diagnosed in both legs and groin area. A previously undiagnosed lung nodule was found and he was given a cancer diagnosis. He was discharged home on apixaban (Eliquis) and comfort measures 2 days after admission. Over the following weeks, he had a permanent lung drain placed. He died on May 5th or 6th at home. No autopsy performed.



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1301967	5/10/2021			F			BLOOD CLOT IN HEART; This spontaneous report received from a consumer concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total, administered on 2021 for prophylactic vaccination. The batch number was not reported and it has been requested. No concomitant medications were reported. On 2021, the patient died due to blood clot in heart. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0 20210506615-COVID-19 VACCINE AD26.COV2.S- blood clot in heart. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: BLOOD CLOT IN HEART
1302550	5/10/2021	TX	69	M	4/30/2021	4/30/2021	patient received 1st Moderna dose on 4/30/21. The next morning on 5/1 he felt pain on his left leg. He waited to see if would get better or worse. On the afternoon at an unknown time, his leg had gotten worse. He had severe pain on his left leg; it was painful to the touch; it was swollen and was hard as a rock. He called 911. He was taken to Hospital. Pt wanted me to report that he did not receive any treatment for his blood clot. He received a Lidocaine patch on his knee and was given a prescription for Voltaren Gel. (he was expecting to receive TPA to dissolve the clot like a few times before when he had blood clots but this particular time he did not)
1302479	5/10/2021	RI	64	M	3/27/2021	4/17/2021	Blood Clots in left leg and both sides of lungs
1302108	5/10/2021		23	F	4/30/2021	5/9/2021	Spontaneous cerebral infarct suspected to be from venous thrombosis complicated by intracranial hemorrhage requiring intubation, EVD placement and emergent OR. Admitted to Neuro ICU

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1301984	5/10/2021	CA	69	F		3/1/2021	TIGHTNESS IN HAMSTRINGS; BUTT PAIN; PAIN IN THIGHS AND CALVES AND ARM; GREAT DIFFICULTY IN MOVING; This spontaneous report received from a patient concerned a 69 year old female. The patient's height, and weight were not reported. The patient's past medical history included polio, and concurrent conditions included arthritis in the arms, and other pre-existing medical conditions included the patient had no known allergies. The patient was previously treated with abaloparatide. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose was not reported, administered on 06-MAR-2021 for prophylactic vaccination. Batch number was not reported and has been requested. No concomitant medications were reported. On MAR-2021, the subject experienced great difficulty in moving. On 15-MAR-2021, the subject experienced tightness in hamstrings. On 15-MAR-2021, the subject experienced butt pain. On 15-MAR-2021, the subject experienced pain in thighs and calves and arm. Laboratory data (dates unspecified) included: Diagnostic ultrasound (NR: not provided) no blood clots, not reported. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from tightness in hamstrings, pain in thighs and calves and arm, and butt pain, and the outcome of great difficulty in moving was not reported. This report was non-serious. This case, from the same reporter is linked to 20210509287.

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1301979	5/10/2021	CA		F	4/1/2021		HEAVY AND LONG MENSTRUAL BLEEDING; HEADACHE; This spontaneous report received from a patient concerned a 44 year old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808980, expiry: UNKNOWN) dose was not reported, administered on 03-APR-2021 to right deltoid for prophylactic vaccination. No concomitant medications were reported. On 09-APR-2021 or 10-APR-2021 the patient had Heavy and long menstrual bleeding with large blood clots. Patient went to emergency room on 17-APR-2021 and was given Medroxyprogesterone (Provera) which minimized the bleeding but didn't stop it. On 02-MAY-2021 the bleeding started back heavier with the blood clots once again. Patient again visited ER and injection was given to stop the bleeding (lupron) and Megestrol was prescribed. On 04-MAY-2021, Laboratory data included: Biopsy (NR: not provided) patient did not note diagnosis. On an unspecified date, patient experienced headache. Treatment medications (dates unspecified) included: leuporelin acetate, medroxyprogesterone acetate, and megestrol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the heavy and long menstrual bleeding and headache was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210509200-covid-19 vaccine ad26.cov2.s-heavy and long menstrual bleeding . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1301978	5/10/2021	PA	71	F	4/1/2021		SEVERE CHEST PAIN ON RIGHT RIBCAGE AND LEFT HAND SIDE; This spontaneous report received from a consumer concerned a 71 year old female. The patient's weight was 120 pounds, and height was 64 inches. The patient's concurrent conditions included rheumatoid arthritis since approximately 14 years, penicillin and IV contrast solution allergy, no alcohol use, and non-smoker, and other pre-existing medical conditions included the patient was not pregnant at the time of reporting and had no history of drug abuse or illicit drug use. The patient received covid-19 vaccine ad26.cov2. s (suspension for injection, intramuscular, batch number: Unknown, and expiry date: unknown) dose was not reported, 1 total administered on APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. Concomitant medications included adalimumab (Humira) for rheumatoid arthritis. On APR-2021, four to five days after the vaccination, the patient experienced mild soreness or discomfort initially and progressively worsened over time. Later the symptoms developed into a severe chest pain on right hand side of the ribcage, and it hurt to breath and move; the patient felt relieved only while lying flat. The patient had visited emergency room and physician room for severe chest pain on right ribcage and left-hand side. The patient went to the hospital after 6 to 7 days after the vaccination and got admitted. The patient was put on blood thinner immediately after the admission as the staff thought the patient had blood clot. On performing D-dimer test, the levels showed 3.49 (units unspecified) and was identified that the patient had no clots. The patient was discharged from the hospital on 28-APR-2021. The patient was pain free for 2 days; However, she started experiencing severe pain on left hand side of the chest on the day before reporting. The patient stated that the pain moved over. Rheumatologist suggested the patient to take Ibuprofen for the chest pain. The patient had reached out to her rheumatologist who advised the patient to take ibuprofen for the pain in her chest; However, the patient did not take before chest pain started. It was reported that the patient would be seeing the rheumatologist the next day of the report. The action taken with covid-19 vaccine ad26.cov2. s was not applicable. The patient had not recovered from severe chest pain on right ribcage and left-hand side. This report

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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1301971	5/10/2021						
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1301971	5/10/2021			M			
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was serious (Hospitalization Caused / Prolonged).;  
 Sender's Comments: V0:20210509152-covid-19 vaccine  
 ad26.cov2.s -severe chest pain on right ribcage and left-  
 hand side.. This event(s) is considered not related. The  
 event(s) has a compatible/suggestive temporal  
 relationship, is unlabeled, and has unknown scientific  
 plausibility. There are other factors more likely to be  
 associated with the event(s) than the drug. Specifically:  
 MEDICAL HISTORY

BLOOD CLOT; This spontaneous report received from a  
 consumer via a company representative concerned a  
 male of unspecified age. The patient's weight, height,  
 and medical history were not reported. The patient  
 received COVID-19 VACCINE AD26.COV2.S  
 (suspension for injection, route of admin not reported,  
 batch number: Unknown) 1 total dose, start therapy date  
 were not reported for prophylactic vaccination. The Batch  
 number was not reported. The company is unable to  
 perform follow up to request batch/lot numbers. No  
 concomitant medications were reported. On an  
 unspecified date, the reporter stated that her husband  
 had blood clot after vaccination. The action taken with  
 COVID-19 VACCINE AD26.COV2.S was not applicable.  
 The outcome of blood clot was not reported. This report  
 was serious (Other Medically Important Condition).;  
 Sender's Comments: V0: 20210508168-COVID-19  
 VACCINE AD26.COV2.SI-BLOOD CLOT. This event(s)  
 is considered unassessable. The event(s) has a  
 compatible/suggestive temporal relationship, is  
 unlabeled, and has unknown scientific plausibility. There  
 is no information on any other factors potentially  
 associated with the event(s).

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1301959	5/10/2021			F	4/1/2021		<p>VARICOSE VEIN RED AND HARD; UPPER RIGHT THIGH PAIN; SUPERFICIAL CLOTS; This spontaneous report received from a patient concerned an adult female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose was not reported, 1 total administered on 08-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 09-APR-2021, the patient experienced varicose vein red and hard, and was hospitalized. She sought care at the Vein Institute in Voorhees, NJ, as she says she had been treated there in the past. On 09-APR-2021, the patient experienced upper right thigh pain. On Apr-2021, the patient experienced superficial clots, and was hospitalized. Laboratory data included: Diagnostic ultrasound (NR: not provided) confirmed Superficial clots. Treatment medications included Motrin and Heating pad for Varicose veins. She was told to return in 2 weeks for a follow up ultra sound. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the superficial clots, varicose vein red and hard and upper right thigh pain was not reported. This report was serious (Hospitalization Caused / Prolonged, Other Medically important condition). This case, from the same reporter is linked to 20210501531.; Sender's Comments: V0 : 20210500162 - Covid-19 vaccine ad26.cov2.s - Superficial clots and Varicose vein red and hard . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

<i>VAERS_ID</i>	<i>RECVDATE</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1301969	5/10/2021			M			<p>BLOOD CLOT IN LEG; This spontaneous report received from a patient via a company representative concerned an adult male. The patient's weight, height, and medical history were not reported. The patient received ibrutinib (tablet, oral, batch number was not reported) dose, frequency, and therapy dates were not reported for an unspecified indication. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: UNKNOWN) dose, start therapy date were not reported, 1 in total for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient experienced blood clot in leg, and was hospitalized (date unspecified) for two days. The action taken with covid-19 vaccine ad26.cov2.s was not applicable; and action taken with ibrutinib was not reported. The outcome of blood clot in leg was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0. 20210507935-covid-19 vaccine ad26.cov2.s -blood clot in leg. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
1301958	5/10/2021	PA		M	3/5/2021		<p>RENAL ARTERY THROMBOSIS; KIDNEY INFARCTION; LEFT FLANK PAIN; RED CELLS IN URINE; ELEVATED SEDIMENTATION RATE AND C-REACTIVE PROTEINS; FLU LIKE SYMPTOMS; FEVER;</p> <p>This spontaneous report received from a physician concerned a 38 year old male. The patient's height and weight were not reported. The patient's pre-existing medical conditions included patient had no trauma, no illegal drug use, no predisposing medical conditions with no evidence of infection. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose was not reported, 1 total administered on 05-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 05-MAR-2021, the patient experienced fever and flu like symptoms. On 24-APR-2021, the patient experienced elevated sedimentation rate and C-reactive protein, acute onset of steady left flank pain. He went to emergency room (ER) and discovered red cells in urine. In ER did a Computerized tomography (CT) scan and ruled out kidney stones. Found infarctions of the lower half of the left kidney and thrombosis of the ventral inferior distal renal artery branch that supplied the lower pole of the left kidney. Echocardiogram was normal. On 28-APR-2021, Laboratory data showed C-reactive protein was 172 mg/L, sedimentation rate was 110 mm/h and Fibrinogen (NR: not provided) 677 mg/dL. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from flu like symptoms, and fever on 08-MAR-2021, was recovering from left flank pain, and had not recovered from renal artery thrombosis, kidney infarction, red cells in urine, and elevated sedimentation rate and c-reactive proteins. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0:20210500068-COVID-19 VACCINE AD26.COV2.S-1.RENAL ARTERY THROMBOSIS,KIDNEY INFARCTION,LEFT FLANK PAIN , RED CELLS IN URINE, ELEVATED SEDIMENTATION RATE AND C-REACTIVE PROTEINS- These events are considered unassessable. The events have a compatible/suggestive temporal relationship, are unlabeled, and have unknown scientific plausibility. There is no information on any other factors</p>



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							potentially associated with the events.
1302520	5/10/2021	CA	59	F	4/19/2021	4/28/2021	developed abd pain days after 2nd dose of Pfizer vaccine, came in 3 wk later for PEA arrest with dead gut secondary to extensive bud chiari syndrome w thrombosis of the portal vein, splenic vein, and superior mesenteric vein. Admitted to ICU/OR for ischemic small bowel removal.
1300702	5/9/2021	UT	43	M	4/29/2021	5/2/2021	2-3 days after the first injection, I developed a blood clot in my lower right leg.
1301096	5/9/2021	MD	61	M	5/6/2021	5/7/2021	32 hours after the vaccine, he suffered a massive heart attack due to a blood clot and a massive clot in the right arm. He went to the hospital and under went surgery at 12 am on Saturday. The coronary surgeon mentioned that this was not from heart disease as all vessels were clear. Rather, this was due to an embolism due to an unknown origin. A further work up concluded that he also had blood clots throughout his body (both lungs, one kidney, heart, liver, legs, arms, and possibly brain). By 12 p.m. we were asked back to the hospital as he was worsening. Treatment options included a heparin drip, which caused a brain hemorrhage. He was just at the doctors two times this week, on Tuesday and Wednesday and was fine no issues found. They went through with the 2nd dose and came to our home on Thursday.
1301151	5/9/2021	CA	44	M	4/17/2021	4/24/2021	Developed Deep VEIN thrombosis (DVT) in the left leg and a Pulmonary Embolism. Was hospitalized for 5 days and had to have a surgical procedure to insert a screen into my inferior vena cava

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1301254	5/9/2021	CA	36	M	3/7/2021	3/12/2021	For 2 days, typical arm soreness, flu-like symptoms with significant muscle pain and general weakness and malaise. However, on the 5th day, EXTREME abdominal pain, left side. Pain level up to 9. Incapacitating. Two visits to urgent care. This was in March before any info came out about adverse blood clot events for the J&J vaccine, so the doctors were not really interested at the time that I had just gotten my shot. They gave me antibiotics, thinking it may be diverticulitis (diagnosis based on symptoms only - no diagnostics - it was the doctor's "best guess"). Pain did not subside, only got worse. 4 days later I could barely move, abdominal pain was extreme. Went back to clinic and they did a PET scan to check for diverticulitis. There was none; PET scan revealed nothing out of the ordinary. So they told me they had no idea what it was and sent me home. PET scan reading by the doctor notes specifically that blood/vascular was not able to be observed because no contrast or dyes were used. Bottom line was over 10 days of extreme abdominal pain 5 days after receiving the shot. I've never experienced anything like that before.
1301256	5/9/2021	FL	61	F	3/31/2021	4/5/2021	Pain in right leg in knee area beginning on 4/6/2021. Pain worsened over the weekend. Went to the doctor on 4/14/2021. She sent me for a doppler on my legs where a blood clot was found behind my right knee. I started taking Xarelto that night - 15mg twice daily for 21 days. The pain increased considerable and by 4/20/2021 I could hardly walk. I went back to the doctor that day and she ordered a second doppler study. The blood clot was stable but there was no change. Continued on the Xarelto. Third visit to the doctor on 5/5/2021. Some lessening of the pain by then. Doctor changed the Xarelto dosage to 20 mg. one a day for the next two months. Then we'll schedule another doctor visit and probably another Doppler Study.
1301337	5/9/2021	NC	51	M	3/8/2021	5/2/2021	Blood clots in lungs was diagnosed after so many test. Treatment ongoing
1301483	5/9/2021	IN	44	F	3/24/2021	5/9/2021	Blood clots in lungs. Had trouble breathing for 3 days before it was diagnosed in the er.

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1300829	5/9/2021	IL	52	F	3/23/2021	3/23/2021	This is my second report (same vaccine Johnson and Johnson on March 23 lot #1805031) because my symptoms are still present; my first report was on 04/07/2021. I currently have depression, tinnitus, fatigue, brain fog, sometimes I feel shaky on the inside, swaying at times, and dizziness/vertigo. I sent follow-up information for my first VAERS report via mail and a pdf document to VAERS webpage; I attempted to fax several times but it came back unsuccessful; I left a message for a representative to return my call and nobody called back. I want to make sure you get this information, hence this second report. Additional Follow-up Information: Hospital Emergency Room visit on April 8, 2021: purple finger, racing heart, chest pain. EKG, body scan for blood clots, and blood panel. Doctor video visit on April 16, 2021: chest pain, feeling horrible, shortness of breath, metallic taste in the mouth, tinnitus, insomnia, anxiety, and depression. Doctor office visit on April 29, 2021: headache, dizziness, fatigue, brain fog, stress, depression, thirsty, pressure at temples and back of head and forehead, rocking, anxiety.
1300701	5/9/2021	CA	62	F	4/9/2021	4/10/2021	Headache for over 4 weeks and developed blood clot in each lung.

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1299176	5/8/2021	TN	64	F	4/5/2021	4/1/2021	feeling so bad; couldn't hold anything down/Vomiting that wouldn't stop/vomiting; Diarrhea; Nauseous; It was just bile coming up; Headache; Was passing clots/were clots/in the vaginal area; Was passing clots/were clots/in the vaginal area/vaginal bleeding; Being dehydrated; couldn't hold her own weight up; stomach pain; So sick; White blood cell count and kidney and liver function were all elevated; White blood cell count and kidney and liver function were all elevated; White blood cell count and kidney and liver function were all elevated; A sharp pain in her side; Stools were dark tarry stringy stuff; Stools were dark tarry stringy stuff; Passing blood in her urine; allergic internal reaction; Weighing 130 pounds but lost about 4 pounds during this illness, so 4 pounds lighter; This is a spontaneous report from a contactable consumer (patient herself). A 64-year-old female patient received BNT162B2 (PFIZER BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, at age 64 years, administered in left arm on 05Apr2021 10:30 (Batch/Lot Number: ER8734) as single dose, for COVID-19 immunization, in order to go back to normal, without a mask so she was told she had to have one. Medical history included hysterectomy, anxiety, disorder in thyroid and cholesterol. Patient had family history of dementia, had to stay home and take care of her mom who is a heart patient and has dementia. Patient had no history of previous immunizations. Patient's concomitant medication includes unspecified medications one is for thyroid, one is for cholesterol and the other 2 are for anxiety. Patient had no prior vaccinations within 4 weeks. No additional vaccines administered on the same date. Patient's symptoms started with a headache the morning after the shot (05Apr2021), was on and off for a couple of days, lasted 3 days or so for a couple days and she took paracetamol (TYLENOL). On 09Apr2021, Friday morning, patient woke up so nauseous she couldn't hold anything down. It was just bile coming up, and she had severe diarrhea and so sick vomiting that wouldn't stop, stomach pain, couldn't hold her own weight up. She got medication at a walk in clinic and that didn't stop it. She started out at acute/urgent care, where she was taken by her daughter on Sunday, 11Apr2021, because she was feeling so bad and was tested for COVID and they said if it does not get better to go to the Emergency Room and

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she continued having problems. It was not COVID. They said she was dehydrated and send her home to push fluids and drink Pedialyte. Monday or Tuesday (Apr2021) she was in the ER all night (she does not remember the day because all of her days are mixed up). They did CAT scans on her abdomen and ran blood work. They didn't see anything in her abdomen. Her white blood cell count and kidney and liver function were all elevated and they said it was from being dehydrated from diarrhea and vomiting. They gave her fluids and sent her home. Within another 48 hours she still had vomiting and diarrhea, it was a clear bile and a sharp pain in her side. Her stools were dark tarry stringy stuff so she went back to the ER and waited in the lobby for 9 hours. In that 9 hours as she was waiting, she felt like she had to go to the bathroom. She was then wheeled into the bathroom and started passing blood. It wasn't coming from the urethra. It must have come form the vagina, she doesn't have a uterus. There were clots. She started passing blood in her urine but most was in the vaginal area but she has already had a hysterectomy. She was passing clots and her doctor who works in the healthcare field looked at it and said they were clots. Very shortly after, she passed the clot and the pain went away. The pain was passing clots/were clots/in the vaginal area at one point went away but she still have nausea and diarrhea and they gave her more fluids and sent her home. They didn't really want to address the vaginal bleeding. Patient have not been back and was not sure if she is still dehydrated. Patient was still pushing fluids and still not back to normal. Patient's daughter told her that since it was 5 days later it was not a reaction. Patient was thinking maybe it was an allergic internal severe reaction. Patient was weighing 130 pounds but lost about 4 pounds during this illness, so 4 pounds lighter. She stated her daughter-in-law was doing research and found a blog and there are woman the caller's age complaining of these symptoms (unexplained bleeding) after the vaccine. She asked if this was from the vaccine. She stated she was so sick that if there is even a chance then she doesn't want the second dose. She asked if this is a coincidence or has it been reported. She stated she is trying to make a decision on if she should get the second dose because she heard other people have symptoms and take the second shot. The outcome of the events passing

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1299361	5/8/2021	MI	29	F	4/30/2021	5/2/2021	<p>clots/were clots/in the vaginal area, headache, a sharp pain in her side, passing blood in her urine, passing clots/were clots/in the vaginal area/vaginal bleeding was recovered on Apr2021, while for the other events, it was unknown.</p> <p>Blood clot on the cerebellum that caused a stroke; Blood clot on the cerebellum that caused a stroke; This is a spontaneous report from a contactable consumer (patient). A 29-year-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: EW0167), first dose via an unspecified route of administration, administered in Arm Left on 30Apr2021 11:30 (at 29 years old,(not pregnant), single dose for covid-19 immunisation. The patient's medical history was not reported. The patient's concomitant medication included an unspecified vitamin. The patient previously took ibuprofen and experienced Ibuprofen drug allergy. On 02May2021 08:30, patient experienced a Blood clot on the cerebellum that caused a stroke. The outcome of the events was recovering. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The adverse event resulted in visit to Emergency room/department or urgent care. Treatment received for the adverse event was Blood clot meds. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19 (02May2021), negative for swab test. Events caused 3 days of hospitalization. Information on Lot/Batch number was available. Additional information has been requested.</p>

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1299356	5/8/2021	KY	40	F	1/15/2021	2/22/2021	<p>blood clots in left lung which turned into an infarction; blood clots in left lung which turned into an infarction; This is a spontaneous report from a contactable other healthcare professional (patient). A 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot number: EL3248) via an unspecified route of administration, administered on the left arm on 15Jan2021 (at the age of 40-year-old) at a single dose for COVID-19 immunisation. Medical history included lupus. Concomitant medication included hydroxychloroquine sulfate (PLAQUENIL [HYDROXYCHLOROQUINE SULFATE]). The patient had blood clots in left lung which turned into an infarction on 22Feb2021. The event resulted in a doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). The patient was hospitalized for the events for 3 days. Therapeutic measures were taken as a result of the events which included blood thinners and anti-inflammatory meds. COVID test post vaccination on 03Mar2021 Nasal Swab: Negative. Patient was not pregnant. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Outcome of the events was recovering.; Sender's Comments: Drug causality would seem unlikely for BNT162B2 since there is no plausible mechanism implicating the subject drug to the events. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>

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1299351	5/8/2021			F			My wife is having side effects that have to do with the formation of blood clots in the reproductive system.; This is a spontaneous report from a contactable consumer (consumer's wife). A female patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Formulation: solution for injection, Batch/Lot Number and Expiration Date were not reported), via an unspecified route of administration on an unspecified date as single dose for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The reporter has been reporting on COVID. His wife and he has been vaccinated. His wife was having side effects that have to do with the formation of blood clots in the reproductive system. Consulted in different forums in two countries there are many women reporting the same. The outcome of event was unknown on an unspecified date. Information on lot/batch number has been requested.



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1299345	5/8/2021	NV	71	M	2/28/2021	4/7/2021	cerebral hemorrhage; Multiple pulmonary embolism in both lung; He merely died twice; he was still tired; This is a spontaneous report from a contactable consumer (patient's wife). A 72-year-old male patient (patient's husband) received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: EN6203), via an unspecified route of administration on 28Feb2021 (at the age of 71-year-old) as a single dose for COVID-19 immunization. The patient's medical history included liver replacement from 29Nov (unspecified year), cold, sore shot. When probed for medical condition, reporter stated no, she could remember that he had a cold when he get the sore shot every year and get pneumonia vaccine. He had liver replacement on 29Nov (unspecified year), no side effects or anything, no blood clot. He walks every day. No diabetic no any other complicated factor. Concomitant medications were not reported. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: EL3249) on 07Feb2021 (at the age of 71-year-old) as a single dose for COVID-19 immunization and Pneumonia vaccine. It was reported that, reporter stated, she don't know how she just brief, but she would give the best she could. Reporter's husband has the Pfizer vaccine on 07Feb2021 and for the second does on 28Feb2021. He was 73-year-old now with no complicated factor, no history, and no adverse reaction anything like no allergy. Everything was fine, and on 07Apr2021 approximately five and half week after the second dose. He had to go to the emergency room as he could not breathe and he was diagnosed with multiple pulmonary embolism in both lung on 07Apr2021, no precipitating of event, no logical explanation that the doctors could tell, they put him on Eliquis to recover up the blood clots, 19 days later 26Apr2021 he was back in to ER. He was severe headache, nausea, vomiting. Side effects of the blood thinner. He was diagnosed with cerebral hemorrhage on 26Apr2021. We flight to hospital because we live in a small town no neuro surgeon available to get immediate surgery. The doctor told he was calm down, but they took him off from blood thinners and she don't know what she expect more blood clot, what going next, he feels fine, he still had some headache which doctor said it would leave

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the month because of the blood in the brain. There was no after explaining and no logical explanation what have happen other than the blood thinner, he could take blood thinner. She don't know why the clots come back, that's why she want to report this because this all way comes on with the Pfizer. He was fine with the other vaccine that have five weeks after later. When probed any question regarding side effects, reporter stated, well she just kind a need to know, what to expect. If this going to be ongoing thing with in and out of ER. What to expect, we don't know. Doctor was following up. He has Hematology appointment on Wednesday to try to figure out the consequences. Reporter stated, she was on hold for 40 minutes and she could not even report this as a serious possible adverse reaction of the vaccine and to the drug. He merely died twice. When probed was patient still experiencing the side effects, reporter stated, well he was still tired. He still have the headache it's not severe. He went to the emergency room. We are watching him on helping here to follow up. He was taking medication of anti-seizure Keppra because body has strains body so that's making him tired. The outcome of the events was unknown. Information on Lot/Batch number was available. Additional information has been requested.

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1299332	5/8/2021	TX	57	M	3/29/2021	4/27/2021	Heart Attack due to blood clot in RCA. Occurred on 4/27/2021 at 11 pm; Heart Attack due to blood clot in RCA. Occurred on 4/27/2021 at 11 pm; This is a spontaneous report from a contactable consumer. A 57-year-old male patient received first dose of BNT162B2 (BNT162B2) via an unspecified route of administration, administered in Arm Right on 29Mar2021 03:00 (Batch/Lot Number: ER8733) as SINGLE DOSE for covid-19 immunization. The patient's medical history was not reported. Concomitant medications included pitavastatin calcium taken for an unspecified indication, start and stop date were not reported. The patient experienced heart attack due to blood clot in rca. occurred on 27Apr2021 at 11 pm. The patient was hospitalized for the reported events and was Life threatening (immediate risk of death from the event). The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 27Apr2021 Nasal Swab. Therapeutic measures were taken as a result of the events which includes Emergency Heart Cath and Stent. The outcome of the events was recovered with sequel. No follow-up attempts are needed. No further information is expected.
1299293	5/8/2021	UT		U	4/5/2021	4/1/2021	bloodclots in my leg and lungs; bloodclots in my leg and lungs; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: unknown), single dose, dose 2 via an unspecified route of administration on 05Apr2021 for COVID-19 immunization. The patient's medical history was not reported. The patient's concomitant medications were not reported. The patient experienced blood clots in the leg and lungs in Apr2021 within days of receiving the second dose. The clinical outcome of blood clots in the leg and lungs were unknown. Information on the lot/batch number has been requested.

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1299281	5/8/2021	PA	54	U	4/15/2021		<p>bad pain in the leg, near the calf/ confirmed the patient had blood clot in the leg; hurting in the arm; chills; This is a spontaneous report from a contactable consumer (patient). A 54-year-old patient of an unspecified gender received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration, administered in the right arm on 15Apr2021 (batch/lot number and expiration date were unknown) as a single dose for COVID-19 immunization. The patient had no medical history. The patient was taking other unspecified medications. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 19Mar2021 at the age of 54 years old for COVID-19 immunization. The patient reported having the normal side effect like the hurting in the arm, chills, and stuff on an unspecified date, but after that the patient got a really bad pain in the leg, near the calf and left it go for a week maybe, thinking it would go away, but didn't go away, so the patient went in to the emergency room and the emergency room work on it. That's what they did something to come up wrong with one of the blood test, so then they did an ultrasound and they confirmed the patient had blood clot in the leg, for which the patient was currently on a blood thinner. The patient didn't know if this was going to fix the problem or this was not going to fix the problem. The patient knew that some of the other vaccine caused blood clots, but the patient's doctor won't give any kind of pain medicine, and all they do was to give paracetamol (TYLENOL). They did start the patient on a pill called apixaban (ELIQUIS) taken at 25 mg tablet in the morning and 25 mg in the evening, and this was the thing the patient had never had; anything like this had never happened with the patient before, since the patient had been healthy in all his/her life, so the patient called to ask if there would be any relief as the patient didn't want this. Before the patient went into the emergency room, the patient had taken TYLENOL as treatment for all the events. The patient underwent lab tests and procedures on an unspecified date, which included blood test and chest x-ray with unknown results and an ultrasound, which revealed blood clot in the leg. The outcome of the events was unknown. Information on the batch/lot number has been requested.</p>

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1299254	5/8/2021	WV	56	F	2/12/2021	3/29/2021	<p> bilateral pulmonary blood clots; This is a spontaneous report from a contactable consumer (patient). A 56-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EN6201, expiration date not reported) via an unspecified route of administration, administered in the right arm on 12Feb2021 as single dose for COVID-19 immunisation. Medical history included ongoing diabetes mellitus diagnosed 1.5-2 years ago, ongoing neuropathy peripheral diagnosed about two years ago, and ongoing glaucoma diagnosed about 9 months ago. Concomitant medications included metformin for diabetes mellitus; rosuvastatin calcium (CRESTOR) for neuropathy peripheral; dorzolamide for glaucoma; latanoprost for glaucoma; all ongoing. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot Number: EL9261) administered on 21Jan2021 (at the age of 56 years old) for Covid-19 Immunization. No other vaccine was given within four weeks prior to the first administration date of the suspect vaccine. The patient experienced bilateral pulmonary blood clots on 29Mar2021 and will have to be on apixaban (ELIQUIS) for the rest of her life. She stated that she was fine before the shot and stated that it was not that long between the second dose and diagnosis. The patient was hospitalized for bilateral pulmonary blood clots from 29Mar2021 to 31Mar2021. The event required a visit to the emergency room. The outcome of the event was recovered with sequelae on an unspecified date. </p>

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1299252	5/8/2021	WI	85	F	4/10/2021		<p>blood clot it is from my hip all the way down to my left leg to my ankle; blood clot but it is the big one from my hip all the way down to my foot; foot going down the swelling went up to my leg/foot and my leg is swelled my toes all over up to my leg swelled; This is a spontaneous report from a contactable consumer (patient). An 85-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; Batch/Lot Number: EW0162), via an unspecified route of administration, administered in left upper arm on 10Apr2021 at the age of 85-years-old as single dose for COVID-19 immunization. The patient's medical history included ongoing arthritis and ongoing chronic obstructive pulmonary disease (COPD). The patient reported that she was not taking anything for arthritis, just some Tylenol once in a while over the counter (it was not prescription). The patient was taking an inhaler for COPD. The patient was taking unspecified concomitant medications. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; Batch/Lot Number: ER2613), administered in left upper arm on 20Mar2021 at the age of 85-years-old for COVID-19 immunization and experienced bladder infection and viral infection. The patient got the first Pfizer vaccine on 20Mar2021 and was alright for a few days afterwards. Then all of a sudden, she started getting infections on 28Mar2021, 8 days after she had the first vaccine. She got a real bad bladder infection then she went to the doctor and she got medication for that. She was with bladder infection then she came down with the viral infection. The patient reported that she has not even been going anywhere because of the virus and she has been staying home. She just goes to the grocery store and clinic to the doctor, that was it. The patient had an antibiotic for the bladder infection. Sulfamethoxazole was the name of the medication that was for bladder infection. They didn't give the medication for the viral infection. The patient reported that it was just a viral infection, it was not the Covid. Since then, she had her second dose of the vaccine on 10Apr2021 and from an unspecified date in 2021, her foot started, her foot swelled up and she didn't know. She takes lot of retention pills, so she thought maybe it was that. So she took her pills and everything and washed and start getting but the next day instead of the foot</p>

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							going down, the swelling went up to her leg and then the next day it went all away up to her hip. The swelling on the left side from the foot all away up to the hip. She went to urgent care on 21Apr2021 (reported as "21st") and saw a doctor and she was tested and she had blood clots. Regarding lab test, the patient reported she had two infections and then she got the blood clot that was from her hip all the way down to her left leg to her ankle. She could not figure out that they called the test and what they tested. But they had a lab work done then one has a test, veins, and everything. She can't remember. The patient reported that her foot and her leg was swelled, her toes all over up to her leg swelled. She had a fat foot and a fat leg just one side. She would say since she has started taking medicines for that, she took the first dose at the evening of 21st (21Apr2021), the day she went to the urgent care, and she would say it was not any worse. The medication was supposed to break up the blood clot, but it was the big one from her hip all the way down to her foot. Just a little bit better. The outcome of the events was recovering.
1299242	5/8/2021	CA		F	2/17/2021	2/20/2021	This is a spontaneous report from a contactable consumer(Patient). A 83-years-old non pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection Formulation, Batch/Lot Number: EN6200), via an unspecified route of administration on Arm left on 17Feb2021 10:00 AM as single dose for covid-19 immunisation. Medical history included colitis ulcerative. Concomitant medications included mesalamine (MESALAMINE). Patient had no past drug history. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. post Covid vaccine patient did not test for Covid. The Device Date given was 25Apr2021. The patient received treatment for raised blood thinner as Elequis 5mg. On 20Feb2021 at 10:00 (Three days after injection), the patient suffered severe pain in the right leg. She went to ER next day and blood clot was discovered behind right knee and later she subsequently had been seen by hematologist. The outcome of the events was not recovered. Follow-up attempts are required. Further information was expected.

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1299222	5/8/2021	KY	83	F	2/3/2021	2/15/2021	<p>This is a spontaneous report from a contactable consumer (patient). An 83-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 03Feb2021 (Batch/Lot number was not reported) as a single dose (at the age of 83-years old) for COVID-19 immunisation. Medical history included the patient had known allergies (unspecified) and unspecified chronic health conditions from an unknown date. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient was not pregnant. The patient received unspecified concomitant medications. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 15Feb2021 at 13:00 the patient experienced getting out of breath, three blood clots/clots were in my leg heart and lung, and cough. The events resulted in emergency room visit and the patient was hospitalized (from an unknown date) for the events getting out of breath, three blood clots/clots were in my leg heart and lung, and cough for 6 days. The clinical course is as follows: 2 or 3 weeks after the patient got the vaccine she started getting out of breath when she walked. Each day she got worse. Then the patient was taken to the hospital where they discovered the patient had three blood clots. The clots were in the patient's leg, heart and lung. The patient stated the Doctors do not understand where the clots came from. The patient was in the hospital 6 days. The patient stated they are still having breathing problem and still on oxygen as needed and they still cough at night. The patient asked if there have been any other reports of this happening to other people who got the vaccine as the patient never had blood clots before this. The patient underwent lab tests and procedures which included COVID test (nasal swab): negative on 15Mar2021. Therapeutic measures were taken as a result of getting out of breath, three blood clots/clots were in my leg heart and lung, and cough and included blood thinners and oxygen therapy and complete bed rest. The clinical outcome of the events getting out of breath, three blood clots/clots were in my leg heart and lung, and cough was not recovered. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.</p>



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1299197	5/8/2021	MO	51	M	4/14/2021	4/16/2021	I had an ultrasound done on my leg where a blood clot was found. I had a chest CT performed where several clots were found; Two days after my vaccine I began having severe pain in my right leg in the calf area and pain in my chest when I took a deep breath or coughed. Over the weekend it got worse and worse, on Tuesday th; Pain in my chest; This is a spontaneous report from a contactable consumer (patient). A 51-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration, administered in left arm on 14Apr2021 13:00 (Batch/Lot Number: Ew0153) (at the age of 51 years old) as single dose for COVID-19 immunization. The patient medical history was not reported. Concomitant medications included duloxetine; trazodone; pregabalin (LYRICA); oxycodone hydrochloride, oxycodone terephthalate, paracetamol (PERCOCET [OXYCODONE HYDROCHLORIDE;OXYCODONE TEREPHTHALATE;PARACETAMOL]); and meloxicam, all taken for an unspecified indication, start and stop date were not reported. The patient previously took vancomycin and daptomycin and experienced drug allergy to these medications. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 16Apr2021 09:00, two days after the vaccine, the patient began having severe pain in his right leg in the calf area and pain in his chest when he took a deep breath or coughed. Over the weekend, it got worse and worse, on Tuesday 20Apr2021, the patient had an ultrasound done on his leg where a blood clot was found. He had a chest computerized tomography (CT) performed where several clots were found. The event resulted in doctor or other healthcare professional office/clinic visit. The treatment included blood thinners. No COVID prior vaccination and not COVID tested post vaccination. The case was assessed as non-serious by the reporter. The outcome of the event was not recovered.

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1299856	5/8/2021	MN	37	F	1/11/2021	1/12/2021	Calf pain started 1/12/21, worsening over the next 6 days. Diagnosed with deep vein thrombosis (DVT) in left popliteal and left soleal vein on 1/18/21. Put on Apixaban for treatment for 6 months. Repeat ultrasound on 4/17/21 showed resolution of popliteal DVT (scar tissue in soleal vein remains). Will remain on Apixaban until July 18 and then assess long-term risk (low dose long-term prevention versus going off medicine).

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1299184	5/8/2021	NY	67	M	3/30/2021	3/1/2021	Right knee swelled and felt like it dislocated; Right knee swelled and felt like it dislocated; Pain in groin; Felt like a muscle cramp; Blood clot as well as fluid on that knee/blood clot right leg; Muscle tear; the pain went to his knee; Pain in the arm opposite that he received the injection; his other leg "got messed up"; Blood clot as well as fluid on that knee; Knee was stiff as a board; He could not walk on either of his knees for a couple of days; Inflammation in the calf; His leg was stiff; This is a spontaneous report from a contactable consumer (patient). A 67-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: ER8730), via an unspecified route of administration, administered in left arm on 30Mar2021 10:45 as single dose for COVID-19 immunization. Medical history included knee surgery, dislocated shoulder (he has dislocated that shoulder in the past several times but had no recent issues), carpal tunnel syndrome and, rheumatoid arthritis, all from an unknown date and unknown if ongoing. There were no concomitant medications. In Mar2021, the patient experienced pain in the arm opposite where he received the injection. He reported he like had a muscle tear that it has an intense excruciating pain. He took three aspirin and put a heating pad on it that didn't touch it. He then reported that the pain went to his knee and it "got all blow up" and stated that that knee had to be drained. He then stated that the calf on his other leg "got messed up" and was found to have a blood clot as well as fluid on that knee. He reported that it was as stiff as a board and that he could not walk on either of his knees for a couple of days. He reported that he still has problems with the one knee that "blew up" and had to be drained but stated that the inflammation in the calf where blood clot was has receded and is back to normal. He stated that he had to visit the emergency room twice and see an orthopedic surgeon for these issues and has been prescribed Xarelto to take to treat the blood clot. In the morning his leg was stiff. It was also reported that the patient's right knee swelled and felt like it dislocated on 16Apr2021, blood clot on right leg on 12Apr2021, and pain in groin on 13Apr2021. The pain in his groin went down, but his calf swelled to twice the size and it felt like a horse because he was favoring it. It felt like a muscle cramp. The orthopedic saw him for his left knee and he was seen in

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1299807	5/8/2021	IA	32	F	4/28/2021	5/1/2021	the Emergency Room for his right and they called his primary doctor. He tried to work and paid the price with his left knee. He has been taking Tylenol and icing it. The last two days (unspecified date) he has been babying it, the weather has been not so great, so he is laying low and give it a rest, but knows he is supposed to get up and move around so he has been doing that and elevating it. He would like to know if, based on these symptoms he experienced after the vaccine, he should get the second dose of the vaccine, which he states he is supposed to get on Tuesday. The outcome of the events "Right knee swelled and felt like it dislocated", and "Pain in groin" was recovering, and for other events was unknown.
							2 days of headache, encephaloapthy, L arm weakness + paresthesia. CT head found Cerebral venous sinus thrombosis with intraparenchymal hemorrhage transformation and developed seizures. currently on therapeutic heparin drip, lacosamide, and keppra

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1299152	5/8/2021	MD	30	F	4/15/2021	4/21/2021	<p>period is extremely heavier than it's ever been, I have large blood clots; period is extremely heavier than it's ever been, I have large blood clots; cramping; irritability; premenstrual symptoms like cramping and irritability were the worst they've ever been; This is a spontaneous report from a contactable consumer, reporting for herself. A 30-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration, administered in the right arm on 15Apr2021 (Batch/Lot Number: Er8729) as a single dose (at the age of 30 years old) for covid-19 immunization. The patient medical history was not reported. Concomitant medication(s) included ethinylestradiol, levonorgestrel (SEASONIQUE) taken for an unspecified indication, start and stop date were not reported; spironolactone taken for an unspecified indication, start and stop date were not reported; magnesium taken for an unspecified indication, start and stop date were not reported; polycarbophil calcium (FIBER) taken for an unspecified indication, start and stop date were not reported, and an unspecified multivitamin taken for an unspecified indication, start and stop date were not reported. Historical vaccine information included BNT162B2, dose 1 via an unspecified route of administration, administered in the right arm on 25Mar2021 at 12pm (Batch/Lot Number: Er8730) as a single dose (at the age of 29 years old) for covid-19 immunization. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient experienced period is extremely heavier than it's ever been, she has large blood clots on 21Apr2021 at 08:00 with outcome of not recovered, cramping on 21Apr2021 at 08:00 with outcome of not recovered, irritability on 21Apr2021 at 08:00 with outcome of not recovered, and premenstrual symptoms like cramping and irritability were the worst they've ever been on 21Apr2021 at 08:00 with outcome of not recovered. The patient underwent lab tests and procedures which included sars-cov-2 test (nasal swab): negative on 31Mar2021. Treatment was not received for the events.</p>

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1299150	5/8/2021		46	M	3/31/2021	4/1/2021	He completely lost mobility on the left side of his body; Stroke; They found they clot, but could not extract it from what he understood; This is a spontaneous report from a contactable consumer. A 46-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on 31Mar2021 (Batch/Lot number was not reported) as single dose (at the age of 46 years old) for COVID-19 immunisation. The patient has no medical history. Concomitant medications included aspirin [acetylsalicylic acid] (ASPIRIN [ACETYLSALICYLIC ACID]) taken for an unspecified indication, start and stop date were not reported. Since his stroke, he is doing better. He completely lost mobility on the left side of his body. His mobility on the left side of his body is slowly coming back. His job is in jeopardy. The doctors told him that there is no guarantee that he will regain full mobility. They did not give him a patient record card. If they did give him one, he left it at the house. He has been in the hospital ever since his stroke. They put him on blood thinners after his stroke. Whenever he was in the ambulance, he did not have high blood pressure. They were able to catch his stroke quick. They found they clot, but could not extract it from what he understood. Adverse events required Emergency Room. The patient was hospitalized on 01Apr2021. The outcome of clot was unknown and other events was recovering. Information on the lot/batch number has been requested.

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1299140	5/8/2021		57	M	3/25/2021	4/8/2021	DVT and PE, 2 weeks after first vaccine; DVT and PE, 2 weeks after first vaccine; This is a spontaneous report from a contactable physician. A 57-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 25Mar2021 (Batch/Lot number was not reported) at the age of 57-years-old as single dose for covid-19 immunisation. Medical history included hypertension and hypothyroidism from an unknown date and unknown if ongoing. Concomitant medications included lisinopril; levothyroxine; amlodipine all taken for an unspecified indication, start and stop date were not reported. The patient experienced DVT (deep vein thrombosis) and PE (pulmonary embolism), 2 weeks after first vaccine on 08Apr2021. The patient was hospitalized due to the events for 1 day. Therapeutic measures were taken as a result of the events. The patient recovered from the events on an unspecified date in Apr2021. Information on lot/batch number has been requested.; Sender's Comments: Based on chronological connection to the vaccine a causal relationship between events DVT (deep vein thrombosis) and PE (pulmonary embolism) and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1299126	5/8/2021	WA	66	F	1/11/2021	1/12/2021	<p>deep vein thrombosis left leg/Vascular u/s showed clot from the ankle to the groin in left leg; This is a spontaneous report from a contactable nurse (patient). A 66-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 11Jan2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation, administered at the hospital. Medical history included prediabetes, relapsing polychondritis, obesity, intolerant to gluten and cow's milk protein, and penicillin allergy. The patient is not pregnant at the time of report and vaccination. The patient had no COVID prior vaccination and was not tested for COVID post vaccination. Concomitant medications included fish oil; ergocalciferol (VIT D); methylfolate; metformin; and desvenlafaxine succinate (PRISTIQ). On 12Jan2021 at 19:00, the patient's left ankle swelled double normal size. On 13Jan2021, left leg swelled. On 14Jan2021, patient knew it was a deep vein thrombosis left leg based on pain and swelling and past experience but waited till her day off on 15Jan2021 to seek medical care. Vascular u/s (ultrasound) on 15Jan2021 showed clot from the ankle to the groin in left leg. Sent to emergency department and started on Zarelto x 6 months for long term anticoagulation. The event resulted in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The patient received the second dose on 01Feb2021 at 16:45. Outcome of the event was recovering. Information on the lot/batch number has been requested.; Sender's Comments: Based on known drug safety profile, there is reasonable possibility of causal association between the event deep vein thrombosis and the suspect drug. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Committees, and Investigators, as appropriate.</p>



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1299104	5/8/2021	MI	46	F	4/19/2021	4/20/2021	Two large hot swollen areas on right leg Went to ER ultrasound detected superficial clot; This is a spontaneous report from a contactable consumer (patient). This 46-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in arm right on 19Apr2021 12:15 (Batch/Lot Number: EWO164) as a single dose for COVID-19 immunization. The patient's medical history was not reported. Patient is not pregnant at the time of vaccination. Concomitant medications included fluticasone propionate (FLONASE), fexofenadine hydrochloride (ALLEGRA), and ibuprofen. The patient previously took tobramycin and Wellbutrin and experienced allergies for both. Patient received the first dose of bnt162b2 for COVID-19 immunization on an unspecified date (lot number unknown). Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. Patient has not been tested for COVID-19 since the vaccination. On 20Apr2021 18:30, patient had two large hot swollen areas on right leg. She went to the ER. Ultrasound detected superficial clot. AE resulted in emergency room/department or urgent care. Patient has not recovered from the event. Treatment included antibiotics and ibuprofen.

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1299103	5/8/2021	NJ		U	4/2/2021	4/10/2021	Blood clot in the calf; Swelling/pain behind the knee; Swelling/pain behind the knee; A 62-years-old patient of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 02Apr2021 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. The patient's medical history was not reported. Concomitant medication included vitamin d3 (VITAMIN D3). The patient experienced blood clot in the calf and swelling/pain behind the knee on 10Apr2021. The events resulted in emergency room visit. The patient underwent lab tests and procedures which included nasal swab: negative on 17Apr2021. Therapeutic measures were taken as a result of thrombosis, joint swelling and arthralgia included anticoagulation medication. The patient did not have COVID prior vaccination. Outcome of the event was recovering. Information on the lot/batch number has been requested.
1299100	5/8/2021	NC	71	M	4/18/2021	4/19/2021	Bright red blood and blood clots in urine on 4 consecutive days; Bright red blood and blood clots in urine on 4 consecutive days; This is a spontaneous report from a contactable nurse (patient). A 71-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 71 years of age), dose 2 via an unspecified route of administration, administered in arm left on 18Apr2021 10:30 (Batch/Lot Number: ER8733) as a single dose for COVID-19 immunisation. Medical history included hypertension and penicilline allergy, both from an unknown date and unknown if ongoing. Concomitant medication included bisoprolol taken for an unspecified indication, start and stop date were not reported. Historical vaccine included BNT162B2, dose 1 via an unspecified route of administration, administered in arm left on 22Mar2021 14:30 (Batch/Lot Number: ER8737) (at 70 years of age) for COVID-19 immunisation. The patient had no other vaccine in four weeks prior to covid vaccine. He had no covid prior vaccination. He had not been tested for covid post vaccination. It was reported that the patient experienced bright red blood and blood clots in urine on 4 consecutive days. The events started on 19Apr2021 10:30 AM with outcome of not recovered. The patient had not received any treatment for the events.

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1299097	5/8/2021			M			<p>blood clot; This is a spontaneous report received from a contactable pharmacist from a Pfizer-sponsored program. A 70-year-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The pharmacist was asking if there have been any reports of blood clots associated with the COVID-19 vaccine as the patient developed blood clot 1.5 weeks after receiving his first Pfizer COVID vaccine on an unspecified date. The outcome of the event was unknown. Information about batch/lot number has been requested.; Sender's Comments: Based on the information currently available, a possible contributory role of the suspect vaccine BNT162B2 or comirnaty in triggering the onset of Blood clots cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>

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1299083	5/8/2021	VA	36	M	4/21/2021	4/22/2021	blood drops in my urine and possibly passed a blood clot.; blood drops in my urine; When I woke up to use the bathroom, I noticed some blood coming out of my penis.; This is a spontaneous report from a contactable consumer. A 36-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in Arm Left on 21Apr2021 13:45 (at the age of 36-years-old) (Batch/Lot Number: ER8735) as SINGLE DOSE for covid-19 immunisation. The patient's medical history was not reported. The patient received first dose of BNT162B2 for COVID-19 immunization on 31Mar2021 (Product=COVID-19, Brand=Pfizer, Lot number=ER8734, Lot unknown=False, Vaccine location=Left arm, Administration date=31Mar2021, Administration time=14:00 PM, Dose number=1). Concomitant medications included ibuprofen (ADVIL [IBUPROFEN]); cetirizine hydrochloride (ZYRTECNO). On 22Apr2021 06:30, When the patient woke up to use the bathroom, he noticed some blood coming out of his penis. At 06:45, it was reported, The morning after his second dose, he had blood drops in his urine and possibly passed a blood clot. The outcome of the events was unknown. The event "blood drops in my urine and possibly passed a blood clot" and "When I woke up to use the bathroom, I noticed some blood coming out of my penis" was assessed as serious (medically significant).

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1298817	5/8/2021	MA		F	4/14/2021		LEFT ARM NUMBNESS; LEG CRAMPING; NUMBNESS UNDER LEFT EYE; NAUSEA; CHEST PRESSURE; SEVERE HEADACHES; This spontaneous report received from a parent concerned a 43 year old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) frequency 1 total, dose not reported, on approximately 08-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. The patient was not pregnant at the time of report. Patient had the Janssen Covid-19 vaccine on approximately 08-APR-2021 and started experiencing side effects on 14-APR-2021 (six days later) which included severe headaches, nausea, left arm numbness, cramping in one leg, and chest pressure. Patient went to Emergency room several times for these symptoms and was discharged each time. Patient also had numbness under left eye and was admitted to hospital on or about 16-APR-2021 or 17-APR-2021 to rule out blood clot on MRI and was diagnosed with arachnoid granulation and released on 20-APR-2021. Patient was hospitalized for approximately 3-4 days. Patient then started with chest pressure, slight headache and leg cramping and went to Emergency room on evening of 02-MAY-2021. On an unspecified date in APR-2021, Laboratory data included: MRI(Magnetic resonance imaging) (NR: not provided) arachnoid granulation. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the chest pressure, severe headaches, left arm numbness, leg cramping, numbness under left eye and nausea was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0-20210504059- Covid-19 vaccine ad26.cov2.s- left arm numbness, leg cramping, numbness under left eye. These events are considered unassessable. The events have a compatible/suggestive temporal relationship, are unlabeled, and have unknown scientific plausibility. There is no information on any other factors potentially associated with the event. 20210504059-covid-19 vaccine ad26.cov2.s –nausea. This event is labeled per RSI and is therefore considered potentially related.

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1298761	5/8/2021	CO	70	F	1/13/2021	1/14/2021	<p>Amnesia; Cardiac disorder; Thrombosis; Transient ischaemic attack; This case was received via another Manufacturer (Reference number: vsafe) on 27-Apr-2021 and was forwarded to Moderna on 27-Apr-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of AMNESIA (Amnesia), CARDIAC DISORDER (Cardiac disorder), THROMBOSIS (Thrombosis) and TRANSIENT ISCHAEMIC ATTACK (Transient ischaemic attack) in a 70-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 027L20A) for COVID-19 vaccination. The patient's past medical history included Glaucoma and Hypothyroidism. Concurrent medical conditions included Stroke. Concomitant products included LEVOTHYROXINE, BRIMONIDINE, LATANOPROST and TIMOLOL for an unknown indication. On 13-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 14-Jan-2021, the patient experienced AMNESIA (Amnesia) (seriousness criterion hospitalization), CARDIAC DISORDER (Cardiac disorder) (seriousness criterion hospitalization), THROMBOSIS (Thrombosis) (seriousness criteria hospitalization and medically significant) and TRANSIENT ISCHAEMIC ATTACK (Transient ischaemic attack) (seriousness criteria hospitalization and medically significant). At the time of the report, AMNESIA (Amnesia), CARDIAC DISORDER (Cardiac disorder), THROMBOSIS (Thrombosis) and TRANSIENT ISCHAEMIC ATTACK (Transient ischaemic attack) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Jan-2021, Catheterisation cardiac: inconclusive. On 14-Jan-2021, Echocardiogram: inconclusive. On 14-Jan-2021, Magnetic resonance imaging: inconclusive. On 14-Jan-2021, Ultrasound scan: inconclusive. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The next day, the patient had short term memory loss, patient went to the hospital, and they said patient had some type of heart episode. The patient was taken by ambulance to the hospital and was told had a blood clot in brain and had suffered a mini stroke. The patient was hospitalized</p>

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							for 4 nights. The patient was given blood thinner and got improved. Company comment: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine, the onset of the reported events, a causal relationship cannot be excluded. However patient had an underlying risk in the past history of stroke.; Sender's Comments: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine, the onset of the reported events, a causal relationship cannot be excluded. However patient had an underlying risk in the past history of stroke.
1299195	5/8/2021	FL	55	F	4/1/2021	4/1/2021	Blood clot, inner right upper leg; Chills; stomach upset; nausea; headache; This is a spontaneous report from a contactable consumer (patient). A 55-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 01Apr2021 11:30 (Batch/Lot Number: Er8735) as single dose for covid-19 immunisation. Medical history included covid-19 prior to vaccination. The patient has no known allergies. The patient's concomitant medications were not reported. The patient has no other vaccine in four weeks. The patient experienced blood clot in inner right upper leg, chills, stomach upset, nausea, and headache on 01Apr2021 at 20:00. The events were not treated. The patient was not tested for covid post vaccination. The patient had the second dose on 22Apr2021 at 11:30 AM in the left arm (lot: Er8731). The outcome of the events was recovered with sequel. No follow-up attempts are possible. No further information is expected.
1299907	5/8/2021		32	F	4/23/2021	5/7/2021	cerebral venous sinus thrombosis causing tonic-clonic seizures

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1299919	5/8/2021	NV	67	F	5/5/2021	5/7/2021	67 yo female with PMH of HTN, DM who has two days of left sided numbness that has progressed to left hemiparesis and dysarthria in the setting of having received the Johnson and Johnson vaccine on Wednesday(48hours prior). Patient was found to have a right parietal multifocal parenchymal hemorrhage measuring 19x36x37mm and small right temporal lobe SAH. Subsequent CTA showed thrombosis of the superior sagittal sinus and the right frontoparietal cortical veins as well as nonocclusive thrombus of right transverse and sigmoid sinus. The patient was also noted to have focal seizure of mouth and tongue and was loaded with fosphenytoin. After discussing case with neurology, neuro IR, NSGY and family it was decided to transfer the patient to sunrise for close monitoring and consideration of cerebral venous sinus thrombectomy if she worsens. I had a long discussion with multiple sisters about the risks of anticoagulation with argatroban given the IPH but the necessity given the cerebral venous thrombosis. I also discussed that argatroban is not readily reversible and that heparin is contraindicated if there is concern about vaccine induced thrombotic thrombocytopenia due to possible PF4 ab related to HIT. The patients VITT modified 4T score is 4 and she is intermediate risk for this being VITT. #Right parietal IPH, right temporal SAH and Superior sagittal sinus thrombosis with nonocclusive thrombus of right transverse and sigmoid sinus -concern for vaccine induced thrombotic thrombocytopenia given johnson and johnson vaccine 2 days prior -modified VITT 4T score of 4- intermediate -send fibrinogen, d dimer, consider IVIG 1gm/kg per day for two days if high dimer, low fibrinogen and falling platelets -will start argatroban, avoid heparin until HIT ab (PF4) is resulted, if HIT positive avoid heparin -neuro IR consulted for possible IR intervention if worsens -transfer accepted by sunrise ICU, appreciate transfer for IR evaluation -continue fosphenytoin -SBP goal <150 with nicardipine and esmolol gtts -monitor daily fibrinogen, dimer, coags #AKI- monitoring uop and cr, consider renal US if worsens #DM- ISS #HTN- nicardipine and esmolol gtts for SBP <150, target 140 Patient seen, examined, labs and imaging reviewed, agree with resident note



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1300022	5/8/2021	OH	62	F	4/12/2021	4/21/2021	Patient admitted to hospital after 2-3 days of shortness of breath and calf pain, swelling in foot distal to calf with pain. Admission date 4/23, vaccinated with second moderna dose on 4/12 Two clots identified: right lower extremity DVT "Positive study for acute DVT in the right lower extremity, extending from the calf veins up through the right external iliac vein. Positive study for acute superficial thrombophlebitis involving the imaged lesser saphenous vein." and PE: "Acute pulmonary embolism involving the main pulmonary arteries (saddle pulmonary embolism) and extending to the lobar, segmental branches bilaterally with some extension of the subsegmental branches in the right lower lobe, overall worse in the right lower lobe with occlusive segmental branches. " Was initially started on lovenox when admitted, switched to Eliquis, no IVC filter was placed discharged in stable condition on 4/26, Of note: Patient had bone marrow biopsy of right iliac crest of April 15th 2021 - carries diagnosis of chronic lymphocytic leukemia but is currently in remission
1300025	5/8/2021	NY	33	M	4/2/2021	4/28/2021	I received the vaccine on 4/2/21. I started feeling tightness, soreness and throbbing pain in my right calf on 4/28/21. On 5/4/21 the pain was unbearable and there was swelling in my calf/ankle. On 5/5/21 I got an ultrasound that confirmed I have a DVT blood clot in my right calf and I got blood work done that confirmed everything was normal with my health (liver function, platelet counts...). I was prescribed Xarelto 15mg and began taking Xarelto on 5/8/21.
1300080	5/8/2021	IA	51	F	4/15/2021	4/27/2021	I felt sluggish after my second Moderna shot on April 15th. On the evening of April 27th, I really started to feel horrible and was scared as it was hard to breathe and my chest pains were just horrible. I head to ER and am told I have blood clots in both lungs and 2 blood clots in lower leg. Taken by ambulance to the hospital.
1300185	5/8/2021	NC	26	M	4/7/2021	4/26/2021	Blood clots in right arm and lungs. Swollen right arm.
1300430	5/8/2021	WA	46	F	4/19/2021	4/26/2021	Blood Clot in right shoulder VAS Upper Extremity Venous Right

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1299360	5/8/2021	IN	40	M	4/26/2021	4/28/2021	This is a spontaneous report from a contactable consumer (patient). A 40-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 26Apr2021 08:15 (Batch/Lot Number: EW0171) (at age 40 years old) as single dose for covid-19 immunisation. Medical history included high blood pressure, high cholesterol, carpal tunnel, absent vas deferens, all from unspecified dates. No COVID prior to vaccination. He underwent Covid test post vaccination (nasal swab) on 29Apr2021 with negative result. The patient's concomitant medications included unspecified prescribed and store-bought medications. No other vaccines in four weeks. On 28Apr2021 22:00, the patient experienced chest pains and shortness of breath testing of EKGs, echo, CT scan, and cardiac cath show- NSTEMI heart attack showing from damage to heart caused by blood clot. No problems with arteries or existing with heart. Also, lower lobe of left lung shows collapsed. The events resulted in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The events were considered serious: hospitalization (2 days), life threatening illness (immediate risk of death from the event), disability or permanent damage. Treatment included blood thinners- apixaban (ELIQUIS) and metoprolol. The patient was recovering from the events.
1299873	5/8/2021	IN	72	M	3/3/2021	4/13/2021	Right leg burning, red, swollen. Doppler showed XL blood clot and numerous small clots in right leg. Put in Eliquis for 2-3 wk. brought to hospital on 5.6.21 with worse swelling, red, and right foot very painful. CT showed clots in legs and in lungs. Still in hospital as of 5.8.21
1296332	5/7/2021	CA	55	F	2/6/2021	2/22/2021	Left transverse sinus venous thrombosis

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1294714	5/7/2021	TN		M		3/8/2021	Cerebral venous sinus thrombosis; This is a spontaneous report from a contactable consumer, the patient. This 69-year-old male patient the second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EN5318; Expiration Date: 31May2021), via an unspecified route of administration in the left arm on an unspecified date as single dose for COVID-19 immunization. The patient's medical history was not reported. There were no concomitant medications. The patient previously took the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: Unknown) via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunization. On 08Mar2021, the patient experienced cerebral venous sinus thrombosis and treated with PRADAXA. The patient underwent multiple "over 100" unspecified lab tests in the hospital with unknown results. The patient was hospitalized for cerebral venous sinus thrombosis from 26Mar2021 to 28Mar2021. The clinical outcome of cerebral venous sinus thrombosis was improved/resolving.

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1294713	5/7/2021	FL	52	F	4/13/2021		<p>24 hours later my neck started swelling up, my left lymph node; abnormal mass in my neck which was my lymph node; I developed a headache over the whole left side of my head; I could hardly move my neck; All of a sudden I kind of broke out in the sweat; Left side of my head just went totally numb; Started feeling tingling in my left hand; I went to eat some yoghurt and I could not swallow at all; Airway is being compromised by the swelling in my neck; I cannot walk my left leg is dragging, so I am lurking around having to hold on; My voice was like had to whisper; Right side of my body started shaking; Later that evening the numbness subsided. I could speak better my left lymph node was still sore; blood pressure went up; white blood cells count was really, really extremely high; This is a spontaneous report from a contactable consumer (patient). A 52-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 1 via an unspecified route of administration, administered in left arm on 13Apr2021 (Lot Number: EW0153), at the age of 52 years, as single dose for COVID-19 immunization. Medical history included covid-19 in Sep2020. Concomitant medication was not reported. The patient experienced 24 hours later, after vaccination, her neck started swelling up, her left lymph node; abnormal mass in her neck which was her lymph node, which required hospitalization. The patient she developed a headache over the whole left side of her head. She could hardly move her neck. All of a sudden she kind of broke out in the sweat, left side of her head just went totally numb. Started feeling tingling in her left hand. She went to eat some yoghurt and she could not swallow at all, airway was being compromised by the swelling in her neck. She cannot walk her left leg was dragging, so she was lurking around having to hold on. Her voice was like had to whisper. Right side of her body started shaking, Later that evening the numbness subsided. She could speak better, her left lymph node was still sore. Blood pressure went up, white blood cells count was really, really extremely high. The patient was hospitalized from 14Apr2021 to 16Apr2021. The clinical course was reported by the patient as follows: When probed for the reason of hospitalization, consumer stated, "The symptoms I had was, I got the vaccination in my left arm, 24 hours after getting the COVID vaccination shot on 13Apr2021, almost exactly 24 hours later my</p>

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neck started swelling up, my left lymph node, which I was expecting to have that problem. And I could hardly move my neck and then I developed a headache over the whole left side of my head and behind my eye and it was hurting and then it hurt my ear. So, I was having ear ache too. So, that went on for about an hour and a half and then all of a sudden I kind of broke out in the sweat and the left side of my head just went totally numb and then I started feeling tingling in my left hand and so I went to the bathroom to see if my face was numb, to see if I had any paralysis of my face which I did not have any at all, it was just numb. So, then I am concerned, so I decide I am going to take an Aspirin and so before I took the Aspirin I wanted to eat something because I had not had anything to eat that day. I went to eat some yoghurt and I could not swallow at all, I couldn't swallow the yoghurt. So, then I am concerned my airway is being compromised by the swelling in my neck. So, I got to call # and then I cannot walk my left leg is dragging, so I am lurking around having to hold on and then when I called # my voice was like had to whisper and it was hard to get an information where I was at. Finally they arrived and I was taken into the ambulance and when I was in the ambulance my blood pressure went up and also the right side of my body started shaking, they took me to the hospital. I was in the hospital. I had MRI, a CT scan and all of those things and it was negative for a blood clot or anything, heart problems or brain bleed. So, they ruled all of that out, my white blood cells count was really, really extremely high that is what the doctor said and anyway so I was admitted in the hospital and now I can talk better and the numbness is going away on the 14th a day later which went on for the symptom. So, later that evening the numbness subsided. I could speak better my left lymph node was still sore and everything and of course they did noticed that in the scan, MRI stuff about the abnormal mass in my neck which was my lymph node.". The patient stated, "I was hospitalized on 14Apr2021 and I was released the evening of 16Apr2021. Treatment: the patient stated they did not treat her for anything except for the high blood pressure when out there and that is it. The clinical outcome of Lymph node pain was not recovered. The clinical outcome of the remaining events was unknown.

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1294675	5/7/2021	TX	36	F	4/4/2021	4/1/2021	<p>blood clot; anemia; knee down felt tingly/like her legs were falling asleep; knee down felt tingly/like her legs were falling asleep; could not sleep; She was feeling uncomfortable constantly/she did not feel well; Shortness of breath; Her arm started hurting/was just at the injection site; This is a spontaneous report from a contactable consumer. This consumer (patient) reported for herself that a 36-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EP7533) at the age of 36-years, via an unspecified route of administration in left arm on 04Apr2021 12:15 at single dose for COVID-19 immunisation. Medical history included had a pregnancy (a while ago, not ongoing). No other products. The patient stated that she experienced shortness of breath on 08Apr2021 (4 days after receiving the first dose), it got so severe on day 7 that she went to the ER on 11Apr2021. She started getting progressively more shortness of breath. Twice, she called the nurse line for her doctor and was advised to go to the emergency room. Added she could not catch her breath, and it was worse at night, could not sleep, so she went to the emergency room, she was in emergency room for 2 and a half hours and then went home. She wanted to know if the second dose could cause issues or if she should get it, added that the paperwork said that people should not get the vaccine if they received an adverse reaction to the first dose or any vaccination. She did not know if this was normal for it to get progressively worse and 2 to 14 days later. Patient wanted to know if the shortness of breath was something that can get worse, if this was a reaction to the vaccine even though it happened so many days later. Patient added it was the only thing she could think of and that her heart rate, oxygen levels, and everything was good minus she felt like she could not catch her breath. The doctor in the ER gave her anti-anxiety medicine, something with an L, but the doctor gave her that and it really seemed to help. It was kind of like, she did not know, it made her feel calm enough to fall asleep. Caller added that she has that and an salbutamol (ALBUTEROL) inhaler. She was not sure whether progressively worsening shortness of breath had gotten any better or was still going on, added that yesterday was the day she did not need either treatment medication. The day before, she took just the anxiety</p>

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medicine and not the albuterol. Yesterday, she took none. During the day on 11Apr2021 (Sunday), she had called because she was feeling uncomfortable constantly. She has two children and all day she did not feel well. She told her husband she did not feel well at all. Sunday when she went to lay down, she could not sleep. Patient reported that as her shortness of breath subsided, her arm started hurting again, thought this began on 19Apr2021 and was not sure, it went away completely and was just at the injection site, probably lasting half a day or so and then it went away, clarified as left arm, same as injection. Caller added that 15Apr2021 was after the ER visit, was that she was standing up doing things and from her knee down felt tingly. Stated that knee down felt tingly on 15Apr2021, which was after her ER visit occurred, she was standing up and doing things. She had not been doing things for long periods but her knee down felt tingly. Added not like numb, but like her legs were falling asleep. She was preparing dinner and moving around and felt tingling in both legs. This probably lasted about three hours. She just kind of took it easy and it started to subside and then it was gone. While mentioned investigations, patient stated the ER did an EKG, where they put stickers and monitor her heart. They did a chest x-ray, and they took blood. She believed they checked for blood clot tests and anemia. Patient did not know any results but stated the doctor came into the room and told her everything was clear and nothing came back with anything on it. She stated the date was either the night of 11Apr2021 or the morning of 12Apr2021 for the tests. Outcome of the events shortness of breath and arm hurting was recovered/resolved in Apr2021; of the event knee down felt tingly/like her legs were falling asleep was recovered/resolved on 15Apr2021; while of remain was unknown. No follow-up attempts are needed. No further information is expected.

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1294665	5/7/2021	MO		M	3/6/2021	3/9/2021	three smallest toes on both feet (left/right) feel swollen; discomfort in wearing shoes and sleeping at night; balance is affected; nerve damage; discoloration; blood clots; This is a spontaneous report from a contactable consumer (patient). A 57-years-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date: unknown), via an unspecified route of administration, administered in Arm Left on 06Mar2021 11:00 as single dose for COVID-19 immunization. The patient had no medical history and known allergies. Patient did not have COVID prior vaccination. Patient was not tested for COVID post vaccination. Concomitant medications were not reported. It was reported that patient had three smallest toes on both feet (left/right) feel swollen. He had discomfort in wearing shoes and sleeping at night. He had movement of the toes but balance is affected. Just really troubling as nothing like this was affecting him before. He had been told it was COVID toe. He first thought it is was nerve damage. Could be blood clots small based on reading information. He never got sick. He was attempting to set a doctors appointment. There is a small amount of discoloration. He was hopeful with time this will get better. Events started on 09Mar2021 14:00 with outcome of not recovered. No treatment received. Events resulted in Doctor or other healthcare professional office/clinic visit, Disability or permanent damage. Events were reported as serious due to disability. Patient had second dose of bnt162b2 (lot no.: ER2613) on 27Mar2021 on Left Arm. Information on the lot/batch number has been requested.



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1294661	5/7/2021	VA	30	U	4/7/2021	4/7/2021	Blood clots on my legs; tired; This is a spontaneous report from a contactable consumer (the patient). A 30-year-old patient of an unspecified gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot number ER8737), via an unspecified route of administration, on 07Apr2021 at 12:30 (at the age of 30 years old) as a single dose in he left arm for COVID-19 immunization. Medical history included COVID-19 from an unknown date and unknown if ongoing. The patient has no known allergies. The patient's concomitant medications were not reported. The patient had received no other vaccines within fourteen days prior to vaccination. The patient experienced "blood clots on my legs" on 07Apr2021 at 17:00 with outcome of unknown, and "feeling drained and tired for two weeks now" begining on 07Apr2021 at 17:00 with outcome of unknown. The patient has not been tested for COVID-19 since the vaccination .
1294526	5/7/2021	OR	60	F	4/20/2021	4/26/2021	intensive lower abdominal pain, electrical nerve pain in right knee, Late night Charlie horse that wrapped around upper abdomen (liver area), Massive headaches, severe leg pain (rt only)Working up from back of knee to top of thigh (VERY intense and most concerning because it felt very much like a blood clot, severe loss of short term memory for 3 days, Dizziness, loss of appetite, nausea All this starting on day following vaccine and for 5 days.

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1294744	5/7/2021	CA	63	M	2/18/2021	3/1/2021	<p>urinating blood; might be a UTI; arm pain; fatigue; blood clots; he started bleeding after the first shot; This is a spontaneous report from a contactable consumer, the patient. This 63-year-old male patient reported that he received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: EL3249) on 18Feb2021 (also reported as 17Feb2021) (at the age of 63-years-old) via an unspecified route as a single dose for COVID-19 immunization. Medical history included enlarged prostate, urinary health issues (gets up in the middle of the night), and has glasses as he had cataract surgery last year (2020) so he lost his close-up vision. Concomitant medications were not reported. On 18Feb2021, the patient got his first shot. Three weeks later, he had an episode of urinating blood and blood clots profusely. The patient stated the amount of blood and blood clots was scary at best. The patient reached out to his daughter who is a nurse who advised him to go to the Emergency Room (ER). He reached out to the nurse hotline as well, which recommended that he go to the emergency room that day as well. He went to the ER (it was a Sunday). They did a blood test, a sonogram or some kind of sonogram, and a urine sample. They also flushed the patient's bladder out with a catheter. This emergency room visit determined that it might be a urinary tract infection (UTI) and started him on antibiotics. The patient confirmed he was not admitted to the hospital. The patient then made an appointment with his doctor because that was on a weekend. He saw his doctor who referred him to a urologist. The patient also reported that he did have the normal arm pain and fatigue the second day or the day after the shot. The patient reported 11Mar2021 or 12Mar2021 was when he started bleeding after the first shot, he was unsure of the exact date, and stated he went to the hospital on 14Mar2021. The patient reported he is going to the doctor today (21Apr2021), to see the urologist but the urologist is going to do a scope in his bladder because that is the only thing that they cannot see. The clinical outcome of events urinating blood, blood clots, UTI, bleeding, arm pain, and fatigue was unknown.; Sender's Comments: Linked Report(s) :PFIZER INC-2021471072 same patient/reporter, different AE/2nd dose</p>

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1296328	5/7/2021	NY	31	F	4/9/2021	4/10/2021	4/9/2021 vaccination 4/10/2021 fever, malaise, body aches, chills. Lasted for 24 hours. 4/16/2021 cramping in leg, calf pain. Tried stretching, ibuprofen. Telemed. Keep eye on it, seemed muscular. Didn't get better over next few days 4/18/2021 Couldn't r/out blood clot. Noticed heart murmur. Sent me to ER to r/out blood clot. Referral to cardiologist. 4/20 observed heart murmur. blood work; normal. Echocardiogram week later 4/28 Echocardiogram results; 'Reaction to the vaccine'. Didn't see anything alarming. To do normal check-ups with PCM. *COVID +; 12/9/2020
1295392	5/7/2021	NC	56	M	4/22/2021	4/23/2021	Pt developed R calf and knee pain about 24 hours after his first dose of the Moderna Covid vaccine. We saw him first on 5/4/21 and he had a R LE doppler which showed a deep vein thrombosis in his Right posterior tibial vein.
1296468	5/7/2021	SC	63	M	3/30/2021	4/7/2021	One week after vaccination, I had to all 911 and was put in the hospital, I had a stroke, I had a blood clot in my brain, and severe abdominal pain, and terrible headache where the clot was, I couldn't see, my legs weren't working right. My head was sensitive on the right side, like a tingling and sore to touch, then the headache started in the center of my head. I stayed in the hospital for 3 weeks. I'm home but have slurred speech and I use a walker now.
1296528	5/7/2021	NY	79	M	3/10/2021	5/3/2021	Blood clot in right eye resulting in permanent loss of vision.

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1294515	5/7/2021	PA	54	F	4/23/2021	4/28/2021	After receiving the first dose on 4/1/21 Lot# ER8733, I had light spotting for 2 days. Second dose given 04/23/21 and by 04/28/2021 I started bleeding again And by the second day I was soaking through pads and huge clots were coming out. This has never happened to me before. After 7 days of bleeding heavily I woke up on May 5th at 4:00 a.m. with intense abdominal cramping The only way I can describe was labor. I felt back labor, pelvic pressure, frequent urination and intense pain. I reached out to my gynecologist And he immediately told me to remove my estrogen patch and later that morning he started me on progesterone treatment for 10 days to stop the bleeding. After 7 hours of pain on May 5th, I went to the emergency department and an ultrasound revealed a blood clot. From ultrasound results "there is a complex area in the area of the cervix measuring 5.7 x 3.6 x 2.6 cm." After several hours I was released from the emergency room taking toradol for pain. That evening I passed a huge blood clot! I'm very grateful it was where it was and I could expel it. But there's no doubt the second vaccine caused this issue that has never happened to me before. I still get my periods though irregular and very light. So this event was highly unusual and very painful

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1294746	5/7/2021	CA	63	M	3/17/2021	4/1/2021	<p>blood clots; urinating blood; arm pain; fatigue; he started bleeding from the second one; This is a spontaneous report from a contactable consumer, the patient. This 63-year-old male patient reported that he received the second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: EN6206) on 17Mar2021 (at the age of 63-years-old) via unspecified route as a single dose for COVID-19 immunization. Medical history included enlarged prostate, urinary health issues (gets up in the middle of the night), has glasses as he had cataract surgery last year (2020) so he lost his close-up vision. Concomitant medications were not reported. The patient previously received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Batch/lot number: EL3249) on 18Feb2021 (also reported as 17Feb2021) (at the age of 63-years-old) via unspecified route as a single dose for COVID-19 immunization and experienced urinating blood and blood clots profusely, UTI, bleeding, arm pain, and fatigue. The patient received his second shot on 17Mar2021 and almost to the date three weeks later, had the same incident with urinating blood and passing blood clots. He waited an extra day because he could not go to the bathroom and then he went to the ER that same day so that they could flush him out. He also had an appointment on that same day with his urologist. A CT scan was done at the ER and then in the afternoon he went to the doctor. The doctor did a catheter flush. The patient was unclogged but he was passing blood. The patient also reported that he did have the normal arm pain and fatigue the second day or the day after the shot. He has no other adverse reactions at this time. The patient reported 11Apr2021 or 12Apr2021 was when he started bleeding from the second one (shot). He went to the hospital on 14Apr2021. The patient confirmed he was not admitted. The patient reported he is going to the doctor today (21Apr2021) to see the urologist but the urologist is going to do a scope in his bladder because that is the only thing that they cannot see. The clinical outcome of the events urinating blood, blood clots, bleeding, arm pain, and fatigue was unknown. The patient stated he does not know if this is an issue, however, it coincided with both of his shots. The patient was calling to see if this is something that has been seen or if it is in his head.; Sender's Comments: Linked</p>

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1294816	5/7/2021	CA		M			<p>Report(s) : US-PFIZER INC-2021470922 same patient/reporter, different AE/first dose</p> <p>BLOOD CLOTS; UNABLE TO WALK/TEMPORARY DISABLED; This spontaneous report received from a source from a consumer via a company representative concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: Unknown) frequency one total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. The consumer reported that the patient on an unspecified date experienced blood clots and was unable to walk. The patient was under doctor care and was temporary disabled. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clots, and unable to walk/temporary disabled. This report was serious (Other Medically Important Condition, and Disability Or Permanent Damage).; Sender's Comments: 20210502999-covid-19 vaccine ad26.cov2.s-Blood clots, unable to walk. This event(s) is considered un-assessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1294828	5/7/2021	NJ	79	F	3/31/2021		<p>very tired, slept all day; slept all day; She had trouble breathing; pain in back of right shoulder; found two blood clots on lungs and two in legs; found two blood clots on lungs and two in legs; there was damaged to his wife's heart too; weighed 165 pounds initially and then went down to 145; This spontaneous case was reported by a consumer and describes the occurrence of DYSPNOEA (She had trouble breathing), ARTHRALGIA (pain in back of right shoulder), FATIGUE (very tired, slept all day), HYPERSOMNIA (slept all day), PULMONARY EMBOLISM (found two blood clots on lungs and two in legs), DEEP VEIN THROMBOSIS (found two blood clots on lungs and two in legs) and CARDIAC DISORDER (there was damaged to his wife's heart too) in a 79-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 028A2 or 078A2 and 028A2 or 078A2) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 31-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced DYSPNOEA (She had trouble breathing) (seriousness criterion hospitalization), ARTHRALGIA (pain in back of right shoulder) (seriousness criteria medically significant and life threatening), FATIGUE (very tired, slept all day) (seriousness criteria hospitalization, medically significant and life threatening), HYPERSOMNIA (slept all day) (seriousness criteria hospitalization, medically significant and life threatening), PULMONARY EMBOLISM (found two blood clots on lungs and two in legs) (seriousness criteria hospitalization and medically significant), DEEP VEIN THROMBOSIS (found two blood clots on lungs and two in legs) (seriousness criteria hospitalization and medically significant), CARDIAC DISORDER (there was damaged to his wife's heart too) (seriousness criterion hospitalization) and WEIGHT DECREASED (weighed 165 pounds initially and then went down to 145). At the time of the report, DYSPNOEA (She had trouble breathing), ARTHRALGIA (pain in back of right shoulder), FATIGUE (very tired, slept all day), HYPERSOMNIA (slept all day),</p>

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							<p>PULMONARY EMBOLISM (found two blood clots on lungs and two in legs), DEEP VEIN THROMBOSIS (found two blood clots on lungs and two in legs), CARDIAC DISORDER (there was damaged to his wife's heart too) and WEIGHT DECREASED (weighed 165 pounds initially and then went down to 145) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Computerised tomogram: two blood clots on lungs and two (abnormal) two blood clots on lungs and two in legs. On an unknown date, Weight: 145 (Low) weighed 165 pounds initially and then went down to 145. The patient was hospitalized for around four days. The patient size of clots as 10 cm and 9cm in the lungs. The reporter stated that Heparin was used in the hospital and after the discharge the patient was put on Eliquis for the next 6 months. The reporter reported that the patient weighed 165 pounds initially and then went down to 145 afterwards. Action taken with the mRNA-1273 is considered as not applicable. Company comment: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine, the onset of the reported events, a causal relationship cannot be excluded.</p>
1295292	5/7/2021	FL	28	F	4/7/2021	4/14/2021	<p>When I got the vaccine I had an immediate sharp pain in my arm, almost like a nerve was pinched, and it went down my left leg. It lasted for about 20 minutes then went away. Seven days later I admitted myself to the hospital because my left leg was tingling. No blood clots in my leg were found and a head CT didn't show any abnormalities. I still have the tingling in my left leg that I am going to see a neurologist for and will be getting blood tests done to see what else could be going on.</p>
1295454	5/7/2021		28	F	4/24/2021	5/7/2021	<p>My period is not due for 2 more days and I am having heavy bleeding with visible blood clots from my vagina. I do NOT have blood clots in a typical menstrual cycle. I noticed the bleeding when I woke up this morning and it is still going.</p>



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1295545	5/7/2021		19	F	4/10/2021	4/13/2021	Pt is a 19 YO female with NKA who received her J&J COVID-19 vaccination on 4/10/2021. On 4/13, she calls this instiution stating she has developed a severe headache, sores on her vagina, shortness of breath, is light-headed and tired. Pt was recommended to call 911 or go to the ER but declined. She had a Ob/Gyn appointment scheduled for the next day (4/14) and says she will discuss her symptoms with them. RN on the phone call reviewed signs and symptoms of blood clot and recommended immediate assessment. Unable to gather any additional information.

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1295618	5/7/2021	VA	24	M	3/6/2021	3/15/2021	A week and a half approximately after the initial vaccination of the J+J covid vaccine I started having a course of strange symptoms. Insomnia, inability to focus on things directly in front of me (a hand in front of my face would go out of focus automatically after a second), blurred vision, short term/long term memory loss, severe emotional issues, difficulty breathing, anxiety. Shortness of breath at a certain point was so bad I thought I was not going to make it. One very troublesome symptom that culminated after weeks of 4 hours of sleep was that my brain started feeling "funny". The best way to describe it was a brain "orgasm" which I have never experienced before. At the same time I experienced dry heaving for several minutes, and severe shortness of breath. After this experience my symptoms gradually improved over the next week or two. Prior to this it felt like my brain was not getting enough oxygen/blood, which could have been feeding my insomnia. When I would try to sleep, I would wake up at 4 am gasping for air, as I felt like my breathing was labored when sleeping. I could not focus on my computer screen to do my job at home. Large amounts of melatonin seemed to help my brain feel better and get some rest. I took hydroxyzine for unrelated reasons prior to the vaccine injection as needed, however not too often. During March I did not take it, as I had experienced disruptions in circadian rhythm due to the medication. I feel it is possible I had a blood clot that has been described in the news, although now there may be no way to know for sure. I talked with my primary care physician about this, and he did not think this was the case because I was male. However I have a BMI of 18.7 and some issues females have such as TMJ and inability gain weight/anorexia diagnosis when younger. I also was recently diagnosed with an only recently described actual medical issue called R-CPD, which is the complete inability to burp or belch. I felt like during the time when I experienced the side effects, that this condition was heightened (bloating/loss of appetite). I lost quite a bit of weight during March, I usually weigh 135-140, and was down to 115 at a certain point. I am now back up to 130. I now take sertraline at 1/4 pill dosage to treat the anxiety I experienced as a result of these symptoms as well as some other personal issues. I experienced severe side effects from the sertraline taking it at full dosage, and still experience some at 1/4 pill dosage.

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1295866	5/7/2021	PA	52	M	4/20/2021	4/23/2021	Swollen red left arm. Diagnosed with blood clots in all his veins in left arm and spent 4 days in hospital on blood thinners and had 2 surgeries to remove them
1296132	5/7/2021	OH	72	M	3/8/2021	3/18/2021	- 3/8/21 Had Johnson and Johnson covid-19 vaccination (lot 1802068). - 3/16/21 MRI abd/pelvis showed that mass was likely a large bowel lipoma. MRI also incidentally showed a thrombosis of the middle hepatic vein. Mild hepatic steatosis was also noted. Incidental pancreatic cystic lesion at 0.5 cm was noted. - Referred to vascular.
1296176	5/7/2021	KS	59	F	4/9/2021	4/21/2021	On 04/21 left knee pain, outside/back of knee 04/23 - left side tingling , went to urgent care and then referred to ED due to concern about stroke. Sent home after leg scan - was told it was normal and referred to neurologist 04/29 - back to ED, admitted overnight, scan from 04/23 showed blood clot behind the knee. Also diagnosed by neuro with TIA. Also stated she had swelling, redness, and headaches for 4-5 days after vaccine
1296550	5/7/2021	ND	66	F	3/17/2021	5/1/2021	Patient began to experience minor pain in upper left leg in mid-April; patient noticed extreme swelling and discoloration in left leg evening of 05/01/2021; Admitted to ER morning of 05/02/2021. Diagnosis: Acute deep vein thrombosis (DVT) of left lower extremity; no family history of blood clots and no falls reported by patient. DVT resolved after 24 hours of catheter directed thrombolysis. Residual nonflow limiting disease still present in the below-knee deep veins and popliteal vein with good collateralization of the deep venous system. Minimal residual disease still present in the femoral vein without flow limitation.

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1296129	5/7/2021	OR	39	F	5/5/2021	5/5/2021	pt says she had some uncomfortableness in her private area the morning she woke up to get her vax. She urinated before getting the vax. About 30 minutes after taking the vax she has to urinate again and she had pain while urinating and blood clots in her urine. She contacted her PCP and was told to the emergency room. On 5/5/21 she went to ER. They took vitals and gave her a urine test. Pt was diagnosed w/ UTI. They told her that the vax had flared up this condition. They gave her Nitrofurantoin mono-mcr 100mg and Phenazopyridine 200mg. She has other flu like symptoms including cold sweats, shivers, and body aches and pain, body is hot to the touch but no fever.
1295140	5/7/2021	FL	62	M	4/30/2021	5/1/2021	Very sore arm, fatigue, headache, then about 30 hours afterwards, extreme pain on right side under ribs, hard to breathe, went to ER, after several test performed, finding is PE in right lung and DVT behind right knee. I had signs of these weeks to months prior, have no underlying conditions before this happen, now I on Eliquis for blood clots! Also due to the blood clots have pneumonia!
1296561	5/7/2021	NY	45	M	4/7/2021	4/26/2021	Presents with cardiomyopathy, eosinophilia --cardiac bx done pt is postive for eosinophilia. MRI suggest acute cardiac inflammation with possibility of apical clot and endomyocardial biopsy suggestive of acute eosionophilic myocarditis. Smear for parasites negative. quantaferon gold negative. Currently in the CICU unit
1296659	5/7/2021		86	M	4/1/2021	5/1/2021	patient says they got a STEMI (from a clot) and is now in the hospital. also left arm bruise where shot is.
1296700	5/7/2021	NC	38	M	4/5/2021	4/23/2021	Severe flu like symptoms occured approximately 12 hours after 2nd dose of Moderna vaccine. Blood Clot formed approximately 2 weeks later and created stroke on 4/23/2021.

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1296737	5/7/2021	CO	67	M	4/2/2021	4/10/2021	On 4/10/2021 pt developed headache, nausea and vomiting and eventually ataxia. Admitted to Swedish Medical Center 4/12/2021 diagnosed with dural venous sinus thrombosis with associated left parietal intracerebral hemorrhage. Did not have thrombocytopenia. No records of hospital staff checking PF4 antibodies. Patient was treated with catheter thrombectomy X 2 and anticoagulation. Discharged 4/20/2021 on dabigatran. All symptoms resolved and patient doing well. Plan for outpatient neurology follow-up.
1297529	5/7/2021	TX	80	F	3/17/2021	4/14/2021	pt told me she had the Johnson and Johnson one covid shot and slept for 3 days afterwards and then had to be hospitalized for a blood clot
1295851	5/7/2021	PA	78	F	4/2/2021	4/14/2021	Admitted with generalized weakness, lethargy, and muscle aches for a couple weeks (since receiving vaccine). Planned to rule out atypical PNA. Blood cultures positive for bacteroides, likely abdominal source. Abdominal CT scan showed portal vein thrombosis, confirmed on MRI.
1293193	5/6/2021	NE	75	F	4/8/2021	4/24/2021	Patient received her first Pfizer vaccine on April 8, 2021. On April 24, her home health care nurse noticed swelling of the left calf. Pt is wheelchair dependent and has little sensation below the waist due to MS. She never had any pain. She was seen in the office on April 27 with significant swelling and discoloration of her left leg. A venous duplex scan revealed a large clot burden from the groin to the ankle. She was started on Eliquis and evaluated by vascular surgery. She required surgical embolectomy which was preformed 5/5/21.
1293356	5/6/2021	NY	51	M	4/10/2021	4/11/2021	4/10/2021 vaccination 4/11 or 4/12 at the latest, I started feeling a pain in my R calf. It was constant pain for a week and decided to go to the walk in clinic. Blood work which was high and they referred me to the ER and administered a sonogram. *positive for blood clot Eloquence for 30 day starter pack. PCM is going to extend till July in which he will administer another sonogram. *COVID +; 01/2021

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1293400	5/6/2021	CA	59	M	4/1/2021	4/7/2021	From Physician H&P: Patient is a 59-year-old man multiple medical chronic conditions, including known protein S deficiency not on anticoagulation, sinus bradycardia, hypercholesterolemia, chronic neuropathy of the lower extremities, who presented to the emergency room at the recommendation of his primary care office for possible stroke and persistent headache. He reports that his history of present illness begins on 4/7/2021, for which after he had received the COVID-19 Johnson & Johnson vaccine he started to have throbbing headache. He stated that it was diffuse and pounding in quality, up to 10 out of 10 pain. However this resolved on its own, and since then and has been intermittent with this type of headache. He did report 2 weeks ago, that he had a brief episode of tunnel vision as he describes it, where his vision seemed to narrow while he was looking at his phone. This only lasted no more than 10-30 minutes, and this resolved on its own as well. He continues to have intermittent headaches, again otherwise nonspecific with pounding quality however the intensity is improved. Humidifier regarding the Johnson & Johnson vaccine to report any side effects, for which she had notified his primary care doctor who then decided to proceed with MRI of the brain to evaluate for possible etiology. The MRI was done with and without contrast at facility on 5/4/2021, for which there was concern for possible left temporal posterior stroke, and if there was any concern for venous thrombosis, further imaging was necessary. He was then recommended to go to the emergency room for evaluation. He otherwise is in his regular state of health. He denies any recent fever or chills or cough, no chest pain or shortness of breath, nausea, vomiting, abdominal pain. No changes in bowel or bladder habits.
1293543	5/6/2021	TX	58	F	4/12/2021	4/14/2021	Feet turned black blood thinner 3 blood clots in lungs 1 clot in heart

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1293612	5/6/2021	MA	79	F	3/6/2021	3/9/2021	Details of Hospital Stay History of Present Illness The patient is a 79-year-old woman with a past medical history of hypertension, hypothyroidism, lumbar compression fracture, hiatal hernia, metastatic adenocarcinoma primary lung to bone and question liver, on immunotherapy pembrolizumab started 12/3/2019, changed to osimertinib, right leg superficial thrombosis, on Xarelto presented to hospital on 3/10/2020 with complaints of 2 months duration shortness of breath, worsened over a 4-day period. She was admitted to the hospital with a diagnosis of acute respiratory failure with concerns of acute PE. For all details regarding the patient's initial presentation please refer to history and physical exam dated 3/10/2021.
1293095	5/6/2021	TN	34	F	3/15/2021	5/5/2021	Patient admitted to acute care hospital approximately 7 weeks after receiving Janssen vaccine with thrombocytopenia. Platelet count 4000 at PCP and patient advised to present to the ED. On admission 5/5/21, repeat platelet count 8000. Emergent CT completed which ruled out cerebral venous sinus thrombosis. PT, INR, fibrinogen and d-dimer were normal. Hematology felt that it was most consistent with immune thrombocytopenia and unknown if any relation to her COVID vaccination.
1293871	5/6/2021	NY	64	F	3/25/2021	3/26/2021	Blood clot
1292715	5/6/2021	WI	56	F	4/20/2021	5/5/2021	Client has a history of former tobacco abuse, CAD, DVT on apixaban, PAD s/p stenting, COPD, end-stage interstitial lung disease, chronic hypoxic respiratory failure (4L), sepsis complicated by aorto-embolic lower extremity thrombosis ultimately requiring L BKA, aorto-embolic RUE embolism treated with thrombectomy, RLE stent thrombosis while on anticoagulation, GERD, steroid-induced diabetes, C difficile colitis, stress-induced cardiomyopathy. Client presented to the Emergency Room with shortness of breath, fever, and respiratory failure in the setting of COVID-19 and severe underlying pulmonary illness. Admitted with: Severe COVID-19 bronchopneumonitis

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1293926	5/6/2021	CA	71	F	4/5/2021	5/3/2021	Patient presented 3-4 weeks after receiving the Janssen COVID vaccine with right MCA stroke with mass effect, mild midline shift and right MCA thrombus. Carotid ultrasound showed thrombosis of the right common and internal carotid arteries and right carotid siphon. She was found down, last seen normal 2 days prior to admission. She was not a candidate for tPA given the delayed presentation and unlikely to benefit from thrombus extraction. She was treated with aspirin and atorvastatin and treated for rhabdomyolysis. Patient is currently still admitted to the hospital but transitioning to comfort focused care.
1293945	5/6/2021	CA	44	M	3/24/2021	4/8/2021	Flashes and blurred vision in the left eye, various eye exams conducted and fluid drained in an attempt to lower pressure and remove clot (unsuccessful). The event resulted in Central Retinal Artery Occlusion and loss of vision.
1294030	5/6/2021	MA		M		5/3/2021	HIGH SUGAR LEVELS POST VACCINATION; FLUSH FEELING ON FACE; FELT LIKE FEVERISH; This spontaneous report received from a patient concerned a male of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included 5 blood clots, and concurrent conditions included type 2 diabetes, and other pre-existing medical conditions included patient had no known allergies and taking lit of anticoagulants for type ii diabetes mellitus. The patient received covid-19 vaccine (suspension for injection, route of admin not reported and batch number: 2058A21A expiry: UNKNOWN) dose was not reported, administered on 03-MAY-2021 for prophylactic vaccination. Concomitant medications included gliclazide for type 2 diabetes, metformin for type 2 diabetes, atorvastatin calcium, and metoprolol. On 03-MAY-2021, the subject experienced high sugar levels post vaccination. On 03-MAY-2021, the subject experienced flush feeling on face. On 03-MAY-2021, the subject experienced felt like feverish. Laboratory data included: Blood sugar increased (NR: not provided) Quite high. The action taken with covid-19 vaccine was not applicable. The patient had not recovered from high sugar levels post vaccination, and the outcome of felt like feverish and flush feeling on face was not reported. This report was non-serious.



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1293848	5/6/2021	OH	78	M	3/16/2021	4/17/2021	My father suffered a heart attack due to blood clots clogging the artery to his heart. He coded and was resuscitated and had four stents installed after the blockage was cleared. He had a second heart attack several days later when the stents clogged and had to be cleared. He was hospitalized for several days for each heart attack.
1294034	5/6/2021	PA	22	M		5/3/2021	FEVERISH AND FEVER LIKE SYMPTOMS; SHAKING; SWEATING; FELT COLD; POUNDING HEADACHE; FELT TIRED; This spontaneous report received from a patient concerned a 22 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included prothrombin gene mutation - increased risk for blood clot (predisposition), amoxicillin allergy, occasional alcohol use, and non-smoker. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 205A21A expiry: UNKNOWN) .5 ml, administered on 03-MAY-2021 for prophylactic vaccination. No concomitant medications were reported. On 03-MAY-2021, the subject experienced feverish and fever like symptoms. On 03-MAY-2021, the subject experienced shaking. On 03-MAY-2021, the subject experienced sweating. On 03-MAY-2021, the subject experienced felt cold. On 03-MAY-2021, the subject experienced pounding headache. On 03-MAY-2021, the subject experienced felt tired. Treatment medications included: ibuprofen. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from feverish and fever like symptoms, shaking, sweating, felt cold, pounding headache, and felt tired on 04-MAY-2021. This report was non-serious.
1292738	5/6/2021	NY	62	F	3/18/2021	3/19/2021	pt experienced SOB and was seen by pcp and referred to ER where evaluation identified PE and DVT of There is deep venous thrombosis present within the left popliteal vein which is nonocclusive and may be acute on chronic. Acute appearing deep venous thrombosis is present within both of the left posterior tibial veins which is occlusive. Likely acute deep venous thrombosis is present within the proximal aspect of a left peroneal vein focally.

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1293664	5/6/2021	CA	59	F	3/18/2021	3/18/2021	The day of the vaccine, in the evening, I got severe stomach cramps and then I got diarrhea really bad. The cramps went on all night into the next day. They were so painful - like labor pain. The next day, I had a GI hemorrhage - it was clots of blood coming out of the digestive system. I contacted my regular practitioner doctor and sent him a picture of the clots and he instructed me to go to ER. I ended up going to Urgent Care. I went to the Urgent Care on Saturday or Sunday. The Urgent Care doctor there thought I had food poisoning. But that day I didn't eat anything - I just had had ginger ale, cranberries and cashews. He was puzzled as to why I had these symptoms. He gave me medication to stop the cramping in my stomach. Medication is: Hyoscyamine. I used it even two weeks after the fact because I would occasionally get real bad stomach cramps. I was also referred to get a colonoscopy - haven't been able to get in yet. The GI hemorrhaging lasted two or three days and then disappeared.

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1292685	5/6/2021	MN	56	F	4/12/2021	4/26/2021	Vaccine Induced Thrombotic Thrombocytopenia - confirmed with Lab testing Elisa PF4 highly positive 1.chills, generalized body aches, and noted that some glands in her neck were swollen. for 24-48 hours post vaccine 2. 4/27/2021, worsening headaches, bifrontal, along with some bruising in her right leg and left wrist area. Evaluated at ER. white count was 6.1, her hemoglobin was 12.5 and her platelet count was 91,000.( PLT previously 301,000). MR venogram of the head was performed with and without contrast. There was no dural, venous, sinus thrombosis or significant stenosis. The clinical impression at the time of the treating ER physician was that she had acute sinusitis 3. 4/30/2021 PCP visit Additional testing was obtained PLT 149,000. white count and hemoglobin were in the normal ranges. D-dimer was elevated at greater than 20. The fibrinogen was low at 143. Heparin platelet antibody test - lab - Negative 4. 5/3/2021 presents to Hospital. 12 to 16-hour history of back pain, bilaterally, left greater than right. It also was very painful to take a deep breath. She also noted that her fatigue was progressively worsening. CT Pulmonary Angiogram shows Thrombus within multiple right lower lobe, right middle lobe and posterior left upper lobe and medial left lower lobe pulmonary arteries. white count of 11.4, a hemoglobin of 13, and a platelet count of 254,000. Her ANC was 9. Her reticulocyte count was 1.3 and absolute reticulocytes were 0.06. Treated with Non heparin anticoagulant - argatroban IV infusion titrated to PTT lab results Discharged from Hospital with rivaroxaban ( Xarelto) 5/6/2021
1292675	5/6/2021	NY	61	M	4/8/2021	4/9/2021	After my vaccine, I experienced redness sensation to my arm. My left arm was swollen and raised bump with a rash. I called my doctor and he thought it was possible cellulitis. He prescribed Prednisone and an antibiotic for seven days. After the seven days my rash was gone but I still had the raised bump. I went to an urgent care facility where they performed an ultrasound of left upper extremity and no blood clot was found. I was told to apply warm compresses to my left arm once a day. To this day I still have an aching sensation to my left arm and is also sore and my left arm is still red but flat in shape.

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1292420	5/6/2021	FL	52	M	3/29/2021	4/21/2021	On Wednesday evening April 21st around 11:00 pm i could not catch my breath while trying to lye down or sit up, i went to the Hospital ER on Thursday morning at 8:00 am and they did a cat scan with contrast and found multiple blood clots (PE ) in my right lung.
1292206	5/6/2021	NY	61	M	3/27/2021	3/27/2021	Extreme blood clots in lungs and legs
1292143	5/6/2021	ME	58	F	3/30/2021	3/31/2021	lips and nail beds blue, 4/3/21 bumped left leg,,big bruise, felt clots, headache, metallic taste in mouth,
1291930	5/6/2021	MA	45	F	4/26/2021	4/26/2021	Immediate chest pain (tightening) , then arm pain while in store/pharmacy Next Day began spotting (menstrual bleeding) and lasted for 2.5 days Chest pain continued and has not stopped for last 10 days, intermittent throughout the day - tigheting of left side and right side of chest, radiates to theback Sunday following Monday vaccination (6 days later) got a blood clot on palm of hand, lasted for 4 days that started bleeding out and blood spread to front of hand like a birthmark as it bleed out

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1291587	5/6/2021			U			<p>BLOOD CLOT; This spontaneous report received from a consumer via social media through a company representative and concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient experienced blood clot three weeks later without any underlying conditions. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210504574.; Sender's Comments: V0:20210503763-Covid-19 vaccine ad26.cov2.s-Blood clot. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p>

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1291581	5/6/2021	MD		F			POSSIBLE CLOT IN THE LEFT ARM; PAIN IN THE LEFT ARM/SIDE; This spontaneous report received from a patient via a company representative concerned a 6 decade old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced possible clot in the left arm, and pain in the left arm/side, and was hospitalized (date unspecified). it was reported that the patient had reaction to the JnJ vaccine. She was being watched closely and taken care of. Pain on the left arm/side. They think it as clot in the left arm. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the pain in the left arm/side and possible clot in the left arm was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: v0;20210456346-Covid vaccine ad26.cov2.s-Possible clot in the left arm. Follow-up received regarding Clinical Details. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). v0;20210456346-Covid vaccine ad26.cov2.s-Pain in left arm. Follow-up received regarding Clinical Details. This event(s) is labeled per RSI and is therefore considered potentially related.
1291529	5/6/2021	PA	49	M	4/26/2021	5/3/2021	Acute bilateral pulmonary embolism and acute right leg deep vein thrombosis, both of unknown etiology
1291528	5/6/2021	MO	62	F	3/12/2021	3/17/2021	Developed blood clot on my left lung

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1293009	5/6/2021	IA	32	F	4/20/2021	5/3/2021	Patient got her second dose of the Pfizer vaccine on 4/20 and started to feel a headache come on and believed it was due to a migraine. On 5/1 she went to her local ED and was given migraine treatment. She continued to have worse headaches and developed subsequent L homonomous hemianopsia, L sided weakness, and L sided neglect. She presented to the ED on 5/5 and was found to have cerebral venous sinus thrombosis confirmed by head CT. Other risk factors include active COVID-19 infection (unknown at time of vaccine administration) and OCP usage.
1293595	5/6/2021	FL	57	M	3/30/2021	3/30/2021	The evening of the shot I woke up with pain in my legs near my hips which lasted for a day. On 04/12/2021 my left leg was swollen and painful. I was already taking blood thinner. I went to the Emergency Room the next day and they found a blood clot in my leg. The Thrombosis was behind my left knee. My leg was swollen from the knee down and my ankle was very swollen. My Eliquis dosage has been increased from 2.5mg to 5mg twice daily. I did not have a repeat sonogram but my leg is no longer swollen.

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1294073	5/6/2021	FL		F	2/15/2021	2/20/2021	Blood clots in both lungs; Swelling in left breast; The arm showed Small spots; This spontaneous case was reported by a consumer and describes the occurrence of DEEP VEIN THROMBOSIS (Blood clots in both lungs) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 15-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced DEEP VEIN THROMBOSIS (Blood clots in both lungs) (seriousness criterion medically significant). At the time of the report, DEEP VEIN THROMBOSIS (Blood clots in both lungs) outcome was unknown. No concomitant medications were reported. Treatment of the events were not reported. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 28-Apr-2021: Follow up received on 28APR2021 included a new event of "blood clots in both legs" - making this case serious.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
1294490	5/6/2021	NJ	68	M	4/5/2021	4/13/2021	blood clot in left leg calf
1294485	5/6/2021	LA	60	F	4/8/2021	4/11/2021	Migraine headache for a week, had a MRI of the brain to rule out blood clots. A torn rotor cuff that happened 10 years ago that was a no issue, became very painful and inflamed to the point of needing a Cortisone shot and MRI to see what is going on.
1294370	5/6/2021	TN	67	M	3/25/2021	4/4/2021	Patient received the COVID-19 vaccine on Thursday, March 25, 2021. On Tuesday April 6, 2021 he had a massive stroke, blood clot to left side of his brain. On Friday morning April 9, 2021 doctor's advised he had another stroke due to bleeding in the brain (paralysis on right side and racing heart beat). He died on Saturday, April 10, 2021 @ 5:45 AM.



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1294226	5/6/2021	NY	55	M	3/10/2021	3/19/2021	NSTEMI, treated with PCI, DES evidence of multivessel coronary artery disease PCX 100% occluded submitting out of abundance of caution in case vaccine poses risk of clots in coronary artery disease patients
1294148	5/6/2021	IN	44	F	4/1/2021	4/11/2021	Pt received vaccine 4/1/2021, started to feel ill 4/11/2021 thought it was allergies. Continued to current date 5/6/2021. Had 3 different occurrences where she passed out. Dates were 4/30/2021, 5/5/2021, and today 5/6/2021 which lead to current admission. Came to ER found to have saddle PE from CTA scan. Went to Cath Lab and had INARI procedur to remove clot. Sent to ICU afterwards, was found to have DVT in left leg from ultrasound, started on argatroban. Currently is still in ICU, was admitted to ICU from cath lab today.

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1288528	5/5/2021	NJ		F		4/1/2021	DEEP VEIN THROMBOSIS IN LEGS; This spontaneous report received from a patient concerned a female patient of unspecified age. The patient's height, and weight were not reported. The patient's concomitant medical conditions included non smoker. The patient is a Zumba teacher. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 041821A expiry: UNKNOWN) dose was not reported, administered on 08-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, reported as several days after vaccination, the patient felt some discomfort in the leg. The patient took Tylenol and rested for two weeks, however it did not improve. The patient went to the doctor for a follow up and physical and the doctor ordered a doppler, which showed blood clots in both legs. The doctor immediately placed the patient on Eliquis 5mg. Patient reported that she needs to see a cardiologist and hematologist because she now has a DVT (deep vein thrombosis). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the DVT was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210505469-Covid-19 vaccine ad26.cov2.s-Deep vein thrombosis. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.
1289286	5/5/2021	OH	41	M	3/23/2021	5/3/2021	Patient ended up at the Emergency Room with a blood clot in his lungs

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1288955	5/5/2021	OH	51	M	4/8/2021	4/20/2021	Exactly 11 days after receiving the J&J vaccine my husband developed leg pain in his right lower inner leg, he was taken to the hospital on 04/20/2021 which a ultrasound was completed but resulted no blood clots, no other labs or treatment was performed that day, the next day he developed severe diarrhea and flu like symptoms with continued leg pain and difficulty breathing, He was then rushed to the hospital by ambulance where he was suffering from very low BP 41/31 was the lowest, a line was placed and he was put on pressors to increase his BP. He was transferred to the hospital where he was diagnosed with a flesh eating bacteria in the right leg where the pain was at and Sepsis. He was taken to surgery to debride the right leg and was started on CVVHD because his new kidney was now failing, he eventually was started back on Hemodialysis and taken to surgery 2 more times where he cardiac arrested on the table in surgery and died. A private autopsy is being performed but the preliminary results shows he had multi-system organ failure, including his liver which was NEVER a problem in the past.

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1288631	5/5/2021	TX	55	M		4/1/2021	<p>BLOOD CLOT IN LEFT LEG; DIFFICULTY SLEEPING; SOME LEG CRAMPS; SWELLING; This spontaneous report received from a patient concerned a 55 year old male. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry date: unknown) dose, 1 total on an unknown date in APR-2021 (reported as about three weeks ago from the date of reporting) on left arm for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. Since an unknown date in APR-2021 (reported as about a week ago), the patient experienced swelling and some leg cramps. It was reported that nothing (swelling and leg cramps) was dramatic initially, however, they worsened. On 28-APR-2021 (reported as last night), the patient had difficulty in sleeping. On 29-APR-2021, the patient was diagnosed with blood clot in left leg by his doctor. At the time of report (reported as currently), the patient was in transport to a hospital for further evaluation. The patient further mentioned that he did not have possession of the vaccination card, but his wife had it and she would be arriving at hospital later. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clot in left leg, swelling, and some leg cramps, and the outcome of difficulty sleeping was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: -COVID-19 VACCINE AD26.COV2.S-Blood Clot in leg. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p>

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1288635	5/5/2021			M			<p>BLOOD CLOTS; This spontaneous report received from a consumer via social media through a company representative and concern a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, expiry date: Unknown) dose, 1 total dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient experienced blood clots. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clots was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0- Covid-19 vaccine ad26.cov2.s-blood clots.This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p>

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1288636	5/5/2021	FL	64	M	4/7/2021		<p>CEREBRAL VENOUS THROMBOSIS; VISUAL IMPAIRMENT; HYPOAESTHESIA/ NUMBNESS IN ARM; This spontaneous report was received from a health care professional via a Regulatory Authority Vaccine Adverse event Reporting system (VAERS) (VAER reference number 1207958) and concerned a 64 year old male of unspecified race and ethnicity. The patient's height and weight were not reported. The patient's concurrent conditions included pollen allergy. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805029 expiry: UNKNOWN) dose was not reported. 1 total, administered on 16-MAR-2021 for prophylactic vaccination on left arm. Concomitant medications included atorvastatin and lisinopril; both for unknown indication. On 07-APR-2021, the patient experienced cerebral venous thrombosis, hypoaesthesia, and visual impairment. The patient had cerebrovascular thrombus with partial loss of sight and numbness of his left arm. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from cerebral venous thrombosis, hypoaesthesia, visual impairment. This report was serious (Disability Or Permanent Damage). This case version (1) was created on 30-APR-2021 for the purpose of quality improvement the following corrections were made. The MAC was added for the pharmacovigilance narrative.; Sender's Comments: V1: This spontaneous report was received from a health care professional via VAERS (ID: 1207958) and concerned a 64-year-old male of unspecified race and ethnicity who experienced cerebral venous sinus thrombosis (CVST) 22 days after vaccine. Concurrent conditions included pollen allergy and concomitant medications included atorvastatin and lisinopril. Twenty-two days after vaccine, the patient experienced CVST, hypoaesthesia, and visual impairment. The patient had cerebrovascular thrombus with partial loss of sight and numbness of his left arm. Specific imaging and laboratory results, including platelet count, were not reported. Information is limited in this case, and the occurrence of CVST could represent background incidence of such events in the general population. The platelet count is not reported and thus this case does not meet the Brighton Collaboration (BC) definition for Thrombocytopenia Thrombosis Syndrome (TTS) with BC Level 5 (not a case</p>

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							of TTS.)
1288839	5/5/2021	VA	93	M	2/20/2021	4/23/2021	Systemic: Blood Disorder (diagnosed by MD)-Severe, Additional Details: Patient passed away on 4/23/21 and had blood clots throughout body. Patient did not have any other symptoms that were reported. Patients family requested a VAERS report be submitted.
1288934	5/5/2021	MN	42	F	4/27/2021	5/4/2021	Systemic: Extreme pain in upper right leg-Severe, Additional Details: sudden upper right leg pain came on today. Doesn't remember straining her leg. Sent to urgent care for evaluation for possible rare blood clot. Pt called and said tests came back negative for blood clot. Told to rest, elevate, and ice leg.

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1288539	5/5/2021	CA		M	3/28/2021	4/20/2021	Multiple Pulmonary Emboli on both sides of the lungs\ multiple Pulmonary emboli like a spray of blood clots in the lungs; had trouble breathing; sharp pain on the right side of the chest; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Multiple Pulmonary Emboli on both sides of the lungs\ multiple Pulmonary emboli like a spray of blood clots in the lungs), DYSPNOEA (had trouble breathing) and CHEST PAIN (sharp pain on the right side of the chest) in a 75-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 020B21A and 007C21A) for COVID-19 vaccination. The patient's medical history was not provided. Concomitant products included SIMVASTATIN for an unknown indication. On 28-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 20-Apr-2021, the patient experienced PULMONARY EMBOLISM (Multiple Pulmonary Emboli on both sides of the lungs\ multiple Pulmonary emboli like a spray of blood clots in the lungs) (seriousness criteria hospitalization and medically significant), DYSPNOEA (had trouble breathing) (seriousness criterion hospitalization) and CHEST PAIN (sharp pain on the right side of the chest) (seriousness criterion hospitalization). The patient was hospitalized from 20-Apr-2021 to 21-Apr-2021 due to CHEST PAIN, DYSPNOEA and PULMONARY EMBOLISM. At the time of the report, PULMONARY EMBOLISM (Multiple Pulmonary Emboli on both sides of the lungs\ multiple Pulmonary emboli like a spray of blood clots in the lungs), DYSPNOEA (had trouble breathing) and CHEST PAIN (sharp pain on the right side of the chest) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 21-Apr-2021, Computerised tomogram: multiple pulmonary emboli CT scan showed multiple Pulmonary emboli like a spray of blood clots. Patient was taken to emergency room (ER) on 20-APR-2021. Patient was discharged next day given prescription of blood thinners and pain medications. Action taken with mRNA-1273 in response to the events was not applicable. Based on the



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							current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
1288959	5/5/2021	PA	70	F	4/10/2021	5/1/2021	Patient received vaccine on 4/10/21. Went to ED, got IV placed due to side effects. Came to clinic on 5/4/21 with right arm pain. Found to have occlusive cephalic vein clot.
1288442	5/5/2021	MA		M	4/3/2021		minor blood clot on his leg; This is a spontaneous report from a Pfizer-sponsored program received from a contactable consumer (patient). A male patient of unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not reported), on 03Apr2021 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that patient had the first dose on 03Apr2021 and he was scheduled on Saturday 24Apr2021 to get the second dose of the vaccine. However, the patient had a minor blood clot on his leg, and he was taking blood thinners. Patient asked if it was okay to get the vaccine while talking to the blood thinners (as reported). The outcome of the event was unknown. Information about lot/batch number has been requested.
1289095	5/5/2021	WA	51	M	4/9/2021	4/29/2021	Having lunch on 04/29/21, around 11:30 am. Talking with co-worker started noticing by vision went blurry. My hands & feet started tingling. I turned very pale in facial color. Had co worker call 911, paramedics to me to ER. All my vitals showed normal, ekg, blood work, platlet count all good !! Went home and over next few days felt a little off, made regular doctor appt. follow up. Doctor said all my vitals look normal. Not sure what the cause is, had a ultra sound done of my left leg pain also. Showed no blood clots. Waiting for a heart monitor appt. On 05/03/21 woke up at 3 am drenched in sweat. Still feel a little off, for no reason . At times I feel like I might pass out. Had epilepsy as a you child. But out grew with medications. No seizures in 40 years.
1289995	5/5/2021	VA	53	F	4/18/2021	4/21/2021	deep vein thrombosis

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1289320	5/5/2021	WA	79	F	3/24/2021	4/1/2021	Difficulty breathing, hospitalized, blood clots in lungs found

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1289333	5/5/2021	KY	80	F	3/2/2021	3/3/2021	<p>March 2 - second Moderna bruising appears March 3 - spontaneous bruising appears March 4 - visit with primary care doctor, blood work shows significant drop in platelets March 9 - first visit with oncologist/haematologist &amp; hospitalized March 9-19 - hospitalized for tests, treatment to increase platelets, &amp; many blood panels. No official diagnosis, treat as ITP. Follow up visits with oncologist/haematologist to keep an eye on platelets as they increase. March 30-Apr 4 - ER visit due to swelling of ankles, feet, and left arm. Tests show superficial blood clot, fluid on lungs, and pneumonia. Oncologist said that "we have no official diagnosis", that she's being treated for ITP. April 6-14 - follow up visit to oncologist/haematologist show elevated kidney enzymes, then later liver enzymes, low sodium. April 14 - decision to move to short term rehab for regular PT and OT. Continued swelling (fluid in third spaces.) April 21 - visit to cardiologist to perform cardioversion, successful (during first week of hospital stay, heart rhythm med had to stop). April 23 - facility nurse discovered significantly low Hemoglobin and a blood transfusion was ordered. April 24 - returned to short term rehab facility. April 25 - discovered my mother on O2 and state of health was different, extremely weak and not moving, arm hurting badly. I insisted that her oncologist is contacted. Transported to ER. Discovered her blood work abnormal. After stabilizing her, rushed to the hospital ICU. April 26 - Discussed with her ICU doctor the history of what you have read above. He explained that the covid-19 vaccination has a tendency to affect three proteins specifically that clot and thin blood. I begged him to "get it out of her system." Her bleeding was significant and platelets dropped, again. Still has her mental facilities. Responding well to aggressive treatment: albumin transfusion, plateletpheresis, and CRRT. Pleural catheter to remove fluid from the lungs. Mention of Sepsis. April 27 - Lifted her head up today, opened her eyes, making doctors very happy. Her cardiologist and the ICU doctor both said they were "confused" and everything happening to my mom was "a mystery." Though going in to the evening, her nurse expressed to me that she's worried. The ICU oncologist called me at home in the evening. He asked me if she had been having a fever on a regular basis. He said he thought it could be TTP or a rare disease called HTH, but both</p>

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							results wouldn't be back for one week. He planned to consult with a doctor. He explained to me that the blood was attacking itself and "confused," and that her organs were shutting down. He indicated that the blood work wasn't indicating significant infection. He referenced how the vaccination has made her auto immune system "go crazy." April 28 - I get a call very early from the nurse that she has been fighting with my mother's blood pressure all night, trying to keep it elevated. She told me to come to the hospital, because she had taken a turn for the worse. I arrive to find my mother's eyes wide open, breathing shallow, and blood pressure steady, but drops without assistance from medication. She continues to have her mental facilities. She passed away, organs shutting down, and blood pressure dropped.
1289335	5/5/2021	TX	69	F	2/1/2021	3/7/2021	Blood clot(s) thrown by heart, admitted to hospital 3/8/21. I was in atrial flutter at the time. Resulted in kidney infarction. Eventually heart reset itself, however with a five second pause, resulting in the need for a pacemaker. Also, now on Eliquis for life.
1289628	5/5/2021	MI	34	F	4/22/2021	4/24/2021	Patient received Pfizer vaccine 4/22/2021. She developed severe headaches 48 hours later. She has loss of balance and difficulty with fine motor skills. She presented to an ED. Neuroimaging detected significant central venous thrombosis. Admitted to hospital and started on anticoagulation therapy. Neurology and Hematology/Oncology consulted.
1289783	5/5/2021	OH	71	M	4/7/2021	4/29/2021	Developed COVID symptoms for a "few" days. Called his physician who referred him to the local hospital for suspected COVID. Tested positive for COVID at the hospital and blood clots in the lungs were discovered by CT scan. Patient was admitted to ICU for treatment. Details reported to VAERS by hospital and the Health District

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1289795	5/5/2021	CA	54	M	3/6/2021	3/8/2021	on 3/8/21 patient describes numbness which starts on left hip which goes down left leg. on 3/21/21 patient complains of 3 days of pain and swelling in left lower leg, calf, edema of the foot and ankle which is painful with movement. ultrasound negative. on 3/23/21 ultrasound shows Deep vein thrombosis is visualized in the left popliteal vein. progress note indicates no immobility or long car rides. No history of DVT or pulmonary embolus. Begin enoxaparin x5 days and then dabigatran.
1289927	5/5/2021	KS	78	F	4/12/2021	4/24/2021	Patient was discharged from the hospital after massive PE. She went to the hospital at 2am last Saturday. Patient described unbelievable pain from shoulder neck and arms. She could hardly walk to her car. Went to ER. There they ran tests and found many blood clots in lungs. Blood clots had stopped the blood in that area. They were not definitive but said it sounded like that. Got a breathing apparatus after because it's been hard to breathe and she has been shaky. Her shot was administered 04/12 during chemo. Hospital April 24. She was discharged and given a blood thinner and pain medication - Oxycodone & Eliquis.
1289024	5/5/2021	NY	57	F	4/2/2021	4/7/2021	5 days after shot, vision in left eye became blurry- went to primary eye doctors- sent to Surgeons- determined a blood clot in the back of the eye

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1288388	5/5/2021	TN	18	M	4/5/2021	4/13/2021	Developed two blood clots in my left calf; This is a spontaneous report from a contactable consumer, the patient. An 18-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot unknown, first dose) solution for injection intramuscular in the right arm on 05Apr2021 at 10:00 (at the age of 18-years-old) as a single dose for COVID-19 vaccination. Medical history included ADD (attention deficit hyperactivity disorder). Concomitant medication included mirtazapine (AVANZA). The patient had no known allergies. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient developed two blood clots in my left calf on 13Apr2021 at 14:00 which resulted in emergency room/department or urgent care visit. Treatment for the event blood clots included rivaroxaban (XARELTO). The outcome of the event blood clots was recovering. The patient was not tested for Covid post vaccination. Information on the lot/batch number has been requested.

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1287929	5/5/2021		47	F	4/5/2021		CAVERNOUS SINUS THROMBOSIS; THROMBOCYTOPENIA; COMPUTERISED TOMOGRAM HEAD ABNORMAL; FIBRIN D DIMER INCREASED; MAGNETIC RESONANCE IMAGING HEAD ABNORMAL; PLATELET COUNT DECREASED; VENOGRAM ABNORMAL; FULL BLOOD COUNT; This spontaneous report received from a patient via a Regulatory Authority VAERS (Vaccine Adverse Event Reporting System) and concerned a 47 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included aspirin allergy, and hypertension. On 31-MAR-2021, the patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose was not reported, administered in left arm for prophylactic vaccination. The batch number was not reported. The company was unable to perform follow up for Batch/lot numbers. The concomitant medications included unspecified natural pills. On 05-APR-2021, the patient was hospitalized for venous thrombotic cavern sinus and thrombocytopenia 25,000, computerised tomogram head abnormal, fibrin d dimer increased, magnetic resonance imaging head abnormal, and developed platelet count decreased, venogram abnormal. On 05-APR-2021, the subject experienced full blood count. The patient was hospitalized (date unspecified) for 12 days. The following laboratory data (dates unspecified) included: CT scan results not provided, Complete blood count results not reported, Fibrin D dimer was elevated (value not provided), MRI results were not reported and Venogram was abnormal. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the cavernous sinus thrombosis, thrombocytopenia, computerised tomogram head abnormal, fibrin d dimer increased, magnetic resonance imaging head abnormal, platelet count decreased, venogram abnormal and full blood count was not reported. This report was serious (Hospitalization Caused / Prolonged, and Life Threatening). This case version (1) was created on 30-APR-2021 for the purpose of quality improvement the following corrections were made. The MAC was added to the pharmacovigilance narrative.; Sender's Comments: V1: This spontaneous report received from a patient via VAERS (ID: 1238777) concerned a 47-year-old woman who experienced cavernous sinus thrombosis with

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thrombocytopenia 5 days after vaccine. Concurrent conditions included hypertension and concomitant medications included unspecified natural pills. Five days after vaccine, the patient was hospitalized for venous cavernous sinus thrombosis and thrombocytopenia (25,000) with an elevated D dimer (unspecified.) CT head and MRV were performed with results not provided. The patient was hospitalized for 12 days and treatment details were not provided. Based on evolving knowledge of Thrombosis with Thrombocytopenia Syndrome (TTS, per definition from Brighton Collaboration-BC), the low platelet count and temporal relationship to vaccination (BC Criteria level 1), the events are assessed to have a plausible relationship with vaccination. Reporter contact information was not provided which precludes meaningful additional information in this version.



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1287947	5/5/2021	OH	22	F	4/1/2021		SEVERE CHEST PAIN RADIATING TO LEFT ARM; HEARTBURN; NECK PAIN IN RIGHT SIDE RADIATED TO JAW AND EAR; PURPLE TOES; FEELING WORSE; LOSS OF APPETITE; NAUSEA; CHEST PAIN; LEG PAIN; HEADACHE; ABDOMINAL PAIN; LOWER BACK PAIN; DIARRHEA; SEVERE UNEXPLAINED ANXIETY; SHAKING; LOW GRADE FEVER; ARM PAIN; COLD FINGERS / COLD TOES; LOW VITAMIN D; ELEVATED BLOOD PRESSURE; This spontaneous report received from a patient concerned a 22 year old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808978, and expiry: 13-JUN-2021) dose was not reported, administered on 02-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On APR-2021, the subject experienced low vitamin d. On APR-2021, the subject experienced elevated blood pressure. On APR-2021, the subject experienced cold fingers / cold toes. Laboratory data included: Pain scale (NR: not provided) HEADACHE (6 on pain scale), RIGHT LEG PAIN ( 5 ON PAIN SCALE), CHEST PAIN (3 ON PAIN SCALE). On 02-APR-2021, the subject experienced arm pain. On 02-APR-2021, the subject experienced low grade fever. Laboratory data included: Body temperature (NR: not provided) 99 F. On 08-APR-2021, the subject experienced abdominal pain. On 08-APR-2021, the subject experienced lower back pain. On 08-APR-2021, the subject experienced diarrhea. On 08-APR-2021, the subject experienced severe unexplained anxiety. On 08-APR-2021, the subject experienced shaking. On 08-APR-2021, the subject experienced chest pain. On 08-APR-2021, the subject experienced leg pain. On 08-APR-2021, the subject experienced headache. On 09-APR-2021, the subject experienced loss of appetite. On 09-APR-2021, the subject experienced feeling worse. On 09-APR-2021, the subject experienced nausea. Laboratory data included: Blood test (NR: not provided) NORMAL, and CT scan (NR: not provided) NORMAL. On 10-APR-2021, the subject experienced neck pain in right side radiated to jaw and ear. On 10-APR-2021, the subject experienced purple toes. Laboratory data included: COVID-19 virus test negative (NR: not provided) NEGATIVE. On 13-APR-2021, Laboratory data included:

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Blood test (NR: not provided) LOW VITAMIN-D. On 14-APR-2021, Laboratory data included: COVID-19 virus test negative (NR: not provided) NEGATIVE. On 15-APR-2021, Laboratory data included: Ultrasound Doppler (NR: not provided) normal. On 16-APR-2021, Laboratory data included: COVID-19 virus test negative (NR: not provided) NEGATIVE. On 17-APR-2021, the subject experienced severe chest pain radiating to left arm. On 17-APR-2021, the subject experienced heartburn. Laboratory data included: Blood test (NR: not provided) NORMAL, CT scan (NR: not provided) NORMAL, and EKG (NR: not provided) NORMAL. Other relevant diagnostics included: Mono test on 10-apr-2021 result - negative D-dimer test for blood clot on 13-apr-2021 result - normal I. On 19-APR-2021, treatment medications included: omeprazole. On 26-APR-2021, Laboratory data included: Blood test (NR: not provided) NORMAL. Additional treatment medications (dates unspecified) included: paracetamol, pantoprazole, and prednisolone. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from diarrhea, and shaking on 15-APR-2021, loss of appetite, and nausea on 12-APR-2021, and arm pain, and low grade fever, had not recovered from headache, leg pain, severe chest pain radiating to left arm, and chest pain, and the outcome of abdominal pain, lower back pain, severe unexplained anxiety, neck pain in right side radiated to jaw and ear, purple toes, low vitamin d, elevated blood pressure, cold fingers / cold toes, feeling worse and heartburn was not reported. This report was non-serious.

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1288102	5/5/2021	NJ	67	F	4/19/2021	4/19/2021	<p>blood clot coming out of the mouth when coughing; Nose bleed; pain in her left arm; This spontaneous case was reported by a consumer and describes the occurrence of RESPIRATORY TRACT HAEMORRHAGE (blood clot coming out of the mouth when coughing) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. K10C) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 19-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Apr-2021, the patient experienced VACCINATION SITE PAIN (pain in her left arm). On an unknown date, the patient experienced RESPIRATORY TRACT HAEMORRHAGE (blood clot coming out of the mouth when coughing) (seriousness criterion medically significant) and EPISTAXIS (Nose bleed). At the time of the report, RESPIRATORY TRACT HAEMORRHAGE (blood clot coming out of the mouth when coughing) and EPISTAXIS (Nose bleed) outcome was unknown and VACCINATION SITE PAIN (pain in her left arm) had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No treatment information was provided. No concomitant medication was provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Reporter did not allow further contact. Most recent FOLLOW-UP information incorporated above includes: On 29-Apr-2021: patient's address was updated (changed), adverse events updated; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1288120	5/5/2021	CA	56	F	3/25/2021	3/25/2021	Chest Pain; Dry mouth; Could not start hydrated; This spontaneous case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest Pain) in a 56-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 008B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 25-Mar-2021 at 1:45 PM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Mar-2021, the patient experienced DRY MOUTH (Dry mouth). 25-Mar-2021, the patient experienced DEHYDRATION (Could not start hydrated). On 28-Mar-2021, the patient experienced CHEST PAIN (Chest Pain) (seriousness criterion hospitalization). The patient was hospitalized from 09-Apr-2021 to 10-Apr-2021 due to CHEST PAIN. On 10-Apr-2021, DRY MOUTH (Dry mouth) and DEHYDRATION (Could not start hydrated) had resolved. On 12-Apr-2021, CHEST PAIN (Chest Pain) had resolved with sequelae. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Apr-2021, Blood pressure measurement: 192/99 (abnormal) 192/99. On 09-Apr-2021, Troponin: elevated (Inconclusive) elevated troponin levels. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medications were not reported. On 25Mar2021, the patient reported initial minor side effects of dry mouth while sitting in her car, but no other noteworthy side effects immediately following injection. Then, 2 or 3 days later the patient experienced chest pain that she reported started out as very mild, however, it grew in intensity over the following weeks, and she presented to the Emergency Room (ER) on Friday, 09Apr2021 per the caller's estimation. Blood pressure taken at the ER was 192/99mmHg. Full hospital work-up performed with the patient noted that she was negative for blood clots but had elevated troponin levels. She said the hospital staff evaluated her heart's condition and found no sign of a heart attack. On 10Apr2021, she was discharged with a new prescription of metoprolol. On the Monday after discharge, the patient had felt symptoms of chest pain again along with elevated blood pressure levels, so she returned to the ER where she was discharged without hospitalization

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and given a clonidine patch for any future blood pressure fluctuations. Since then she had visited her Cardiologist and he has substituted her prescription metoprolol for amlodipine and losartan combination therapy, and to discontinue her prescription for clonidine patches. Patient indicated her cardiologist is hopeful that her blood pressure should normalize over time and instructed patient not to receive her second dose of the vaccine. Additionally, patient reported that, from the time she received her vaccination, until she was discharged, she could not start hydrated. She reported drinking large quantities of water, electrolyte replacement liquids, and Gatorade with no success. Event of chest pain was resolved with Sequelae of elevated blood pressure. Treatment included clonidine patches and metoprolol. On an unspecified date, the clonidine patches and metoprolol were stopped and amlodipine and losartan combination therapy was started.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1288125	5/5/2021	NY	50	F	1/16/2021	1/18/2021	<p>Back pain have been severely bad after she took both doses; Arthritis have been severely bad after she took both doses; Drug Rash; Diagnosed with DVT; This spontaneous case was reported by a consumer and describes the occurrence of DEEP VEIN THROMBOSIS (Diagnosed with DVT) in a 50-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 11020A and 004M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Arthritis, Migraine and Back pain. Concomitant products included GALCANEZUMAB (EMGALITY [GALCANEZUMAB]) for Migraine. On 16-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 18-Jan-2021, the patient experienced DEEP VEIN THROMBOSIS (Diagnosed with DVT) (seriousness criterion medically significant). On an unknown date, the patient experienced BACK PAIN (Back pain have been severely bad after she took both doses), ARTHRITIS (Arthritis have been severely bad after she took both doses) and DRUG ERUPTION (Drug Rash). At the time of the report, DEEP VEIN THROMBOSIS (Diagnosed with DVT), BACK PAIN (Back pain have been severely bad after she took both doses), ARTHRITIS (Arthritis have been severely bad after she took both doses) and DRUG ERUPTION (Drug Rash) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. After getting the first shot on 16 Jan2021, she was diagnosed with DVT on 18 Jan 2021 and has been on blood thinner ever since then. She also takes Emgality, a migraine injection every month. She states that ever since she received the vaccine and has been put on blood thinner, she gets rash every month when she take Emgality injection. She also reported that her underlying conditions like back pain and arthritis have been severely bad after she took both doses of the vaccine. Patient is going to speak with her doctor first thing in the morning tomorrow. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot</p>

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1288280	5/5/2021			F			<p>be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> <p>he passed out/fell out during court; covid-19; diarrhea; This is a spontaneous report received from a contactable consumer. A 61-year-old female consumer (patient) reported for herself that she received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; Lot number: unknown) via an unspecified route at a single dose for COVID-19 immunization. The patient had a history of shortness of breath often, had fatigue, muscle and body ache and headache, loss of taste and smell not that one. People had told her that so many people have died from it from blot clots. She also had a history of irritated bowel syndrome and had these side effects because she went through it anyways. She had a history of anxiety but had not had an attack in a long time. The patients niece broke out in hives (she did not know which vaccine). She had been high step and said that she was a hand washer at a restaurant and once she was done and got home and it started piling up at the end of the day when she layed down. She had heard that people were having heart attacks so must take a baby aspirin. The patients concomitant medications were not reported. After receiving the vaccine she passed out/fell out during court. Some people told her that some costumers died of covid 19 infection. On an unknown date she had covid-19 (she and her husband had covid and both got vaccinated with both shots) and had diarrhea for a month and got over. Someone had told her that they would chip her. The outcome of events was unknown for passed out and Covid-19 and recovered on unspecified date for diarrhea. Information about the Lot/batch number has been requested.</p>

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1288353	5/5/2021	CA	83	F	2/22/2021	3/12/2021	may be blood clot; Something happened with my knee and it has just got worse; I was thinking maybe it is a pulled muscle or something but it is very bad now; This is a spontaneous report received from a contactable consumer (patient). An 83-year-old female patient (5 feet 1 inches, about 120 pounds) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EN6198, patient was not sure) via an unspecified route of administration at left arm on 22Feb2021 (83-year-old at time of vaccination), at single dose; the second dose of BNT162B2 (lot number: unknown) via an unspecified route of administration on 15Mar2021 (83-year-old at time of vaccination), at single dose, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Patient stated she has got both the shots of Pfizer (Covid-19 vaccine) and at the end of the first one or it is like eighteen days, just before the second shot, something happened with her knee and it has just got worse (from 12Mar2021). She did not connect that with the Pfizer shot and I was thinking maybe it is a pulled muscle or something but it is very bad now. She would like to know what she can do. Also, she is thinking may be blood clot at this point and she would like to have it checked. She thinks that she should be able to contact somebody to actually get some physical test on this. She tried heat and cold alternate and Absorbine Jr. and Aspirin. It varied with the days, she thinks she has taken Aspirin about twice a day and it is a tablet and it was 325 mg and she took two of those, orally. Therapeutic measures were taken as a result of the event and included "heat and cold alternate and Absorbine Jr. and Aspirin". The outcome of the event was not recovered. Information on the lot/batch number has been requested.



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1288355	5/5/2021	NC	81	F	2/10/2021	2/10/2021	Blood clot in lungs and leg; Trouble breathing/Shortness of breath, but not as bad; didn't feel right; Chest tightness; Slightly ill; Sore arm, in left arm where the shot was; Slightly tired; This is a spontaneous report from a contactable consumer. An 81-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in the left arm on 10Feb2021 (Batch/Lot Number: EN6201) as SINGLE DOSE for covid-19 immunization. Medical history included Type 2 Diabetes from 2004 and ongoing, High Blood Pressure from 2000 and ongoing (reporter stated she was 81; it's not very high, usually when she goes to the doctor). Concomitant medications not specified but reporter mentioned that everything she has been on she has been on long time; she takes blood pressure medication because sometimes it is high. She has not had started any new medication prior to starting vaccines or during both vaccines. The patient previously received flu shot (September). The patient received her first vaccine dose of bnt162b2 (Lot # EL9262, Expiry date UNKNOWN), on 20Jan2021, at 1:30-1:45, in the left arm and experienced sore arm and slightly tired. The reporter stated that after her second vaccine on 10Feb2021, she had a sore arm, (left, where shot was) and was slightly tired from 10Feb2021 until 12Feb2021. She confirmed she noticed this started the same day, 10Feb2021. On 31Mar2021, she felt slightly ill and had some slightly trouble breathing. She saw her doctor who did some tests. The next day 01Apr2021, her tests came back and the doctor told her to go to the hospital. While in the emergency room she had a CT of the lungs that showed blood clots in both lungs. She was admitted to the hospital where on 02Apr2021 they did a ultrasound of her legs. She was told she had blood clots in her right leg. She stated she had no symptoms of blood clots in her legs like redness, sore, swelling, or hot. She was asked if she had fallen suddenly, had an accident, or was sitting for a long time, traveled a long distances. On 02Apr2021 she had a Echocardiogram and was told her heart was ok. Caller stated she was given Lovenox shots in the hospital. She did not have Lot # or Expiry date on the Lovenox. She stated on 02Apr2021 after having two Lovenox shots that day, she met with a Vascular Surgeon who started her on Eliquis that evening. She

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							<p>stated she started taking Eliquis that evening. She stated she took 2 tablets, twice a day, for a week. Now she takes one tablet, twice a day, ongoing. The Eliquis tablet says 5mg. She stated she was discharged on 03Apr2021, that evening. Patient went back to the emergency room on 10Apr2021 after speaking with a nurse at (university name withheld) because she had tightness in the chest but the shortness of breath, her breathing was not as bad. She just didn't felt right. She stated she was not admitted. Patient stated she saw a NP (name withheld) with (university name withheld) Pulmonary the day of 31Mar2021. When discussing the tests performed that day, Chest X-ray, D-Dimer, and Pro INT, CH asked caller the results from them. She did not provide results, just stated she had looked up her results in "EPIC mychart" while getting the result information from the office. Where she was instructed to go to the hospital. She went to the Clinic of the Vascular Surgeon at (Hospital withheld) on Wednesday 14Apr2021 and was feeling better. Her second appointment with them will be in July. Where they will do another ultrasound of her legs and talk about the medication. She has an appointment with her primary on 19Apr2021. The outcome of events Trouble breathing (recovered on 14Apr2021), Shortness of breath, but not as bad (recovered on 12Apr2021), Sore arm, in left arm where the shot was (recovered on 12Feb2021), Slightly tired (recovered on 12Feb2021) Chest tightness (recovered on 12Apr2021), and didn't feel right was recovered. The outcome of event Blood clot in lungs and leg was unknown.</p>
1291252	5/5/2021	MN	22	F	4/10/2021	4/12/2021	<p>abnormally sever abdominal cramping began afternoon of 4/12/21; felt more painful than appendix bursting (~3/2015); later began menstrual bleeding, despite being on birth control with no expected period for 2 weeks (never spotted/broke through on this form of birth control in ~9 months of taking); had full period over week of 4/12-20/2021 with unusually heaving bleeding, several large clots (~diameter of quarter) and painful cramping</p>

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1288373	5/5/2021	TX	40	F	3/15/2021	3/15/2021	vaginal bleeding/blood clots at mid-cycle; vaginal bleeding/blood clots at mid-cycle; vaginal bleeding/blood clots at mid-cycle; This is a spontaneous report from a contactable consumer. A 40-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) lot number: EN6206, via an unspecified route of administration, administered in left arm on 15Mar2021 10:30 as single dose for Covid-19 immunisation. Medical history included folate deficiency and allergies to sulfa. There were no concomitant medications. After the first dose on 15Mar2021, the patient had vaginal bleeding/blood clots at mid-cycle. No treatment information was provided. The outcome of the events was not recovered.; Sender's Comments: Based on temporal association reported events causal relationship with BNT162B2 cannot be excluded. Case to be re-assessed upon receipt of new information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

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1288434	5/5/2021	OK	38	M	2/9/2021	2/11/2021	Cellulitis of the leg; This is a spontaneous report from a contactable physician. A 38-year-old male patient received first dose of BNT162B2 (Lot/batch number and expiry date was not reported), via an unspecified route of administration on 09Feb2021 as a single dose for COVID-19 immunization. Medical history included ongoing eczema (Topical steroids), deep vein thrombosis (DVT) since 10 years ago and stopped 6months after treatment, Fasciotomy for compartmental syndrome s/p gunshot wound (Stop date: After surgery) and ongoing Allergies (PRN medication), all on an unknown dates. Patient has history of gunshot wound subsequent compartment syndrome of DVTs status post treatment 10 years ago of the left lower extremity. Family medical history of gunshot wound of compartment syndrome DVT on this side following. Patient had cellulitis of the leg 1 month prior to "11Feb". The patient experienced cellulitis of the leg on 11Feb2021. The outcome of the event was recovered on an unknown date. The physician reported that the patient provided information regarding the reported adverse event with the use of the product. The physician considered that the Pfizer vaccine had no causal effect to the adverse event. The following information on the lot/batch number has been requested.; Sender's Comments: Based on information provided, the event cellulitis is an inter-current condition, thus unrelated to the suspect drug.

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1288390	5/5/2021	PA		F	4/16/2021	4/1/2021	<p>passing blood clots/having a total of 4 of them she has passed/noticing one when she went to the bathroom to urinate; she went into the bathroom and wiped, without actually going to the bathroom, she noticed the blood clot(s); felt like she needed to go to the bathroom/felt weird like something needed to come out; headache; dizziness; hot and cold sweats; This is a spontaneous report from a contactable consumer (who is also the patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date not reported), via an unspecified route of administration, on 16Apr2021, as single dose, for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. In Apr2021, after the first vaccination, the patient experienced "some of the usual side effects" described further as headache, dizziness, and hot and cold sweats. On 18Apr2021, 2 days after the first vaccination, the patient experienced passing blood clots having a total of 4 of them she has passed. She reported noticing one when she went to the bathroom to urinate. For the other blood clots, she reported it felt like she needed to go to the bathroom further described as "felt weird like something needed to come out." When she went into the bathroom and wiped, without actually going to the bathroom, she noticed the blood clot(s). The outcome of the events was unknown. No follow-up attempts are needed; information about lot/batch number cannot be obtained.</p>

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1288398	5/5/2021	PA	36	F	4/13/2021	4/14/2021	superficial thrombophlebitis clot behind left knee; chills; headaches; This is a spontaneous report from a contactable consumer reporting for herself. A 36-years-old female patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in the Left Arm on 13Apr2021 11:45 (Batch/Lot Number: Ew0162) as single dose for covid-19 immunisation . The patient medical history was not reported. Concomitant medication(s) included hydroxychloroquine (HYDROXYCHLOROQUINE) taken for an unspecified indication, start and stop date were not reported; sertraline hydrochloride (ZOLOFT) taken for an unspecified indication, start and stop date were not reported. The patient experienced superficial thrombophlebitis clot behind left knee on 14Apr2021 with outcome of recovering , chills on 14Apr2021 with outcome of recovering , headaches on 14Apr2021 with outcome of recovering. The reported events were considered serious because caused the patient to visit Emergency room/department or urgent care. Follow up information has been requested. Lot number has already been provided.

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1288411	5/5/2021	TX	56	F	4/12/2021	4/18/2021	sustain cramps in her right leg; limited range of motion; not sure if there was a nerve that has been damaged or early stage of thrombosis; not sure if there was a nerve that has been damaged or early stage of thrombosis; severe arm pain; This is a spontaneous report from a contactable consumer reporting for herself. A 56-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number/expiration date: not provided), via an unspecified route of administration, on 12Apr2021 at 09:30 (at the age of 56 years old) as a single dose in the right arm for COVID-19 IMMUNIZATION. Relevant medical history and concomitant medication was none. The patient did not have any known allergies. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not pregnant at the time of vaccination. On 18Apr2021 at 18:00, the patient experienced severe arm pain that was described as arm pain was too painful and have been woken up out of her sleep and she has limited range of motion and she was not sure if there was a nerve that has been damaged or early stage of thrombosis. On 20Apr2021, the patient experienced sustain cramps in her right leg. The patient did not receive treatment for the events. The outcome of the events was not recovered. Since the vaccination, the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.

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1288414	5/5/2021	PA		M	4/9/2021	4/11/2021	<p>bilateral pulmonary embolism; right DVT; sinus tachycardia; Afib with RVR.; This is a spontaneous report from a contactable physician. This report was received via a sales representative. A 68-year-old male patient received BNT162B2 (Pfizer COVID vaccine), dose 2 via an unspecified route of administration on 09Apr2021 (Batch/Lot Number: Unknown) as single dose for Covid-19 immunisation. Medical history included hypertension, gastroesophageal reflux disease (GERD), and deep vein thrombosis (DVT) original diagnosis from Jan2018. The patient previously received the first dose of BNT162B2 on 19Mar2021 for Covid-19 immunisation. The physician reported the patient had bilateral pulmonary embolism and a right DVT on 11Apr2021. The patient went to the ER on 11Apr2021. She confirms the pulmonary embolisms and the DVT were diagnosed 11Apr2021 when the patient went to the ER. She has more of the patient's story, caller does not think this would be linked to the vaccine but that is for someone else to decide she is reporting. The day of the event the patient's heart was racing, he passed out and went to the ER, he had sinus tachycardia and Afib with RVR (date/s unspecified). His heart rate was up to 140s and 150s. The patient has history of hypertension, GERD, and previous DVT, the original DVT that patient had was diagnosed in Jan2018 and he was placed on Xarelto at that time and he was on Xarelto until Jun2019. He has not been on anything for this since that time, until this episode. Caller says reporter did not provide any specific treatment information that the patient has received for the event she is reporting. Reporter provided the patient went to the emergency room, he did not say if the patient was admitted or had hospitalization. The outcome of events was unknown. Information about the Lot/batch number has been requested.; Sender's Comments: Drug causality would seem unlikely for BNT162B2. The reported events may be regarded as natural progression of patient's pre-existing conditions. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Committees and Investigators, as appropriate.</p>



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1288420	5/5/2021	MI		U			clots; I received the pfizer vaccine and within 2 weeks had bruising; low platelets; This is a spontaneous report from a contactable consumer, the patient. This patient of unspecified age and gender received BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: UNKNOWN) via unspecified route on unspecified date as a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient reported that he/she received the vaccine and within 2 weeks had bruising, low platelets and clots (unspecified date). Lab data included platelets: low on unspecified date. The clinical outcomes of bruising, low platelets and clots were unknown. The lot number for the vaccine, BNT162b2, was not provided and will be requested during follow up.

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1288423	5/5/2021			F			<p>Blood clots in her nose; Nose bleed; her arms are both numb on her; Couldn't move them; She feels lethargic; This is a spontaneous report from a contactable consumer (patient herself) via a medical information team. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that, enquired have people died from the vaccine or not. Enquired what do you know about the news in the media about reports of death in nursing home elderly patients. Response: Pfizer and BioNTech are aware of reported deaths following administration of Pfizer-BioNTech COVID-19 vaccine . We are working with the (withheld) to gather all the relevant information. (Withheld) Authorities have prioritized the immunization of residents in Nursing Homes, most of whom are very elderly with underlying medical conditions and some which are terminally ill. (Withheld) confirm the number of incidents so far was not alarming, and in line with expectations. All reported deaths would be thoroughly evaluated by (Withheld) to determine if these incidents are related to the vaccine. (Withheld) Health Authorities have now changed its recommendation in relation to vaccination of the terminally ill (Clinical Frailty Scale 8 or higher). Our immediate thoughts are with the bereaved families. The Global Advisory Committee on Vaccine Safety (GACVS) COVID-19 Vaccine Safety subcommittee met virtually on Tuesday, 19Jan2021, to review available information and data on deaths reported in frail, elderly individuals who had received the Pfizer BioNTech COVID-19 mRNA vaccine, BNT162b2 (hereafter, BNT162b2). Experts invited from the (Withheld) and the (Withheld) provided an overview of deaths reported in (Withheld) and in the WHO global database (VigiBase) following vaccination with BNT162b2." Based on a careful scientific review of the information made available, the subcommittee came to the following conclusions: The current reports do not suggest any unexpected or untoward increase in fatalities in frail, elderly individuals or any unusual characteristics of adverse events following administration of BNT162b2. Reports are in line with the expected, all-cause mortality</p>

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rates and causes of death in the sub-population of frail, elderly individuals, and the available information does not confirm a contributory role for the vaccine in the reported fatal events. In view of this, the committee considers that the benefit-risk balance of BNT162b2 remains favourable in the elderly, and does not suggest any revision, at present, to the recommendations around the safety of this vaccine." Enquired what was the efficacy after one dose. Caller had a terrible experience after her first dose of the Pfizer BioNTech COVID19 vaccine. She had blood clots in her nose, every time she blew her nose, blood clots would come out. She never had a nose bleed before. She also added that her arms are both numb on her. She couldn't move them, she feels lethargic. She's supposed to get her second dose next Friday. Enquired do we have any information regarding blood clots or not. Caller was upset and disconnected the call before some of the answers were given. Caller also asked the following questions: Has there been deaths reported from the vaccine or not, what was the efficacy after 1 dose, any guidance on getting the second dose after having side effects after the first dose. Response: Proposed response : CONS-Blood clots. Caller said "this was ridiculous" when I tried providing her with a long website with more information. She feels like we are withholding information from the public. She thinks the deaths should have been on the media. Caller hung up. Enquired do you have any guidance on getting the second dose after having side effects with the first dose. I had a side effect after the first dose of the vaccine. Should I get the second dose or not. Caller disconnected before agent could provide response. Response: Proposed response: As noted in the Fact Sheet for Recipients, you should not get the Pfizer-BioNTech COVID-19 Vaccine if you had a severe allergic reaction after a previous dose of the vaccine or if you had a severe allergic reaction to any ingredient of the vaccine. The decision to receive the second dose for any other reason could not be made by Pfizer. We refer you to speak to your healthcare provider about the risks of the vaccine compared to the risks of potentially not being fully protected against COVID-19 infection. Your healthcare provider knows your health situation and has access to information that can better help inform this decision. The outcome of the events was unknown. No follow-up attempts are needed. Information

*VAERS\_ID RECVDATE STATE AGE\_YRS SEX VAX\_DATE ONSET\_DATE SYMPTOM\_TEXT*

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about lot/batch number cannot be obtained.

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1288429	5/5/2021	CA	54	F	3/29/2021	3/29/2021	I went back to the hospital and couple days later they told me that actually I have Deep vein thrombosis now in my legs; my Crohn's had caused really bad flare up/I have been in the hospital for 5 days now with the clot and Crohn's Flare; I also have superficial clot in that left leg that was the pain began on the edges/blood clot; the arm is much better now. You know that's not really sore; I just was too tired/extreme fatigue; really bad like pain; Shortness of breath; This is a spontaneous report received from a contactable consumer (patient). A 54-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Right on 29Mar2021 (Batch/Lot Number: EN6201) as SINGLE DOSE for covid-19 immunisation. Medical history included multiple sclerosis from an unknown date and unknown if ongoing, ileostomy from an unknown date and unknown if ongoing, back surgery from an unknown date and unknown if ongoing, Crohn's disease from an unknown date and unknown if ongoing, blood clot in arm back from 2014 to an unknown date. Historical vaccine included BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 1 on 08Mar2021 and experienced terrible diarrhea and neuralgia. Concomitant medication(s) included gabapentin (GABAPENTIN) taken for an unspecified indication, start and stop date were not reported; valaciclovir hydrochloride (VALTREX) taken for an unspecified indication, start and stop date were not reported; diazepam (DIAZEPAM) taken for an unspecified indication, start and stop date were not reported; (ZOFRAN) taken for an unspecified indication, start and stop date were not reported; oxycodone (OXYCODONE) taken for an unspecified indication, start and stop date were not reported; lansoprazole (PREVACID) taken for an unspecified indication, start and stop date were not reported. After second dose on 29th (29Mar2021) immediately he was really bad like pain and had shortness of breath. The patient stated that she had a back surgery and so she always felt bad, so she didn't think anything of it. But then she ended up into ER after the second dose and discovered that her Crohn's had caused really bad flare up. She mentioned her foot was looking strange but she was just too tired and left the ER. She then went back to the hospital and couple days later they told her that she actually had deep

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1288432	5/5/2021	NV		F			<p>vein thrombosis now in her legs. She also had superficial clot in that left leg where the pain began on the edges. The patient reported that the vaccine was basically started the Crohn's flare up. The patient also stated that "the arm was much better now and not really sore". The patient was hospitalized for DVT from unknown date and for Crohn's flare up for 5 days. The patient underwent lab tests and procedures which included endoscopy, sigmoidoscopy, ultrasound scan: all on unknown date with unknown result. The patient was treated with Entyvio and on blood thinners now for a blood clot. The outcome of pain in extremity was recovering while others was unknown.</p> <p>My grandma got a PFIZER COVID VACCINE and has now experienced a blood clot that caused a stroke.; My grandma got a PFIZER COVID VACCINE and has now experienced a blood clot that caused a stroke.; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot number unknown), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunization. The patient's medical history was not reported. The patient's concomitant medications were not reported. The reporter stated that "my grandma got a pfizer covid vaccine and has now experienced a blood clot that caused a stroke." The patient experienced a cerebrovascular accident on an unspecified date with outcome of unknown and thrombosis on an unspecified date with outcome of unknown. No further information was provided. Information on the Lot/Batch number has been requested.</p>

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1288357	5/5/2021	OH	92	F	2/21/2021	2/1/2021	condition aggravated; Breaking out in my auto-immune; since February and all through March until today has broken out into red welts; This is a spontaneous report from a contactable consumer. A 92-years-old female patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in right arm on 21Feb2021 at 12:30 (Batch/Lot Number: EN6201; Expiration Date: 30Jun2021) as a single dose for covid-19 immunisation. First dose: Date: 24Jan2021; Lot Number: EL9261; Expiry Date: 31May2021; Anatomical Location: Right arm. Medical history included neuropathy in hands for 3 years at least , ongoing autoimmune disorder she was diagnosed with the auto-immune condition at least 5 years ago. Concomitant medications included quinapril (QUINAPRIL) taken for high blood pressure for at least 5 years; apixaban (ELIQUIS) taken for blood clots in lungs for at least 5 years and ongoing; vitamin d3 (VITAMIN D3) for at least 5 years taken to keep bones in order and ongoing; prednisone (PREDNISONE) taken for autoimmune condition, for about 5 years, start and stop date were not reported and gabapentin for at least 5 years. The patient reported that she has been vaccinated with the Pfizer Covid-19 vaccine and that she has received both doses. Patient reported that she has the auto immune system and that since Feb2021 when she had her Covid-19 vaccine, she has been broken out. Patient reported that she wanted to know if there was a possible relation between getting the Covid-19 vaccine and breaking out in her auto-immune. Patient reported that the red welts have come out on different parts of her body since Feb2021. Patient reported that she has had the welts on her neck and on her face. Patient reported on 19Apr2021, she was breaking out in welts on her arms. Patient reported that she has had welts behind her legs and that the welts break out anywhere. Patient reported that the welts are just ongoing. Patient reported that the welts are breaking out the same as when they first started. The patient was not hospitalized for the events. The outcome of the welts was not recovered and remaining events was not reported. Follow-up attempts are completed. No further information is expected.

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1291268	5/5/2021	OH	59	M	3/22/2021	3/26/2021	<p>This is a spontaneous report from a contactable consumer (patient). A 59-year-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8732) at the age of 59-years-old, via an unspecified route of administration in left arm on 22Mar2021 at 15:00 at single dose for COVID-19 immunisation. The patient's medical history was reported as none. He has no known allergies and has COVID prior to vaccination. Concomitant medications included metoprolol, rosuvastatin, oxybutynin, and tamsulosin. There were no other vaccines in four weeks and no additional vaccines administered on the same date of the COVID-19 vaccine. The patient reported that he was having some wild effects from the vaccine and did not know what to do. On 26Mar2021 at 15:00, he was having neuropathy like effects. His hands, arms, legs, and feet were experiencing pain and burning sensations, they were burning like nerve damage; he also has a little burning sensation in his nose and cheeks. He has never had this before. The events resulted in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. He was also having some weird sensations in his calf muscles, these sensations started within the past week and a half (Apr2021) which prompted physician office visit. The physician placed him on gabapentin 100 mg to start from 12Apr2021, but it was not enough, it was titrated up to 300 mg, three times a day and he is scheduled to see specialist soon. The patient mentioned that this vaccine has ruined his health. He also went to an urgent care center because his leg was bothering him, it was swelling on an unspecified date in 2021; he thought he had a blood clot; they did some kind of test where they looked at the leg and did not find anything. He didn't have a particular question. He would just like to talk to someone to see if this was going on with anyone else, if it will go away, or if this was permanent problem he will have. The patient was not tested for COVID post vaccination. He received his second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0161), via an unspecified route of administration in left arm on 13Apr2021 at 15:00 at single dose for COVID-19 immunisation. The outcome of the events was not recovered.</p>



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1290108	5/5/2021	SC	59	F	3/13/2021	3/14/2021	Left knee was swollen, bright red, and extremely painful the day after the vaccine. Patient thinks she had a clot, even though she stated she was on a blood thinner. Symptoms resolved naturally by the next day.

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1291184	5/5/2021	AZ	46	M	4/18/2021	4/19/2021	<p>This is a spontaneous report from a contactable consumer (patient's fiancé). A 46-year-old male patient received the first dose bnt162b2 (BNT162B2), via an unspecified route of administration, administered in Arm Left on 18Apr2021 11:20 (Lot Number: EW0162) (received at the age of 46-years-old) as SINGLE DOSE for COVID-19 immunisation. Medical history included right knee pain. Concomitant medications were not reported. The patient received the Pfizer 1st shot 18Apr2021 11:20 am. On 19Apr2021, at midnight, he had low grade fever then swelling right leg. On the day of the report, 20Apr2021, he had swelling to both legs. The patient had taken ibuprofen as treatment beside propping legs up. The reporter wanted more information on the swelling and if it's related to taking ibuprofen. It was further reported that the patient experienced severe swelling from the knees down to the calves on both legs on 19Apr2021. He also experienced night sweats, fever, lightheadedness and dizziness on 19Apr2021. They want to know if there are any reports regarding the swelling side effects and if it is from the vaccine. The first dose of the vaccine was given 2 days ago (18Apr2021) and the second dose is due on 09May2021. The patient got his first shot on 18Apr2021 about 11:20am. After about 15 hours he developed swelling in one leg, she later clarified this to be his right leg, and now reports that both of his legs are swollen at the time of report (20Apr2021). She noted that patient told her his legs are not painful. She doesn't know if it's a blood clot or if they needed to go to the hospital. She also wanted to know if there is information about this as a side effects or if other people are having this too. She then reported that the patient started experiencing a fever, profuse sweating, and was spacey about 12 hours after the vaccine, a little after midnight 19Apr2021. She doesn't know if the dehydration made it worse. His fever was low-grade 99.8 degrees and lasted 4 and a half to 5 hours and has now resolved. When asked if patient received any treatment for fever, caller said it was so recent, and that was listed as a common side effect that goes away. Reported the patient drank fluids and she kept an eye on him. Leg swelling was about 15 hours after the vaccine, early morning 19Apr2021. She noted that the swelling in the right leg got bigger and didn't go down, but the left leg did. But today the left was more swollen and more</p>

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prominent today. She further clarified that the patient takes ibuprofen for pre-existing right knee pain. Caller also reported that the patient propped his legs to alleviate the swelling, it has improved some but the swelling did not go away. The adverse events did not require a visit to the physician office or emergency room. Outcome of the event fever was resolved on 19Apr2021 (lasted 4 and a half to 5 hours); outcome of the event "severe swelling from the knees down to the calves on both legs" was not resolved; outcome of the remaining events was unknown.

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1291312	5/5/2021	OH	46	F	2/5/2021	2/5/2021	Throwing up; nausea; chest pain & tightness to the point I could not move my arm to use my emergency inhaler prescribed after COVID/ I couldn't move; tremor increased; post COVID syndrome & orthostatic hypertension.; post COVID syndrome & orthostatic hypertension.; Lymph node pain; Tilt Table Testing confirmed Covid-induced POTS; mild injection site pain; COVID symptoms in same order as the Oct2020 COVID (upper respiratory, less intense headache, shortness of breath, chest pain); COVID symptoms in same order as the Oct2020 COVID (upper respiratory, less intense headache, shortness of breath, chest pain); COVID symptoms in same order as the Oct2020 COVID (upper respiratory, less intense headache, shortness of breath, chest pain); COVID symptoms in same order as the Oct2020 COVID (upper respiratory, less intense headache, shortness of breath, chest pain); chest pain & tightness to the point I could not move my arm to use my emergency inhaler prescribed after COVID; dizzy; Fatigue; vasovagal response; Passed out; This is a spontaneous report from a contactable other health professional (patient). A 46-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in arm left on 05Feb2021 at 10:30 (Lot Number: EL9261) (at the age of 46-year-old) as single dose for COVID-19 immunisation. The patient was not pregnant. Medical history included infectious mononucleosis (Recent mono) in 2020 (Spring), urinary tract infection (UTI) in 2020 (Summer), venous Insufficiency on Dec2020, shingles in past on an unspecified date, lactose & gluten intolerance from an unknown date and unknown if ongoing, COVID-19 from Jun2020 to an unknown date (I had recovered from mild COVID in Jun and Oct2020 that required no hospitalization and was managed with DAYQUIL, XYZAL, Prednisone, Vit D and melatonin). Concomitant medications included ibuprofen at 2400 mg and 800 mg; pregabalin (LYRICA); progesterone; bifidobacterium bifidum/bifidobacterium lactis/bifidobacterium longum/lactobacillus acidophilus/lactobacillus rhamnosus (PROBIOTIC), all concomitants were taken for an unspecified indication, start and stop date were not reported. The patient experienced mild injection site pain, COVID symptoms in same order as the Oct2020

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COVID (upper respiratory, less intense headache, shortness of breath, chest pain), dizzy, fatigue, vasovagal response, passed out, nausea, throwing up, tremor increased, chest pain & tightness to the point I could not move my arm to use my emergency inhaler prescribed after COVID/ I couldn't move, post COVID syndrome and orthostatic hypertension, tilt table testing confirmed COVID-induced POTS (postural orthostatic tachycardia syndrome) and lymph node pain, all on 05Feb2021 at 11:00. All events were serious disabling and required hospitalization. The patient underwent lab tests and procedures which included computerized tomogram (CT): unknown results on an unspecified date, D-dimer: 1300 is very elevated, it shows that I have a lot of inflammation in my body or I could have the clot, 1300, almost 3 times the normal value; magnetic resonance imaging head (MRI): unknown results on an unspecified date, SARS-COV-2 test (nasal swab): negative on 19Feb2021, tilt table test: COVID-induced pots on 05Feb2021 . Unspecified therapeutic measures were taken as a result of the events. The patient outcome of the event passed out was unknown and not recovered for all the other events.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of reported events cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1291246	5/5/2021	MO	65	F	3/9/2021	3/17/2021	leg was bruised; heart spasms; Diarrhea; inflammation along the major vein in her leg; heart palpitation; light headed/dizzy; severe muscle pain; tenderness and soreness in her inner thigh of the left leg/throbbing pain; Chills; This is a spontaneous report from a contactable consumer (patient, self-reported). A 65-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EN6208), via an unspecified route of administration in unspecified arm on 09Mar2021 (12:00) at single dose for Covid-19 immunization. The patient's medical history included ongoing hypothyroidism. Concomitant medication included levothyroxine been taking for 10-11 years for hypothyroidism. On 17Mar2021, Wednesday, the patient received the vaccine and had chills. On 18Mar2021, the patient had tenderness and soreness in her inner thigh of the left leg. On 19Mar2021, the patient had severe muscle pain on her calf of leg to inner thigh and it was throbbing so bad behind her knee on her left leg that she called her physician, and a sonogram was performed on 23Mar2021 which had found there was not a blood clot but there was severe inflammation along the major vein in her leg. On 20Mar2021, the patient had heart palpitation, her doctor told her to drink water and propel, she had heart spasms for 6 hours and felt lightheaded and dizzy. she thought she would go to the hospital, but she lives in a rural community and felt it did not make sense to go to the hospital. Palpitations and tenderness recovering. Her doctor and she was put on a heart monitor for her heart palpitations. She had heart palpitations with her hypothyroid but, this was totally different when she has had heart palpitations in the past. On an unknown date in Apr2021, the patient had diarrhea for 6 days. Patient had not been back to the doctor, but the nurse thought it was ok for her to take the second vaccine, but the patient was not comfortable with it. No prior vaccinations within the week. The patient never taken the flu shot. She had never received the flu vaccine or pneumonia nothing, so this was new for her getting the COVID vaccine. Caller clarified the chills started the week after she received the vaccine on Wednesday 17Mar2021. Severe muscle pain: Caller stated this happened on the 19, 20, 21, and 22 as well as the throbbing pain and then the next day on Monday

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22Mar2021 she went to call her doctor and had a sonogram that next day on Tuesday (23Mar2021). Caller stated she still had the muscle pain in her left leg on the inner thigh but it was more so when she was active and once in a while she felt like her leg was bruised for a day or two but then it went away and she did not have a blood clot. Left leg throbbing: Caller stated this continually got worse and then on Sunday she felt so bad she laid in bed with her knee up and it throbbed like crazy. Caller stated this stopped about 2 days after she got the sonogram and it was not that severe it was just really tender and sore. Heart palpitation: Caller clarified that the heart murmurs she referred to earlier was actually heart palpitations. Caller stated this started at 8 in the morning and then at 10 in the morning she started getting light-headed and thought about going to the emergency room and figured no she will get through this. Caller stated she called her physician for the heart palpitations on Monday and she saw her doctor the following Tuesday and that is when her doctor had given her the heart monitor. Caller stated for 6 hours she felt horrible on Saturday since she knows the difference from her normal heart palpitations from her thyroid. Diarrhea: Caller stated this last for 6 days and was last week or so. Treatment: Caller stated no she is not a medicine taker she does not even take Tylenol or Advil unless it is a necessity. Outcome of the event: Chills recovered on 18Mar2021, tenderness and soreness in her inner thigh of the left leg/throbbing pain was resolving, severe muscle pain and inflammation along the major vein in her leg was not resolved, heart palpitation was resolving, light headed/dizzy was resolved on 20Mar2021, diarrhea was resolved on Apr2021, leg was bruised was resolved, heart spasms was unknown. No follow-up attempts are needed. No further information is expected. follow up(20Apr2021): New information was reported from a contactable consumer (patient) included: new events (coronary spasm, pain in extremity, phlebitis lower limb and bruising of leg) and event details. Case is upgraded to serious upon this follow up. No follow-up attempts are needed. No further information is expected.

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1291181	5/5/2021			F	4/12/2021	4/19/2021	<p>left jugular left vein thrombosis; This is a spontaneous report from a contactable consumer physician (reporting for herself). This 35- year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE Lot number: EN6208), via an unspecified route of administration, on 12Apr2021 as a single dose for COVID-19 vaccination. No relevant medical history and concomitant medications was reported. States: no past medical history of blood clots, not on birth control pills and had two children with no issues. She received her first dose of the Pfizer BioNTech Covid 19 vaccine on 12Apr2021, she developed symptoms 5 days later, and then went to the ER and was diagnosed with a left jugular left vein thrombosis on 19Apr2021. Patient was released on Xarelto starter pack and then will be on Xarelto 20mg. The clinical outcome of the events was unknown. Information about the Lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Jugular vein thrombosis cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>



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1291138	5/5/2021	IL		F			<p>The pain I feel, Could be due to a blood clot?; pain on my arm; felt numbness in my arm; now I feel it on the inside, like if it was in the bone.; This is a spontaneous report from a contactable consumer (patient). A 42-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration in the arm on an unspecified date (Batch/Lot number was not reported) as a single dose for COVID-19 immunization. Medical history was not reported. Concomitant medication included paracetamol (TYLENOL) taken for an unspecified indication, start and stop date were not reported. The patient received the Pfizer Covid 19 vaccine on Friday, since then she felt pain on her arm, it got stronger in the afternoon, she couldn't lift anything or move that arm. On Saturday, the pain diminished. On the day of the report, the patient still feel pain, but now is like an internal ache, like if it is in the bone. She had trouble getting dressed, specially putting on t-shirts, when she goes to sleep, she cannot lay on that arm. It was reportedly very painful, and she was feeling as if it has moved to the other arm. On the day of the report, she applied heat on her arm and took Tylenol on Friday and Saturday. On Friday, she couldn't do anything, she felt numbness in her arm. Initially the pain was external, now she feels it on the inside, like if it was in the bone. The patient also asked if the pain she feel could be due to a blood clot. The event pain on my arm resolved on an unknown date in 2021, while the outcome of the rest of the events was unknown. Information about lot/batch number has been requested.</p>

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1291133	5/5/2021	PA	33	F	3/19/2021	3/20/2021	several large clots/globs; I got my period and experience several large clots/globs resembling what you would expect when having a miscarriage but it was not a miscarriage; This is a spontaneous report from a contactable consumer (patient). A 33-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 19Mar2021 08:30 (Lot Number: EL9266) as SINGLE DOSE for COVID-19 immunisation. The patient was not pregnant at time of vaccination. Medical history included autoimmune disease from an unknown date and unknown if ongoing. Concomitant medications included ergocalciferol (VITAMIN D), VITAMIN C and docosahexaenoic acid (DHA) and Prenatal Multivitamin; all taken for an unspecified indication, start and stop date were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient stated, "The day after the vaccine, I got my period and experience several large clots/globs resembling what you would expect when having a miscarriage but it was not a miscarriage as I definitely was not pregnant" on 20Mar2021 07:00 AM. The outcome of event was unknown. No treatment was given to the patient for the events.

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1291116	5/5/2021			M	3/9/2021	3/16/2021	severe pain in the leg, it got worse, checked for clot, pain was from inner thigh to calf, it was swollen; severe pain in the leg, it got worse, checked for clot, pain was from inner thigh to calf, it was swollen; severe pain in the leg, it got worse, checked for clot, pain was from inner thigh to calf, it was swollen; heart palpitation for 6 hours; muscle pain; light headiness; chills; This is a spontaneous report from a contactable consumer. This consumer (patient) reported for herself that a 65-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 09Mar2021 at single dose for COVID-19 immunization. Medical history included she had COVID-19 in the past and thyroid. Concomitant medications included she was also taking medications for the thyroid. Patient stated that she had already reported her symptoms with Pfizer COVID-19 vaccine she received on 09Mar2021 and a week after she experienced severe pain in the leg, it got worse, checked for clot, pain was from inner thigh to calf, it was swollen, had heart palpitation for 6 hours, light headiness, chills, she was wearing a heart monitor now, she still had the muscle pain. Patient wanted to know if with second dose she would have more sever side effects, should she take or not take the second dose. She was scheduled to take it this Thursday. Patient also wanted to know how she would know if she was allergic to the vaccine/ingredient. Outcome of the event severe pain in the leg was not recovered while of remain was unknown. No follow-up attempts are needed; information about lot/batch number cannot be obtained.

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1290956	5/5/2021	WA	62	M	4/17/2021	4/17/2021	After the vaccination in the morning, Sa-04-17-2021, have been in Urgent Care in the afternoon for an ongoing kidney stones issue that had occurred earlier this week. Felt tightness and pain in both lower legs which continued the next day, and it became worse. Mentioned this issue to the primary physician the following Monday 04-19-2021, but predominance had been given to the Kidney stones issue. On 04-26-2021 mentioned again the pain predominantly in the left calf to the primary physician. The same day, blood clots were found in both lower legs by Urgent Care. Had received information for Deep Vein Thrombosis by physician who prescribed Lovenox (enoxaparin) injections and advised to report the findings to V-safe. Continued narrative: Being informed by Urgent Care on 04-30-2021 that blood clots were not only in both lower legs, but also in both upper legs, now, after complaining about more pain. Ultrasound checks. Being advised to move and rest moderately. Received again information about Deep Vein Thrombosis. Advised to consider to skip the second Pfizer vaccination. Being on sick leave since 04-13-2021. Had switched from Lovenox to Pradaxa per prescription starting from Sa-05-01-2021. Urgent Care, 05-03-2021 conducted another ultrasound check. Another blood clot had developed. Again advised to consider to skip the second Pfizer vaccination, on SA-05-08-2021, to avoid more complications and risks. Under continued observation. Being alerted that this condition can lead to permanent damage and can turn life-threatening. Continued sick leave, considering medical leave. Concerned about the decision to take the second Pfizer vaccination, on Sa-05-08-2021.
1290944	5/5/2021	IL	24	M	5/2/2021	5/5/2021	Patient called and reported leg pain and numbness starting today. I advised patient to go to the emergency room as similar side effects were reported by other patients who had clots after receiving the Janssen vaccine.
1290152	5/5/2021	TX	44	F	4/1/2021	4/21/2021	Blood clot in Right peroneal vein and bilateral lung blood clots
1290875	5/5/2021	GA	66	F	3/16/2021	3/28/2021	Pulmonary embolism. Had surgery to remove blood clots in lungs

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1290770	5/5/2021	CA		F	3/15/2021	3/15/2021	Blood clot; Couldn't breathe; Heart palpitations; Hives; vertigo; This spontaneous case was reported by a health care professional and describes the occurrence of THROMBOSIS (Blood clot) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Medical History not reported. On 15-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Mar-2021, the patient experienced THROMBOSIS (Blood clot) (seriousness criterion medically significant), DYSPNOEA (Couldn't breathe), PALPITATIONS (Heart palpitations), URTICARIA (Hives) and VERTIGO (vertigo). At the time of the report, THROMBOSIS (Blood clot), DYSPNOEA (Couldn't breathe), PALPITATIONS (Heart palpitations), URTICARIA (Hives) and VERTIGO (vertigo) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. On 15 Mar 2021, within 1 hour of receiving first dose of the Moderna COVID-19 vaccine, the patient couldn't breathe, she had heart palpitations, hives, vertigo, and a blood clot. The patient stated that she was able to feel the blood clot. At the time of the report it was unclear if the patient had seen a physician for the events. Treatment for the event was cetirizine, and the patient stated that she has no hives when she takes cetirizine, but once she stops the cetirizine the hives return. Treatment provided with cetirizine for hives.

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1290426	5/5/2021	UT	17	M	4/21/2021	4/21/2021	17-year-old male who presents with 8 days of headache. He received his first dose of the Pfizer vaccine on 4/21. He felt like he had the flu after getting the vaccine and developed right-sided neck pain and a temperature to 100. The patient did endorse being elbowed in the neck playing basketball during this time as well, as he played in a basketball tournament in right after this. He got his Covid vaccine in his right deltoid. He saw his pediatrician on 4/26 and a CT scan of his neck with IV contrast was done and this showed significant diffuse right-sided deep spatial neck edema and right-sided adenopathy. The pediatrician discussed the findings with ENT who recommended augmentin and a medrol dosepak. The patient developed a headache several days after this and went to urgent care for evaluation. There was concern that the augmentin and steroids had caused the headache, so the steroids were stopped and he was switched to keflex on 4/30. He was given phenergan and toradol at Urgent Care and discharged home. His mom notes that several days ago he had fevers of 101-104. He has not had a fever for several days now. His headache continued and he felt unwell at basketball practice so he returned to urgent care on 5/4. A CT scan of his head was done which showed right sigmoid and transverse sinus thrombosis as well as thrombophlebitis of the right IJ. He was sent to ED for further management at that time. In the ED, the patient was hemodynamically stable and well-appearing. The CTs were overread by our radiologists here. The patient had some labs done at the outside urgent care but PT/PTT/INR and a CRP were drawn here, which were unremarkable. A Covid PCR is negative. Neurosurgery, neurology, and hematology were consulted. Neurology recommended heparin and a hypercoagulable workup and hematology agreed with this plan. The patient was admitted to the ICU for neuro checks and monitoring during initiation of heparin.
1290340	5/5/2021	GA	39	M	4/12/2021	4/29/2021	Developed Bell's Palsy on morning of 4/29, with left side of face paralyzed. Was examined by emergency room physicians for stroke and blood clot, cleared and given prescription for Valacyclovir 1GM (3x day 7days) and Prednisone 50mg (1x day 5 days). As of 5/5 condition has improved significantly, though paralysis around mouth and neck areas persists.

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1290307	5/5/2021	AZ	54	F	5/1/2021	5/2/2021	I woke up at approximately 9:30 AM the morning of Sunday May 2nd 2021 the day after getting my covid vaccine and had to rush to the bathroom. I proceeded to have blood and blood clots come out my urethra very urgently. I had abdominal pain and pressure. I proceeded to need to urinate blood and blood clots for approximately 4 hours urgently. I could not go far from the bathroom without having to return quickly to the toilet. I wet myself several times. The clots stopped coming around 1:30 PM. I proceeded to have to have no control over urination urge and could not leave the bathroom. Around approximately 2:00 PM I could leave the bathroom without fear of wetting myself. I continued to have a small amount of a mix of blood and normal urine passing for another hour or so. I have a picture of the blood and clots that came out of my urethra. I continue to have dull pain and pressure in my abdomen.
1290123	5/5/2021	KY	51	F	4/16/2021	4/23/2021	Received Moderna COVID 19 vaccine second dose on April 16th 2021 and days later began having chest pressure and shortness of breath. Was seen in doctor office and sent to ER. Was diagnosed with several blood clots in the lungs
1290301	5/5/2021	OH	61	F	5/1/2021	5/1/2021	Patient received Johnson and Johnson vaccine on Saturday May 1st. I administered the vaccine. Today, 5/5 she came to the pharmacy to show me the circle rash that had developed around injection site. It was also swollen and felt like a bruise. I counseled patient on "covid arm" and that it was likely her immune system activating. I explained this can be a common reaction after getting the COVID vaccine. Patient had no other symptoms. I went over things to look out for in relation to blood clots and any warning signs and when to reach out to her doctor. I suggested she fill out Vsafe and I told her I would report to VAERS.

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1290132	5/5/2021	OH	64	F	3/30/2021	4/10/2021	4/10/21-Patient presented to an outlying hospital ED w/acute N/V/D and abdominal pain. She was found to have pancreatitis and was found to be SARS-CoV-2 with screening for admission. She had a history of symptomatic COVID with a positive NP swab 1/2/21. Because the patient had no respiratory symptoms she was considered "asymptomatic." She rapidly progressed to having severe necrotizing pancreatitis. She was transferred to tertiary care center where she remains hospitalized. Her hospitalization has been complicated by acute hypoxic and hypercapnic respiratory failure requiring intubation x 24 hours. She had mental status changes and an MRI revealed posterior reversible encephalopathy syndrome, acute kidney injury, splenic vein thrombosis -parital occlusion.
1290888	5/5/2021	NY	58	M	4/25/2021	4/26/2021	Blood Clot discovered in my leg my Wednesday April 27. Incredible amounts of pain. By May 5 pain caused by unknown bruise on foot on same leg.
1285459	5/4/2021	MS	40	F	4/7/2021		BLOOD CLOTS
1285378	5/4/2021	ME	70	M	2/26/2021	3/4/2021	7 days following vaccination patient reported swelling to right lower extremity with pain and shortness of breath. 10 days post vaccine, patient admitted to hospital with pulmonary embolism as well as very large deep vein thrombosis.
1285270	5/4/2021		71	F	4/5/2021	4/22/2021	Presented with seizures on 4/22. Found to have bilateral frontal hemorrhagic contusions. Later found to have venous sinus thrombosis.
1285213	5/4/2021	CT	54	F	2/28/2021	5/1/2021	On 2/28/21, had first COVID Shot. On 3/16/21 had Hysterectomy. On 3/30/21 had second COVID shot. On 4/19/21, was diagnosed with blood clot. The doctor reported that it was not the norm for someone my age and with my good health to get a blood clot after a hysterectomy.
1285193	5/4/2021	AL	73	M	4/8/2021	4/25/2021	Multiple Blood Clots in Right Lung, clots passed through his heart and caused his death
1285475	5/4/2021	AZ	95	M	4/21/2021	4/28/2021	Blood clots, organs shut down, death.



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1284864	5/4/2021	WV	96	F	1/29/2021	2/1/2021	blood clot in her leg; blood clot in her leg; Cardiac arrest; Heart attack; This is a spontaneous report from a contactable consumer (patient's daughter). A 96-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration on 29Jan2021 (Lot Number: EL9265) as SINGLE DOSE for COVID-19 immunization. Medical history included blood clots in her legs from an unknown date and unknown if ongoing , diabetec, bone infection, surgery and anemic; all from an unknown date and unknown if ongoing; and a family history of gangrene from an unknown date and unknown if ongoing of her mother. Concomitant medications included apixaban (ELIQUIS) taken as blood thinner and furosemide (FUROSEMIDE) taken for an unspecified indication; both start and stop date were not reported. The patient previously had BNT162B2 (Lot Number: EL1283) dose 1 on 08Jan2021 for COVID-19 immunization. The facility where the most recent COVID-19 vaccine was administered was in the military facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 15Mar2021, the patient died due to a heart attack and cardiac arrest. The patient developed a blood clot in her leg and had to have her leg taken off. The date of surgery was 05Feb2021, not early Mar2021 like was originally stated at the hospital. The patient was admitted either on 01Feb2021 or 02Feb2021 and discharged on 23Feb2021. They had a bunch of bad weather and then they put the patient in the nursing facility for about a month and when she was brought home she had a heart attack and died due to cardiac arrest. She doesn't know about the blood clot and this being related to the COVID vaccines but the patient had surgery a week after she had her second shot. The heart attack was on 15Mar2021. The patient had a history of blood clots in her legs before and she had problems with that so that might of made it worse but she doesn't know for sure. The patient died on 15Mar2021. An autopsy was not performed. The outcome of the event blood clot in her leg was unknown. No follow-up attempts are possible; information about lot/batch number has been obtained.; Reported Cause(s) of Death: heart attack; cardiac arrest

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1284857	5/4/2021	CT	86	M	4/8/2021	4/9/2021	small blood clot in brain; This is a spontaneous report from a contactable consumer (patient). A 86-year-old male patient received the second dose of bnt162b2, via an unspecified route of administration on 08Apr2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included Type two diabetes b, covid prior vaccination in 2021, blood clot in lung. Concomitant medication included exenatide (BYETTA). The patient previously received the first dose of bnt162b2, via an unspecified route of administration on unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient experienced small blood clot in brain on 09Apr2021. The event resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization (4 days), Life threatening illness (immediate risk of death from the event), Disability or permanent damage. Patient received the treatment Heparin for event. Covid test post vaccination (Blood test) was negative on 12Apr2021. The outcome of the event was not recovered. Information on Lot/Batch number has been requested.

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1284917	5/4/2021	FL	51	F	4/1/2021		PALPITATIONS; CHEST PAIN; CATARACTS; BILATERAL EYE PAIN; INTERMITTENT HEADACHE/LIGHTHEADEDNESS; This spontaneous report received from a pharmacist concerned a Vietnamese female of unspecified age. The patient's weight, height, and medical history were not reported. The patient's concurrent conditions included high cholesterol. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration and vaccination site not reported, batch number: Unknown) dose was not reported, 1 total, administered in APR-2021 (reported as approximately 2 weeks prior to the date of the report) for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. In APR-2021, reported as 5 days ago, the patient experienced with intermittent headache, bilateral eye pain and blurry vision, in addition to chest pain and palpitations. She was seen in the emergency Room on 26-APR-2021, and was subsequently diagnosed with acute cavernous venous thrombosis. Patient was hospitalized and number of days were unspecified. On an unspecified date, the patient experienced bilateral eye pain, blurry vision, cataracts, and intermittent headache/lightheadedness. On 26-APR-2021, Laboratory data included: Magnetic resonance imaging (NR: not provided) grossly abnormal indicative of clot, and Platelet count (NR: not provided) 251000 on admission. On 27-APR-2021, Laboratory data included: Magnetic resonance imaging (NR: not provided) no evidence of thrombus, mild white matter (units unspecified), and platelet count (NR: not provided) 246,000. On 28-APR-2021, Laboratory data included: Anti-thrombin III decreased (NR: not provided) unknown, erythrocyte sedimentation rate (nr: not provided) 21 (normal), factor V leiden mutation (NR: not provided) unknown, Fibrin D dimer abnormal (NR: not provided) 0.29 (unit not reported) (normal 0-0.49), Platelet count (NR: not provided) 227,000, Protein C (NR: not provided) unknown, Protein S antigen (NR: not provided) unknown, and Serotonin syndrome (NR: not provided) unknown. Laboratory data (dates unspecified) included: Ammonia (NR: not provided) high ammonia level. Treatment medications (dates unspecified) included: acetylsalicylic acid. The action taken with covid-19 vaccine ad26.cov2.s

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							was not applicable. The patient recovered from intermittent headache/lightheadedness on 28-APR-2021, and the outcome of chest pain, palpitations, bilateral eye pain and cataracts was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0.20210451865-covid-19 vaccine ad26.cov2.s-cataract,palpitations,chest pain. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
1285493	5/4/2021	VA	68	F	3/7/2021	4/1/2021	(1) Approximately one month after vaccine, swelling in the muscle behind my left leg. I went to my Primary Care doctor, he examined my leg and immediately sent me to hospital ER because he was concerned that it might be a blood clot. They performed an ultrasound, but the results were negative and showed no signs of any blood clots. (2) Approximately three weeks after vaccine, I developed stiffness on the left side of my body in my arm, thigh and hip area. The stiffness was intense, uncomfortable and bothersome enough for me to take Tylenol for the pain the next 5 days and it lasted for about a week.
1285576	5/4/2021	MA	71	F	3/8/2021	4/23/2021	Shot on 3/8/21 & on 4/23/21 had pain in chest. MWH tested & NOT heart UT LUNGS that a clot in each.
1285721	5/4/2021		90	F	3/25/2021	4/24/2021	I82.611 - Acute embolism and thrombosis of superficial veins of right upper extremity
1285646	5/4/2021	CO	47	M	4/10/2021	4/11/2021	My foot left foot swelled up, I am taking water pills to reduce the swelling. Had an ultrasound for blood clots in my leg which came back negative.

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1285649	5/4/2021	NY	56	M	4/9/2021	4/28/2021	ON 4/28 felt intense pain in legs and blurry eyes, slowly went away after taking advil, came back at night, on thursday 4/29 pain continued and had shortness of breath decided to go to urgent care made appt for 4/30 813AM, at Urgent Care symptoms pointed to blood clots was told to go to local imaging company to get sonogram, sonogram showed blood clots in leg told to go to emergency room, went to Hospital and was admitted, confirmed blood clots and put on blood thinner neprin IV, released 5/2 at 1PM, at home now on blood thinner pills 10mg Eliquis

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1285703	5/4/2021	OH	58	F	4/20/2021	4/25/2021	<p>4/25 Pt presented to urgent care with complaint of HA and earache. Her pulse ox was in the 80's and she was sent to the ED for further evaluation and admission. D/C summary from 4/26 : Patient is a 58 y.o. female patient of, DO with history of OSA cannot tolerate CPAP, depression, rheumatoid arthritis, chronic pain syndrome, obesity, diabetes type 2, CAD, hypertension, hyperlipidemia, TIA who presents with shortness of breath. Patient was placed on 4 L NC but quickly weaned off. She tested positive for covid on 4/25. She was started on dexamethasone and covid cocktail for 10 days. Her CTPA and venous duplexes were negative for blood clots. There was bronchitis on CTPA so pt was placed on albuterol, mucinex and advised to use IS. Her Cr was elevated to 1.52 and improved to 1.25 this morning. Her hydrochlorothiazide was held. Her AST was 186, ALT 245 previously normal. Her atorvastatin and metformin were held. She was tolerating po and her VS were stable so she was discharged home. She was advised to have repeat labs with her PCP in 1 week and if at that time her Cr, AST, ALT improved, then her hydrochlorothiazide, atorvastatin, metformin could be resumed at her PCP's discretion. She was at home for one day and presented to another ED with CP and SOB. Admitted 4/27-5/1 D/C Summary :Clinical Summary Patient is a 58 y.o. female with a history of positive covid test 4/25/21, CKD, CAD s/p PCI, depression OSA rheumatoid arthritis morbid obesity, HTN and DM2 who just discharged from hospital 4/26/21 after diagnosis of COVID and starting on dexamethasone. She presented to hospital 4/27/2021 with chest pain and shortness of breath. CXR negative 4/27/21, CTPA negative 4/26/21, LEVD negative 4/26/21 labs stable from last admission.</p> <p>1. COVID 19 Pneumonia: Suspected re-infection. Husband reported was positive mid - January. Continued dexamethasone to complete 10 days (started 4/25/2021). Remdesivir not started with LFT elevation on admit. 2. Acute hypoxic respiratory failure: with increasing O2 requirement 4/28/2021. CXR 4/28/2021 with underaeration of lungs. ABG 4/28/2021 without hypoxemia. Likely d/t COVID, resolved 3. Chest pain: Suspect in setting of COVID infection and component of costochondritis. CTPA and LEVD negative 4/26/21. Troponins stable from last admission in setting of CKD, ekg without acute findings on admit. 4. Elevated LFT: on</p>

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							admit AST 186, ALT 245, total bilirubin 0.2. likely d/t COVID. Improving, AST 93, ALT 163 4/30/2021. will need outpatient repeat in 1-2 weeks with PCP 5. CKD3: Baseline creat 1.2-1.5. Cr on admit 1.52, improved 0.99 4/30/2021. Repeat chem in 1-2 weeks 6. T2DM: Per history, on Januvia at home (held on admit). A1C 8 1/29/21. Hyperglycemia on admission, improved with SSI, discussed continuing on discharge while on steroids and following up with PCP in next week
1285704	5/4/2021	VA	46	F	4/11/2021	4/11/2021	I had chills, fatigue, headache, and bilateral calf and thigh muscle pain that started about 6 hours after the vaccination and lasted about 36-48 hours. I took Tylenol 500mg after the onset of symptoms and three times a day. The symptoms went away by mid-day on 4/13/2021. Since then, I have been experiencing bilateral calf muscle pain off and on. I also had an enlarged axillary lymph node n the left side (side of vaccination). I reported it to urgent care on 4/18/2021 and was told the muscle pain was unlikely to be a clot since it was bilateral and there was no swelling or discoloration. I was told to hydrate and follow up with my primary care provider if it continues. The calf muscle pain has continued - almost every other day - and responds to Advil. I have an appointment to talk to an MD tomorrow (May 5th)

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1284856	5/4/2021	FL	53	M	3/29/2021	4/14/2021	5-6 Blood clots, blood clots were present; heart attack; This is a spontaneous report from a contactable consumer reporting for himself. A 54-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Mar2021 12:00 on left arm at single dose for COVID-19 immunization. Facility type vaccine was at Pharmacy or Drug Store. Medical history included high blood pressure, high cholesterol. Concomitant medications included atorvastatin (LIPITOR), amlodipine besilate (NORVASC). Historical Vaccine included first dose of BNT162B2 on 08Mar2021 12:00 on left arm for COVID-19 immunization. The patient experienced 5-6 Blood clots, had heart attack and blood clots were present on 14Apr2021 13:00. The events were resulted in Emergency Room Visit, Hospitalization, Life threatening illness (immediate risk of death from the event). Treatment was received for the events included Stent. The outcome of the events were resolving. Information on Lot/Batch number has been requested.
1284727	5/4/2021	IL	67	F	3/18/2021	3/23/2021	heart attack; Bood clot; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of MYOCARDIAL INFARCTION (heart attack) and THROMBOSIS (Bood clot) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 18-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, the patient experienced MYOCARDIAL INFARCTION (heart attack) (seriousness criteria death and medically significant) and THROMBOSIS (Bood clot) (seriousness criterion death). The patient died on 23-Mar-2021. The reported cause of death was Heart attack and Clot blood. It is unknown if an autopsy was performed. Not Provided No concomitant medication were reported. No treatment information was provided.; Reported Cause(s) of Death: Heart attack; Clot blood



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1285757	5/4/2021	PA	40	M	4/28/2021	4/28/2021	Developed severe abdominal cramps on my left side around 7 p.m. on Wednesday, April 28. Cramps were intermittent and in varying degrees of intensity. Cramps continued through Friday, April 30 with varying intensity. Attempted to treat with Tylenol and GasX. Starting around 10:30 a.m. on Saturday May, 1, the pain in my left side increased in intensity and was not waning. After consulting with a telehealth practitioner, I went to the emergency room and was quickly admitted. My blood and urine were tested, along with CT scans of my body. The CT scan revealed that blood was no longer reaching two parts of my left kidney and I was diagnosed with a arterial thrombosis. I was fully admitted to the hospital and a heparin drip was immediately started.
1285611	5/4/2021	OH	43	F	2/24/2021	3/3/2021	My periods since receiving the vaccination have had significantly more and larger clots than normal.
1286453	5/4/2021		23	F	3/30/2021	3/31/2021	I had a red, hard, spot on my arm that lasted over two weeks. I also had a bruise that was changing colors. My arm was painful and the redness was spreading. I was given antibiotics for ten days afterwards. My mother also had a rash at the injection site, and was given same shot as me on same day. The lot number for my shot is 1808609. I have many pictures of the reaction if you want me to upload. Furthermore, the doctor said that my reaction would be aligned with a "moderna" reaction but is NOT typical of a J and J reaction (which is the shot that I had received and obtained a record of receiving from the Pharmacy). I got an ultrasound and blood test around two weeks after vaccine, no blood clot found.
1284470	5/4/2021		46	F	4/10/2021	4/25/2021	Headache onset 2 weeks after vaccination. Brain MRI on 4/30/2021 showed subacute dural venous sinus thrombosis affecting the superior sagittal, left transverse and sigmoid sinuses.

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1284516	5/4/2021	AK	41	F	1/7/2021	1/7/2021	<p>About 15 mins after vaccine I felt a sudden onset of lightheadedness and feeling as if i would pass out, told the nurse I was going to throw up. I was given zofran and Dr monitored Vs. I continued to experience waves of dizziness, nausea, abdominal pain. Shaking followed (I felt so cold), along with frequent need to urinate and urgency to have a BM (loose) for several hours. I was given fluids and monitored. They gave Ativan 0.5mg 2.5 hrs later? I was discharged home at 8:45p.m. by Dr and told not to get the 2nd Vaccine. Symptoms continued and worsened on day 3 with Shortness of breath, chest pain and tingling in my arms that spread to my legs, back and neck. The first week I could barley walk and was seen in the ER 2 times for chest pain, shortness of breath, dizziness, tingling, heart racing, diarrhea, nausea, muscle weakness, insomnia due to shortness of breath (gasping) with heart racing, &amp; unable to control my body temperature. Given Prednisone 40mg which exasperated symptoms. 1/13/21 In ER and given Benadryl 3 bags of fluids, potassium and sodium. Postural tachycardia was noticed. Referral to Neurologist. High D-dimer at ER on 1/16/21 CT scan performed to rule out blood clot in lungs. Referred to Cardiologist. Metoprolol and Colchicine was started in Jan by Cardiologist Dr . Weekly visits with Dr for the first couple months. More meds started to decrease inflammation. Furthur referrals to Immunologist, infectious disease, and Rheumatology. At 3 months worsening of tingling in my neck and headaches/burning that felt like shocks and shooting down neck and ears. Neurologist performed 3 view MRI to rule out transverse Myelitis. In ER early April for new onset of Petechiae, CBC labs normal. Immunologist states he felt i experienced an allergic reaction followed by secondary anaphalaxis. He is testing me for Mast cell activation syndrome (not diagnosed yet). Now almost 4 months later still unable to work. Waiting results to rule out POTS. Currently battle daily fatigue, chest pressure/pain, lung SOB, heavyness/pressure, with any exertion. I am limited with daily walking/normal activities. Symptoms that come and go are tingling, nausea, diarrhea, flushing of frequent urination, neck pain, regulating temperature.</p>

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1284648	5/4/2021		68	F	3/7/2021		<p>PULMONARY EMBOLISM; THROMBOSIS; COR PULMONALE ACUTE/ DYSPNOEA; HYPOXIA; DIZZINESS; COUGHING; This spontaneous report received from a patient via a Regulatory Authority Vaccine Adverse Event Reporting System (VAERS) (VAER reference number 1120494) concerned a 68 year old female unknown ethnicity. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805020, and expiry: UNKNOWN) dose was not reported, administered on 06-MAR-2021 14:15 for prophylactic vaccination. Concomitant medications included amitriptyline for sleep, and zolmitriptan for migraine. On 07-MAR-2021 08:30, the subject experienced pulmonary embolism, thrombosis, cor pulmonale acute/ dyspnoea, hypoxia, dizziness, coughing, and was hospitalized (date unspecified). On 12-MAR-2021, Laboratory data included: COVID-19 virus test negative (NR: not provided) Negative. Laboratory data (dates unspecified) included: Blood pressure (NR: not provided) normal, Blood test (NR: not provided) normal, CT scan (NR: not provided) Pulmonary Embolism, Chest X-ray (NR: not provided) normal, Diagnostic ultrasound (NR: not provided) No blood clots or vein thrombosis, Echocardiography (NR: not provided) Increased pressure on the right side of heart due to blood clots, and Heart rate (NR: not provided) elevated. Treatment medications (dates unspecified) included: oxygen, salbutamol, and rivaroxaban. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the pulmonary embolism, thrombosis, cor pulmonale acute/ dyspnoea, hypoxia, dizziness, coughing was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition); Sender's Comments: V2:Additional version created for MAC update. This updated information does not alter the causality of previously reported events. 20210441745-Covid-19 vaccine ad26.cov2.s-Thrombosis, pulmonary embolism ,Cor pulmonale acute, Hypoxia, dizziness, cough. These events are considered unassessable. These events has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially</p>

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1284650	5/4/2021	MD	35	F	4/1/2021		<p>associated with the events.</p> <p>MIGRAINE; FEVER; HEADACHE; ARM PAIN; POTENTIAL BLOOD CLOT; This spontaneous report received from a patient concerned a 35 year old female. The patient's height, and weight were not reported. The patient's past medical history included stroke, and concurrent conditions included non-smoker, and sulfa allergy (anaphylactic). The patient experienced drug allergy when treated with nitrofurantoin. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 206A21A, expiry: UNKNOWN) dose was not reported, administered on 10-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 10-APR-2021, patients arm was hurting and on the 11-APR-2021, night patient started having a headache. On 11-APR-2021, the patient had a fever of 103 and a migraine on 12-APR-2021. Patient took 2 Tylenol and rested in bed for the whole day. On 12-APR-2021, patient saw the physician due to her migraine. The physician was concerned that the patient may have a potential blood clot since the patient has had a stroke in 2016. Physician wanted her to get a MRV (Magnetic Resonance Venography) with contrast of the brain to make sure patient does not have another stroke and also prescribed baby aspirin until she can get the MRV The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from arm pain, fever, and headache, had not recovered from migraine, and the outcome of potential blood clot was not reported.. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210443400-Covid-19 vaccine ad26.cov2.s-Potential blood clot. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY</p>

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1284651	5/4/2021		34	F		4/4/2021	<p>HEADACHE; BLURRY VISION; NECK STIFFNESS; NAUSEA; VOMITING; CEREBRAL VENOUS SINUS THROMBOSIS; DURAL VENOUS SINUS THROMBOSIS; RIGHT INTERNAL JUGULAR VEIN THROMBOSIS; INTRAPARENCHYMAL HEMORRHAGE; LOW PLATELET COUNT; This spontaneous report received from a patient via the VAERS (Vaccine Adverse Event Reporting System)(VAERS ID: 1224712) and concerned a 34-year-old white female. The patient's weight and height were not reported. The patient medical history included being 4 months post-partum. The patient had no drug, food or other product allergies, and had no chronic or long-standing conditions. The patient received COVID-19 vaccine Ad26.CoV2.S (suspension for injection, route of administration and batch number not reported), dose was not reported, administered on 23-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. From an unspecified date, the patient had 2 weeks of headaches and blurry vision, 2 to 3 days of neck stiffness and nausea with 1 episode of vomiting and had been transferred to the current hospital from another. On 04-APR-2021 (12 days post-vaccination), the patient was diagnosed with dural venous sinus thrombosis (DVST), transverse/sigmoid (cerebral venous) sinus thrombus (CVST) with associated intraparenchymal hemorrhage in the right temporal lobe as well as thrombosis of the right internal jugular vein (thrombus). Magnetic resonance imaging (MRI) impressions showed there was a re-demonstrated of intraparenchymal hematoma in the right posterior temporal lobe measuring approximately 6.2 x 3.6 cm in maximal axial dimensions. There was surrounding edema and associated mass effect with effacement of the right temporal horn and right-to-left midline shift measuring 5 mm. There was medialization of the right uncus without transtentorial herniation. The basal cisterns were otherwise patent. There was dural thickening and hyperenhancement overlying the hemorrhage. There was prominent cortical veins along the right frontal temporoparietal convexity consistent with venous congestion. There was also a small are of vasogenic edema in the right anterior temporal lobe separate from the hematoma. There was a right mastoid effusion, but normal orbitals and the calvarium and skull base were unremarkable. Magnetic</p>

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resonance venography (MRV) results revealed non-opacification of the torcula, right transverse sinus, right sigmoid sinus and upper internal jugular vein compatible with occlusive thrombosis. A small amount of thrombus also extended into the left transverse sinus. The superior sagittal sinus, remainder of the left transverse sinus, left sigmoid sinus, left upper internal jugular vein, straight sinus, vein of Galen and bilateral internal cerebral veins demonstrated normal contrast opacification. The patient's platelet count was 126 upon admission (normal range [NR] not provided), with other workup laboratory test results reported as pending. The action taken with COVID-19 vaccine Ad26.CoV2.S was not applicable. The outcome of the right internal jugular thrombus, intraparenchymal hemorrhage, DVST, CVST, headache, blurry vision, neck stiffness, nausea and vomiting was reported as unknown. This report was serious (caused/prolonged hospitalization and other medically important condition).; Sender's Comments: V0: This case concerns a 34-year-old white female who experienced cerebral venous sinus thrombosis (CVST), dural venous sinus thrombosis, right internal jugular vein thrombosis, and cerebral hemorrhage 12 days after receiving covid-19 vaccine ad26.cov2.s for prevention of symptomatic SARS-CoV-2 virus infection. The patient was noted to be 4 months post-partum. She presented for medical assistance with a 2-week history of headaches, blurry vision, and neck stiffness for 2 to 3 days as well as nausea with 1 episode of vomiting. Magnetic resonance imaging showed a large hematoma in the right posterior temporal lobe with surrounding edema and associated mass effect resulting in effacement of the right temporal horn and right-to-left midline shift measuring 5 mm and occlusive thrombus within the torcula, right transverse sinus, right sigmoid sinus, and upper internal jugular vein. A small amount of thrombus extended into the medial aspect of the left transverse sinus. The platelet count on admission was 126,000. Although the post-partum status of the patient may have contributed, based on evolving knowledge of Thrombosis with Thrombocytopenia Syndrome (TTS, per definition from Brighton Collaboration) and considering the low platelet count and temporal relationship to vaccination, we consider the events to have a plausible relationship with vaccination.

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1284654	5/4/2021	PA	71	F	4/1/2021		<p>BLOOD CLOT INSIDE THE BUMP (INJECTION SITE); WHEEZING; HIVES ON NECK; BLADDER INFECTION/ABDOMINAL PAIN TO GROIN; BLADDER INFECTION/ ABDOMINAL PAIN TO GROIN; INJECTOR PULLED THE NEEDLE BACK AND PUT IT IN AGAIN; COULD HARDLY WALK; COULDN'T TOUCH THE ARM; REDNESS IS STILL AS BIG AS A BASEBALL; NAUSEA; VOMITING; HALLUCINATIONS; DIARRHEA; This spontaneous report received from a consumer concerned a 71 year old white (Hispanic/Latino) female. The patient's height, and weight were not reported. The patient's past medical history included bladder infection, and concurrent conditions included high blood pressure, high cholesterol, and asthma/ bronchitis/ get asthma attacks often. The patient's other pre-existing medical conditions included that she had no history of heart attack or pain. The patient's family history included that her mother had bladder infection and lady part infections. The patient was not pregnant at the time of reporting. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 202A21A and expiry: 23-JUN-2021) dose was not reported, 1 total administered on 10-APR-2021 around 10:00 AM for prophylactic vaccination on right arm. No concomitant medications were reported. On 10-APR-2021, the patient almost passed out after she got the shot (vaccination), they (vaccine facility) had to take her out to the car, and she could hardly walk. The patient reported that injector pulled the needle back and put it in again (Wrong injection technique). It was reported that right after injection when she turns around her arm was big as baseball, mushy, swollen and it was painful (injection site). The mushiness was going down, but it was still mushy. The patient's arm was hard as a marble, redness was still as big as a baseball and she could not touch her arm. On 20-APR-2021, the patient had bladder infection/abdominal pain to groin and had infection from lady's problem and further stated it as bladder infection. The patient think that the bladder infection was not because of the Janssen vaccine. On 21-APR-2021, the patient experienced hives on the neck and she applied Benadryl cream on it. The patient went to her physician on 22-APR-2021 (Thursday) and Nurse looked at her arm and said that it was perfusion and there was blood clot inside the bump. The patient's physician told her to</p>

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take Benadryl and put ice and heating pad on it. The patient reported that she was already putting ice packs 3-4 times a day and heating pads 3 times a day. The patient also showed her hives to her physician and she was told to keep putting Benadryl on it. The patient had a follow up with her physician on 03-MAY-2021 for her arm checkup. On an unknown date in APR-2021 (reported as first night), she could see penguins walking around, marching up the stairs on first night (Hallucinations) and then no more penguins after the first night. On the same first night, the patient experienced nausea, diarrhea, and vomiting. On an unknown date, the patient experienced wheezing and she thinks that her wheezing was not related to the Janssen Covid-19 vaccine. According to patient her wheezing is related to her asthma. The patient did not have any trouble sleeping since she was taking the Benadryl. The patient stated that she could move her arm up and down, but she was scared to do so. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from hallucinations, bladder infection/abdominal pain to groin, diarrhea, vomiting, and nausea, and the outcome of almost passed out, hives on neck, couldn't touch the arm, blood clot inside the bump (injection site), wheezing, could hardly walk, injector pulled the needle back and put it in again and redness is still as big as a baseball was not reported. The reporter considered the causality between Covid-19 vaccine ad26.cov2.s and wheezing, and bladder infection as not related. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210452551-covid-19 vaccine ad26.cov2.s- blood clot inside the bump (injection site), hallucinations. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).



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1284656	5/4/2021	CA		M		4/1/2021	<p>ESCALATING PAIN IN THE LOWER BACK; PAIN IN LEG; BLOOD CLOT IN LEG; This spontaneous report received from a consumer (representative) concerned a 4 decade (early 30's) old adult male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose was not reported, 1 total administered on 08-APR-2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up would be requested for this case. No concomitant medications were reported. On 16-APR-2021, the patient experienced escalating pain in the lower back and in leg. The patient also experienced blood clot in leg, and was hospitalized in an unknown date in APR-2021. The patient had improvement and scheduled to leave the hospital in a few days at the time of this report. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from blood clot in leg, escalating pain in the lower back, and pain in leg. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210452829-COVID-19 VACCINE AD26.COV2.S-BLOOD CLOT IN LEG, ESCALATING PAIN IN THE LOWER BACK. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). 20210452829-COVID-19 VACCINE AD26.COV2.S-PAIN IN LEG . This event(s) is labeled per RSI and is therefore considered potentially related.</p>

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1284660	5/4/2021	FL		U			<p>CLOTS; This spontaneous report received from a physician concerned a patient of unspecified age and sex. The patient's weight, height and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: Unknown) frequency one total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient died due to clot. It was unknown if autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died to clots on an unspecified date. This report was serious (Death). This case, from the same reporter is linked to 20210457363.; Sender's Comments: V0: 20210456400-Covid-19 vaccine ad26.cov2.s-Death. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: CLOTS</p>

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1284680	5/4/2021			U			<p>SIDE EFFECTS INVOLVING SANGUINEOUS CLOTS; This spontaneous report received from a consumer (source: article published) concerned 6 patients. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: unknown) dose, start therapy date were not reported, frequency 1 total administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. It was reported that the center for disease control and prevention (CDC) and arm of food and drug administration (FDA), the agency responsible for health surveillance, was about to discuss whether the pause in the use of covid-19 vaccine ad26.cov2.s is expected to continue after 6 people developed rare side effects involving sanguineous clots on an unspecified date. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of side effects involving sanguineous clots was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0-20210460381-covid-19 vaccine ad26.cov2.s-side effects involving sanguineous clots. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1284764	5/4/2021	CA		F	3/17/2021		<p>with right leg, severe pain and had DVT diagnosed/ diagnose with DVT (deep vein blood clot) in my leg; This is a spontaneous report from a contactable consumer (patient). A female patient (Age: 60; Unit: Unspecified) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in left arm on 17Mar2021 (Batch/Lot number was not reported) as single dose for COVID-19 immunisation. Medical history included COVID-19 from 02Oct2020 to an unknown date. Concomitant medications were not reported. The patient experienced with right leg, severe pain and had dvt diagnosed/ diagnose with dvt (deep vein blood clot) in my leg on an unspecified date in 2021 with outcome of unknown. Patient states she had COVID-19 on 02Oct2020. She received her first Pfizer vaccine dose in her left arm on 17Mar2021. On 01Apr2021, she went to the hospital ED with right leg, severe pain and had DVT diagnosed. She was sent home from the ED with Xarelto. On 07Apr2021, 2nd vaccine dose received by patient. Consumer stated, "I called the health department and I just wanted you to record that I called you guys back on 17Mar I've had my first COVID shot and then 01Apr, I went to the hospital (further details for the hospitalization not available hence not checked as seriousness criteria) and diagnose with DVT (deep vein blood clot) in my leg. I just felt, I just know that what going on right now with Johnson and Johnson but I am just trying to kind of understand that 2 weeks to the day that I had my first COVID shot I came down with the blood clot in my leg. So I just wanted to see if that's anything that I need to be concerned, it's very painful, fortunately I have been able to work from home but it's very painful and I did get my second round because level one I need to think about it. So, with everything going on. I never had blood clot now before that I have now." Information on the lot/batch number has been requested.</p>

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1284725	5/4/2021	TN	69	M	3/3/2021	3/7/2021	<p>Diagnosed Two Pulmonary Embolism; DVT on left leg; Coughing; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Diagnosed Two Pulmonary Embolism), DEEP VEIN THROMBOSIS (DVT on left leg) and COUGH (Coughing) in a 69-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 07-Mar-2021, the patient experienced PULMONARY EMBOLISM (Diagnosed Two Pulmonary Embolism) (seriousness criterion medically significant), DEEP VEIN THROMBOSIS (DVT on left leg) (seriousness criterion medically significant) and COUGH (Coughing) (seriousness criterion medically significant). At the time of the report, PULMONARY EMBOLISM (Diagnosed Two Pulmonary Embolism), DEEP VEIN THROMBOSIS (DVT on left leg) and COUGH (Coughing) outcome was unknown. After his 2nd dose of Moderna vaccine on 01-Apr-2021, the patient's coughing become worst again. His pulmonologist prescribed prednisone and his family physician prescribed him Azithromycin. No concomitant medications were not provided. Treatment included as Eliquis, Azithromycin, cough medicine, prednisone. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to (Patient Link).</p>

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1284855	5/4/2021	FL	49	M	3/16/2021	3/16/2021	DVT left lower extremity; Bilateral Pulmonary Emboli; first dose: 23Feb2021; second dose: 16Mar2021; first dose: 23Feb2021; second dose: 16Mar2021; This is a spontaneous report from a contactable nurse (patient). A 49-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6199 and expiration date not provided) intramuscular, administered in the left arm on 16Mar2021 13:30 as a single dose for COVID-19 immunization. The patient has no relevant medical history. Family history included diabetes (mother). The patient's concomitant medications were not reported. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6200 and expiration date not provided) Injected intramuscularly in left upper arm on 23Feb2021, 13:30 for COVID-19 immunization and experienced DVT symptoms, soft tissue injury, muscle pull and ankle strain. The patient experienced DVT left lower extremity and bilateral pulmonary emboli on 23Apr2021. The patient called regarding the Pfizer COVID vaccine. He had adverse events to report. He has a DVT on his left calf, which he later clarified was left lower extremity. He is currently on double dose of apixaban (ELIQUIS) since Friday. He finally went and got it looked at. He is still being treated and will be seeing a hematologist. He stated that DVT symptoms occurred after first dose and was undiagnosed. He treated it as soft tissue injury and thought it was a muscle pull and ankle strain. Eliquis was started on 23Apr2021 and dose is 5 mg. He is taking two tablets twice daily for 7 days and then 1, 5mg tablet bid (twice a day) as well. No emergency room or physician's office required but Urgent care facility was visited on 23Apr2021. During this visit, they did Lab work, D Dimer results 1590 on 23Apr2021; Venous Doppler resulted in positive DVT in Left Lower Extremity. Chest CT resulted in positive peripheral defects in small branches of the lower lobes bilaterally, left greater than right, consistent with Pulmonary Emboli. Left sided pleural effusion and left basillary infiltrate, possibly atelectasis or developing infarct. Few pleural based nodular densities at right lung base, again atelectasis versus developing infarcts. The rest just states what was normal. Eliquis was prescribed on

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							23Apr2021, 5 mg two tablets twice daily for 7 days, then regular dose times 7 days. He is to report to hematologist on 29Apr2021. The outcome of the events deep vein thrombosis and pulmonary embolism was unknown. The reporter assessed the events as serious (life-threatening).; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events DVT of legs and Pulmonary embolism cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
1284761	5/4/2021	MD	56	M	4/8/2021	4/12/2021	blood clot at upper right chest underneath collar bone; Swollen right arm and fingers; tingling and numbness in arm; numbness in arm; headaches; This is a spontaneous report from a contactable consumer (patient). A 56-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) dose 1 via an unspecified route of administration, administered in Arm Left on 08Apr2021 04:00 (Lot Number: EWO153) as SINGLE DOSE for covid-19 immunisation. Medical history included Implantable cardioverter defibrillator insertion from 2005. Concomitant medication in two weeks included verapamil 120 mg. No other vaccine in four weeks. No Covid prior vaccination. No Covid tested post vaccination. No Known allergies. On 12Apr2021, the patient experienced blood clot at upper right chest underneath collar bone. Swollen right arm and fingers with tingling and numbness in arm. Also, suffering from occasionally headaches. The patient was relatively healthy with no known blood clot issues. Events resulted in Doctor or other healthcare professional office or clinic visit. Unknown if treatment was received for events. The outcome of events was not recovered.

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1285794	5/4/2021	NJ	71	F	4/5/2021	4/23/2021	Dural venous sinus thrombosis complicated by intracranial hemorrhage and seizure
1284766	5/4/2021	KY	53	F	2/12/2021	3/24/2021	I had a stroke. The blood clot is on the left side of the brain which has affected the right side of my body: right leg, right foot, right arm, right hand, and the right side of my face.; I had a stroke. The blood clot is on the left side of the brain which has affected the right side of my body: right leg, right foot, right arm, right hand, and the right side of my face.; This is a spontaneous report from a contactable consumer. A non-pregnant 53-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in left arm on 12Feb2021 15:00 (Batch/Lot Number: EL9269) as single dose (at the age of 53 years old) for COVID-19 immunisation. Medical history included depression, pre-diabetes and hysterectomy from 2003 hormones due to hysterectomy in 2003. Concomitant medications included metformin, semaglutide (OZEMPIC), estradiol, amphetamine aspartate, amphetamine sulfate, dexamphetamine saccharate, dexamphetamine sulfate (ADDERALL), lisdexamphetamine mesilate (VYVANSE) and ascorbic acid (C [ASCORBIC ACID]), all taken for an unspecified indication, start and stop date were not reported. The patient previously took BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 (lot number=EL9262) at 20Jan2021 03:00 AM, on the right arm for COVID-19 immunisation. The patient stated on 24Mar2021, "I had a stroke. The blood clot is on the left side of the brain which has affected the right side of my body: right leg, right foot, right arm, right hand, and the right side of my face." Patient received blood thinners as treatment. The patient had emergency and physician visit. The patient was hospitalized for 2 days. The outcome of the event was not recovered.



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1284783	5/4/2021	FL	68	F	3/20/2021	3/1/2021	fever; fatigued; Did not have much energy/having no energy/low energy; Left Arm was painful and it got swollen a bit; Left arm painful; Foggy and not clear; extreme shortness of breath/cannot catch her breath; almost hyperventilating/Hyperventilation; This is a spontaneous report from two contactable consumers (including husband and patient self) and patient self. A 68-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EN6204) at single dose on 20Mar2021 14:54 injected in left arm in the muscle for Covid-19 immunization. Medical history included shortness of breath, hypothyroidism and COVID-19 back in Dec2020. She had some food allergies that were diagnosed prior to getting the vaccine. Patient was tested positive for COVID on 21Dec2020 and negative on 20Jan2021. The symptoms followed for patient was a little coughing and no smell for 3 days and a little shortness of breath. Family medical history was none. Concomitant drug included levothyroxine 0.75 ug, once daily for hypothyroidism, which was taking for 15 years (as of 19Apr2021). No previous history of all previous immunization with the Pfizer vaccine considered as suspect. No Prior Vaccinations (within 4 weeks). No additional vaccines administered on same date of the Pfizer suspect. Patient experienced left arm painful on 20Mar2021 about an hour or two after she got the injection, did not have much energy on 21Mar2021 08:00, foggy and not clear from 21Mar2021 to 22Mar2021 08:00, shortness of breath started 24Mar2021 or 25Mar2021, and hyperventilation on an unknown date in Mar2021 (reported as a week or 9 days after receiving vaccine). The shortness of breath was what she referred to as hyperventilating. That came a week after the vaccine. The same date they took shot was when the arm pain started and the low energy was the day after. Foggy and not being clear was from 21Mar2021 to 22Mar2021. Shortness of breath started 24Mar2021 or 25Mar2021. In addition to shortness of breath, she had been hyperventilating. That began approximately a week or 9 days after receiving vaccine. Left arm was painful and it got swollen a bit and lasted for 48 hours. The husband experienced arm pain and said he almost had a fever and felt fatigued. The reporter thinks patient (his wife) felt the same. She had arm pain

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and not much energy. They came out of that ok. About a week after the first injection, she just cannot catch her breath. She started hyperventilating to the point where the husband thought she would expire. She also experienced being foggy and not clear and having no energy. First, she went to a Cardiologist and he said there was nothing wrong. She then saw a lung doctor who send for respiratory chest and did chest CT scans and everything was clear on both test. He did not prescribe any medications. A week after she saw him, she went to the ER on 31Mar2021for hyperventilation and shortness of breath. They prescribed Xanax (AER 2021434900). She said it did not work and they prescribed something else. It was 25 mg twice a day which was in a pharmacy vial. They then prescribed Lorazepam. She was afraid to take it. She took one instead of two. The dose was 0.25 mg twice daily. The ER did CT scan of chest with Contrast. It was negative for thromboembolism (also reported as CAT scan's negative for blood clots). She had shortness of breath before the vaccination and it got worse. She was managing it though. Outcome of left arm painful, foggy and not clear, did not have much energy/having no energy/low energy was resolving. Outcome of shortness of breath and hyperventilation was not resolved. Outcome of the other events was unknown. Information about lot/batch number has been requested.

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1284805	5/4/2021	TX	40	F	4/5/2021	4/1/2021	more than usual vaginal bleeding/with very dark blood with clots.; menstrual cramps; sharp pelvic pain; more than usual vaginal bleeding; more than usual vaginal bleeding; This is a spontaneous report from a contactable consumer (patient). A 40-year-old female non-pregnant patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 05Apr2021 10:30 (Batch/Lot Number: ER8734) as single dose for covid-19 immunisation. Facility type Vaccine: Other. Medical history included known allergies: Sulfa and Folate deficiency. The patient's concomitant medications were not reported. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EN6206) on 15Mar2021 10:30 AM in left arm for covid-19 immunisation and experienced vaginal bleeding/blood clots at mid-cycle on 15Mar2021 08:00 PM. If other vaccine in four weeks: No. Other medications in two weeks: No. If Covid prior vaccination: No. If Covid tested post vaccination: No. The patient experienced more than usual vaginal bleeding/with very dark blood with clots, menstrual cramps, sharp pelvic pain, all on Apr2021 with outcome of not recovered. Clinical course: After the first dose, the patient had vaginal bleeding/blood clots at mid-cycle. The same day after the 2nd dose, she started feeling menstrual cramps and sharp pelvic pain. After taking paracetamol (TYLENOL) and feeling a bit of relief, she stood up and started having more than usual vaginal bleeding at the level that it reached the floor as if it was a hemorrhage with very dark blood with clots. This lasted for 1 minute. This lasted for 5 days and 7 days later, she started bleeding again with dark blood clots for a period of 3 days. The events resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. No treatment received for events more than usual vaginal bleeding/with very dark blood with clots.

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1284810	5/4/2021	KY	50	F	4/5/2021	4/1/2021	heart attack; tingling down left arm/tingling down right arm /tingling down left leg/tingling across back/tingling down right leg; burning sensation in her shoulder blade; muscle pain; muscle tightening; aching to left shoulder; This is a spontaneous report from a contactable consumer (patient). A 50-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number FR8732, on 05Apr2021 at single dose in left arm for COVID-19 immunisation. Medical history included blood clot in lung from 26Mar2021 (according to the chest X-ray she did not still have it but she had not been to her pulmonologist yet), complete hysterectomy in Jan2021, liver condition, high cholesterol and blood clot. Concomitant medications included apixaban (ELIQUIS) for blood clot, ursodiol for liver condition, and pravastatin for high cholesterol. The patient had the first dose on 05Apr2021. She began feeling muscle pain and a burning sensation in her shoulder blade the Thursday after receiving the vaccine (08Apr2021) and into Friday (09Apr2021). She had muscle tightening and aching in her left shoulder on 08Apr2021. By Monday mid morning (12Apr2021) she had tingling all down her left arm, across her back, down her right arm and into both legs. She began having tingling in her arms and legs bilaterally since last Monday (12Apr2021), however it was more prominent in her left extremities rather than the right. She wanted to know if this was a side effect of vaccine. She got the shot in her left arm. She went to the hospital and they admitted her. She had tests in the ER. She had MRIs, CTs and a battery of blood tests. They could only tell her what it was not and not what it was. It was not cancer, stroke, heart attack, aneurysm or a brain tumor. She was released and did not know what caused it. Again from the above that on Thursday (08Apr2021) her left shoulder muscle started aching and on Monday a week later she experienced tingling. She thought she was having a heart attack and was hospitalized for 4 days. She asked the doctor if this was a side effect and she was told to call the place where the vaccine was administered. She called the nurse and she could not give answers and recommended that she call Pfizer. Several conditions were ruled out but she was not given a reason for her symptoms. Her HCP has not been helpful. She stated she had a complete hysterectomy in January but doesn't

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1284814	5/4/2021	VA	55	M	3/3/2021		<p>think that would have any effect. She had a CT on 12Apr2021, a MRI of her head and neck on 12Apr2021, a MRI with contrast on 14Apr2021 of her upper neck, a MRI of her lower back on 15Apr2021 and a bone scan on 15Apr2021. Stated that they all came back normal no abnormalities. The outcome of muscle tightening was resolving. The outcome of heart attack was unknown. The outcome of other events was not resolved.</p> <p>Afib; sometimes sharp and sometimes dull pains that would last 10-60 seconds throughout her body-calves, things, forearms, toes, finger and even his stomach; sometimes sharp and sometimes dull pains that would last 10-60 seconds throughout her body-calves, things, forearms, toes, finger and even his stomach; sometimes sharp and sometimes dull pains that would last 10-60 seconds throughout her body-calves, things, forearms, toes, finger and even his stomach; This is a spontaneous report from a contactable consumer (patient). A 55-years-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 03Mar2021 (Batch/Lot Number: EN6198) (age at vaccination: 55-year-old) as SINGLE DOSE for covid-19 immunisation. The patient's medical history was not reported. Concomitant medications included nebivolol nebivolol hydrochloride (BYSTOLIC) taken for an unspecified indication from 2013 and ongoing; doxycycline (ORACEA) taken for an unspecified indication from Jul2020 and ongoing. Historical vaccine included first dose of bnt162b2 (Batch/Lot number: EC9269) on 02Feb2021 as single dose in Left arm for covid-19 immunisation. The patient had been experiencing pains on and off for about 5-6 days after his first slot. Then he read an article (he swear, he was not researching anything online) about a 56 year old man who developed ITP days after receiving Pfizer vaccine. since he had Afib this article worried him. He had no idea what blood clots felt like, but he was having sometimes sharp and sometimes dull pains that would last 10-60 seconds throughout her body-calves, things, forearms, toes, finger and even his stomach. The doppal came back negative. The doctor suggested symptoms finally disappeared for good about two days after his second dose. The outcome of the events was unknown.</p>

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1284832	5/4/2021	NY	80	F	3/28/2021	4/17/2021	Big Blood Clot in left leg; This is a spontaneous report from a non-contactable consumer (Patient). A 80-years-old female patient (Non-pregnant) received bnt162b2 (Pfizer-Biontech COVID-19 vaccine, Solution for injection), via an unspecified route of administration on 28Mar2021 11:00 as single dose for COVID-19 immunisation. The patient medical history included allergies to Demerol. The patient's concomitant medications were not reported. On 17Apr2021 21:30 patient experienced big blood clot in left leg. Patient was hospitalized for 2 days. The patient underwent lab tests and procedures which included Nasal swab test results negative on 16Apr2021. Treatment received for the adverse event was blood thinners. The outcome of event was Not recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained
1284853	5/4/2021	NJ	46	M	4/10/2021	4/15/2021	I had a Stroke; Blood clot travelled to my brain; effected left side of my body; ability to speak; This is a spontaneous report from a contactable consumer (patient). A 46-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot: ER 8729), via an unspecified route of administration in left arm on 10Apr2021 (at the age of 46-years-old) as single dose for covid-19 immunisation. The vaccination facility type was a pharmacy/drug store. The patient's medical history and concomitant medications were not reported. The patient had no known allergies. The patient did not have covid prior vaccination. The patient had no other vaccine in four weeks and no other medications in two weeks. The patient had a stroke. Blood clot travelled to his brain and effected left side of his body and ability to speak on 15Apr2021 at 17:30. The events resulted to emergency room/department or urgent care, hospitalization for 3 days, life threatening illness (immediate risk of death from the event), disability or permanent damage. The patient received unspecified treatments for the event. Covid test post vaccination on 15Apr2021 with result of negative. The outcome of the events was recovering.

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1284721	5/4/2021	MA	58	M	3/25/2021	4/23/2021	<p>Superficial blood clot; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Superficial blood clot) in a 58-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 014C21A and 018B21A) for COVID-19 vaccination. No Medical History information was reported. On 25-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 23-Apr-2021, the patient experienced THROMBOSIS (Superficial blood clot) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Superficial blood clot) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Apr-2021, Ultrasound scan: abnormal (abnormal) Ultrasound of left arm was done and determined a blood clot in that arm.. Patient went to the emergency room on 24 Apr 2021, approximately 7 pm. The patient was a healthy individual and used to do bike ride 11 miles per day with average speed 16mph. He did bike ride the evening of his second covid shot. No relevant concomitant medications were reported. Treatment information included anti-inflammatory medicine. Action taken with mRNA-1273 in response to the events was not applicable. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 26-Apr-2021: Additional information was received on 26 Apr 2021. Added lab data and treatment; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1287662	5/4/2021	UT	67	M	4/10/2021	4/14/2021	A few days after the vaccine started feeling uncomfortable in the left leg. It did not get better with rest and time so went to the ER and an ultrasound and found a clot from the groin to the ankle. He had no injury to preclude this clot. He was put on an anticoagulant (Xarelto) and standing and walking is very painful. He has a follow up appointment set with his PCP 5/6/21 He was told he might have to be on this medication for months maybe longer.
1286382	5/4/2021	FL	53	F	4/1/2021	4/26/2021	portal vein thrombosis
1285795	5/4/2021	WA	75	F	4/9/2021		o Patient with several complaints that started after receiving her Johnson&Johnson COVID vaccine 3 weeks ago. She has swelling in her medial malleolar area with negative calf tenderness or Homans' sign. Due to recent findings with Johnson&Johnson vaccine, will send patient for doppler testing to look for the presence of a clot. Her swelling could be due to mild injury while working in her garden or varicose veins. o Will obtain CBC to evaluate platelets due to patient's concerns for recent vaccine. o Other complaints that may be related to the vaccine (visual change and fluid area on shin) have now resolved. Discussed with patient that based on the vaccines being new, difficult to know what side effects may be seen, but she should continue to watch for changes and encouraged her to see an eye specialist for an eye check. o Last vitamin D was normal and advised that no check necessary at this time and that she can take Vitamin D 1000-2000 units daily.



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1287981	5/4/2021	TX	49	F	3/8/2021	3/8/2021	<p>Shortly after getting the shot she reported feeling "off" as she was driving she started feeling short of breath and her heart was racing. When she got home around 5 PM she was still feeling short of breath and reported that her heart was racing. She was unable to speak clearly, but was stating that it was due to be being short of breath. She also reported feeling lethargic and fell asleep until the next morning. She slept until approximately 12 pm the next day. When she woke up she reported feeling right sided cheek tingling. At that time she thought she had just slept wrong. When she attempted to walk down stairs she was limping and reported just feeling very weak on her left side. On Wednesday she slept in late again complaining of lethargy. When she awoke that Wednesday (3/10) her speech was markedly slurred. She was also saying things that didn't make sense. She was dragging her left leg when she tried to walk. We immediately took her to the ER and she was worked up for stroke. When she was triaged in the ER we mentioned that she had just had her COVID vaccine and voiced concerned that maybe she had a reaction to her COVID vaccine. She was admitted to hospital on 3/10 for a possible stroke. Her MRI was done later on 3/11, Her MRI showed that she has strokes on both sides of her brain in the frontal, parietal and occipital lobes. The doctor referred to her stroke as being caused by a "showering of clots". The doctor said this usually only happens to someone with cardiac issues. My mom has no cardiac history. Her doctor ordered an 2D Echo of her heart and no abnormalities were found (3/12). She is still disabled from her stroke. She was hospitalized from 3/10 - 3/16. She was discharged to other care facility from 3/16-3/26. She is currently needing outpatient rehab in a day neuro program. She attends this at outpatient facility. She has to walk with a cane due to persistent left leg weakness. Her speech has a slight slur, and she suffers from short term memory loss. She intermittently has trouble with her equilibrium and reports feeling dizzy. She sometimes has a hard time swallowing or says that it doesn't feel right when she swallows. She also trouble with word retrieval. She has left-sided neglect which correlates left eye visual deficits. She currently requires care from a general physician, neurologist, physical therapist, occupational therapist, speech therapist, neuro ophthalmologist and neuro psychologist. She was started</p>

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							on a new medication regime 325 mg aspirin daily, plavix for 21 days (now completed), metformin, amlodipine, coreg and losartan. She is going to need outpatient rehab until at least June from the last update we received from her rehab doctor.
1287872	5/4/2021	WA	66	M	4/5/2021	4/9/2021	Pt presented to pharmacy to receive his 2nd Covid19 dose. During counseling he stated that he received his first dose of Moderna Covid19 on Monday, 04/05/2021. On Friday, 04/09/2021 he experienced pain on his left side ('pain in lungs). Then, on Saturday, 04/10/2021 he went to the hospital, where an x-ray showed a clot in his lungs, He also experienced a stroke. He we home on Eliquis 5 mg : TAKE 2 TABLETS BY MOUTH 2(TWO) TIMES DAILY FOR 7 DAYS, THEN 1 TABLET 2(TWO) TIMES DAILY FOR 23 DAYS. INDICATIONS VENOUS THOMBOEMBOLISM ('Dr not sure this was related to vaccine'. His doctor 'approved a second dose of Covid19')
1287843	5/4/2021	CA	34	F	4/26/2021	5/1/2021	Vaginal blood hemorrhaging started at 4am. Admitted to ER. Severe bleeding and passing of large blood clots. Required an emergency D&C and a blood transfusion, plus fluids.
1286717	5/4/2021	TX	37	F	4/19/2021	4/23/2021	Blood clot causing the need for emergency surgery
1286682	5/4/2021	TX	64	M	3/3/2021	3/3/2021	My Father received the first dose of CV19 on 03/02/21 and the second dose on 03/03/2021 in the morning, and at night he had a stroke, we called 911 they hospitalized him within a week he was out of danger and had physical therapies for a month at facility he got out on the 31st of March 2021 and on April 4th he once again went into the hospital for lack of oxygen, they detected blood clots in his legs and his lungs and also an aneurysm in his heart.
1286676	5/4/2021	NY	70	F	3/16/2021	5/1/2021	Venous sinus thrombosis

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1286668	5/4/2021	CA	34	M	3/31/2021	4/6/2021	After my J&J vaccine, I experienced fever, chills and a left sore arm and those symptoms resolved in 24 hours. On 04-06-2021 I experienced headaches on and off and on 04-07-2021, I had light headiness, an air-filled pressure sensation to my eyes, forehead, more like a sinus headache. On 04-14-2021, I went to see my PCP due to my headaches continuing, the doctor ran complete blood panel test were performed along with a D-dimmer test to rule out blood clots and he told me to take Advil as pain medication. My D-dimmer test was normal. I noticed when bending down my headaches became worse. On 04-20-2021, an MRI of the brain was performed. On 05-01-2021, I experienced muscle body aches, fever and continued with headaches. I went to a walk-in clinic, where a Covid-19 test was performed and it was negative. I started taking antibiotics and the fever and muscle bode aches started to go away. I still have to this day headaches and an air-filled pressure sensation around my eyes and eyebrows. As of today, my headaches are consistent, and they come and go.
1286548	5/4/2021	NC	75	F	2/9/2021	3/27/2021	The blood vessels to the pt's spleen burst due to a clot causing removal of her spleen. During surgery she was given 2 units of blood. Due to blood clots (albeit in other parts of the body) with other vaccines, the lack of splenic trauma preceeding this event, the pt's lack of history re: blood clots, and in the interest of furthering this emerging COVID-19 vaccine technology/progress, the pt's PCP and this POA thought it worth noting.
1286090	5/4/2021	MA	25	F	4/23/2021	4/26/2021	Heart felt like it was pounding out of my chest on Monday evening on April 26, 2012. On Wednesday morning, around 8:30, April 28, I collapsed at at kickboxing class and was sent by ambulance to Hospital Emergency Room as my heart rate was very high and my oxygen was low. In the ER I was diagnosed with blood clots in my lungs, pulmonary embolism, and was sent by ambulance to another facility where I had a procedure to try to break up the clots (catheter directed thrombolysis). I spent 24 hours in the ICU, and another 24 hours in Cardiac Care. I was released on Friday, April 30 at around 2:30 pm. I am now prescribed Eliquis, have a follow up with my PCP on Monday, , May 10, a follow up with cardiology on May 24, and a follow up on June 14 with the Pulmonary Embolism group.

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1285878	5/4/2021	CA	48	F	4/26/2021	5/3/2021	Janssen COVID-19 Vaccine EUA. 7 days after shot I have the worst headache/migraine. I have gone to Er for CT scans that show clear so no blood clots. I do not have a history of migraines. I am unable to move. Work. Do anything. This is day 2. Idk how I'm to get thru this!!
1287853	5/4/2021		21	F	4/30/2021	5/4/2021	21 yo f w/stated hx of factor V leiden deficiency c/o new acute atraumatic onset of diffuse ha w/mild nausea w/o vomiting x3hrs, states concern for blood clot etiology given recent J&J vaccine w/i past week; Pt states sensitivity to noise during this time; Pt states paternal hx of 'blood clot that shredded my dad's arteries and veins' in the brain but denies this as stroke; Pt denies any fevers/ns/chills, other hearing changes, nasal congestion, sore throat, recent illness, hx of sig head inj/trauma/surg/procedure

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1286545	5/4/2021	OR	81	F	4/7/2021	4/28/2021	<p>Pt received vaccine in her home state, unable to get details of vaccine administration such as date, site, lot #, etc. Per ED MD note : 81-year-old female with reported history of atrial fibrillation found down at hotel room. Patient states she has been on the ground in the room for 3 days, she was found covered in feces. Alert and oriented x4 however intermittently appears confused and has varying history. She does not know how she got on the ground, however denies fall or syncope. No significant current complaints. Slightly tachycardic and febrile, slightly hypertensive, exam without any significant acute findings, no obvious skin source of ulcer or infection, no focal neurological deficits, no pain. Initiated aggressive fluid hydration and sepsis work-up. EKG appears normal with no signs of ischemia or arrhythmia. Labs show slightly elevated troponin, low magnesium, metabolic/lactic acidosis. VBG relatively normal. Urine negative for infection chest x-ray without evidence of pneumonia, no clinical signs or symptoms to identify source of infection. Nothing to suggest meningitis at this time. CT head is negative. Unclear source of fever however empirically treated with antibiotics and fluids. Patient remains hemodynamically stable with no hypotension. She did arrive slightly hypoxic and with increased respiratory rate however clear lung sounds and no indications of heart failure, COPD/asthma. CT chest without evidence of pulmonary embolism, focal pneumonia, or fluid overload. Respiratory status possibly related to compensation for metabolic acidosis that is likely due to lack of fluid intake due to being on the ground. CK is normal and kidney function is normal. Consulted medicine for admission for further evaluation and treatment. Cardiology was also consulted for NSTEMI, agrees with current plan. per H&amp;P 4/28/21: Altered mental status (R41.82): Etiology is not clear. Patient states she had J&amp;J Covid vaccine about 3 weeks ago. Need to rule out cerebral venous sinus thrombosis. Get a CT scan of the brain with contrast. If negative will get CT venogram or MRV and MRI of the head. Neuro checks. Request PT OT and speech therapy evaluation. Check urine drug screen. Check blood alcohol level. Non-STEMI (non-ST elevated myocardial infarction) (I21.4): Start argatroban drip until cerebral vein sinus thrombosis is excluded then we can switch to heparin drip. Start aspirin and statin. Check fasting lipid panel.</p>

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Monitor on telemetry. Trend troponin. Request echocardiogram. Cardiology to consult. Dr. was consulted from the ER. » Beta-Blocker Ordered: Beta-Blocker Ordered » Aspirin Ordered: Aspirin Ordered » Statin Ordered: Statin Ordered Fall (W19.XXXA): Plan as documented above. Rhabdomyolysis (M62.82): Hydrate and recheck CPK. Elevated liver enzymes (R74.8): Check hepatitis panel. Monitor levels. Fever (R50.9): No clear source of infection. Follow up on blood cultures. CT chest negative for infectious process. Check CT of the abdomen and pelvis. Start empiric antibiotics: Vancomycin and Zosyn. Hypomagnesemia (E83.42): Administer magnesium sulfate. Repeat level in the morning. Diabetes (E11.9): Start sliding scale insulin. Monitor fingersticks. Hypoglycemic protocol. Check hemoglobin A1c. Hypertension (I10): Fortunately patient is hemodynamically stable. We will cautiously start metoprolol. Adjust antihypertensives to optimal blood pressure control. Acidosis, lactic (E87.2): Likely due to profound volume depletion. Rule out sepsis. Hydrate and trend level. VTE: Argatroban. » VTE Prophylaxis Assessment: Risk Level documented as Low Risk Discharge Planning: » Discharge Planning: » Discharge To, Anticipated: Home independently Per Intensivist note 4/30/21: . Another consideration was TTP, however, patient has normal renal function with no significant evidence of microangiopathic hemolytic anemia (no schistocytes on smear). Also does not seem consistent with ITP. Suspect more a result from sepsis given bacteremia Per attending note 4/30/21: Altered mental status (R41.82): Likely septic encephalopathy due to sepsis. No cerebral venous sinus thrombosis. MRI negative for stroke. AMS has resolved. Continue antibiotics. Per attending note 5/2/21: Addendum by MD, on May 02, 2021 09:58:55 (Verified) Discussed with cardiologist, Dr. . Possible need for TEE with regards to persistent bacteremia. We will keep n.p.o. overnight for TEE tomorrow. Repeat blood culture from 4/30/2021 just came back positive for Enterococcus. Suspect endocarditis due to TAVR. ? need for TEE to evaluate the valves (TAVR) more closely. Duration of antibiotics depends on bacterial clearance: To be determined. Get another set of cultures. On Zosyn. per attending note 5/4/21: Enterococcal bacteremia (R78.81): Etiology not entirely

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							clear but suspect GI source or endocarditis. Repeat blood culture from 4/30/2021 is positive for Enterococcus. PCP he is accepting to follow-up for IV antibiotics management: Will arrange home IV infusion through care . Antibiotics end date to be determined: Pending bacterial clearance. Repeat blood cultures pending. Infectious disease specialist following: Patient is currently on Unasyn. Will need 4 weeks of IV antibiotics.
1285984	5/4/2021	IL	83	F	3/1/2021	4/19/2021	She received her second COVID shot at the end of March first week of April. My mother had a stroke, several seizure and her lungs were filled with blood clots. She had to have a procedure to remove the largest one next to her heart. My mother has always been healthy and has never had any of the following issues in her life. She gets regular checkup and I spoke with her on April 19, 2021 at 12:00pm Central time and she was fine but at 1:20pm my brother who is staying at her house said she was having a seizure. I talk to my mother at least four times a day and she has never in 83yrs experienced anything like this. She doesn't remember right now where her shot was administered but my brother took her but he is mad at me because I have full power of attorney and he is not happy. Therefore, he will not give me the information that is needEd to give to your office. My mother was admitted to the ICU. She is now at their rehab center in a hospital. Once my mother is released from the hospital she is moving with me out of state. This is and unexpected expense that I will need assistance with but I don't mind because it is my mother and now someone has to be with her 24/7.
1285922	5/4/2021	WA	38	F	4/12/2021	4/19/2021	Pulmonary embolism also blood clot in leg
1286171	5/4/2021		34	M	4/25/2021	5/1/2021	This patient was admitted on 5/1/21 with chest pain. He was found to have an inferior STEMI with a thrombotic lesion in the proximal circumflex artery that was stented. He was also found to have a chronic right gastrocnemius deep vein thrombosis on a lower extremity ultrasound on 5/3/21. He is currently undergoing a hypercoagulable workup. There is potential concern that the thromboses may have been related to his COVID vaccine, as he received the second dose on 4/25/21.

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1286241	5/4/2021	MI	59	M	3/20/2021	4/16/2021	The patient developed a blood clot in the left calf 2 weeks after the first dose of Moderna COVID vaccine, which required treatment with Eliquis 5 mg twice daily. The patient also reported hearing loss that needed treatment with a tapering steroid protocol. The sense of hearing did not recover after the most recent loss event.
1286342	5/4/2021	OH	34	M	4/21/2021	4/23/2021	34 y.o. male with history of depression admitted to the hospital on 4/23/2021 for chest pain and leg pain found to be due to Deep Vein Thrombosis and bilateral Pulmonary Embolism. Patient started on heparin infusion in the hospital with stabilization of vital signs then transitioned to apixaban at DVT/PE dosing prior to discharge
1286446	5/4/2021	AL	73	F	3/12/2021	3/14/2021	Bilateral pulmonary clots, bilateral lower extremity clots, right heart strain, atrial fibrillation, right atrial clot, heart attack
1286499	5/4/2021	FL	61	F	3/19/2021	5/1/2021	May 1, 2021, Patient was admitted to the hospital with Blood clots in both lungs. The hospital is unable to figure out what has caused the blood clots. We do not know if this is related to the vaccine but would like to know if it is.
1282638	5/3/2021	TN	66	F	3/10/2021	4/30/2021	Ultrasound done on 4-30-2021 for pain in calf of left leg and numbness of the toes for 7 days. Result came back positive for blood clot.
1283045	5/3/2021	TN	69	M	3/28/2021	3/30/2021	On March 30th the patient had loss of appetite and headache. On March 31st the patient collapsed and was taken to the ER, the patient's oxygen was low. Patient's blood pressure had dropped and you could not wake him up all afternoon. The Ambulance took him to the hospital on April 1st where he had shortness of breath and blood clots in lungs. On April 1-2 the patient was leaking blood but the hospital staff could not find where so they gave him 3 units of blood. Patient also received 3 antibiotics for a rare pneumonia.
1282884	5/3/2021	OR	48	F	4/10/2021	4/25/2021	Large DVT and pulmonary embolism requiring anticoagulation and hospitalization. Also found to have a large fibroid uterus compressing IVC which likely contributed to IVC. Patient ended up needing mechanical thrombectomy to help relieve clot burden.



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1283019	5/3/2021	WA	43	F	3/30/2021	4/29/2021	Patient present to ED on 5/3 with leg pain. found to have blood clot in left leg via ultrasound. started on rivaroxaban and discharged
1282845	5/3/2021	AZ	56	F	4/6/2021	4/7/2021	After my vaccine, I had a fever and my leg started to swell up. I also had pain in my right arm, injection site. I also had a covid test because of how I was feeling and the test was negative. I had an u/s of my right leg to check for blood clots. An x-ray of the chest was also performed. I also have had a bad cough since my vaccine which I can not get rid off. I am still not feeling 100% from the vaccine, still tired, fatigued and diarrhea. I do not have my lot #, but I will call back when I get that information.
1283397	5/3/2021	CA	32	F	4/24/2021	4/27/2021	got my vaccine Saturday morning 4/24/21 - woke up in the middle of the night on Tuesday morning around 2am to my lower left leg from the knee down cramped up. Woke up to the same pain and continued all day Tuesday to the point of not being able to walk well . Wednesday morning went to urgent care to be treated due to extreme pain. Did an ultrasound and they diagnosed me with DVT - found two blot clots in my left calf and back of the knee.
1283160	5/3/2021	CO	58	M	4/21/2021	4/29/2021	Patient is a 58-year-old male with history of DM2 on insulin, bovine aortic valve replacement, nonischemic cardiomyopathy (unknown EF), hypertension, obesity, presented to Medical Center on 4/26/21 for left leg pain and swelling. Symptoms began about 2 days ago when he drove to visit some friends and started to " feel under the weather" hence drove back yesterday. He then had acute onset of left leg swelling and pain which prompted him to present to the ED. He was reportedly concerned about " having a clot" as he just received the Johnson & Johnson Covid vaccine this past week.
1284449	5/3/2021	TX	82	F	4/12/2021	4/14/2021	Approximately 40 hours after second Pfizer vaccine, patient complained of pain in lower right leg, and a cold foot, lethargy, weakness, feeling unwell. 3 days later, shortness of breath, difficulty breathing, rapid heartbeat, and confusion began. Went to Medical center on 4/20/21, diagnosed with DVT, PE and clots in and around the heart and passed away on 4/21/21 of cardiac shock in the setting of pulmonary and arterial thrombosis.

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1283479	5/3/2021	TN	32	F	4/9/2021	4/14/2021	On Day give I began having left leg pain, shooting pains starting at my knee going down my leg. As the next few days progressed my leg began to get numb and go cold as ice. I have lost my ability to walk and my leg still has shooting nerve pains, gets numb, and twitches. I have gone to the ER, the doctor twice, and a neurologist. Nobody seems to have any answers for me. It is not a blood clot but that is the only thing that has been ruled out.
1282626	5/3/2021	NJ	52	F	4/13/2021	4/13/2021	Within hours of my vaccination I got a headache, fatigue and within five days after my vaccination I got a severe migraine which lasted a total of eight days. I went to the hospital to get an MRI which was clear of a blood clot. All side effects have passed now.
1281071	5/3/2021	CA		F	1/14/2021	2/4/2021	had a stroke on 04Feb2021 that resulted in her left side being paralyzed; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of CEREBROVASCULAR ACCIDENT (had a stroke on 04Feb2021 that resulted in her left side being paralyzed) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Clot blood and Stroke in 2017. On 14-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Feb-2021, the patient experienced CEREBROVASCULAR ACCIDENT (had a stroke on 04Feb2021 that resulted in her left side being paralyzed) (seriousness criteria hospitalization and medically significant). At the time of the report, CEREBROVASCULAR ACCIDENT (had a stroke on 04Feb2021 that resulted in her left side being paralyzed) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medications and treatment information were not reported. Reporter did not allow further contact
1283410	5/3/2021	WI	85	F	3/10/2021	3/15/2021	Patient had a stroke on March 15, 2021 as described as a blood clot in her brain. Medical personnel were unable to correct it surgically and she passed away that evening in the hospital. Death was the final result.

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1282623	5/3/2021		48	F	4/9/2021	4/12/2021	Two days after the injection, I started having leg cramps and dull pain in my lower legs. On monday the 19th, I went to the acute care because I was having more leg pain. Dr ordered D dimer test that came back elevated. I was asked to go to the hospital for a doppler test of legs that showed no clots in legs.
1282273	5/3/2021	VA	60	F	3/30/2021	4/24/2021	Blood Clot in Right Leg
1282231	5/3/2021	IL	83	M	4/3/2021		I experienced blood clots, also had bilateral leg pain and lower back pain. I currently in the hospital.
1282151	5/3/2021	FL	20	F	4/19/2021	4/25/2021	The patient was presented to ER 4/27 with progressive swelling of R arm associated with shoulder pain. Admitted to ER 4/27-4/29 admitted by the doctor for right subclavian vein thrombus, right axillary and right brachial vein thrombus and bilateral pleural blebs largest measuring 2.1cm with small pulmonary emboli within segmental artery to the right lung base posteriorly and within the segmental artery to the left lower lobe, right sided thoracic outlet syndrome She was on Heparin drip and started on Eliquis Discharged on Eliquis She was on Xulane patches for birth control and was taken off Xulane after finding the clots Also of note she received Pfizer vaccine 1 week prior to presenting to ER
1282102	5/3/2021	NV	47	M	4/26/2021	4/27/2021	Leg cramp alerted me to deep vein thrombosis (DVT) and pulmonary embolism (PE) . I had the second dose of Moderna Monday afternoon. First cramp Tuesday evening. Mild infrequent leg pain Wednesday. Intense morning cramp on Thursday, hospitalized Thursday night with confirmed DVT w/PE. Discharged Sunday afternoon. Was fully hydrates at the time, no recent travel by car or plane. No extended period of inactivity such as bed rest or sitting. No evidence I?d internal trauma or injury. No recent surgery. No sign of any form of cancer. Vaccine listed as suspected cause of the DVT
1281599	5/3/2021	KY	32	M	4/7/2021	4/23/2021	Culminated in myocardial infarction. Chest pains started next day and leg pains. By April 23, I had severe chest pains and had to see medical at work. On April 30, 2021 was at emergency department for heart attack symptoms. Was transferred for myocardial infarction. Test results show myocardial infarction, coronary spontaneous arterial dissection, and blood clot.

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1281533	5/3/2021	PA	71	F	4/11/2021	4/14/2021	Blood clot in the lungs, Death
1281516	5/3/2021	NJ	66	M	4/1/2021	4/18/2021	Pt experienced sever headache, loss of speech transported to Medical Center. 4/19/21 Reports overnight stay and "blood clots" affecting speech, causing HA. Reports clots seen around his heart on MRI Discharged 4/20/21
1281374	5/3/2021	OH	79	M	2/19/2021	3/11/2021	Woke up in the middle of the night dizzy on the evening of 3/11/21,started vomiting blood, syncope, when woke up had altered mental state, when reoriented he was able to call EMS, taken to hospital where he was diagnosed with an abdominal clot size of a grapefruit
1281336	5/3/2021	NY	32	F	4/8/2021	4/1/2021	Overly tired, shortness of breath, chest pain, leg pain After 3wks of symptoms patient(self) went to hospital and it has been discovered patient has ( self) has a blood clot in Right lung. Patient (self) has no record or history of blood clots. Was treated with heparin while in hospital. Has since been discharged and sent home with a prescription for anticoagulant.

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1281053	5/3/2021			M	3/20/2021		ADVERSE EFFECT OF VACCINE; SHORTNESS OF BREATH; FATIGUE; HEADACHE; LOW PLATELETS; NIGHT SWEATS; DIAPHORESIS; BLURRED VISION; FEVER; BODY ACHES; This spontaneous report was received from a physician via a company representative and concerned a white nonhispanic or Latino 50 year old male. Initial information was received on 28-APR-2021, with additional information obtained via telephone follow up from a physician on 29-APR-2021. The patient's height was 73 inches and weighed 252 lbs; approximate body mass index was 32.68 kg/m2. Medical history included: lung infection in 2014 which led to aortic valve disease which required biologic aortic valve replacement (2014); prolapse of right coronary aortic valve cusp, severe aortic insufficiency. There was no history of hyperlipidemia and was positive for family history of cardiovascular disease. Concurrent conditions included attention deficit disorder (ADD), back and neck problem, other congenital anomaly of heart, hypertension, lumbago, shortness of breath and thyroid nodule. The patient received COVID-19 vaccine Ad26.CoV2.S (suspension for injection, intramuscular, batch number and expiry date unknown) on 19-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. Concomitant medications included: carvedilol, losartan and atorvastatin (all for aortic valve replacement). Also aspirin, Adderall (dextroamphetamine-amphetamine) both for unspecified indication. On 20-MAR-2021, the day after receiving the vaccine, the patient developed fevers, body aches and headache which resolved within 24 hours. Then a week on an unspecified date, he developed more symptoms which included fatigue, shortness of breath for the most part and some headaches. On 27-MAR-2021 the patient experienced a single episode of visual disturbance of blurred vision while driving. At a stoplight vision in both eyes were blurred and he had trouble see the road; he no longer could drive. The blurred vision resolved within a few minutes and not vertigo or headache occurred at that time; and there were no other reported visual changes. The patient visited his physician 28 days after receiving the vaccine on 16-APR-2021. He reported ongoing fatigue, body aches and headaches. No further visual changes or disturbances. He felt fatigue and shortness of

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breath were the most noticeable. He denied chest pains and fevers but has been experiencing night sweats (unspecified start date); and generally feels unwell and described himself as "feeling off". No leg edema or leg pain currently. Also no coughing, wheezing or bruising. His concentration was stable and there was no loss of memory. No other neurological symptoms. Physical exam was positive for chills diaphoresis, fatigue, fever and shortness of breath; cardiovascular examine revealed a murmur present, and pulmonary examine was normal breath sounds, no decreased breath sounds, wheezing, rhonchi or rales. Vital signs: blood pressure 104/68, pulse 93, temperature 98. The physician's assessment also included an adverse effect of vaccine. Laboratory results form 16-APR-2021 included: Creatinine (normal range 0.50 - 1.30 mg/dl) 1.09, white blood count (WBC) (normal range 3.8 - 10.8) 3.4, red blood cell count (RBC) (normal range 4.20 - 5.8) 4.92, hemoglobin (normal range 13.2-17.1 g/dL) 13.9, glucose (normal range 71-99mg/dL) 109, D-Dimer elevated at 286 (normal range <230), elevated C-Reactive Protein (CRP) (normal range 0 - 5 mg/L) 32.3, fibrinogen (results not reported), Covid-19 Antigen Antibody negative, platelet count 123,000 (lower limit of normal <140,000). The patient has a baseline platelet count of 200,000 from JAN-2021 and for the past 9 years had ranged from 180,000 - 240,000. A heparin-induced thrombocytopenia (HIT) was negative anti-PF4 antibody. On 20-APR-2021, the patient received Computerized tomogram (CT) of the head with and without contrast which was normal - no acute hemorrhage, mass effect or abnormal enhancement. The patient also had a CT chest with contrast with no evidence of pulmonary embolism to the segmental level; a 16 by 16 mm nodule with small calcification was noted, this was nonspecific but could reflect primary lung cancer, correlation with PET/CT is indicated. Additional laboratory results on 20-APR-2021 concerning serotonin release stated as follows: Positive, 6%, 40%, 37%. HIT panel negative with less than 0.6 antibody On 27-APR-2021 additional laboratory results were as follows: WBC 4.1, RBC 4.95, hemoglobin 14.0 g/dL, D-Dimer 275, fibrinogen 427 and HIT panel negative with less than 0.6 antibody. A hematologist was consulted and a complete blood count and HIT panel were performed on 28-APR-2021. Results were platelet

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1281337	5/3/2021	NJ	79	F	4/7/2021	4/21/2021	<p>count of 159,000, D Dimer of 275, HIT negative anti-PF4 antibody screen and the SRA assay was pending. On 29-APR-2021 the duplex of left lower extremity was negative for deep vein thrombosis (DVT). Additional laboratory reports included a platelet factor 4 antibody test test methodology which used latex particle enhanced immunoassay to detect anti -pF4/heparin antibodies (reference range 0.0-9), with the patient's value was &lt;0.6 (negative). A COVID PCR test was not performed. An enzyme-linked immunosorbent assay (ELISA) test was ordered for 30-APR-2021 for anti-PF4 antibodies. The action taken with COVID-19 vaccine Ad26.CoV2.S was not applicable. The outcome of the event blurred vision and fever were resolved; the outcome of low platelets, adverse event of vaccine, shortness of breath, fatigue, headache, body aches, night sweats and diaphoresis were not reported. This report was serious (other medically important condition).; Sender's Comments: V0.20210456790-COVID-19 vaccine Ad26.CoV2.S -Low platelet counts,blurred vision,adverse affect of vaccination. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> <p>pt says she started having trouble breathing so went to an Urgent Care where she was told she had allergies and prescribed some allergy medication. She continued to decline so on 4/28/21 she went ER. They did Chest X-Rays and other test and was diagnosed w/ blood clots in both lungs. She was admitted and stayed overnight. She was released and told to FU w/ Pulmonologist on 5/4/2021 @ 1 PM.</p>

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1286934	5/3/2021	IL	72	F	3/18/2021	3/20/2021	NO symptoms for 2 days after 2nd dose, but 58 hours later I woke up at 1am and couldn't walk. I could not lift my left leg off the floor to put weight on right leg. Didn't want to take Tylenol/ibuprofen so took a Xanax (low dose) to help sleep. Had a chiropractic adjustment the next day; needed cane & wheelchair for access (extremely painful & slow walking.) Took a 4 hour flight 2 days later. Was semi mobile, but knee stiff & needed a walker. Throbbing behind right knee & in groin; went to the ER for a dopplar ultrasound to rule out blood clots. It was osteoarthritis with no evidence of blood clots. Came home on 4/7. had several chiropractic adjustments. Now more mobile, still need cane/walker for stability.
1287150	5/3/2021	TX	57	F	4/9/2021	4/9/2021	FIRST DOSE ALL OK A BIT OF A FEVER. SECOND DOSE HIT ME VERY HARD FEVER TO HALUCINATIONS ALL NIGHT, BOTH LEGS CRAMPING FOR MORE THAN 5 DAYS LEFT ANKLE SWOLLEN, MY DOCTOR DID AN ULTRASOUND FROM LEFT LEG TO LOOK FOR CLOT, XRAY'S LEFT LEG TOO, BLOOD TEST URINE TEST. I HAD SCHEDULED MY YEARLY MAMMOGRAM WAS DENIED TO PERFORM IT BECAUSE IT HAD ONLY BEEN TWO WEEKS OF THE SECOND DOSE AND I WAS STILL FEELING TERRIBLE. THEY SAID RESULTS COME OUT ALTERED AFTER THE VACCINE TO WAIT AT LEAST 1 MONTH. TO THIS DAY I AM STILL SICK I KNOW PRESENTED A HEAVY COLD WITH FEVERS MY DOCTOR JUST GAVE ME TYLENOL AND REST I AM TOTALLY UNDER THE WEATHER. 3.5 WEEKS AFTER 2ND VACCINE. TODAY IS MAY 2ND 2021
1283021	5/3/2021	WA	35	F	4/8/2021	4/8/2021	On the way home after my vaccine, I had Chest pain. The next day I felt unusual early the next day and normal symptoms in the afternoon. On the third day I had a slight headache in the morning. I then got a significant nosebleed, and my right leg was painful. On the fourth day I tried to work out and I felt lightheaded and got some chest pain and tightness with shortness of breath. I seemed to bruise easily. I was advised to see my doctor and I went to the ER. I followed up with my doctor and she advised that there were no signs of blood clots.



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1285078	5/3/2021	CA	92	M	1/11/2021		Patient was a well and active 92 year old man, who walked 2 miles daily with a walker. He received Covid vaccine dose 1 on 11 Jan. On or before 30 Jan, he noted pains in one leg while walking. Newly dilated veins on the lower leg were noted. On feb 2 a doppler US revealed a superficial saphenous vein venous thrombosis, also new onset A flutter. Aspirin begun. On Feb 5 he woke with a cold foot (same side) and was found to have an arterial thrombus from SFA through distal posterior tibial. He underwent emergency thrombectomy, went to rehab for recovery, on Feb 23 suffered intracranial hemorrhage and died on Mar 10.
1280064	5/2/2021	FL	80	F	4/1/2021	4/13/2021	4/13/2021 heartburn like symptoms started. 4/20/2021 admitted to emergency room, received diagnosis of 3 blood clots in the heart, 4/27/2021 died as a result of blood clots in heart

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1280871	5/2/2021		46	M	4/9/2021	4/10/2021	<p>Patient presented to the emergency department on 4/10 with a complaint of left leg pain. Patient reports onset of symptoms on Wednesday (4/7). He states that initially it just felt like a cramp in his calf. He states that over the past couple days, the pain has gotten significantly worse. He states the pain is now sharp and severe in nature. He states that he is having due to the severity of the pain. He states the pain is now moving up into his medial thigh. Patient states that around noon on 4/10, he began having chest pain and shortness of breath. Patient describes a tightness across his chest and states that he cannot breathe associated with this. Patient does have a history of asthma and states that he has had a couple of episodes like this in the past. Patient also reports a history of diabetes, hypertension. Patient does report a family history of coronary artery disease as well as a family history of blood clots. He received his Pfizer Covid vaccine 2nd dose on 4/9/2021 (Lot # ER8729) and 1st dose (Lot # EN6204) given on 3/12/2021 at an outside facility. He does report arm soreness but is otherwise doing well. No recent travel. No recent immobilization. Upon evaluation in the ED, he was noted to have positive US for DVT in the LLE. Follow up CTA Chest was positive for bilateral lobar and segmental PE with right heart strain. CVM was consulted for possible PE intervention evaluation. Patient started on therapeutic Lovenox, but discharged home on 4/11 with Eliquis. . The next day 4/12/21 he returned to ED for SOB/Wheezing and LLE pain. On 4/15/21 he underwent EKOS, IVCF and iliac stent placement per Vascular surgery and subsequently sent home on Eliquis 4/16/21. Pt returned to the ER again 4/21/21 for recurrent SOB. CTA chest with no significant change in clot burden, no associated hypoxia.</p>

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1280839	5/2/2021	TX	39	F	3/27/2021	4/7/2021	I had the first vaccine on March 27, that night just felt flu-like symptoms, and my left arm was sore. My left arm was still sore from the 27 through April 11. April 7, I was having a hard time breathing, and my left arm swelled up where the injection was given. My husband took me to Hospital, and they said I was having a reaction to the COVID vaccine and gave me prednisone to help with the reaction. I went back to the same ER on April 9 and April 11 with the same problem, but worse. April 14, I went to work and passed out in the bathroom and called my husband to come to pick me up from work. He said our primary doctor, and then I went to . There they discovered a blood clot in my lungs. The doctor said it was a combination of my birth control pill and the COVID vaccine.
1280759	5/2/2021	OH	64	M	3/12/2021	4/2/2021	Loss of Breath after 5 days after both Vaccines Urgent Care concerned about Blood Clot Hospitalize 3 days - New diagnosis - Congestive Heart Failure
1280655	5/2/2021	NC	44	F	4/28/2021	4/28/2021	First 2 days: fever 101.5, whole left side pain, abdominal pain, headache, lower right leg pain 3rd day: low grade fever 100.5, lower right leg pain, left arm pain 4th day: lower right leg pain increased along with redness, swelling, red lines, and eventually I couldn't apply weight on my right leg. After visiting Urgent Care hospital, blood clots were found in my small veins.
1280599	5/2/2021	NY	66	F	3/8/2021	4/15/2021	Deep venous thrombosis
1280886	5/2/2021	NY	40	F	3/24/2021	4/17/2021	Abnormally heavy bleeding during the menstrual period following the vaccination, including a large blood clot (also abnormal)

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1280289	5/2/2021	TN	33	F	4/9/2021	4/9/2021	I was very ill on Friday night after receiving the vaccination. Flu-like symptoms, high fever, shortness of breath, pain in my abdomen, horrible headache, nausea, dizziness, loss of consciousness and leg pain (both legs). The flu-like symptoms passed on Saturday, but by Tuesday, April 13 I was continuing to have a terrible headache, abdominal pain and leg pain. I saw my primary doctor on the 13th and was sent over to the hospital for an ultrasound of my leg. No clots were found and I was told to continue trying to recover at home unless it got worse. I was seen at the emergency room on April 14th for abdominal pain, leg pain, dizziness and headache. The nurse told me I was probably hysterical over the vaccination being pulled, and I told him this was not the case. They performed CT (without contrast) on my abdomen and head, then released me with instructions to return if I was worse. By the 16th I was unable to walk as my left side was completely numb. I went back to the ER. I had a CT of my abdomen and head with and without contrast. I had a lumbar puncture and several labs. I was given IV antibiotics for some infection they found in my urine. I was given fluids and pain meds, and my BP was shooting up to 145/94 (which is very high for me), when standing. My vision was blurry and I was unable to remember much of the last week. I was admitted from the 16th through the 20th and had an MRV, 2 MRIs, more lab work and medicine for my headache. I was released on the 20th and the headache was unbearable and I was still numb on my left side, going back to my doctor on the 22nd. He suggested the ER, and the ER admitted me back to the stroke unit. I was released on the 22nd with a diagnosis of a hemiplegic migraine that could cause stroke-like symptoms (ZERO history of headaches previously). I was sent home with a walker and home health services. PT visited on April 30th and ordered two visits per week for the next month. I am unable to walk without a walker. I cannot shower or use the stairs without assistance. My memory is still foggy. I am unable to concentrate for long. I often stutter and can't remember basic words. I have also stopped and forgotten where I am at a given moment. I am on Depakote nightly for the headaches, and they have lessened slightly, but when they flare up it is debilitating and I often vomit. I have instructions to follow up with my primary tomorrow morning and see

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							what the next steps are.
1280011	5/2/2021	CT	78	F	4/10/2021	4/15/2021	Blood clot in the brain resulting in inter-cranial bleeding... affected speech, processing , vision
1279696	5/2/2021	SC	50	F	3/27/2021	4/19/2021	patient reported to the pharmacy that they had to go to ER for blood clot on 04/19/2021
1279430	5/2/2021	TX	100	F	1/11/2021	1/11/2021	episodes of 4.5 seconds with non pulse; she experienced a basal artery blood clot stroke; lightheaded; This is a spontaneous report from a contactable consumer (patient's son). A 100-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 11Jan2021 14:30 (at the age of 100years) as single dose for Covid-19 immunization. The patient is not pregnant at the time of vaccination. The patient's medical history was not reported. Concomitant medication included furosemide taken for an unspecified indication, start and stop date were not reported. The patient was not diagnosed with COVID-19 prior to vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. It was reported that the patient had medical issues starting within hours of the first dose of Covid vaccine. Prior, the patient was in independent living, no medications (as reported), walking about 1/2 daily and completely lucid. Immediately thereafter (after the vaccine, 11Jan2021 16:00), she experienced lightheaded, a hospital stay, and episodes of 4.5 seconds with non-pulse. A pacemaker was installed. During rehab, the patient experienced a basal artery blood clot stroke. The patient is still in rehab. The adverse events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event), Disability or permanent damage. The patient was hospitalized on an unspecified date for 8 days. Treatment received included pacemaker, numerous medicines (e.g. AFIB). The patient had Covid test post vaccination: Nasal Swab on 15Jan2021 with negative result. The outcome of events was recovering. Information about lot/batch number has been requested.

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1280421	5/2/2021	MA	52	F	4/29/2021	4/30/2021	52F with no known PMH developed progressive chest pain on 4/30/2021, admitted to Medical Center 5/2/2021 and found with NSTEMI with 95% proximal LAD occlusion w/ moderate thrombus successfully treated with drug-eluting stent x1. Pt received Pfizer vaccine #1 on 4/29. Of note, pt has not seen a doctor in several years, but labs notable for leukocytosis (WBC 14.0), polycythemia (Hgb 16.9) and thrombocytosis (PLT 959) concerning for undiagnosed polycythemia vera. If so, it is not clear whether her NSTEMI was a coincidence or whether the vaccine increased her risk of thrombosis.
1279439	5/2/2021	CA	29	F	4/11/2021	4/12/2021	chills; fever; nausea; rapid heart rate; body aches; headaches; lose my mental capacity; I was incoherent; threw up; This is a spontaneous report from a contactable consumer (patient). A 29-Year-old female (pregnant: No) patient received 1st dose of BNT162B2 (COVID vaccine, lot number=ER8729) on 11Apr2021 11:45 AM on Left arm for covid-19 immunization. Medical history was hospitalizations for heat exhaustion in 2014 and 2017, Herpes Type 2, covid prior vaccination. No other vaccine in four weeks. Concomitant drugs included Vitamin D, One-A-Day Vitamin. Symptoms started at 12:00 am midnight on 12Apr2021 with chills and fever. The morning of 12Apr2021, symptoms progressed into nausea, rapid heart rate, body aches, headaches, and I started to lose my mental capacity. I didn't know my address when I called an ambulance. When at the hospital, I didn't recognize my wife and forgot my mother's name. I was incoherent. I threw up. I don't remember 7 hours of time from my first day at the hospital. I got a spinal tap to test for meningitis which came back negative. I had an MRV brain scan which came back clear (no blood clots). Hospitalized for 5 days (12Apr2021-16Apr2021). AE resulted in Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). Outcome of the event was recovering. AE treatment was IV fluids, sodium, spinal tap, MRV brain scan. No covid tested post vaccination. No follow-up attempts needed. No further information expected.

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1276686	5/1/2021	NJ	68	M	1/14/2021	1/15/2021	<p>Blood Clot; left knee had red marks above it; pain in thigh; swelling from the knee up to the thigh; left knee was in pain tremendously; difficulty walking; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood Clot) in a 68-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 013620A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 14-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Jan-2021, the patient experienced GAIT DISTURBANCE (difficulty walking) and ARTHRALGIA (left knee was in pain tremendously). On 16-Jan-2021, the patient experienced ERYTHEMA (left knee had red marks above it), PAIN IN EXTREMITY (pain in thigh) and JOINT SWELLING (swelling from the knee up to the thigh). On an unknown date, the patient experienced THROMBOSIS (Blood Clot) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood Clot), GAIT DISTURBANCE (difficulty walking), ERYTHEMA (left knee had red marks above it), PAIN IN EXTREMITY (pain in thigh), JOINT SWELLING (swelling from the knee up to the thigh) and ARTHRALGIA (left knee was in pain tremendously) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications like high blood pressure medication, cholesterol medication and medication for irregular heartbeat were reported. On 15 Jan2021, the patient said that his left knee was in pain tremendously and had difficulty walking. On 16 JAN 2021, the left knee had Red marks above it. He also had swelling from the knee up to the thigh. He also experienced pain in the thigh and knee. He went to the doctor on 20 JAN 2021 and was sent for an ultrasound. The doctor thought it could be related blood clot. No laboratory details were provided. On 20-Jan-2021, the patient was sent for an ultra sound, results unknown. Treatment included ibuprofen and paracetamol. Company comment: Based on the current available information and temporal</p>

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association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.



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1276549	5/1/2021	CA	58	F	4/23/2021		<p>LEFT SIGMOID SINUS VEIN THROMBOSIS; PORTAL VEIN THROMBOSIS; SPLENIC VEIN THROMBOSIS; SUPERIOR MESENTERIC VEIN THROMBOSIS; LEFT INTERNAL JUGULAR VEIN THROMBOSIS; THROMBOCYTOPENIA; ABDOMINAL PAIN; HEADACHE; This spontaneous report was received from a physician and concerned a 58-year-old white female. Initial information was received on 27-APR-2021, with additional information obtained via telephone follow up from the physician on 29-APR-2021. The patient's specific height and weight were not reported. The patient's past medical history included fatty liver, and the patient was overweight. Family history was significant for a deep venous thrombosis treated with anticoagulants in the patient's mother, and a history of unspecified blood clots in her maternal grandmother. The patient was on no medications, including no estrogen containing pharmaceutical products or supplements. She has never been exposed to heparin. The patient had no history of COVID-19 infection. The patient received COVID-19 VACCINE AD26.COV2.S (suspension for injection, route of administration not reported, batch number not reported) on 12-APR-2021. The batch number has been requested. No concomitant medications were reported. On 18-APR-2021, 6 days after receiving vaccine, the patient developed a headache. On 23-APR-2021, 11 days after receiving vaccine, the patient presented to the hospital with complaints of headache and abdominal pain. COVID test in the emergency room was negative. On 23-APR-2021, imaging of the head and abdomen revealed: left sigmoid sinus vein thrombosis, portal vein thrombosis, splenic vein thrombosis, superior mesenteric vein thrombosis, left internal jugular vein thrombosis. The patient also had thrombocytopenia, with platelet count on presentation 22,000 (units not provided). D-dimer was elevated at &gt;12.8 (units not provided), Fibrinogen was low at 103 (units not provided), HIT antibody test by ELISA was positive, and physicians made the diagnosis of Vaccine-induced Thrombotic Thrombocytopenia (VITT). The patient was hospitalized in the intensive care unit. Treatment medications included argatroban, steroids and IVIG. Following treatment, the platelet count remained low, with a nadir of 17,000. On 27-Apr-2021, she underwent thrombectomy and thrombolysis of the intra-abdominal clots. This was</p>

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performed due to the potential for portal hypertension in the future, given the extent of the thromboses. Repeat CT venogram of the head on an unknown date, revealed resolution of the sigmoid sinus vein thrombosis; the internal jugular thrombosis persisted. The patient has steadily improved since the thrombectomy. Abdominal pain and headache are improving. Platelet count has steadily risen, to 138,000 on 29- Apr-2021. Her transaminases were slightly elevated on admission and have not worsened, and she appears to have no organ dysfunction. A dialysis catheter had been placed in the event she would require plasmapheresis, but this was never used. Additional laboratory data included: IgG and IgM antibodies against the SARS-COV2 nucleocapsid protein positive; Protein C deficiency negative; Protein S deficiency negative; Homocysteine level (NR: not provided) negative. Serotonin release assay, anticardiolipin panel and Factor V Leiden tests were pending. The plan was to transition the patient to an oral anticoagulant and remove the dialysis catheter on 30-APR-2021, with a possible discharge on 01-MAY-2021. The patient had not recovered from left sigmoid sinus vein thrombosis, portal vein thrombosis, splenic vein thrombosis, superior mesenteric vein thrombosis, and left internal jugular vein thrombosis, and was recovering from left sigmoid sinus vein thrombosis, thrombocytopenia, headache and abdominal pain. This report was serious (Hospitalization Caused / Prolonged, and Life Threatening). Additional information was received from physician on 29-APR-2021. The following information was updated and incorporated into the case narrative: patient history, disease course, events, outcome, lab data, concomitant drugs.; Sender's Comments: V0: This spontaneous report concerns a 58-year-old female patient who experienced left sigmoid sinus vein thrombosis, portal vein thrombosis, splenic vein thrombosis, superior mesenteric vein thrombosis, left internal jugular vein thrombosis, thrombocytopenia, headache and abdominal pain, 11 days after receiving COVID-19 VACCINE AD26.COV2.S. The patient is overweight and there is a family history of clots in her mother and maternal grandmother. Imaging of the head and abdomen revealed multiple sites of thrombus formation, platelet count was 22,000, D-dimer was elevated at >12.8 (units not provided), Fibrinogen was

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1276551	5/1/2021			F			
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low at 103 (units not provided), and HIT antibody test by ELISA was positive. Physicians made the diagnosis of Vaccine-induced Thrombotic Thrombocytopenia (VITT). The patient was treated with argatroban, IVIG, and steroids. Platelet counts remained low and she underwent thrombectomy of the intra-abdominal thrombi. Following thrombectomy the platelet counts rose and abdominal pain began to improve. Lab data included a positive test for IgG and IgM antibodies against the SARS-COV-2 nucleocapsid protein. Based on the evolving knowledge of Thrombosis with Thrombocytopenia Syndrome (TTS, per definition from Brighton Collaboration), the low platelet count and temporal relationship to vaccination, we consider the events to have a plausible relationship with vaccination.

BLOOD CLOTS; This spontaneous report received from a consumer (source: news report) concerned a female of age under 60. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: unknown) dose, start therapy date were not reported, 1 total administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case No concomitant medications were reported. It was reported from a news story that, on an unspecified date, the patient experienced blood clots which was in investigation by an agency. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clots was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210454646.; Sender's Comments: V0:20210454446-covid-19 vaccine ad26.cov2.s- Blood clots. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1276556	5/1/2021			M			<p>BLOOD CLOT; This spontaneous report received from a consumer concerned an adult male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) 1 total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient experienced blood clot. The reporter stated that as per news report, the agency was investigating this case of blood clot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210454446.; Sender's Comments: V0:20210454646-covid-19 vaccine ad26.cov2.s -blood clot. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1276561	5/1/2021	MA	69	M	4/26/2021		DEEP VEIN THROMBOSIS IN RIGHT LEG (PAIN AND SWELLING); This spontaneous report received from a physician concerned a 69 year old White and not Hispanic or Latino male. The patient's height, and weight were not reported. The patient's concurrent conditions included arterial fibrillation, and sedentary lifestyle. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 207A21A expiry: 23-JUN-2021) dose was not reported, frequency 1 total, administered on 11-APR-2021 at left arm for prophylactic vaccination. Concomitant medications included apixaban for chronic atrial fibrillation. It was stated by internist that, on 26-APR-2021, the patient experienced deep vein thrombosis in right leg with symptoms pain and swelling, and was hospitalized on unspecified date. On unspecified date doctor was screening patient for covid-19 infection. On 27-APR-2021, Laboratory data included: Platelet count (NR: not provided) 167000. Laboratory data (dates unspecified) included: Duplex ultrasound (NR: not provided) definite clot in right leg. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of deep vein thrombosis in right leg (pain and swelling) was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: 20210455157-JANSSEN COVID-19 VACCINE Ad26.COV2.S- Deep vein thrombosis. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY, UNDERLYING DISEASE.

<i>VAERS_ID</i>	<i>RECVDATE</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1276566	5/1/2021	CA		F			<p>BLOOD CLOT; SEVERE HEADACHE/ FEEL LIKE A CAP ON HER HEAD; This spontaneous report received from a consumer concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced blood clot, and severe headache/ felt like a cap on her head. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the severe headache/ feel like a cap on her head and blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: AER 20210455412- Covid-19 vaccine ad26.cov2.s-BLOOD CLOT. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1276570	5/1/2021	OH		F			<p>MID-STROKE; BLOOD CLOTS IN BRAIN; POST STROKE DEPRESSION; CANE USER; This spontaneous report received from a consumer (sister) concerned a 69 year old female. The patient's weight, height, and medical history were not reported. Patient was a completely healthy woman and was not on any medications. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) frequency once total, dose, start therapy date was not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient suffered a mid-stroke. Stroke showed that she suffered from blood clots in her brain. All of this happened after receiving Janssen vaccine. Patient had to walk with a cane (coded as cane user) and had been prescribed medication. Patient had to deal with other issues including depression (coded as post stroke depression) because of her new life long issues. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the mid-stroke, blood clots in brain, cane user and post stroke depression was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210455571-Covid-19 vaccine.ad26.cov2.S-Mld-stroke,Blood clots in Brain,Post stroke depression. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1276571	5/1/2021			M			<p>THROMBOSIS (RED PATCHES ON HANDS, ARMS, LEGS AND FEET); SEVERE MIGRAINES; SEVERE VACCINATION REACTION; This spontaneous report received from a patient via a company representative concerned a 3 decade old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown and expiry date: Unknown) dose, 1 total administered, start therapy date was not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. The patient had a severe vaccination reaction, experienced red patches on hands, arms, legs and feet. The patient had visited the hospital and was diagnosed with thrombosis by the physician. Patient was monitored and later discharged. The patient had reattended hospital for severe migraines, also had contacted centers for disease control and prevention regarding vaccination reaction. The patient was unknown for company representative and had only this information. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the thrombosis (red patches on hands, arms, legs and feet), severe migraines and severe vaccination reaction was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0.20210455657- COVID-19 VACCINE Ad26.COV2. S - Thrombosis, severe migraines , severe vaccination reaction. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>



<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1276590	5/1/2021	MA	45	M	4/14/2021		<p>CLOT IN SPLENIC ARTERY; CELIAC ARTERY THROMBOSIS; BODY SWEATING; SHORTNESS OF BREATH; CHILLS; This spontaneous report received from a patient concerned a 45 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 043A21A) dose was not reported, administered to left arm (left deltoid) around 15:00 to 16:00 on 09-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 14-APR-2021, after 5 days of vaccination, in the morning, while driving patient had very severe abdominal pain, very hard time breathing, had to get out of the car because of that, patient thought he was going to die, after 5-10 minutes he felt chills and body was sweating. His wife took him to the hospital on same day. At the hospital unspecified tests and CAT scans were done, and found clot in splenic and celiac artery. Patient was hospitalized on 14-APR-2021 for 1 day and was discharged around 3pm the next day on 15-APR-2021. Patient had another visit with a hematologist on 28-APR-2021 in morning, he found nothing wrong with the body. Patient now had to take Eliquis for 6 months. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from chills, body sweating, shortness of breath, on APR-2021, and had not recovered from clot in splenic artery, and celiac artery thrombosis. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0- 20210456348 - Covid-19 vaccine ad26.cov2.s-clot in splenic artery, and celiac artery thrombosis. These events are considered unassessable. The events have a compatible/suggestive temporal relationship, are unlabeled, and have unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p>

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1276610	5/1/2021	FL		F		4/12/2021	LONG HEAVY PERIOD WITH CLOTS; LOWER BACK PAIN; SLEEPINESS; WEAK; HEADACHE; This spontaneous report received from a patient concerned a 46 year old female. The patient's height, and weight were not reported. The patient's past medical history included asthma, and concurrent conditions included seasonal allergy, no alcohol use, and non smoker, and other pre-existing medical conditions included no drug abuse. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 202A21A, and batch number: 202A21A expiry: UNKNOWN) dose was not reported, administered on 12-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 12-APR-2021, the subject experienced long heavy period with clots. On 12-APR-2021, the subject experienced lower back pain. On 12-APR-2021, the subject experienced sleepiness. On 12-APR-2021, the subject experienced weak. On 12-APR-2021, the subject experienced headache. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from long heavy period with clots, headache, lower back pain, weak, and sleepiness. This report was non-serious.

<i>VAERS_ID</i>	<i>RECVDATE</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1276617	5/1/2021			F			SEVERE ANXIETY ABOUT THE POTENTIAL FOR BLOOD CLOTS; This spontaneous report received from a consumer concerned a 23 year old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the subject experienced severe anxiety about the potential for blood clots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of severe anxiety about the potential for blood clots was not reported. This report was non-serious.; Sender's Comments: V0:20210456869 covid-19 vaccine ad26.cov2.s- Medical Assessment comment not required as per standard procedure as case assessed as Non serious

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1276626	5/1/2021		49	M	4/19/2021		DEEP VEIN THROMBOSIS; This spontaneous report received from a consumer concerned a 49 year old male. The patient's weight was 80.3 kilograms, and height was 182.9 centimeters. The patient's past medical history included post-operative deep vein thrombosis (more than 30 years ago), depression, heart murmur, and back surgery, and his concurrent conditions included non-smoker, no alcohol use, and marijuana abuse. The patient had no history of known allergies. The patient's mother had a history of aneurysm. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, and expiry date: unknown) dose was not reported, administered on 08-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. Concomitant medications included fexofenadine hydrochloride (Allegra) for allergy, rivaroxaban (Xarelto) for venous thromboembolism, and omeprazole (Prilosec) for unknown indication. About one and half weeks after vaccination, on 21-APR-2021, the patient was taken to the emergency department and was admitted with the complaints of leg pain since 2 days with suspected blood clot in leg. Over the last days, patient's left leg looked swollen compared to the right leg. The patient also had pain, initially started in groin area and radiated down across the anterior portion of the leg, then to posterior leg, and into toes. The patient also had some intermittent tingling in toes. The patient denied of weakness, numbness or persistent paresthesia. The patient was concerned regarding the pain as it felt similar to the post-operative deep vein thrombosis he had in the past. The patient had been anxious since vaccination when hearing about the development of blood clots. The patient also denied of fevers, chills, chest pain, shortness of breath abdominal pain, nausea, vomiting, diarrhea, and difficulty walking. On 21-APR-2021 16:25, the patient's laboratory data included: Blood pressure (148/66 mmHg), Body mass index (24), Body temperature (98.8 F), Oxygen saturation (100 %) Pulse rate (88), and Respiratory rate (16). On 21-APR-2021 16:32, laboratory data included: Blood pressure (148/66 mmHg), Body temperature (97.8 F), Oxygen saturation (100 %), Pulse rate (91), and Respiratory rate (15). Other general physical examinations included: General: Well-developed well-nourished in no acute distress. HEENT

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(Head, Eye, Ear, Nose, Throat) examination: normocephalic atraumatic extra ocular motions are intact. Neck examination: Supple without jugular vein distention or meningismus. Lung examination: Clear auscultation bilaterally without wheezes rales or rhonchi. Heart examination: Regular rate and rhythm without murmurs rubs or gallops. Abdomen examination: Soft no tender non-distended without rebound or guarding. Extremities: Without clubbing cyanosis edema, no lacerations or abrasions or ecchymosis noted, no appreciable size difference in the left leg compared to the right, the patient had some tenderness throughout palpation of the medial thigh on the left with radiation up into the left inguinal region, no calf tenderness or swelling, no erythema, palpable posterior tibialis pulse. Skin examination: Warm and dry and well perfused. Psych examination: Appropriate mood and affect. Neuro examination: Cranial nerves 2-12 are grossly intact, strength is 5/5 in upper and lower extremities, full distal sensation in the left lower extremity, full plantar and dorsiflexion of the left foot including the left great toe, sensation is grossly intact, awake, alert and oriented x3. On ultrasound Doppler venous lower extremity test, identified sub occlusive thrombus in the left superficial femoral veins, likely related to organizing/chronic thrombus, however no prior imaging was available at the institution for comparison, no evidence of occlusive deep vein thrombosis. The final diagnosis was made as Deep Vein Thrombosis (DVT). At no time the patient had ever endorsed any chest pain/pleuritic pain, shortness of breath or exertional dyspnea. Due to the nature of this clot, a course of anticoagulation was planned. Patient was prescribed with Xarelto at twice daily starting doses, with transition to 20 mg doses. During the initiation of treatment, the patient should be followed up by his primary care physician for further evaluation. The patient stated that he would call the primary care physician in the following morning for follow-up appointment. The patient was discharged from the hospital on APR-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of deep vein thrombosis was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: 20210457179-Covid-19 vaccine ad26.cov2.s-deep vein thrombosis. This event is

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1276633	5/1/2021	FL		F			<p>considered not related. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event than the drug. Specifically: MEDICAL HISTORY</p> <p>CLOTS; This spontaneous report received from a physician (source: news report) concerned 6 female patients. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry unknown) dose, start therapy date were not reported, frequency 1 total administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. The reporter called in regarding an event of clot experienced by 6 patients in the news on an unspecified date. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of clots was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210456400 and 20210457363.; Sender's Comments: 20210457370-covid-19 vaccine ad26.cov2.s-Blood clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1276541	5/1/2021	TN		F	4/3/2021		FACE WENT SOLID WHITE; UNABLE TO GET WORDS OUT; SWEATING OF THE PALMS AND FEET AND FACE; DIZZY/ VERY LIGHTHEADED; FATIGUE/FELT DRAINED/VERY TIRED/EXHAUSTED; ELEVATED D-DIMER; ELEVATED BLOOD PRESSURE; HEAVINESS IN THE CHEST; PINKY FINGER FELT TINGLE-Y AND NUMB; HEADACHE; This spontaneous report received from a patient concerned a 48 year old white, Not Hispanic or Latino female. The patient's height, and weight were not reported. The patient's past medical history included urinary tract infection, and concurrent conditions included occasional migraines. The patient was not pregnant at the time of this report. The patient had family history of heart problems and was doing exercise three times per week. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805031, expiry: 26-MAY-2021) dose was not reported, 1 total administered on 30-MAR-2021 around 13:15 to the left arm for prophylactic vaccination. No concomitant medications were reported. On 03-APR-2021, she felt dizzy, had a headache which was a different kind of headache from her migraines and was very lightheaded. The patient was out riding motorcycles when the symptoms occurred, but she was drained so she had to leave early. On 04-APR-2021, on her way home from visiting her grandmother she felt the same type of headache. Her chest started feeling heavy, her pinky finger felt tingly and numb, and her palms and feet were sweaty. On 05-APR-2021, all of her symptoms kept magnifying and worsened, but she was not able to get in to see her physician. On 06-APR-2021, the patient went to the gym and had to get off the elliptical because she was so fatigued and had chest heaviness. She went to the MD later that day where they did an EKG (electrocardiogram) which showed an abnormal line, but nothing major and her CXR (chest X-ray) was clear, although her BP (blood pressure) was elevated. They wanted to do a stress echo at a later date. On 07-APR-2021, the patient symptoms got even worsened when she was at work. The patient's face turned solid white, her face, palms, and feet were sweaty, and she was dizzy. After the end of the episode, she was not able to get words to come out, like she was having a mini stroke, which had lasted 30 minutes. The patient then became

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very tired and exhausted. The patient's coworkers drove her to the Emergency Room around 13.00. The patient was administered with heparin and also took an echocardiogram. They wanted her to do more tests including nuclear stress echo as an outpatient with her physician. The patient was discharged on 08-APR-2021. The episodes continued after her hospital visit. She went back to work on 12-APR-2021 and it happened again, so the patient was taken back to her doctor. The patient underwent a d-dimer test and it was slightly elevated. The patient also took an MRI (magnetic resonance imaging) and it was clear with no clots or bleeding, but the episodes were still happening. The patient was feeling better at the time of this report and would be going to meet her neurologist. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from unable to get words out on 07-APR-2021, and elevated blood pressure on APR-2021, had not recovered from dizzy/ very lightheaded, headache, fatigue/felt drained/very tired/exhausted, heaviness in the chest, and sweating of the palms and feet and face, and the outcome of pinky finger felt tingle-y and numb, face went solid white and elevated d-dimer was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210454164-COVID-19 VACCINE AD26.COV2.Sweating of the palms and feet and face, face went solid white, Dizzy/very lightheaded. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). 20210454164-COVID-19 VACCINE AD26.COV2.S-fatigue/felt drained/very tired/exhausted. This event(s) is labeled per RSI and is therefore considered potentially related.



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1276697	5/1/2021	TX	76	F	1/22/2021	1/29/2021	clot in her lungs; This spontaneous case was reported by a non-health professional and describes the occurrence of PULMONARY EMBOLISM (clot in her lungs) in a 76-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event (No medical history reported). On 22-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 29-Jan-2021, the patient experienced PULMONARY EMBOLISM (clot in her lungs) (seriousness criterion medically significant). At the time of the report, PULMONARY EMBOLISM (clot in her lungs) had not resolved. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No relevant concomitant medications were provided. No treatment information was provided. Based on the current available information and temporal association between the use of the product and the onset date of the reported event of pulmonary embolism, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-075030 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported event of pulmonary embolism, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-075030:Patient's brother in law case; cross linked case

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1276717	5/1/2021	KY	72	F	1/25/2021	4/9/2021	blood clots in both legs; heart attack/blood clot in heart; Blood clots in lungs/shortness of breath; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (blood clots in both legs), MYOCARDIAL INFARCTION (heart attack/blood clot in heart) and PULMONARY EMBOLISM (Blood clots in lungs/shortness of breath) in a 72-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 8077727310 and 012LZ0A) for COVID-19 vaccination. No Medical History information was reported. On 25-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 09-Apr-2021, the patient experienced THROMBOSIS (blood clots in both legs) (seriousness criteria hospitalization prolonged and life threatening), MYOCARDIAL INFARCTION (heart attack/blood clot in heart) (seriousness criteria hospitalization prolonged and life threatening) and PULMONARY EMBOLISM (Blood clots in lungs/shortness of breath) (seriousness criteria hospitalization prolonged and life threatening). The patient was hospitalized on 09-Apr-2021 due to MYOCARDIAL INFARCTION, PULMONARY EMBOLISM and THROMBOSIS. At the time of the report, THROMBOSIS (blood clots in both legs), MYOCARDIAL INFARCTION (heart attack/blood clot in heart) and PULMONARY EMBOLISM (Blood clots in lungs/shortness of breath) outcome was unknown. No concomitant medications were reported. Treatment of the events included Xarelto and unspecified IV medications. Action taken with mRNA-1273 in response to the events was not applicable. Company Comment: Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1276724	5/1/2021	IN	78	F			Stroke, Left side of her body effected/Something was wrong, Movement effected, Coordination abnormal, Blood clot; Woke up shaking; Eyesight effected; This spontaneous case was reported by an other caregiver (subsequently medically confirmed) and describes the occurrence of CEREBROVASCULAR ACCIDENT (Stroke, Left side of her body effected/Something was wrong, Movement effected, Coordination abnormal, Blood clot), TREMOR (Woke up shaking) and VISUAL IMPAIRMENT (Eyesight effected) in a 78-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Seizure. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1. On an unknown date, the patient experienced CEREBROVASCULAR ACCIDENT (Stroke, Left side of her body effected/Something was wrong, Movement effected, Coordination abnormal, Blood clot) (seriousness criteria hospitalization prolonged, disability and life threatening), TREMOR (Woke up shaking) (seriousness criterion hospitalization prolonged) and VISUAL IMPAIRMENT (Eyesight effected) (seriousness criterion hospitalization prolonged). The patient was hospitalized on sometime in March 2021 due to CEREBROVASCULAR ACCIDENT. The patient was treated with Rehabilitation therapy for Cerebrovascular accident. At the time of the report, CEREBROVASCULAR ACCIDENT (Stroke, Left side of her body effected/Something was wrong, Movement effected, Coordination abnormal, Blood clot), TREMOR (Woke up shaking) and VISUAL IMPAIRMENT (Eyesight effected) outcome was unknown. Unknown For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Products known to have been used by the patient, within two weeks prior to the event, included seizure medication. Treatment for the event included intensive care and stroke unit. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, Very limited information regarding

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this event has been provided at this time. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, Very limited information regarding this event has been provided at this time. Further information has been requested.

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1276749	5/1/2021	IN		M	3/5/2021	3/19/2021	<p>Blood clots in the legs and lungs; he passed out and still currently admitted in hospital; Blood clots in the legs and lungs; 2nd dose given 2 weeks from the 1st dose; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Blood clots in the legs and lungs), LOSS OF CONSCIOUSNESS (he passed out and still currently admitted in hospital) and DEEP VEIN THROMBOSIS (Blood clots in the legs and lungs) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 05-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 19-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 19-Mar-2021, the patient experienced PRODUCT ADMINISTRATION ERROR (2nd dose given 2 weeks from the 1st dose). On 22-Apr-2021, the patient experienced PULMONARY EMBOLISM (Blood clots in the legs and lungs) (seriousness criteria hospitalization and medically significant), LOSS OF CONSCIOUSNESS (he passed out and still currently admitted in hospital) (seriousness criteria hospitalization and medically significant) and DEEP VEIN THROMBOSIS (Blood clots in the legs and lungs) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 22-Apr-2021 due to DEEP VEIN THROMBOSIS, LOSS OF CONSCIOUSNESS and PULMONARY EMBOLISM. On 19-Mar-2021, PRODUCT ADMINISTRATION ERROR (2nd dose given 2 weeks from the 1st dose) had resolved. On 22-Apr-2021, LOSS OF CONSCIOUSNESS (he passed out and still currently admitted in hospital) had resolved. At the time of the report, PULMONARY EMBOLISM (Blood clots in the legs and lungs) and DEEP VEIN THROMBOSIS (Blood clots in the legs and lungs) outcome was unknown. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was reported by the reporter. Patient reported that he had diagnosed to have blood clots in the leg and lungs and had unspecified</p>

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procedure. Patient reported that he was given a unknown medication.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, the reported drug administration error (2nd dose administered 2 weeks from 1st dose) may remain a confounder.

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1276756	5/1/2021	TX	92	M	1/14/2021	3/8/2021	<p>Blood clot after receiving his second dose. Found out that he has Deep Vein Thrombosis (DVT); This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (Blood clot after receiving his second dose. Found out that he has Deep Vein Thrombosis (DVT)) in a 92-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 030M20A and 027L20A) for COVID-19 vaccination. No medical history was provided by the reporter. Concomitant products included IRON for Iron supplementation, APIXABAN (ELIQUIS), MIDODRINE, CLOPIDOGREL BISULFATE (PLAVIX), HYDROXYCHLOROQUINE, METHYLPREDNISOLONE, MIRABEGRON (MYRBETRIQ), MONTELUKAST, TAMSULOSIN, VITAMIN D3 and CYANOCOBALAMIN (VIT B12) for an unknown indication. On 14-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 08-Mar-2021, the patient experienced DEEP VEIN THROMBOSIS (Blood clot after receiving his second dose. Found out that he has Deep Vein Thrombosis (DVT)) (seriousness criterion medically significant). At the time of the report, DEEP VEIN THROMBOSIS (Blood clot after receiving his second dose. Found out that he has Deep Vein Thrombosis (DVT)) outcome was unknown.</p> <p>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Mar-2021, Ultrasound scan: clear (normal) Clear. On 08-Mar-2021, the reporter noticed that the patient's left arm was swollen. The patient was taken to the emergency room and was diagnosed with deep vein thrombosis. The patient was discharged on the same day. The patient was put on apixaban 10mg and later switched to apixaban 5mg. The patient would be monitored until ??-Sep-2021.</p> <p>Company Comment: Very limited information regarding this event has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.</p>

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1276770	5/1/2021	WA	47	F	3/24/2021	3/24/2021	very mild heart attack; chest started burning; couldn't breath; incomplete course of vaccination; very sick; arm got little sore; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of MYOCARDIAL INFARCTION (very mild heart attack) in a 47-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 045A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product SIMVASTATIN for an unknown indication. The patient's past medical history included Allergic reaction (MMR vaccine allergic reaction as an infant) in 1973. Concomitant products included PANTOPRAZOLE, SERTRALINE and VARENICLINE TARTRATE (CHANTIX) for an unknown indication, ACETYLSALICYLATE LYSINE (ASPARIN). On 24-Mar-2021 at 1:00 PM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient started SIMVASTATIN (unknown route) at an unspecified dose. On 24-Mar-2021, the patient experienced VACCINATION SITE PAIN (arm got little sore). On 25-Mar-2021, the patient experienced ILLNESS (very sick), DYSPNOEA (couldn't breath) and INCOMPLETE COURSE OF VACCINATION (incomplete course of vaccination). On 25-Mar-2021 at 8:00 AM, the patient experienced MYOCARDIAL INFARCTION (very mild heart attack) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (chest started burning). The patient was hospitalized on 25-Mar-2021 due to MYOCARDIAL INFARCTION. At the time of the report, MYOCARDIAL INFARCTION (very mild heart attack), ILLNESS (very sick), CHEST PAIN (chest started burning), DYSPNOEA (couldn't breath), INCOMPLETE COURSE OF VACCINATION (incomplete course of vaccination) and VACCINATION SITE PAIN (arm got little sore) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Mar-2021, Angiogram: normal (normal) no signs of plaque buildup. On 25-Mar-2021, Blood creatinine: abnormal (abnormal) levels determined patient was having a mild heart attack. On 25-Mar-2021, Electrocardiogram: normal (normal) Normal. The action taken with mRNA-1273 (Moderna COVID-19



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Vaccine) (Intramuscular) was unknown. The patient was very panicky about getting the second dose for fear that she would have another heart attack. She went to the cardiologist for a follow up and the doctor could not determine why she had a heart attack. The patient reported that it was not a normal heart attack in that her blood pressure and pulse were not raised, but instead, were low. The patient agreed to follow up with her HCP (health care provider). Treatment for the heart attack included SIMVASTATIN and BABY ASPIRIN to prevent blood clots. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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1276772	5/1/2021	MD	56	F	4/2/2021	4/23/2021	<p>blood in her urine with clots; felt bad like the flu; went to sleep and woke up dizzy; buzzing in her ears; she feels with altitude sickness; Plugged ears; tiredness; nausea; headache; This spontaneous case was reported by a consumer and describes the occurrence of HAEMORRHAGE URINARY TRACT (blood in her urine with clots) in a 56-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No patient medical history reported. Concomitant products included METOPROLOL for an unknown indication. On 02-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 23-Apr-2021, the patient experienced HAEMORRHAGE URINARY TRACT (blood in her urine with clots) (seriousness criterion medically significant), INFLUENZA LIKE ILLNESS (felt bad like the flu), DIZZINESS (went to sleep and woke up dizzy), TINNITUS (buzzing in her ears), HYPOBARISM (she feels with altitude sickness), EAR DISCOMFORT (Plugged ears), FATIGUE (tiredness), NAUSEA (nausea) and HEADACHE (headache). At the time of the report, HAEMORRHAGE URINARY TRACT (blood in her urine with clots), INFLUENZA LIKE ILLNESS (felt bad like the flu), DIZZINESS (went to sleep and woke up dizzy), TINNITUS (buzzing in her ears), HYPOBARISM (she feels with altitude sickness), EAR DISCOMFORT (Plugged ears), FATIGUE (tiredness), NAUSEA (nausea) and HEADACHE (headache) outcome was unknown. Additional concomitant medications included reflux medication when needed and asthma medication when needed. This case concerns a 56-year-old female with a serious unexpected event of hemorrhage urinary tract, and nonserious unexpected Influenza like illness, dizziness, tinnitus, ear discomfort, hypobarism, and expected headache, fatigue, nausea. Hemorrhage urinary tract latency 22 days after first dose mRNA-1273. Event outcomes unknown. Based on current available information and temporal association between use of the product and the start date of the event, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-</p>

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090443	US-MODERNATX, INC.-MOD-2021-090371						(E2B Linked Report).; Sender's Comments: This case concerns a 56-year-old female with a serious unexpected event of hemorrhage urinary tract, and nonserious unexpected Influenza like illness, dizziness, tinnitus, ear discomfort, hypobarism, and expected headache, fatigue, nausea. Hemorrhage urinary tract latency 22 days after first dose mRNA-1273. Event outcomes unknown. Based on current available information and temporal association between use of the product and the start date of the event, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-090443:Dose 1 US-MODERNATX, INC.-MOD-2021-090371:Son's case
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1276790	5/1/2021	NJ	56	F	2/12/2021	3/29/2021	having a blood clot down whole right leg / up right side into right chest / under right breast / several clots in her lower abdomen; she almost died; urinary tract infection; right leg is very swollen; Kept losing consciousness/Passed out; hard time walking; had to use a walker; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (having a blood clot down whole right leg / up right side into right chest / under right breast / several clots in her lower abdomen), LOSS OF CONSCIOUSNESS (Kept losing consciousness/Passed out) and FEELING ABNORMAL (she almost died) in a 56-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002b21a and 004m20a) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included LEVOFLOXACIN, RIVAROXABAN (XARELTO), LISINAPRIL, HYDROCHLOROTHIAZIDE, OXYCODONE and LEVOTHYROXINE SODIUM (SYNTHROID) for an unknown indication. On 12-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 29-Mar-2021, the patient experienced GAIT DISTURBANCE (hard time walking) and WALKING AID USER (had to use a walker). On 12-Apr-2021, the patient experienced THROMBOSIS (having a blood clot down whole right leg / up right side into right chest / under right breast / several clots in her lower abdomen) (seriousness criteria hospitalization prolonged, medically significant, life threatening and intervention required) and LOSS OF CONSCIOUSNESS (Kept losing consciousness/Passed out) (seriousness criterion medically significant). 12-Apr-2021, the patient experienced FEELING ABNORMAL (she almost died) (seriousness criteria hospitalization and medically significant). On 26-Apr-2021, the patient experienced PERIPHERAL SWELLING (right leg is very swollen). On an unknown date, the patient experienced URINARY TRACT INFECTION (urinary tract infection). The patient was hospitalized from 12-Apr-2021 to 19-Apr-2021 due to FEELING ABNORMAL and THROMBOSIS. On 12-Apr-2021, LOSS OF CONSCIOUSNESS (Kept losing

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consciousness/Passed out) had resolved. At the time of the report, THROMBOSIS (having a blood clot down whole right leg / up right side into right chest / under right breast / several clots in her lower abdomen) was resolving and FEELING ABNORMAL (she almost died), URINARY TRACT INFECTION (urinary tract infection), GAIT DISTURBANCE (hard time walking), PERIPHERAL SWELLING (right leg is very swollen) and WALKING AID USER (had to use a walker) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 12-Apr-2021, Computerised tomogram: blood clots (abnormal) blood clot. On 12-Apr-2021, Ultrasound scan: blood clots (abnormal) blood clots. Action taken with mRNA-1273 in response to the events was not applicable. Patient stated she was in the ICU24-48 hours then transferred to another area of the hospital where she spent another 5-6days. She is still having to use a walker. Her right leg is very swollen. She has to walk and keep her right leg elevated. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Further information has been requested. This case was linked to MOD-2021-090647 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Further information has been requested.

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1276281	5/1/2021	KY		M	1/28/2021	4/1/2021	Blood clot in the right eye; This is a spontaneous report from a contactable consumer(patient) based on information received by Pfizer, license party for apixaban (ELIQUIS). This spontaneous case was reported by a consumer and describes the occurrence of OPTHALMIC VEIN THROMBOSIS (Blood clot in the right eye) in male patient of an unknown age who received apixaban (Eliquis) for an unknown indication. CO-SUSPECT PRODUCTS included Covid-19 Vaccine for an unknown indication. On an unknown date, the patient started Eliquis (unknown route). On 07-Jan-2021, the patient started Covid-19 Vaccine (unknown route). In April 2021, the patient experienced OPTHALMIC VEIN THROMBOSIS (seriousness criterion medically significant). The action taken with Eliquis (Unknown) was unknown. At the time of the report, OPTHALMIC VEIN THROMBOSIS outcome was unknown. The consumer received his first Pfizer covid 19 shot on 07-Jan-2021 and the second one on 28-Jan- 2021, and 10 days prior to this report he got a blood clot in his right eye. He takes a blood thinner and remarks this should keep him from getting blood clots, should not it. Blood thinner provided was Eliquis. The event was related to covid 19 vaccine and causality with Eliquis was not provided. For Eliquis (Unknown), the reporter did not provide any causality assessments. This case was received via pfizer. BMS Medical Evaluation Comment: This patient had ophthalmic vein thrombosis while on therapy with apixaban and after taking covid 19 vaccine. Underlying thromboembolic risk as ascertained by the use of apixaban is a significant factor that likely predisposed the patient to develop ophthalmic vein thrombosis and considered not related to apixaban therapy. Causality Assessment: For apixaban: the causal relationship of the event Ophthalmic vein thrombosis with the suspect product apixaban was not provided Per Reporter; the causal relationship of the event Ophthalmic vein thrombosis with the suspect product apixaban was Not Related Per Company (Bristol-Myers Squibb)

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1276794	5/1/2021	OH	67	F	2/26/2021	4/2/2021	Blood clot in leg; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clot in leg) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002B21A and 002A21A) for COVID-19 vaccination. No Medical History information was reported. On 26-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 2 dosage form. On 02-Apr-2021, the patient experienced THROMBOSIS (Blood clot in leg) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 02-Apr-2021 to 06-Apr-2021 due to THROMBOSIS. The patient was treated with Surgery (Angioplasty) for Thrombosis. On 06-Apr-2021, THROMBOSIS (Blood clot in leg) had resolved. Not Provided Concomitant product use was not provided by the reporter. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the mRNA-1273 in response to the events was not applicable.; Sender's Comments: Based on current available information and the temporal association between product use and the stat date of the events a causal relationship cannot be excluded.

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1276796	5/1/2021			F			<p>blood clot; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (blood clot) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (blood clot) (seriousness criterion death). The reported cause of death was Clot blood. It is unknown if an autopsy was performed. The reporter stated that his wife had recently passed away from a blood clot after receiving a second dose of the Moderna COVID-19 vaccine. Treatment information was not provided. Very limited information regarding this event has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Clot blood</p>



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1276632	5/1/2021	FL		M			<p>CLOTS; This spontaneous report received from a physician concerned a male of unspecified age. The patient's weight, height and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: Unknown) frequency one total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. The physician reported that on an unspecified date, the patient experienced clots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of clots was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210456400.; Sender's Comments: V0.20210457363-COVID-19 VACCINE AD26.COV2.S - Thrombosis. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1276425	5/1/2021	LA	35	F	3/1/2021		<p>DIFFICULTY BREATHING(LOW OXYGEN); ELEVATED D-DIMER; INABILITY TO MOVE; LOW BODY TEMPERATURE; TINGLY FACE; RED FACE; FELT BAD AND AWFUL; This spontaneous report received from a patient concerned a 35 year old female. The patient's height, and weight were not reported. The patient's past medical history included anaphylaxis reaction, and concurrent conditions included fibromyalgia. The patient did not had previous history of allergy to vaccine. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1605018,expiry: unknown) dose was not reported,1 total administered on 20-MAR-2021 to the right arm for prophylactic vaccination. No concomitant medications were reported. On 20-MAR-2021, 20 minutes after vaccination, the patient's felt her face red and tingly and it went away. On 29-APR-2021, nine days after receiving the vaccine, the patient woke up not able to breathe or move and had a temperature of 94 degree F. The patient went to hospital and had low oxygen, an elevated d-dimer and had no evidence of blood clots in CT (computed tomography) scan. The patient was treated in ER (emergency room) with epinephrine, steroids, diphenhydramine (Benadryl) and a unspecified nebulizer and then she could breathe. The patient's physician tested her d-dimer for second time following the patient's visit to the hospital and it was elevated, but not as high. The patient had history of fibromyalgia and mysterious health condition but it was reported that she did not have anything like what she experienced after vaccination and she felt really bad and super awful. The patient was not feeling great, but better and can breathe again at the time of this report; her oxygen level also was normal. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from difficulty breathing(low oxygen) on 2021, and red face, was recovering from felt bad and awful, had not recovered from elevated d-dimer, and the outcome of tingly face, inability to move and low body temperature was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210446229- covid-19 vaccine ad26.cov2.s -Difficulty breathing(Oxygen). This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown</p>

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1276478	5/1/2021	OH		F			<p>scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> <p>BLOOD CLOT; This spontaneous report received from a consumer via news concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration was not reported, batch number: unknown) dose, start therapy date were not reported, 1 total, for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient developed a blood clot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: -Blood clot. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1276487	5/1/2021	VA		M	3/25/2021		STROKE/HEADACHE; BLOOD CLOT; INJECTION SITE REACTION; PAIN IN ARM; This spontaneous report received from a patient concerned a 79 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805020, expiry: UNKNOWN) dose was not reported, administered to left arm on 11-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 25-MAR-2021, 2 weeks after receiving the vaccination, the patient stated his injection site on his left arm "felt horrible" "like someone was stabbing him in that joint" (both events captured as injection site reaction). The patient reported his doctors did not know what was causing this and he could not get rid of it. On an unspecified date the patient experienced headaches with one being described as going from the back of his head to his left temple, he reported not usually having headaches. The patient also experienced severe pain when moving left arm with pain worsening at night when not moving. The patient was unable to reach up to grab things. On 24-APR-2021, the patient was taken to the hospital and was diagnosed as had a stroke. On an unspecified date results of Magnetic Resonance Imaging (MRI) were 'blood clots in the artery that goes up middle of spine and back of neck. The patient stated the results also had "right side numbness, vertigo, slurred speech". Results of Computerised Tomogram (CT) (date unspecified) were per the patient "internal carotid arteries demonstrated calcified plaque, stenosis, arteries demonstrate localized three-four segment of left local artery". The patient was discharged on an unspecified date and had not seen his regular physician yet. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the stroke, blood clot, injection site reaction, pain in arm and headache was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0 -covid-19 vaccine ad26.cov2.s-Stroke/Blood clot. This case concerns a patient of 79 year old male. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1276499	5/1/2021	WA		M		4/1/2021	LOW PLATELET COUNT; RASH ON LEGS AND FEET WHICH SPREAD TO GROIN AND ABDOMEN; NAUSEA; This spontaneous report received from a consumer (company representative) concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, Expiry Date: UNKNOWN) dose was not reported, 1 total, administered on 10-APR-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 19-APR-2021, the patient developed rash on legs and feet. On 20-APR-2021, the rash spread to groin and abdomen. The patient visited the Emergency Room. The patient's platelet counts were low. There was no thrombosis reported. Patient was admitted to ICU on 20-APR-2021 to investigate about the low platelet counts. On an unspecified date in APR-2021, the patient undergone an antibody test which was found to be negative. IVIG treatment was administered in ICU. The patient got discharged on the 23-APR-2021. The patient was fine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from low platelet count, rash on legs and feet which spread to groin and abdomen, and nausea on APR-2021. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210452143-Covid-19 vaccine ad26.cov2.s-Low platelet count. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1276503	5/1/2021	CA		U		4/1/2021	LEG PAIN DIAGNOSED AS BLOOD CLOT; HEADACHE; MILD FEVER; This spontaneous report received from a patient concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 201A21A expiry: unknown) dose was not reported, 1 in total administered on 09-APR-2021 to left arm for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, in APR-2021, the patient experienced mild fever (99 degrees fahrenheit), headache and leg pain diagnosed as blood clot (leg pain) on 21-APR-2021. On an unspecified date in APR-2021, laboratory data included: Body temperature (NR: not provided) 99 F, and Diagnostic ultrasound (NR: not provided) unknown. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the leg pain diagnosed as blood clot, headache and mild fever was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:2021045225-covid-19 vaccine ad26.cov2.s-Leg pain diagnosed as blood clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1276504	5/1/2021	LA		U			<p>TRANSIENT ISCHEMIC ATTACK MORE FREQUENT; POSSIBLE BLOOD CLOT; SHORTNESS OF BREATH; CHEST PAIN; SWELLING IN ONE LEG; PULSATING HEADACHE; This spontaneous report received from a patient via social media concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose, 1 in total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, after took vaccine the patient had major health problems which was described as transient ischemic attack which was more frequent and lasted longer, headaches were a pulsating headache, shortness of breath(more than usual),chest pains, swelling in one leg and seems to be blood clots. The patient was enquire about the involvement of people in vaccine study with conditions like hepatitis C, strokes, chronic obstructive pulmonary disease, chronic headaches, liver problems, transient ischemic attack. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the transient ischemic attack more frequent, pulsating headache, shortness of breath, chest pain, swelling in one leg and possible blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0-20210452291JANSSEN COVID-19 VACCINE Ad26.CO2.S This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p>

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1276515	5/1/2021			M		4/1/2021	CLOT IN LEGS; ESCALATING PAIN IN LOWER BACK; ESCALATING PAIN IN LEG; This spontaneous report received from a patient via news story concerned a 4 decade (early 40s) male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose was not reported, 1 total, administered on 08-APR-2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. In APR-2021, the patient experienced clot in legs and was hospitalized. The patient was improving and scheduled to leave the hospital in few days. On 16-APR-2021, the Patient experienced escalating pain in lower back and leg. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from clot in legs, and the outcome of escalating pain in lower back and escalating pain in leg was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: - Clot in legs (PT-Thrombosis). This event is considered unassessable. The event has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.



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1276516	5/1/2021	IL	51	F	4/1/2021		<p>SWOLLEN ANKLE WITH RED STREAKS; PAIN IN LEG; This spontaneous report received from a patient concerned a 51 year old female. The patient's weight was 160 pounds and height was 67.2 inches. The patient's concurrent conditions included psoriatic arthritis, fibromyalgia, insomnia, restless leg syndrome, anxiety, nightmares and headache. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805025 and expiry: unknown) dose was not reported, administered at left arm on 26-MAR-2021 for prophylactic vaccination. Concomitant medications included Prazosin for nightmares, Methotrexate for psoriatic arthritis, Norco (hydrocodone bitartrate/paracetamol) for psoriatic arthritis pain, Pramipexole for restless leg syndrome, Bupropion for smoking cessation, sleeping pills, anxiety medication as needed and headache medication. On APR-2021, the patient experienced swollen ankle with red streaks (her leg was huge and going over her shoe) and pain in leg. She went to hospital and did several tests like an ultrasound which ruled out blood clots and was also prescribed a 7 day course of antibiotics. On 22-APR-2021, she was admitted to hospital due to events and was prescribed IV antibiotics. On an unspecified date in APR-2021, Blood pressure result was good, Diagnostic ultrasound ruled out infection and blood clot and X-ray ruled out infection and blood clot. On 26-APR-2021, she was discharged and another 7 day course of antibiotics was given. Treatment medications included: fentanyl and IV pain medication. She had purchased compression hose for the swelling and had been wearing these. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from swollen ankle with red streaks and pain in leg. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0- 20210452933-Covid vaccine-swollen ankle. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY V0- 20210452933-Covid vaccine-pain in leg. This event(s) is labeled by standard procedures. The event(s) is considered not related.</p>

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1276523	5/1/2021	AR	56	F	4/13/2021		<p>PULMONARY EMBOLISM; SHORTNESS OF BREATH; MIGRAINE HEADACHE; ELEVATED BLOOD PRESSURE; NAUSEA; FATIGUE; DIZZINESS; This spontaneous report received from a patient concerned a white 56 year old female. The patient's weight was 185 pounds, and height was 67 inches. The patient's past medical history included minor surgery on 14-APR-2021 to have a cyst removed from knee. The patient had a thyroidectomy in 1997 or 1998. Concurrent conditions included migraines when she was a child (only has 1 to 2 migraine a year), allergy to penicillin, social alcohol drinker, and was non smoker. The had no history of drug abuse or illicit drug usage. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 043A21A, expiry: UNKNOWN) dose was not reported, administered on 07-APR-2021 at left arm for prophylactic vaccination. No concomitant medications were reported. On 13-APR-2021, the patient experienced shortness of breath, dizziness, nausea, and fatigue. On 14-APR-2021, the patient experienced elevated blood pressure. On 17-APR-2021, the patient experienced pulmonary embolism and was hospitalized. Blood pressure was measured at 199/98 (approximately); blood test revealed "some kind of count from heart being elevated" and CT (computed tomogram) revealed multiple blood clots in both lungs. On 18-APR-2021 was admitted into the ICU (intensive care unit) and on the same day also experienced migraine headaches. On 19-APR-2021, a diagnostic ultrasound was negative for clots. At 17:00 the patient was discharged. Patient was hospitalized for 3 days. On 20-APR-2021, magnetic resonance imaging (MRI) and magnetic resonance venography (MRV) were performed by her pulmonologist, results not provided. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from shortness of breath, dizziness, and nausea on 20-APR-2021, and migraine headache on 22-APR-2021, had not recovered from pulmonary embolism, and fatigue, and the outcome of elevated blood pressure was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0 20210453258-COVID-19 VACCINE AD26.COV2.S-Pulmonary embolism and shortness of breath. This event(s) is considered unassessable. The event(s) has a compatible/suggestive</p>

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1276467	5/1/2021			M		4/1/2021	<p>temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> <p>LOST NIGHT VISION; HAD A SHARP PAIN IN THE SIDE OF HEAD; HURT SHOULDER; HAD A SHARP PAIN IN THE SIDE OF JAW; SLIGHT CHEST PAIN; CHEST HEAVINESS; STABBING PAIN IN BACK; LIGHT-HEADNESS; PAIN IN HIPS; DIFFICULTY BREATHING; This spontaneous report received from a patient concerned a male of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included blood clots, and other pre-existing medical conditions included sick for at least 6 weeks, started with a fever for several days. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose was not reported, administered on 10-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On APR-2021, the subject experienced difficulty breathing. On APR-2021, the subject experienced slight chest pain. On APR-2021, the subject experienced chest heaviness. On APR-2021, the subject experienced stabbing pain in back. On APR-2021, the subject experienced light-headness. On APR-2021, the subject experienced pain in hips. On 10-APR-2021, the subject experienced hurt shoulder. On 10-APR-2021, the subject experienced had a sharp pain in the side of jaw. On 10-APR-2021, the subject experienced had a sharp pain in the side of head. On 11-APR-2021, the subject experienced lost night vision. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from difficulty breathing, and stabbing pain in back, and the outcome of pain in hips, had a sharp pain in the side of head, had a sharp pain in the side of jaw, lost night vision, slight chest pain, chest heaviness, light-headness and hurt shoulder was not reported. This report was non-serious.; Sender's Comments: V0:Medical assessment comment not required as per standard procedure as the case assessed as non-serious.</p>

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1276466	5/1/2021	TX	59	F	4/1/2021		WEAK AND HEAVY FEELING ON THE FACE; FEELS LIKE THE CIRCULATION IS LOW; WEAKNESS ON THE RIGHT LEG RIGHT ARM AND LEFT FOOT; NUMBNESS ON THE RIGHT LEG RIGHT ARM AND LEFT FOOT; COLD LIMBS; ABDOMINAL PAIN; SORE INJECTION SITE; HEADACHE; NECK PAIN; CLOUDY CLEAR URINE; SWOLLEN VEIN ON RIGHT FOOT; HIGHER BP THAN NORMAL; WEIGHT LOSS; This spontaneous report received from a patient concerned a 59 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included raynaud, and other pre-existing medical conditions included the patient had no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808980, expiry: UNKNOWN) dose was not reported, administered on 03-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On APR-2021, the subject experienced abdominal pain. On APR-2021, the subject experienced neck pain. On APR-2021, the subject experienced cloudy clear urine. On APR-2021, the subject experienced swollen vein on right foot. On APR-2021, the subject experienced higher bp than normal. On APR-2021, the subject experienced weight loss. On APR-2021, the subject experienced sore injection site. On APR-2021, the subject experienced headache. On 14-APR-2021, the subject experienced numbness on the right leg right arm and left foot. On 14-APR-2021, the subject experienced cold limbs. On 14-APR-2021, the subject experienced weak and heavy feeling on the face. On 14-APR-2021, the subject experienced feels like the circulation is low. On 14-APR-2021, the subject experienced weakness on the right leg right arm and left foot. On 19-APR-2021, Laboratory data included: CT scan (NR: not provided) No thrombosis findings, and Laboratory test (NR: not provided) No thrombosis finding. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from headache, neck pain, sore injection site, numbness on the right leg right arm and left foot, cold limbs, cloudy clear urine, swollen vein on right foot, abdominal pain, weak and heavy feeling on the face, higher bp than normal, weight loss, weakness on the right leg right arm and left foot, and feels like the circulation is low. This report was non-serious.; Sender's

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1276435	5/1/2021	TX	54	F	4/7/2021		<p>Comments: V0: Medical Assessment comment was not required as per standard procedure as the case assessed as non-serious.</p> <p>RIGHT LEG DEEP VEIN THROMBOSIS; PERIPHERAL VEIN OCCLUSION; This spontaneous report received from a patient via VAERS (Vaccine Adverse Event Reporting System) (VAERS ID: 1201107) concerned a 54 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included penicillin allergy, and chronic obstructive pulmonary disease. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805031 expiry: UNKNOWN) dose was not reported, administered on 12-MAR-2021 for prophylactic vaccination. Concomitant medications included ferrous sulfate, ipratropium bromide/salbutamol sulfate, montelukast, salbutamol sulfate, budesonide, ipratropium, olodaterol hydrochloride/tiotropium bromide monohydrate and prednisone for chronic obstructive pulmonary disease. On 07-APR-2021, the patient experienced right leg deep vein thrombosis. Patient was hospitalized for 4 days. On 07-APR-2021, the patient experienced peripheral vein occlusion. On 07-APR-2021, the patient had ultrasound scan abnormal. Laboratory data included: Ultrasound Doppler (NR: not provided) unknown, and right leg duplex Ultrasound Scan confirms right leg occlusive DVT involving common femoral, superficial femoral, and popliteal vein. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from right leg deep vein thrombosis, and peripheral vein occlusion. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210447773-Covid-19 vaccine ad26.cov2.s-Right leg deep vein thrombosis. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events.</p>

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1276544	5/1/2021	TX		F			<p>BLOOD CLOT IN BRAIN; This spontaneous report received from a consumer concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported, 1 total for prophylactic vaccination. The batch number was not reported. Per procedure, no follow up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient experienced blood clot in brain. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot in brain was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210453717.; Sender's Comments: V0:20210454254-covid-19 vaccine ad26.cov2.s-blood clot in brain. This event(s) is considered related. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There are no other factors more likely to be associated with the event(s) than the drug.</p>

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1276430	5/1/2021			F	4/1/2021		<p>RARE BLOOD CLOT; LOW PLATELETS; This spontaneous report received from a consumer concerned about 50 years old female. The reporter obtained the information from news/media. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total administered on APR-2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unknown date in APR-2021 after vaccination, the patient experienced severe headache, abdominal pain, leg pain and shortness of breath. The patient developed a rare blood clot and low platelets on an unspecified date in APR-2021, within two weeks of receiving JANSSEN COVID-19 vaccine. The patient was hospitalized on an unspecified date in APR-2021. On APR-2021, the patient died from blood clot. The reporter was not sure whether the events was related to the vaccination. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of rare blood clot on APR-2021, and had not recovered from low platelets. This report was serious (Death, and Hospitalization Caused / Prolonged).; Sender's Comments: V0: This female patient in her 50s was reported to have developed a rare blood clot and low platelets within two weeks of receiving JANSSEN COVID-19 vaccine. On an unspecified date, symptoms reported were severe headache, abdominal pain, leg pain and shortness of breath. The patient was hospitalized on an unspecified date and subsequently died from blood clot. It was not known if autopsy was performed. No other details reported. The information available precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded.; Reported Cause(s) of Death: BLOOD CLOT</p>

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1276543	5/1/2021	AZ	52	U	4/17/2021		BLOOD CLOTS IN THE LUNGS; CHEST PAIN; SHORTNESS OF BREATH; This spontaneous report received from a patient concerned a 52 year old of unspecified sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose was not reported, administered on 06-APR-2021 for prophylactic vaccination in the left arm. The batch number was not reported and has been requested. No concomitant medications were reported. On 17-APR-2021, the subject experienced chest pain and shortness of breath and was taken to the Emergency Room. The patient was hospitalized and a diagnosis of blood clots in the lungs was made. The patient was hospitalized for 4 days. Corrective treatment included blood thinners ( to be taken for 6 months) and a follow-up appointment with the pulmonologist was scheduled. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the blood clots in the lungs, chest pain and shortness of breath was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210454248-Covid-19 vaccine ad26.cov2.s-Blood clots in the lungs, chest pain and shortness of breath. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).



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1276413	5/1/2021	IN	43	F		4/17/2021	COVID-19; BRONCHITIS; This spontaneous report received from a consumer (patient's husband) concerned a 43 year old female. The patient's height, and weight were not reported. The patient was not pregnant at the time of report. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: 042A21A, and expiry: 21-JUN-2021) dose was not reported, administered at Left Deltoid on 09-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 09-APR-2021, the patient was given a dose of the vaccine and she did not show up. On next day 10-APR-2021, she started shivering very badly and was feverish. On 11-APR-2021, the patient also had a headache. On 12-APR-2021, all symptoms gone. The next day on 13-APR-2021 when she got up she had chest tightness and went to doctor due to fever, chills, headache resumed. Since that day was the clot information in the news and they did testing for clot stuff which was all negative. Also the patient diagnosed with bronchitis. After the 13th she had 'on/off' days of experiencing symptoms. On 16-APR-2021, she tested for covid-19 via 'non-rapid' test and the results of test came on the 17th were positive for covid-19 (diarrhea, vomiting, chest tightness, shivering, chills, headache, feverish and nausea). On 17-APR-2021, she developed diarrhea and vomiting. By the 19-APR-2021, they went to the hospital where she received unspecified fluids and pain pills for the fever and to calm her down. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the bronchitis and covid-19 was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0-20210443606 - Covid-19 vaccine ad26.cov2.s-Covid 19. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

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1276409	5/1/2021	NJ		M		3/31/2021	BLOOD IN URINE; BLOOD CLOTS IN URINE; SLEEPY; SORE ARM; This spontaneous report received from a patient concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808609, expiry: 09-Jun-2021) dose was not reported, administered on 30-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 31-MAR-2021, the patient got the shot experienced sore arm. On 01-APR-2021, at morning he was very sleepy. On 21-APR-2021, the patient went to the bathroom he had blood in urine and again he noticed there were some clots in the urine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from sore arm, and sleepy, and had not recovered from blood in urine, and blood clots in urine. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:-Covid-19 vaccine ad26.cov2.s.Blood clot in urine and blood in urine. This event is considered unassessable. The event has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

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1276398	5/1/2021	AR	48	F	3/1/2021		POSSIBLE BLOOD CLOT; INCREASED HEART RATE; CHEST TIGHTNESS; HIGH BLOOD PRESSURE; NECK PAIN; ARM PAIN; HEAD PAIN; BODY SHAKING; CHILLS; HIP JOINT PAIN; BACK PAIN; This spontaneous report received from a patient concerned a 48 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included high blood pressure, osteoarthritis, fibromyalgia, non smoker, and non alcohol user. The patient experienced drug allergy when treated with diphenhydramine hydrochloride. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805022) dose was not reported, 1 total, administered on right arm on 14-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 14- MAR-2021, around 9 pm the patient experienced body shaking, and chills for which she took Theraflu. On 15-MAR-2021, morning the patient experienced high blood pressure, chest tightness and increased heart rate of 156 BPM for which she went to the ER. She also experienced neck pain, arm pain and head pain. lung and chest examination was normal. Laboratory data included: Blood pressure (NR: not provided) increased, Fibrin D dimer (NR: not provided) 780, and Heart rate (NR: not provided) 156 pm. As the- d dimer test result was high, the doctor said she has a blood clot. She was given a shot of Toradol at the ER. On 17-MAR-2021, Laboratory data included: Fibrin D dimer (NR: not provided) 650. On 30-MAR-2021, She had another episode, she was in a lot of pain. She went back to ER. Laboratory data included: CAT scan (NR: not provided) normal. They sent her home and prescribed her Meloxicam. The patient went to see her Cardiologist after that, She stated that her cardiologist didn't do any blood work or mention anything regarding a blood clot. Treatment medications (dates unspecified) included: ketorolac tromethamine, acetylsalicylic acid, meloxicam, and dextromethorphan. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from high blood pressure, chest tightness, increased heart rate, body shaking, chills, and head and neck pain and arm pain on MAR-2021, had not recovered from hip joint pain, back pain, and the outcome of blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's

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							Comments: V0:-covid-19 vaccine ad26.cov2.s-possible blood clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
1278155	5/1/2021	OH	42	M	3/23/2021	4/21/2021	Stroke caused by blood clot. Spent 6 days in medical facility as a result. Unknown if vaccine and blood clot are related - but it seemed wise to report for further investigation
1276390	5/1/2021		32	M		3/15/2021	LARGE EXTERNAL THROMBOSED HEMORRHOID (BLOOD CLOT); This spontaneous report received from a consumer concerned a 32 year old male of unknown race and ethnic origin. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: UNKNOWN) dose was not reported, 1 total, administered on 11-MAR-2021 for prophylactic vaccination. The batch number was not reported and it has been requested. No concomitant medications were reported. On 15-MAR-2021, the patient underwent surgery for a large external thrombosed hemorrhoid (blood clot). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of large external thrombosed hemorrhoid (blood clot), surgery was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:-covid-19 vaccine ad26.cov2.s-large external thrombosed hemorrhoid (blood clot) . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1277344	5/1/2021	WI	57	F	3/31/2021	4/6/2021	headache; nausea; light headed/ dizziness; unsteady gait; vomiting; chills; sweats; superficial blood clot; pain to back of Rt knee; bruising; swelling; This is a spontaneous report from a contactable Nurse. A 57-year-old non-pregnant female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly, administered in Arm right on 31Mar2021 (Batch/Lot Number: EW0150) (at age of 57-year-old) as single dose for COVID-19 immunisation. Medical history included osteoarthritis, and migraines. The patient's concomitant medications were not reported. The patient previously took the first dose of BNT162B2, intramuscularly, administered in left Arm on 10Mar2021 (at age of 57-year-old) (Lot number: EN6207) for COVID-19 immunisation. It was unknown if other vaccine in four weeks. It was unknown if COVID prior vaccination. The patient experienced onset of pain to back of Rt knee, bruising, and swelling on 06Apr2021. She called doctor on 09Apr2021, provider diagnosed her with superficial blood clot. Treating with applying warm compress to area. Client had onset of headache, dizziness, nausea, light headed, unsteady gait, vomiting, chills and sweats on 10Apr2021. Patient called doctor on 14Apr2021, they recommended covid-19 testing, results are negative on 12Apr2021. Symptoms ongoing since 14Apr2021. The outcome of events was not resolved.; Sender's Comments: Based on plausible temporal association, a causal association between the reported event thrombosis and suspect drug bnt162b2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

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1276388	5/1/2021			U			<p>BLOOD CLOTS; SEVERE PAIN; This spontaneous report received from a consumer concerned a patient of unspecified sex and age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, the patient experienced blood clots and severe pain, and was hospitalized (date unspecified). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the blood clots and severe pain was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: This is a report of a patient, unspecified age, unspecified gender, unknown ethnicity, who was hospitalized for pain and blood clots on an unspecified number of days after receiving the covid-19 vaccine ad26.cov.2.s. The information provided precludes a meaningful medical assessment. Additional information requested.</p>

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1276526	5/1/2021	FL	72	F	3/1/2021		<p>BLOOD CLOT WITH DYING PAIN IN RIGHT SHOULDER; This spontaneous report received from a patient concerned a 72 year old female. The patient's weight was 141 pounds, and height was 164 centimeters. The patient's concurrent conditions included back pain, two cysts on kidney, high blood pressure, anxiety, high cholesterol, non smoker, non alcoholic, and spine issue, and other pre-existing medical conditions included it was unknown that patient had drug abuse or illicit drug usage. she was health healthy and always doing exercises, she lifts 3kg dumbbells and walked and use indoor bicycle for exercise. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029, expiry: UNKNOWN) dose was not reported, frequency one total administered on 15-MAR-2021 for prophylactic vaccination. Concomitant medications included citalopram for anxiety, lorazepam for anxiety, oxycodone for back pain, and spine issue, and acetylsalicylic acid for drug used for unknown indication. Patient received vaccine on March 15, 2021 at a local vaccination center. she woke up with pain and had this for several days before. somebody suggested going to the Emergency room. Patient proceeded to ER on 26-March-2021 and was seen by Doctor. Doctor suspected a blood clot and told the if its blood clot it could moved to lung and cause stroke. The patient reports the following tests were performed X-ray, ultrasound and blood tests. Test results all showed blood clot that the patient describes as deep vein in the right shoulder between shoulder and neck. Patient reported that she was given a blood thinner in her tummy and then a prescription for 30 days of Eliquis 5mg. Patient reported that the pain was killing her and stated she was dying of pain. The pain was in the area of the blood clot (right shoulder). Patient was also seen by a specialist who prescribed Eliquis prescription for 1 year. she was taking baby aspirin which told to continued. she finished her 30 days prescription ,she planning to visit ER as pain had not go away. She has been told not to stop the blood thinner as it is dangerous. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clot, and dying of pain s in the area of the blood clot (right shoulder). This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210453704-COVID-19 VACCINE</p>

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1276530	5/1/2021	OR	40	F			<p>AD26.COV2.S - BLOOD CLOT WITH DYING PAIN IN RIGHT SHOULDER. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> <p>DEATH; BLOOD CLOT; This spontaneous report received from a consumer news/social media platform concerned a 5 decade old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient developed a rare blood clot and died within two weeks of getting the Janssen covid vaccine. On an unspecified date, the patient died from unknown cause of death. It was unknown whether autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Death, and Other Medically Important Condition). This case, from the same reporter is linked to.; Sender's Comments: V0-covid-19 vaccine ad26.cov2.s-This case concerns with 5 decade old female. Death, Blood clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH</p>



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1276538	5/1/2021	TX		F		4/8/2021	<p>COLLAPSED LUNG; PAIN IN RIBS; PAIN IN BACK; PAINFUL BREATHING; COULDN'T FUNCTION; MASSIVE ALLERGIC REACTIONS; BUMPS; SORE ARM; SLEEPY; DIZZY; SHAKY; HURTS TO WALK; HURTS TO TALK; BURNING SENSATION ON RIB CAGE TO THE BACK; MASSIVE CHILLS AND TEETH CHATTERING; JOINT PAIN; MASSIVE HEADACHE;</p> <p>This spontaneous report received from a patient concerned a 55 year old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 042A21A, expiry: UNKNOWN) dose was not reported, administered on 08-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On the night of 08-APR-2021, after her vaccination, patient had massive chills, teeth chattering, a massive headache, and her knees felt like they were going to break. The next day of the vaccination, 09-APR-2021, patient had a slight headache and felt really weak and not good at all. On 10-APR-2021, patient felt just fine but her arm was sore for like a week but thought that was normal. On 15-APR-2021, patient felt hurt to breath, walk and talk and patient had a burning sensation on her rib cage that went all the way to her back. The patient went to the Emergency Room(ER) and at the ER, they said she had a collapsed lung. At the ER, patient underwent computerized tomogram scan, Electrocardiogram, chest X-ray and lab work. No blood clots found in test reports. The patient was recommended to take deep breaths and drink lots of water by doctor at the ER, which she did. On the 22-APR-2021 patient saw her regular doctor who told her that she had a massive allergic reaction to the shot. The patient's doctor gave her gabapentin 100mg three times daily, along with tramadol. The patient had no relief hence the medication dose was increased to 300 mg of gabapentin in the morning and 300 mg at night. Patient took 300 mg at night and 300 mg morning of the reporting but by 11:00 on the day of reporting she was sleepy, shaky and dizzy, she couldn't function. Patient lay down for a while and got back up at 2:30pm. After waking up the pain was worse. It was hard to breathe while she was deep breathing. Every time she breathes there was a sharp pain between her lungs and chest. Patient was not able to drive because of the bumps. Laboratory data</p>

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(dates unspecified) included: CT scan (NR: not provided) No blood clots, Chest X-ray (NR: not provided) No blood clots, EKG (NR: not provided) No blood clots, and Lab test (NR: not provided) No blood clots. Treatment medications (dates unspecified) included: tramadol, and gabapentin. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from massive chills and teeth chattering, massive headache, joint pain, and sore arm, had not recovered from collapsed lung, pain in ribs, painful breathing, and pain in back, and the outcome of burning sensation on rib cage to the back, massive allergic reactions, sleepy, dizzy, couldn't function, bumps, shaky, hurts to walk and hurts to talk was not reported. This report was serious (Hospitalization Caused / Prolonged, and Life Threatening).; Sender's Comments: V0.-covid-19 vaccine ad26.cov2.s -Pneumothorax, Musculoskeletal chest pain,Back pain,Painful respiration . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).-covid-19 vaccine ad26.cov2.s -Hypersensitivity ,rash erythematous. This event(s) is labeled per RSI and is therefore considered potentially related.

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1276539	5/1/2021	TX		F		4/1/2021	BLOOD CLOT; This spontaneous report received from a patient concerned an adult female. This report was received from news/social media platform reported by a consumer/other non health care professional. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date in APR-2021, after vaccination the patient experienced blood clot, and was hospitalized (date unspecified). This report was notified through VAERS on 22-APR-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Hospitalization Caused / Prolonged). This case, from the same reporter is linked to 20210453777.; Sender's Comments: V0: 20210454136-COVID-19 VACCINE AD26.COV2.S - BLOOD CLOT. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

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1276477	5/1/2021	OH	66	M		4/1/2021	DIARRHEA; LETHARGIC; GENERALISED ACHING; HEADACHE; SWELLING AT INJECTION SITE; REDNESS AT INJECTION SITE; BLOOD CLOT FROM THIGH TO CALF; This spontaneous report received from a consumer concerned a 66 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included paralyzed on left side from a previous injury and not very active. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered 1 total administered on 06-APR-2021 on right arm for prophylactic vaccination. The batch number was not reported and it has been requested. No concomitant medications were reported. On 07-APR-2021, the patient had blow-out diarrhea, lethargic, body aches, headache. On APR-2021, the patient experienced leg pain (started week ago), swelling at injection site and redness at injection site. His left foot was swollen, and called physician to check for blood clot or break. The doctor said that the test showed a blood clot from his thigh all the way down to his calf that was a medical emergency. Reporter thinks there was a possibility that they were already exposed to COVID. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot from thigh to calf, diarrhea, lethargic, generalised aching, headache, swelling at injection site and redness at injection site was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0. 20210450241- COVID-19 VACCINE Ad26.COV2. S - Blood clot. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1276433	5/1/2021	TX		F			BLOOD CLOTS; This spontaneous report received via social media/news from a patient concerned an adult female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, 1 in total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient had clot blood and was hospitalized. The symptoms appeared were found to be consistent with the six cases reported elsewhere last week. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clots was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: -Covid-19 vaccine ad26.cov2.s-Blood clot. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.
1279122	5/1/2021	WA	58	M	1/24/2021	2/9/2021	Blood clot on 2/9/2021, just thought it was a severe calf cramp and took ibuprofen for several days until the calf felt somewhat better. Went to ER on 3/20 for dual pulmonary embolisms.

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1278916	5/1/2021	MA	60	F	3/26/2021	3/27/2021	DVT blood clot; ankle was still swollen and uncomfortable; ankle was still swollen and uncomfortable/discomfort; nights were the worst for the pain; pulse ox was low; d-dimer was very high; fainted; Fracture of ankle/two fractures on her ankle; severely nauseous; Vomiting; Diarrhea; deathly sick; This is a spontaneous report from a contactable consumer, reporting for herself. A 60-year-old female patient received the first dose of the bnt162b2 (BNT162B2; Lot Number: ER8727), via an unspecified route of administration in the left arm on 26Mar2021 at 14:00 at a single dose for covid-19 immunisation. Medical history included osteoporosis at least 10 years, terrible nausea, mild case of covid from Nov2020 to an unknown date. There were no concomitant medications. The patient previously took alendronate from 2008 to an unknown date and experienced very sick, nausea, diarrhoea and zoledronic acid (RECLAST) from Dec2017 and experienced nausea and vomiting. On 27Mar2021 at 2:00, the patient experienced deathly sick, fainted, fracture of ankle/two fractures on her ankle, severely nauseous, vomiting, and diarrhea. On an unknown date, the patient experienced dvt blood clot, ankle was still swollen and uncomfortable/discomfort, the nights are the worst for the pain, pulse ox was low, and d-dimer was very high. The event, deathly sick, was life-threatening. The clinical course was as follows: the patient had the first dose of the vaccine on 26Mar2021 at 14:00 in the afternoon in her left arm. Twelve hours after the first dose, later in the night about 02:00 AM she woke up deathly sick; and severely nauseous. She remembered she was going to the bathroom then she must have fainted because they were taking her to the hospital. She went to the ER and they found she had a fractured ankle. She was not admitted to the hospital. She was in the ER from about 03:00 AM to noon the next day. There must have been something in there; she knew there must be something in the vaccine because of her reaction. Adds a few years ago, something like this happened before. She had osteoporosis and had similar reactions with other products she had tried for osteoporosis; she had terrible nausea. The other products she tried included: in 2008 she took alendronate, it made her very sick but not as severe as this time, she never fainted. She had nausea and diarrhea. Then in Dec2017 she had zoledronic acid.

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She went for an infusion at the hospital then went shopping, and was fine until the early morning, when she woke up with nausea and vomiting. In the ambulance, they gave her ondasetron (ZOFTRAN) for the nausea so the vomiting stopped. With regard to her ankle, first they thought it was a DVT blood clot. They did the xray and saw actually two fractures on her ankle but she does not need surgery. She saw the orthopedic doctor the other day and he said her ankle was healing but she still will have no weight bearing for 6 weeks and she was in a boot. Adds her ankle was still swollen and uncomfortable. She hated to take medications and they gave her oxy but she didn't want to take it. She was taking ibuprofen but that messed up her stomach. The nights are the worst for the pain and discomfort. Doctor at the hospital and primary care agreed she should not have the second dose. She did have mild case of COVID in Nov2020 and they are hoping she had antibodies from the infection and the first dose. Her primary care doctor was reviewing the blood work she had done at the hospital and told her they were surprised the hospital didn't admit her for observation because her pulse ox was low and there was another test that she was questioning because the d-dimer was very high. They did a chest x ray with unknown results. The doctor was questioning why they didn't do something else to rule out a blood clot. Therapeutic measures were taken as a result of the events, deathly sick, DVT blood clot, fainted, fracture of ankle/two fractures on her ankle, severely nauseous, vomiting, diarrhea, ankle was still swollen and uncomfortable/discomfort, nights were the worst for the pain, pulse ox was low, and d-dimer was very high. The clinical outcome of the events, deathly sick, fainted, severely nauseous, vomiting, diarrhea, was recovered on 27Mar2021. The clinical outcome of the events, DVT blood clot and nights were the worst for the pain, pulse ox was low, and d-dimer was very high, was unknown. The clinical outcome of the event, fracture of ankle/two fractures on her ankle, was recovering. The clinical outcome of the event, ankle was still swollen and uncomfortable/discomfort, was not recovered. No follow-up attempts are needed. No further information is expected.

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1278921	5/1/2021	CA	52	F	4/2/2021	4/3/2021	diagnosed with DVT/slight pain in right calf/severe pain in right calf (unable to weight bear); This is a spontaneous report from a contactable consumer (patient). A 52-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: ER8737), via an unspecified route of administration, administered in arm left on 02Apr2021 at 10:45 (at the age of 52-years-old) as a single dose for COVID-19 immunisation. Medical history included retinoblastoma, menorrhagia and fibroids from an unknown date and unknown if ongoing. Concomitant medications included ethinylestradiol, norgestrel (OGESTREL-28) taken for menorrhagia, uterine leiomyoma; iron taken for an unspecified indication, start and stop dates for both were not reported. On 03Apr2021, the patient woke up with slight pain in right calf. On 04Apr2021, she woke up with severe pain in right calf (unable to weight bear), then went to Urgent Care and was diagnosed with deep vein thrombosis (DVT) 7cm. Started apixaban (ELIQUIS) for 3 months, stopped low norgestrel. Therapeutic measures were taken as a result of the event. The outcome of the event was recovering.



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1278923	5/1/2021	FL	75	M	3/5/2021	3/6/2021	numbness is in both hands, but the right hand is worse; developed afib; was told he developed COPD/he had mild COPD years ago; diagnosed with pneumonia; shortness of breath; wheezing; dizziness; This is a spontaneous report from a contactable consumer (patient). A 75-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EN6199) via an unspecified route of administration into right arm on 05Mar2021 (at the age of 75-year-old) as single dose for COVID-19 immunisation. Medical history included diabetic, arthritis in hip and back, shingles, ongoing mild chronic obstructive pulmonary disease (COPD) started years ago. There were no concomitant medications. Historical vaccine include first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EM9810) into left arm on 13Feb2021 (at the age of 75-year-old) for COVID-19 immunization and experienced no adverse effect; influenza vaccine (INFLUENZA VACCINE), pneumococcal 13-valent conjugate vaccine (diphtheria crm197 protein) (PREVNAR 13) and tetanus vaccine (TETANUS VACCINE); all on an unspecified date for immunization and patient experienced no adverse effect. Patient did not receive any other vaccinations within four weeks prior to the first administration date of the vaccine. On 06Mar2021, patient experienced shortness of breath, wheezing and dizziness. On an unspecified date patient also experienced numbness is in both hands, but the right hand is worse. Patient was brought to the emergency room on an unspecified date where he was told that he developed afib (atrial fibrillation) and COPD (chronic obstructive pulmonary disease) to which the patient stated he had mild COPD years ago. On 09Mar2021, patient had a chest X-ray and was told he has pneumonia. The patient was hospitalized for the events reported from 09Mar2021 to 12Mar2021 and was treated with SPIRIVA RESPIMAT inhaled 2 puffs by mouth 1 time each day, PROAIR HFA two puffs by mouth every 4 hours as needed for shortness of breath, APIXABAN one tab by mouth every 12 hours and some medications (unspecified). The patient underwent lab tests and procedures which included computerised tomogram: no blood clots on an unspecified date, electrocardiogram: unknown results on an unspecified date, SARS-CoV-2 test: unknown results on an

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unspecified date. Outcome of event dizziness was recovered on an unspecified date; event "numbness is in both hands, but the right hand is worse" was not recovered; while for all other events was unknown.

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1278927	5/1/2021			F			<p>drug ineffective; rash on tongue; feeling tired, decreased strength and difficulty walking; feeling tired, decreased strength and difficulty walking; COVID-19; This is a spontaneous report from a contactable consumer based on information received by Pfizer (manufacturer control number US-AMGEN-USASP2021052584). This case was split from master case #2021402787 to capture a female patient taking BNT162B2 and experienced drug ineffective, COVID-19, and tongue disorder. A 77-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 1 on an unspecified date (Batch/Lot number UNKNOWN) as single dose, dose 2 unknown on an unspecified date (Batch/Lot number UNKNOWN) as single dose for covid-19 immunisation. Medical history included ongoing rheumatoid arthritis with rheumatoid factor of right hand without organ or systems involvement. Concomitant medication(s) included etanercept (ENBREL) taken for rheumatoid arthritis,; fluticasone propionate, salmeterol xinafoate (ADVAIR HFA); citalopram hydrobromide (CITALOPRAM HYDROBROMIDE); clotrimazole (CLOTRIMAZOLE); levothyroxine sodium (LEVOTHYROXINE SODIUM); meclizine hcl (MECLIZINE HCL), methotrexate (METHOTREXATE); omeprazole, sodium bicarbonate (OMEPRAZOLE/SODIUM BICARBONATE); clopidogrel (CLOPIDOGREL); clorazepate dipotassium (CLORAZEPATE DIPOTASSIUM); doxycycline hyclate (DOXYCYCLINE HYCLATE). The patient stated she has had both the COVID vaccines and developed rash on tongue as a result. Since on an unknown date, the patient was feeling tired, decreased strength and difficulty walking. Patient was using walker. Patient stated she was unable to participate in exercise programs as she would like because of health. Recently, on an unknown date in 2021, the patient was diagnosed with COVID. The patient stated, along with recent COVID diagnosis has caused some anxiety. No treatment information was received. The outcome of the event covid-19 was reported as not recovered/not resolved. Action taken with Enbrel and Single Dose Prefilled Autoinjector was reported as unknown for the event covid-19. The causal relationship between the event covid-19 and Enbrel with Single Dose Prefilled Autoinjector was not provided by the consumer. The reporter declined consent for follow</p>

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up. No follow up attempts are possible. No further  
information is expected. No follow-up attempts possible.  
No further information expected.

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1278947	5/1/2021	IL	57	F	4/12/2021	4/1/2021	swollen submandibular lymph nodes; swelling/swelling went to the back, the shoulder blade up the left side of her neck; swelling/swelling went to the back, the shoulder blade up the left side of her neck; redness; pain started at injection site; pain went from her elbow to shoulder and then up her shoulder and up to the neck; pain went from her elbow to shoulder and then up her shoulder and up to the neck/she still has arthritic type pain in left arm socket.; couldn't lift her left arm at all; deep ache/ to her back; crying; This is a spontaneous report from a contactable nurse (patient). A 57-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in left arm on 12Apr2021 at 16:30 (lot number reported as "EN or W 0161, EN0161 or EW0161") at a single dose for COVID-19 immunisation. Medical history included diabetic from 2008, blood clots , COVID-19 (reported as April; year unknown), insulin dependent in 2014 , Protein S deficiency, genetic disorder that makes her have blood clots, neuropathy. Concomitant medications included warfarin sodium (COUMADIN) taken for Protein S deficiency, genetic disorder that makes her have blood clots from 2007 to an unspecified stop date; gabapentin taken for neuropathy from Sep2019. Patient stated that she gets a mild case of the flu when she gets the flu vaccine, but she doesn't remember back to childhood. She got an MMR booster about 20 years ago and had no problems then. Family Medical History: both parents had diabetes; mother has Protein S deficiency as well that causes blood clots. The vaccine was administered at healthcare facility. The patient did receive previous immunization with a Pfizer vaccine. The patient did not receive other vaccines within four weeks prior to COVID vaccination. The patient received her first shot on Monday 12Apr2021 and was fine until 12 hours later. Her arm swelled up and she couldn't lift it. Then the swelling went to the back, the shoulder blade up the left side of her neck. She could feel her lymph nodes and so she was icing it, taking Tylenol and the swelling has gone down. The redness was gone but she still has arthritic type pain in left arm socket. She can lift and move the left arm, but it hurts, and it also hurts when she turns her head to the right. She received the Pfizer COVID vaccine in her left arm. The pain started at injection site and then went from her

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elbow to shoulder and then up her shoulder and up to the neck. Her family was commenting on her neck being swollen. She received her shot at 4:30 PM on 12Apr2021. The redness and swelling started at around 5:00 AM on 13Apr2021. A couple hours after Pfizer COVID vaccine injection the pain started. She waited for 30 minutes because she takes coumadin for a history of blood clots, nurse wanted to wait to make sure her arm wouldn't bleed. She has been taking Benadryl ointment and icing it for 3 days as treatment for the events. She got up at two this morning to go to the bathroom and noticed she could still feel the pain when she turns her head to the right. She had swollen submandibular lymph nodes and could feel two of them before. When she woke up, she could not feel her lymph nodes. Everything has recovered except for the pain. The patient stated that on the first day the symptoms were disabling, and she couldn't lift her left arm at all. They got better once she started icing it and rested instead of doing chores. She keeps popping Tylenol every 6 hours, Benadryl and refilling ice bag with one ice bag on neck and one ice bag on arm. There was a deep ache right now in the socket that goes up her neck and down the shoulder blade to her back. Right now, she doesn't like to be in any pain and would say the pain was mild compared to how it was, the pain was so bad she was rocking and crying. Her brother gave her one of her mother's pain pills, one Vicodin because she was in so much pain. She can control the pain now with the extra strength Tylenol. She got the Pfizer COVID vaccine for lots of reasons. She has a lot of health problems, she had COVID virus last April and that was why she was having this reaction since she already has antibodies. She takes care of her mother who was sicker than she was. She was out in the real world and she doesn't want to bring anything home or get anything herself. She thought gabapentin would have made it to where she did not have the arthritic pain from vaccine. She takes gabapentin for neuropathy. She was diabetic and that may have something to do with it too. Patient stated that everyone else in her family got Johnson and Johnson and nobody had reactions. She was supposed to get at the Johnson and Johnson shot first but with the shortage it was switched over the to Pfizer COVID vaccine. This was her first dose of the Pfizer COVID vaccine. Redness and swelling started at

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around 5:00 AM 13Apr2021. Pain started around 6:30 PM. The events did not require emergency room visit or hospitalization. She was at the urgent care yesterday where she gets her INR checked and the nurse said she didn't see any swelling but believed she was in pain because she didn't want to lift the left arm. The reporter assessed the events swelling, redness, and pain were considered serious (disabling). Outcome of the events vaccination site pain, neck pain, arthralgia, and back pain was recovering, for event crying was unknown, for event swollen submandibular lymph nodes was recovered on unspecified date, while for events swelling, joint swelling and redness was recovered on 16Apr2021. Information on the lot/batch number has been requested.dft; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate

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1278972	5/1/2021			M	4/17/2021		<p>find out if his side effects are normal or if he maybe has a "blood clot."; the shoulder and neck on the side where he received his injection are swollen and painful; the shoulder and neck on the side where he received his injection are swollen and painful; the shoulder and neck on the side where he received his injection are swollen and painful; the shoulder and neck on the side where he received his injection are swollen and painful; across his collar bone is painful; my lips, nodes and top of my right my trap area is swollen; my lips, nodes and top of my right my trap area is swollen; I was told you might swollen on arm where shot went it or under your armpit not on top on my neck; This is a spontaneous report from a contactable consumer (patient). A male patient of an unspecified age received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Apr2021 (lot number and expiry date not reported) as single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Historical vaccine included first dose of bnt162b2 on an unspecified date for COVID-19 immunization. The patient stated that he received his second dose of the Pfizer COVID-19 vaccine on Saturday 17Apr2021. He stated that he called Pfizer yesterday, Sunday 18Apr2021 and reported his side effects, but was not able to have his questions answered. He was calling back to find out if his side effects were normal or if he maybe had a "blood clot."</p> <p>The patient stated that the shoulder and neck on the side where he received his injection were swollen and painful. The patient stated that across his collar bone was painful. He stated that the swelling and pain had improved slightly since yesterday. He stated that other than these side effects he feels great. He added, "I just got my second shot yesterday. No symptoms showed up except my lips nodes and top of my, right my trap area is swollen. So I want to make sure, is that normal? Because I was told you might swollen on arm where shot went it or under your armpit not on top on my neck." Clinical outcome of blood clot was unknown, while for the other events was recovering. Information on the lot/batch number has been requested.</p>



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1278908	5/1/2021	MD	50	F	3/12/2021	4/5/2021	<p>A Blood clot was found; Cellulitis; Migraine started within 24 hours; left calf pain/Leg increased in swelling and burning pain; severe swelling and burning sensation; severe swelling and burning sensation; Leg increased in swelling and burning pain; Phlebitis; This is a spontaneous report from a contactable consumer (patient). A 50-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EN6199/EN5318), via an unspecified route of administration administered in left arm at doctor's office/urgent care facility on 12Mar2021 15:00 as SINGLE DOSE for COVID-19 immunisation. The patient was not pregnant at the time of vaccination. The patient was not COVID tested post vaccination. The patient had no other vaccines in four weeks. Medical history included high blood pressure and sleep apnea. Concomitant medications included amoxicillin, valsartan, amlodipine, and vitamin d [vitamin d nos]. The patient previously took doxycycline and experienced allergies. Historical vaccine includes first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on an unspecified date for COVID-19 immunisation. On 05Apr2021 at 03:00 PM, the patient experienced a blood clot was found, cellulitis, migraine started within 24 hours, left calf pain/leg increased in swelling and burning pain, severe swelling and burning sensation, leg increased in swelling and burning pain, and phlebitis. It was further reported that migraine started within 24 hours. 48 hour left calf pain that got increasingly worse leading to a severe swelling and burning sensation. The patient went to right time urgent care on Friday, 09Apr2021. The patient was diagnosed with cellulitis. It was also reported that pain increased swelling spread and went to emergency room (ER) on 10Apr2021 for ultrasound of leg. No clots and was advised if worsened to come back. The patient's leg increased in swelling and burning pain. The patient went to urgent care patient first on 11Apr2021 and then the doctor on Monday, 12Apr2021 where she was sent for a STAT ultrasound due to major pain and swelling. A blood clot was found. Phlebitis was diagnosis. The patient was sent to a vascular surgeon on 13Apr2021 and vein specialist on 15Apr2021. The patient was given Xarelto blood thinners and started taking them on 15Apr2021. All of this began 48 hours after taking the second vaccination (pending</p>

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clarification) and has the patient worried. The events resulted to doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. Therapeutic measures were taken as a result of all events. The patient had not yet recovered from all events.

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1279063	5/1/2021	MI	67	M			<p>Thrombocytopenia; He had clot in the legs and in the lungs; He had clot in the legs and in the lungs; Low platelet count; This is a spontaneous report from a contactable Other-HCP. A 67-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation (Age at vaccination: 67 years). Medical history included diabetes. Concomitant medication(s) included atorvastatin (LIPITOR [ATORVASTATIN]); colecalciferol (VITAMIN D [COLECALCIFEROL]); lisinopril; insulin taken for diabetes mellitus. The patient experienced thrombocytopenia, he had clot in the legs and in the lungs and have a low platelet count on an unspecified date. The patient was hospitalized for the events on an unspecified date. The patient underwent lab tests and procedures which included CBC: unknown result on 08Apr2021, Heparin associate antibody: unknown result, comprehensive metabolic panel (CMP): unknown result and platelet count: low on an unspecified date. Therapeutic measures were taken as a result of thrombosis included Heparin drip and Argatroban. Outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: The reported events are considered unrelated to BNT162B2 vaccine, being rather intercurrent occurrences. Clots in the legs and in the lungs were likely favored by the mentioned diabetes and by a possible hyperlipidemia (the patient was taking atorvastatin) in a setting of possible arterial hypertension (the patient was taking lisinopril). The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>

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1279205	5/1/2021			U		4/1/2021	I got a blood clot in my varicose vein in my left leg; This is a spontaneous report from a contactable consumer(patient). A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number was not reported), on an unspecified date at single dose for covid-19 immunisation. The patient medical history included varicose vein in the left leg. Concomitant medications were not reported. On an unspecified date in Apr2021, the patient developed a blood clot in the varicose vein in the left leg. Patient clarified that after talking to the doctor patient thought may had the adverse reaction to the first vaccine. Patient was supposed to get Pfizer Vaccine at the day of reporting but when talk to doctor and the urgent care where was supposed to be getting it, rescheduled it for 04May2021 because 3 days before (in Apr2021) patient got a blood clot in varicose vein in left leg so, they didn't want to go and get the vaccine and rescheduled it for 04May2021. Patient asked if he/she should even get the second vaccine.The final outcome of the event was unknown. Information on the lot/batch number has been requested

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1279144	5/1/2021	NY	48	U	1/21/2021	1/31/2021	Passed out; Blood clots in lungs; almost died from the vaccine; Problem in breathing; This is a spontaneous report from a contactable consumer (patient) reported that a 48-year-old patient of an unspecified gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3247), via an unspecified route of administration, administered in arm right on 21Jan2021 (at the age of 48-years-old) as a single dose for covid-19 immunisation. The patient was healthy and had no suffering from any medical condition. Concomitant medication included sertraline hydrochloride (ZOLOFT) taken for an unspecified indication, start and stop date were not reported. The patient had his/her shot on 21Jan2021 and about 10 days later he/she was having problem in breathing. When the patient went to work, he/she passed out at work and they sent him/her to the hospital and he/she wound up in the hospital on 12Feb2021 and they found out that he/she have blood clots in his/her lungs. The patient added that the matter of concern was he/she almost died from the vaccine. The patient was discharged on 14Feb2021 and he/she went in on 12Feb2021 and they did the catheter to remove the blood clot. The patient was hospitalized due to blood clots in his/her lungs and prior to going to the hospital, a week, and a half before that he/she was having breathing issues. The patient underwent lab tests and procedures which included blood test with unknown results on Feb2021. The patient was supposed to get the 2nd dose on 11Feb2021, but he/she never went because he/she wound up in hospital. The patient right now was taking blood thinner named Eliquis after he/she wind up with clot. The outcome of the events was unknown.

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1279190	5/1/2021	KY	57	M	2/8/2021		two blood clots in his leg; This is a spontaneous report from a contactable consumer reporting on behalf of the patient. A 57-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose on 08Feb2021 (Lot Number: EM9810, unknown expiration) and second dose on 02Mar2021 (Lot Number: ENU202, unknown expiration; pending clarification), both received at the age of 57 years old via unspecified route of administration as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The reporter called to report that the patient had a Pfizer vaccine, received second COVID vaccine on 02Mar2021, and couples of weeks ago, a week longer that the patient was diagnosed with two blood clots in his leg. The patient got both of COVID-19 vaccine. Outcome of the event was unknown. Information on the lot/batch number has been requested.
1277768	5/1/2021	CA	82	M	4/20/2021	4/30/2021	Pt presented to my office on 4/30 after being vaccinated on 4/20 with left arm swelling. Outpatient stat DVT study in LUE showed extensive thrombosis in veins of LUE and subocclusive thrombosis in BL Internal Jugular veins. I referred pt to hospital for inpatient admission.

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1279276	5/1/2021	MO	53	F	4/8/2021	4/13/2021	big knot there and now its black and blue and it's also like ball/could be a blood clot on her hand; Headache; sickness; felt like little vomit; not having a very good appetite; feeling like sinusy; feeling little nauseas; bruise on the top of her hand and then that bruise move to left part of her upper hand; This is a spontaneous report from a contactable consumer (patient) reported that a 53-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8727), via an unspecified route of administration on 08Apr2021 (at the age of 53-years-old) as a single dose for covid-19 immunisation. The patient medical history included cardiovascular disease. She has had open heart surgery, a double bypass when she was 44. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 18Mar2021 (at the age of 53-years-old) for covid-19 immunisation, and experienced face got swollen and got red and she think she got wet nose right there swelling a little bit same time her face swollen. Additional medical history included anxiety and depression. Concomitant medications included acetylsalicylic acid, ascorbic acid (ASPIRIN [ACETYLSALICYLIC ACID;ASCORBIC ACID]; atorvastatin; midodrine; metoprolol; clopidogrel; ranolazine; meclizine hydrochloride (MECLIZINE HCL); hydrocortisone; glyceryl trinitrate (NITROGLYCERIN); zinc sulfate (ZINC SULPHATE); gabapentin; colecalciferol (VITAMIN D [COLECALCIFEROL]); and paracetamol (ACETAMINOPHEN); all were taken for an unspecified indication, start and stop date were not reported. Additional concomitant medications included duloxetine taken for depression and anxiety; and alprazolam (XANAX) taken for anxiety; both start and stop date were not reported. On 13Apr2021 5 days after the second vaccination, the patient experienced headache every single day with sickness and felt like little vomit and not having a very good appetite at all. She was feeling "sinusy" but she don't have any sinus issues and then she was feeling little nauseas and then her right hand for some reason she got bruise on the top of her hand and then that bruise move to left part of her upper hand and gotten a big knot there and now its black and blue and it's also like ball; her husband and she think that could be a blood clot on her hand. The outcome of the events was unknown.

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1278070	5/1/2021	OK	83	F	3/10/2021	3/22/2021	UTI 3/16/2021-3/20/2021. UTI 4/28/2021. Sensitivity to light 3/24/2021 - current. Blurry Vision 3/20/2021 - 3/24/2021. Partial blindness 4/04/2021 - current. Headaches 3/24/2021 - current. Doctor ruled not a stroke. Stroke of the eye due to blood clot or plaque build up is the highest suspected cause. No previous incidents of this nature had occurred.



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1276281	5/1/2021	KY		M	1/28/2021	4/1/2021	<p>Blood clot in the right eye; This is a spontaneous report from a contactable consumer(patient) based on information received by Pfizer, license party for apixaban (ELIQUIS). This spontaneous case was reported by a consumer and describes the occurrence of OPTHALMIC VEIN THROMBOSIS (Blood clot in the right eye) in male patient of an unknown age who received apixaban (Eliquis) for an unknown indication. CO-SUSPECT PRODUCTS included Covid-19 Vaccine for an unknown indication. On an unknown date, the patient started Eliquis (unknown route). On 07-Jan-2021, the patient started Covid-19 Vaccine (unknown route). In April 2021, the patient experienced OPTHALMIC VEIN THROMBOSIS (seriousness criterion medically significant). The action taken with Eliquis (Unknown) was unknown. At the time of the report, OPTHALMIC VEIN THROMBOSIS outcome was unknown. The consumer received his first Pfizer covid 19 shot on 07-Jan-2021 and the second one on 28-Jan- 2021, and 10 days prior to this report he got a blood clot in his right eye. He takes a blood thinner and remarks this should keep him from getting blood clots, should not it. Blood thinner provided was Eliquis. The event was related to covid 19 vaccine and causality with Eliquis was not provided. For Eliquis (Unknown), the reporter did not provide any causality assessments. This case was received via pfizer. BMS Medical Evaluation Comment: This patient had ophthalmic vein thrombosis while on therapy with apixaban and after taking covid 19 vaccine. Underlying thromboembolic risk as ascertained by the use of apixaban is a significant factor that likely predisposed the patient to develop ophthalmic vein thrombosis and considered not related to apixaban therapy. Causality Assessment: For apixaban: the causal relationship of the event Ophthalmic vein thrombosis with the suspect product apixaban was not provided Per Reporter; the causal relationship of the event Ophthalmic vein thrombosis with the suspect product apixaban was Not Related Per Company (Bristol-Myers Squibb)</p>

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1279051	5/1/2021	TX		M			DVTs in both legs; Femoral artery clotted from my thigh to my ankle; This is a spontaneous report from a Pfizer-sponsored program, PFIZER RXPATHWAYS. A contactable consumer (patient) reported that a male patient of an unspecified age received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number and expiration date were not reported) as a single dose, with route of administration and therapy date unspecified, for COVID-19 immunization. The patient's medical history was not reported. Concomitant medication included apixaban (ELIQUIS). The patient had previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number and expiration date were not reported) on an unspecified date for COVID-19 immunization. On an unspecified date, the patient had deep vein thrombosis (DVTs) in both legs; and femoral artery had clotted from the thigh to the ankle. The events were assessed as serious (medically significant). The outcome of the events was unknown. Information about batch/Lot number has been requested.
1278097	5/1/2021	CA	34	F	4/26/2021	4/30/2021	Pt develop heavy vaginal bleeding with clots 5 days after receiving the shot. Bleeding was heavy enough to drop her hemoglobin and require an emergency D&C.

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1279319	5/1/2021	GA	64	M	3/17/2021		<p>IgM and IgG (antibodies not detected) and stated that it does not preclude acute sars-cov 2 infection; he experienced a little bit of soreness,runny nose, coughing up phlegm,Around 09Apr2021 he lost his taste and smell; His doctor told him his D dimer was elevated.; This is a spontaneous report from a contactable consumer (patient). A 64-years-old male patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in Arm Left on 17Mar2021 11:30 (Batch/Lot Number: EN6207; Expiration Date: 31Jul2021) as SINGLE DOSE for covid-19 immunisation. Medical history included history of COPD treated by CPAP, high blood pressure, Cancerous tumors removed from bladder- He is cancer free, atrial fibrillation (From: 28Feb2021 To: Ongoing), In Feb2021, prior to receiving his first dose of the Covid 19 vaccine he had some heart problems. He had gone into atrial fibrillation. His doctor prescribed Eliquis and put him on a heart monitor. He took a nuclear stress test and that was ok and now he's wearing a heart monitor. Concomitant medication(s) included lisinopril (LISINOPRIL) taken for an unspecified indication from an unspecified start date and ongoing; metoprolol (METOPROLOL) taken for an unspecified indication from an unspecified start date and ongoing; apixaban (ELIQUIS) taken for atrial fibrillation from Feb2021 and ongoing. History of all previous immunization with the Pfizer vaccine considered as suspect (or patient age at first and subsequent immunizations if dates of birth or immunizations are not available) was none. No additional Administered Vaccines on same date with the Pfizer vaccine considered as suspect. No Prior Vaccinations (within 4 weeks). No AE(s) following prior vaccinations. The patient received the 1st dose of the Pfizer covid vaccine on 17Mar2021, he experienced a little bit of soreness, no complaints, no issues. He was scheduled for the 2nd shot on 09Apr2021 or somewhere. However, on 04Apr2021, he started having a runny nose, coughing up phlegm. He has a history of COPD treated by CPAP. He lost his sense of smell and taste. On 7 or 8Apr2021, he took a covid test. He did not get 2nd shot. Covid test results were negative: IgM and IgG (antibodies not detected) and stated that it does not preclude acute sars-cov 2 infection. The D-dimer part of the blood work came back as 0.44 (reference says it should be less than 0.5).</p>

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At the end of Feb 2021, he had A-Fib treated by Eliquis. The doctor said it should be 0 if on Eliquis, but attributes that result to him taking the Pfizer vaccine and explained it as a higher blood clot risk. His 2nd shot is scheduled for tomorrow. He was told by the doctor to wait until mid May and start all over again with the [Redacted]. Caller would like to know whether increased blood risk has been reported as related to the covid vaccine. Referenced EUA Fact sheet for HCPs under section 6 OVERALL SAFETY SUMMARY, Unsolicited Adverse Events: There were no other notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine. The patient wanted to know it is normal to test negative for antibodies after his initial dose. Caller requesting assistance interpreting his blood work results. Provided basic information and referred caller to his HCP for interpretation of his results. The patient had his first Covid 19 vaccine on 17Mar2021. He had no issues with the first vaccine. About 2 weeks after he received his first Covid 19 vaccine maybe around 01Apr2021 he started sneezing, having some phlegm, and coughing stuff up. He does use a CPAP machine at night. Around 09Apr2021 he lost his taste and he lost his smell. He was scheduled for his second Covid 19 vaccine on 10Apr2021 but thought his symptoms were worse than he originally thought. He went to his doctor on 09Apr2021. His doctor did the nasal swab for the Covid 19 virus. He never had a fever or chills. His doctor gave him some erythromycin. He also did some blood tests. His Covid 19 virus test came back negative. On the results of his blood tests on the first page, the first thing it says are that his Covid 19 results are negative. His doctor told him that his body showed no response to the Covid 19 vaccine. He doesn't see that this blood test is testing for antibodies. Later in his blood test paperwork he sees that it says "antibodies not detected, does not preclude acute Sars-Cov-2 infection". His paperwork says IgG and IgM were negative. He provides the following in a historical context. In Feb2021, prior to receiving his first dose of the Covid 19 vaccine he had some heart problems. He had gone into atrial fibrillation. His doctor prescribed Eliquis and put him on a

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heart monitor. He took a nuclear stress test and that was ok and now he's wearing a heart monitor. He's reading from his blood test results. His D-dimer result was 0.44. In the reference range it says anything less than 0.50 is a normal range. But he is taking Eliquis and his doctor told him his D-dimer should be zero. His doctor told him his D dimer was elevated. His doctor believes the first Covid 19 vaccine has something to do with his D-dimer result. The caller reports that he has heard about the [Redacted] and [Redacted] vaccine and blood clots but he hasn't heard anything about Pfizer having problems with blood clots or anything of that nature. His doctor told him that his body showed no response to the Covid 19 vaccine. Later in his blood test paperwork he sees that it says "antibodies not detected, does not preclude acute Sars-Cov-2 infection". His paperwork says IgG and IgM were negative. AE(s) did not require a visit to Emergency Room/Physician Office. The primary infection site was Unknown. There were no predisposing factors. A culture was not performed. Outcome of the events was unknown. No follow-up attempts are needed. No further information is expected.

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1278778	5/1/2021	AZ	46	M	4/2/2021	4/12/2021	<p>calf feels tight, stiff, it feels like dead weight/started within the last 2- 3 weeks; calf feels tight,; pain running up the right arm up to the shoulder; pain running up the right arm up to the shoulder/his calf pain, started to feel tight, started within the last 2- 3 weeks; He asks if someone can tell him if it is a blood clot in the back of his calf; his eyes also hurt a little bit; This is a spontaneous report from a contactable consumer (patient). A 46-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose at the age of 46-years-old via an unspecified route of administration, administered in arm left on 02Apr2021 (Batch/Lot Number: ER8734) as single dose for covid-19 immunisation. There was no medical history reported. There were no concomitant medications. The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 12Mar2021 (lot number: EN6202) at the age of 46-years-old for covid-19 immunisation and experienced If it is a blood clot in the back of his calf, Regular pain feeling, Headache, Muscle pain, Calf feels tight, stiff, it feels like dead weight, Pain running up the right arm up to the shoulder and Calf pain, started to feel tight. The patient reported that he has been feeling the regular pain feeling, a headache, muscle pain before, it comes and goes on 12Mar2021. However, he says that the last few days there had been, by his calf muscle in the back there, they've been tightening, like stiffening up on him when he's sleeping on an unspecified date. It wakes him up at times. He also reports pain running up the right arm up to the shoulder on an unspecified date. He says he is just curious in terms of what that might be. He asks if someone can tell him if it is a blood clot in the back of his calf on an unspecified date. The headache went away after 2-3 days. He says his eyes also hurt a little bit on 12Apr2021 and was the same time frame as the headache. He says those things were just mild, nothing major. He did not take anything for it. He confirmed he no longer has muscle pain. He just has pain behind the calf and right arm up to his shoulder. He says his calf pain, started to feel tight, started within the last 2- 3 weeks. The arm pain in right arm up to shoulder started maybe within the last 2 days. The outcome of the events was unknown. Follow-up attempts completed. No further information expected.</p>

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1277879	5/1/2021	MD	60	F	4/22/2021	4/25/2021	3 days after 2nd vaccine shot I started experiencing sporadic chest pain and a feeling of being light headed. The next day I still had the same symptoms so I described them to my doctor. She recommended going to a urgent care facility. I was diagnosed with 2 small blood clots - one in each lung. I'm on anti-coagulants for the next 6 months.
1278415	5/1/2021	MO	70	M	4/1/2021	4/13/2021	listening to a slow ceiling fan motor whooshing and constantly hears it in both ears; began experiencing hearing loss, noise disappeared suddenly in both ears; very deadening sound in both ears; This is a spontaneous report from a contactable consumer (patient). A 70-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8733), via intramuscular route of administration on 01Apr2021 at 09:30 (at the age of 70 years) at a single dose in the left arm for COVID-19 immunization. Medical history included blood clot in leg almost 10 years ago. Concomitant medications included rivaroxaban (XARELTO, strength: 20 mg) taken for blood clot in leg and other unspecified medications. The patient previously took silodosin (RAPAFLO) a number of years ago for urination and he broke out in hives. Patient had no family medical history. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient had first shot done on 01Apr2021 at 09:30. On the evening of 13Apr2021 at 19:30, he kind of got a very deadening sound in both ears and then began experiencing hearing loss, noise disappeared suddenly in both ears. He woke up the next day (14Apr2021 at 05:00) with what he described as listening to a slow ceiling fan motor whooshing and constantly hears it in both ears. He called his doctor because he thought it may disappear but his doctor instructed him to see an ear and throat doctor about this (for clarification). He called to report the events and to know if it's safe to get the second dose of the vaccine. The outcome of the events was not recovered.

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1278440	5/1/2021	DC		F			tongue swelled immediately; chin and lip remained swollen; chin and lip remained swollen; This is a spontaneous report received from a contactable consumer (the patient). A female patient of an unspecified age received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number not provided), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunization. The patient's medical history included: allergy and blood clots. The patient was not pregnant at the time of vaccination. Concomitant medications were not reported. The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number not provided), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunization. The patient received both shots. After receiving the second shot, the patient's tongue swelled immediately; after a week the tongue swelling went down, but the chin and lip remained swollen. The outcome of tongue swelled immediately was recovering. The outcome of chin and lip remained swollen was not recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained.



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1278466	5/1/2021	MO	77	F	2/6/2021	2/7/2021	stroke caused by a blood clot; stroke caused by a blood clot; right arm went completely numb; She is tired; shortness of breath; her eyes were blurry; her head felt like somebody put a spike in it on the right side; sore arm; This is a spontaneous report from a contactable consumer. A 77-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 06Feb2021 13:15 (Lot Number: EM9809) (at age of 77-year-old) as single dose for COVID-19 immunisation. Medical history included colitis ulcerative from Oct2020 (dropped weight, she dropped from 127 pounds to 109 pounds) , cardiac disorder, atrial fibrillation, and osteoporosis, all were ongoing. Concomitant medications included carvedilol taken for cardiac disorder, atrial fibrillation from an unspecified start date and ongoing; cyanocobalamin (VITAMIN B12) taken for cardiac disorder from 2018 (reported as has taking it close to 3 years) and ongoing; denosumab (PROLIA) taken for osteoporosis from an unspecified start date and ongoing; ubidecarenone (Q10) taken for cardiac disorder from unknown start date and ongoing; calcium, colecalciferol (CALCIUM + D3) taken for osteoporosis from 2020 (reported as a year ago) and ongoing; influenza vaccine (FLU VACCINE VII) taken for an unspecified indication, start and stop date were not reported, and vitamins NOS (MULTIVITAMIN) from an unspecified start date and ongoing, the patient started taking it when she was a senior in high school and stated because she is not the best eater in the world. There was no prior vaccinations (within 4 weeks). AE(s) following prior vaccinations: The patient stated arm is sore with flu shot and probably did when she was little when she got the loaded shot, the mumps one. She wouldn't remember that because she was little. The patient experienced stroke caused by a blood clot on 20Feb202114:30 with seriousness criteria hospitalization, sore arm on 07Feb2021, and right arm went completely numb, tired, shortness of breath, her eyes were blurry, her head felt like somebody put a spike in it on the right side on an unspecified date. The event stroke caused by a blood clot result in emergency room visit. The patient was hospitalized for stroke caused by a blood clot from 23Feb2021 to 24Feb2021. The patient reported that she received the first dose and she is thankful she got it on

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06Feb2021 and the only side effect she had was a sore arm. Stated on 20Feb2021 she had a stroke caused by a blood clot obviously, she ended up in the hospital. She didn't think at the time, doesn't fault the physicians that took care of her. She didn't think it was related and her eldest son thought it was related. The patient stated they thought it was a mild stroke and after they did the C scan the neurosurgeon, while she was lying in the hospital bed, looked at her assistant and said he couldn't believe that she was talking and walking. The patient stated part of it was ignorance on her part, everyone thought it was the left side that numbs, but hers was the right side. Stated she didn't fall, she dropped something and went down to get it and her right arm went completely numb and she couldn't get back up and she tried to push with legs and couldn't get up. Stated all of a sudden her eyes were blurry and then she never gets headaches and her head felt like somebody put a spike in it on the right side, stated it is supposed to affect the left side. stated she has a heart problem. The patient stated she had a sore arm for about a week, lasted for a few days. stated she gets a sore arm with the flu shot. stated when she would roll over to lay on her left side and roll over on that arm it was enough to wake her up. stated it lasted about 5 days. She couldn't figure out why it was lasting so long. Stated the second thing that happened was that she went to her son's home that night for dinner, hadn't told him about it and while she was eating dinner she asked am i she leaning to the left and he said yes, she was and that her words were being slurred and only lasted for about 10 mins. Stated she didn't call and ignorance is unreal with this stuff. She went to urgent care the next day and they didn't call the ambulance. When she went to the doctor on 23 Feb2021 she was sent immediately to Hospital so she could go through the ER and that's when the neurosurgeon became involved. Stated right now her balance isn't quite right but she is driving and she was taking care of herself and they didn't send anyone home to help her. She was not having any problem talking. Stated she was not going to get into this and will beat it and get back to normal. She was tired a lot, which they said it's normal. Stated she was a real dynamite. Stated it is improving slowly, she was extremely tired and not taking her long walk like she was used to and has shortness of breath, she was not trying to over do it.

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Stated she always gets a sore arm with the flu shot. Stated her pain level is lower than most people. The patient stated the sore arm started late evening but the next day was really hurting and the main thing was rolling over. The patient stated she didn't take anything for her sore arm, she won't even take an aspirin because some of these Advil medications will mix with the heart medications. Stated in the hospital they were giving her medications she had through an IV in her arm but doesn't know what was going through that. Stated they put her on a blood thinner and they were testing the blood thinner through the IV. She was so miserable, she just wanted to go home and get a good nights sleep. Stated they took all kinds of test, checked her oxygen and had to have a certain number before she could go home. The patient received treatment for event stroke caused by a blood clot and not received treatment for sore arm . The outcome of events stroke caused by a blood clot was resolving, of event sore arm was resolved on 12Feb2021, of other events was unknown.

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1278470	5/1/2021	MA	42	F	3/18/2021	3/18/2021	Palpitations; a weird feeling under her skin; Shortness of breath; the chest pressure was in the middle of her chest. She said the chest pressure felt like something sitting on her lungs; Dizziness; At the time she was given her COVID-19 Vaccine shot, she had a warmth that went down her left arm (the arm she received her COVID-19 Vaccine in) to her left fingertips & to her left back; dry eyes; she was coughing more; the increase in coughing had made her voice huskier sounding; This is a spontaneous report from a contactable consumer (patient). This 42-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Mar2021 08:45 Arm Left (Lot Number: EP6955, Expiration Date: 30Jun2021) single dose for covid-19 immunisation. Medical history included ongoing Crohn's disease from 1999, ongoing Hidradenitis suppurativa at the end of 2019, ongoing Small Fiber Peripheral Neuropathy diagnosed at the end of 2019. She said her doctor was not sure of the Small Fiber Peripheral Neuropathy's cause, or if the Small Fiber Peripheral Neuropathy was associated with any of her other medical conditions. She said she had symptoms for sometime, and was diagnosed with a lot of things at the end of 2019 because she was finally able to see a specialist. Concomitant medications included adalimumab (HUMIRA AC) from in Feb2020 at 40mg injection pen once a week for her Crohn's disease. Reported she has had no reactions to flu or pneumonia vaccines for immunisation in the past. She said she had her first COVID-19 Vaccine dose on Thursday, 18Mar2021. She said on Saturday morning (20Mar2021), she had shortness of breath, dizziness, and chest pressure. She said her shortness of breath, dizziness, and chest pressure has been lasting for 20-something days, and she doesn't know why. She said she had taken two (different) week long prescriptions of Prednisone. She said she had 2 EKGs, 2 chest x-rays, and blood work, which were all normal on 13Apr2021 and 2021. She said her doctors don't know why she was having the shortness of breath, dizziness, and chest pressure. She said she was using inhalers, medications, and everything, and still had her symptoms. She asked if what she was experiencing was a side effect of the COVID-19 Vaccine, or due to her 2 autoimmune

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diseases because her doctors were grasping at straws at this point. Reported she had so many medical conditions, and was taking so many different medications. Reported she has had shortness of breath and chest pressure every day, but the dizziness wasn't constant, and had lessened. She said she has never had the shortness of breath and chest pressure before. She said she has never had anything last that long either. She said she was wondering if her shortness of breath and chest pressure were caused by the COVID-19 Vaccine. Clarified the chest pressure was in the middle of her chest. She said the chest pressure felt like something sitting on her lungs, saying it was an odd feeling. Reported she was coughing more, and she believed the increase in coughing had made her voice huskier sounding in 2021. She said she had a cough associated with outdoor allergies, but the cough she had now didn't feel like her normal allergy cough. She said she had no mucus. She said she was not sneezing, or coughing out anything. She said the cough she had now was different. Reported at the time she was given her COVID-19 Vaccine shot 18Mar2021, she had a warmth that went down her left arm (the arm she received her COVID-19 Vaccine in) to her fingertips. She said the warmth feeling also went to the left side of her back. She said she was kept longer after she got her COVID-19 Vaccine for monitoring. She said the warmth feeling in her left arm, left fingertips, and left back didn't last long, and went away. Reported she had gone to the Emergency Room on Tuesday, 13Apr2021, because she had palpitations, and a weird feeling under her skin. She said while at the Emergency Room, she had an EKG, chest x-ray, and blood work. She said the doctor was looking for a blood clot. She said all her testing came back negative for a blood clot. She said earlier that day (13Apr2021) was her 3rd visit to her doctor since her symptoms had started. Reported she had started Restasis on 19Mar2021, the day after her first COVID-19 Vaccine. She said she was prescribed Restasis for dry eyes, and didn't have the dose, NDC, Lot, and Expiration Date because she was not at home. AEs require a visit to Emergency Room and Physician Office. Treatment included Stated she had taken 2 different week long doses of Prednisone to treat her symptoms. She said she first took Prednisone 40mg, once a day, for 7 days. She said she was off the

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Prednisone 40mg for 2 days, and had instructions to call her doctor if she wasn't feeling better. She said she went back to her doctor, and was prescribed Prednisone 60mg for 3 days, then Prednisone 40mg for 3 days, and then Prednisone 20mg for 3 days. She said she did not have the 2 Prednisone prescription NDC, Lot, and Expiration Dates. She said she was also put on a 10-day Azithromycin 250mg tablet prescription. She said she took a Azithromycin 500mg (2-250mg tablets) dose the first day, and then Azithromycin 250mg, once a day, for the next 9 days. She said she did not have the Azithromycin 250mg tablet NDC, Lot, and Expiration Date. She said she was also prescribed an Albuterol (90mcg per actuation) inhaler, providing: NDC Number: 66993-019-68, Lot Number: A63H, Expiration Date: Jan2022. She said she didn't feel like the Albuterol inhaler was doing the rescue part, and that she could take the Albuterol inhaler every half hour. Reported she was prescribed an Albuterol inhaler (90mcg per actuation) for shortness of breath. Outcome of the event Shortness of breath, the chest pressure was in the middle of her chest. She said the chest pressure felt like something sitting on her lungs, coughing more, the increase in coughing had made her voice huskier sounding was not recovered. Outcome of the event Palpitations, a weird feeling under her skin was unknown. Outcome of the event Dizziness was recovering. Outcome of the event had a warmth that went down her left arm (the arm she received her COVID-19 Vaccine in) to her left fingertips & to her left back was recovered on 18Mar2021. No follow-up attempts are needed. No further information is expected.

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1278538	5/1/2021	NC	56	F	3/31/2021	4/10/2021	Woke up with chest pains diagnosed as blood clots in both lungs.; Mental confusion; This is a spontaneous report from a contactable consumer reporting for herself. A 56-years-old female patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in Left Arm on 31Mar2021 13:00 (Batch/Lot Number: ER8730) as single dose for covid-19 immunisation . Medical history included sleep apnoea syndrome , depression , drug hypersensitivity to penicillin. Concomitant medications included escitalopram (ESCITALOPRAM) taken for an unspecified indication, start and stop date were not reported; meloxicam (MELOXICAM) taken for an unspecified indication, start and stop date were not reported. The patient previously took Biaxin and experienced drug hypersensitivity, first dose of bnt162b2 for covid-19 immunisation on 10Mar2021. The patient woke up with chest pains diagnosed as blood clots in both lungs on 10Apr2021 08:30 with outcome of recovering , mental confusion on 10Apr2021 08:30 with outcome of recovering. The patient was hospitalized for 3 days because of the events. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 14Apr2021 . The patient is receiving apixaban (ELIQUIS) as treatment of the reported events. Follow up information has been requested. Lot number already received.

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1278551	5/1/2021	MA		F		4/9/2021	short of breath; chest pain; she had a blood clot and was diagnosed with a blood clot/diagnosed with DVT; Red splotches on leg; This is a spontaneous report from a contactable Nurse. A 62-year-old female patient received first dose of BNT162B2 (BNT162B2), via an unspecified route of administration, administered in Arm Right on an unspecified date (Batch/Lot Number: EW0150) as SINGLE DOSE for covid-19 immunization. Medical history included she had a blood clot after surgery 100 pounds ago, around 18 years ago, she had the heart attack at age 41 and thrombophlebitis from an unknown date and unknown if ongoing. Concomitant medications included aspirin [acetylsalicylic acid] (ASPIRIN [ACETYLSALICYLIC ACID]) taken for cardiac disorder from an unspecified start date and ongoing. The patient experienced she had a blood clot and was diagnosed with a blood clot/diagnosed with DVT on 10Apr2021 and red splotches on leg on 09Apr2021. She states she got the vaccine on Thursday 08Apr2021. She confirms that the painful red splotches showed up on 09Apr2021. The blood Clot was diagnosed on the 10Apr2021. She states that the doctors put her on Lovenox. She states that it is only significant if she gets short of breath and/or has chest pain. If it travels then it is significant. She states that her doctor said she had a good sized clot, but she didn't ask specifics. Outcome of the event was not recovered.; Sender's Comments: On the basis of the available information, the reported event DVT would seem most likely related to underlying medical conditions which is not related to BNT162B2.



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1278671	5/1/2021	MN	68	M	3/28/2021	3/31/2021	Blood clots in lungs and UTI; Blood clots in lungs and UTI; This is a spontaneous report from a contactable consumer. A 68-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Mar2021 (Batch/Lot number was not reported) as SINGLE DOSE (at the age of 68 years) for covid-19 immunisation. Medical history was none. Known allergies was none. The patient did not have Covid prior to vaccination. No other vaccine was given in last four weeks. There were no concomitant medications. The patient experienced blood clots in lungs on 31Mar2021 with outcome of recovering and UTI (urinary tract infection) on 31Mar2021 with outcome of recovering. Adverse event blood clots in lungs and UTI resulted in Emergency room/ department or urgent care and then hospitalization for 6 days. The patient underwent lab tests and procedures which included sars-cov-2 antibody test: negative on 11Apr2021. Therapeutic measures were taken as a result of blood clots in lungs and UTI and included blood thinner. Information about lot/batch number has been requested.

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1278714	5/1/2021	WI	67	F	3/18/2021	3/28/2021	A little over a week after the First vaccination, I developed two blood clots in my leg; This is a spontaneous report from a contactable consumer (patient). A 67-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: unknown), dose 1 via an unspecified route of administration, administered in the left arm on 18Mar2021 as SINGLE DOSE, for covid-19 immunization (at the age of 67 years-old). The patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: unknown), dose 2 via an unspecified route of administration, administered in the left arm on 14Apr2021 as SINGLE DOSE. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Medical history included peripheral arterial occlusive disease from an unknown date and unknown if ongoing and bad circulation. There were no known allergies. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any concomitant medications. The patient developed two blood clots in her leg on 28Mar2021 a little over a week after the first vaccination. There was no treatment provided for the blood clots. The outcome of the blood clots was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

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1278527	5/1/2021	TN	43	F	4/1/2021	4/1/2021	problem with her cholesterol; pain on the top of my head and my hands hurt/headache; pain on the top of my head and my hands hurt; Nauseous; my hands and feet started going numb; they itch they burn; feet are painful; uncomfortable; blood clot/a clot or something in her legs; from the knees down I was having a lot pain/leg pain felt like it is really deep in the vein; she thought she was having a stroke; cramps; burning from my calf to my feet; pain in her neck then to her back; pain in her neck then to her back; different temperatures like hot and cold make it bad and irritating; can't sleep well because of her symptoms; Swelling in her Feet; can't think right; This is a spontaneous report from a contactable consumer. A 43-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration in the right arm in the morning of 01Apr2021 (Batch/Lot Number: ER8727) as a single dose for COVID-19 immunization. Medical history included ongoing complex regional pain syndrome, ongoing fibromyalgia, ongoing arthritis - all diagnosed 20 years ago. Her mother has lupus and rheumatoid arthritis and she can't have the vaccine, states she doesn't know if something could be genetic. Low potassium in the past and stated that she has a lot of allergies to medications, but she consulted with the pharmacist and he said it would be okay. There were no concomitant medications. No additional vaccine was administered on the same date of BNT162B2 and no prior vaccination within four weeks. The patient was having weird symptoms and she tried looking online and in different groups to find out if anyone has similar symptoms, but she hasn't been able to find anything. She began by saying she has health issues; she has Fibromyalgia and Complex Regional Pain Syndrome. She doesn't know if studies were performed on patients with those disorders that took the vaccine. It's been about 3 weeks since getting the vaccine (Apr2021) and she started having symptoms that she thought could be a blood clot. From the knees down, she was having a lot of pain, cramps, burning from her calf to her feet. She would keep rubbing them and massaging them. It was excruciating pain. She was having symptoms and she did go see her Nurse Practitioner on 14Apr2021 because she thought she was having a stroke or a clot or something in her legs or that

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she was having a problem with her cholesterol. The nurse thought maybe it was her electrolytes, because she had low potassium in the past, but everything came back normal. Her feet were painful but not as bad in Apr2021. She felt like her condition but it's flaring up like 200% it's like over a 10 on the pain scale. She can't think right, she can't work, and was very uncomfortable in Apr2021. The leg pain felt like it is really deep in the vein, it doesn't feel like it is superficial, and she can feel stuff or liquid flowing. Her pain alternates from her head to her neck to her feet and it is very uncomfortable. Her hands and feet started to go numb, not completely numb but like when they fall asleep from sitting on them and then hit something and it hurts. Her arms were burning like crazy; they itch, they burn in Apr2021. Different temperatures like hot and cold make it painful, bad and irritating, and she can't sleep well because of her symptoms. She doesn't know the exact dates, but it has been about a week, but it is changing. It started with cramps in her legs from her knees down. That is where she had injuries and she thought it was her cholesterol. From her knees down, she has cramps and pain and it is very uncomfortable, she felt a really deep pain. She has pain in her neck then to her back, it started in her lower extremities and it is going up. It has stayed the same and she has to keep taking Tylenol to control the pain. Her symptoms got worse and she started taking Tylenol and that helped and then on 15Apr2021, her hands and feet started going numb and she had a headache and pain on the top portion of her head (reported as brain) and her hands hurt, and she was nauseous. She hasn't heard back from the nurse practitioner, so she decided not to go and get it done because she felt it is from the vaccine. She also has swelling of feet in Apr2021, and now she just woke up an hour ago and she slept somewhat okay, but she had to take Tylenol. Now that she is standing, it felt like her legs are starting to hurt again. Treatment included Tylenol, which helps a little and she has to keep taking it. If she doesn't take Tylenol, she can't even function. The events from the knees down I was having a lot pain/leg pain felt like it is really deep in the vein, cramps, my hands and feet started going numb, they itch they burn, feet are painful, uncomfortable, pain on the top of my head and my hands hurt/headache, swelling in her feet, nauseous, pain in her neck then to her back, different

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temperatures like hot and cold make it bad and irritating  
had not resolved, while the event can't sleep well  
because of her symptoms was resolving, and the  
outcome rest of the events was unknown.

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1278730	5/1/2021	TX	52	F	4/5/2021	4/7/2021	big bump on arm; rash/red blotch on arm; nose bleed, blood clots coming out of nose; nose bleed, blood clots coming out of nose; This is a spontaneous report from a contactable consumer (patient). A 52-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular, administered in the left arm on 05Apr2021 (Batch/Lot Number: EW0151) as single dose, for covid-19 immunization. Medical history included ongoing sjogren's syndrome and ongoing lupus. Concomitant medications included levothyroxine sodium (SYNTHROID) taken for an unspecified indication, start and stop date were not reported. 07Apr2021, she started having a nose bleed. She explains she wasn't doing anything in particular, just talking on the phone, and blood just started pouring out of her nose. Blood clots started coming out as well. She ended up calling 911 and they sent an ambulance. The EMS helped her stop the bleeding. She didn't go to the ER or anything. However, she is getting implants done for her upper teeth so she wanted to double check and make sure nothing was pressing against her nasal cavity because the nose bleeds were so off/random. The doctor said there was no pushing. The doctor completed a panoramic exam/x-ray and confirmed there was nothing pushing. The doctor did suggest she go to the ENT. She made an appointment with an ENT doctor for the following day, 08Apr2021, and the ENT put a camera down. She confirms she explained to them she just had the vaccine and she was googling information. She was told to not google anything and to let them check it out. The caller states she explained to the ENT the reason she was there was because she was concerned, she is not a nose bleeder and nose bleeds never happened to her. Once blood clots started coming out that way, she was terrified. They didn't see anything alarming, but they wanted to make sure and do further research, so basically they planned to do a CT/CAT scan. She was scheduled for a CT/CAT scan on Monday, 12Apr2021, but she was allergic to the contrast and was sent home because they were not prepared for pre-medication. She is waiting for the doctor to schedule another appointment so she can go back. She felt she needed to report these nose bleeds because she has been seeing Johnson & Johnson had severe blood clots, but she took Pfizer's vaccine, and was also getting blood clots. Her nose

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							bleeds just happened right after both vaccines. On an unspecified date, she had a little bump that went away. She had this big bump on her arm and a big rash developed. At first, the bump was the size of a quarter and then grew double in size. The bump finally went down, but the rash she can still see. The rash hasn't grown, it's just there- there is just a red blotch on her arm. She has not had another nose bleed since the one that occurred on 07Apr2021. She just noticed when she had her first dose on 15Mar2021, the nose bleed happened within that week also. The outcome of events was unknown.
1277834	5/1/2021	PA	20	F	4/23/2021	4/26/2021	Initially presented with a headache 3 days past vaccine, presented to hospital now found to have dural venous sinus thrombosis. Currently stable on anticoagulation drip.
1278723	5/1/2021	OH	45	M	3/25/2021	4/9/2021	three blood clots in right leg; This is a spontaneous report from a contactable consumer. A 45-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: ER2613, Expiry date not reported), via an unspecified route of administration, administered in the left arm on 25Mar2021 15:00 (age at vaccination was 45 years) as single dose for COVID-19 immunization. Medical history included drug hypersensitivity (sulfonamide allergy) from an unknown date and unknown if ongoing, and seasonal allergy from an unknown date and unknown if ongoing. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was vaccinated at a clinic. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient has not been tested for COVID-19. Concomitant medications included fluticasone propionate taken for an unspecified indication, start and stop date were not reported; olopatadine hydrochloride (PATADAY) taken for seasonal allergy, start and stop date were not reported. The patient experienced three blood clots in right leg on 09Apr2021 20:00 with outcome of recovering. Therapeutic measures were taken as a result of three blood clots in right leg (thrombosis) that included blood thinners (Eliquis). The event was reported as serious, medically significant. No follow-up attempts are possible. No further information is expected.

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1274409	4/30/2021	CA	52	F	4/1/2021	4/11/2021	Sunday April 11 at about 11pm I started feeling extremely drained of energy and was experiencing some mild abdominal pain. I went to bed shortly after. Was woken at approximately 5am with severe abdominal pain, and extreme back pain in my left kidney. Kidney area was worse than abdominal pain but both were severe. I have had kidney stones in the past, the pain of this was way worse. Was unable to take a bowel movement. Suffered thru with pain increasing until unspecified date at around 2 am I drove myself to unspecified hospital. Was admitted to emergency room and given an in mild pain meds and anti nausea meds. Was given a ct scan of kidney, then a second ct scan with contrast, as well as blood test. After awhile they came back to re draw blood because they said my blood had clotted and they were unable to use it. I was released after 5 hours with no prescriptions or knowing what or why I was in so much pain. Pain lasted until unspecified date
1273263	4/30/2021	IL	52	F	4/12/2021	4/25/2021	Woke up April 25, 2021 at 9:00 am with left shoulder pain. Throughout the day the pain became intense and unbearable. It had also swelled considerably. I could not lift my arm at that point. At approximately 10:00 pm I went to the hospital. I was given an Ultrasound on left arm and shoulder to check for blood clots which was negative. I was also given an Xray on left shoulder to check for bone abnormalities which was negative. I was diagnosed with "COVID shoulder", released and given pain medication. Was told to follow up with family practitioner. Went to Dr. on Tuesday, April 27, 2021 who confirmed the diagnosis. Blood was taken which showed elevated white blood cells.
1273203	4/30/2021	CO	52	M	4/3/2021	4/13/2021	Severe headache followed by abdominal pain, eventually confirmed portal vein thrombosis (fully blocked), treated as TTS with hospitalization for 5 days



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1273190	4/30/2021	OH		F	3/31/2021	4/26/2021	I recieved my second vaccination on 3/31/21 while I was still pregnant. I had my third scheduled c-section on 4/16/21 (due date of 4/21/21). All previous pregnancies and cesarians went well with no complications - including my most recent on 4/16. On 4/23/21 I was rushed to ER for a pulmonary embolism in my RT lung and potentially more blood clots in my legs. That day I was having a difficult time breathing and intense pain in my back at the bottom of my RT lung. I went to bed early, woke up soaked in sweat to stabbing pain in my back lower RT lung and could barely breath or move without intense pain, went by ambulance to Hospital, released at 9 PM 4/28 on blood thinner regimen
1273149	4/30/2021	GA	66	F	3/16/2021	4/26/2021	Patient presented to hospital with four days chest pain, dyspnea on exertion and weakness. Work up revealed an acute submassive pulmonary embolism without evidence of deep vein thrombosis in bilateral lower extremities.

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1272645	4/30/2021	WA	58	F	3/31/2021	3/31/2021	03/31/2021: began feeling aches/pain/feverish about 10 hours after receiving the first Moderna vaccine and had a temperature of 100.3 F. 04/01/2021: continued feeling aches/pains/feverish and had a temperature of 99 F. 04/02/2021: aches/pains/fever subsided. 04/03/2021: left leg began to hurt and kept feeling worse throughout the day; took ibuprofen for pain. 04/04/2021: left leg continued to hurt; took ibuprofen for pain. 04/05/2021: visited Urgent Care clinic and an ultrasound confirmed the presence of a blood clot in the left leg. Urgent Care Doctor prescribed Eliquis for treatment. See Continuation Page for subsequent events/treatments. 04/07/2021: Meeting with Primary Care Physician (PCP). PCP changed treatment for the blood clot [acute deep vein thrombosis (DVT)] from Eliquis to Lovenox/Coumadin. Additional tests ordered: CBC with Differential; PTT; Comprehensive Metabolic Panel; Protime INR; Sedimentation Rate. 04/08/2021: Meeting with PCP to discuss DVT. PCP ordered Noninvasive Vascular Imaging - External Scan. 04/15/2021: Meeting with PCP to discuss DVT. PCP instructed to continue treatment with Lovenox and keep appointment with hematologist on 04/20/2021. PCP ordered the following tests: CBC no Differential; Comprehensive Metabolic Panel; Protime INR. 04/20/2021: PCP changed recommended treatment of DVT from Lovenox to Eliquis. 04/20/2021: Meeting with hematologist to discuss DVT. Dr. agreed with PCP to change treatment from Lovenox to Eliquis. Dr. ordered the following immediate tests: Antiphospholipid Ab Panel; CK Total; Comprehensive Metabolic Panel; Dilute Russel Viper Venom Confirm; Fibrinogen; Lupus Anticoagulant Profile; NT-PRO BNP; Phospholipid, Hexagonal Phase; VAS Porto Hepatic Duplex. Additional future tests were ordered as follows: Antiphospholipid Ab Panel, CK Total; Fibrinogen; Lupus Anticoagulant Profile; NT-PRO BNP. 04/23/2021: Meeting with hematologist to discuss DVT. Dr. suspects the DVT is related to pre-existing conditions (includes vitamin K deficiency) plus the effect of the first Moderna vaccine. Dr. concluded that vitamin deficiencies (due to malabsorption issues) are the root cause of several ills. Dr. ordered an injection of vitamin K and recommended continued treatment with Eliquis. Dr. also stated "I think no to second vaccination #2. She might be vaccinated later if vitamin def are resolved." Dr. plans to review the

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							case in three months to determine if Eliquis treatment can be discontinued. Dr. also ordered an "ECHO Complete" to rule out additional clots in the heart/lungs.
1274172	4/30/2021	PA	70	M	4/1/2021	4/7/2021	Admitted to hospital on 04/07/2021 with acute Pulmonary Embolism ( no history of thrombosis in past)
1274347	4/30/2021	OR	31	F	4/10/2021	4/28/2021	On the 28th of April, 18 days from the shot, I went for a walk and came home around 6:30 p.m. to the outside of my right calf bright red and hot. I went to the ER where an ultrasound was performed and they found a DVT blood clot. I am now on an anticoagulant, Xarelto and have an appointment with my doctor on the 5th to schedule more imaging and blood work.
1274418	4/30/2021	MO	49	F	4/15/2021	4/20/2021	(1) Pulmonary embolism: Unclear whether there had been a provoking event. Reports symptoms for about a week. Left lower extremity VTE found on ultrasound requested by her PCP. She reports she may have had COVID-19 in December. She reports she had just completed second dose of COVID-19 vaccine on 4/15. Appears it would give about 7 days since the second dose, and onset of her symptoms. She does state she had been somewhat less mobile after her illness. She does not smoke. She is not on any hormone therapy. Not entirely clear that this is related to the vaccination, however, will discuss with pharmacy regarding whether this should be reported. We discussed anticoagulation. She started on Lovenox and ER. Discussed subsequently switching to oral anticoagulation. We will assess TTE. Monitor oxygenation, blood pressure, heart rates. Status: Acute (2) Deep vein thrombosis of lower extremity: Initiated on anticoagulation as above. Ultrasound reports VTE including common femoral vein. We will try to see if we can get a limited study to assess more proximal veins. Discussed with her in case of concern symptoms, iliofemoral VTE, consideration may be given as well to catheter directed TPA. She understands that this procedure is not available at the current facility. We discussed also regarding possibility of post phlebitis syndrome, especially with more proximal VTE. Discussed strategies going forward to reduce the symptoms.

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1273276	4/30/2021	IL	19	F	4/12/2021	4/24/2021	19 y.o. female with h/o Hashimoto's thyroiditis now admitted 4/29/2021 with cerebral venous thrombosis. She received J&J COVID vaccine on 4/12.
1273764	4/30/2021	AR	60	F	3/1/2021	4/23/2021	Cerebral venous sinus thrombosis Patient received vaccine in March (exact date is unknown but around March 8-12 per husband); in mid-April patient started reporting intermittent low intensity headaches. On April 23, patient had severe headache and vomiting, went to urgent care and was thought to have sinusitis and started on antibiotics and discharged home. On April 24th, patient became more drowsy with worsening headache and unresponsive. On April 25, she was taken to outside hospital and was noted to have abnormal brain MRI. She was transferred to our facility on April 26 after clinical worsening. Imaging revealed venous sinus thrombosis in deep cerebral veins and patient was intubated due to worsening mentation. Imaging also revealed a venous stroke with hemorrhage in her left thalamus and diffuse brain edema. Treatment includes extraventricular drain placement, anticoagulation (heparin), hypertonic saline to manage brain edema. We also did extensive workup but no history of hormone therapy, contraceptive pills, underlying cancers. Tumor markers are negative. Hypercoagulable panel and rheumatologic panel are negative. Body imaging did reveal multiple uterine fibroids but no other cancer. Patient remains in the ICU, on the ventilator, heavily sedated for management of refractory intracranial hypertension.
1274572	4/30/2021	NY	30	F	4/3/2021	4/13/2021	On April 16, 2021 (Day 13 after Vaccine) I was diagnosed with acute deep vein thrombosis (DVT) of my femoral vein in my left leg by Hospital. In other words, I was diagnosed with a blood clot in my upper left leg. Pain in both my legs had started on April 13, 2021 (Day 10 after Vaccine). On April 16, I had a virtual appointment with my doctor who prescribed an ultrasound to rule out DVT. I went to an ultrasound appointment at Radiology at 3:30pm where a blood clot was found in my left leg. I was admitted into the emergency room at Hospital and prescribed medication and follow ups from there...

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1274234	4/30/2021	MN	52	M	4/9/2021	4/27/2021	Symptoms started 4/27 in patient - presented to the ED on 4/30 for sinus pain and headache. Confirmed venous sinus thrombosis on CT scan on 4/30/21 during emergency department visit. Platelets were with normal limits.
1273301	4/30/2021	KS	37	M	4/2/2021	4/10/2021	NSTEMI and left leg arterial thrombi after first vaccine. In addition, he is in hospital again now after his second vaccine being evaluated for a second NSTEMI.
1273422	4/30/2021	NM	69	F	4/2/2021	4/2/2021	10 min. post inject Lt upper arm started swelling. No pain. 5min. later intense pressure/pain/surge to nose & sinus's. Couldn't breathe thru nose. Within 15 sec sinus/nose rush went to entire head with dizziness & passing out intensity. Did not lose consciousness. RN on scene. 10min later made comeback. Beads of sweat on forehead. Lt. upper arm swelling gone. Felt fine for 3 days. On 3rd day rt & lt knees to ankles began off & on sporadic (static electricity like) shocks concentrated to one area at a time. Coming & going in daytime, not at night. Continuing for 10 days. On 9th shocks lessening but then started experiencing pressure in lt. leg calf. Went to ER & had lt leg doppler. Neg. for clots. Now 4wks. later shocks gone but pressure in rt. & lt. calves continue off & on.
1273426	4/30/2021	MA	42	F	3/6/2021	4/23/2021	Headache and nausea for 1 week, found to have cavernous sinus thrombosis on MRI 4/29/2021. Started on apixaban
1273521	4/30/2021	CO	57	M	3/18/2021	3/23/2021	On 3/23/21. Pt admitted w/R sided, pulsatile HA associated w/vomiting. Patient was found to have occlusive dural venous sinus thrombosis involving the dominant R transverse and sigmoid sinuses, extending into upper jugular vein. He received his second COVID-19 vaccination 5 days prior to onset of HA. Report this for record keeping.
1273546	4/30/2021	PA	38	F	3/17/2021	3/31/2021	pt presented on 3/31/21 with facial numbness and headache. patient had follow up with OB and blood clot was found behind the placenta and there were no fetal heart tones on 4/23/21.

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1273607	4/30/2021	MI	51	F	4/6/2021	4/14/2021	hepatic thrombosis - Pt is a 51 y.o. female with a history of hyperthyroidism s/p radioactive iodine ablation who presents for abdominal distention with MR liver revealed extensive Hepatic, portal, SMV thrombosis consistent with acute Budd-Chiaria. Patent IVC. S/p DIPS/thrombectomy w/ IR
1273705	4/30/2021	TX	55	F	3/11/2021	3/30/2021	Early in the morning I started developing a headache. I typically have migraines and thought this was just what I was getting. I took Excedrin Migraine to try to keep it from getting worse, but it continued to get worse and worse and worse. About noon I found that I could not stand any light or sound - this is not typical for me as I can usually listen to things during a headache even if I can't open my eyes. I ended up spending all the rest of the day and the night alone in a dark noiseless room. I told my husband it was the worse headache I had ever had. It was only later that we found out the shot caused blood clots in the head. I did not correlate the two because it had been so long - almost 3 weeks - since my vaccination.
1273816	4/30/2021	NC	24	M	4/7/2021	4/21/2021	24-year-old male patient with no past medical history received Johnson & Johnson Covid vaccine on April 7 presented to ED with abdominal pain and was found to have portal vein, splenic vein, superior mesenteric vein thrombosis. Patient was also found to be thrombocytopenic he was admitted to the stepdown unit placed on bivalirudin. Patient remains hospitalized at the time of this report.
1273918	4/30/2021	PA	42	F	3/15/2021	4/9/2021	Leg swelling started on April 9th, had ultrasound to check for blood clot. Negative for blood clot. Still swollen doctor told me to report it to vaccine page

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1273977	4/30/2021	CO	51	F	4/17/2021	4/28/2021	Patient s/p second Pfizer COVID vaccine 4/17/21. Presents to ED 4/28 with slurred speech & left hemiplegia. CT imaging revealed R MCA CVA. Patient s/p thrombectomy for CVA. CT also had question of L transverse venous sinus thrombosis. On 4/29, patient went for MRI which confirmed multiple anterior and posterior circulation strokes and nonocclusive left transverse dural vein thrombus. Platelets at the time of presentation are normal. Heparin drip initiated 4/29 after consult with hematology (patient also high bleeding risk due to HHT). IF CT head stable 4/30, Patient will be transitioned to oral anticoagulation with close monitoring by hematology given bleeding risk.
1274088	4/30/2021	WA	62	M	4/13/2021	4/14/2021	Pulmonary embolism, pea, heart arrest x2. 0100 4/14, some up with difficulty breathing. O2 sats low 80's and tachycardia low 100's. 4/15, says in mid 90's yacht at mid 120' s. 4/15 increased difficulty breathing. Went to ed. Troponin in 800's. Saddle pe discovered on ct. Clots in rt leg found also. 4/16 is removed pe, ir decided to let clots in let reabsorb. 4/17, ready to d/c, when acute onset of respiratory distress occurred. Went into PEA x 's 2. Back to ir to remove pe and place filter.
1274118	4/30/2021	FL	42	F	4/2/2021	4/3/2021	24 hours after rec' the vaccine she had started her cycle with blood clots. Her cycle did not come on that day. She had to use the bathroom no matter what time for it to come on. Doctor office, Doctor performed a series of lab test. Doctor states that she is getting blood clots and think it may be from the vaccine. SHe had her cycle for 16 days straight and now has become anemic.
1274134	4/30/2021	AZ	28	F	4/5/2021	4/5/2021	4/5 vaccination. By 1pm, I felt fatigue, HA, light headed, feverish, loss of appetite. 4/6 same symptoms but worsened; 101.5 fever. flu like symptoms. Abnormal menstrual period 4/7 fever was low. Diarrhea, upset stomach 4/8 low grade fever; 99. HA, fatigue, diarrhea. 4/9 really bad nose bleed with 2 really large clots. Continuing of flu like symptoms. 4/14 HA and flu like symptoms persisted till this date. 4/16 fever and HA stopped. 4/5-4/22 menstrual bleeding continued. *clots in nose bleeds and menstrual bleeding. Tele med on 4/14, 4/15 MRI. *still experiencing some intermittent spotting but not as much.

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1274581	4/30/2021	WA	36	M	4/8/2021	4/10/2021	Patient states he had no soreness to his left arm. Patient states he got a blood clot. He went to the doctor and his doctor told him that the blood clot he had was not related to the vaccine.
1273679	4/30/2021	PA	70	F	4/22/2021	4/25/2021	Patient received her second dose of moderna on 4-22-21. On 4-25-21, patient states she began to experience chest pain when she took deep breaths. On 4-28-21, patient states she went to the emergency room. She states the hospital did a chest x-ray, a scan, and a heart echo. She was diagnosed with a lung clot. Patient states she was put on a blood thinner. On 4-29-21, the patient was discharged with a prescription of Eliquis.
1274669	4/30/2021	LA	21	F	4/9/2021	4/24/2021	She developed red dots (petechiae) and bruising on Saturday. She also developed vaginal bleeding on Saturday that was heavy and had clots. Her period was ending on Saturday and had been normal up to that point. She continues to have heavy vaginal bleeding. Went to PCP and routine labs revealed thrombocytopenia. She has never had thrombocytopenia before. Was sent to ED for blood transfusion and was admitted to hospital. Discharged home 4/27 after platelet infusion.
1274563	4/30/2021	NY	30	F	4/3/2021	4/13/2021	On April 16, 2021 (Day 13 after Vaccine) I was diagnosed with acute deep vein thrombosis (DVT) of my femoral vein in my left leg by Hospital. In other words, I was diagnosed with a blood clot in my upper left leg. Pain in both my legs had started on April 13, 2021 (Day 10 after Vaccine). On April 16, I had a virtual appointment with my doctor who prescribed an ultrasound to rule out DVT. I went to an ultrasound appointment at Radiology at 3:30pm where a blood clot was found in my left leg. I was admitted into the emergency room at Hospital and prescribed medication and follow ups from there...
1275252	4/30/2021	SC	76	F	3/18/2021	3/21/2021	Shortness of breath intermittent after first vaccine. 2nd vaccine 4/5/21 same facility same vaccine. ER and admission on 4/11/21. Cat scan revealed bilateral blood clots in lungs. Dismissed 4/18/21. I am convinced this was my body's reaction to the vaccine



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1275233	4/30/2021	IL	46	F	4/10/2021	4/23/2021	Pt had headache for the last week. J&J vaccine on 4/10, dxed with cerebral venous thrombosis. Pt's age is 47, not 46. Form would not allow me to put in pt's age and cited an error with pt's DOB.
1275007	4/30/2021	NY	57	M	3/20/2021	3/27/2021	patient was fine until a week later when started getting dizzy and throwing up. taken to ER, but didn't tell them had been vaccinated. Couldn't find anything wrong and was sent home after a few days. Went to ER again and this time wife told them he had been vaccinated week before symptoms started. Did brain MRI and found a blood clot. Pt currently in rehab.
1274722	4/30/2021		45	M	4/20/2021	4/28/2021	Pt presented to the hospital after a cardiac arrest. Work up showed renal artery thrombosis b/l causing renal failure and hyperkalemia. ROSC was achieved and pt coded multiple times after. We were unable to obtain CT A 2/2 to pt being unstable so only U/S imaging with doppler was used for diagnosis. Pt was treated with heparin gtt., hematology work up was sent but cause not identified. ECHO did not show thrombosis in the heart. CCRT was attempted but pt expired.
1274672	4/30/2021	NY	51	F	3/13/2021	3/20/2021	Body aches, fever, nose blister, headaches swollen and arm diarrhea. On 3/2021 I statdetedbtonget pain on my left foot and calf. I went to the hospital and on 3/22/2021 I had a ultrasound and the results showed that I have a blood clot.
1275047	4/30/2021	NY	69	M	2/26/2021	2/27/2021	About 6 ? 7 days w/ side effects ? Significant Malaise, tiredness. Unable to function or concentrate. Likely a "self inflicted" situation by unknowingly sitting in chair in a daze ultimately developing blood clots (pulmonary edema), blood clots in legs, leading to mild heart attack, hospitalization. I believe there may be a direct connection to a medical procedure (vedolizumab (Entyvio) 300 mg intravenously infusion) that preceded the vaccination on the previous Friday (2/19/21).

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1269773	4/29/2021	MA	53	F	2/24/2021	3/13/2021	cardiac arrest; on the ground turning purple and lifeless/ immediate risk of death from the event; she had no pulse; on the ground turning purple and lifeless; This is a spontaneous report received from a contactable consumer. A 53-year-old female patient (reporter's mother) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EN6200), administered in left arm on 24Feb2021 (at the age of 53-year-old) at single dose for COVID-19 immunisation. The vaccination facility type was reported as other. The patient was not pregnant. The patient's medical history was reported as none. No known allergies were reported. The patient had not had COVID prior vaccination. The patient's concomitant medications were not reported. No other vaccine was administered in four weeks. It was reported that on 13Mar2021 08:15 exactly 17 days after reporter's mother received her first Pfizer vaccine she had a cardiac arrest, luckily reporter was with her when this happened and he/she called immediately and followed the steps of cardiopulmonary resuscitation (CPR) etc. When the emergency team arrived she had no pulse and they used the defibrillator on her 4 times. The entire day they did not know if she would survive. She was sedated and tested, they got the news that she had survived and there was not brain damage. The doctors had no clue what the cardiac arrest was caused by, she had no prior health conditions and the tests show nothing to what could have caused this event (no blood clots, no clogged arteries etc.). The only thing that changed leading up to the event was her receiving her first vaccine. Luckily reporter was there when this happened or else she would in fact be dead. She now had a defibrillator implanted and reporter had a post-traumatic stress from the traumatic event and witnessing his/her mom on the ground turning purple and lifeless. They need answers. The events resulted in emergency room/department or urgent care. The events were reported as serious since resulted in hospitalization and life-threatening illness (immediate risk of death from the event). Treatments were received for the events and they were reported as multiple lifesaving treatments, tests, and defibrillator implant. The patient underwent lab tests and procedure which included COVID test (negative) on unspecified date post vaccination. The outcome of the events was resolved for the event "she had no pulse" and

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1269796	4/29/2021	VA	67	F	2/25/2021	3/1/2021	resolved with sequel (reported as recovered with lasting effects) for all other events.  I developed severe lower back/flank pain about 4 days after receiving my 2nd Moderna vaccination. The pain was most pronounced while lying supine and , while in that position, manifested a creeping , fluid nature, i.e. migrating from my lower back to my shoulder. I was unable to lie down comfortably. In thinking about the nature of this pain, I determined that it was possibly/probably from a PE as it seemed as if pain was migrating from my lower back to my shoulder. I'm "not a doctor but play one on TV" (LOL ) so surmised that it was something serious that decided that this was something needing attention. I presented to a hospital ER for care and was ultimately told I had 2 small PE blood clots - 1 in the base of each lung. My diagnosis was confirmed by a CT scan and I was subsequently admitted for observation. I was discharged the following day with blood thinners and blood pressure medication.

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1269934	4/29/2021	TN	64	M	4/8/2021		<p>BLOODSHOT IN EYE/EYES WERE RED; KNOT IN CENTER OF RIGHT ARCH OF FOOT; NECK HURTS/COULD NOT MOVE NECK; HEAD SWELLING AND TENDER; SLEEPY; HEADACHE; CHILLS; HEART ACHE; This spontaneous report received from a patient concerned a 64 year old African American, not Hispanic or Latino male. The patient's height, and weight were not reported. The patient's concurrent conditions included blood pressure. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805020, expiry: unknown) dose was not reported, 1 total administered on 08-APR-2021 between 09.30 and 09.40 to left arm for prophylactic vaccination. Concomitant medications included acetylsalicylic acid (Aspirin) for blood pressure. On 08-APR-2021, 20 minutes after vaccination, the patient started having symptoms. The patient's heart started aching and that lasted for 15-20 minutes and then went away. On 09-APR-2021, the patient had chills that had lasted for four hours. On 10-APR-2021, the patient could not move his neck left or right and back of his head felt like it was swelling and tender; he also had a headache, and he was extremely sleepy. The patient's neck and head tenderness lasted three to four days. On 11-APR-2021, the patient eyes had blood shot and were red and reported that he might had a stroke or blood clot. On 17-APR-2021, he had a knot came up in the center of right arch on foot. On 19-APR-2021, at the time of this report, the patient's eyes were still red and had a slight headache; the patient's neck still hurts, he was sleepy, and the knot was still there on his right arch of his foot. The patient took acetylsalicylic acid (Aspirin) but he was already taking that for his blood pressure. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from heart ache on 08-APR-2021, head swelling and tender on 14-APR-2021, and chills on 09-APR-2021, and had not recovered from neck hurts/could not move neck, bloodshot in eye/eyes were red, headache, sleepy, and knot in center of right arch of foot. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This 64-year-old African American (non-Hispanic/Latino) hypertensive male patient reported "heart aching" 20 minutes after receiving COVID-19 VACCINE AD26.COV2.S for the prevention of symptomatic SARS-</p>

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CoV-2 virus infection. The event lasted for 15-20 minutes. Other associated symptoms developed in the succeeding 3 days: chills that lasted for hours, could not move his neck and felt it was swelling and tender, headache, sleepiness, blood shot eyes. Nine days after vaccination, the patient reported he had a knot in the center of arch right foot. The patient took Aspirin. No other details was reported. The event is confounded by the underlying hypertension. The information available precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information was requested.

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1269940	4/29/2021	WI	47	F		4/1/2021	<p>BLOOD CLOT IN ARM; FEELING SICK; This spontaneous report received from a patient via a company representative concerned a 47 year old female. The patient's weight, height, and medical history were not reported. The patient was not pregnant at the time of report. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total, administered on 05-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date in APR-2021, the patient experienced burning sensation in arm, tenderness of arm, and pronounced veins on arm; also she was feeling sick. She saw the healthcare professional (HCP) after these symptoms. She was told about a blood clot (tenderness / burning sensation/ pronounced veins) in the arm. HCP recommended her taking aspirin and applying heat to the arm. Treatment medications (dates unspecified) included: acetylsalicylic acid. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clot in arm, and the outcome of feeling sick was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: This 47-year-old female patient reported burning sensation and tenderness in arm, pronounced veins in arm, and feeling sick after an unspecified duration from receiving COVID-19 VACCINE AD26.COVS for the prevention of symptomatic SARS-CoV-2 virus infection. HCP was consulted and was "told" about a blood clot and prescribed aspirin with advice to apply her to the arm. No other details reported. The information available precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information was requested.</p>

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1269942	4/29/2021	MN	44	M	4/1/2021		<p>CHEST PAIN (WHOLE CHEST HAD LOT OF PAIN)/THOUGHT THAT HE HAD HEART ATTACK; SHORTNESS OF BREATH/COULD NOT BREATHE; SEVERE CRAMPING IN LEFT SHOULDER AND UPPER BODY; DIFFICULTY IN STANDING; SINUS; THOUGHT THAT HE WAS ABOUT TO PASS OUT; BUNCH OF CLOTS IN THE BOTTOM SIDES OF BOTH LUNGS AND ON THE TOP OF ONE OF THE SIDES; BEGINNING STAGES OF PNEUMONIA ON BOTH LOBES OF THE LUNGS (COLLAPSED); CRAMPING IN CHEST; This spontaneous report received from a patient concerned a 44 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) frequency 1 total, dose was not reported, administered to left arm on 06-APR-2021 at 12 noon for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 6-APR-2021 at 12 noon, patient got vaccinated and was fine that day . Next morning on 07-APR-2021, patient woke up with sever cramping in same shoulder which he got the shot in, most pain was in the upper left quarter of his torso to down half way to chest up to the shoulder till the neck . By the end of the day it spread to his whole chest and upper body. Also he had shortness of breath ,could not breath .The cramping and shortness of breath came at same time. He took Advil and went along with his day . He took 3 tablet of Advil 200mg every 4-5 hours all day ( total of 3 dose that day) . By night time the case was progressively worse as the whole chest had a lot of pain . He thought that he had heart attack . He thought that he was about to pass out . He could not stand on his own . So his wife took him to emergency room at mid night at 12:30 am on 08-APR-2021. He stayed there for 5 hours and they did bunch of tests , EKG which rolled out the heart attack .They did Chest X-ray which found things then did D-dimer which its level was very high . They found bunch of clots in the bottom sides of both lungs and on the top of one of the sides. They did ultra sound on the legs which had no evidence of blood clots . They discharged him from the emergency room as they felt that he was ok to be out . After couple of hours after discharge , patient's health care professional wrote for</p>

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him Eliquis, antibiotic and pain reliver. He was given antibiotic because he had beginning stages of pneumonia on both lobes of the lungs (collapsed) . It was found air sacs in lung with signs of pneumonia in both lobes . He came home and started to monitor his blood oxygen . He stayed in the same position till recovery . He was better each day since last week but still had sinus and cramping in the chest ( very minor but was still there). The lung capacity was very limited to take some steps. Patient stated that he needed a specialist to understand his condition. He had no medical history before that incidence . He was wondering regarding which type of blood thinner was good for this type of blood clots because he read that the regular blood thinners are not good for that type of blood clot which his HCP gave (regular blood thinner). Laboratory data included: Total lung capacity decreased (NR: not provided) lung capacity is very limited. On 08-APR-2021, Laboratory data included: Chest X-ray (NR: not provided) found things, EKG (NR: not provided) rolled out heart attack, Fibrin D dimer (NR: not provided) level was very high, and Ultrasound scan (NR: not provided) no evidence of blood clots. Treatment medications (dates unspecified) included: apixaban, and ibuprofen. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the severe cramping in left shoulder and upper body, chest pain (whole chest had lot of pain)/thought that he had heart attack, shortness of breath/could not breath, thought that he was about to pass out, difficulty in standing, bunch of clots in the bottom sides of both lungs and on the top of one of the sides, beginning stages of pneumonia on both lobes of the lungs (collapsed), cramping in chest and sinus was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: This 44-year-old male patient reported blood clots of both lungs 2 days after receiving COVID-19 VACCINE AD26.COV2.S for the prevention of symptomatic SARS-CoV-2 virus infection. The patient denies any medical history/condition prior to vaccination. The symptoms reported were severe cramping of arm that spread to his whole chest and upper body and shortness of breath; the patient thought he had a heart attack, about to pass out and could not stand because of the progression of pain. EKG done at the emergency room ruled out heat attack,



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D-Dimer was reported to be very high, clots were found in the bottom sides of both lungs and on the top of one of the sides, x-ray showed beginning stages of pneumonia on both lobes of the lungs (collapsed). The patient was prescribed with Eliquis, an unspecified antibiotic and pain reliever. Outcome of the events were not reported. Based on the information that is available, the event is assessed as plausible with the causal association to immunization, per WHO causality classification of adverse events following immunization based on a lack of a definitive plausible biological mechanism. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information was requested.

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1269945	4/29/2021		60	F	4/21/2021		<p>IDIOPATHIC THROMBOCYTOPENIC PURPURA; This spontaneous report received from a company representative concerned a 60 year old female. Initial information was processed with additional information received from the patient's physician, in response to telephone follow-up, on 26-APR-2021. The patient's weight and weight were not reported. The patient's concurrent conditions included hypertension, hyperlipidemia, and obesity. She was a non-smoker and had no history of acute illness. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: Unknown) frequency one total, dose was not reported, administered on 27-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. Concomitant medications included blood pressure medication, vitamins, and a statin (all unspecified). On 21-APR-2021, the patient experienced Idiopathic thrombocytopenic purpura and was in critical condition. The patient presented with petechiae on her legs. Her platelet count was low, less than 9000 and all other labs were normal. The patient was hospitalized on 21-APR-2021 and the duration of hospitalization was not reported. The patient did not have any clots and she was treated with decadron and Intravenous immunoglobulin. On 22-APR-2021, the patient's and improved the next day with platelet of 30,000 and she was discharged same day. on an unspecified date anti-PF 4 antibodies were performed and were normal. Fibrin D-dimer tests were not performed. The reporter stated the discharge diagnosis was Idiopathic thrombocytopenic purpura which could have been related to recent vaccination. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from Idiopathic thrombocytopenic purpura. This report was serious (Hospitalization Caused / Prolonged, Other Medically Important Condition, and Life Threatening).;</p> <p>Sender's Comments: V0: This 60-year-old female was hospitalized for immune thrombocytopenia 25 days after receiving the Janssen Covid-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. Concurrent conditions included hypertension, hyperlipidemia, and obesity. She was a non-smoker and had no history of acute illness. Concomitant medications included unspecified blood pressure medication, a statin,</p>

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and vitamins. Twenty-five days post-vaccination, she developed petechiae on her legs and was found to have a platelet count of 9000; all other labs were normal including anti-platelet factor 4. She did not have clots. She was admitted to the hospital the same day and was treated with dexamethasone and iv immunoglobulin. The next day, her platelet count improved to 30,000 and was discharged. Based on the available information, the relationship with Janssen Covid-19 vaccine is considered indeterminate. Additional information has been requested.

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1269949	4/29/2021			F		4/1/2021	<p>BLOOD CLOTS IN THE BRAIN; EXTRAORDINARY PAIN; This spontaneous report received from a consumer via a company representative concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, start therapy date were not reported, 1 total, administered for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date in APR-2021, the patient had clots in the brain. The patient was flown to the hospital and had been in Intensive Care Unit (ICU) for the past 2 weeks from the report. The patient underwent multiple procedures for it, and was in extraordinary pain. The patient was currently receiving plasmapheresis. The number of days of hospitalization was not specified. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clots in the brain, and extraordinary pain. This report was serious (Hospitalization Caused/Prolonged).; Sender's Comments: V0: This female patient of unspecified age and ethnicity was reported to have been admitted in ICU for clots in the brain after an unspecified duration of receiving COVID-19 VACCINE AD26.COV2.S for the prevention of symptomatic SARS-CoV-2 virus infection. The patient underwent multiple unspecified procedures and currently undergoing plasmapheresis. No other details reported. The information available precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information was requested.</p>

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1269950	4/29/2021	GA	53	F	3/1/2021		<p>PULMONARY EMBOLISM; HAEMOPERITONEUM; MESENTERIC HAEMORRHAGE; SPLENIC HAEMORRHAGE; SPLENIC RUPTURE; SPLENIC THROMBOSIS; SPLENOMEGALY; LEFT UPPER QUADRANT/ABDOMINAL PAIN; DYSPNOEA; This spontaneous report received from a physician concerned a 53 years old female The patient's height, and weight were not reported. The patient had no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805029, and expiry: UNKNOWN) dose was not reported, 1 total administered on 16-MAR-2021 for prophylactic vaccination. Concomitant medications included Centrum Multi-Gummies for Women. On an unspecified date in MAR-2021 the patient began to experience slowly progressive shortness of breath; on 01-APR-2021 she had left upper quadrant pain. On 03-APR-2021 the patient presented to the emergency room. Laboratory data included: Pulmonary Angiogram/CT Chest - abnormal and computerised tomogram abdomen/pelvis at 09:37, showed segmental and subsegmental pulmonary emboli in the lower lobes of both lungs. Small volume perisplenic hemorrhage and small volume pneumoperitoneum in the pelvis or findings concerning for spontaneous splenic rupture and moderately enlarged spleen. Additional CT abdomen and pelvis with IV contrast at 23:05 showed: Small to moderate amount of hemoperitoneum, slightly increased since the earlier study. There is definitely new blood adjacent to the liver. The hemorrhage adjacent to the spleen appears similar to the earlier study. Due to the timing of the scans with relation to the contrast injection, the physician could not confirm a splenic laceration, although it was suspected to be the source of hemorrhage. Small amount of mesenteric blood was slightly increased. Continuous heparin infusion was started for bilateral pulmonary embolism. On 04-APR-2021, an inferior vena cava filter was placed and patient was vaccinated with Acthib (HIB Vaccine), Bexsero (meningococcal vaccine) and Prevnar (pneumococcal vaccine) in anticipation of splenectomy. On 07-APR-2021, a laparoscopic splenectomy was performed. The spleen was evaluated by pathology which reported that organizing blood clot on surface was consistent with rupture. No evidence of malignancy was reported. The</p>

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patient was also treated with anticoagulant therapy (dates unspecified). The patient remained inpatient while recovering from surgery. On 12-APR-2021, the patient was transitioned to rivaroxaban for therapeutic anticoagulation. Patient remained hospitalized as of 12-APR-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from pulmonary embolism, haemoperitoneum, mesenteric haemorrhage, splenic haemorrhage, splenic rupture, splenic thrombosis, splenomegaly, dyspnoea, abdominal pain upper, and left upper quadrant/abdominal pain. This report was serious (Hospitalization Caused / Prolonged, Disability Or Permanent Damage).; Sender's Comments: V0: This 53-year-old female patient of unspecified ethnicity was found to have pulmonary embolism and spontaneous splenic rupture 18 days after receiving COVID-19 VACCINE AD26.COV2.S for the prevention of symptomatic SARS-CoV-2 virus infection. No concurrent illness and medical history reported. Emergency room consult for slowly progressive shortness of breath and left upper quadrant pain that starts on an unspecified date after vaccination. Pulmonary Angiogram/CT Chest showed segmental and subsegmental pulmonary emboli in the lower lobes of both lungs; small volume perisplenic hemorrhage and small volume pneumoperitoneum in the pelvis; moderately enlarged spleen with findings concerning for spontaneous splenic rupture. CT abdomen and pelvis with IV contrast showed small to moderate amount of hemoperitoneum, slightly increased since the earlier study; definite new blood adjacent to the liver. Continuous heparin infusion was started; vaccinated with Acthib (HIB Vaccine), Bexsero (meningococcal vaccine) and Prevnar (pneumococcal vaccine). Laparoscopic splenectomy was done 22 days after vaccination; pathology report is consistent with splenic rupture with no evidence of malignancy. The patient was shifted to rivaroxaban. No other details reported. The information available regarding splenic rupture precludes a complete and meaningful assessment. Based on the information that is available, the event pulmonary embolism is assessed as plausible with the causal association to immunization, per WHO causality classification of adverse events following immunization based on a lack of a definitive plausible biological mechanism;

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considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, the potential vaccine contribution cannot be excluded. Additional information was requested.

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1269951	4/29/2021	NJ	58	M	3/25/2021		<p>BLOOD CLOT IN UPPER THIGH; NO PULSE FROM KNEE DOWN ON RIGHT LEG; RINGING AND BUZZING IN EARS; PURPLE TOE; COULD NOT MOVE; FEELING CRAPPY; TIRED; NAUSEOUS; This spontaneous report received from a patient concerned a 58 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included Barrett's esophagus, and controlled high blood pressure. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular batch number: 1805031, and expiry: unknown) dose was not reported, 1 total administered in left arm on 24-MAR-2021 for prophylactic vaccination. Concomitant medications included Nexium (esomeprazole sodium) for Barrett's esophagus, and lisinopril for high blood pressure. On 25-MAR-2021, the day after the vaccination, patient felt crappy and could not move, had tiredness and nauseous. After 10 to 12 days of vaccination on an unspecified date in APR-2021, the patient had ringing and buzzing in ears, pain in the bottom of feet on walking, and purple discoloration to front of the right toe. The patient had visited health care professional (HCP). The patient had undergone some tests and HCP identified no pulse from the knee down on his right leg and a blood clot in upper thigh. The patient had experienced pins and needles and buzzing on his leg. He has also has a ringing and a buzzing in his ears and the bottom of his feet hurt when he walked on them. The patient was scheduled for an appointment with cardiovascular surgeon on 28-APR-2021, prior to the visit the patient has to tested negative for COVID. The patient went to take test on 23-APR-2021 and results not yet received. Laboratory data included: Peripheral pulse absent (NR: not provided) no pulse from the knee down on right leg. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the feeling crappy, tired, nauseous, no pulse from knee down on right leg, blood clot in upper thigh, ringing and buzzing in ears and could not move was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to. This spontaneous report received from a patient concerned a 58 year old male.; Sender's Comments: V0: This 58-year-old male patient was found to have blood clot in upper thigh with no pulse from the knee down 10 to 12 days after receiving COVID-19 VACCINE</p>



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AD26.COVS.S for the prevention of symptomatic SARS-CoV-2 virus infection. Concurrent conditions include Barrett's esophagus and "controlled" high blood pressure; concomitant medications includes Nexium and lisinopril. The symptoms reported were ringing and buzzing in ears, pain in the bottom of feet on walking, pins and needles and buzzing on his leg, and purple discoloration to front of the right toe that prompted consult with HCP, who advised the patient that there was no pulse from the knee down on his right leg and a blood clot in upper thigh. Prior COVID test was negative. No other details reported. The information available precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information was requested.

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1269952	4/29/2021	FL	50	M	4/23/2021		<p>BLOOD CLOT IN LEG; SHORTNESS OF BREATH; HEART RATE INCREASED; GANGRENE IN TOE; RIGHT LEG SWOLLEN; RIGHT FOOT SWOLLEN; CHILLS; RUNNY NOSE; FEELING HOT; This spontaneous report received from a patient concerned a 50 year old male. The patient's height and weight were not reported. The patient's concurrent conditions included high blood pressure and diabetes. The patient received COVID-19 vaccine Ad26.CoV2.S (suspension for injection, route of administration not reported, batch number 1802070, expiry date unknown), dose not reported, 1 total administered on 19-APR-2021 for prophylactic vaccination on left arm. Concomitant medications included amlodipine besilate for drug used for unknown indication, empagliflozin for drug used for unknown indication, fenofibrate for drug used for unknown indication, insulin aspart for drug used for unknown indication, insulin glargine for drug used for unknown indication, losartan for drug used for unknown indication, and pioglitazone hydrochloride for drug used for unknown indication. On an unspecified date (reported as 22-MAR-2021; 28 days prior to vaccination), the patient experienced shortness of breath, heart rate increased, runny nose, chills and was hospitalized (date unspecified). He reported that on this past Saturday, 17-APR-2021 (2 days prior to vaccination), he went to the emergency room. He reported that his toenails were coming off, the skin on his toes was coming off, and he had swelling in his right foot and up his leg. He says there was no circulation going to his toe and he was diagnosed with having a blood clot in his right leg. He says he had surgery to open up the arteries in his leg, and also reported gangrene in his toe. The subject was discharged on 21-APR-2021. On 23-APR-2021, the patient experienced feeling hot. He also reported that he may need to have his right pinky (fifth) toe amputated because it has gangrene. He reported that he is going to go back to the hospital, to which he would seek medical attention if he was having issues. Treatment medications (dates unspecified) included paracetamol. When called back due to his vaccination dates being after event start dates, the patient said that his memory is not too good, so he 'had to take his time to remember the correct dates'. The action taken with COVID-19 vaccine Ad26.CoV2.S was not applicable. The patient was</p>

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recovering from blood clot in leg, and had not recovered from runny nose, shortness of breath, heart rate increased, chills, feeling hot, gangrene in toe, right leg swollen, and right foot swollen. This report was serious (caused hospitalization).; Sender's Comments: V0: This 50-year-old hypertensive and diabetic male patient reported that he was feeling hot and may need to have his fifth toe amputated because it has gangrene 4 days after receiving COVID-19 VACCINE AD26.COV2.S for the prevention of symptomatic SARS-CoV-2 virus infection and 2 days after discharge from the hospital. The patient was hospitalized for shortness of breath, heart rate increased, runny nose, and chills 28 days prior to vaccination. The patient went to the emergency room 2 days prior to vaccination because his toenails/skin on his toes were coming off, swelling in his right foot and up his leg, gangrene in his toe; he reported that there was no circulation going to his toe and was diagnosed with having a blood clot in his right leg; the patient reported he had surgery to "open up" the arteries in his leg. Four days after vaccination, the patient felt hot and reported reported that he may need to have his right pinky (fifth) toe amputated because it has gangrene. The patient is taking paracetamol as treatment. No other details was reported. Based on the lack of temporal association, the causality is considered not related for the events blood clot in leg, shortness of breath, heart rate increased, right leg swelling, right foot swelling, chills, and runny nose. The information available regarding event gangrene of fifth toe and feeling hot precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information was requested.

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1269967	4/29/2021	VA		M		4/14/2021	<p>A LEFT UPPER EXTREMITY DVT INVOLVING THE SUBCLAVIAN AND AXILLARY VEIN; LEFT UPPER ARM SWELLING; LEFT UPPER ARM PAIN; This spontaneous report received from a health care professional (nurse practitioner) and concerned a 74 year old male. The patient's height, and weight were not reported. The patient's past medical history included DVT (deep vein thrombosis) of lower extremity and was not on anticoagulation since and was treated with warfarin times 3 months only. The concurrent conditions included type 2 diabetes, chronic hypoxemic respiratory failure, chronic kidney disease, anemia, and hypertension. The patient was previously treated with warfarin. The patient received COVID-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1802070, and batch number: 1802070 expiry: 25-MAY-2021) dose was not reported, administered in left deltoid on 09-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 14-APR-2021, the patient developed a left upper extremity DVT involving the subclavian and axillary vein, left upper arm swelling and had left upper arm pain. On 19-APR-2021, the patient called and notified the office that the left arm was sore and swollen times 4-5 days. A registered nurse did a home visit on 20-APR-2021 and recommended an ultrasound to be done. On 26-APR-2021, the ultrasound confirmed a left upper extremity DVT involving predominantly the subclavian and axillary vein. On 26-APR-2021, Laboratory data included: CT Angiogram (to rule out pulmonary embolism) pending, COVID-19 virus test (NR: not provided) pending, Computerized tomogram thorax (NR: not provided) pending, Creatinine (NR: not provided) 1.59, ECG (Electrocardiogram) results not provided, Fibrin D dimer (NR: not provided) 3.95, Glomerular filtration rate (NR: not provided) 52, Hematocrit (NR: not provided) 33.2 %, Hemoglobin (NR: not provided) 10.4, International normalised ratio (NR: not provided) 2.8, NT-proBNP (NR: not provided) normal, Platelet count (NR: not provided) 309, and Prothrombin time (NR: not provided) 28.4. The patient was treated with rivaroxaban, 15 mg, oral, twice a day. The patient was currently in the emergency room with testing pending. The patient did not have other symptoms to report or note. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from left upper arm</p>

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swelling, left upper arm pain, and a left upper extremity dvt involving the subclavian and axillary vein. This report was serious (Life Threatening).; Sender's Comments: V0: This 74-year-old male patient was found to have left upper extremity deep vein thrombosis (DVT) confirmed by ultrasound 17 days after receiving COVID-19 VACCINE AD26.COV2.S for the prevention of symptomatic SARS-CoV-2 virus infection. The patient has underlying type 2 diabetes, chronic hypoxemic respiratory failure, chronic kidney disease, anemia, and hypertension; the patient had prior history of DVT of lower extremity of unspecified date and was treated with warfarin for 3 months. No concomitant medications were reported. The symptom reported left upper arm pain and swelling 5 days after vaccination; persistence prompted consult with a registered nurse the recommended ultrasound; which revealed left upper extremity DVT involving predominantly the subclavian and axillary vein. Platelet count 309, Prothrombin time 28.4, INR 2.8, NT-proBNP normal, Fibrin D-dimer 3.95, GFR 52; awaiting result of CT and CT angiogram, COVID test, and ECG. The patient was treated with rivaroxaban. No other details reported. Based on the information that is available, the event is assessed as plausible with the causal association to immunization, per causality classification of adverse events following immunization based on a lack of a definitive plausible biological mechanism. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information was requested.

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1269968	4/29/2021	NC	47	F	4/10/2021		LOWER BACK PAIN; UPPER LEG PAIN; INNER KNEE PAIN; BRIEF SHORTNESS OF BREATH; This spontaneous report received from a patient concerned a 47 year old female. The patient's weight was 130 pounds, and height was 160.02 centimeters. The patient's concurrent conditions included asthma, allergic to reglan, non smoker, and non alcohol user, and other pre-existing medical conditions included no drug abuse or illicit drug usage. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 207A21A, and batch number: 207A21A expiry: UNKNOWN) dose was not reported, administered on 08-APR-2021 for prophylactic vaccination. Concomitant medications included ibuprofen for pain in extremity. On 10-APR-2021, the subject experienced brief shortness of breath. On an unspecified date, the subject experienced lower back pain, upper leg pain, and inner knee pain. Laboratory data (dates unspecified) included: Diagnostic ultrasound (NR: not provided) No clots were found. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from brief shortness of breath, and had not recovered from upper leg pain, lower back pain, and inner knee pain. This report was non-serious.

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1270180	4/29/2021	FL	26	F	4/7/2021	4/14/2021	Exactly one week after my shot (4/14) I felt a headache in the evening. It felt like it was sinus related so I figured it was allergies. However it continued the next day so I tried Advil. It kept going. It has now been 2 weeks and a day since the headaches started and I still have them. They go away late at night and return shortly after I wake up. They feel like tension headaches in the back of my head and also sinus headaches. I was concerned about clots so I went to the dr on 4/19. She did not think it was clots because the headaches were not severe and I had no other symptoms. She had me do different tests and concluded I had no neurological issues. She gave me a prescription for butalb-apap-caf50. This did not help. She also told me not to drink alcohol so I didn't. I started feeling better on 4/24. I had a little to drink and my head hurt really bad. My headache was practically nonexistent 4/25 so I had one glass of wine. Not even half way through that glass, the head feeling from last night came back. The next day my headaches were back and have now continued since. I stopped drinking and have not felt that bad feeling in my head at night since. The headaches aren't severe but they really suck. They make it hard to do things and all I want to do is lie down even though that doesn't help. Exercise and walks sometimes help. No medication has made any noticeable difference.

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1269991	4/29/2021	MI	60	F	4/10/2021		<p>LEG SWOLLEN; CANNOT PUT PRESSURE ON FOOT, WALKS ON TIP TOES; TENDERNESS ON OUTSIDE OF LEFT LEG; PAINFUL KNEE/LEG; This spontaneous report received from a patient concerned a 60 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included blood pressure abnormal, knee disorder, and hand arthritis. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808978, expiry: UNKNOWN) dose was not reported, administered on 30-MAR-2021 for prophylactic vaccination. Concomitant medications included methotrexate for hand arthritis, and acetylsalicylic acid. On 10-APR-2021, the subject experienced leg swollen. On 10-APR-2021, the subject experienced cannot put pressure on foot, walks on tip toes. On 10-APR-2021, the subject experienced tenderness on outside of left leg. On 10-APR-2021, the subject experienced painful knee/leg. On 14-APR-2021, Laboratory data included: Diagnostic ultrasound (NR: not provided) No blood clots. On 20-APR-2021, Laboratory data included: Blood test (NR: not provided) Unknown. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from tenderness on outside of left leg, painful knee/leg, leg swollen, and cannot put pressure on foot, walks on tip toes. This report was non-serious.</p>



<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1269745	4/29/2021		20	F			<p>after 3 years of not having her period, she suddenly started bleeding heavily and having menstrual cramps. The bleeding was very clotted and seemed somewhat abnormal; after 3 years of not having her period, she suddenly started bleeding heavily and having menstrual cramps. The bleeding was very clotted and seemed somewhat abnormal; after 3 years of not having her period, she suddenly started bleeding heavily and having menstrual cramps. The bleeding was very clotted and seemed somewhat abnormal; This is a spontaneous report from a non-contactable consumer. A 20-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation (Age at vaccination: 20 years). The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient stated that after 3 years of not having her period, she suddenly started bleeding heavily and having menstrual cramps. The bleeding was very clotted and seemed somewhat abnormal. The patient underwent lab tests and procedures which included nasal swab: negative on an unspecified date. The patient did not have COVID prior vaccination. The patient was not pregnant. Outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.</p>

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1270282	4/29/2021	PA	54	F	4/7/2021	4/8/2021	She got the vaccine, when they put the needle in she said it was far in. The pain was bad, but she could deal with it. Then 5 days later something hit her and hit her bad. She went to the ER and they gave her Bentyl, diarrhea medicine as she was vomiting, not eating anything, and they gave her some anti-vomiting medicine. They sent her home and said she would feel better. The diarrhea and vomiting stopped but she then started with a rash. it's all over her hands, arms, back, itching, and taking Claritin for it. it won't go away. Her symptoms continued to worsen, and woke up one morning and had so much pain that she could not move or breath and her husband called an ambulance and they took her hospital and diagnosed with a blood clot. She was in the hospital for 3 days and now discharged on Eliquis. She has bruises all over her coming out and very upset that she is still feeling bad and doesn't know how the rash is going to go away. She was also prescribed Oxycodone for pain and also Tessalon Perls to take for coughing.
1270320	4/29/2021	NY	57	M	3/25/2021	4/15/2021	On April 15, exactly 3 weeks after vaccination, patient developed abdominal pain, eventually prompting an ER admission 4/20 and was subsequently found to have a portal and superior mesenteric vein thrombosis prompting admission and initiation of anticoagulation. He tolerated the anticoagulation well and was discharged on 4/23.
1270463	4/29/2021	NJ	54	F	2/23/2021	3/9/2021	Hospitalized on April 27, 2021 with blood clots in my lungs.

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1270488	4/29/2021	MD	39	F	4/11/2021	4/11/2021	I had to go to the emergency room, high d-dimer (.95), elevated Pro B Type Natriuretic Peptide (152 pg/mL) --- Days 1-2 (12-22hrs post-vaccine) were horrific - fever, body aches, extreme pain everywhere, my eyes hurt so bad I thought I'd lose my vision, I was in so much pain that I couldn't talk to ask for help. Saying they were flu-like symptoms is a euphemism. ---Days 2-9 I was weak and shaky on my legs, easily winded (e.g. breathing hard when doing laundry). Fever returned off and on. ---Days 4-13 It felt like someone was sitting on my chest. ---Day 10 I had a blood draw per my doctors request. ---Day 12 Blood draw results showed high d-dimer, and my doctor told me I need to go to the ER for a ct scan to look for blood clots. ---Day 12 Went to Emergency Department - ct scan showed no clots, but elevated Pro B Type Natriuretic Peptide ---Day 15 Finally started feeling better, but still winded easily, fatigued, dizziness, heart palpitations
1270545	4/29/2021	ME	73	F	3/17/2021	4/2/2021	Spontaneous total loss of vision in right eye. Blood clot formed and had stroke. CRAO--Central Retina Arterial Occlusion; will not recover use of eye. All tests have turned out normal
1270689	4/29/2021	NY	66	F	3/21/2021	3/22/2021	Entered hospital on 3/22/21 At around 8am in the emergency room. Had ultrasound of left leg and was placed in ICU for a massive blood clot in the left leg. Had surgery at around 4pm on 3/22/21 and placed back in ICU until the next surgery on 3/23/21 to remove the blood clot. Was released on 3/25/21.
1270699	4/29/2021	IL	59	F	4/8/2021	4/23/2021	superficial blood clot in right leg

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1269973	4/29/2021	CA		F	4/6/2021		WEAKNESS; UNABLE TO BALANCE; DIARRHEA; FOGGY FEELING IN HEAD; CONCENTRATION IMPAIRED; DIZZINESS; EXHAUSTED; FEVER; NAUSEA; SWEATS; VOMITED; BODY ACHES; IMPAIRED DRIVING ABILITY; CHILLS; SORE ARM; This spontaneous report received from a patient concerned a 52 year old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 042A21A, and expiry: UNKNOWN) dose was not reported, administered on 06-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 06-APR-2021, the subject experienced sweats. On 06-APR-2021, the subject experienced vomited. On 06-APR-2021, the subject experienced body aches. On 06-APR-2021, the subject experienced impaired driving ability. On 06-APR-2021, the subject experienced chills. On 06-APR-2021, the subject experienced sore arm. On 06-APR-2021, the subject experienced fever. On 06-APR-2021, the subject experienced nausea. On 07-APR-2021, the subject experienced dizziness. On 07-APR-2021, the subject experienced exhausted. On 08-APR-2021, the subject experienced concentration impaired. On 09-APR-2021, the subject experienced diarrhea. On 09-APR-2021, the subject experienced foggy feeling in head. On 10-APR-2021, the subject experienced unable to balance. On 11-APR-2021, the subject experienced weakness. Laboratory data (dates unspecified) included: Blood test (NR: not provided) No Blood clots, Normal platelets, CT scan (NR: not provided) waiting to get it done, and Coronavirus test (NR: not provided) Negative. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from sweats, diarrhea, and nausea on 10-APR-2021, vomited on 07-APR-2021, body aches on 13-APR-2021, chills, and fever on 08-APR-2021, and sore arm, was recovering from dizziness, and had not recovered from exhausted, concentration impaired, weakness, foggy feeling in head, impaired driving ability, and unable to balance. This report was non-serious.

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1269558	4/29/2021	MI	77	F	3/8/2021	3/18/2021	massive pulmonary embolism in both lungs; This is a spontaneous report from a contactable consumer. A 77-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in arm left on 08Mar2021 10:40 (Batch/Lot Number: EN6199) at 0.3 mL, single dose for COVID-19 immunization. Medical history included overweight and high blood pressure. Family history of her sister included medical conditions after dementia including a blood clot in pancreas and leg a few years ago. Her other sister had a blood clot in her leg within the last year. The patient's concomitant medications were not reported. The first dose of the Covid-19 vaccine on 08Mar2021. On 17Mar2021 she had symptoms and went to the emergency room on 18Mar2021. She was diagnosed with a massive pulmonary embolism in both lungs. She had a procedure and was in ICU for 2.5 days. They put a needle in her arm and gave her medication for the blood clots and monitored her very closely for two hours. They continued to monitor her for 24 hours but not as close. There was no previous immunization/ vaccination and no vaccine administered on the same date of the Pfizer suspect. The event required a visit to the emergency room and was hospitalized for 3 days (18Mar2021-21Mar2021). She does not have the results of any tests that were performed. The outcome of the event was unknown.

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1269502	4/29/2021	MD	35	F	3/29/2021	3/30/2021	<p>Caller states she was not due for her monthly menstrual period for another week, so she found, passing the clot, odd.; Blot clot/Very big blood clot, that passed out of body; Fever, of 102; Sore arm; This is a spontaneous report from a contactable Other HCP (patient). A 35-years-old female patient (no pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Right on 29Mar2021 09:00 (Lot Number: ER2613) as single dose for covid-19 immunisation. Medical history included ongoing asthma , contraception. Concomitant medication included ethinylestradiol, norgestimate (SPRINTEC) taken for contraception from an unspecified start date and ongoing. The patient previously took bacrim and experienced drug hypersensitivity. The blood clot only was for one day on 31Mar2021, and it was one blood clot. The patient went to the bathroom and it was passed, one time. The patient was not due for her monthly menstrual period for another week, so she found, passing the clot, odd. The patient menstrual period did happen on time and it was normal. The patient was not due for her menstrual period for another week, and she takes birth control. The patient contacted her Gynecologist, and it was confirmed that she was not pregnant, and states her menstrual period happened on time. The clot did not happen again. The patient had Fever, of 102 on 30Mar2021, the temperature resolved in a day. The patient took Aleve, drank a lot of water and napped, reclarifies, and the temperature improved. The patient experienced sore arm on 30Mar2021. The outcome of event Clot blood was recovered on 31Mar2021; outcome of event Fever was recovered on 30Mar2021; outcome of event Sore arm was recovered on 01Apr2021, outcome of other event was unknown. No other vaccine in four weeks; No covid prior vaccination; No covid tested post vaccination.; Sender's Comments: Based on the temporal relationship, A possible contributory role of the suspect product to the development of Thrombosis and Menstrual Disorder cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this</p>

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1269503	4/29/2021	TX	61	F	1/7/2021	1/14/2021	review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
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review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Blood clots in colon; 2nd dose 07Jan2021; This is a spontaneous report from a contactable other hcp (patient). A 61-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19), second dose at the age of 61-years-old via an unspecified route of administration, administered in arm left on 07Jan2021 (Batch/Lot Number: Ek5730) as single dose for covid-19 immunisation. The patient medical history was not reported. The patient has no known allergies. Concomitant medication included unspecified medication. The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), administered in the left arm on 22Dec2020 (lot number: Ek5730) at the age of 61-years-old for covid-19 immunisation. The patient experienced blood clots in colon on 14Jan2021. It was noted that the patient received the second dose on 07Jan2021. The patient was hospitalized for blood clots in colon for 30 days. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 21Jan2021. Therapeutic measures were taken as a result of blood clots in colon which included surgery. The patient was recovering from the event.; Sender's Comments: Based on event-vaccine chronological association a causal relationship between event blood clots in colon and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), cannot be completely excluded. . The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1269505	4/29/2021	TX		F	4/12/2021	4/12/2021	asked if this was a blood clot; a big black spot next to her knee, and if she touched it, it hurt; a big black spot next to her knee, and if she touched it, it hurt; This is a spontaneous report from a contactable consumer (patient). A (age: 70; unit: unspecified) female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection) via an unspecified route of administration on 12Apr2021 as a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. On 12Apr2021 the patient experienced a big black spot next to her knee, and if she touched it, it hurt. The patient called to report that she received the first dose of the COVID-19 vaccine yesterday 12Apr2021 and she was supposed to receive the second dose on 03May2021. When she got home yesterday afternoon, she ended up with a big black spot next to her knee, and if she touched it, it hurt. It was a little larger than a quarter coin, about the size of a silver dollar. She stated it was next to the inner part of her knee. The patient asked if this was a blood clot. She stated that she was worried with all the information about blood clots and the COVID-19 vaccines. She stated that she did not know if it was a blood clot but asked if it was a blood clot. The clinical outcomes of the events a big black spot next to her knee, and if she touched it, it hurt were both unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.



<u>VAERS_ID</u>	<u>RECVD</u>	<u>STATE</u>	<u>AGE_YRS</u>	<u>SEX</u>	<u>VAX_DATE</u>	<u>ONSET_DATE</u>	<u>SYMPTOM_TEXT</u>
1269509	4/29/2021	FL	75	F	1/13/2021	4/7/2021	<p>clot on the left pulmonary vein; This is a spontaneous report from a contactable nurse (patient) from a Pfizer-sponsored program COVAX US Support. A 75-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in left arm on 13Jan2021 09:30 (lot number: FL3022; expiration date: May2021) at the age of 75 years old, as single dose for COVID-19 immunisation. Medical history included high blood pressure (taking losartan), anxiety with COVID; both from an unknown date and unknown if ongoing. Concomitant medications included losartan taken for high blood pressure from Jun2020 to an unspecified stop date; escitalopram oxalate (LEXAPRO) taken for anxiety with COVID from Jun2020 to an unspecified stop date. The patient previously received first dose of bnt162b2 on 23Dec2020 at the age of 75 years old for COVID-19 immunisation (lot number: ELD140; Pfizer product; expiry date: unknown). It was the first time they found a clot on the left pulmonary vein of the patient on 17Apr2021. The patient stated that she felt this was medically significant and that she had no symptoms. She stated that her inner voice said it was related to the vaccine. She started apixaban (ELIQUIS) 5mg twice a day on 09Apr2021 for the clot. She had nothing medical and she was in denial and shock as she had never had an issue until now and she never took pills. She is waiting to get a heart monitor and after that to have a TEE as they want to be sure the clot doesn't go to her heart. She was in complete denial, that she has no symptoms and she is feeling fine. She was told no exertion for 2 weeks, that she can go for walks, she thought it may be until the apixaban kicks in. The patient underwent lab tests and procedures which included chest scan: everything came back normal on unspecified date (6 months ago she had another chest scan), chest scan: unknown result on 07Apr2021. The patient has not recovered from the event.; Sender's Comments: Based on the current available information, the event Pulmonary venous thrombosis is most likely related to an intercurrent or underlying condition which is not related to the suspected drug (weak temporal association). The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as</p>

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1269519	4/29/2021	MD
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74	M
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part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Committees and Investigators, as appropriate.

Large DVT in leg femoral popliteal; This is a spontaneous report from a contactable consumer, the patient. A 74-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN) via an unspecified route of administration on an unspecified date (at the age of 74-years-old) as a single dose for COVID-19 immunisation. The patient medical history was none. Prior to vaccination, the patient was not diagnosed with COVID-19. There were no concomitant medications. The patient previously received the first dose of BNT162b2 on 18Jan2021 at 12:00 (Lot Number: Unknown) for COVID-19 immunisation. The patient had not received any other vaccines within 4 weeks prior to the COVID-19 vaccine. The patient experienced large DVT in leg femoral popliteal without other cause on 24Mar2021, diagnosed 3-4 weeks after the 2nd vaccine. The patient underwent lab tests and procedures which included PCR COVID test on 24Mar2021 (post vaccination), which was negative. Therapeutic measures included rivaroxaban (XARELTO) as a result of large DVT in leg femoral popliteal (deep vein thrombosis). The patient was recovering from the event, large DVT in leg femoral popliteal. No follow up attempts are possible; Information about Lot and batch number could not be obtained.

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1269520	4/29/2021	CT	78	M	3/11/2021	3/14/2021	blood clots in urine for 36 hours commencing about three days after second shot; This is a spontaneous report from a contactable consumer, the patient. A 78-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN) via an unspecified route of administration, administered in the right arm on 11Mar2021 (at the age of 78-years-old) as a single dose for COVID-19 immunisation. Medical history included arrhythmia from an unknown date and unknown if ongoing, and sulfa allergy from an unknown date and unknown if ongoing. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Concomitant medication included apixaban (ELIQUIS) for an unspecified indication, start and stop date were not reported. The patient had not received any other vaccines within 4 weeks prior to the COVID-19 vaccine. The patient previously received the first dose of BNT162b2 on 18Feb2021 (Lot Number: Unknown) in the right arm for COVID-19 immunisation. On 14Mar2021, the patient experienced blood clots in urine for 36 hours commencing about three days after second shot. No treatment given for the event. The patient with outcome of recovered from the event, blood clots in urine for 36 hours on an unknown date in Mar2021. Information on the lot/batch number has been requested.

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1269525	4/29/2021	MO	68	M	3/23/2021	4/6/2021	atrial fibrillation; atrial fibrillation; splenic infarction; extreme left upper abdominal pain; large portion of his spleen unusable; blood clots causing that portion of his spleen to die; blood clots causing that portion of his spleen to die; This is a spontaneous report from a contactable consumer (patient). A 68-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot: EN6206), via an unspecified route of administration in right arm on 23Mar2021 09:00 (at the age of 68-years-old) as single dose for covid-19 immunisation. The vaccination facility type was a health department. Medical history included atrial fibrillation (under control with medicine). The patient's concomitant medications were not reported. The patient previously took ciprofloxacin hydrochloride (CIPRO) and experienced allergies: Cipro. The patient had no COVID prior vaccination and was not COVID tested post vaccination. No other vaccine in four weeks. It was reported that within 13 days of the injunction (on 06Apr2021 at 04:00), the patient had three atrial fibrillation events on three separate days between 01:00 and 03:00 while sleeping and on day 13 was admitted to the hospital with extreme left upper abdominal pain they diagnosed with splenic infarction and rendering a large portion of his spleen unusable from blood clots causing that portion of his spleen to die. Now the patient have to take blood thinners the rest of his life. The events resulted in emergency room/department or urgent care, hospitalization for 1 day, disability or permanent damage. The events treatment included several pain shots administered then given enoxaparin sodium (LOVENOX). The outcome of the events was recovered with sequel.

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1269527	4/29/2021	NC	60	F	4/7/2021	4/7/2021	multiple pulmonary embolisms/Pulmonary embolism and subsegmental pulmonary embolus; felt sluggish directly; feeling discomfort in my lungs; pain in my lung/chest area; pain in my lung/chest area/right-sided chest pain under the rib; difficult and extremely painful to breathe/significant shortness of breath/shortness of breath due to extreme pain; blood clots; This is a spontaneous report from a contactable consumer (patient) and physician. A 60-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EP7534 and expiration date not provided), via an unspecified route of administration, administered in Arm Left second dose on 07Apr2021 17:00 at single dose for covid-19 immunisation. The patient medical history was not reported. The patient was not pregnant at time of vaccination. The patient's concomitant medications included cetirizine, diphenhydramine, and phenylephrine. The patient historical vaccine includes bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EN6203), right arm first dose on 10Mar2021 for COVID-19 Immunization. On 07Apr2021 21:30, the patient felt sluggish directly after receiving the second dose. The patient began feeling discomfort in my lungs about 5 hours after the dose. The pain in my lung/chest area grew worse throughout the night to the point where it was difficult and extremely painful to breathe. The patient went to urgent care in the morning, and they ran an EKG, urine analysis, and chest X-ray: all with unknown results. They were concerned it could be something worse along with potential pneumonia, so they sent me to the emergency room. In the emergency room, I received a CT scan where they found multiple pulmonary embolisms (1 large one in my right and multiple in my left lung). The patient stated that she had just had my yearly physical the previous week (Apr2021), with no signs of any health issues. With that, the doctors believed my condition to be related to my 2nd dose, so I was admitted to the hospital. I had to stayed for 2 nights. I am now on blood thinners, other meds (pain medications), and require oxygen during sleep (O2 levels drop too low). I have been referred to lung and hematology specialists. Also, reported that patient experiencing significant shortness of breath and right-sided chest pain under the rib. This persisted for some time until she presented to the

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emergency department found to have segmental and subsegmental pulmonary embolus. Additionally, the patient experienced blood clots, chest pain, and shortness of breath due to extreme pain. Hypercoagulable work-up pending. The patient underwent lab tests and procedures which included COVID-19 virus test (nasal swab) with result of negative. The outcome of the events was recovering.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events occurred in a plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified.

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1269532	4/29/2021	OH	78	F	1/23/2021	1/26/2021	hurting on right side of face, in and around R ear; hurting on right side of face, in and around R ear; severe headache; nausea; vomiting; severe dizziness; All over body rash; This is a spontaneous report from a contactable consumer or other non hcp. A 78-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in Arm Right on 23Jan2021 08:00 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. Medical history included high BP, hx of blood clots/CAD, covid-19 from 10Dec2020 to an unknown date. Concomitant medications included warfarin sodium (COUMADIN); and atorvastatin calcium (STATIN [ATORVASTATIN CALCIUM]); both taken for unspecified indications, start and stop dates were not reported. On 26Jan2021, 12:00 AM, 3 days later started hurting on right side of face, in and around R ear, severe headache/nausea/vomiting & severe dizziness. All over body rash occurred. 10 days later and lasted 3 weeks. The patient received treatment for the events: antibiotic/anti nausea/MRI/CT. The patient was hospitalized for five days for the events. The outcome of the events was not recovered. The patient underwent lab tests and procedures which included computerised tomogram: unknown results on an unspecified date, magnetic resonance imaging: unknown results on an unspecified date. The patient has not been COVID tested post vaccination. Information on the lot/batch number has been requested.

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1269533	4/29/2021	CT	51	M	4/2/2021	4/2/2021	<p>he reports discoloration resolved but developed worsening bilateral lower extremity edema; lower extremity pain and swelling; lower extremity pain and swelling; blue toes on both feet; extensive deep vein thrombosis in left lower extremity requiring treatment and thrombectomy; legs were cool to touch; This is a spontaneous report from a contactable physician reporting for a patient. A 51-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 intramuscular on 02Apr2021 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation, at 51 years old. Medical history included triplegia, neurogenic bladder, hyperlipidaemia, chronic abdominal pain, type 2 diabetes mellitus, chronic opioid use, known allergies: Latex from an unknown date and unknown if ongoing. No other vaccine in four weeks. No COVID prior vaccination and was not tested for COVID post vaccination. The patient's concomitant medications were not reported. The patient previously took sulfamethoxazole;trimethoprim and experienced allergies to Sulfamethoxazole-trimethoprim. The patient experienced lower extremity pain and swelling, lower extremity pain and swelling, blue toes on both feet, extensive deep vein thrombosis in left lower extremity requiring treatment and thrombectomy, legs were cool to touch on 02Apr2021; and he reported discoloration resolved but developed worsening bilateral lower extremity edema on an unspecified date. Clinical course was reported as follows: The patient presented to the hospital on "4/7" (as reported) with lower extremity pain and swelling. Patient reports received 1st dose on pfizer vaccine on 4/2 (as reported) and immediately noticed blue toes on both feet and legs were cool to touch. He reports discoloration resolved but developed worsening bilateral lower extremity edema. Imaging revealed extensive deep vein thrombosis in left lower extremity requiring treatment and thrombectomy. The patient underwent lab tests and procedures which included sars-cov-2 antibody test: negative on 07Apr2021, and sars-cov-2 antibody test (nasal swab): negative on 13Apr2021. Treatment was received for the events. The events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization (Apr2021). Outcome of the events was recovering.</p>



<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1269761	4/29/2021	PA		F	4/15/2021		Information on the lot number has been requested.  blood clot; feels like there is a worm in between her ankle and knee, crawling around her leg; This is a spontaneous report from a contactable consumer (patient reported for herself) received from a Pfizer sponsored program. A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection, Lot Number: Unknown) via an unspecified route of administration on 15Apr2021 as single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. She felt like there was a worm in between her ankle and knee, crawling around her leg. She thought that it might be a blood clot and it might crawl going to her brain. She said she's been up all night and she put an elastic bandage on her leg so that it won't crawl going to her brain. The outcome of the event was reported as unknown. Follow up attempts are needed. Information about lot/batch number has been requested
1269546	4/29/2021	CO	49	M	3/18/2021	3/22/2021	Portal Vein Thrombosis; abdominal pain; This is a spontaneous report from a contactable consumer (patient). A 49-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EN6206 and expiration date not provided), via an unspecified route of administration, administered in Arm Left first dose on 18Mar2021 17:00 at single dose for covid-19 immunisation. The patient's medical history included obesity. There were no concomitant medications. About four days after vaccine on 22Mar2021, the patient started having abdominal pain. On 31Mar2021, the pain caused the patient to go to the ER and physician office visit, where the patient was diagnosed with a portal vein thrombosis. The patient was then hospitalized for 2 days. The patient was treated with Eliquis. The outcome of the events was recovering.

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1269769	4/29/2021	CA	37	F	3/29/2021	3/31/2021	<p>Blood clots; Major blood loss; Blurred vision; Heart palpitations; Shortness of breath; Extreme fatigue; Dizziness; This is a spontaneous report from a contactable other hcp (patient). This 37-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in arm left on 29Mar2021 12:00 (Lot number was not reported) as single dose (at 37 years old) for COVID-19 immunisation. Medical history none. There were no concomitant medications. On 31Mar2021 01:00, the patient experienced blood clots, major blood loss, blurred vision, heart palpitations, shortness of breath, extreme fatigue, dizziness. The outcome of the events was unknown. Therapeutic measures were taken as a result of the events included blood transfusion, ongoing tests, ultrasounds. The events required a visit to the emergency room and a visit to the physician's office. Seriousness criteria of the events was reported as serious due to disability and life threatening. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. No allergies. The patient was not pregnant at the time of vaccination. The information on the Lot / Batch number has been requested.; Sender's Comments: Based on the limited information currently available, a possible association of the suspect drug administration with the reported events cannot be completely excluded, due to a plausible temporal relationship. This case will be reassessed when additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>

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1269617	4/29/2021	AZ	81	M	2/23/2021	3/1/2021	<p>Got worse and the leg swelled and was also having foot swelling because blood flow wasn't there; sore arm; blood clot; pain behind left knee; This is a spontaneous report from a contactable consumer (patient's wife). An 81-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration, administered in right shoulder on 23Feb2021 (Batch/Lot Number: EN6202) (at the age of 81-years-old) as single dose for covid-19 immunisation. Medical history included diabetes mellitus, stage 3 renal failure (was not bad, was in stage 5 couple of years ago, was a month or so away from full failure, was in the hospital and had dialysis, was able to get reversed with medication and diet), high blood pressure, and blood cholesterol increased/high cholesterol. The reporter stated that with regards to patient's height, he shrunk a little. Patient had no prior vaccinations within 4 weeks, didn't get flu shots. Concomitant medications include about 12 other unspecified drugs, takes statins, has high blood pressure and high cholesterol. Patient started experiencing pain behind his left knee about 6 or 7 days later in Mar2021 (also reported as 04 or 05Apr2021, pending clarification). By that Sunday, it had gotten worse. The leg swelled and was also having foot swelling because blood flow wasn't there. There was no TIA's no stroke, no heart racing, no sweating, was all pain. Got leg up and kept elevated until they could get to the doctor and get imaging. Patient went Monday 08Mar2021 to see the doctor. Patient was brought to the doctor and was then sent to the imaging place. Radiology read the imaging around 5:15pm on the Monday, 08Mar2021. The radiologist said there was 2.5" blood clot behind the left knee. He had never had a blood clot before. Patient was then sent to the Emergency Room at (Name) Hospital, in (Name) where they live. Was kept there several hours. Did a lot more blood tests. He was immediately put on 10mg ELIQUIS 10mg, once in the morning, and once at night. He is now taking 5mg Eliquis in the morning, and 5mg at night. He has not had any of these problems before the Pfizer shot. The reporter knew that not a lot had been reported. It seemed it should be safe. The correlation and timing having the shot on 23Feb2021 and all of a sudden a week and a half later this happened. It was 10 days later. There was nothing they can do about</p>

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it. Just continuing with the ELIQUIS, trying to dissolve the blood clot, will be staying on it for 4 to 6 months. It was a pretty big blood clot and were worried about it breaking up and traveling. The patient had no other symptoms, had a sore arm, that was it. Patient going back to (Name) 01Jun2021 and he will have another CT scan or ultra sound when they get back. The reporter did not want to need to get the leg amputated. Patient was only in the ER, was not admitted to the hospital. Patient was concerned because of his age. If it doesn't dissolve, they know there will be a lot more trouble. The event of pain left knee, blood clot and sore arm required a visit to the emergency room and physician's office. The patient received the second dose of BNT162B2 on 01Apr2021 (lot number: ER8730) in the right arm. The outcome of events was unknown.

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1269706	4/29/2021	CA	47	M	4/2/2021	4/4/2021	DVT behind left knee detected at ER on 08Apr. Pain behind left knee started on 4Apr; This is a spontaneous report from a contactable consumer (patient himself). A 47-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 2 via an unspecified route of administration, administered in the left arm on 02Apr2021 at 12:00 (Batch/Lot Number: ER8734) as a single dose for COVID-19 immunization. Relevant medical history included prior deep vein thrombosis (DVT) behind right knee from an unspecified date in 2010 to an unknown date. Concomitant medication included finasteride (PROPECIA) taken for an unspecified indication, start and stop date were not reported. The patient previously took ibuprofen (ADVIL), acetylsalicylic acid (ASPIRIN), and unspecified salicylates, from which the patient had known allergies. The patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) on 12Mar2021 at 12:00 PM (lot number: EN6204) at the age of 47 years, administered in the left arm for COVID-19 immunization. The patient had no other vaccine in four weeks. The patient had no COVID-19 prior vaccination. The patient was not tested for COVID-19 post vaccination. The patient had DVT behind left knee detected at the emergency room (ER) on 08Apr2021; the pain behind left knee started on 04Apr2021. The adverse event (AE) resulted in an emergency room/department or urgent care. Therapeutic measures were taken as a result of the event, which included that the patient was prescribed apixaban (ELIQUIS). The patient was not recovered from the event.

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1269707	4/29/2021	PA	73	M	2/12/2021	2/25/2021	left leg deepvein thrombosis; blood clot; This is a spontaneous report from a contactable consumer (patient). A 73-year-old male patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EL9269), via an unspecified route of administration, administered in Arm Right on 12Feb2021 19:30 (7:30 pm) as single dose for COVID-19 immunization in a hospital. Medical history included high blood pressure and high cholesterol both from an unknown date. No known allergies. The patient took an unspecified medication. No other vaccines in four weeks. No COVID-19 prior to vaccination. The patient received the first dose of bnt162b2 (lot number: EL9261) on 22Jan2021 07:15 am on the right arm for COVID-19 immunization. On 25Feb2021 21:00 (9:00 pm), the patient experienced left leg deep vein thrombosis and blood clot which required a visit to the emergency room and subsequent hospital admission. The patient was given Eliquis as treatment. The patient was tested for COVID-19 post vaccination via nasal swab on 08Apr2021 with a negative result. The outcome of the events was reported as recovering.
1269718	4/29/2021	CO	48	F	3/1/2021	4/2/2021	Developed a blood clot in peroneal vein of left leg.; This is a spontaneous report from a contactable consumer. A 48-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: ER8732), via an unspecified route of administration, administered on the right arm, at the age of 48 years, on Mar2021 at a SINGLE DOSE for covid-19 immunisation. Medical history included drug hypersensitivity to Penicillin from an unknown date and unknown if ongoing. Concomitant medications included vitamin b complex (VITAMIN B); astragalus mongholicus (ASTRAGALUS 6000); lysine (LYSINE) and multivitamins; all taken for an unspecified indication, start and stop date were not reported. The patient developed a blood clot in peroneal vein of left leg on 02Apr2021 06:00. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 07Apr2021. Therapeutic measures (blood thinners) were taken as a result of developed a blood clot in peroneal vein of left leg. The outcome of the event was recovered with sequelae.

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1269722	4/29/2021	RI	20	F	3/28/2021	4/12/2021	had two blood clots on her lungs; This is a spontaneous report from a contactable consumer. A 20-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose at the age of 20-years-old via an unspecified route of administration, administered in arm left on 28Mar2021 12:30 (Batch/Lot Number: ER8730) as single dose for covid-19 immunisation. Medical history included birth control from an unknown date and unknown if ongoing. Concomitant medication included ethinylestradiol, norgestimate (SPRINTEC) taken for birth control from Dec2020 to 12Apr2021. The patient experienced had two blood clots on her lungs on 12Apr2021 18:00. The patient was hospitalized due to the event from 12Apr2021 to 14Apr2021. The patient was recovering from the event.

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1269723	4/29/2021	CT	58	M	3/10/2021	3/15/2021	DVT in right leg; Swelling in right leg; Discomfort in right leg while walking; This is a spontaneous report from a contactable consumer (patient). A 58-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration, administered in the left arm on 10Mar2021 at 16:30 (batch/lot number: EN6208) as a single dose for COVID-19 immunisation (wanted the protection). Medical history included deep vein thrombosis (DVT) from Jul2018 and ongoing. No family medical history relevant to the adverse events. Concomitant medication included warfarin taken for maintenance level for history of DVT from Aug2020 and ongoing. The patient experienced DVT in right leg on 02Apr2021, swelling in right leg on 15Mar2021 and discomfort in right leg while walking on 15Mar2021. The patient reported that he had a reaction to the COVID-19 vaccine and he believes that it was directly related to the COVID-19 vaccine. He reported that he has a history of blood clots in his right leg going back to 2018. He reported that his most recent DVT was in Aug2020 and he was cleared in Nov2020. He reported that he received the COVID-19 vaccine on 10Mar2021. He reported that on 15Mar2021, he started to notice his right leg swelling. He reported that he called his physician on 29Mar2021 and that his physician ordered an ultrasound. He reported that he had the ultrasound on 02Apr2021 and a deep vein thrombosis was found again. Swelling in right leg: he reported that the swelling has gone down. He reported that the reason that he mentioned that he has a history of blood clots was because of his warfarin dosage. He reported that he was first diagnosed with a deep vein thrombosis in Jul2018. He reported that he went through that cycle and that his maintenance level of warfarin was maybe 10 or 12 mg of warfarin per day. He reported that he had another deep vein thrombosis in Aug2020, and since Aug2020 he has been on 17 mg of warfarin daily. He reported that the blood level on warfarin maintenance was supposed to be between 2 and 2.5. He reported that now because of the deep vein thrombosis he experienced in Aug2020, his doctor wanted his level to be at 2.5 to 3.5. He stated that he doesn't think that at that blood level for his warfarin that he should have gotten a blood clot. He reported that something compromised or interfered with the warfarin,



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resulting in a deep vein thrombosis. Discomfort when walking; he reported that it feels like his leg was compressing. He reported that the discomfort seems to have gotten better. He was queried for details of warfarin prescription. He reported that the 10 or 12 mg warfarin tablets that he had been taking when the blood clot was diagnosed in Aug2020 have been consumed and he no longer has the bottle. He reported that he did not have the bottle with him for his current warfarin prescription. He reported that the warfarin was not auto-refilled by the pharmacy. He reported that the warfarin was only prescribed a week or two at a time. Investigations: he reported that since Aug2020 when the deep vein thrombosis returned, he started doing self INR tests at home. He reported that he constantly self-monitors his INR at home and his levels were consistently at 3.0 to 3.1. He reported that he monitors his INR at least once a week, sometimes twice a week depending on how he feels. He reported that sometimes his INR goes over 4 and he can feel it. He reported that his system was a little off when it feels too high so he knows how to adjust. He reported that he last checked his INR today, 15Apr2021, and that it was 4.0. He reported that he typically checks his INR on Wednesday. He reported that he keeps a log of his INR levels. He reported that he did not see his physician on 29Mar2021, but that he called his physician and his physician wrote a prescription for the caller to get an ultrasound. Vaccination facility type was pharmacy. Vaccine was not administered at military facility. The adverse events did not require a visit to the emergency room and physician office. No prior vaccinations (within 4 weeks). He reported that he doesn't usually get vaccines. BNT162B2 second dose (lot number: ER5729) was administered on an unspecified date; anatomical location: left arm. The outcome of the events was recovering.

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1269733	4/29/2021	PA	52	F	4/1/2021	4/1/2021	<p>blood clot; swelling and pain in right leg; swelling and pain in right leg; right arm hurting tremendously; This is a spontaneous report from a contactable Nurse. A 52-years-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Right on 01Apr2021 13:45; at the age of 52-years-old, (Batch/Lot Number: ER8734) as SINGLE DOSE for covid-19 immunisation. Medical history included ongoing hypertension, ongoing memory impairment (She states that she was diagnosed either last year or the year before that she can't remember. She states that it is ongoing, but it is well controlled). Historical vaccine included vaccine to tetanus (About 3 or 4 years ago). There were no concomitant medications. The patient experienced blood clot (thrombosis) (disability) on 13Apr2021 with outcome of not recovered, swelling and pain in right leg (disability, medically significant) on 09Apr2021 with outcome of not recovered, right arm hurting tremendously (disability) on 01Apr2021 with outcome of recovered on 04Apr2021. The patient underwent lab tests and procedures which included ultrasound scan: positive on 13Apr2021 had a blood clot. Therapeutic measures were taken as a result of blood clot (thrombosis) included Xarelto and due to pain in extremity the patient received ibuprofen (7 ibuprofen every day); Sender's Comments: Based on the information available and a close temporal association, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events of Thrombosis. The case will be reassessed once new information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified.</p>

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1270278	4/29/2021	OR	41	F	3/12/2021	3/19/2021	Next day full body red rash, 103-104 degree fever, deep body aches, skin sensitivity, joint pain, headache, brain fog, lasted 4 days, One week later period started with large chicken-egg sized blood clots, heavy flow lasted 2 days longer than typical period for me. Second cycle after vaccine started 4.22.21 with same very large clots, intense cramping and bloating

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1269746	4/29/2021	AZ	46	M	3/12/2021	3/12/2021	Regular pain feeling; Headache; Muscle pain; Calf feels tight, stiff, it feels like dead weight; Calf feels tight, stiff, it feels like dead weight; Pain running up the right arm up to the shoulder/Calf pain; He asked if someone can tell him if it is a blood clot in the back of his calf; This is a spontaneous report from a contactable consumer (patient). A 46-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in left arm (shoulder) on 12Mar2021 10:07 (Lot Number: EN6202) as single dose for covid-19 immunization. There were no medical history and concomitant medications. The patient has no prior vaccinations within 4 weeks. The patient was not sick at time of vaccination. The patient reported that on 12Mar2021, he has been feeling the regular pain feeling, a headache, muscle pain before, it comes and goes. However, he said that the last few days (2021), there had been, by his calf muscle in the back there, they've been tightening, like stiffening up on him when he's sleeping. His calf feels tight, stiff, it feels like dead weight. It wakes him up at times. He also reported pain running up the right arm up to the shoulder on unknown date in 2021. He was just curious in terms of what that might be. He asked if someone can tell him if it is a blood clot in the back of his calf. The headache went away after 2-3 days. He also reported that his eyes also hurt a little bit and was the same time frame as the headache (onset date reported as 12Apr2021: after the second dose, pending clarification). He stated that those things were just mild, nothing major. He did not take anything for these. He confirmed he no longer had muscle pain. He just has pain behind the calf and right arm up to his shoulder. His calf pain, started to feel tight, started within the last 2- 3 weeks (2021). The arm pain in right arm up to shoulder started maybe within 2 days. The patient received the second dose on 02Apr2021. Outcome of the events muscle pain and headache was recovered in Mar2021, events pain running up the right arm up to the shoulder/Calf pain was not recovered, and outcome of other events was unknown.

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1270837	4/29/2021	OH	50	F	3/18/2021	3/21/2021	a few days after the shot i was having a hard time breathing, made appointment with Pulmanologist he ordered a ct scan but no ultra sound. ct scan showed no clots in the lungs at that time. Woke up a day or two later with severe back and leg pain was transported to the emergency room. I was then transported to facillity because i could not move my left leg and was in severe pain. During my stay i coughed up a blood and requested the doctor to do blood work. The blood work showed high levels of clots. I was not taken to the hospital or treatment for the clots at that time. When i left the facility i saw my Doctor she ordered immediatly another ct scan of the chest and an ultra sound

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1269535	4/29/2021	CO	59	F	4/5/2021	4/5/2021	<p>blood clot under her eye; bright red bruise in the corner of the eye to the middle of the eye underneath; feeling crummy; she was down; headaches; couldn't move; arm hurt all the way below her arm pit into her breast; arm hurt all the way below her arm pit into her breast; arm hurt all the way below her arm pit into her breast; got very sick; This is a spontaneous report from a contactable consumer (patient). A 59-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: ER8737), dose 1 via an unspecified route of administration, administered in Arm Left on 05Apr2021 08:30 (at the age of 59years) as single dose for Covid-19 immunization. Medical history included ongoing rheumatoid arthritis and osteoarthritis (not bad enough that she takes treatment, but she is diagnosed; she was diagnosed way back in 2006). Concomitant products: patient stated she takes some medications (not further specified). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient reported that she had her first dose of the Pfizer Covid-19 vaccine on 05Apr2021 and got very sick. She was down for two days and after day 10 (as reported) she has a blood clot under her eye. She would like to know what would happen if does not get a second dose. She consulted if there is any talk on whether or not people should receive an additional dose of the Pfizer Covid-19 vaccine next year. The patient further reported that on 06Apr2021 she woke up feeling crummy right away and a couple of hours into that day she couldn't lift her arm, literally couldn't lift arm for 6 inches and stated it went on for 2 days. She further stated that her arm hurt all the way below her arm pit into her breast. She stated that it all ended on 08Apr2021 and she went back to work on 08Apr2021. The patient added that she was down for two days, had headaches, and stated she never knew what people meant when they said they got hit by train. She doesn't believe she had a fever and couldn't move. The patient further stated that she got pretty darn sick and this morning 14Apr2021, she woke up with a blood clot under her eye. She is an esthetician and is pretty good with skin. She stated that she doesn't know how she could get this overnight unless she injured herself in her sleep, but she is a light sleeper. She does not know if it is a clot. She also stated that she called a medical esthetician who told her to take a baby</p>

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							aspirin and cold compress. The patient clarified that she didn't feel so good and today she feels better. She doesn't know that it is a blood clot, it is not raised and not hard, it looks like she has a bright red bruise in the corner of the eye to the middle of the eye underneath, not in the eye. She wants to make it clear she doesn't know if it is a blood clot. She feels like if she hurt herself, that would be the reason, but it would be painful, and it is not. She added that the bruise is about the same. Therapeutic measures were taken as a result of the events (except for feeling down and couldn't move). The outcome of events thrombosis and contusion was not recovered; the outcome of other events was recovered on 08Apr2021.
1272388	4/29/2021	TX	54	M	4/3/2021	4/3/2021	is at the er with blood clots in right leg
1270168	4/29/2021	CO	48	F	4/10/2021	4/26/2021	Cerebral vein thrombosis - saggital sinus, right sigmoid and trasnverse extending to right jugular vein thrombocytopenia SAH bilateral frontal sulci
1270853	4/29/2021	FL	79	F	3/9/2021	4/22/2021	STATES SHE HAS BEEN FEELING RUN DOWN AND SICK FOR SOME TIME. STATES SHE HAS COVID IN NOV 2020 AND HAS NOT FELT WELL SINCE THEN. MADE AN APPT WITH HER HEART DOCTOR FOR FOLLOW UP TO TRY AND SEE IF THEIR WAS ANYTHING SHE COULD FIND TO HELP IMPROVE HER FEELING. WENT ON 4/22 FOR APPT AND MD SENT HER STRAIGHT TO THE HOSPITAL. WAS ADMITTED THAT NIGHT WITH FINDING OF BLOOD CLOT IN HER LUNG. CLIENT REPORTS AFTER EACH VACCINE SHE HAS SEVERE WEAKNESS WITH CHILLS AND FEVER OF 99-100. FEVER CHILLS RESOLVED WITHIN 1-2 DAYS BUT WEAKNESS JUST PROGRESIVLY GOT WORSE.
1272492	4/29/2021	FL	65	F	3/19/2021	4/21/2021	Patient experienced a severe heart attack and was diagnosed with a blood clot

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1272424	4/29/2021	CA	48	M	3/12/2021	4/4/2021	48yoM (h/o childhood asthma, GERD, lipomas, preDM, obesity BMI 30) who had Covid J&J vaccine 3/12/21, then 4/4/21 had dizziness and a little SOB, seen in ER with neg brain MRI/MRA and trop/EKG neg. and labs. Later had DDIMER 560 on 4/15/21 due to h/o J&J vaccine and CTA lung 4/29/2021 shows Right lower lobe pulmonary emboli. Patient is clinically much better. No more SOB. Dizziness a little residual but significantly better. Never had hypoxia/tachycardia and BP always reassuring. Pt read about some blood thinner making clot worse and doesn't want to to start a blood thinner without checking with hematology first. I've prescribed rivaroxaban so that pharmacy can start authorization and ensure coverage, but patient strongly states that he will not take it yet until hearing from hematology.
1272229	4/29/2021	NE	54	F	4/10/2021	4/12/2021	4/13/21 - Lymph nodes in armpit (size of lemon), breasts, and near collar bone became very large and extremely painful. Leg weakness, exhaustion, and dizziness also began. Contacted doctor when symptoms did not subside. Visited doctor on 4/22/21 for leg pain and dizziness. Lymph nodes no longer painful or as large but still present. Ordered a doppler on right leg - no clots. Visited doctor on 4/29/21 because legs hurt all the time, still exhausted, still occasional dizziness. Ordered blood tests for 4/30/21.



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1272205	4/29/2021	MI	68	F	1/1/2021		<p>Blood clots; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clots) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 011J20A and 038K20A) for COVID-19 vaccination. No Medical History information was reported. On 01-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clots) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood clots) outcome was unknown. Not Provided No concomitant medications were reported. The patient had no problems after her second dose. Treatment information was not provided. Action taken with mRNA-1273 in response to events was not applicable. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1272201	4/29/2021	CA	83	M	3/5/2021	4/4/2021	<p>Pulmonary embolism; died - autopsy showed multiple blood clots all over his body - pelvic area, hearts,arteries, lungs; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (died - autopsy showed multiple blood clots all over his body - pelvic area, hearts,arteries, lungs) and PULMONARY EMBOLISM (Pulmonary embolism) in an 83-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 039A21A and 003A21A) for COVID-19 vaccination. Concurrent medical conditions included Diabetes, Prostate cancer and Memory loss. Concomitant products included METFORMIN for Diabetes. On 05-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 04-Apr-2021, the patient experienced THROMBOSIS (died - autopsy showed multiple blood clots all over his body - pelvic area, hearts,arteries, lungs) (seriousness criterion death). On an unknown date, the patient experienced PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criterion death). The patient died on 04-Apr-2021. The reported cause of death was Pulmonary embolism. An autopsy was performed. The autopsy-determined cause of death was multiple blood clots. Action taken with mRNA-1273 in response to the event was not applicable Other concomitant medications were reported included unspecified medications for memory loss and diabetes. No treatment information was provided.; Sender's Comments: This is an 83-year-old, male patient who received mRNA-1273 Vaccine who experienced multiple thrombosis and died, 2 days after receiving second dose of vaccine. Medical history includes Diabetes, and Prostate cancer. Conmeds including some unspecified medications for memory loss and diabetes. The autopsy-determined cause of death was multiple blood clots. Very limited information has been reported at this time. Further information is expected,; Reported Cause(s) of Death: Pulmonary embolism; Autopsy-determined Cause(s) of Death: multiple blood clots</p>

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1272190	4/29/2021	MD	64	F	1/27/2021	3/28/2021	BLOOD CLOT IN THE LUNGS AND PNEUMONIA (AS REPORTED PER PATIENT)
1272137	4/29/2021	MA	66	M	4/1/2021	4/5/2021	Patient received the second dose of Moderna vaccine on 4/1/21. Approximately 5 days afterwards he began to have a headache. This lingered and progressed to the point that presented to the emergency room. A CT head revealed cerebral venous sinus thrombosis. No evidence of thrombocytopenia but notably, the patient's platelets clump.
1272068	4/29/2021	OR	42	F	4/19/2021	4/26/2021	Pulmonary embolism. Catheterization to break the clot. Now on blood thinners.
1271962	4/29/2021	MT	22	F	2/20/2021	4/5/2021	On April 5th, 2021 I went to the E.D. , for shortness of breath and severe right shoulder pain. While there they got a chest x-ray, ran labs, and did a chest CT. The CT revealed that I had one blood clot in my left lung and two blood clots in my right lung, as well as slight pleural effusion in the right lower lobe. They put me on Xarelto for the next 3-6 months and monthly follow up visits with my primary care provider. I was also given Hydrocodone as need. I experienced extreme pain with breathing and sort of movement for a week and half but currently only have occasional shoulder and back pain usually at the end of the day.
1271930	4/29/2021	MA	50	M	4/1/2021	4/22/2021	starting have shortness of breath/difficulty breathing and back and chest pain. light headed, pain unbearable. Saturday April 23rd Went to er was treated for kidney stones but they could only find one small one, Was sent home with pain medication. Shortness of breath persisted as did bloody cough and pain in chest and all over. Went back to the er on 4/28 as pain was unbearable (chest pain) once given a cat scan and diagnosed with blood clots in my lungs and then an ultra sound and found a blood clot in my leg (just above knee). It is thought that I was mis-diagnosed on the original trip to the er with kidney stones. I have been put on blood thinners and pain medication and will be following up with my doctor.
1271920	4/29/2021	MI	63	M	3/16/2021	4/8/2021	3 weeks after Patient got this shot he got blood clots in his leg and amputated next week .The problem is he has ITP platelets were 12,000 He can't make blood clots!!!

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1271852	4/29/2021	OR	65	F	4/3/2021	4/3/2021	Hospitalized with TIA due to blood clot. Continues to have issues and will see a neurologist. MD reported event to VAERS and she was given a number 479277.
1271329	4/29/2021	IN	66	F	3/10/2021	3/11/2021	Blood clots in both lungs upper and lower chambers New stage 2 HBP Chest pain and tightness Shortness of breath Fever, headache, joint pain severe, chills, nausea

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1272491	4/29/2021	CA	40	F	4/11/2021	4/11/2021	<p>Patient is a 40 y.o. female who presents for evaluation of adverse reaction to Johnson and Johnson COVID vaccine (received on 4/11/21). She received the vaccine on April 11th, around 2:30 p.m. at 8:00 p.m. that night she developed fever with temp 100.4°, chills, headache, nausea and body aches. At 10:00 p.m. that night she developed palpitations, heart racing, shortness of breath, tightness in her throat and chest. She was unable to sleep that night. The next day on April 12th, she continued to have low-grade fever with temp 99°, shortness of breath, chest tightness. She reports taking a pregnancy test at home which revealed a faint positive pink line. That night she took Tylenol which helped relieve some of her symptoms. On April 13th, she continued to have shortness of breath and chest tightness, her heart palpitations improved slightly. She reports retaking the home pregnancy test and this time it was negative. On April 14th, she had a same-day clinic visit, labs that day revealed slightly elevated D-dimer and normal chest x-ray. She continued to have shortness of breath and on April 16th, she presented to the ER due to sudden onset of bad headache, nausea, diarrhea and heart palpitations. She was discharged from the ER with close follow-up with her primary care doctor. Her symptoms did not improve and subsequently on April 20th, she began to have left-sided facial numbness. On April 21st, she went to the ER and was found to have left-sided facial weakness and suspected Bell's palsy. She was admitted for further diagnostic workup (CT Brain normal, MRI Brain normal, and MRV Brain with no evidence of venous sinus thrombosis, carotid doppler normal, MRA Brain normal, MRI sella (pituitary) normal), and treatment was initiated with prednisone and antiviral medications. On April 23rd she developed left arm weakness as well. She was discharged with closed follow up with her PMD and specialists. She recently was seen by pulm Dr and scheduled for PFTs. She is nearly completed with course of prednisone and valacyclovir, left facial weakness slightly improved but not resolved, has follow up with neuro this week.</p>

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1271013	4/29/2021	CA	46	F	3/12/2021	3/16/2021	After my J&J vaccine, I experienced severe headaches all day starting from 03-16-2021 lasting till 03-17-2021. I had some soreness at the injection site. The headache pain was located on the top right of my head towards the back, above my right ear. I took two Tylenol as well as an Aleve as pain medication. I had an U/S of the right leg to check for main vein in my leg to check for any blood clots. The results of my exam were negative. I have been fine since these symptoms.
1271151	4/29/2021	MD	56	M	3/9/2021	4/26/2021	deep venous thrombosis Left leg
1271850	4/29/2021	AZ	73	M	4/9/2021	4/22/2021	shortness of breath, blood clots in lungs, blood clot in right thigh, blood clot behind right knee
1271233	4/29/2021	NC	52	F	3/15/2021	3/22/2021	BLOOD CLOT 100% occluding Internal Jugular Vein
1271081	4/29/2021	RI	49	M	3/16/2021	4/24/2021	I received the J&J vaccine on 3/16/2021 and then flew to watch over my dads house while he went through cancer treatment. I began to have pain in my chest that was getting progressively worse, yesterday I had a very sharp pain when taking a shallow breath. I went to the hospital they thought I had pneumonia, but then saw a blood clot in right upper side, I've had a prior event but that was attached to an injury in 2012. I've not had any other issues.
1271346	4/29/2021	OK	53	F	3/6/2021	3/11/2021	Blood clot behind left knee found on 3/11/21 and traveled to lungs. Admitted to hospital for Heart Failure from Chemo, PE and pneumonia.
1271429	4/29/2021	WV	58	F	4/8/2021	4/27/2021	Patient developed acute dyspnea with exertion 04/27. Went to hospital ED, found to have acute hypoxic respiratory failure. CT-PE showing submassive saddle pulmonary embolism with several large emboli in bilateral upper and lower pulmonary arteries. Transferred from outside hospital to another Hospital. Started on IV Heparin infusion with transition to Enoxaparin. Had significant drop in platelet count and developed peripheral thrombi in all extremities. Concerned for HIT at that time, and review of CDC recommendations for COVID vaccine-associated thrombi, patient transitioned to Fondaparinux and remains on at present.

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1271486	4/29/2021	MN	36	F	4/23/2021	4/26/2021	Patient had vaccine on 4/23/21 and developed calf pain on 4/26/21. No other symptoms. No other triggers known at that time for a DVT. US did confirm a small blood clot
1271574	4/29/2021	TX	86	M	3/11/2021	3/13/2021	Flu like symptoms for 3 days, then continue loss of appetite, weakness, so much so that on April 5, 2021, I was taken to the emergency room for immediate treatment. The hospital then discovered 2 pulmonary embolisms (blood clots), one in each lung and pneumonia. At this time, I was extremely weak and in major physical stress. NOTE: I do not have a history of ever having blood clots.
1271703	4/29/2021	CA	53	F	3/12/2021	3/17/2021	Blood clot in right wrist area: On the evening of 3/17/21, I felt sudden pain in the palm of my right hand, just above the wrist. Then the vein just below my wrist swelled up and turned blue. The next morning when I woke, the vein was no longer swollen, but the area below my wrist had a large bruise, which lasted several days. I contacted my physician that day (3/18) who said just to monitor/observe and come in if continuing issues (which there were not).

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1271783	4/29/2021	MI	51	M	4/1/2021	4/26/2021	<p>BRIEF OVERVIEW: Bilateral PE Discharge Provider: MD Primary Care Provider at Discharge: NP Admission Date: 4/26/2021 Discharge Date: 4/26/2021 Active Hospital Problems (Diagnosis Date Noted) ? Pulmonary embolism without acute cor pulmonale, unspecified chronicity, unspecified pulmonary embolism type (HCC) 04/26/2021 Resolved Hospital Problems No resolved problems to display. CONSULTS: None INPATIENT PROCEDURES: None DETAILS OF HOSPITAL STAY: Patient is a 51 y.o. male with a past medical history of psoriasis, environmental allergies who presents today with sudden shortness of breath, left side pleuritic chest pain 7/10, worsened with deep inspiration. No recent travel, no family history, no history of malignancies, no immobilization or surgeries. He had his 2nd dose of Pfizer COVID vaccine on April 1. He does not have a history of COVID-19 infection, and COVID-19 PCR test was negative in ER. His blood pressure is a little high at 170 6/83 mm, pulse 76 per minute saturating 96% on room air, troponin less than 6, BNP 16, WBC 12.3,, EKG without any significant ST T-wave changes. CT angiogram of the chest shows nonocclusive thrombi in almost all the lobes, there is no saddle embolus noted. There is no evidence of right heart strain. Echo: The technical quality of the exam was limited due to suboptimal acoustic windows. The left ventricle is normal in size. There is normal left ventricular wall thickness. The left ventricular ejection fraction is 60%. Regional wall motion abnormalities cannot be excluded due to limited visualization. The right ventricular size, thickness, and function are normal. No significant valvular pathology identified with Doppler examination. There was insufficient tricuspid regurgitation envelope detected to calculate right ventricular systolic pressure. Injection of contrast documented no interatrial shunt. There is no comparison study available. He was started on Heparin gtt. And admitted for observation. He required no supplemental oxygen. He was discharged later pm on Eliquis 10 mg bid for 7 days, than 5 mg bid for 3 months. I am questioning did he had COVID-19 vaccine related bilateral PE. His hypercoagulable profile is pending. He has no sign of malignancy, no new symptoms, no weight loss. He had normal colonoscopy 2 yrs ago. He should follow up with his PCP. He was given work excuse from 4/26-5/3/21. She shouldn't take non steroidal anti-</p>



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							inflammatory (Ibuprofen (Motrin), Naproxen, Naprosyn, Voltaren, Relafen ... meds because of blood thinner Eliquis. He can take Tylenol 500 mg 1-2 tabs 3-4x a day as needed. He was also prescribed Lidoderm patch. For HTN he was started on DASH diet and Norvasc 5 mg daily. He should follow up with PCP next week. Also he was instructed to quit smoking.
1271834	4/29/2021	CA	49	F	3/22/2021	4/5/2021	Blood Clot and pulmonary embolism from first shot.
1270988	4/29/2021	MA	81	F	3/6/2021	3/8/2021	After 2nd Vaccine on 3/6/21, she became ill on 3/8/21, fever and chills was in bed all day on 3/9/21 with the same symptoms. Woke up on 3/9/21 with shingles, Her PCP was treating her with Famciclovir and Gabapentin for pain. She no longer had the fever or chills but still didn't feel well. On 3/17/21 she was admitted at Medical Center which she was treated for a blood clot in her lung and for pericardial effusion. She was put on blood thinners which then caused a bleed in her hip bone. She had a surgery to put a filter in to stop more blood clots and to drain the fluid from her heart. She died on 3/27/21 around 3:30pm.
1266576	4/28/2021	NY	41	F	4/1/2021	4/1/2021	Within 4 hours had nausea, headache. Lasted for about a day. 12 days later vertigo, nausea, headache resumed. Went to primary who detected a drop in oxygen levels, was then sent to ER where many tests were done. Included chest scan, to look for clots. None were found. Took dramamin for vertigo which helped. Symptoms of nausea, headache, vertigo continue to persist off and on. On Friday 4/23 I died my hair. Within 2 minutes an allergic reaction too place: sudden nausea, some shaking, headache. Took benedryl which help. At this point, I have continued bouts of nausea and no appetite. Its been close to a month and I'm really scared for my health. I was completely healthy before.
1266422	4/28/2021	FL	79	F	4/5/2021	4/22/2021	Patient stated that her doctor says she has blood clots and believe it could be due to the vaccine.

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1266417	4/28/2021	NY	54	M	3/20/2021	3/30/2021	<p>Patient is a lovely 54 year old- year old male initially seen 4/5/2021, kindly referred by Dr. History of COVID pneumonia in 4/2020 which was complicated by ARF and shingles, Ramsay Hunt Syndrome, with subsequent post-herpetic pain on right side of scalp.He recently received his COVID-19 Pfizer vaccine 3/20/2021 11 days prior to presentation to the hospital with shortness of breath, worsening dypnea on exertion which started 2 days after vaccine. Before this he was biking twice a week, and swimming nearly daily. He did report any medical problems before COVID, was on no meds. 3/31/2021- CT PE protocol showed multiple bilateral PEs without right heart strain. Pulmonary Vasculature: Bilateral filling defects consistent with pulmonary emboli are visualized involving the following: Distal right main pulmonary artery extending to the right lower lobar, segmental, and subsegmental branches, right middle lobar, segmental, and subsegmental branches and proximal right upper lobe artery. Left lower lobar, segmental, and subsegmental arteries. The right heart is not dilated.COVID/flu swab neg, trop x2 neg, BNP wnl. - Started on therapeutic lovenox then plan to transition on discharge to PO xarelto 15 mg bid x21 days then continue with xarelto 20 mg daily. He was seen by Dr. and referred to me for follow up. He had US 4/5/2021- which showed Right Lower Extremity: There is acute thrombus of the femoral proximal vein.Right Lower Extremity: There is no evidence of deep or superficial venous thrombosis in the common femoral, popliteal, posterior tibial, peroneal, GSV and SSV veins. Left Lower Extremity: There is no evidence of deep or superficial venous thrombosis.' 4/5/2021: Initial hematology visit Currently does not have any pain in legs, swelling. Reports that he still is not back to 100%, he got on peloton yesterday and was only able to go 5-6 miles at a slower pace. Denies fevers, chills, sweats. He has some intermittent pain where his previous zoster scalp lesions were. He has been undergoing facial PT. Thrombophilia workup sent which was grossly negative.</p>

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1266384	4/28/2021	WA	65	F	3/30/2021	4/26/2021	Patient with dementia NOS received COVID-19 vaccination first dose (as reported) on 3/30/2021. Family reported she was feeling unwell with vague complaints thereafter. Found dead on 4/27/2021. Autopsy performed on 4/28/2021 revealed ischemic bowel with an acute superior mesenteric artery thrombosis. She had little other cardiovascular disease to account for the thrombosis.
1266361	4/28/2021	KS	65	F	4/22/2021	4/23/2021	April 22, 2021 morning my auntie got her first dose of Pfizer vaccine. She happily shared here vaccine experience with family member and relative. April 23 morning, she told us she has severe abdominal pain, has the need to have a bowel movement, but she was defecated. She also told us that she vomit couple times already, then she has no more energy to talk. She got into the hospital and she was announced death right after midnight at 12:04 April 25th. Reason of death given is "septic shock secondary to ischemic bowel & intra-abdominal sepsis". But it is the blood clots issue that is causing it. I was told that after my auntie got into hospital the very next day after Pfizer vaccine, hospital later found out that my auntie has blood blockage issue that is causing blood couldn't flow to her intestines. The acid in her blood was very high, 6+. After more than 6 hours without blood to her intestines, her intestines tissues start dying and turned black color. Doctor found out about this at the night of April 23, 2021 nighttime. April 22, 2021 morning is the day my auntie got her Pfizer covid vaccine. There is a very high chances of the Pfizer vaccine is causing the blood clots that lead to blood blockages.
1266356	4/28/2021	CO	61	F	3/7/2021	4/2/2021	For the past 2 1/2 - 3 weeks I have had a pain in my left leg. Today it was extremely painful so I went into the dr. office and after an examination and ultra sound it was determined that I have a blood clot.

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1266655	4/28/2021	OH	22	F	4/2/2021	4/8/2021	4/2 vaccination 4/8 severe HA, leg, arm, lower back pain, chest pain, diarrhea, bad anxiety with shaking 4/9 PCM (NP) appt; CT scan of abdomen and blood panel 4/10 felt worse, nauseous. Diarrhea continued 4/11 At 11PM, pain right side of neck, to jaw, and toes turned purple. 4/13 PCM; vit D prescribed as they were extremely low, extra strength Tylenol release for leg and arm pain, ordered a D-dimer for possible blood clot. Doppler for right leg. COVID; neg 4/17 chest pain was extremely severe. Radiated to L arm. Went back to ER. EKG, CT Scan, BNP. All normal. Stated probably really bad heartburn. 4/19 Prilosec. I called my dr on 4/22 to follow up. They told me to keep eye on BP as been elevated thru this whole thing. 4/22 My chest, arm and leg pain with HA are still present despite Tylenol and Prilosec. My PCM said to come back in . She prescribed Prednisone and Pantropical and did a blood test to check for inflammation which was normal. I have been taking both medications since Tuesday. *My HA still present. My right side still has pain and I still have chest pain.

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1266245	4/28/2021	MD		F	3/13/2021		<p>PRESSURE IN LEFT REAR SIDE OF HEAD; SEVERE HEADACHE; BAKER CYST; SHOULDER SWOLLEN LIKE A BALL; RIGHT ARM STARTED TO SWELL AND TIGHT; ARM PAIN AND SEVERE LEG PAIN BEHIND LEFT KNEE AND SWOLLEN; NAUSEOUS; SEVERE BACK PAIN; This spontaneous report received from a patient concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included bladder surgery, and concurrent conditions included hypertension, frozen shoulder, and bladder problem. The patient experienced drug allergy when treated with cefalexin. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805022, and expiry: UNKNOWN) dose was not reported, administered on 06-MAR-2021 15:15 for prophylactic vaccination. Concomitant medications included mirabegron for bladder problem, amitriptyline hydrochloride for frozen shoulder, naproxen for frozen shoulder, and losartan for hypertension. On 28-NOV-2020, Laboratory data included: COVID-19 PCR test (NR: not provided) negative. On 13-MAR-2021, the subject experienced severe back pain. On 13-MAR-2021, the subject experienced nauseous. On 15-MAR-2021, the subject experienced shoulder swollen like a ball. On 15-MAR-2021, the subject experienced right arm started to swell and tight. On 15-MAR-2021, the subject experienced arm pain and severe leg pain behind left knee and swollen. On 26-MAR-2021, the subject experienced baker cyst. Laboratory data included: Doppler scan (NR: not provided) no clots in arm or leg, had a 5 cm Baker cyst behind left leg. On 28-MAR-2021, treatment medications included: sulfamethoxazole/trimethoprim. On 05-APR-2021 15:00, treatment medications included: cortisone. On 06-APR-2021, the subject experienced severe headache. Laboratory data included: Blood pressure (NR: not provided) Normal. On 13-APR-2021, the subject experienced pressure in left rear side of head. Additional treatment medications (dates unspecified) included: ibuprofen. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from severe back pain on 14-APR-2021, shoulder swollen like a ball, and right arm started to swell and tight on 03-APR-2021, nauseous, and severe headache on 07-</p>

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							APR-2021, was recovering from arm pain and severe leg pain behind left knee and swollen, and pressure in left rear side of head, and had not recovered from baker cyst. This report was non-serious.; Sender's Comments: V0: Medical assessment comment not required as per standard procedure as case assessed as non-serious
1266996	4/28/2021	NY	46	M	3/31/2021	4/1/2021	I started to have weakness on my left side around 9 hours after receiving the vaccine. I went to the hospital and was told I had a stroke in the right side of my brain from a clot in my brain, which they took the clot out using a catheter through my leg. I am currently undergoing rehabilitation at a rehab hospital.
1266039	4/28/2021	MI	66	M	3/21/2021	3/23/2021	big heart blood clot; This is a spontaneous report from a contactable consumer. A 66-year-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 21Mar2021 12:00 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation (Age at vaccination: 66 years). Medical history was reported as none. There were no concomitant medications. The patient experienced big heart blood clot on 23Mar2021 14:00. Therapeutic measures were taken as a result of big heart blood clot. Outcome of the event was not recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained.
1266340	4/28/2021	AL	44	F	1/27/2021	1/28/2021	1/28/2021-swollen lymph nodes and pain to left side of chest and injection site. This pain continued and I went to Dr. on 4/06/2021. Dr. treated me with Toradol and Tylenol#3. Schedule me to have a mammogram and ultrasound on 4/20/2021. This is when it was discovered I had a clot in left arm. Currently being treated with blood thinners(Eliquis).
1266689	4/28/2021	LA	85	F	3/5/2021	3/17/2021	BLOOD CLOTS IN BOTH LUNGS. SHORTNESS OF BREATH. UPPER BACK PAIN. WEAKNESS. SWEATING AND COLD. NO COLOR IN FACE -- GREY. LOSS OF EYE SIGHT -- STARTED WITH BLURRED VISION.

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1266733	4/28/2021	CT	57	F	3/11/2021	4/6/2021	Patient reported left calf pain on 4/6/2021. She underwent lower extremity duplex which was positive for left deep vein thrombosis.
1266769	4/28/2021	MA	53	F	2/24/2021	3/13/2021	On the morning of Saturday, March 13th my mother had a CARDIAC ARREST, luckily i was with her when this happened and called 911 immediately and followed an emergency/cpr protocol. She had no pulse when the emergency team arrived and they used the defibrillator on her three times in our house before they took her in the ambulance where they used the defibrillator another time. She was rushed to the Hospital where she was sedated and put on a breathing machine. It did not seem as if she would survive, the entire morning was a whirlwind and traumatizing. In the afternoon they transferred her to the ICU unit. Luckily after 24 hours they lowered sedation and she had no brain injury etc., we were all amazed she was alive. The doctors ran tests etc. to find out what caused this cardiac arrest event, they found NOTHING - no blood clot, no clogged arteries, nothing that could have caused this. My mother also has had not health conditions before this that would have caused this. She now has a defibrillator implanted and her life will never be the same, her families either, we will constantly worry. I have post traumatic stress from witnessing my mother turn purple and lifeless right in front of my eyes and the emergency team working on her all morning and in the ER. Thank gosh i was with her that morning and that the emergency team arrived within a few minutes or else my mother would not be here today. The only thing that changed leading up to her Cardiac Arrest was that she got the Pfizer Covid-19 vaccine on February 24th - we need answers, did the vaccine have anything to do with this?
1266799	4/28/2021	WI	38	M	4/12/2021	4/17/2021	Venous thrombosis of proximal greater saphenous vein
1266872	4/28/2021		50	F	4/6/2021	4/15/2021	ITP diagnosed 9 days following vaccination; platelet count 5000. Testing for VIPIT was negative: brain/head imaging negative for thrombosis, d-dimer and PT/PTT/INR within normal limits, heparin antibody ELISA negative. She was treated with IVIG and corticosteroids with a partial response (platelet count up to 43000), then placed on Promacta.

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1267181	4/28/2021	CA	64	F	1/16/2021	1/18/2021	On Monday January 18th, I woke up grappling for air, unable to breathe. Was taken to the ER at hospital and admitted with blood clots in my lungs.
1267199	4/28/2021	WV	69	M	4/5/2021	4/22/2021	patient developed severe chest pain, ambulance was called and patient was taken to ER. Patient was transferred to higher level facility and was told he had a heart attack and that it was caused by a "blood clot~~
1267264	4/28/2021	WI	48	M	3/31/2021	4/13/2021	I have a major blood clot in my left leg. I had two ultrasounds and now starting blood thinners.
1267304	4/28/2021	CA	51	F	4/6/2021	4/21/2021	Pt reported left arm pain and swelling on 4/21/21. She received the J&J COVID vaccine on 4/6/21 and had an ultrasound done which showed an acute left axillary vein thrombosis



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1266095	4/28/2021	FL	41	F	4/10/2021	4/10/2021	As soon as I took the vaccine shot I had an immediate headache, after taking the vaccine I took Tylenol and slept in the rest of the day. The next day I woke up and my arm was red and swollen. I was running fever, still had the headache and now blurry vision. My entire body was hurting. My left side of my body felt numb and tingling. The next two days the pain became worse. I did not really have an appetite. When I did eat I could barely hold my food down. On Wednesday morning I could barely get out of bed, I also felt extreme pain in my lower legs, stabbing pain in stomach and right lower side. I also had ringing in my ears, more in the right ear. I then notice a bruise on my left leg, that it was not originally there, and was also tender to touch. I went to the emergency room on the same day and I was admitted. I was in there for 4 days, they tested my leg and stated it was not a blood clot, although it look and felt like one. They discharge me and advise me that it was a migraine that was causing all my pain. This was on Sunday, I had a follow up with my PCP on the Friday, however to being in so much pain and shortness of breath, and arm pain I was advise to go to the ER on the Thursday and was admitted again. I was told in the ER I had a blood clot in my right arm and it was most likely from the IV from the previous visit. My blood pressure and heart rate was so high that they put me on medication. No matter the pain medication they gave me, it would not completely take the pain away. They discharge me again on Monday and after me begging them to get run any and all test, they said they found nothing. I'm still in the same amount of pain and same symptoms, still having trouble keeping my food down. The only thing that changed is my left arm is not as sore, however I still have a huge knot and its still warm to touch. I don't know what else to do that is why im contacting the CDC for help. I'm in a extreme amount of pain and pounding headaches. Please help

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1265991	4/28/2021	PA	79	F	2/23/2021	2/24/2021	Blood clot in lung; Shortness of breath; Felt tired; Slight headache; This is a spontaneous report from a contactable consumer (patient). A 79-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EN6201), dose 2 intramuscular, administered in Arm Right (also reported as "injected intramuscularly in right arm") on 23Feb2021 13:00 (at the age of 79years) as single dose for Covid-19 immunization. The patient received the first dose of BNT162B2 (lot number: EL8982) on 02Feb2021 (at the age of 79years) for Covid-19 immunization. Medical history included high blood pressure (diagnosed prior to 10 years ago), respiratory illness, genetic/chromosomal abnormalities, endocrine abnormalities including diabetes, diagnosed allergies, compromised immune status, and obesity (Little on the heavy side but she does not think she is obese); all from an unknown date and unknown if ongoing. Concomitant medication included lisinopril taken for high blood pressure at 20 mg once daily, started at least 10 years ago. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. It was reported that the patient had received the two doses, she had shortness of breath in the morning around 08:30 on 08Mar2021 and went to her doctor. They did blood work and she was put in the hospital because the doctor found out she had blood clots in her lungs (11Mar2021, 13:00). The patient was hospitalized for blood clot in lung from 11Mar2021 to 13Mar2021. She doesn't know if it came from the vaccine or not. She was sent home on Eliquis for 6 months to get blood clots from her lungs. She also has oxygen for when she needs it and mostly for when she is ambulatory. It was further clarified that when she went to her doctor's office, they did blood work. When they got results, they called her at home and told her that she had to call the ambulance and go the hospital in the ambulance, so she did; Ambulance to ER (hospital) on 11Mar2021. There was also a problem with the left ventricle of her heart (12 Mar2021 12:30). She stated whichever part pumps blood into the pulmonary vein, something is wrong there. She was going to have an echocardiogram to check that out again on 29Apr2021. She does not know the outcome of that yet until she gets that done. They gave her Eliquis as a blood thinner and oxygen. She has not really needed the oxygen around the house. But if she goes outside,

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1266861	4/28/2021	OH	69	F	4/15/2021	4/16/2021	<p>she may. She took it to the grocery store with her and if she needed it, she used it. She also had a headache after second dose on 24Feb2021 09:00. She felt tired on 24Feb2021 21:00 and stuff (as reported). The outcome of event blood clot in lung was unknown; the outcome of other events was recovering.</p> <p>4-16-21 @ 2PM SHE HAD A 'SHADOW IN HER RT EYE'. DROVE TO ER. DX WITH CLOT TO RT EYE AND LT OCCIPITAL AREA OF BRIAN. NO SURGERY. WAS GIVEN PLAVIX. HAS APPT WITH EYE DOCTOR ON MAY 3RD. SAW A NEUROLOGIST AND PCP. SHE IS DOING BETTER NOW AND RT EYE HAS 'CLEARED UP'. WILL NOT BE GETTING SECOND DOSE.</p>

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1265977	4/28/2021	GA	69	F	3/17/2021	4/1/2021	blood clot in her lung; Shortness of breath; blood pressure dropped extremely low; blood pressure fluctuates; This is a spontaneous report from a contactable consumer (patient). A 69-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; Batch/Lot Number: EL3247), via an unspecified route of administration, administered in the left arm on 17Mar2021 at the age of 69-years-old as single dose for COVID-19 immunization. The patient had no medical history. There were no concomitant medications. The patient previously received the first dose of BNT162B2 on 24Feb2021 (Batch/Lot number was not reported) at the age of 69-years-old for COVID-19 immunization. On 07Apr2021, the patient experienced shortness of breath and blood dropped extremely low. On 08Apr2021, the patient experienced blood clot in her lung. And on Apr2021, the patient experienced blood pressure fluctuates. The patient had her final Pfizer Covid vaccine on 17Mar2021. The patient reported that she had to go to the hospital for shortness of breath and her blood pressure dropped extremely low. She stated that they did tests and found out she had a blood clot in her lung. The patient reported that she came home Sunday evening and took the drip thing out and started her on blood thinner that started with an E (as reported). The patient stated that she was told her cardiologist told her to report this. The patient wanted to know if there have been any other reports called in about people calling in with blood clots. The patient was hospitalized due to events shortness of breath, blood dropped extremely low, and blood clot in her lung from 08Apr2021 to 11Apr2021. The patient reported that her blood pressure fluctuates. She stated that it was better than when she was in the hospital. They gave her the drip. The patient reported that her values did come down and this was the only thing they could go by. The outcome of the events shortness of breath and blood pressure dropped extremely low was recovering. The outcome of the events blood clot in her lung and blood pressure fluctuates was unknown.

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1269327	4/28/2021	CA		F	2/10/2021		<p>little pain in the arm; very tired and falling in and out of sleep; very tired and falling in and out of sleep; lymph nodes near the tonsils on her left side were protruding out; she gets sore throats a lot; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in Arm Left on 10Feb2021 10:40 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. Medical history included heart attack, two blood clots and anxiety. Concomitant medication was not reported. Patient previously took first dose of BNT162B2 for covid-19 immunization. On an unspecified date in 2021, the patient experienced little pain in the arm, very tired, falling in and out of sleep and lymph nodes near the tonsils on her left side were protruding out. Patient got 2nd Pfizer covid vaccine 10Feb2021, yesterday, tired, falling in and out of sleep, she read paper and knows tiredness is a reaction, she put her hand on her left side of neck which is also the injection side, Patient was notorious for sore throats, but, she had no sore throat. her lymph node felt like it was protruding out on unspecified date in 2021. She had some hot soup and it went away. She woke up this morning and it was there again. She had a couple of cups of hot tea, it was gone down. No pain to touch, it was really protruding, a good size. When I have hot stuff, it kind of shrunk it. I saw my health care provider on 11Feb2021, the day after her shot, she did lab work, but she didn't this when she saw her. She got this on Valentines Day. She took Coumadin and there are vegetables she cannot have, she like to had vegetable soup for the warmth. Once she had that the lump goes away. If she tells me to go to the hospital, she was going to go over the bridge. Caller was asked what she meant by that statement, Caller states, That was a figure of speech. She was too afraid to do that. Her throat was not red, she had looked. she had read the documentation, front and back, she was a worrier, since 27 years old, she can turn something into nothing. That was how her anxiety gets. She had a heart attack at age 49, and two blood clots years after. She hasn't been anywhere in over two years. She has done everything. She hasn't seen her family and grandkids. She goes to</p>

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1266038	4/28/2021			F			
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the market gloved up and masked up. No one has been in her house. She has been tested for COVID because she gets sore throats a lot. The COVID test have been negative. Nothing has ever shown. Caller states she is not going to the hospital. She has a new doctor. She doesn't know what to do. She wants to know if that is a side effect. The patient underwent lab tests and procedures which included sars-cov-2 test: negative. Outcome of the event lymph nodes near the tonsils on her left side were protruding out was recovered on unspecified date in 2021. Outcome of the other events was unknown. Information about lot/batch number has been requested.

Subsequently - a doctor discovered numerous blood clots in that leg; then a blood clot in one of her lungs; her left leg (she was inoculated on the left side) swelled up; it was painful; She is being treated but the lymphadenopathy has not subsided in her leg; she is now unable to walk without a cane; This is a spontaneous report from a contactable consumer. A 69-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number not reported) on an unspecified date in 2021 at single dose (inoculated on the left side) for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received the vaccine few weeks ago, in 2021, and within 3 hours, she recounted her left leg (she was inoculated on the left side) swelled up dramatically it was painful. Subsequently a doctor discovered numerous blood clots in that leg, then a blood clot in one of her lungs. She is being treated but the lymphadenopathy has not subsided in her leg and she was now unable to walk without a cane. The outcome of lymphadenopathy and unable to walk without a cane events was not recovered; outcome of the other events was unknown. Reporter asked if there were reports of blood clots that have been validated as a result of the Pfizer shot. Information on the lot/batch number has been requested.

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1267477	4/28/2021	NC	57	M	3/25/2021	4/8/2021	Left leg pain and swelling a couple weeks after shot one of Pfizer vaccine. After a few more days of leg not getting any better, saw Doctor who ordered Ultra sound of left leg and CT scan of lungs. Extensive DVT clot found in left leg, low density bi lateral pulmonary embolism in both lower lobes of lungs found from CT scan. Hospital stay for 2 days, Heparin given in hospital and now I'm on eliquis blood thinner. Had gotten my second Pfizer shot 3 days before admittance to hospital.
1266035	4/28/2021	NJ		U	2/1/2021		have developed 2 massive blood clots; This is a spontaneous report from a contactable consumer (patient). A patient of unknown gender and age received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) in Feb2021 at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. Historical vaccine included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) in Jan2021 for COVID-19 immunisation. Since then, the patient had developed 2 massive blood clots. The patient did not have a history of blood clots. The outcome of the event was unknown. There was no doubt this was related. No follow-up attempts are needed; information about lot/batch number cannot be obtained.
1266028	4/28/2021			F	3/9/2021		portal vein thrombosis; thrombocytopenia; This is a spontaneous report from a contactable consumer (former colleague). A 6-decade-old (in her 50s) female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot and expiry were not reported), via an unspecified route of administration on 09Mar2021 as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient received the first dose of bnt162b2 around 09Mar2021 and was hospitalized 2 weeks later. It was reported that the patient experienced portal vein thrombosis and thrombocytopenia in 2021. The patient died in 2021 due to portal vein thrombosis and thrombocytopenia at a State hospital. No autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Thrombocytopenia; portal vein thrombosis

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1266022	4/28/2021		34	F	4/3/2021	4/3/2021	<p>Blood clots; headache; nervousness; anxiety; This is a spontaneous report from a non-contactable consumer (patient). A 34-year-old female patient not pregnant received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 03Apr2021 09:00 (Lot Number: ER8733) as single dose (at the age of 34-years-old) for covid-19 immunisation. Medical history included allergies (known allergies: yes). Concomitant medications in two weeks prior to the vaccination included vitamin B complex (B-COMPLEX), magnesium (MAGNESIUM), chlorophyll (CHLOROPHYLL), vitamin D NOS (VITAMIN D NOS). Patient did not receive other vaccine in four weeks prior to the COVID vaccine. It was unknown if patient had COVID prior vaccination. Patient was not tested for Covid post vaccination. On 03Apr2021 patient experienced blood clots, headache, nervousness and anxiety. Events resulted in Doctor or other healthcare professional office/clinic visit. No treatment was required. Outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the available information, the known safety profile and the temporal association of BNT162B2 administration to the event of Thrombosis, a possible contribution of the drug to the event cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.</p>



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1265998	4/28/2021	NJ	33	M	3/26/2021	3/31/2021	Blood clot in right lung; This is a spontaneous report from a contactable consumer (patient). A 33-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EN6204; Expiration date was not reported) on the right arm on 26Mar2021 (18:45) as a single dose, with route of administration unspecified, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number and expiration date were not reported) on an unspecified date for COVID-19 immunization. On 31Mar2021, the patient had blood clot in the right lung. The event resulted into doctor or other healthcare professional office/clinical visit and emergency room/department or urgent care, and the patient was hospitalized on an unspecified date in 2021 for two days due to the event. The patient did not receive any treatment for the event. The outcome of the event, 'blood clot in the right lung', was recovered on an unspecified date in 2021 with lasting effects. The patient was not diagnosed with COVID-19 prior to vaccination, and had tested negative for COVID-19 nasal swab test on 01Apr2021.

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1265997	4/28/2021	GA	53	M	3/28/2021	4/10/2021	This is a spontaneous report from a contactable consumer, the patient. This 53-year-old male patient reported that he received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: UNKNOWN) via an unspecified route in the left arm on 28Mar2021 at 12:00 (at the age of 53-years-old) as a single dose for COVID-19 immunization. Medical history was reported as healthy. The patient had a known allergy to amoxicillin/clavulanic acid (AUGMENTIN). The patient did not receive any other vaccines within four weeks. The patient did not have COVID prior to the vaccination. Concomitant medication included over the counter (OTC) product (unspecified). Ten days after (as reported), on 10Apr2021, the patient had blood clot in retina of eye which caused temporary blindness. The events resulted in: Doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care. The patient was doing additional testing to see what damage occurred (test name and results not provided). The patient was not treated for blood clot in retina of eye and temporary blindness. The clinical outcomes of blood clot in retina of eye and temporary blindness was unknown. The patient was not tested for COVID-19 post vaccination. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

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1265987	4/28/2021		35	F	4/9/2021	4/13/2021	4 days later minor blood clot in my finger (not sure it is drug related); Bruise at site of injection; This is a spontaneous report from a non-contactable consumer (patient). A 35-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 09Apr2021 (Batch/Lot number was not reported) as SINGLE DOSE for COVID-19 immunization. Medical history and concomitant medications were not reported. On 13Apr2021, the patient had bruise at site of injection and 4 days later (17Apr2021) minor blood clot in her finger was noted (not sure it was drug related). The patient had no COVID-19 prior vaccination and not tested post vaccination. The patient requires doctor or other healthcare professional office/clinic visit for the events and unknown if treatment was received. The patient had not yet recovered from the events. No follow up attempts are possible. information about lot/batch number cannot be obtained

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1265986	4/28/2021	NC	62	F	3/30/2021	3/30/2021	<p>Doppler showed a blood clot; Pain behind her cast; Really bad case of diarrhea; Swelling in her knee; Leg was swelling/right shoe was tight; Lower extremity venous ultrasound right calf vein acute deep vein thrombosis of the right lower extremity involving the popliteal vein; It was tender on her right leg on the left side of the tibia/It is very tender to the touch; Red mark on her leg with a little nodule; Red mark on her leg with a little nodule; Calf pain; This is a spontaneous report from a contactable consumer. A 62-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EP7533; Expiration date was not reported) on the right arm on 30Mar2021 as a single dose, with route of administration unspecified, for COVID-19 immunization at the clinic. Medical history included pain and headache. Concomitant medications included paracetamol (TYLENOL ARTHRITIS) for pain; hydrocodone for pain; amitriptyline for headache; and ongoing paracetamol (TYLENOL EXTRA-STRENGTH) for pain. The patient had previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EN6208; Expiration date was not reported) on the right arm on 11Mar2021 (when the patient was 62 years old) for COVID-19 immunization. On 07Apr2021, the patient's doppler showed a blood clot. On 30Mar2021, the patient had a really bad case of diarrhea; swelling in her knee; and leg was swelling/right shoe was tight. On 02Apr2021, the patient had pain behind her cast. On an unspecified date in 2021, the patient's lower extremity venous ultrasound showed right calf vein acute deep vein thrombosis of the right lower extremity involving the popliteal vein; was tender on the right leg on the left side of the tibia that was very tender to the touch; had a red mark on her leg with a little nodule; and had calf pain. The events had resulted into an emergency room visit and physician's office visit. The patient had received treatment for the events, 'blood clot', 'lower extremity venous ultrasound right calf vein acute deep vein thrombosis of the right lower extremity involving the popliteal vein', 'leg was swelling/right shoe was tight', 'pain behind her cast' and 'tender on her right leg on the left side of the tibia that was very tender to the touch'. The outcome of the events was recovered on 30Mar2021 for 'really bad case of diarrhea'; was recovering for 'leg</p>

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1265981	4/28/2021	NJ	46	F	4/1/2021	4/10/2021	<p>was swelling/right shoe was tight', 'pain behind her cast' and 'red mark on her leg with a little nodule'; and was unknown for all the other events.</p> <p>This is a spontaneous report from a contactable pharmacist (patient's husband). A 46-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in left arm on 01Apr2021 (lot number: ER8733) at the age of 46 years old, as single dose for COVID-19 immunization. The patient's medical history was not reported. Concomitant medication included desogestrel, ethinylestradiol (ISIBLOOM) taken for birth control from an unspecified start date and ongoing. On Saturday, 10Apr2021, she was fine, but she had some pain on the left side of her body. On Sunday (11Apr2021), the pain was much "much" worse, and her breathing was affected. On Monday (12Apr2021), she had the same symptoms and was taken to the Emergency Department for her problems breathing. On 13Apr2021, she had blood clots, 2 of them in both lungs. She is on pain medication and it is improving for her. The only medication she is taking is birth control pills. She has been taking them for years with no complications. The reporter added not long ago, she was in the doctor for a physical and all was fine. The patient was hospitalized due to the events and was still admitted. The events resulted in emergency room visit. The patient was recovering from the events. Event assessment by the reporter for the events blood clot in both lungs, problem breathing and left side pain was reported as related to the Pfizer COVID-19 vaccine. Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.</p>

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1266075	4/28/2021	NY	40	M	4/12/2021	4/16/2021	Multiple blood clots in the left leg had to be submitted to the Emergency Room at the hospital for immediate treatment; This is a spontaneous report from a non-contactable consumer. A 40-years-old male patient received 1 dose of bnt162b2 ((PFIZER-BIONTECH COVID-19 VACCINE) lot number: ER2613 via an unspecified route of administration, in arm left on 12Apr2021 at the age of 40 years as SINGLE DOSE for covid-19 immunization. The patient medical history was not reported. There were no concomitant medications. The patient experienced multiple blood clots in the left leg and he had to be submitted to the emergency room at the hospital for immediate treatment on 16Apr2021 12:00 with outcome of recovering. The patient was hospitalized for 2 days and was treated with unspecified treatment. Covid test post vaccination: Nasal Swab on 20Apr2021 result Negative No follow-up attempts are possible. No further information is expected.

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1265973	4/28/2021	CA	72	M	2/3/2021	2/1/2021	Blood clot in right lung; Sore left arm at injection site; Shortness of breath; This is a spontaneous report from a contactable consumer (patient). A 72-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose intramuscular, administered in the left upper arm on 03Feb2021 at 09:00 (batch/lot number: EL3248) as a single dose for COVID-19 immunisation (prevention). Medical history included rheumatoid arthritis from Dec2009 to an unknown date (takes daily pills for rheumatoid arthritis), squamous cell lung cancer early stage from Aug2018 to an unknown date, lung surgery to remove small portion of that and went on chemo in Aug2018, skin cancers prior to getting the vaccine, reading glasses (he needed prior to getting vaccine), blood pressure (abnormal) (takes blood pressure medication; takes daily pills). Family medical history was reported as none. Concomitant medications included nivolumab (OPDIVO) taken for squamous cell lung cancer early stage from 17Jan2019 to an unspecified stop date (getting it every 4 weeks for 2 years and 3 months; the bag was 480 ml); and unspecified blood pressure medication and rheumatoid arthritis medication. The patient experienced blood clot in right lung on 25Feb2021, sore left arm at injection site on 03Feb2021 and shortness of breath on Feb2021. The patient had the first Pfizer COVID vaccine on 03Feb2021 and second one on 01Mar2021. He did not really have any special events but then he had a CT scan on 23Feb2021, which was about 20 days after first shot. When he went in for doctor's meeting a couple of days later, they said he had a blood clot in right lung. He later stated he was not positive it was in the right lung. He told his doctor that he just got the shot, but they said they had not heard of any reports from Pfizer of people getting blood clots in their lungs after getting it. He thought about reporting then, but did not. He has no evidence that the blood clot in his lung was related to the vaccine. He was also a lung cancer patient and was on an immune therapy drug nivolumab from (name). He has been on it for over 2 years and started Jan2019. He was diagnosed with cancer back in Aug2018. It was squamous cell lung cancer early stage. He had lung surgery to remove small portion of that in Aug2018 and went on chemo. On 17Jan2019, he started on nivolumab immune therapy drug. Fortunately, it worked extremely well. He

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immediately started recovering and was feeling better. The last few CT scans indicated he had no sign of disease. It does not mean he was cured, but was healthy otherwise. The nivolumab spurred his immune system to eat the cancer cells. It stimulates your immune system. It has been a pretty successful drug and has been on the market for about 5-6 years. He and his wife both got shot on same date. The word on the street was that you should ask for Pfizer because it seems to have less side effects that people can get for vaccines. Pfizer's reputation has been known for having less common serious side effects. He had a sore arm and it went away about a day later. They prescribed rivaroxaban (XARELTO), a blood thinner, for his blood clot which he went on and got on a day or two later. He was hoping it was gone. He feels better. At the time, he did not know he had the blood clot. He visits his doctor for treatment for nivolumab every 4 weeks and every 4 months, they do a CT scan. At his last visit, he reported that he was still fine but lately experienced some shortness of breath. It was occasional and it comes and goes and was not all the time. He plays golf and noticed the shortness of breath during his game. He quit a couple of holes early and did not want to take any chances. The doctor later told him that a blood clot in your lung can contribute to shortness of breath. When he started rivaroxaban it was 2 pills a day for about 2-3 weeks and it was a starter dose. It was a little more in the beginning. He thinks it was 10 mg twice daily and then it went to 1 tablet a day for the last week at dinner and now it was 15 mg once daily. The two combined were greater to jump start you. It was not a special dose. He then corrected dose to 15 mg rivaroxaban twice daily for the starter dose for 2-3 weeks and one tablet daily for the last week of the starter. Then he switched to maintenance dose of 20 mg daily. He did not have a lot or expiration for the previous dose of 15 mg. The lot and expiration for the 20 mg was unknown because he believes the label was covering it. He stated he needed to get his glasses to read bottle. They were reading glasses and he needed prior to getting vaccine. Nothing has changed with his vision. He was hoping to get off of them and has never been on them. He hopes it was not a long term thing. Second dose was given 01Mar2021, Pfizer COVID vaccine, BNT162B2, expiration was unknown. Injected in left upper arm in the



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muscle (intramuscularly). Second dose administered at 09:20-09:30. He takes blood pressure medication and did not see it was relevant. Takes daily pills for that and rheumatoid arthritis. In the past, he had a few skin cancers. All were prior to getting the vaccine. They were some squamous and basal cell. He has had nothing in quite a while. Nivolumab was helping skin issues. Squamous cell skin cancer was the same family as lung cancer. He did not have a lot of expiration for the nivolumab. He received it by IV infusion. Shortness of breath was mid Feb2021, on and off for a couple of weeks prior to doctor visit on 25Feb2021. He usually does not have much to report and mentioned it. It did not prevent him from doing anything and was not debilitating. One of his fellow golfers said he was huffing and puffing and he just poo poed it away. He had a flu vaccine in Oct2021 (as reported). No further details provided. Blood clots in right lung morning time, unknown time. Sore left arm at injection site noon - to late in the day of the shot. Shortness of breath - sometimes he feels it in the morning or midday if active. He cannot say a straight time. No emergency room (ER) or physician's office visit required. Vaccination facility type was clinic. Not a military facility. On 25Feb2021, normally scheduled office visit and did the CT scan on 23Feb2021. He went in separate for that. He had the treatment on Thursday. He has another CT scan scheduled in third week of May2021. They were doing it early because of the blood clot. Hopefully, it was gone by then. Prior vaccinations (within 4 weeks): 1st and 2nd Pfizer COVID vaccine as mentioned above. CT scan on 23Feb2021, positive for small blood clot in single vessel in what he thinks was his right lung. All of his previous trouble with the lung cancer was in his right lung. He has never heard of anyone else having blood clots related to the Pfizer COVID vaccine. He does not think he has heard of any and wanted to know if there were any. He knows there was something in the press about the (name) vaccine with blood clots. When you do 120 million and have a handful of people, you may have a few things. He did not have any information on the people for (name) to report on. He knows of others who have had the vaccine and no one had any symptoms. No further details provided. The outcome was recovered on 04Feb2021 for the event "sore left arm at injection site"; recovering for the event

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1265958	4/28/2021	OH	34	F	2/26/2021	3/17/2021	<p>"shortness of breath"; and unknown for the event "blood clot in right lung".</p> <p>Developed blood clot in right leg (behind knee); This is a spontaneous report from a contactable consumer (patient). A 34-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not provided), via an unspecified route of administration, administered in Arm Left first dose on 26Feb2021 11:15 at single dose for covid-19 immunisation. The patient's medical history included Developed blood clots after twin c section. The patient has been off blood thinners for 2.5 years. The patient was not pregnant at time of vaccination. The patient's concomitant medications included venlafaxine hydrochloride (EFFEXOR) and vitamin d [vitamin d nos]. On 17Mar2021, the patient Developed blood clot in right leg (behind knee). The patient was put on blood thinners as treatment. The events cause the patient emergency room visit and physician office visit. The outcome of the event was recovering. Information on the lot/batch number has been requested.</p>

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1265948	4/28/2021	TX	52	F	3/20/2021	4/9/2021	<p>Pulmonary embolism; Shortness of breath; she tested positive for Covid; she tested positive for Covid; This is a spontaneous report from a contactable consumer (patient) via Pfizer sponsored program. A 52-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 52 years of age), dose 1 via an unspecified route of administration on 20Mar2021 12:00 (Batch/Lot Number: ER8727; Expiration Date: 31Jul2021) as a single dose for COVID-19 immunisation. Medical history included allergies wherein she mentioned that her allergies were acting up so she took Tylenol 500mg, 1 pill; and insomnia. Concomitant medications included paracetamol (TYLENOL) taken for hypersensitivity; cetirizine hydrochloride, pseudoephedrine hydrochloride (ZYRTEC DUO) taken for hypersensitivity, start and stop date were not reported; and dextromethorphan hydrobromide, doxylamine succinate, ephedrine sulfate, ethanol, paracetamol (NYQUIL) taken for insomnia (it helps her sleep at night), start and stop date were not reported. It was reported that the patient already received 1st dose of the Pfizer-BioNTech Covid-19 Vaccine and was scheduled to receive the 2nd dose on 17Apr2021. Yesterday, she tested positive for Covid and got hospitalized. She said she got discharged today and is now on medication which includes a blood thinner. She wanted to know if she needed to reschedule her 2nd dose, and how. It was clarified that the patient had Covid test on 12Apr2021 with Positive result. She mentioned that she was reading paperwork and it said something about to let her vaccination provider know about medical conditions, allergies, bleeding or if she take blood thinners. She stated that she was prescribed blood thinners yesterday evening and she was going to be taking them for 3-6 months. She questioned if it was going to affect if she takes the shot on Saturday. She added that she will be on the blood thinner 5-6 days by then. She stated that she was tested for Covid in the hospital that she went in with shortness of breath and they did the test yesterday. She had shortness of breath Saturday (09Apr2021) and she went to the ER on 12Apr2021 and was admitted and was released 13Apr2021. She stated that she was diagnosed from being discharged with blood clots and she is now on a blood thinner and a steroid pill for inflammation. She</p>

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clarified that she was diagnosed on 12Apr2021 with pulmonary embolism and was put on ELIQUIS and will take it for the 1st 7 days, 2 tablets twice a day and they are 5mg each and then she will take 1 tablet twice a day until she follows up with her primary doctor and will either stop taking it at 3 months or 6 months. She will also be taking Dexamethasone 2mg tablet taking 3 tablets once a day for 8 days. She stated that they did a C scan to identify blood clots. There was no other vaccine administered on the same date the Pfizer vaccine was given. The outcome of events was unknown.

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1265944	4/28/2021	CA	42	F	1/28/2021	1/29/2021	DVT; PE; This is a spontaneous report from a contactable physician. A 42-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly in the left arm, on 28Jan2021 (at the age of 42-years-old) as a single dose for COVID-19 immunisation. Medical history included hypertension (HTN) and fibroids. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had no known allergies. Concomitant medication included amlodipine besilate (MANUFACTURER UNKNOWN). The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly in the right arm, on 07Jan2021 (at the age of 42-years-old) for COVID-19 immunisation. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced deep vein thrombosis (DVT) and pulmonary embolism (PE) on 29Jan2021, which caused hospitalization for 5 days from an unspecified date to an unspecified date. Therapeutic measures were taken as a result of the events, which included direct oral anticoagulants (DOAC). The clinical outcome of DVT and PE was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: Based on the information currently available, a possible contributory role of the suspect vaccine BNT162B2 or comirnarty in triggering the onset of Deepvein thrombosis,pulmonary embolism cannot be excluded.But also consider relevant medical history of hypertension and fibroids tendency to form blood clots and concomitant medications also have possible contributory role. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1265912	4/28/2021	NC	60	M	1/18/2021	3/8/2021	DVT; This is a spontaneous report from a contactable physician (patient). This 60-year-old male patient received 2nd dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number Ek4176) at single dose via an unknown route in left arm on 18Jan2021 for Covid-19 immunization. Medical history included factor 5 leiden and prior DVT. Patient did not have Covid prior vaccination. Patient had no known allergies. Concomitant drug was not provided. Historical vaccine included 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Eh9899) on 26Dec2020 for Covid-19 immunisation. On 08Mar2021, patient experienced DVT which resulted in doctor or other healthcare professional office/clinic visit. Treatment included blood thinner. Outcome of the event was unknown. Patient did not have Covid tested post vaccination.; Sender's Comments: Based on the information currently available, the event deep vein thrombosis was most likely associated with the patient's underlying medical condition and was unrelated to Bnt162b2 vaccine. Case will be re-assessed upon the additional information provided. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

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1265873	4/28/2021	PA		M			<p>STROKE; BLOOD CLOT IN LEG; This spontaneous report received from a consumer concerned a 51 year old male. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included the patient was healthy with no health issues. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose, start therapy date were not reported, 1 total administered for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. It was reported that on an unspecified date in 2021, the patient started with symptoms after 13 days of vaccination. The patient woke with leg pain That morning, he got in the vehicle to go to work and pulled over due to heaviness in his left arm and slurred speech. An ambulance was called and they took him to the emergency room. From there he was life flighted to another hospital and was continued with laboratory tests. Laboratory data included: doppler ultrasound (NR: not provided) not reported, MRI (magnetic resonance imaging) (NR: not provided) not reported, scan (NR: not provided) not reported and other tests. It was due to the blood clot in his leg that caused him to suffer a stroke. He spent days in the hospital and had to wear a heart monitor for two weeks. He was on blood thinners until further notice to prevent this from happening again. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the blood clot in leg and stroke was not reported. This report was serious (Hospitalization Caused / Prolonged).;</p> <p>Sender's Comments: V0: This case concerns a 51 year-old male with no prior medical issues who was hospitalized for a stroke and blood clot in his leg 13 days after receiving the Janssen Covid-19 vaccine. Concomitant medications, family history, and social history were not reported. Thirteen days post-vaccination, the patient awoke with leg pain. While driving to work, he experienced heaviness in his left arm and slurred speech and pulled his car over. An ambulance took him to a local hospital and from there, he was air-lifted to another hospital where doppler ultrasound, MRI, and other unspecified tests were performed. He spent an unspecified number of days in the hospital and wore a heart monitor for 2 weeks. He was treated with blood thinners. Per the reporter (patient's daughter), the blood</p>

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clot caused the stroke. Outcome was not reported. Based on the available information, the relationship with Janssen Covid-19 vaccine is considered indeterminant. More information (e.g. platelet count, D-dimer, fibrinogen, anti-platelet factor 4 antibodies, medical records) is being sought.



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1265810	4/28/2021	PR	61	M	3/21/2021	3/1/2021	sweating; felt cold/intense cold even in his bones; He was told by the professional health care that he had small clots in his blood; death cause: Medication; arm started to sore; Doctor identified he had DVT; her husband during that night was not able to sleep; He started having fever; This is a spontaneous report from a contactable consumer (patient's spouse). A 61-year-old male patient received bnt162b2 (BNT162B2), via an unspecified route of administration on 21Mar2021 09:00 (Batch/Lot number was not reported) as single dose f(at the age of 61-year-old) or COVID-19 immunisation. Medical history included dialysis, diabetes mellitus, known allergies: A7, Penicillin, Aspirin, Iodine, Povidone, Pepcid, dyes, Iodine allergy. The patient's concomitant medications were not reported. The patient previously took Aspirin, povidone and pepcid ac and experienced drug hypersensitivity with all. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient experienced death cause: medication on 18Apr2021, he was told by the professional health care that he had small clots in his blood in Mar2021, felt cold/intense cold even in his bones on 21Mar2021, sweating on 26Mar2021, her husband during that night was not able to sleep on 21Mar2021, he started having fever on 21Mar2021, arm started to sore and DVT on 29Mar2021. The patient was hospitalized for he had small clots in his blood, felt cold/intense cold even in his bones, sweating for 27 days. The event DVT was medically significant. The course of events was as follows: After getting the vaccine in 21Mar2021 her husband during that night was not able to sleep. He started having fever and felt cold. Days later he continued with the symptoms. On 26Mar2021 after vaccination he had dialysis same day in the afternoon. When arriving home the person notifies symptoms of intense cold even in his bones and then he started to sweat excessively on 26Mar2021 (Friday). The reporter decided to take her husband to the emergency room on 28Mar2021 (Sunday) where he had a general checkup. He was told by the professional health care that he had small clots in his blood. After some time he had health complications where they had suggested to amputate some of the limbs because of this, the reporter alleges those complications were due to the vaccine. On Monday 29Mar2021 same symptoms reappeared and he was admitted to Hospital. Had a blood test and notified to

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1266045	4/28/2021	CO	50	F	3/27/2021	4/7/2021	<p>health professional that blood presents small clots. His arm started to sore severely after the sample. Doctor identified he had DVT. Doctor decided to proceed with various medications. Patient received treatment and he was injected: Percose, Morphine, Benadryl, Triphetarin for blood clot reduction. The patient underwent lab tests and procedures which included blood test: blood clot in Mar2021, Sars-cov-2 Nasal swab test: negative in Mar2021 post vaccination. The patient died on 18Apr2021. It was not reported if an autopsy was performed. The outcome of death cause: medication was fatal, of the other events was unknown. Information about the lot/batch number has been requested.; Reported Cause(s) of Death: death cause: Medication</p> <p>15cm Blood clot in left leg - lower calf.; Superficial vein prominence; This is a spontaneous report from a contactable consumer (patient herself). This 50-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number ER8732), via an unknown route in the left arm, on 27Mar2021 at 14:45 (at the age of 50-year-old) at single dose for COVID-19 immunisation, administered at hospital. Relevant medical history included Factor V Leiden and varicose veins. The patient did not have allergies. The patient did not have COVID-19 before vaccination. Relevant concomitant medications included acetylsalicylic acid (ASPIRIN), levothyroxine sodium and Women's multivitamin (unspecified). On 07Apr2021, the patient presented 15 cm blood clot in the left leg-lower calf and superficial vein prominence. The events required a physician office visit. An ultrasound was done but results were not provided. Therapeutic measures taken as result of the events included enoxaparin sodium (LOVENOX) injections for 14 days. Post-vaccination COVID test was not performed. The patient was recovering from the events.</p>

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1266051	4/28/2021		69	F			<p>blood clot; lymphadenopathy; unable to walk without a cane; her left leg swelled up dramatically; painful leg; This is a spontaneous report from a contactable consumer. A 69-year-old female patient received her first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date (at the age of 69-years-old) as single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. It was reported that patient received Pfizer shot a few weeks before reporting. Within 3 hours her left leg (she was inoculated on the left side) swelled up dramatically - - it was painful. Subsequently - a doctor discovered numerous blood clots in that leg; then a blood clot in one of her lungs. She was being treated but the lymphadenopathy has not subsided in her leg and she was now unable to walk without a cane.</p> <p>Lymphadenopathy was not resolved; the outcome of the other events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.</p>

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1266057	4/28/2021	OH	64	F	3/10/2021	3/1/2021	<p>strokes signs; Two blood clots in the veins in legs; This is a spontaneous report from a contactable consumer. A 64-year-old female consumer (patient) reported that she received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number EN6199/EN6207 (as reported)) intramuscular into the left arm on 10Mar2021 (at the age of 64-years-old) at single dose for COVID-19 immunization. She received the second dose of BNT162B2 dose on 31Mar2021 (lot number unknown). Medical history included high blood pressure and GERD. Concomitant drugs included Toprol 25mg, oral , twice a day for blood pressure stated "in Feb some time she don't know" and Protonix 40mg, oral twice a day for years for GERD. The consumer reported that 'she got her first vaccine and she has had the strokes signs". Further she reported she got her first vaccine dose, then she had leg pain, she went to see the doctor and ordered a doppler. She was put on blood thinners and three days later she got two blood clots in the veins of her legs, right. On 20Mar2021, her leg pain went pretty severe since I had the blood clot, when I got the second shot, it was still there. On 27Mar2021 she started treatment receiving Eliquis 5mg, twice a day for the blood clot and she did take a Physical therapy. When she got the second vaccine dose on 31Mar2021 she was on blood thinners. At the time of reporting the outcome of the event was reported as 'hasn't gotten better, it's the same not better not worse.</p>

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1265982	4/28/2021	MO	76	F	3/17/2021	3/29/2021	Blood clot in her lower abdominal area; had the worst pain through her side that ran down her left leg and to her ankle; had the worst pain through her side that ran down her left leg and to her ankle; nerves are all tangled up; This is a spontaneous report from a contactable consumer (patient). A 76-year-old female patient received the second dose of bnt162b2 (BNT162B2, Solution for injection, Lot Number: EN6207), via an unspecified route of administration, administered in Arm Right on 17Mar2021 13:50 (at 76-years-old) as single dose for COVID-19 immunisation. The vaccine was administered at a hospital. It was not administered at a military facility. Medical history included hip replacement four years ago in 2017 (First right then 2 months later left) and knee replacement six years ago in 2015 (both 2 months apart). There were no concomitant medications. The patient previously received the first dose of bnt162b2 (BNT162B2, Solution for injection, Lot Number: EN6203), administered in Left Arm on 25Feb2021 (at 76-years-old) for COVID-19 immunisation and experienced bad headaches. The patient received the second dose of vaccine on 17Mar2021. On 29Mar2021, she was not hurting and went to brunch with friends. Afterwards (on the same date, 29Mar2021), she was sitting and got the worst pain through her side that ran down her left leg and to her ankle. She drove herself home but was in such misery. She went to the emergency room the next day, on 30Mar2021, wherein she had a CT (computerized tomography) scan that showed a blood clot in her lower abdominal area. She was taking pain medication every 6 hours, or she could hardly stand it. On 08Apr2021, she went back to the emergency room because she could hardly stand it. She was kept in observation status but was not admitted. She was scheduled to have another CT scan on 06May2021. She is not sure what they will do because the nerves are wrapped around it. She also mentioned that her doctor wants to do a biopsy. The pain was also running down to her ankle. She stated that she has had both of her hips replaced in the past. She added that her doctor will do an MRI (magnetic resonance imaging). He will put in a drain if it has not shrunk. The doctor can't do anything because the nerves are all tangled up (2021). As corrective treatment, the patient was taking pain medication for the blood clot and pain through her side that ran down her left leg and to her

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							ankle. Outcome of nerves are all tangled up was unknown, while outcome of the other events was not recovered.
1284975	4/28/2021		85	F	3/18/2021	4/4/2021	My mother Received vaccine on 3/18/21. Approximately the week of 4/4/21 she started to experience shortness of breath and got progressively worse. On 4/9/2021 she was admitted to hospital and diagnosed with extensive clot burden within the interlobal pulmonary arteries bilaterally as well as upper lobar branches. Venous Doppler was a performed on 4/10/21 blood clots found in both lower legs Please note that I attempted several times to report this to Pfizer, I was disconnected once and was on hold for over hour with the same automated message replaying that there were 6 callers ahead of me. There was no option to leave a message for a return call to share what I feel is important safety information.
1267579	4/28/2021	NE	65	F	4/8/2021	4/19/2021	4/19/2021: Woke up in the middle of the night with an achy arm. Had this for a week. Went to chiropractor as she thought it was neck trouble. Chiropractor states arm is swollen and see MD. MD sent patient for ultrasound and blood clot confirmed in right arm pit. Patient started on eliquis.
1269842	4/28/2021	UT		M		4/11/2021	Pain in chest beginning April 9, 2021. Entered the emergency room with blood clot in the lungs on April 11. Last dose Moderna vaccine received March 25, 2021. No known prior blood clot issues or causative health issues. Suspected prior infection with Covid 19 due to symptoms of illness approximately June 2020, but not confirmed with testing or afterward or with antibodies. Blood clot confirmed with CT Scan in hospital

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1269415	4/28/2021	GA	64	F	4/6/2021	4/8/2021	? Tuesday, April 6th ? Patient receives the 2nd Pfizer vaccine shot ? Thursday, April 8th ? Patient is sick with vomiting and diarrhea ? Friday, April 9th ? Patient is delirious and still sick with vomiting and diarrhea. She is also has pain in her stomach. An ambulance is called to take her to the hospital. The hospital determines her white blood count is elevated, indicating an infection. Blood sugar is very high ? approximately 400. Covid test is negative. She is restless upon arrival. She tries to climb out of bed continuously. She is restrained. o Saturday, April 10th ? Patient is running a fever and is in pain. She is also confused and doesn?t recognize her oldest sister. Meds are administered to handle both items. (Toradol?). Blood sugar around 200. She continuously counts and calls for Mother and Father. Patient continues to be restless o Sunday, April 11th - at request of family, a CT scan is done of her stomach and abdomen. Nothing is found. Potassium was at 3.2 (normal is 3.5) so she received an IV drip to help with potassium levels. Sugar ? 206. Later drops to 176. Patient calms down some. She is still confused and doesn?t recognize her oldest sister. ? Monday April 12th ? the hospital attempts to do an MRI, but patient panics. This is a closed MRI and her 1st husband died in one. The MRI isn?t done. ? Tuesday, April 13th ? she is asked by the doctor to state her name and wiggle her toes. She complies. Doctor orders speech therapy. She is sedated for an MRI and a CT scan. Both are successfully completed. She sleeps for the rest of the day. Blood sugar ? 274 @ 5:09pm. ? Wednesday, April 14th ? Patient was asleep all day. Most of the day she isn?t responsive when nurses come in and do things like take blood. She normally responds even if she is asleep. Around 5pm she starts to respond and make noises; she briefly opens her eyes then falls asleep. She continues to run a temperature. ? Thursday, April 15th ? Patient is asleep most of the day. She is responsive when nurses do things like take blood. A spinal tap is performed. There was mention of dementia. Hospital is sharing little information, varying from she is retreating into herself vs. something worth isolating is going on. Temp was 102.3 at 7:37, but later dropped to 99.3 without meds. Dr. (neurologist) provides an update to the family. Tests so far are negative. EEG showed sleeping brain (she was asleep during test). MRI showed

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nothing. Spinal tap negative so far. No infection or anything has shown up. Orders another EEG and MRI ? Friday, April 16th ? Patient tried to open her eyes. ? Saturday, April 17th ? a met code was called on her and she was moved to ICU. A circulation issue was found in right leg. Occlusion was really bad. Initially the doctor was concerned about blood clots. None were found, just swelling. Pressure was relieved. Blood pressure issues. She was put on 2 blood pressure meds, at least. She was dehydrated and acidic. Diabetic ketoacidosis was mentioned. A cytokine storm was expected. ? Sunday, April 18th ? blood pressure not stable. She was put on dialysis. Peripheral circulation was worse. ? Monday, April 19th ? she coded around 5am. Doctors were trying to save her. She passed away about 30 minutes later .



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1269279	4/28/2021	FL	73	F	4/2/2021	4/1/2021	<p>DVT (blood clot) in leg/her leg started to hurt; Dizziness; Headache; Fever; Chills; Didn't feel well; felt bad; had to go to bed for 3 days; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (DVT (blood clot) in leg/her leg started to hurt) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Blood pressure abnormal. On 02-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Apr-2021, the patient experienced VACCINATION COMPLICATION (Didn't feel well), PYREXIA (Fever) and CHILLS (Chills). On 08-Apr-2021, the patient experienced DIZZINESS (Dizziness) and HEADACHE (Headache). In April 2021, the patient experienced FEELING ABNORMAL (felt bad) and DECREASED ACTIVITY (had to go to bed for 3 days). On 18-Apr-2021, the patient experienced DEEP VEIN THROMBOSIS (DVT (blood clot) in leg/her leg started to hurt) (seriousness criterion medically significant). On 04-Apr-2021, PYREXIA (Fever) and CHILLS (Chills) had resolved. At the time of the report, DEEP VEIN THROMBOSIS (DVT (blood clot) in leg/her leg started to hurt), DIZZINESS (Dizziness), FEELING ABNORMAL (felt bad) and HEADACHE (Headache) outcome was unknown and VACCINATION COMPLICATION (Didn't feel well) and DECREASED ACTIVITY (had to go to bed for 3 days) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The patient did not feel well for a couple of days. The events, fever and chills lasted for a day and half. On 07 Apr 2021 or 08 Apr 2021, the patient felt bad, experienced headaches and dizziness, and she had to go to bed for 3 days. On 13 Apr 2021, the patient's leg started to hurt and she ended up going to hospital. On 18 Apr 2021, the patient was diagnosed with DVT in her leg. Concomitant medications reported included drug unspecified for blood pressure. Treatment for the event included blood thinners.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a</p>

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1269286	4/28/2021		38	M		4/25/2021	causal relationship cannot be excluded. However, Further information has been requested.  Clots; This spontaneous case was reported by a health care professional (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Clots) in a 38-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Apr-2021, the patient experienced THROMBOSIS (Clots) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 25-Apr-2021 due to THROMBOSIS. At the time of the report, THROMBOSIS (Clots) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications reported. No treatment information provided.; Sender's Comments: Limited information regarding the event has been provided at this time and a causal relationship cannot be excluded
1269251	4/28/2021	CA	51	F	4/9/2021	4/10/2021	Severe arthritic pain in full body. Notably in left calf. Negative ultrasound for blood clot in leg. Intermediate burning sensation in limbs. Prednisone issued by Rheumatologist for 6 days beginning 4/27/21.

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1269156	4/28/2021	CA	74	F	3/9/2021		NOSE BLEED; BODY ACHES; HEADACHE; FATIGUE; NAUSEA; DIZZINESS; WARM FEELING IN THE VEINS OF THE PALMS AND FEET; SEVERE CHILLS; This spontaneous report received from the patient concerned a 74 year old mixed race female. The patient's height and weight were not reported. The patient's concurrent conditions included penicillin allergy. The patient took no concomitant medications. The patient received COVID-19 vaccine Ad26.CoV2.S (suspension for injection, route of admin not reported, batch number: 1805020 expiry: 25-MAY-2021) dose was not reported, 1 total, administered on 09-MAR-2021 to left arm for prophylactic vaccination. On 09-MAR-2021, the patient experienced severe chills at around 21:00, 5 hours post vaccination. On 10-MAR-2021 around 04:30, the patient woke up with a pounding headache, chills, body aches. During day the patient also felt fatigue, nausea, dizziness and a feeling of warmth in the veins of her palms and feet. It was reported that the symptoms disappeared on the morning of 11-MAR-2021, which was 2 days post vaccination. It was reported that about 30 minutes prior to call on reporting day of 25-APR-2021, the patient blew her nose and she said a little bloody clot came out, followed by a nose bleed lasting about 30 minutes. The patient reported that she never got nose bleeds and she had no fever, shortness of breath or chest pain. The action taken with COVID-19 vaccine Ad26.CoV2.S was not applicable. The patient recovered from dizziness, warm feeling in the veins of the palms and feet, body aches, severe chills, fatigue, nausea, and headache on 11-MAR-2021, and nose bleed on 25-APR-2021. This report was non-serious.

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1269148	4/28/2021	NM		F	4/8/2021		<p>ELEVATED D-DIMER; SHORTNESS OF BREATH; HEADACHE; CHEST PAINS; DECREASED APPETITE; FEVER; This spontaneous report received from a physician concerned a 25 year old female. The patient's height, weight and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration, dose and batch number were not reported) administered on 07-APR-2021 for prophylactic vaccination. Batch number will be requested via follow up. Concomitant medications included unspecified oral contraceptives. On 08-APR-2021, the subject experienced shortness of breath, headache, chest pains, fever, and decreased appetite. Physician saw the patient on 14-APR-2021 and ordered D-dimer which came back at "0.80" and again on 20-APR-2021 which came back "0.82" (units and normal range unspecified). Physician reported that the patient's platelet count had not been done yet, but the d-dimer was a little elevated and given her chest pains, he wanted to evaluate for a blood clot and possibly order CT (computed tomography) scan of her chest. The physician did mention VAERS report filed case # 446427. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from headache, shortness of breath, and chest pains, and the outcome of decreased appetite, fever, and elevated d-dimer was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This case concerns a 25-year-old female who had elevated d-dimer test results 7 days after receiving the Janssen Covid-19 vaccine. Full medical history was not provided. Concomitant medications included unspecified oral contraceptives. The day after vaccination, the patient experienced shortness of breath, headache, chest pains, fever and decreased appetite. Seven days post-vaccination, she went to see her physician who ordered a d-dimer test which came back elevated at 0.80 (normal range not reported). Repeat d-dimer test 6 days later came back at 0.82. A platelet level had not been checked, nor other diagnostic tests to evaluate for possible thrombosis. As of the the time of this report, the outcome was unknown. Based on the available information, the relationship with Janssen Covid-19 vaccine is considered unclassifiable. Further information (e.g. full medical history, social history, family</p>

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1269146	4/28/2021		52	M	4/1/2021		<p>history, CBC, doppler ultrasound, anti-platelet factor 4 antibodies, fibrinogen) will be requested.</p> <p>DVT POST COVID INJECTION; This spontaneous report received from a patient concerned a 52 year (also reported as 53 year) old male. The patient's height, and weight were not reported. The patient's past medical history included provoked DVT (deep vein thrombosis) 10 years ago, and concurrent conditions included hypertension. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose was not reported, administered on 12-APR-2021 into left deltoid for prophylactic vaccination. The product was properly stored from receipt to administration. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. Patient received J&amp;J vaccine at place of employment. After 24 hours on an unspecified date in APR-2021, the patient developed lower leg DVT (deep vein thrombosis) post COVID injection. It was confirmed by positive d-dimer (coded as Fibrin D dimer) and US (ultrasound scan). Exact results and date of the tests were not provided. The patient was started on rivaroxaban. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of DVT post COVID injection was not reported (captured as unknown). This report was serious (Other Medically Important Condition).; Sender's Comments: This 52/53-year-old hypertensive male patient of unspecified ethnicity developed lower leg deep vein thrombosis (DVT) after 24 hours of receiving COVID-19 VACCINE AD26.COVS for the prevention of symptomatic SARS-CoV-2 virus infection. The was prior history of "provoked" DVT 10 years ago. No concomitant medications reported. The patient reported that D-Dimer was positive and ultrasound showed DVT. The patient was started on rivaroxaban. No other details reported. The information available precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information was requested.</p>

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1268919	4/28/2021	CA	47	F	4/9/2021	4/9/2021	Fever lasted two days, severe headache lasted two days, body aches lasted over a week, nausea is still present, fatigue is still present, arm soreness lasted a little over a week, dizziness is still present. Stabbing pains in my hands, feet and legs started a few days after the vaccine and my rheumatologist ordered ultrasounds on my legs, which showed no presence of clots. The pains lasted for about 12 days. Pain in my chest and breasts occurred yesterday and lasted about 2 minutes. Nipples are tender.

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1268728	4/28/2021	CT	49	F	4/12/2021		<p>HEADACHE/PAIN IN HEAD; HEAD FELT FLUIDY,FLOATING,FOGGY,/FREAKING OUT; FLUCTUATING LUCIDITY/FELT LUCID; PAIN IN NECK; WOKE UP AND STUMBLED; RED BLOOD (AND CLOT) WHEN BLEW NOSE; RED BLOOD (AND CLOT) WHEN BLEW NOSE; DREAMING DIZZY/DIZZY; FEELS JITTERY/NOT FEELING WELL; This spontaneous report received from a 49 year old female patient reporting on self. The patient's height, and weight were not reported. The patient's concurrent conditions included seasonal allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808982,expiry: UNKNOWN) dose was not reported,1 total administered on 12-APR-2021 09:00 in right arm for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, in the evening she had headache. On 12-APR-2021 the patient was dizzy and not feeling well at night she woke up in sleep feeling dizzy as she was dreaming dizzy, got up from bed and stumbled. She told her husband not feeling well but he tried to brush it aside. up from bed and stumbled. She took Advil. The doctor on-call told her to calm down and to take 2 Advil and went to sleep and if it did not went away to ER. The consumer did so. On 13-APR-2021, (Tuesday morning) the consumer blew her nose and noticed red blood and clots (coming from further up higher than sinuses). She was concerned and talked to people (friends). On 14-APR-2021, around 3:00 Wednesday morning she was freaking out she called her doctor and was not available she was referred to another physician. The patient was lucid, head felt fluidy, floating and dizzy. She had pain in the head and the neck. On 15-APR-2021, Thursday morning the physician called her back and said to stop taking Advil and went to ER. Her head was heavy and fog, everything was slow and lucid. In the hospital as soon as they gave her saline IV fluid, the fog was half lifted. Laboratory data (dates unspecified) included they also did MRI and blood work which were normal. They discharged her the same day and suggested she could take Tylenol which she did Thursday night. On 16-APR-2021, Friday she felt jittery but good and will buy some Gatorade for hydration and patient also stated that both dizzy and heavy head was reduced to faint (coming down from 10 to 3.5 on a scale). The consumer suggested that</p>

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							the dose of the vaccine may be too much for certain individuals and suggested to reduce the dose to like half the dose or to give it in 2 shots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from red blood (and clot) when blew nose, and stumbling on 15-APR-2021, was recovering from dizziness, fluctuating lucidity, head felt fluidy, floating, foggy,/freaking out, pain in neck, and feels jittery/not feeling well, and the outcome of headache/pain in head was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210436432- covid-19 vaccine ad26.cov2.s-head felt fluidy, floating, foggy,/freaking out, red blood (and clot) when blew nose. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
1268669	4/28/2021	WI	42	F	4/8/2021	4/10/2021	Ended up with a blood clot in left leg, not a dvt clot.
1268127	4/28/2021	WI	74	F	4/9/2021	4/16/2021	The patient got the second Moderna COVID vaccine on 4/9/2021. Then 1 week later on 4/16/2021, she developed pain in left calf that got progressively worse. Then came to ER on 4/18/2021 and was diagnosed with thrombosis/occlusion in left popliteal artery. She was admitted and put on IV heparin. This was thrombolized by interventional radiology on 4/19/2021. She was discharged on 4/23/2021. She has had resolution of pain in the left leg. She has never had this before. She does have some apical hypokinesis on echocardiogram but that is not really new. EF 45%. Now is on warfarin.
1267664	4/28/2021	OH	72	M	3/2/2021	4/5/2021	Physician reported on 4/28/2019 that patient presented to hospital and was diagnosed with Transverse Sinus Thrombosis. Was admitted to hospital 4/25/2021. No other information. Hospital wanted the Health Department to report this since the vaccine was given by us.



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1268579	4/28/2021	CA	67	M	4/5/2021	4/7/2021	PATIENT PRESENTED TO THE HOSPITAL WITH SHORTNESS OF BREATH, EVIDENCE OF PULMONARY EMBOLISM 2 DAYS AFTER 2ND SHOT OF MODERNA VACCINATION. DISCOMFORT WAS MOSTLY PLEURITIC ON THE LEFT SIDE. PATIENT ALSO HAD SOME SWELLING OF RIGHT LOWER EXTREMITY. HE WAS DIAGNOSED WITH ACUTE RIGHT LOWER EXTREMITY DEEP VEIN THROMBOSIS AND BILATERAL (LEFT GREATER THAN RIGHT) PULMONARY EMBOLISM. PATIENT WAS HOSPITALIZED FOR 3 DAYS. HE WAS STARTED ON ANTICOAGULATION WITH LOVENOX INPATIENT AND WAS TRANSITIONED TO PRADAXA OUTPATIENT. HE RETURNED TO THE HOSPITAL 11 DAYS LATER WITH NEW LEFT LEG SWELLING AND PERSISTENT SHORTNESS OF BREATH. COMBINED PAST ADMISSION AND MOST RECENT ADMISSION, PATIENT WAS IN THE HOSPITAL FOR 5 DAYS
1268089	4/28/2021	CA	57	M	4/10/2021	4/18/2021	Two blood clots in right leg below the knee, calf pain, swelling of lower leg and foot, painful to walk
1267593	4/28/2021	IL	73	F	1/30/2021	2/8/2021	Headache, Increasing fatigue and difficulty breathing over two weeks before 2nd dose -- exacerbated by 2nd dose. Worsening condition led to visit to Primary Care. In office tests indicated presence of blood clots and need for emergency hospital treatment. Emergency surgery to remove blood clots throughout her body and attempt to put her on ECMO were unsuccessful and patient succumbed at 12:06 AM 3/3/21.
1268259	4/28/2021	VA	21	M	2/5/2021	2/5/2021	Chronic Insomnia - ~3 Months Chronic vomiting - ~1-2 Months Intestinal Metaplasia diagnosis following upper endoscopy Worsened PTSD and anxiety Called 911 on 4/15/21 - Police, Fire, and 2 ambulances lights and sirens to hospital. After hospitalization, taking 500 mg Depakote in Morning, 1000 mg Depakote at night, 200mg Seroquel in morning, 200 mg Seroquel at night as prescribed by Dr. Was seen by a different Dr. prior to hospitalization. 911 brought me to ER. Received oxygen via nasal cannula + Nonrebreather, Was instructed by Dr. to visit a different ER to test for blood clots. Multiple PTSD episodes in Hospital during Hospitalization.

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1268350	4/28/2021	MA	63	F	4/7/2021	4/16/2021	a week after receiving the vaccine I started feeling shortness of breath. It progressively got worse and on April 23, 21 was admitted into Hospital with blood clots to the left leg and to my lungs.
1268363	4/28/2021	CT	63	M	3/5/2021	4/24/2021	Patient received Johnson Johnson COVID vaccination on March 5th (Its not listed as an option for me to choose - Hence Janssen). Two weeks later patient and wife described symptoms of significant abdominal pain and headache, which improved after 24 hours, since then, abdominal pain on and off with worsening, nausea vomiting and diarrhea. Presented to Hospital with sepsis, negative evaluation, possibly GI etiology, given symptoms. MRI of the abdomen shows left portal vein thrombosis/which is an unusual site. Patient has no liver cirrhosis or metastatic cancer. Is being investigated for idiopathic or acquired thrombophilia
1268364	4/28/2021	AL	60	M	4/15/2021	4/16/2021	Stroke from blood clot. .Surgical thrombectomy . After initial full paralysis on left side, not adverse effects.
1268387	4/28/2021	SC	79	F	3/30/2021	4/23/2021	Bilateral dural sinus and jugular vein thromboses. Has viridans streptococcal bacteremia. Thrombosis may be infected. Patient also tested positive for SARS-CoV2 4/23/2021. Being treated with antibiotics, Eliquis. Not thrombocytopenic. HIT studies pending.
1268424	4/28/2021	WI	47	F	4/24/2021	4/26/2021	The decedent was found in her bedroom by her daughter. Medical history only includes previous blood clots. Decedent has been complaining of coughing and shortness of breath the past few days. There is no history of drug use. The decedent had a foam cone when found.

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1268576	4/28/2021	CA	41	M	4/6/2021	4/26/2021	A 40 year old man with no apparent risk factors for current disease presents with an anterior myocardial infarction. At acute in far related angioplasty is LAD is found to be completely included by fresh red clot that was removed using an instruction catheter. Imaging of the interior endothelial surface of the left anterior descending which was occluded by clot did not reveal any ruptured plaque or abnormality in the endothelium. He experience extensive anterior myocardial infarction and now has a left ventricular ejection fraction between 35 and 40%. This was an and usual presentation in a young man who appears to be fit with no family history of cardiac disease. A non-smoker. Normal lipid profile. The nature the invite itself was unusual in that no abnormality of the vessel that was occluded by fresh thrombus could be detected

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1267830	4/28/2021	NM	43	F	4/7/2021	4/7/2021	4/7/21 around 630pm began to feel ill and had sore arm. By about 1030pm, had significant body aches, headache, clammy skin, vomiting, diarrhea, near passing out, fast heart beat, with fever. These symptoms lasted about 48 hours. The next 48 hours just had ill feeling with extreme fatigue. Come 4/12/21, I had nausea, headache, fever of about 100.4 and body aches. By 4/14/21, I ended up going to the ER for shortness of breath, chest tightness, extreme fatigue and voice hoarseness. Those doctors performed several labs to include Chest CT which showed elevated D-Dimer levels. An EKG was performed which was baseline. Ultrasound of my veins was performed. They also did a COVID test which was negative. They sent me home and told me to rest and drink lots of fluid. On 4/16/21, I had a video call with my doctor who didn't like the sound of my voice and straining to catch my breath and I was sent to urgent care/ER. They admitted me as an ER visit due to my continued shortness of breath, cough, sore throat, night sweats, dizziness, chest tightness along with my voice being hoarse. Another COVID test was performed and was negative. During their exam, my oxygen levels were dropping into the low 80s and my heart rate was in the 120s and 130s. Their CT scan was down so they sent me to another ER where another CT scan was performed. Another COVID test was performed and was negative. My D-Dimer was elevated, liver enzymes was slightly elevated and again my oxygen levels were lower than would like to see and elevated heart rate. I ended up being admitted into the hospital for an overnight stay to monitor my symptoms. They treated me for suspected blood clot, shortness of breath, chest tightness. I was given 2 shots of heparin in the stomach, IV fluids, multiple vitamins in attempt to boost my immune system, along with ADVAIR and Albuteral. My discharge diagnose from the hospital was Acute Bronchitis, Anxiety disorder, Recent Moderna 2nd dose COVID vaccine with significant side effects in the form of fever, generalized weakness and dizziness.

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1261831	4/27/2021	TN	69	M	4/15/2021	4/15/2021	Blood Clots both legs; had other vaccine same date at 2nd dose in the left arm; had other vaccine same date at 2nd dose in the left arm; This is a spontaneous report from a contactable Consumer (patient). A 69-year-old male patient received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9269) via an unspecified route of administration in the left arm on 15Apr2021 12:00 PM at single dose for COVID-19 immunization. Medical history was unknown. The patient had no known allergies. The patient had no covid prior vaccination, no covid tested post vaccination. The patient had no other vaccine in four weeks or other medications in two weeks. Concomitant medications were none. The patient had other vaccine same date at 2nd dose in the left arm. The patient experienced blood clots both legs on 15Apr2021 12:15 PM. The patient had extensive dvt IVC and both legs as treatment for event. Outcome of the event blood clots both legs was not recovered. AE resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization (duration: 5 days), Life threatening illness (immediate risk of death from the event).
1261830	4/27/2021	KY	42	M	4/1/2021	4/3/2021	Blood clot in leg; This is a spontaneous report from a non-contactable consumer reported for himself. A 42-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route of administration on 01Apr2021 02:00 PM at 42-year-old at single dose for COVID-19 immunisation. Patient had known allergies (unspecified) and other medical history (unspecified). There was no covid prior vaccination. There is no other vaccine in four weeks. Other medications in two weeks included antibiotics. Patient experienced adverse event: blood clot in leg on 03Apr2021 02:00 AM. The adverse event resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event). Patient received treatment for events included blood thinners. Patient had covid tested post vaccination on 21Apr2021: Nasal Swab: Negative. Patient was not recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

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1261824	4/27/2021	CA	52	F	3/31/2021	4/3/2021	swelling in her right foot and right calf and pain/blood clot was diagnosed in her right calf under her knee; This is a spontaneous report from a contactable consumer (patient). A 52-year-old female patient received the second dose of bnt162b2, via an unspecified route of administration, administered in left arm on 31Mar2021 (Lot Number: ER8732) as single dose for covid-19 immunisation. There were no medical history and concomitant medications. The patient previously received the first dose of bnt162b2, at the age of 52-year-old, via an unspecified route of administration, administered in left arm on 10Mar2021 11:15(Lot Number: EN6206) as single dose for covid-19 immunization. Started experiencing swelling in her right foot and right calf and pain 3 days following 2nd injection (03Apr2021). Went to the doctor and blood clot was diagnosed in her right calf under my knee 9 days following 2nd injection (09Apr2021). Event resulted in Doctor or other healthcare professional office/clinic visit, Life threatening illness (immediate risk of death from the event). The treatment for event was 21 Days Xarelto BID then Pradaxa for 90 days. The patient was not pregnant. The outcome of the event was recovering.

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1261820	4/27/2021	ID	68	M	4/1/2021	4/14/2021	102 deg F temp; shivering; abnormal general body fatigue; Atelectasis; double blood clot in left lung lower left lobe; This is a spontaneous report from a contactable consumer (Patient). A 68-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Right on 01Apr2021 17:00 (Batch/Lot number was not reported) at the age of 68-years-old as single dose for covid-19 immunisation. The COVID-19 vaccine was administered at Doctor's office/urgent care. Medical history included Inclusion Body Myositis, Sjogren's syndrome and Known allergies included Penicillin, Lamisil, Sulfa drugs. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient concomitant medication included unspecified other medications in two weeks. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Got up 9:30AM on 14Apr2021. Experienced abnormal general body fatigue. Began shivering at 1:00 PM and went back to bed. 102 degree F temp at 3:00 PM. Called primary care physician, who advised we go to Emergency room (ER). Got into ER about 6:00pm. Covid polymerase chain reaction (PCR) Nasal Swab test negative, full viral panel negative. Chest X-Ray showed some Atelectasis, Computerised tomogram (CAT) scan revealed double blood clot in left lung lower left lobe. Sent to Hospital at about 1:00 AM 15Apr2021. Treatment with 16ml/hr Heparin plus 5mg/day warfarin. Discharged 06:00 PM on 16Apr2021. Adverse event resulted in: [Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event)]. The outcome of the events was recovering. Information on the lot/batch number has been requested.

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1261816	4/27/2021	FL	54	M	4/7/2021	4/17/2021	<p>had pulmonary embolism in both lungs; blood clots/blood clots in the lungs; This is a spontaneous report from a contactable consumer (patient). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 2 via an unspecified route of administration administered in arm right on 07Apr2021 at vaccination age of 54 years old (Lot Number: EN6208; Expiration Date: Jun2021) as single dose for covid-19 immunisation. There was no medical history. No known allergies. No Covid prior vaccination. The patient's concomitant medications were not reported. The patient previously took BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration administered in arm left on 08Mar2021 14:00 at vaccination age of 54 years old (Lot Number: EN6205; Expiration Date: 30Jun2021) as single dose for covid-19 immunisation. No other vaccine in four weeks. No other medications in two weeks. The patient experienced had pulmonary embolism in both lungs on 17Apr2021 13:00, blood clots/blood clots in the lungs on 17Apr2021 13:00. Events resulted in emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event), disability or permanent damage. The patient had pulmonary embolism in both lungs. He was in the hospital for 3 days and now he will have to take blood thinners in definitely. He was admitted 17Apr2021 and discharged home 19Apr2021. He did not have history of blood clots and zero risk factors. Two doctors blamed the vaccine. He did not want to take blood thinners forever. He needed help figuring out how to determine if this was related to the vaccine. He had a reaction to the second shot and he had been in the hospital the last 3 days and the 2 different doctors that saw him said the only thing that was different was that he had received the COVID vaccine. He had blood clots in both of his lungs, he was in serious condition for a couple days there but his biggest concern now was that they were telling him that he will have to take medication forever to thin his blood because they didn't think there was a genetic reason it happened and that was the protocol that healthcare providers have to follow. They were telling him that he might contact a hematologist and do a blood study but they said they were certain that it came from the vaccine because there was no history of</p>



*VAERS\_ID RECVDATE STATE AGE\_YRS SEX VAX\_DATE ONSET\_DATE SYMPTOM\_TEXT*

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this in his family or himself. He said the condition's medical term was pulmonary embolism but he just said blood clots in the lungs because he thought he would make it easier to explain. Both doctors that saw him felt it was brought on the by the vaccine. He was not looking to sue or anything, he didn't want to be taking a blood thinner for the rest of life. He was not doing this for any reason other than to get well. He realized this situation was very rare with Pfizer, it was like 4 in 1 million with Pfizer according to his physicians. Covid tested post vaccination: Nasal Swab on 17Apr2021 with negative result. Therapeutic measures were taken as a result of had pulmonary embolism in both lungs, blood clots/blood clots in the lungs. The outcome of events was recovered with sequelae.

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1261815	4/27/2021	NY	47	M	2/10/2021	3/26/2021	Portal Vein Thrombosis; This is a spontaneous report from a contactable consumer (the patient). A 47-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: 9809), via an unspecified route of administration in left arm on 10Feb2021 at age of 47-year-old at single dose for COVID-19 immunisation. Medical history included back pain/stenosis and high cholesterol. No known allergies. The patient did not have COVID prior vaccination. Concomitant medications (Other medications in two weeks) included oxycodone taken for an unspecified indication from an unspecified date; docusate sodium (COLACE) taken for an unspecified indication from an unspecified date; pregabalin (LYRICA) taken for an unspecified indication from an unspecified date; atorvastatin calcium (LIPITOR ORIFARM) taken for an unspecified indication from an unspecified date; naloxegol oxalate (MOVANTIK) taken for an unspecified indication from an unspecified date. No other vaccine in four weeks. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL 3247) via an unspecified route of administration in left arm on 20Jan2021 08:00AM for COVID-19 immunisation. The patient experienced portal vein thrombosis on 26Mar2021. The event resulted in: Emergency room/department or urgent care, Hospitalization (for 3 days), Life threatening illness (immediate risk of death from the event)]. Therapeutic measures were taken as a result of the event included treated with Anti Coagulation. Nasal Swab test was done on 02Apr2021 with result of "negative". The outcome of the event was recovering.

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1261806	4/27/2021	OH	69	F	3/30/2021	4/9/2021	blood clot in my lungs/Multiple blood clots; Pains; This is a spontaneous report from a contactable consumer. This 69-year-old female consumer reported for herself that: Patient characteristics: Weight (kg): 102.97 Height (cm): 165 Sex: Female Relevant medical history and concurrent conditions: Structured information (Patient episode name): Hypertension Patient Medical comments: Verbatim: Hypertension Reaction(s)/Event(s): Reaction/event as reported by primary source: Blood clot in my lungs within the first 2 weeks after the second shot Reaction(s)/Event(s): Reaction/event as reported by primary source: Hospitalization Reaction/event in MedDRA terminology (LLT): Hospitalization Reaction/event MedDRA term (PT): Hospitalisation Reaction(s)/Event(s): Reaction/event as reported by primary source: Pains Results of tests and procedures for investigation of the patient: Test: CTA scan More information available (Y/N): No Drug(s) Information: Characterization of drug role: Suspect Proprietary medicinal product name: Covid-19 Vaccine Batch/lot number: ER8732 Date of start of drug: 30Mar2021 Action(s) taken with drug: Unknown Drug(s) Information: Characterization of drug role: Concomitant Proprietary medicinal product name: Lisinopril HCTZ Dosage text: 20-25 mg Tablet Indication for use in the case: Hypertension Narrative case summary and further information: Case narrative: Selected Report Type: Initial Patient Ethnicity: (Ethnicity withheld) Is the patient also the reporter? Yes Reporter type: Consumer or other non-health professional Reporter telephone: (Phone no withheld) Primary / Prescribing Healthcare Professional Info Dates for Blood clot in my lungs within the first 2 weeks after the second shot.: (From: Unspecified To: Unspecified) Dates for Hospitalization: (From: Unspecified To: Unspecified) Dates for Pains: (From: Unspecified To: Unspecified) Is Covid-19 Vaccine a Pfizer product? Yes Covid-19 Vaccine manufacturer: Unspecified Dates for Covid-19 Vaccine: (Start: 30Mar2021 Stop: Unspecified) NDC number of Covid-19 Vaccine: Unknown UPC number of Covid-19 Vaccine: Unknown Expiry Date of Covid-19 Vaccine: 31Jul2021 Other Products: Yes Dates for Concomitant Products Lisinopril HCTZ: (Start: Unspecified Stop: Unspecified) Patient History: Yes Patient history: Hypertension (From: Unspecified To: Unspecified) Investigation Assessment:

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Yes Investigation: CTA scan (Date: Unspecified, Result / Units: ) Additional Context: Consumer stated, "I could not follow on the parts. So may be should have done certainly but I am not technically astute. So, I wanted to report that I just had the second Covid-19 test and as a experience in emergency room discovery of blood clot in my lungs within the first 2 weeks after that second shot. So, I wanted to report that. Is this the place I do that?" When paraphrased, consumer stated, "Multiple blood clots." Start date of event (Multiple blood clots.): Consumer stated, "10Apr2021. I should probably say that the pains were 09Apr. I went in the emergency room on the 10th. So, I am not sure which day." Treatment :Consumer stated, "Yes, I went To the emergency room and was kept in the hospital and then I saw my own Doctor just today who is going to help me try to determine what is going to happen next ? I was released by the hospital." Details of hospitalization: Duration of hospitalization: 24 hrs. (overnight) Date of Admission:10Apr2021 Date of Discharge:11Apr2021 Lab work: Consumer stated, "They did lab. work while in the emergency room and in the hospital. They did Chest CTA scan." This is a spontaneous report from a contactable consumer. A 69-year-old female patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 30Mar2021 (Batch/Lot Number: ER8732; Expiration Date: 31Jul2021) as single dose for covid-19 immunisation at age of vaccination 69-year-old. Medical history included hypertension from an unknown date. Concomitant medication included hydrochlorothiazide/lisinopril (LISINOPRIL HCTZ) taken for hypertension, start and stop date were not reported. The patient experienced blood clot in my lungs/multiple blood clots (thrombosis) (hospitalization) on 10Apr2021 with outcome of unknown , pains (pain) (hospitalization) on 09Apr2021 with outcome of unknown. The patient was hospitalized for blood clot in my lungs/multiple blood clots (thrombosis) from 10Apr2021 to 11Apr2021. The patient was hospitalized for pains (pain) from 10Apr2021 to 11Apr2021. The patient underwent lab tests and procedures which included computerised tomogram: unknown results on , laboratory test: unknown results on . The action taken in response to the event(s) for bnt162b2 was not applicable. Therapeutic

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1261801	4/27/2021	IL	33	F	4/8/2021	4/8/2021	<p>measures were taken as a result of blood clot in my lungs/multiple blood clots (thrombosis), pains (pain).</p> <p>Heavy menstrual bleeding with clots; Heavy menstrual bleeding with clots; This is a spontaneous report from a contactable nurse (patient). A 33-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiration date unspecified), via an unspecified route of administration, administered in left arm on 08Apr2021 13:00 as single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient was not pregnant and had no other vaccine in 4 weeks. On 08Apr2021 13:30, the patient experienced heavy menstrual bleeding with clots. There was no therapy for the events. The patient had no COVID prior vaccination and was not COVID tested post vaccination. Outcome of events was recovered on an unspecified date. Information about Lot/Batch number is requested.; Sender's Comments: Based on the available information the reported events were attributed to an underlying or an intercurrent medical condition and it is assessed as unrelated to the suspect drug bnt162b2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.</p>

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1261799	4/27/2021	OH	49	F	3/3/2021	3/4/2021	I was diagnosed with a blood clot in my right leg; This is a spontaneous report from a contactable consumer (patient). A 49-year-old female patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in right arm on 03Mar2021 15:45 (Lot Number: EN6202), at the age of 49-years at vaccination, as SINGLE DOSE for covid-19 immunisation. Medical history included none. The patient is not pregnant at the time of vaccination. The patient received dose 1 of the vaccine on 10Feb2021, lot number: EM9810, on 10Feb2021 03:45 PM at right arm. The patient did not have COVID-19 prior vaccination. The patient's concomitant medications were not reported. On 04Mar2021 12:00 AM, patient was diagnosed with a blood clot in her right leg. The event required emergency room visit. The patient was put on Xarelto, a blood thinner for clots. The patient has not been tested for COVID-19 post vaccination. The outcome of the event was unknown.
1261865	4/27/2021	OH	91	F	4/1/2021	4/25/2021	Death after experiencing blood clot to the lung
1261778	4/27/2021	GA	26	M	4/8/2021	4/9/2021	Swelling underneath my left arm pit which may be a possible blood clot; Swelling underneath my left arm pit which may be a possible blood clot; This is a spontaneous report from a contactable consumer (patient). A 26-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number and expiration date were not reported) on the left arm on 08Apr2021 (16:15) as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 09Apr2021 (05:45), the patient had swelling underneath my left armpit which may be a possible blood clot. The patient did not receive any treatment for the reported events. The outcome of the events was not recovered. The patient did not have COVID-19 prior to vaccination, and had not been tested post-vaccination. Information on the lot/batch number has been requested.

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1262401	4/27/2021	PA	63	F	4/10/2021	4/18/2021	Throbbing pain at injection site and entire arm. Unable to move up without assistance. Pain grew more and more intense. Went to urgent care on unspecified date. NP examined me and discovered a lump in my arm. Both the lump and the vaccination site hurt when she pressed on them. She prescribed predone and gave me a work order for a vascular ultrasound to be performed on my left arm. I went on unspecified date for the scan. It was discovered that a DVT blood clot had formed in my brachial vein in the left arm. I was then prescribed eliquis, 20 mg a day for 7 days and told not to take the predesone. NP called my pcp, his office immediately called me and asked me to come in as they are concerned about the high dosage of the eliquis.

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1261794	4/27/2021	PA	62	F	4/1/2021	4/1/2021	<p>had a stroke after getting the Pfizer vaccine; weakness left arm and left leg; Headache; Dural venous sinus thrombosis; This is a spontaneous report from a contactable consumer (patient). A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 62-years of age) dose 2 via an unspecified route of administration, administered in arm right on 01Apr2021 10:20 (Batch/Lot number was not reported) as a single dose for covid-19 immunisation (to not get Covid). Medical history included ongoing multiple sclerosis which was diagnosed back in the early 90's and the doctors saw no new reasons on any part of the MRI of the brain, neck, and spine, there were no new lesion and she has had no problems for 30 years; and she had sinus pressure. There were no concomitant medications. Historical vaccine included BNT162B2 (Batch/lot number: EN6208) dose 1 in her left arm on 11Mar2021 (at 61 years of age) for COVID-19 immunisation. It was reported that the patient had a stroke after getting the Pfizer vaccine. She stated that she was in the ICU for 3 days. They tested every part of her body and couldn't find a reason. She added that she had a clot in her brain with a small bleed and they told her it was highly unusual to happen in that part of the brain. It was stated that it was where the blood goes from the brain to the heart. She mentioned that it was a dural venous sinus thrombosis. She was in the neuroscience ICU for 3 days and her left leg and left arm are still weak and she will start PT. She wanted to talk about reporting and let us know this was happening and that the neuroscience team reported it to the CDC online while she was in the hospital. She wanted to talk about her concerns and see if we are seeing this with other people. She added that she was tested, and they found nothing. She mentioned that she got the vaccine in a Thursday morning and by Friday she had weakness in her left arm and left leg and a headache. She added that there was a high probability that it was related, that it was a new vaccine and it was hard to say it definitely happened from that but it was a high probability. She had other questions, she has heard from other people with other vaccines and people with Covid experience blood clots. She stated that she was wondering what if it was with the vaccine that is reacting to what it thinks is Covid, or is it the body's response. She was wondering if Pfizer comes</p>



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1261867	4/27/2021	IN	57	M	3/30/2021	4/15/2021	<p>out with a booster with the variant, should she not take the booster. She stated that it could have killed her if they had not caught the blood clot in her brain and had she not gone to the ER it could have killed her and she was concerned about taking a booster. She provided that she had the Pfizer vaccine on 01Apr2021 in the morning and had a headache that same day and who knows when on Friday morning she had weakness in her left leg and left arm, so within 24 hours. She provided that she went to the ER Saturday 03Apr2021, that she wasn't sure about it and you don't go running for everything. Stated she was admitted 03Apr2021 and was discharged 05Apr2021 or 06Apr2021. She clarified that her headache was totally gone, that she had sinus pressure that was not related and had it as a constant in her life, it was normal for her and happens with changes with the weather. The patient was hospitalized for had a stroke after getting the pfizer vaccine (cerebrovascular accident) from 03Apr2021 to 06Apr2021. The patient underwent lab tests and procedures which included blood work constantly, CAT scan of her torso, several CAT scans of her brain, had MRI's and CAT scans constantly, brain MRI, MRV of the brain all on an unknown date with unknown results. The events resulted from Emergency Room Visit. The outcome of headache was recovered on an unknown date while not recovered for weakness left arm and left leg. The outcome of other events was unknown. Information on the lot/batch number has been requested.</p> <p>Blood clots, heart attack, died, cpr 5 times survived Blood is very thick blood thinners unable to thin</p>

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1261941	4/27/2021	WA	72	F	1/29/2021	4/5/2021	<p>Renal Artery Thrombosis; Severe Back pain; This spontaneous case was reported by a patient (subsequently medically confirmed) and describes the occurrence of RENAL ARTERY THROMBOSIS (Renal Artery Thrombosis) in a 72-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 010A21A and 007M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No relevant medical history was reported. Concomitant products included LISINOPRIL and AMLODIPINE for an unknown indication. On 29-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 2 dosage form. On 05-Apr-2021, the patient experienced RENAL ARTERY THROMBOSIS (Renal Artery Thrombosis) (seriousness criterion medically significant). 05-Apr-2021, the patient experienced BACK PAIN (Severe Back pain). At the time of the report, RENAL ARTERY THROMBOSIS (Renal Artery Thrombosis) and BACK PAIN (Severe Back pain) outcome was unknown. On 05Apr2021, the patient was evaluated in the emergency room for back pain. On 16Apr2021, the patient was diagnosed with renal artery thrombosis approximately 40 days after receiving the second dose of the vaccine. The patient was prescribed Eliquis 5mg bid by her Primary Care Physician. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.</p>

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1261946	4/27/2021		52	F	3/18/2021		<p>Blood clots; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clots) in a 52-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 044A21A and 031B21a) for COVID-19 vaccination. No Medical History information was reported. On 18-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clots) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood clots) outcome was unknown. No treatment information was provided. No concomitant medication was reported. The patient received both scheduled doses of mRNA-1273 prior to the event(s); therefore, action taken with the drug in response to the event(s) is not applicable. Company Comment: Very limited information regarding this event/s has been provided at this time. Further information has been requested. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p>

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1261949	4/27/2021	NC		M			<p>Congestive heart failure; Couldn't breathe in and had short breaths/shortness of breath hit him; Swelling got up his leg; ankles, knees swollen; This spontaneous case was reported by a consumer and describes the occurrence of CARDIAC FAILURE CONGESTIVE (Congestive heart failure) and DYSPNOEA (Couldn't breathe in and had short breaths/shortness of breath hit him) in a 77-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced CARDIAC FAILURE CONGESTIVE (Congestive heart failure) (seriousness criterion hospitalization), DYSPNOEA (Couldn't breathe in and had short breaths/shortness of breath hit him) (seriousness criterion hospitalization prolonged), PERIPHERAL SWELLING (Swelling got up his leg) and JOINT SWELLING (ankles, knees swollen). The patient was hospitalized for 5 days due to CARDIAC FAILURE CONGESTIVE and DYSPNOEA. At the time of the report, CARDIAC FAILURE CONGESTIVE (Congestive heart failure), DYSPNOEA (Couldn't breathe in and had short breaths/shortness of breath hit him), PERIPHERAL SWELLING (Swelling got up his leg) and JOINT SWELLING (ankles, knees swollen) outcome was unknown. Not Provided</p> <p>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, X-ray: no evidence of blood clot no evidence of blood clot. No concomitant medications provided. Treatment of these events included oxygen. Action taken with mRNA-1273 in response to the events was not applicable. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-089692 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start</p>

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							date of the events, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-089692:
1262148	4/27/2021	TX	62	M	4/12/2021	4/16/2021	On day 4 following dose 2 of Moderna series, pt developed fever, chills, fatigue, malaise and self-medicated with ibuprofen and acetaminophen. After a "few" days of feeling unwell despite treatment, presented to ER and was found to have AKI, hyponatremia, and thrombocytopenia. Over the course of several days rapidly deteriorated and developed MSOF, including liver failure, DIC, respiratory failure requiring intubation, and shock requiring pressors. Workup for VTE, including V/Q scan, LE dopplers, and head CT negative for thrombosis. Ferritin was found to be highly elevated (12,000) suggestive of hemophagocytic lymphohistiocytosis (HLH). Per ER report, marrow positive for hemophagocytosis on smear. At time of report, transferred to Cancer Center for HLH treatment, currently in ICU, intubated, sedated, and on pressors. PF4 antibody pending.
1262581	4/27/2021	MD	56	M	4/11/2021	4/20/2021	Developed superficial leg clot on leg from ankle to groin
1262236	4/27/2021	CA	65	F	4/23/2021	4/24/2021	Sudden onset embolic stroke requiring embolectomy two days following first dose of moderna vaccine. Successful clot removal, but residual small stroke causing left-sided weakness.
1262422	4/27/2021	TX	94	F	3/16/2021	4/26/2021	RESIDENT COMPAINED OF PAIN TO BILATERAL THIGHS AND LOWER BACK SENT TO ER. NOTIFIED BY ER, PATIENT HAS BLOOD CLOTS IN ABDOMIN
1262527	4/27/2021	MI	42	M	4/1/2021	4/2/2021	on the 2nd i had the shot in the left upper arm .. two days later i woke up to violently upchucking pure water after that i when to hospital and was admited i was told after a ekg that i was haveing a heart attack after that have no recolection of anything i wake up to a doc telling ,e it was a bad heart attack and had delovped about 5 blod clots in left lung and microcaditis i have been trying since then for a doc to talk to me but so far i been avoided

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1262540	4/27/2021	VA	55	F	3/7/2021	3/19/2021	blood clot in my left eye, swelling of the eye and under the eye. headaches at the base of my skull so bad nothing helped. Joint pain so bad I couldn't walk for 2 days.
1262566	4/27/2021	FL	38	F	3/17/2021	4/20/2021	Blood clot in my left forearm. I first noticed it on 4/20 around 7pm. There was a bump (the size of a dime) and small bruise. Overnight the bump got a bit smaller and the bruise expanded. Over the next several days the bump kept diminishing. The bruise remained about the same size and kept getting darker. It's been one week now and the bump is very tiny (size of a small pea), and the bruise is incredibly dark, but showing more of a healing process color.

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1261769	4/27/2021	MI	46	F	3/25/2021	4/8/2021	Approximately 2 weeks after the vaccine, inexperienced deep leg pain. 3 days later I went to the hospital and was diagnosed with a blood clot/DVT.; Approximately 2 weeks after the vaccine, inexperienced deep leg pain. 3 days later I went to the hospital and was diagnosed with a blood clot/DVT.; Approximately 2 weeks after the vaccine, inexperienced deep leg pain. 3 days later I went to the hospital and was diagnosed with a blood clot/DVT.; This is a spontaneous report from a contactable consumer. A 46-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in Arm Left on 25Mar2021 13:00 (Batch/Lot Number: ER2613) as SINGLE DOSE for covid-19 immunisation. Medical history included none. The patient's concomitant medications were not reported. Approximately 2 weeks after the vaccine, inexperienced deep leg pain. 3 days later, the patient went to the hospital and was diagnosed with a blood clot/DVT. AE resulted in: [Emergency room/department or urgent care]. The patient received treatment for the events: Vitals taken, blood work, prescribed blood thinner. The patient underwent lab tests and procedures which included blood test: unknown result on an unspecified date ae treatment= Vitals taken, blood work , investigation: blood clot/dvt on 08Apr2021 3 days later I went to the hospital and was diagnosed with a blood clot/DVT, investigation: unknown result on an unspecified date ae treatment= Vitals taken, blood work. The outcome of the event was recovering. The patient does not have COVID prior vaccination, and was not COVID tested post vaccination. The patient has no known allergies.

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1261278	4/27/2021			U		3/28/2021	PASSED OUT; BOTH ARMS WENT COMPLETELY NUMB; LEGS CRUMBLLED/COULDN'T STAND UP; VOMITED; THE DAY GOT THE VACCINE IT BLED AND A BLOOD CLOT CAME ON MY ARM; This spontaneous self-report concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose was not reported, administered on 28-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 28-MAR-2021, the day the patient got the vaccine it bled and a 'blood clot' came on my arm (coded to injection site bleeding). On 01-APR-2021, the patient passed out in a store, both arms went completely numb, legs crumbled/couldn't stand up, and vomited. The patient believed this was a side effect of the vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of events (passed out, both arms went completely numb, legs crumbled/couldn't stand up, vomited, and the day got the vaccine it bled/blood clot came on my arm) was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This patient of unknown age and gender passed out 3 days after receiving the Janssen Covid-19 vaccine. The patient was in a store when when both arms became numb, legs "crumbled" and could not stand; the patient also vomited. No other information regarding the serious loss of consciousness was provided. Additionally, on the day of vaccination, the patient experienced bleeding at the injection site and a clot formed. Considering the missing information (e.g., age, sex, medical history, concomitant medications, clinical details leading up the event, corrective treatment, event outcome), the serious loss of consciousness is considered unclassifiable. The nonserious injection site reaction is consistent with a causal association with vaccination.
1262195	4/27/2021		61	M	4/3/2021	4/23/2021	Deep vein thrombosis



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1261282	4/27/2021			F			LARGE BLOOD CLOT; SWOLLEN BALL ON SIDE OF KNEE; This spontaneous report received from a female patient of unspecified age reporting on self. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, Expiry: Unknown) dose was not reported, 1 total administered on 05-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced large blood clot and swollen ball on side of knee. The swollen ball on side of knee was going on for a couple days now. The action taken with covid-19 vaccine ad26.cov2.s was not reported. The patient had not recovered from large blood clot, and swollen ball on side of knee. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This is a report of a female patient, unspecified age, unknown ethnicity, who experienced a large blood clot and swelling on the side of the knee (laterality not reported) on an unspecified number of days after receiving the covid-19 vaccine ad26.cov.2. The information provided precludes a meaningful medical assessment. Additional information requested.
1260997	4/27/2021	CA	54	F	4/5/2021	4/21/2021	Presented to the ED on 4/25 with severe R calf swelling and pain x4-5 days. Found to have ACUTE THROMBOSIS IN THE DEEP VEINS OF THE RIGHT FEMORAL, POPLITEAL, POSTERIOR TIBIAL, PERONEAL VEINS and ACUTE THROMBOSIS IN THE DEEP VEINS OF THE RIGHT CALF. Admitted for systemic anticoagulation and possible catheter-directed thrombolysis given extent of clot burden and symptoms.

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1261010	4/27/2021	OH	75	M	3/4/2021	3/9/2021	Deep Vein Thrombosis right leg. Five days after being vaccinated I began to notice swelling in my right leg from my knee through my ankle-foot area. There was an associated increase in pain in the knee. I tried to shake it off hoping that the swelling and pain would go away, but I finally relented to the concerns of my family and sought care on the 6th of April at the emergency room because my doctor refused an in-person appointment. The emergency room physician prescribed Eliquis which I have been taking. The swelling seems to have leveled off, but my right leg still appears to be twice the size of my left leg

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1261166	4/27/2021	MN	90	F	3/1/2021		LOW GRADE BLADDER INFECTION; EXTREMELY WARM SENSATION IN CHEST AND BACK; COUGH; SHORT TERM MEMORY LOSS; COULD NOT REMEMBER; NOT WELL; HALLUCINATIONS; COULD NOT WALK; COULD NOT FEED HERSELF; CONFUSION; PLATELET COUNT DECREASED; UNABLE TO STAND; FALL; DIZZY; FELT TIRED; WEAKNESS; EYES LOOKED PUFFY; ABDOMEN WAS LARGER; BIBASILAR ATELECTASIS; CARDIOMEGALY; SWELLING IN BOTH LEGS INCLUDING ANKLE AND TOES; LEVEL 4 PITTED EDEMA; This spontaneous report received from a consumer concerned a 90 year old female. The patient's weight and height was not reported. The patient's past medical history included Alzheimer's, and dementia. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose was not reported, 1 total, administered on 08-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 11-MAR-2021, the patient felt tired. On 12-MAR-2021, the patient had a fall, was dizzy and unable to stand. On 13-MAR-2021, the patient was taken to the emergency room and had a low grade bladder infection and was treated with intravenous (IV) antibiotic (unspecified) from 13-MAR-2021 to 15-MAR-2021 and from 15-MAR-2021 she was switched to oral antibiotic (unspecified) until 23-MAR-2021. The patient was confused and could not walk. It was reported that, the patient was unable to feed herself. On 13-MAR-2021, the patient experienced platelet count decreased. On 13-MAR-2021, the patient's laboratory data included: electrocardiogram (ECG) which could not rule out anterior infarct age undetermined and her platelet count was 136 (unit non specified). On 14-MAR-2021, the patient had hallucinations and her platelet count was 130 (unit non specified). On 15-MAR-2021, her laboratory data included: abdomen computerized tomography (CT) scan which showed bibasilar atelectasis and cardiomegaly, likely cyst vs hemangioma. Unchanged incompletely characterized exophytic lesion in the left kidney significant and possibly represented a hemorrhagic cyst, further evaluation with magnetic resonance imaging (MRI) would need to be performed for definitive characterization. On 17-MAR-2021, the

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patient's cognition seemed well. On 19-MAR-2021, the patient started showing symptoms of blood clot. On 19-MAR-2021 to 22-MAR-2021, the patient was not well. The patient was wearing slippers because she had level 4 pitted edema and was swollen from her knees down including ankle and toes. It was reported that, her swelling was greater on the left side than the right side and she had this swelling on 23-MAR-2021. Also, the patient's confusion returned. On 29-MAR-2021, the patient had confusion and her ultra sound of left leg was normal. On 01-APR-2021, the patient's laboratory data included: diagnostic ultrasound revealing contralateral femoral vein was widely patent. On 03-APR-2021 and 09-APR-2021, the patient was confused and did not know where she was. On 07-APR-2021, her electrocardiogram did not mention anterior infarct and it was abnormal ECG no significant change found. On 10-APR-2021, the patient could not remember where she was. On an unspecified date, the patient had cough and extremely warm sensation in chest and back. The patient was in rehabilitation center and was set to be discharged 16-APR-2021. On 13-APR-2021, the patient's platelet count was 171 (unit not specified). On 17-MAR-2021, In rehabilitation center the patient was no longer wearing shoes due to swelling of ankle, legs toes and feet. The patient's eyes looked puffy and her abdomen was larger. The patient was treated with Lasix (furosemide) in the rehabilitation center. According to the patient's physician, the patient had no sign of stroke. The patient was propped up on right side while at rehabilitation center so according to her daughter the patient was experiencing weakness. At rehabilitation center an ultrasound was ordered for left leg. The patient's both legs were swollen and one was more swollen than the other. The patient was having an issue with memory and confusion which was unusual as the patient had previously been treated neurologist for Alzheimer's disease and dementia and was highly intelligent. At the time of this report, the patient was being treated for low grade bladder infection. The patient's primary care physician reports that she had no concerns about the vaccine being linked to the patient's fall and hospitalization and reported that there were no blood clots, no stroke, no deep vein thrombosis, and no coagulation abnormalities. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The

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patient recovered from not well on 22-MAR-2021, was recovering from platelet count decreased, and the outcome of cough, swelling in both legs including ankle and toes, extremely warm sensation in chest and back, confusion, fall, hallucinations, low grade bladder infection, could not feed herself, could not walk, felt tired, dizzy, unable to stand, level 4 pitted edema, could not remember, eyes looked puffy, abdomen was larger, weakness, short term memory loss, bibasilar atelectasis and cardiomegaly was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: v0 This spontaneous report involves a 90-year-old white female patient with the past medical history remarkable for Alzheimer's and dementia who felt tired 3 days after the Janssen COVID-19 Vaccine Ad26.COV2 had administered. The next day the patient had fell, was dizzy and unable to stand. The next, the patient was taken to the emergency room and was diagnosed with a low grade bladder infection. The patient was confused and could not walk and was unable to feed herself. The next day, the patient had hallucinations and her platelet count was 130 (unit non specified), normal range 179-450. While hospitalized, the patient started showing symptoms of blood clot, had pitted edema, could not remember where she was. On an unspecified date, the patient had cough and extremely warm sensation in chest and back. The patient's eyes looked puffy and her abdomen was larger. The patient's primary care physician reports that she had no concerns about the vaccine being linked to the patient's fall and hospitalization and reported that there were no blood clots, no stroke, no deep vein thrombosis, and no coagulation abnormalities. Considering the patient's age, gender – predisposes to urinary tract infections, as well as the underlying Alzheimer's and dementia the causality for the events assessed not related to the vaccine.

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1261176	4/27/2021	TN	51	F	3/16/2021		<p>BLOOD CLOT FOUND IN RADIAL ARTERY OF RIGHT ARM; SWELLING OF LYMPH NODES ON BOTH SIDES OF NECK; ARM SORENESS PROGRESSED TO ACHING OF RIGHT ARM; NUMB RIGHT ARM; FATIGUE; This spontaneous report was received from a patient and concerned a 51 years old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: 1805025, expiry: unknown) dose was not reported, 1 total, administered on 16-MAR-2021 at her right arm for prophylactic vaccination. No concomitant medications were reported. On 16-MAR-2021, after receiving vaccine, the patient felt fatigue and right arm soreness where she got the vaccine. The arm soreness progressed to aching and numbness. On 01-APR-2021, the patient noticed swelling of lymph nodes on both sides of her neck. On the same day she was sent to emergency room (ER) and was told that a blood clot was found in the radial artery of her right arm; diagnostic data not reported. She was given Plavix (clopidogrel) and sent home. On 06-APR-2021, the patient returned to ER because she was not feeling any improvement on her right arm, and it was still hurting. She was told that a surgery was planned to remove the clot but it was later cancelled. She was sent home on the same day with XARELTO (rivaroxaban). At the time of report, the patient had a pending appointment with a surgeon regarding the clot; no date was provided. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fatigue on 19-MAR-2021, was recovering from arm soreness progressed to aching of right arm, and numb right arm, and had not recovered from blood clot found in radial artery of right arm, and swelling of lymph nodes on both sides of neck. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 This report concerns a 51 years old female patient who had a blood clot in the radial artery of her right arm, 15 days after receiving Jansen COVID-19 vaccine. On the same day of vaccination, patient experienced fatigue and right arm sore where she got the vaccine. The arm soreness progressed to aching and numbness. 15 days after vaccination, the patient noticed swelling of lymph nodes on both sides of her neck and</p>

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was sent to ER. She was told that a blood clot was found in the radial artery of her right arm (diagnostic data not reported) and was treated with Plavix and later with Xarelto. Based on the reported information, the causality of event blood clot in the radial artery of her right arm is considered plausible to the vaccination. Additional information has been requested.

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1261184	4/27/2021	NV	76	F		3/17/2021	LOSS OF FINE MOTOR CONTROL IN RIGHT ARM; HEADACHE; This spontaneous report received from a patient concerned a 76 year old female. The patient's weight was 130 pounds, and height was 65 inches. The patient's past medical history included pacemaker for nerve block (4-5 years ago), appendectomy (10 years ago), cataract surgery, and concurrent conditions included alcohol user (occasional, not often), and ex-smoker (used to smoke for 30 years (half pack a day), but quit 10 years ago) and bladder cancer growth (7 years ago). The patient experienced drug allergy with opioids (deathly ill, sick to stomach and passes out). The patient was not pregnant at the time of reporting. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805018, expiry: 25-MAY-2021) dose was not reported, 1 total, administered on right arm on 09-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 17-MAR-2021, the patient experienced headache. On 21-MAR-2021, the patient lost fine motor control in right arm, and was hospitalized for 2 days. It was reported that, the patient had 2 computerized tomography scans showed no evidence of clot however according to the patient's physician, the patient might have had small clot that dissolved. The patient had no high blood pressure. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from loss of fine motor control in right arm on 21-MAR-2021, and headache on 2021. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0 This report concerns a 76-year-old female patient who experienced headache and loss fine motor control in right arm, 8 and 12 days after receiving Jansen COVID-19 vaccine respectively. Patient's medical history included pacemaker insertion, ex-smoker, bladder cancer, and drug allergy with opioids. Eight days after vaccination, the patient had headache. Four days later, the patient lost fine motor control in right arm and was hospitalized for one and a half days. Two CT scans showed no evidence of clot. The patient's physician commented that the patient might have had small clot that dissolved. The treatment was not reported, and patient was recovered from the events. Based on the reported information, the causality is considered possible



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1261192	4/27/2021	KY	30	M	3/30/2021		<p>to vaccine for headache and unassessable for the event of loss fine motor control in right arm.</p> <p>BLOOD CLOT FROM NOSE; TEMPORARILY UNABLE TO WALK, RICKETY KNEES; BURNING LEG PAIN; JOINT PAIN/ SHOULDER PAIN; SHOULDER FEEL TIGHT; This spontaneous report received from a patient concerned a 30 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included cigarette smoker (occasional pot; rarely). The patient's grandfather died from blot clot under knee (thrombosis). The patient had no history of bloody nose. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808609, expiry: UNKNOWN) dose was not reported, administered on left arm on 28-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 30-MAR-2021 (two days after vaccination) the patient experienced really bad burning leg pain for few days and his joints in shoulder and knees were affected two days after vaccination and he could not walk (temporarily unable to walk). The patient also experienced rickety knees. On the same day, the patient blew out a huge blood clot from his nose. On 2021, the patient's shoulder felt tight. At the time of this report, the patient's knees and shoulders were still feeling tight like there was hardly any cartilage. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from blood clot from nose, and temporarily unable to walk, rickety knees, was recovering from joint pain/ shoulder pain, and the outcome of burning leg pain and shoulder feel tight was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0-Covid-19 vaccine ad26.cov2.s-blood clot from nose. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY</p>

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1261217	4/27/2021	CO	60	M	4/1/2021		PULMONARY EMBOLISM; CHEST PAIN; This spontaneous report received from a patient via a company representative via the local news, concerned a 60 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) at an unspecified dose on 06-MAR-2021 for prophylactic vaccination. The anatomical vaccination site was not reported. The batch number was not reported. The company is unable to perform follow-up to request batch/lot number. No concomitant medications were reported. On 01-APR-2021, 26 days after vaccination, the patient went to hospital due to chest pain. On 08-APR-2021, 33 days after vaccination, the patient was diagnosed with pulmonary embolism, and was hospitalized. The patient reported he suffered a blood clot after receiving the vaccine and was diagnosed with a pulmonary emboli. On 11-APR-2021, the patient was discharged. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of pulmonary embolism and chest pain was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: A 60-year-old man experienced chest pain 26 days after vaccine and was hospitalized with pulmonary emboli 33 days after vaccine. Medical history and concomitant medications were not reported. The latency of greater than 3 weeks makes this unlikely related to vaccine. There is insufficient information to make a meaningful medical assessment. Additional information has been requested, including contacting the news station that reported the event.

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1261218	4/27/2021	PA	19	F	4/1/2021		<p>SHORTNESS OF BREATH; CHEST HEAVINESS; DIAPHORETIC; PALPITATIONS; SWELLING IN FACE; SWELLING IN NECK; DIZZINESS; FLUSHED; CHEST PAIN; PAIN; SEVERE HEADACHE; This spontaneous report received from a parent concerned a 19-year-old white and not Hispanic or Latino female. The patient's height, and weight were not reported. The patient's past medical history included migraines, and tachycardia, and concurrent conditions included fibromyalgia, dystonia, neuropathy, chronic pain syndrome, postural tachycardia syndrome, and autoimmune disorder. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 042A21A, and expiry: UNKNOWN) dose was not reported, 1 total administered on 07-APR-2021 at left arm for prophylactic vaccination. No concomitant medications were reported On 07-APR-2021, 10-15 minutes after vaccination the patient became diaphoretic, with palpitations, experienced swelling in face and neck, shortness of breath, dizziness, and chest heaviness. Pharmacist administered her Epinephrine, and the patient was hospitalized. Patient received Solumedrol and Benadryl at hospital, and was sent home on Benadryl for 24 hours. Patient has continued to have a severe headaches and felt dizzy, flushed, diaphoretic, and short of breath. Patient visited her PCP (primary care physician). She got clearance to return at work. Patient also visited ED (emergency department) to check for possible blood clots and where cardiac workup was also performed. Patient continued to complain of shortness of breath and chest pain particularly on exertion and ambulation, and dizzy during these activities. Treatment medications (dates unspecified) included: diphenhydramine hydrochloride, epinephrine, and methylprednisolone sodium succinate non-company. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from shortness of breath, and chest pain, and the outcome of diaphoretic, palpitations, swelling in face, swelling in neck, dizziness, chest heaviness, severe headache, flushed and pain was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: 20210429351- covid-19 vaccine ad26.cov2.s-shortness of breath, chest heaviness. This event(s) is considered</p>

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1261220	4/27/2021	CA					
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related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are no other factors more likely to be associated with the event(s) than the drug.

PARALYSIS; UNABLE TO WALK/ WALKING DIFFICULTY; CHILLS; FEVER; HEADACHE; This spontaneous report received from a patient concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported, 1total, for prophylactic vaccination. The batch number was not reported. the company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient was paralyzed after receiving vaccine, the patient was hospitalized for 7 days. The patient did not had blood clot, but had difficulty walking, fever, chills, headache and was unable to walk. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from paralysis, fever, chills, headache, and unable to walk/ walking difficulty. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: 20210430056-Covid-19 vaccine ad26.cov2.s-Paralysis. This events is considered unassessable. The events has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events.

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1261221	4/27/2021	ME	56	F	4/1/2021		SENSITIVITY AT THE TOP OF THE HEAD; PRESSURE IN THE HEAD; OVERWHELMING AMOUNT OF HEAT COMING FROM HER BODY; UNSTEADY; ITCHING RASH; STABBING HEADACHE; DIZZINESS; FOGGINESS; BRUISING; FLUSHED FACE; EXTREME RIGHT KNEE SWELLING; LEG PAIN; DISTENDED VEINS; BALANCE IS OFF; PULSATING SENSATION; HIVES TO ARMS; This spontaneous report received from a patient concerned a 56 year old female. The patient's height, and weight were not reported. The patient's past medical history included sulfa allergy, and other pre-existing medical conditions included the patient had family history of blood clots. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 043A214 expiry: UNKNOWN) dose was not reported, administered on 02-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On APR-2021, the subject experienced balance is off. On APR-2021, the subject experienced pulsating sensation. On APR-2021, the subject experienced hives to arms. On 07-APR-2021, the subject experienced extreme right knee swelling. On 07-APR-2021, the subject experienced distended veins. On 07-APR-2021, the subject experienced leg pain. On 08-APR-2021, the subject experienced bruising. On 08-APR-2021, the subject experienced flushed face. On 10-APR-2021, the subject experienced dizziness. On 10-APR-2021, the subject experienced foggiess. On 10-APR-2021, the subject experienced stabbing headache. On 11-APR-2021, the subject experienced unsteady. On 11-APR-2021, the subject experienced sensitivity at the top of the head. On 11-APR-2021, the subject experienced pressure in the head. On 11-APR-2021, the subject experienced overwhelming amount of heat coming from her body. On 11-APR-2021, the subject experienced itching rash. On 12-APR-2021, Laboratory data included: CT scan (NR: not provided) Unknown, and Diagnostic ultrasound (NR: not provided) Unknown. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from itching rash, distended veins, dizziness, stabbing headache, foggiess, flushed face, and overwhelming amount of heat coming from her body, had not recovered from extreme right knee swelling, leg pain, unsteady, bruising, sensitivity at the top of the head, and

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pressure in the head, and the outcome of hives to arms, balance is off and pulsating sensation was not reported. This report was non-serious.; Sender's Comments: V0: Medical assessment comment not required as per standard procedure as case assessed as non-serious.

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1261249	4/27/2021	NJ	50	F	4/7/2021		<p>BLOOD CLOT; LEG CRAMPS; ACHE; HEADACHE; FEVER; This spontaneous report received from a patient concerned a 50 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included overweight, high blood pressure, and high cholesterol. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 207A21A expiry: unknown) dose was not reported, 1 total administered on 06-APR-2021 to left arm for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, the patient experienced a mild fever. On 08-APR-2021, the patient was achy and had a mild headache. The headache continued for several day and became pretty bad for about two days. On an unspecified date in Apr-2021 the patient was treated with Tylenol for headache. On 12-APR-2021, the patient experienced leg cramps in her right leg. On 15-APR-2021, the patient had an ultrasound and a blood clot was found in her right leg. The patient started on Apixaban (Eliquis). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from headache on an unknown date in APR-2021, and the outcome of blood clot, ache, leg cramps and fever was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This 50-year-old female was found to have blood clot in her right leg 9 days after receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. There was reported mild fever, headache, and "aches" 1 to 2 days after vaccination that was treated with Tylenol. The symptom reported was leg cramps on right leg 5 days after vaccination, and ultrasound showed blood clot in her right leg 3 days after the symptom of cramps was noted. No other laboratory/diagnostic test reported. The patient was treated with apixaban. The outcome of blood clot in leg was not reported. Based on the information that is available, the event is assessed as plausible with the causal association to immunization, per causality classification of adverse events following immunization based on a lack of a definitive plausible biological mechanism. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded.</p>

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1261284	4/27/2021	PA		M			<p>Additional information is requested</p> <p>BLOOD CLOT IN FOOT; This spontaneous report was received from a patient via a company representative and concerned a male patient of unspecified age. The patient's weight, height, and medical history were not reported. The patient received COVID-19 vaccine Ad26.COV2.S (suspension for injection, route of admin not reported) 1 total dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, two days after vaccination, the patient experienced a blood clot in his foot. The action taken with COVID-19 vaccine Ad26.COV2.S was not applicable. The outcome of blood clot in foot was not reported. This report was serious (other medically important condition).; Sender's Comments: V0: This male of unspecified age and ethnicity reported to have experience blood clot in foot 2 days after receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. No other information was reported. Based on the information that is available, the event is assessed as plausible with the causal association to immunization, per WHO causality classification of adverse events following immunization based on a lack of a definitive plausible biological mechanism. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information is requested</p>



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1261329	4/27/2021		31	F			<p>THROMBOSIS; Dizziness; Pass Out; Weakness in the all side of the body; This spontaneous report received from a patient. The patient's height, and weight were not reported. The patient's concurrent conditions included sea food allergy, and other pre-existing medical conditions included the patient did not had any other illness at the time of vaccination and to one month prior and chronic or long standing health condition. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose was not reported, administered on 02-APR-2021 11:25 for prophylactic vaccination. The batch number was not reported. As per procedure, no follow-up will be requested for this case. Concomitant medications included metformin for drug used for unknown indication. On an unspecified date, the subject experienced thrombosis, dizziness, pass out, and weakness in the all side of the body, and was hospitalized (date unspecified). Laboratory data (dates unspecified) included: X-ray (NR: not provided) heart, head and lungs. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from thrombosis, dizziness, pass out, and weakness in the all side of the body. This report was serious (Hospitalization Caused / Prolonged, and Life Threatening).; Sender's Comments: V0: This is a report of a patient, who was noted to have thrombosis on unspecified time after receiving the covid-19 vaccine ad26.cov.2. Patient's height and weight were not reported. Patient medical history was not reported. Concomitant medications included metformin for unknown indication. Patient is allergic to seafoods. On an unspecified date, the subject experienced dizziness and passed out. She also had weakness on the left side of the body. Patient was noted to have thrombosis. Patient was hospitalized, where laboratory and diagnostic tests were done. Results were not reported. The information provided precludes a meaningful medical assessment. Additional information requested.</p>

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1261717	4/27/2021	NC	51	F	4/7/2021	4/7/2021	portal vein thrombosis; ischemic colitis; This is a spontaneous report from a contactable consumer (patient). A 51-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; Batch/Lot number was not reported), via an unspecified route of administration, administered in the left arm, on 07Apr2021 at 09:30 AM at the age of 51-years-old as single dose for COVID-19 immunization. The vaccination facility type was pharmacy or drug store. The patient was not pregnant. The patient had no other vaccine in four weeks. The patient had no medical history and had no known allergies. Concomitant medications included estradiol patch and cyanocobalamin (VIT B12); both taken for unspecified indications, start and stop dates were not reported (reported as other medications in two weeks). The patient previously received the first dose of BNT162B2, administered in the left arm on 10Mar2021 at 08:45 AM at the age of 51-years-old for COVID-19 immunization. The patient reported that at 11:30 pm on 07Apr2021, she had extreme, spontaneous, stomach cramps that was so bad she thought she was going to pass out. That lasted for one hour, then diarrhea. A few hours later, she started blood red rectal bleeding. At the hospital (on Apr2021), she was diagnosed with Ischemic colitis (from colonoscopy) and a blood clot was also found, portal vein thrombosis. She was 100% certain the extreme stomach cramps were brought on by the vaccine and that in turn caused the ischemic colitis; the blood clot may or may not have already been there. The patient reported that the doctors at the hospital were quite put off to try to tie any relation to this episode with the vaccine which was quite frustrating to the patient as it was quite obvious (as reported). The events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, and hospitalization. The patient was hospitalized for 2 days in Apr2021. On treatment for the events, the patient reported that the colitis healed on its own, and she was on blood thinners. The patient had no COVID prior the vaccination. The patient was test for COVID post vaccination which was a nasal swab with a negative result on 08Apr2021. The outcome of the events was recovering. Information on the lot/batch number has been requested.

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1262596	4/27/2021	FL	50	F	4/8/2021		<p>Feeling numbness, tightness, hotness, warmth, spotting and discoloration in right and alternates to the left leg today. Also started feeling some tightness in the left eye today. Have a Dr appointment but on May 17th and going to urgent care today. Advised to go to HCF instead of urgent just to ensure they can get imaging, US and appropriate testing's to r/o all cause of complications. 4/20-f/u pc to caller; couldn't sleep last night; used a heating pad on her leg but didn't work; states both legs hurt; feel tight; 4/10 pain; worried when also saw spots on her left leg and became concerned because saw news of clots; the episode started with tightness of her right leg which progressed to most of leg as well as left leg. Has not gotten worse today and denies any concomitant effects. Normally healthy. Did not go to the hospital because says she wouldn't be able to afford it. Has appointment with primary care in 2 weeks. rec'd that since she is still ok today then it's likely ok to skip the ER and go see MD as planned; warned to go to the ER right away or dial 911 if any of the following effects: sudden shortness of breath, severe headache, vision changes, loss of motor or/sensory function, chest pain. Call us back if having any effects at all besides the ones already noted so we may help determine if needs ER care.</p>

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1261292	4/27/2021	CA	53	F			STROKE; BRAIN BLEED; BRAIN FISTULA; VOMITING; HEADACHE; This spontaneous report received from a patient concerned a 53-year-old female. The patient's height, and weight were not reported. The patient's past medical history included hormone replacement therapy: bioidenticals, and surgery. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported 1 administered for prophylactic vaccination. Vaccination site was unknown. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, after two week of vaccination, the patient had a brain fistula which was considered as a stroke because it was a bleeding not a clot. She had really bad headache and was throwing up all night (vomiting). She called her primary health care physician they told her to visit hospital. First she went to the community hospital in her local city from where she was transferred to another hospital for surgery. The surgery occurred in first week of April. She was currently hospitalized. Number of days in hospital were unspecified. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the headache, vomiting, brain fistula, brain bleed and stroke was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments:-covid-19 vaccine ad26.cov2.s-Haemorrhagic stroke . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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1261326	4/27/2021	WI	57	F	3/19/2021		FLUID IN THE HIP AREA BELOW THE SPINE; PAIN IN BOTH LEGS; EXTREME LOWER BACK PAIN; TINGLING IN FEET; HEADACHE; This spontaneous report received from a patient concerned a 57 year old female. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included the patient had no known allergies. the patient was not pregnant at the time of reporting. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805031, and expiry: UNKNOWN) dose was not reported, administered on 19-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 19-MAR-2021, the subject experienced headache. On 25-MAR-2021, the subject experienced extreme lower back pain. On 25-MAR-2021, the subject experienced tingling in feet. On 25-MAR-2021, the subject experienced pain in both legs. On 11-APR-2021, the subject experienced fluid in the hip area below the spine. Laboratory data included: Blood test (NR: not provided) No blood clot, CAT scan (NR: not provided) No blood clot but fluid below the spine, and Diagnostic ultrasound (NR: not provided) No blood clot but fluid below the spine. Treatment medications (dates unspecified) included: acetylsalicylic acid, and ibuprofen. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from headache on 21-MAR-2021, was recovering from extreme lower back pain, pain in both legs, and tingling in feet, and the outcome of fluid in the hip area below the spine was not reported. This report was non-serious.

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1261352	4/27/2021	TN		U			<p>BLOOD CLOT IN RIGHT LUNG; This spontaneous report received from a patient via a company representative via email concerned a patient of unspecified age and sex. Patient's race and ethnicity were not reported. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin unknown) dose, anatomical vaccination site, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced blood clot in right lung. The patient emailed in regards to a possible adverse event reaction to the Janssen Covid vaccine that he received on an unspecified date. The patient was in a hospital at the time of report with a blood clot in right lung. One of the doctor insinuated that it may have been caused by the vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the event blood clot in right lung was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: This case concerns a patient of unspecified age and gender who experienced a blood clot in the right lung an unspecified period of time after receiving the Janssen Covid-19 vaccine. Medical history, concomitant medications, diagnostic tests, corrective treatments, and outcome were not provided. Based on the limited available information, the relationship to vaccination is considered unclassifiable. Additional information is being requested.</p>

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1261358	4/27/2021		41	M		4/7/2021	<p>DIAGNOSIS OF BRANCH RETINAL VEIN OCCLUSION VIA BLOOD CLOT; LETHARGIC; CHILLS; MUSCLE ACHE; HEADACHE; This spontaneous report received from a patient concerned a 41 year old male. The patient's weight was 210 pounds, and height was 72 inches. The patient's concurrent conditions included alcohol user, and non smoker, and other pre-existing medical conditions included the patient had no known allergies. the patient did not have any drug abuse/illicit drug use. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, and batch number: 041A21A expiry: UNKNOWN) dose was not reported, administered on left deltoid on 07-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, he reported blurred vision in left eye. Then he experienced lethargic, chills, muscle ache, headache. On 14-APR-2021, he experienced diagnosis of branch retinal vein occlusion via blood clot in the eye. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from lethargic, chills, and muscle ache, and the outcome of diagnosis of branch retinal vein occlusion via blood clot and headache was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This is a report of a 41 year old male patient, who was noted to have branch retinal vein occlusion via blood clot in the eye 7 days after receiving the covid-19 vaccine ad26.cov.2. Patient is 210 pounds and 72 inches. No pre existing medical conditions. No known allergies. Patient is a non smoker and did not have any drug abuse/illicit drug use. On the day of the vaccination, patient reported blurred vision on the left eye. He also experienced lethargy, chills, muscle ache and headache. Seven (7) days after receiving the vaccine, a blood clot was noted leading to branch retinal vein occlusion. The information provided precludes a meaningful medical assessment. Additional information requested.</p>

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1261383	4/27/2021	IL		M		4/18/2021	<p>BLOOD CLOTS IN THE LEG; BLOOD CLOT IN THE CHEST; This spontaneous report received from a consumer (calling on behalf of her husband) concerned a 60 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included diabetes mellitus, asthma, high blood pressure, and penicillin allergy. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin: unknown, batch number: Unknown) on 12-APR-2021, into right arm, for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 18-APR-2021, the patient began experiencing pain and swelling in the left leg. His leg was very hot and red "like a fever" and the pain was radiating up to the chest and heart and also spread to the right side of the chest. The patient was experiencing a lot of pain and couldn't breath. On 19-APR-2021 the patient's wife called the doctor and he was admitted to hospital. An ultrasound was performed which confirmed blood clots in the leg and chest. At the time of this report patient was still in the hospital. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clots in the leg, and blood clot in the chest. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: This 60 year-old male with medical history significant for diabetes, high blood pressure, and asthma was hospitalized for blood clots in the leg and chest 7 days after receiving the Janssen Covid-19 vaccine. Concomitant medications were not reported. Six days post-vaccination, the patient began experiencing left leg pain and swelling. His leg was red and hot and the pain would radiate from his leg to his chest. He was also experiencing difficulty breathing. The following day (7 days post-vaccination), he was admitted to the hospital. An ultrasound confirmed blood clots in the leg and chest. Other diagnostic test results and corrective treatment were not reported. As of the time of this report, the patient was still in the hospital. Based on the limited information, the relationship with Janssen Covid-19 vaccine is considered indeterminant. More information (e.g. platelet count, D-dimer, fibrinogen, anti-platelet factor 4 antibodies, medical records) is being sought.</p>



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1261384	4/27/2021			M			<p>SWOLLEN NECK; SWOLLEN RIGHT ARM; 6 BLOOD CLOTS; SICK; This spontaneous report received from a patient concerned a male of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included surgery. There was no history or family history of blood clots. Prior to vaccination, the patient had several physicals performed due to other health concerns and CAT-scans and MRIs were performed that showed his body was totally without any blood clots. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic indication. Batch number was not reported and has been requested. No concomitant medications were reported. After getting the vaccine patient was sick for 3 days. On an unspecified date, the patient woke with a with swollen neck, swollen right arm that was twice its normal size. The patient went to the hospital and they were concerned it was a blood clot further so he was then sent to hospital where they performed an ultrasound which revealed 6 blood clots. The patient was hospitalized and underwent surgery on his arm to "open up the vein that was causing the swelling". The patient reported he was scheduled for several more surgeries of this kind. Corrective treatment included intravenous blood thinners. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from swollen neck, swollen right arm, 6 blood clots, and sick. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: This male patient of unspecified age noted swelling of right arm and neck that the ultrasound showed 6 blood clots after an unspecified duration from receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. The patient was hospitalized and underwent corrective surgery and was started on unspecified blood thinners. No other details was reported. The information available precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information was requested.</p>

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1261412	4/27/2021	FL		F			SEVERE EAR INFECTION; URINARY TRACT INFECTION; STOMACH CRAMPS; SEVERE/WORSENING HEADACHE; This spontaneous report received from a consumer concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the subject experienced severe ear infection, urinary tract infection, stomach cramps, and severe/worsening headache. Laboratory data (dates unspecified) included: CAT scan (NR: not provided) No blood clots. Treatment medications (dates unspecified) included: cefalexin. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the severe/worsening headache, stomach cramps, severe ear infection and urinary tract infection was not reported. This report was non-serious.; Sender's Comments: V0 Medical assessment comment not required as per standard operating procedure as the case assessed as non-serious.

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1261447	4/27/2021	NC	71	F		4/9/2021	<p>NUMBNESS OF EXTREMITIES; TINGLING OF EXTREMITY; MILD SORE ARM; TIREDNESS; This spontaneous report received from a patient concerned a 71 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included penicillin allergy, and auras with migraines. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 043A21A expiry: UNKNOWN) dose was not reported, administered on 08-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On APR-2021, Laboratory data included: Blood test (NR: not provided) cleared of blood clots, Ophthalmological examination (NR: not provided) clear eyes, and Screening test (NR: not provided) clear stomach, carotids were clear. On 09-APR-2021, the subject experienced mild sore arm. On 09-APR-2021, the subject experienced tiredness. On 10-APR-2021, the subject experienced numbness of extremities. On 10-APR-2021, the subject experienced tingling of extremity. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from numbness of extremities, and tingling of extremity on APR-2021, and mild sore arm on 11-APR-2021, and the outcome of tiredness was not reported. This report was non-serious.</p>

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1261480	4/27/2021	IL	62	F	3/28/2021		VOMITING; FEET AND LEG PAIN; This spontaneous report received from a patient concerned a 62 year old female. The patient's height, and weight were not reported. The patient's past medical history included aspirin allergy, and concurrent conditions included history of blood clot, and chronic inflammatory demyelinating polyneuropathy. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. Concomitant medications included immunoglobulin human normal for chronic inflammatory demyelinating polyneuropathy. On 28-MAR-2021, the subject experienced vomiting. On 28-MAR-2021, the subject experienced feet and leg pain. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the vomiting and feet and leg pain was not reported. This report was non-serious.

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1261538	4/27/2021	FL	50	F	1/15/2021	2/10/2021	<p>Blood clots; Gangrene; Missed her second dose as the hospital where the patient was admitted did not have Moderna vaccine; patient was sent to rehabilitation center; surgery (a leg was amputated); two clots were removed; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Blood clots), THROMBECTOMY (two clots were removed), GANGRENE (Gangrene) and LEG AMPUTATION (surgery (a leg was amputated)) in a 50-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 025J20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Clot blood (blood clots in heart and lungs for last 15 years) and Thrombectomy (40 clots removed from heart and lungs from past 15 years). Concurrent medical conditions included Systemic lupus erythematosus (bad lupus). On 15-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Feb-2021, the patient experienced THROMBOSIS (Blood clots) (seriousness criteria hospitalization and medically significant). On 01-Mar-2021, the patient experienced THROMBECTOMY (two clots were removed) (seriousness criterion hospitalization prolonged) and LEG AMPUTATION (surgery (a leg was amputated)) (seriousness criterion hospitalization prolonged). On 12-Mar-2021, the patient experienced REHABILITATION THERAPY (patient was sent to rehabilitation center). On an unknown date, the patient experienced GANGRENE (Gangrene) (seriousness criterion hospitalization prolonged) and PRODUCT ADMINISTRATION INTERRUPTED (Missed her second dose as the hospital where the patient was admitted did not have Moderna vaccine). The patient was hospitalized on 10-Feb-2021 due to THROMBOSIS, then on 27-Feb-2021 due to LEG AMPUTATION and THROMBECTOMY. The patient was treated with Surgery for Gangrene. On 01-Mar-2021, THROMBECTOMY (two clots were removed) and LEG AMPUTATION (surgery (a leg was amputated)) had resolved. At the time of the report, THROMBOSIS (Blood clots), PRODUCT ADMINISTRATION INTERRUPTED (Missed her second dose as the hospital where the patient was admitted did not have Moderna vaccine) and</p>

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REHABILITATION THERAPY (patient was sent to rehabilitation center) outcome was unknown and GANGRENE (Gangrene) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. As per the patient's doctor, it was too late and dangerous to remove clots from the patient's leg and eventually, the doctor had to amputate the patient's leg because of gangrene. No concomitant medications were reported. Company comment: Based on current available information and the temporal association between product use and het start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on current available information and the temporal association between product use and het start date of the events a causal relationship cannot be excluded.

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1261611	4/27/2021	VA	85	F	1/22/2021	1/23/2021	was achy with the first dose; sore arm with first dose; This is a spontaneous report from a contactable consumer (patient). A 85-years-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: EK4176), via an unspecified route of administration on 22Jan2021 as single dose (at the age of 85-years) in Arm Left for covid-19 immunization. Medical history included: knee arthroplasty from Apr2018 to an unknown date (knee cap was not replaced) and breast cancer from Aug2013 to an unknown date. The patient did not receive any other vaccination within 4 weeks. Concomitant medications included: levothyroxine sodium (SYNTHROID) 200mcg daily taken for hypothyroidism (since 35 years); omeprazole 20 mg daily taken for gastroesophageal reflux disease; furosemide 40mg daily taken for left ventricular failure from 2017 to an unspecified stop date; spironolactone 25mg, takes half tab daily, taken for left ventricular failure from 2017 to an unspecified stop date; ascorbic acid, betacarotene, cupric oxide, tocopheryl acetate, zinc oxide (PRESERVISION), 1 daily taken for macular degeneration from 2011 to an unspecified stop date; colecalciferol (VITAMIN D) 5,000 units daily taken for vitamin d deficiency (since 6-7 years) (all are ongoing). On 23Jan2021, the patient experienced achy and sore arm with first dose. She is always achy. The degree of the achiness went away. On an unspecified date, the patient had ultrasound to check for deep vein thrombosis and results were unknown. The outcome of pain in extremity was recovered on 25Jan2021 and for another event it was unknown.

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1261269	4/27/2021	TX	22	F		4/1/2021	<p>FELT LIGHTHEADED; TINGLING IN HER FACE AND EXTREMITIES; UNABLE TO WALK; CALCIUM LEVELS WERE HIGH; ANXIETY; HYPERVENTILATED DURING SLEEP; BLOOD PRESSURE (BP) WAS OFF; HAND CONTRACTED; CHEST PAIN; CHEST TIGHTNESS; NUMBNESS IN EXTREMITIES AND FACE; SHORTNESS OF BREATH; FATIGUE; PAIN IN EXTREMITY; WEAKNESS; CHILLS; FEVER; MUSCLE ACHES; DECREASED ABILITY TO PERFORM ACTIVITIES OF DAILY LIVING; This spontaneous report received from a consumer concerned a 22 year old female. The patient's weight, height, and medical history were not reported. The patient was not pregnant at the time of report. The patient had no known drug allergy. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 201A21A, expiry: 23-JUN-2021) dose was not reported, administered on 09-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On APR-2021, the subject experienced decreased ability to perform activities of daily living. On 10-APR-2021, the subject experienced pain in extremity. On 10-APR-2021, the subject experienced weakness. On 10-APR-2021, the subject experienced chills. On 10-APR-2021, the subject experienced fever. On 10-APR-2021, the subject experienced muscle aches. On 11-APR-2021, the subject experienced numbness in extremities and face. On 11-APR-2021, the subject experienced shortness of breath. On 11-APR-2021, the subject experienced fatigue. On 12-APR-2021, the subject experienced chest pain. On 12-APR-2021, the subject experienced chest tightness. On 14-APR-2021, the subject experienced hand contracted. On 14-APR-2021, the subject experienced blood pressure (bp) was off. Laboratory data included: Blood pressure (NR: not provided) BP was off, and Chest X-ray (NR: not provided) CLEAR. On 15-APR-2021, the subject experienced hyperventilated during sleep. On 16-APR-2021, the subject experienced calcium levels were high. On 16-APR-2021, the subject experienced anxiety. On 16-APR-2021, the subject experienced tingling in her face and extremities. On 16-APR-2021, the subject experienced unable to walk. Laboratory data included: Calcium increased (NR: not provided) Very High. On 18-APR-2021, the subject experienced felt lightheaded.</p>



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Laboratory data included: MRI (NR: not provided) No clots in her chest or legs. Treatment medications (dates unspecified) included: warfarin. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from hand contracted, and chills on APR-2021, and fever on 11-APR-2021, was recovering from shortness of breath, chest pain, chest tightness, hyperventilated during sleep, and calcium levels were high, had not recovered from numbness in extremities and face, fatigue, pain in extremity, weakness, anxiety, muscle aches and unable to walk, and the outcome of decreased ability to perform activities of daily living, blood pressure was off, tingling in her face and extremities and felt lightheaded was not reported. This report was non-serious.

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1264453	4/27/2021	NY		M		4/9/2021	<p>BENIGN VERTIGO/ON AND OFF LIGHTEADEDNESS/FEELING WEIRD; TIREDNESS/FATIGUE; CHILLS; FEVER; This spontaneous report received from a patient concerned a 27 year old male. The patient's weight was 62 kilograms, and height was 69 inches. The patient's past medical history included fat removal from chest, and concurrent conditions included gastroesophageal reflux disease, somewhat of a hypochondriac, penicillin allergy, and alcoholic, and other pre-existing medical conditions included patient had allergy to all NSAIDS (non-steroidal antiinflammatory drugs). patient had no drug abuse or illicit drug usage. patient consumed one small glass of red wine at night as a preventative for blood clots on the recommendation of a friend who is doctor and the alcohol also thins blood. The patient experienced drug allergy when treated with acetylsalicylic acid. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 206A21A, expiry: 23-JUN-2021) dose was not reported, administered on 09-APR-2021 15:00 for prophylactic vaccination. Concomitant medications included pantoprazole sodium sesquihydrate for gerd. On APR-2021, Laboratory data included: Endoscopy (NR: not provided) unknown. On 09-APR-2021, the subject experienced chills. On 09-APR-2021, the subject experienced fever. Laboratory data included: Body temperature (NR: not provided) 39.5 C. On 10-APR-2021, the subject experienced tiredness/fatigue. Laboratory data included: Body temperature (NR: not provided) 38.5 C. On 16-APR-2021, the subject experienced benign vertigo/on and off lightheadedness/feeling weird. On 21-APR-2021, Laboratory data included: Neuro-ophthalmological test (NR: not provided) Benign vertigo. Treatment medications (dates unspecified) included: meclizine, and paracetamol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from chills, and fever on 11-APR-2021, and tiredness/fatigue on 12-APR-2021, and the outcome of benign vertigo/on and off lightheadedness/feeling weird was not reported. This report was non-serious.; Sender's Comments: MAC- V0: Medical assessment comment is not required as per standard procedure as case assessed as non-serious.</p>

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1264082	4/27/2021	MI	70	F	4/6/2021	4/23/2021	The pt said she developed a blood clot on her posterior hand. I asked her if it was a bruise on the back of her hand and she said it was a blood clot. She said she slapped the bump/clot and it subsequently went down/away.
1264226	4/27/2021	TX	68	F	3/31/2021	4/7/2021	patient reported to hospital with headache for 2 days, and was told she had a blood clot in her liver last week. she reports that she got the Johnson and Johnson vaccine last month. exact date not known.
1264290	4/27/2021	CO	68	F	3/1/2021	3/18/2021	Moderna COVID-19 Vaccine EUA: patient with relapsed AML and right upper extremity deep vein thrombosis (DVT) presented to clinic with headache and found to have subdural hematomas and a cerebral venous sinus thrombosis of unclear acuity. Patient admitted for management of AML, subdural hematomas, and upper extremity DVT. Discharged home improved and medically stable.
1264355	4/27/2021	CO	82	F	2/8/2021	3/8/2021	Moderna COVID-19 Vaccine EUA: one month after vaccination patient presents to emergency department reporting worsening headache for three months. Diagnosed with dural venous sinus thrombosis, admitted to hospital, anticoagulated, and discharged to home stable with symptom resolution.
1264375	4/27/2021	CA	60	F	4/3/2021	4/27/2021	Headache, leg swelling Sent to ED for evaluation blood clot in leg

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1264393	4/27/2021	MI	62	M	4/1/2021		<p>BURNING; SLEEPY; THROMBOSIS AND BURNING WENT AWAY; SORE ARM; FELT TIRED; WARM BANDANA LIKE HEADACHE; DIZZINESS; BLEEDING BY ANKLE; This spontaneous report received from a patient concerned a 62 year old white and not Hispanic or Latino male. The patient's height, and weight were not reported. The patient's past medical history included thrombosis, burning on inner thighs and concurrent conditions included thick varicose vein. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported and batch number: 043A21A expiry: UNKNOWN) dose was not reported, 1 total administered on 05-APR-2021 to left arm for prophylactic vaccination. No concomitant medications were reported. On an unspecified date in APR-2021, the patient experienced bleeding by ankle. On 05-APR-2021, the patient experienced dizziness, sore arm, felt tired and warm bandana like headache. On 05-APR-2021, after getting a shot the patient noticed thrombosis and burning went away. On 06-APR-2021, the patient experienced sleepy. On 16-APR-2021, the patient experienced burning The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from burning on APR-2021, dizziness, sleepy, felt tired, and warm bandana like headache on 06-APR-2021, and sore arm on 07-APR-2021, and the outcome of bleeding by ankle and thrombosis and burning went away was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0; 20210436178-covid-19 vaccine ad26.cov2. s-Bleeding by ankle. This event is considered not related. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the events than the drug. Specifically: MEDICAL HISTORY, UNDERLYING DISEASE</p>

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1264426	4/27/2021	AZ	78	F	4/1/2021		BAD CHEST PAINS, PAIN IN CENTER OF CHEST; FEELING OF HEART NOT BEATING RIGHT; BLOOD PRESSURE OF 212; CELLULITIS IN HER WRIST; This spontaneous report received from a patient concerned a 78 year old female patient. The patient's height was 166 inches and weight was 138 pounds. The patient's concurrent conditions included white coat hypertension, asthma, severe allergy to codeine, abstain from alcohol, and non-smoker. The patient was not pregnant. The patient received vaccination with covid-19 vaccine ad26.cov2. s (suspension for injection, intramuscular, batch number: 1805020, and expiry: UNKNOWN) dose was not reported, administered on 02-APR-2021 09:00 in left arm as prophylactic vaccination. Concomitant medications included estradiol. The patient reported that about 15-20 minutes post-vaccination on 02-APR-2021 as she was waiting in waiting area of vaccination clinic, she started to get bad chest pain which was in the center of her chest. She experienced heavy pressure in her chest. No arm pain or sensation was reported other than her chest. The patient further explained that she could feel that her heart 'wasn't beating right' and reported as 'heart feeling wonky'. The patient felt the top of her heart beating faster than the bottom. The vaccination paramedic took her blood pressure which was 212 (patient did not have any other information on her blood pressure). The paramedics called ambulance and after a 15 minute drive patient arrived at emergency room at 9.30. The patient had an echocardiogram or 'an ultrasound' of her heart and was told that it was not functioning properly that her ventricle was functioning at 40% of normal. The patient was put on nitroglycerin and heparin drip. Blood test was also done which showed troponin levels at 113 or 116, 'somewhere in there'. The patient was told that 'some type of cardiac event had occurred'. The patient's tests were reviewed same night and patient spent the night in emergency room because there were no beds. On 03-APR-2021, the patient was transferred to a hospital where she was put on nitroglycerin and heparin drip. The patient was moved again to another hospital on night of 04-APR-2021. The patient had angiogram and CT of vein and arteries. No clot was found by that time. The patient was discharged on 06-APR-2021. The patient saw a cardiologist on 15-APR-2021 who told patient that 'he thought she had

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some kind of clot that dissolved in the hospital'. Since patient has been home, she experienced pain and discomfort in arm and wrist with cellulitis in her wrist. The patient was taking cephalexin 500 mg three times a day for 10 days. The patient said it was due to angiogram she had because the angiogram team had hard time with her angiogram and had to go in twice. The patient had been taking percocet 5 mg tablet as needed for pain. The patient attempted to report these events online and left a message for someone to call her back but email did not work as she was unable to send. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of bad chest pains, pain in center of chest, feeling of heart not beating right and blood pressure of 212, and cellulitis in her wrist was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: This 78-year-old white (non-Hispanic/Latino) female patient was hospitalized for chest pain, palpitations, and blood pressure of 212 within the hour of receiving COVID-19 VACCINE AD26.COV2.S for the prevention of symptomatic SARS-CoV-2 virus infection. Concurrent illness included white coat hypertension, asthma, severe allergy to codeine; denies smoking and have abstained from alcohol. The patient complained of "bad chest pain" described as heavy pressure on the chest and that she could feel her "heart was not beating right/heart feeling wonky/top of her heart beating faster than the bottom". Blood pressure was 212 when it was checked, the patient was transported to the emergency room where echocardiogram showed that her ventricle was functioning at 40% of normal; Troponin was 113 (or 116). The patient was started on nitroglycerin and heparin drip. CT Angiogram of veins and arteries done 2 days after the vaccination showed no clot; by the attending cardiologist thought that some kind of clot might have been dissolved. Due to difficulty of doing the angiogram, the patient had cellulitis in her wrist with pain and discomfort in arm and wrist; the patient was taking cephalexin and percocet for the cellulitis and pain. No other details reported. The short latency and the advanced age confounded the event. The information available precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the

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1264000	4/27/2021	MD	67	F	3/1/2021	3/22/2021	literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information was requested. My sister suffered a massive stroke with blood clots. Totally paralyzed on right side and limited speech. Unable to function on her own, receiving care at a Nursing Home

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1264445	4/27/2021	NY		F		4/1/2021	<p>LEG CRAMPING; DIFFICULTY BREATHING; SWELLING OF LEG WITH EDEMA; HEAVY LEG; LOSS OF APPETITE; RASH ON LEFT FOREARM; LOSS OF 5 LBS; DIFFICULTY WALKING; DIFFICULTY SLEEPING WELL; This spontaneous report received from a patient concerned a 65 year old female. The patient's weight was 120 pounds, and height was 170.68 centimeters. The patient's concurrent conditions included chronic obstructive pulmonary disease (copd), asthma, interstitial lung disease, herniated disc at cervical lumbar, allergy to sulfa medications, back injury, and oxygen 24/7. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808980, and expiry: UNKNOWN) dose was not reported, administered on 08-APR-2021 14:30 for prophylactic vaccination. No concomitant medications were reported. On APR-2021, the subject experienced loss of 5 lbs. On APR-2021, the subject experienced difficulty walking. On APR-2021, the subject experienced difficulty sleeping well. On 11-APR-2021, the subject experienced leg cramping. On 11-APR-2021, the subject experienced difficulty breathing. On 11-APR-2021, the subject experienced swelling of leg with edema. On 11-APR-2021, the subject experienced heavy leg. On 11-APR-2021, the subject experienced loss of appetite. On 11-APR-2021, the subject experienced rash on left forearm. On 12-APR-2021, Laboratory data included: Ultrasound scan (NR: not provided) No venous clots and no thrombosis. On 20-APR-2021, treatment medications included: prednisone. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from swelling of leg with edema, and heavy leg on 15-APR-2021, and loss of appetite, and rash on left forearm on APR-2021, was recovering from leg cramping, and difficulty breathing, and the outcome of loss of 5 lbs, difficulty walking and difficulty sleeping well was not reported. This report was non-serious.; Sender's Comments: V0: Medical assessment comment not required as per standard operating procedure as the case is assessed as Non-serious.</p>



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1264697	4/27/2021	VA		U			<p>Acute necrotizing pancreatitis; Thrombosis of SMV; Thrombosis of splenic vein; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a pharmacist and describes the occurrence of PANCREATITIS NECROTISING (Acute necrotizing pancreatitis), MESENTERIC VEIN THROMBOSIS (Thrombosis of SMV) and SPLENIC VEIN THROMBOSIS (Thrombosis of splenic vein) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced PANCREATITIS NECROTISING (Acute necrotizing pancreatitis) (seriousness criterion medically significant), MESENTERIC VEIN THROMBOSIS (Thrombosis of SMV) (seriousness criterion medically significant) and SPLENIC VEIN THROMBOSIS (Thrombosis of splenic vein) (seriousness criterion medically significant). At the time of the report, PANCREATITIS NECROTISING (Acute necrotizing pancreatitis), MESENTERIC VEIN THROMBOSIS (Thrombosis of SMV) and SPLENIC VEIN THROMBOSIS (Thrombosis of splenic vein) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Based on the current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded. Very little information is available at this time. Further information has been requested.; Sender's Comments: Based on the current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded. Very little information is available at this time. Further information has been requested.</p>

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1264464	4/27/2021	NJ	43	M	3/20/2021		<p>BLOOD CLOTS IN URINE; URINATING BLOOD; FELT ACHY; This spontaneous report received from a patient concerned a 43 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805020, and expiry: 25-MAY-2021) dose was not reported, administered, 1 total, to left arm on 19-MAR-2021 around 06:00 PM for prophylactic vaccination. No concomitant medications were reported. On 20-MAR-2021, 12 hours after vaccination patient felt achy which had resolved in 24 hours. On 20-APR-2021, patient experienced blood clots in urine and had urinating blood lasted till evening of same day. The patient visited emergency room for same symptoms and admitted on 20-APR-2021, discharged around noon on same day. The patient was given with IV fluids and no other medications were administered. The patient had undergone blood test, urine analysis, computerized tomography (CT) scan and results were nothing urgent to consult. The patient had planned to do follow-up with urologist on 28-APR-2021. Laboratory data included: Blood test (NR: not provided) negative, computerized tomography (CT) scan (NR: not provided) negative, and Urinalysis (NR: not provided) negative. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from blood clots in urine, and urinating blood on 20-APR-2021, and felt achy on 21-MAR-2021. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: - Covid-19 vaccine .Ad26.Cov2.S- Blood clots in urine . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

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1264696	4/27/2021	TX		F	3/1/2021		Blood clots; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clots) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No medical history was provided by the reporter. On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. In March 2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clots) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood clots) was resolving. The patient took the second vaccine on the 29th or 30th of March Company Comment Very limited information regarding this event has been provided at this time. Further information has been requested. This case was linked to MOD-2021-076604 (Patient Link). Reporter did not allow further contact
1264907	4/27/2021	IL	53	F	1/27/2021	2/3/2021	On 02/03/2021 @ 1 am (approx. 1 wk. after 1st vaccine shot), started having pains under ribcage. Pains off and on until on 02/09/2021 about 3 am when the pain got so bad I went to the emergency room. Diagnosed with pulmonary embolism. Never had a blood clot or DVT before. Blood test found I had Factor V. Had pain again under ribcage one week after second vaccine, but blood thinners appears to have dissolved if it was a clot. My father then tested and found positive for Factor V after my diagnosis. He then had a blood clot in leg approx 3 weeks after his second Pfizer vaccine, and had never had a blood clot like that before. Appears to be a connection between Factor V and blood clots after Covid vaccines.

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1265459	4/27/2021	CA	46	F	3/11/2021	4/4/2021	I had sudden sensorineural hearing loss first in my left ear and then in my right. I still have distorted hearing in my left ear and my right ear is still muffled. It happened a little under 3 weeks after the vaccine. The doctor performed a hearing test in my left ear and it showed moderate sensorineural hearing loss compared to the hearing test I had last August. 2 weeks later my right ear showed decreased hearing. I was put on 60 mg of steroids for 2 weeks and given doxycycline for 2 weeks. The dr also had me do a CT scan. I also had an elevated D-dimer test for clots.

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1261322	4/27/2021		46	F	4/11/2021		<p>CLOT BLOOD; ACUTE ISCHEMIC STROKE IN LEFT FRONTAL LOBE; PARTIAL LOSS OF USE IN RIGHT LEG; MUSCLE WEAKNESS; This spontaneous report received from a patient concerned a 46 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included amoxicillin and flexeril allergy, and migraine. The patient experienced drug allergy when treated with cyclobenzaprine hydrochloride. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 042A21A, and batch number: 042A21A expiry: UNKNOWN) dose was not reported, administered on 08-APR-2021 11:30 on left arm for prophylactic vaccination. Concomitant medications included ascorbic acid, ascorbic acid/ergocalciferol/folic acid/nicotinamide/panthenol/retinol/riboflavin/thiamine hydrochloride, ergocalciferol, iron, and withania somnifera. Approximately three days after the vaccine, on 11-APR-2021 08:20, the patient experienced clot blood. Which caused an acute ischemic stroke in left frontal lobe resulting in partial loss of use in right leg and muscle weakness. The patient had a blood test, CT scan, Carotid artery ultrasound, diagnostic ultrasound, electrocardiogram (EKG) and an MRI, results are unknown. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from clot blood, acute ischemic stroke in left frontal lobe, muscle weakness, and partial loss of use in right leg. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This is a report of a 46 year old, female patient who experienced a blood clot that caused an acute ischemic stroke in the left fontal lobe 3 days after receiving the covid-19 vaccine ad26.cov.2. Patient's height and weight were not reported. Patient has migraine and allergies to amoxicillin, flexeril and cyclobenzapine hydrochloride. Concomitant medications included ascorbic acid, ascorbic acid/ ergocalciferol/folic acid/ nicotinamide/ panthenol/retinol/ riboflavin/ thiamine hydrochloride, ergocalciferol, iron, and withania somnifera. Smoking history, drug abuse and alcohol intake were not reported. Three (3) days after receiving the vaccine, patient was noted to have a blood clot (unspecified area) that caused an acute ischemic stroke in the left frontal lobe, resulting in muscle weakness and partial loss of use of the right</p>

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1262665	4/27/2021	WI	43	F	4/5/2021	4/12/2021	leg. Patient had blood tests done as well as CT Scan, carotid artery ultrasound, electrocardiogram and MRI but the results were not reported. The information provided precludes a meaningful medical assessment. Additional information requested.  Mon 4/12/21 - Headaches started and have continued daily. Tue 4/13/21 - Soreness in right calf muscle, continued for 4 days. Headache continued. Wed 4/14/21 - Sharp pain in pelvis (right and left side) same location I experienced pain the day of receiving vaccine. Occasionally felt this pain 2 or 3 times / day for 2 days. Sought medical attention at ED on the advice of our Nurse Call Center. Was evaluated for blood clots, none found on this day. CT scan, ultrasound of both legs, blood tests. Returned home with directions to take Extra Strength Tylenol for headache. Thu 4/15/21 - Shooting pain in random parts of my body, mostly legs and arms. Experienced throughout this day only. As of 4/27/21, 22 days after being vaccinated, I am still experiencing headaches. More noticeable when I am exerting myself - walking outside for 1-2 minutes triggers the headache. Headaches are usually located in the lower back of my head. Before being vaccinated, I would experience less than 1 headache per month, and they go away within the day.
1262854	4/27/2021	KY	59	F	3/5/2021	4/17/2021	had to jansen & jansen vaccine on March 5, 2021 at pharmacy & on march 16 dianosed with covid. April 17 leg started feeling funny & went to ER on the 18th was dianosed with surface clots.

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1264437	4/27/2021	CO	40	F	4/1/2021		<p>STOMACH FLU; CHEST PAIN UNSPECIFIED; SHORTNESS OF BREATH; EKG SINUS TACHYCARDIA, LOW VOLTAGE PERIODICAL, UNCONFIRMED DIAGNOSIS; DIZZINESS; SLEEPING 14 HOURS; LARGE NODULE AT INJECTION SITE; SWELLING AT INJECTION SITE; REDNESS AT INJECTION SITE; SORENESS/PAIN AT INJECTION SITE; HIGH BLOOD PRESSURE; This spontaneous report received from a patient concerned a 40 year old female. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included the patient had no known allergies. The patient was not pregnant at the time of report. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 202A21A, expiry: 23-JUN-2021) dose was not reported, administered on 09-APR-2021 in left arm for prophylactic vaccination. No concomitant medications were reported. On 09-APR-2021 (following vaccination), the patient's area around the injection site was swollen, a large nodule formed, it was red, sore and painful. These local symptoms lasted for a week then disappeared. The patient felt very fatigued, and reports sleeping 14 hours that night. On 10-APR-2021 the patient experienced headache and felt like his head was in a vise around each cheekbone. The fatigue and headache was gone on 11-APR-2021. On 19-APR-2021 the patient had vomiting and diarrhea for about 16 hours. The local symptoms swelling, redness, pain at injection site reappeared. On 19-APR-2021 the patient was very fatigued and took Pedialyte (calcium chloride/glucose/magnesium chloride/potassium chloride/sodium chloride/sodium lactate) to get rehydrated. On 21-APR-2021, the patient visited the emergency room as new symptoms appeared stomach pain, chest pain, shortness of breath and dizziness and her blood work and electrocardiogram(EKG) was done. The health care professional(HCPs) ruled out heart attack and told patient nothing in the symptoms or blood work warranted a scan for blood clots. The patient received anti-nausea intravenous (IV) medication, diagnosis of stomach flu and was sent home. The patient reports that her blood pressure readings were 144/104 and a pulse was 119. The emergency room health care professional instructed the patient to follow up with doctor</p>

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							and discharge diagnosis was made as chest pain unspecified. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from swelling at injection site, redness at injection site, soreness/pain at injection site, and large nodule at injection site, had not recovered from chest pain unspecified, shortness of breath, dizziness, and EKG sinus tachycardia, low voltage periodical, unconfirmed diagnosis, and the outcome of stomach flu, high blood pressure and sleeping 14 hours was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210443030-covid-19 vaccine ad26.cov2.s-Stomach flu. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
1263150	4/27/2021	MD	41	F	4/9/2021	4/23/2021	Deep venous thrombosis at the site of vascular access line-Initially started on heparin, now switched to Rivaroxaban Thrombocytopenia-Supportive treatment and monitoring
1265163	4/27/2021	CA	31	F	4/3/2021	4/17/2021	Blood clot in each lung, chest pain, labored breathing, leg pain and upper back pain.
1262688	4/27/2021	VA	64	F	3/12/2021	3/24/2021	Patient was driving on 3/24 when her vision became blurry in her left eye. She saw her eye doctor on 4/21 and was sent to a specialist. On 4/23 she was diagnosed with a blood clot in her left eye. She is to begin eye injections for treatment.
1262742	4/27/2021	WI	36	F	4/5/2021	4/22/2021	Patient received vaccine on 4/5/21. She presented to her PCP on 4/22 with swelling and redness in the inside upper area of her right arm. Determined to be a superficial thrombosis. Patient has not history of VTE, but does smoke. Uses a Mirena IUD for contraception as well. Platelet count remained normal during this time, and was never affected.
1263068	4/27/2021	NJ	48	F	4/12/2021	4/17/2021	Pain on right leg, between my knee and ankle, 3 round bumps, looked like blood clots....and fatigue
1262857	4/27/2021	TX	63	M	3/4/2021	4/25/2021	Blood clot leading to stroke



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1263940	4/27/2021	CO	46	M	4/8/2021	4/22/2021	Janssen COVID-19 Vaccine EUA: two weeks after vaccination patient reported to an urgent care with right leg swelling and headache. Two days later patient presented an emergency department, diagnosed with left lower extremity deep vein thrombosis (DVT) and bilateral pulmonary emboli (PE). Transferred to current hospital for management including anticoagulation with a direct thrombin inhibitor, intravenous immune globulin (IVIG), and additional laboratory testing.
1263100	4/27/2021	FL	42	F	4/13/2021	4/14/2021	42-year-old female with previous history of chronic/refractory immune thrombocytopenic purpura (ITP). She received the Moderna COVID-19 vaccination on 4/13/2021 and subsequently developed headache, photophobia, diplopia and blurry vision. She had outpatient labs 4/14/2021 with a platelet count of 8000 and presented to the emergency room. She was seen by hematology/oncology and was started on high-dose dexamethasone for 4 days, IVIG x2 doses with an excellent response. Platelet count on discharge was above 200,000. Due to the headache and visual disturbance MRI and MRV was obtained which showed no evidence of cavernous sinus thrombosis however there was a question of idiopathic intracranial hypertension and ophthalmology and neurology was consulted. She had a fundoscopic exam with no evidence of papilledema. Her headache slightly improved with acetaminophen and hydrocodone. The patient was cleared for discharge home by hematology/oncology and will follow up with them in 1 week.
1263011	4/27/2021	NY	28	F	4/9/2021	4/9/2021	Fever over 105, chills, cough, soar throat. aches and pain for 2 days. Led patient to go to the ER on monday 4/12. MD found blood clot at that point. No treatment was given patient was told to follow up with her PCP. Did not go to PCP as yet.

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1263183	4/27/2021	WA	36	F	3/6/2021	4/3/2021	Four weeks after the vaccine I started to have lower abdominal pain for a 24-hour period. I am on Birth Control, Falmira and it was before the Placebo Pills Started. I passed a large clot of blood the next day and went to Urgent Care. It was sent for Pathology and it was deemed a Deciduous casting. I had a Pelvic Ultrasound the following week and it was normal. The clinic I went to for follow up was.
1263254	4/27/2021	AK	60	M	4/7/2021	4/19/2021	Blood clot in left calf muscle
1263266	4/27/2021	FL	54	M	4/11/2021	4/26/2021	Pulmonary embolism, Deep vein thrombosis - treating with Eliquis
1263472	4/27/2021	PA	76	F	4/3/2021	4/5/2021	patient had a blood clot 2 days after receiving the J & J vaccine; she was hospitalized and released. We just learned of this when the patient was in to pick up a Rx-- we are unsure if this was already recorded by the hospital that treated her--we were advised by our market manager to submit just in case they didn't submit at the hospital.
1263497	4/27/2021	CA	43	M	3/17/2021	4/8/2021	Blood clot, L arm (where pic line was located)
1263521	4/27/2021	FL	61	M	4/8/2021	4/12/2021	Symptom: Very sharp pain at top of stomach followed by very low heart rate and brief loss of consciousness after 1 hour Diagnosis: Partial thrombus (blood clot) of celiac axis which extended into the common hepatic artery and splenic artery Treatment: Blood thinners Timeline: Stabilized fairly quickly and then pain subsided after 2 days Course of treatment: Monitor for any additional symptoms through additional CT scans
1263525	4/27/2021	KY	62	M	3/30/2021	4/16/2021	Left leg pain started about 4/16/21. Reports evaluated by nurse practitioner at the medical office of primary care provider on 4/23/21. Ultrasound ordered a hospital and diagnosed with a blood clot in the left leg on 4/23/2021. Placed on a "blood thinner" to take orally BID for one month then once daily for undetermined duration. States MD is not considering the vaccination as the reason for the blood clot because of the duration of time between when the vaccine was given and the onset of the blood clot. When asked, pt reports a platelet count was done.

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1263560	4/27/2021	WA	87	M	3/31/2021	4/13/2021	Per patient's Daughter the patient developed blood clots in his small intestine on 4/13/2021 and died 4/22/21 with physicians unable to explain how or why he developed these clots while on apixaban. She requested his case be reported and reviewed in hopes it helps make the vaccines safer if that was what caused the clots.
1263882	4/27/2021	MD	69	M	3/23/2021	4/1/2021	Patient said that he called 911 with SOB, and he was admitted to the hospital and he stayed in the hospital for about 2 weeks. He is unsure of the date that he went into the hospital. Pt said he had a blood clot in both lungs.
1263085	4/27/2021	TX	34	M	3/29/2021	4/14/2021	SEEN ON 4/16/2021 WITH PROVIDER WITH THE FOLLOWING COMPLAINTS: Pt here for left sided low back pain; he gets it in different spots. Sharp - left mid back , left low back, left hip and left thigh. Does not radiate to foot. Does not cause paraesthesias, numbness, weakness or tingling. No problems urinating, dysuria. The pain started after janssen vaccine along with low grade fever; lasted for 2 days then went away for over 1 week. In fact he drove and hiked 10 miles as well w/o any recurrence of pain. He notes pain restarted 2 days ago. Massage and heat help. Exercising does not worsen. Pain for past 2 days is at a 2 level. No hx of back pain or arthritis. He does have hx of renal stones and cystitis but was cleared last year by his urologist. He has not drunk enough water today and would like to do his cbc on 4/22. He denies any heaches, vision changes, abd pain or leg pain. Most of the time his pain is low back area. It was more intense in the 2 days after vaccine. No hx of blood clots. No chest pain or SOB. No injuries to back. Pain is the same as post vaccine though milder. He denies straining his muscle. No easy bruising or bleeding. kidney stones feel much differently.
1258878	4/26/2021	WI	61	M	4/8/2021	4/24/2021	Received Moderna Covid Vaccine on 3/3/21 and 4/8/2021. Nted onset 4/24 of right calf discomfort, swelling and firmess and at same time began to have exertional dyspnea with chest heaviness. U/S RLE - extensive DVT. CTA - multiple segmental vessels with clot, dilated right ventricle
1259012	4/26/2021	MI	47	M	4/19/2021	4/22/2021	Blood Clot a Localized Vein in the Gastrocnemius Muscle

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1259028	4/26/2021	WI	53	F	3/10/2021	4/8/2021	Short of breath 4/20/21 hospitalization for blood clots in both lungs
1259084	4/26/2021	NY	80	M	3/29/2021	3/31/2021	Left arm swelling, shortness of breath, leg pain, generalized discomfort 4/5/21 - was seen at Urgent Care - no orders 4/6/2021 - seen at Hospital ER - CT showed blood clots/pulmonary embolism of left arm and lungs and lymph nodes. Received IV fluids in ER. Kept overnight for observation and discharged from hospital next day. Sent home on Eliquis and Prednisone
1259187	4/26/2021	MN	80	F	3/15/2021	3/15/2021	March 15, 2021 admitted Hoppital - lost vision in right eye due to blood clot retinal artery occlusion March 15 & 16 CT scan, Blood work, chest X-ray, mri March 16 discharged from Hospital March 17 Retina Center March 22 Clinic March 29 Neuroscience Clinic - ecocardiogram and ACT monitor for 30 days April 19 Retina Center
1259216	4/26/2021	MN	80	F	3/15/2021	3/15/2021	March 15, 2021 admitted Hoppital - lost vision in right eye due to blood clot retinal artery occlusion March 15 & 16 CT scan, Blood work, chest X-ray, mri March 16 discharged from Hospital March 17 Retina Center - March 22 Clinic - March 29 Neuroscience Specialty Clinic - ecocardiogram and ACT monitor for 30 days April 19 Retina Center -
1259250	4/26/2021	MN	80	F	3/15/2021	3/15/2021	March 15, 2021 admitted Hoppital - lost vision in right eye due to blood clot retinal artery occlusion March 15 & 16 CT scan, Blood work, chest X-ray, mri March 16 discharged from Hospital March 17 Retina Center - . March 22 Clinic - March 29 Neuroscience Specialty Clinic - ecocardiogram and ACT monitor for 30 days April 19 Retina Center -
1259329	4/26/2021	FL	70	M	3/13/2021	3/19/2021	Very large P E Blood Clot in lungs

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1259395	4/26/2021	CO	82	F	4/1/2021	4/24/2021	Pt received Dose #1 of COVID-Pfizer vaccine on 3/15/21 and Dose #2 on 4/1/21 (location pt received is unknown by this reporter); pt was presented to ED on 4/25/21 @ 1427 with confusion, dysarthria, R-sided weakness. Head CT showed L sagittal sinus thrombosis and pt was started on a heparin drip per protocol. On 4/26/21 pt still noted to have RUE weakness, however speech had improved. Pt is still hospitalized in the ICU as of this report on 4/26/21.
1259454	4/26/2021	WA	59	F	3/29/2021	4/23/2021	venous sinus thrombosis of the superior sagittal sinus, based on imaging likely occurred 1-2 weeks prior to presentation, ~ 1-3 weeks after vaccination no other clear reason for hypercoag state, no prior thromboembolic events, no h/o malignancy or rheumatological disease.
1257910	4/26/2021	NY	44	F	4/2/2021	4/16/2021	My first menstrual period following the vaccine was exceedingly heavy in flow for the first two days, which is atypical for me. Heavy clots of menstrual discharge were observed. It is not yet known whether these side effects will continue for my next menstrual cycle. Lesser effects followed two days after the vaccine with fatigue, sore arm, armpit, and glands in the injection arm. These side effects dissipated by day 3 status post vaccine administration.
1259526	4/26/2021	CO	52	M	4/3/2021	4/18/2021	Patient developed portal vein thrombosis and thrombocytopenia
1259409	4/26/2021	AZ	52	F	4/17/2021	4/18/2021	4/17 Vaccination @ 530PM 4/18 woke up with stiff neck. Unsure if chest pain started on 4/18 or 4/19. Stiff neck felt like 'being choked'. 2 sharp pains in between breasts. Little pains on left breast, worked up to neck and ear. 4/19 ER. 4/20 ER ultra sound 4/21 cardiologist cb to tell me I had a pulmonary embolism. The Dr. said I needed to go to larger clinic. 4/22 Larger Clinic. They ran some scans with contrast of neck because of pain. CT. Taking blood clot medication. 4/26/2021 Extremely dizzy; going to have a CT scan today **dizziness is so bad right now. *4/29 appt with pulmonologist
1258788	4/26/2021	OH	89	F	3/24/2021	4/20/2021	Blood clots leading to TIAs and strokes

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1258608	4/26/2021	WA	18	M	4/11/2021	4/12/2021	He has had the following symptoms from the 4/12/2021 till present time: constant headache and fatigue. Intermittent low fever (99F). On 4/21/2021, his primary care doctor recommended that we take him to Emergency Room because she was concerned about thrombosis as side effects from the vaccine. His legs had some red patches on the back of the ankles area. At ER, doctor did blood test for blood clot and result was negative. He got an IV injection less headache.
1258387	4/26/2021	NC	62	F	3/8/2021	3/9/2021	3 Blood clots formed in the bottom of my left leg.
1258374	4/26/2021	CA	62	M	4/8/2021	4/12/2021	4/9 thru 4/12, body aches, chills. 4/12 0400 throwing up stomach pain from dry heaving throughout the day, confusion starting at 6pm on 4/12. Seizure on 4/12 at 8 pm. 911, ambulance. to Hospital Seizure so severe caused a Fracture in the Right Scapula. MRI on 4/15 showed a venous thrombosis partial occlusion in the brain.
1258330	4/26/2021		46	M	4/10/2021	4/15/2021	I had a stroke. Assumed blood clot traveled from my leg, up through a hole that was discovered in my heart (PFO) and to my brain.
1258309	4/26/2021	TX	57	M	4/16/2021	4/18/2021	Pt. received COVID19 Moderna vaccination (2nd dose) on 4/16/2021. That evening he developed a low grade fever which he took Tylenol for and it took it away. On Sunday 4/18/2021 in the evening Pt. states his tongue felt sluggish and he wasn't able to pronounce his words like he usually does. By Wednesday 4/21/2021- Pt. felt like mouth had been numbed by the dentist and he was having trouble swallowing. Pt. underwent CT Chest PE protocol as well as CT head to rule out thrombosis/ stroke. Testing was negative at that time. Pt. was changed to Aspirin 325mg and was told to follow up. On 4/26/2021 Pt. returns to clinic with 15 lb weight loss. Continued asphasia and dysphagic sx. An MRI w/w.o contrast of the brain is being ordered.
1258007	4/26/2021	NY	22	F	4/8/2021	4/11/2021	diagnosed with transverse sinus thrombosis, outcome unknown transferred to Hospital upstate
1257827	4/26/2021	ID	60	F	4/5/2021	4/9/2021	Patient developed renal artery thrombosis shortly after getting Pfizer vaccine

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1257670	4/26/2021	TX	47	M	4/3/2021	4/5/2021	Blood clots in nose every day for about 1 week after vaccine administration. Media only reporting about women getting blood clots as it affects their period, but I didn't think it was a side affect until days after I heard that being reported and vaccine being pulled.
1257669	4/26/2021	OH	47	M	4/6/2021	4/15/2021	Pt had vaccine on April 6, 2021 and was in the ER on April 15, 2021 with a right popliteal blood clot
1257659	4/26/2021	NY	98	F	3/16/2021	4/21/2021	Acute occlusive deep vein thrombosis noted in the left proximal and mid femoral and gastrocnemius veins. There is also evidence of acute partially occlusive deep vein thrombosis noted in the left common femoral and distal femoral veins. Patient was initially started on enoxaparin transitioned to apixiban for discharge.
1257638	4/26/2021	NY	41	F	4/4/2021	4/8/2021	My menstrual cycle was extremely heavy and I passed many large clots, similar to when I had a miscarriage except the heavy bleeding slowed in about 3 days and I completed my menstruation course as usual.
1259661	4/26/2021	TX	65	F	2/3/2021	2/24/2021	Shortness of breath; Difficulty breathing; Heaviness in chest; Went to ER and had chest x-rays and CT scan of my lungs. Found out I had numerous pulmonary embolisms in all 5 lobes of my lungs. They did a COVID test and it was negative. They did an EKG and sonogram on my heart and it was fine. They checked for blood clots in my legs. There were none. They checked for signs of cancer. There were none. They started a heparin drip through my IV and the dissolved the largest clot with an embolectomy. I'll be on blood thinners for 6 months.

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1258851	4/26/2021	VA	35	F	4/1/2021	4/25/2021	Caller's husband called the call center on the morning of 4/26 to ask about symptoms that his wife (the patient), who was 24 days post vaccination with Johnson & Johnson COVID-19 vaccine, had experienced the evening of 4/25. He reported that she had developed a severe headache and vomited. She c/o leg and chest pain as well and he reports that she has a history of blood clots but no h/o migraine headaches. At the time of the call his wife was feeling fine. I advised that they discuss with PCP. Having none I advised that she discuss with Urgent Care. I called him back about 6 hours later. They had decided that since she continued asymptomatic they were not going to seek clinical evaluation. They believe that the symptoms were musculo-skeletal after "spending the whole weekend laying a patio".
1258022	4/26/2021	PA	74	F	4/3/2021	4/4/2021	On 4/4/21 pt got 101 temp. Next day her temp was down but she was having problems breathing. She had to get cans of O2 to help her breathe. Her O2 was going from the 80's to 60's. She went to her pulmonologist on 4/22/21 pulmonologist and he sent to Hospital. She was put on O2 and other medicines. They did CT, X-rays, and blood work. They found a blood clot in her lung so was admitted for treatment. She will be there for a minimal for three more days till they can get her an O2 tank to send her home.
1260776	4/26/2021	MA	34	F	3/31/2021	4/12/2021	I've had pain in both legs off and on since the Janssen shot. Had an issue with clots and blood supply in previous and recent pregnancies
1259704	4/26/2021	WA	48	F	4/2/2021	4/9/2021	Went to er on April 11 th for cough and shortness of breathe they said nothing was wrong and sent me home. Did a virtual apt on 21st because my leg hurt and shortness of breathe. They told me to go see doctor in person . Went to Er April 23rd and was diagnosed with a massive blood clot in my lower right leg.they prescribed xarelto.
1258629	4/26/2021	IL	68	F	3/14/2021	4/22/2021	Blood clots in the left leg and in the lungs.



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1260764	4/26/2021	NY	64	F	4/3/2021	4/26/2021	MULTIPLE BILATERAL PULMONARY EMBOLI NONOCCLUSIVE RIGHT POPLITEAL DVT OCCLUSIVE RIGHT POSTERIOR TIBIAL VEIN AND RIGHT SMALL SAPHENEOUS VEIN THROMBOSIS PATIENT BEGAN TO DEVELOP LEFT FLANK PAIN FOUR DAYS FOLLOWING VACCINATION FOLLOWED BY SEVERE SHORTNESS OF BREATH WITHIN THE FOLLOWING DAYS
1260342	4/26/2021	TX	48	F	4/10/2021	4/13/2021	Patient came in this evening 4/26 after emergency room visit for blood clot in leg/shin. She received Janssen IMZ 4/10. Her symptoms of painful leg began several days after her IMZ and continued to worsen with her leg shin swollen, painful, bruised with a knot until she sought medical help in the ER. Ultrasound was done and ruled out deep vein thrombosis, determined to be peripheral blood clot. She was sent home on meloxicam for pain and inflammation.
1260292	4/26/2021		50	F	3/23/2021	4/2/2021	on April 2 nd i had to go to family walk in clinic over chest pains and contractions. The clinic ran vitals with EKG letting me know a ambulance had to be called cause i was having a heart attack. I was not aloud to leave . In the ambulance i was giving Asprin ,Nitros and a blood clot remover with high blood pressure meds. Takin to hospital.
1260272	4/26/2021	IN	50	M	4/1/2021	4/9/2021	Soreness & lump in left lower thigh size of tic tac Swollen and sore left foot Diagnosed with ultrasound as superficial blood clot Heat applied and aspirin Still swollen
1260021	4/26/2021	OH	46	F	4/10/2021	4/11/2021	Got Johnson and Johnson shot 4/10/2021: 4/11/21- 4/12/21 headache, hot and cold chills 4/13/21- abdominal pain and shortness of breath 4/14/21- shortness of breath (sob) 4/15/21- headache, pain right side chest 4/16/21- fatigue, pain left side chest 4/17/21- sob (bad) 4/18/21- 4/21/21 sob 4/22/21 -woke up struggling to breath. Family Physician sent me to hospital. She was thinking blood clot lungs 4/23/21- current sob

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1259807	4/26/2021	NJ	60	F	4/3/2021	4/4/2021	I woke up from almost like a pop in my brain and fluid started pouring down my throat and I started choking. I woke up and was able to spit some of it out. It was clear and also tinged with blood. It stopped once I stood up. I immediately thought my brain was leaking. I told my daughter about this the next day. My balance was off and I had a weird flapping in my head for the next few days. As well as a headache. A few days after I heard about the blood clots. I am not 100% sure if it was from the shot but it was literally hours from when I received it. It was very scary.
1259776	4/26/2021	AZ	53	M	4/4/2021	4/8/2021	Received the vaccine on 4/4/2021. On 4/8/2021 started having pain in lower left leg. Pain off and on for two weeks. Pain intensified on 4/23/2021. I went to the emergency room where they performed on ultra sound examination of my left leg. Confirmed that I have a deep vein thrombosis (DVT) behind my left knee. Prescribed Eliquis. Saw Dr. today. He could not confirm that DVT was caused by vaccine, but I thought I should report it. I am to stay on Eliquis for six months at which time I will be evaluated for a blood clot disorder.

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1255713	4/25/2021	VA	41	F	1/19/2021	1/1/2021	DVT; multiple bilateral pulmonary embolisms; rash; hives on my lower abdomen; calf injury due to extreme pain that felt like a constant cramp; This is a spontaneous report from a contactable Other HCP (patient) . A 41-years-old no pregnant female patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in Arm Left on 19Jan2021 16:30 (Batch/Lot Number: EL1283) as SINGLE DOSE for covid-19 immunisation.Age at vacciantion:41 years. No other vaccine in four weeks. No COVID prior vaccination Medical history included type 1 diabetes mellitus from an unknown date and unknown if ongoing , Hashimoto's Disease from an unknown date and unknown if ongoing. Concomitant medication(s) included metformin (METFORMIN) and levothyroxine (LEVOTHYROXINE) . The patient experienced DVT followed by multiple bilateral pulmonary . The clinical course was reported as follows:"Within 5 hours of the first dose I got a 3" in diameter rash and hives on my lower abdomen, which I reported when receiving my second dose. About a week before the second dose, I self-diagnosed myself with a calf injury due to extreme pain that felt like a constant cramp that lasted until my second dose. After the second dose, I was hospitalized 5 days (16Feb2021-20Feb2021) with multiple bilateral pulmonary embolisms/blood clots in both lungs after being sent to the ER by a nurse practitioner, and told that my previously self diagnosed leg injury was really DVT - I actually left the hospital with one blood clot still in my leg.Hospital's Cardiac ICU by physician's transport because my case was too to be treated at (Withheld). I am lucky to have survived this-please warn people of the symptoms" The patient underwent lab tests and procedures which included antiphospholipid antibodies (unknown date): unknown results (won't be in until mid-Jun because it requires testing 12 weeks apart)-tested negative for genetic conditions that could have caused the clots , sars-cov-2 test: negative on 16Feb2021.The events DVT and pulmonary embolism resulted in Emergency Room vists /Physician office visit .The event "DVT" was treated with Heparin, still on blood thinner. The patient received the second dose on 08Feb2021 left arm (Lot#BL9269).The outcome of the event DVT was recovering.The outcome of the other events was unkonwn; Sender's Comments: Based on vaccine-event chronological association a

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causal relationship between events Deep vein thrombosis, Pulmonary embolism and Pain in extremity and BNT162B2 vaccine cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : same report/patient, different dose/AE

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1255692	4/25/2021	WV	60	F	3/11/2021	3/1/2021	Blood Clot; This is a spontaneous report from a contactable nurse. A 60-year-old female patient (no pregnant) received her second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EN6208), intramuscular at the age 60-year-old at arm right on 11Mar2021 at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient previously received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6200), intramuscular at the 60-year-old at right arm on 19Feb2021 for COVID-19 immunisation and experienced pneumonia. There was no other vaccine in four weeks. Facility type vaccine was reported as public health clinic/administration facility. The patient experienced blood clot on Mar2021 after 2nd. The patient was hospitalized for event for 5 days. Adverse event resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, life threatening illness. The patient received the treatment for event. The outcome of event was unknown.; Sender's Comments: Based on information available, a possible contribution role of the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) to the onset of event clot blood cannot be completely excluded. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021422806 same patient/product, different dose and event

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1255628	4/25/2021	MO		F	3/28/2021	4/14/2021	died yesterday due to blood clots; This is a spontaneous report from a contactable consumer. A 55-year-old female patient (mother) received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 28Mar2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and the patient's concomitant medications were not reported. The patient experienced blood clots and died due to the event. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested. ; Reported Cause(s) of Death: died yesterday due to blood clots

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1255642	4/25/2021	PA	78	F	3/26/2021	3/26/2021	Blood clots in Lungs; No longer able to do activities of daily living; Almost fell to floor from sitting position; short of breath; total body exhaustion/fatigue; sleepy throughout the day; unstable, weak; debilitating symptoms bedridden/unstable, weak; debilitating symptoms bedridden; passed out completely while sitting; Unable to complete daily 1 mile walk at park/Unable to take stairs; Lightheaded/dizzy; This is a spontaneous report from a contactable consumer. A 78-years-old female patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in Arm Right on 26Mar2021 15:00 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. Medical history included patient had COVID-19 Dec2021 and recovered completely in 2 weeks. Symptoms: fever, sleepy. Went back to daily walk after 2 weeks. No loss of smell, no loss of taste, no mental changes- was very happy with my complete recovery. Took vaccine 26Mar2021 at recommendation of doctor to be safe from variants. Regret deeply, still hospitalized as of this writing. Concomitant medications included ramipril; rosuvastatin calcium 40mg; levothyroxine, all taken for an unspecified indication, start and stop date were not reported. The patient previously took sulphur and experienced allergies. The patient experienced unable to complete daily 1 mile walk at park/unable to take stairs on 27Mar2021, lightheaded/dizzy on 27Mar2021, passed out completely while sitting on 28Mar2021, unstable, weak on 30Mar2021, short of breath on 31Mar2021, total body exhaustion/fatigue on 31Mar2021, sleepy throughout the day on 31Mar2021, almost fell to floor from sitting position on 09Apr2021, debilitating symptoms bedridden/unstable, weak on 26Mar2021, debilitating symptoms bedridden on 26Mar2021, no longer able to do activities of daily living on 13Apr2021, blood clots in lungs on 14Apr2021, all with outcome of not recovered. Reported adverse event: 27Mar2021 - Unable to complete daily 1 mile walk at park. Lightheaded, dizzy 28Mar2021 Dizzy, passed out completely while sitting. Revived and taken to hospital by ambulance 28Mar2021 Admitted to (hospital name withheld) 30Mar2021 Discharge from hospital - unstable, weak 31Mar-08Apr2021 - short of breath easily. Unable to take stairs. Discontinued daily walk, weak, total body exhaustion,

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sleepy throughout the day 09Apr2021 - Almost fell to floor from sitting position. Patient's daughter lowered patient gently to the floor. Revived shortly 13Apr2021 Saw primary doctor Dr (name withheld). Shared her debilitating symptoms bedridden since Covid-19 vaccine on 26Mar. BP taken from lying down, sitting and standing was markedly different and explained caused passing out and lightheaded. No longer able to do activities of daily living 14Apr2021 - Exhaustion and fatigue, her daughter to her back to the hospital 14Apr2021 - Passed out in Emergency Room @ (hospital name withheld). Admitted. Blood clots in LUNGS. The events resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event), Disability or permanent damage. The patient was hospitalized for unable to complete daily 1 mile walk at park/unable to take stairs, lightheaded/dizzy, passed out completely while sitting, all from 28Mar2021 to 30Mar2021. The patient underwent lab tests which included blood pressure measurement: markedly different on unknown date. Patient was not pregnant. No other vaccine in four weeks. Patient had covid prior vaccination. No covid tested post vaccination. The treatment received for events included Heparin administered, still hospitalized as of now. Information about Lot/ Batch number has been requested.



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1255643	4/25/2021	OH	36	M	4/6/2021	4/8/2021	<p>Looked like he was in sepsis; thrombus occluding his IMV protruding into part of the SMV; Thrombocytopenia; Bacteremia with E. Coli; Unable to tolerate diet; Abdominal pain; Nausea; Vomiting; Muscle aches; Chills; Fever; This is a spontaneous report from a contactable physician. A 36-year-old male patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration, on 06Apr2021 at 10:00, at the age of 36 years old, for COVID-19 immunization. The patient's medical history included diverticulitis ongoing since 05Nov2018. Concomitant drugs included escitalopram oxalate (LEXAPRO) ongoing since an unspecified date. There were no other vaccinations 4 weeks prior to receiving BNT162b2. Two days after vaccination, on 08Apr2021, the patient developed nausea, vomiting, muscle aches, chills, and fever. The patient continued to have these symptoms and then developed abdominal pain on 11Apr2021, so the patient went to ER. Nausea, vomiting, muscle aches, chills, fever, and abdominal pain were reported as medically significant events. A CT of the abdomen and pelvis was performed on 11Apr2021, which seemed at that time to reveal only uncomplicated diverticulitis. Therefore, the patient was sent home with oral antibiotics. Then, the patient presented back to ER on 14Apr2021: the patient couldn't tolerate his diet and was experiencing worsening of abdominal pain. Another CT of abdomen and pelvis was therefore done on 14Apr2021, which this time revealed a thrombus occluding his IMV protruding into part of the SMV and the portal vein. In light of this finding, on 14Apr2021 the medical staff retroactively looked at the patient's CT scan from 11Apr2021 and they found that the thrombus was already present but less evident than on 14Apr2021. The patient also looked like he was in sepsis, so the medical team was performing a full septic work-up and the patient was hospitalized on 14Apr2021. The patient was terrified, and the medical staff were ruling out acute mesenteric ischemia. On 14Apr2021, blood work showed thrombocytopenia, and a bacteria blood test showed bacteremia with E. Coli. The event thrombus was reported as serious since medically significant, life threatening, and requiring hospitalization. No information regarding seriousness was provided for thrombocytopenia and bacteremia. Treatment with</p>

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heparin drip was started (ongoing at the time of the reporting) and the patient improved. However, the reporter stated that at the time of the last reporting, all of the patient's symptoms were ongoing, that all of the patient's symptoms had worsened. At the time of the last reporting the patient was in the ICU. The patient had not recovered from the all reported events. The reporter did not know if the reported events were related to BNT162b2, however she added that diverticulitis could also cause all the patient's side effects. Information on the lot/ batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the thrombosis, sepsis and other reported events due to temporal relationship. However, the reported events may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including MRI of abdomen and vascular angiogram, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1255644	4/25/2021	NY	39	F	3/25/2021	4/7/2021	pulmonary embolism; blood clots, her lungs were "full" of blood clots; trouble breathing; could barely walk up; This is a spontaneous report from contactable consumer. A 39-year-old female patient received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 25Mar2021 at 11:00AM in left arm at single dose for COVID-19 immunisation. Relevant medical history included minor thalassemia. Past drug history included buprenorphine (SUBLOCADE) taken on 10Mar2021 (location = stomach). Concomitant medications included venlafaxine and zolpidem. The patient had not COVID prior vaccination. The patient began to feel winded doing the most menial of tasks starting the week of 05Apr2021. On the morning of 10Apr2021 she woke up having trouble breathing after walking 10 steps to the bathroom. She could barely walk up 3 steps. It was as if she ran 10 marathons just to get to her bedroom on the second floor (as reported). She went to the ER where a CT scan was performed and it was found that she had a pulmonary embolism and her lungs were "full" of blood clots. Onset date for the events was reported as 07Apr2021 at 02:00PM. The events were serious as life-threatening (immediate risk of death from the event) and as causing hospitalization (for 4 days). Procedure to remove clots and heparin were given as treatments. The patient underwent COVID test (nasal swab) post vaccination on 10Apr2021 and result was negative. The events were resolving at the time of report. Information on Lot/Batch number has been requested.

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1255683	4/25/2021	OH		F	3/26/2021		<p>painful little clot in her front leg; pain/ache; shortness of breath like wheezing; shortness of breath like wheezing; This is a spontaneous report from a contactable consumer via a Pfizer sponsored program. A female patient (consumer) of an unspecified age received first dose of BNT162B2 (Pfizer COVID-19 Vaccine, Formulation: Solution for injection, Lot number and expiration dates were not reported), via an unspecified route of administration on 26Mar2021, at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported that she had the first dose 26Mar2021 and scheduled for the second dose on 21Apr2021, which was more than 21 days. Caller read the news about the adverse events with (Other company vaccine). They experienced pain/ache and shortness of breath like wheezing on an unspecified date in 2021. They also had a painful little clot in her front leg on an unspecified date in 2021. They wants to know if she can take the second dose. The outcome of the events was unknown. Information about lot/batch number has been requested.</p>

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1255613	4/25/2021	MD	37	F	1/19/2021	1/1/2021	Unreported possible deep vein thrombosis day after 1st shot. 4 days of thinking I had a charley horse. Confirmed pulmonary embolism on 24Feb2021; Unreported possible deep vein thrombosis day after 1st shot. 4 days of thinking I had a charley horse. Confirmed pulmonary embolism on 24Feb2021; Unreported possible deep vein thrombosis day after 1st shot. 4 days of thinking I had a charley horse. Confirmed pulmonary embolism on 24Feb2021; This is a spontaneous report from a contactable consumer. This consumer (patient) reported that the 37-year-old female patient received first dose of bnt162b2 (BNT162B2), via an unspecified route of administration, administered in Arm Left on 19Jan2021 11:00 AM at single dose for covid-19 immunization. The patient took second dose of bnt162b2 (BNT162B2), via an unspecified route of administration, administered in Arm Left on 09Feb2021 at single dose for covid-19 immunisation. The patient medical history was not reported. Pas drug event included Known allergies: cinnamon. Concomitant medication(s) included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL) taken for an unspecified indication, start and stop date were not reported; ethinylestradiol, norethisterone acetate (JUNEL) taken for an unspecified indication, start and stop date were not reported. The patient previously took cinnamon and experienced drug hypersensitivity. The patient experienced "unreported possible deep vein thrombosis day after 1st shot. 4 days of thinking i had a charley horse. confirmed pulmonary embolism on 24Feb2021" (medically significant, life threatening) on 20Jan2021 09:00 with outcome of recovering, "unreported possible deep vein thrombosis day after 1st shot. 4 days of thinking i had a charley horse. confirmed pulmonary embolism on 24Feb2021" in Jan2021 with outcome of recovering. The patient underwent lab tests and procedures which included COVID tested post vaccination Nasal Swab, PCR (sars-cov-2 test): negative on 03Feb2021, negative on 10Feb2021, negative on 17Feb2021, negative on 10Mar2021, negative on 17Mar2021, negative on 26Mar2021, negative on 05Apr2021, negative on 07Apr2021. Therapeutic measures were taken as a result of "unreported possible deep vein thrombosis day after 1st shot. 4 days of thinking i had a charley horse.

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							confirmed pulmonary embolism on 24Feb2021". Facility type vaccine was Hospital. No other vaccine in four weeks. AE resulted in Life threatening illness (immediate risk of death from the event). Ae treatment included treatment for Pulmonary Embolism, medications. No COVID prior vaccination. Information on Lot/Batch number has been requested.
1255693	4/25/2021	PA	24	F	2/10/2021	2/1/2021	Blood Clot formed in lung; cough; This is a spontaneous report from a contactable consumer (patient). A 24-year-old female patient received BNT162B2 (lot number: EL3246) second dose on 10Feb2021 (24-year-old) on left arm at single dose for COVID-19 immunisation. Medical history included Hypothyroidism. Patient had allergy to Hydrocodone, Oxycodone and Acyclovir. Patient is not pregnant. No covid prior vaccination. Concomitant medications included sertraline and levothyroxine. No other vaccine in four weeks. Historical vaccine included bnt162b2 (lot number: EL3246) on 16Jan2021 09:00 AM (vaccinate age 24 years old) first dose on left arm for covid-19 immunization. Facility type vaccine was Hospital. Patient had Blood Clot formed in lung on 17Feb2021 12:00 AM and cough a week in Feb2021 after second shot. Event resulted in Emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event)]. Patient received Medication as treatment. The outcome of events was Recovered with lasting effects. No covid tested post vaccination.

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1255698	4/25/2021	MI	48	M	3/22/2021	4/15/2021	NSTEMI; Pulmonary Embolism; left upper arm thrombosis; This is a spontaneous report from a non-contactable other healthcare professional (patient). A 48-year-old male patient received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE), on 22Mar2021 (at the age of 48-years-old) at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. No other vaccine received in four weeks. On 15Apr21, the patient presented to hospital with complaints of dyspnea, chest pain and arm swelling. The patient was found to have left upper arm thrombosis, pulmonary embolism, and NSTEMI. The adverse events started on 15Apr2021 and resulted in emergency room/department or urgent care visit, hospitalization on 15Apr2021 and life-threatening illness (immediate risk of death from the events). An unspecified treatment was received in response to the events. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.
1255700	4/25/2021	OR	54	M	3/26/2021	4/6/2021	Felt something in my leg like a cramp / did a scan of my leg and found the clot; dizzy; nearly passed out; This is a spontaneous report from a contactable consumer (patient). A 54-year-old male consumer received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 26Mar2021 at 16:30 at single dose in right arm for COVID-19 immunisation at the age of 54-year-old. Lot number was ER8732. Medical history included Human papilloma virus (HPV) positive tonsil cancer, ankylosing spondylitis, tinnitus, neuropathy, decreased memory from chemo and radiation. The patient did not have Covid prior to vaccination. Concomitant medications were unknown. The patient felt something in leg like a cramp for a week since 06Apr2021 before ER visit. On 06Apr2021, the patient got dizzy at home nearly passed out, and he went to ER. On 14Apr2021, Doctor did a scan of leg and found the clot. The patient was hospitalized due to the events and they were considered life-threatening. The patient was treated with heparin and ELIQUIS. On 14Apr2021, Rapid Covid test was negative. The patient was recovering from the events.

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1255577	4/25/2021	IN	22	M	4/8/2021	4/1/2021	<p>Passed out; pounding headache/headache symptoms are getting worst; body ache; tiredness; This is a spontaneous report from a contactable consumer. A 22-years-old male patient (Son) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 1 via an unspecified route of administration on 08Apr2021 (Batch/Lot number UNKNOWN) as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. My son is having a tough time with the vaccine. Everyday he has a couple of side effects. He started with body ache and tiredness on unspecified date Apr2021. He had a pounding headache. His headache was moderate today. However, the headache symptoms are getting worst. Generally, the symptoms last a day his have been getting worst for 7 days. He has been taking Tylenol and Advil. But the Advil doesn't even seem to hep anymore." headache is a common side effect reported with the vaccine. If the symptoms persists or get worst please consult your HCP. Please note blood clot has not been associated with the vaccine. Patient is been experiencing what I considered to be pretty severe, I guess reaction in term of aches and headache. This morning he woke up with the pounding headache, he kid described it as pounding and I just I guess I want to ask because everywhere I read, it says mild headaches are common and aches and I understand that but I guess understanding why this, this is considered somewhat as severe reaction or is there anything he can do to alleviate the symptom and should he, I guess my question is actually I guess my question also is should he not possibly get the second dose if he is experiencing such bad headaches with the first dose. When paraphrased the concern, reporter stated, Yes, basically we are thinking if can do to alleviate it and then he could not get the second dose, if you have any advice, I guess and just let you know he went to his health center in the college he went to get a COVID test and a flu test just to make sure he doesn't have actual Covid or flu and those report I got yesterday and so they told him that it's most likely still vaccine reaction. When probed for event start date, reporter stated, I would say a day after, I would say 09Apr2021, I guess it's phantom (not clarified) with symptom, the first day he was just tired, as far as the headache that started on the 09Apr2021. He (son) also</p>



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passed out after the vaccine, which I also did that I didn't have Pfizer I (reporter) had Moderna and I had that same reaction, so I think that sometimes happens to some people but that's it happens also. When probed for vaccination anatomical site, reporter stated, Outside of the body I guess, I don't know that for sure. Patient still having the problem (event), and out event outcome, reporter stated, Yes, I think persisting, I think it varies. Patient has been taking Advil (Ibuprofen) and Tylenol (treatment). The patient underwent lab tests and procedures which included influenza virus test: negative on 12Apr2021, sars-cov-2 test: negative on 12Apr2021. They told him that it's most likely still vaccine reaction. Therapeutic measures were taken as a result of body ache (pain), tiredness (fatigue), pounding headache/headache symptoms are getting worst (headache). The outcome of the events was reported as unknown. QR Comment: Call handler not filed split case. Might have been split case. Information about the lot/batch number has been requested.

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1255710	4/25/2021	VA		F	2/8/2021		<p>DVT; multiple bilateral pulmonary embolisms/blood clots in both lungs after being sent to the ER; one blood clot still in my leg/ blood clots in both lungs; This is a spontaneous report from a contactable Other HCP. A 41-year-old female reported that she received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number BL9269), intramuscular into the left arm on 08Feb2021 at single dose for COVID-19 immunization. No COVID prior vaccination. Medical history included type 1 diabetes mellitus, Hashimoto's Disease. Concomitant medication(s) included metformin (METFORMIN) and levothyroxine (LEVOTHYROXINE) . The patient had received the first dose of BNT162B2 on 19Jan2021. About a week before the second dose, she self-diagnosed with a calf injury due to extreme pain that felt like a constant cramp that lasted until her second dose. After the second dose, she was hospitalized 5 days (16Feb2021-20Feb2021) with multiple bilateral pulmonary embolisms/blood clots in both lungs after being sent to the ER by a nurse practitioner, and told that her previously self diagnosed leg injury was really DVT. She actually left the hospital with one blood clot still in her leg.Hospital's Cardiac ICU by physician's transport because her case was too to be treated at (Withheld). The patient underwent lab tests and procedures which included antiphospholipid antibodies (unknown date): unknown results (won't be in until mid-Jun because it requires testing 12 weeks apart)-tested negative for genetic conditions that could have caused the clots , had a negative COVID nasal swab test on 16Feb2021.The events DVT and pulmonary embolism resulted in Emergency Room visti /Phisician office visit .The event "DVT" was treated with Heparin, still on blood thinner. The outcome of the event DVT was recovering.; Sender's Comments: Based on vaccine-event chronological association causality between reported events and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be excluded. . The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked</p>

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Report(s) : US-PFIZER INC-2021427569 same patient,  
and drug different dose

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1255342	4/25/2021	OH	67	F	3/16/2021	3/1/2021	<p>blood clot; Right leg swelled and achy; Right leg swelled and achy; This is a spontaneous report from a contactable nurse (patient). A 67-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EP7534),dose 1 via an unspecified route of administration, administered in Arm Left on 16Mar2021 (at the age of 67years) as single dose for Covid-19 immunization. Medical history included ongoing Beta thalassemias. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient stated she has never had a problem with vaccinations, and she gets the flu vaccine every year. The patient reported that after the first injection coincidentally she did develop a blood clot in her lower leg. She thinks that it was due to a plane ride, but she has never had a blood clot before the injection. She added that she had the first dose on 16Mar2021 and developed a clot in a week. She further clarified that she got her first injection on 16Mar2021 and realized when she went on a flight, which is not that far she developed that clot and was having problems shortly after flight home on 24Mar2021 where her leg swelled up and she is on blood thinners since she went to the emergency room. She added that she developed the clot sometime between that flight and 02Apr2021. She had a doppler study on an unspecified date and it showed a blood clot. She stated that the outcome was she does not have the blood clot (as reported) but she will be on blood thinners and she needs to follow up on her scan to see if the clot issue is resolved but she will not have a doppler scan for another month or two and the blood thinner she is taking is Xarelto. She also stated that her right leg swelled up and it felt like a log. She reported it felt achy and swollen quite a bit from knee down and her leg was achy. It started between 24Mar2021 and by time she went to the emergency room she was not getting better. She had her symptoms for a week and toward the end of the week she thought she had a blood clot since it was not getting better it just got worse. She added that right now it is not swollen but she has been supine, and she does believe that it is better. The outcome of events was recovering. (As reported "outcome is unknown but pretty sure it has improved because of the blood thinners"./She stated she does not think it has resolved because it takes time for</p>

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clots to resolve./She added that right now it is not swollen but she has been supine, and she does believe that it is better.) The reporter stated for the seriousness criteria for event blood clot: she believes as a nurse that any blood clot is extremely dangerous, and she was not hospitalized but obviously a blood clot is serious, and she could have ended up with pulmonary embolism. The seriousness for events right leg swelled and achy was reported as medically disabling. Causality assessment: Patient stated for the blood clot she has doubts if it was related to the vaccine but is it something that should be known about; for the leg swelling and achy she has doubts but it could have been the plane ride.; Sender's Comments: Based on the current available information, the reported events are most likely related to an intercurrent or underlying condition which is unlikely related to the suspected drug. The plane ride may provide an explanation for the events. The case will be reassessed if additional information becomes available.

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1255715	4/25/2021	MI	81	F	1/13/2021	1/30/2021	This is a spontaneous report from a contactable consumer. This 81-year-old female consumer (patient) reported that she received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number unknown) at single dose for COVID-19 immunisation on 13Jan2021. Relevant history included mild dementia, high cholesterol. Relevant concomitant drugs included memantine 10MG,donepezil 5MG,atorvastatin, cetirizine hydrochloride (ZYRTEC). The patient was not pregnant. No known allergies. On 30Jan2021, the patient fell and became unconscious after getting up from bed to use bathroom, was able to get up and go back to bed. Next day, 31Jan2021, she told her daughter at 2pm what had happened and daughter took her to urgent care. Urgent care was performed EKG and called ambulance as EKG suggested suspicious activity. She was coughing with blood. Cat scan of the lung revealed acute saddle pulmonary embolism with acute cor pulmonale and a large blood clot in the calf. On 02Feb2021 then placed her on blood thinner and discharged her. As soon as arrived home, she began to suffer a massive gastro intestinal bleed and was rushed back to the hospital. On 04Feb2021, she began to have heart issues and suffered a mild heart attack and underwent a procedure to have a stent inserted. She developed the shingles the next day (05Feb2021). The events assessed as serious due to Hospitalization, Life threatening illness (immediate risk of death from the event), Disability or permanent damage. The patient visited Emergency room/department or urgent care. The outcome of events was resolved with sequel. Treatment therapy involved. The patient was not diagnosed with COVID prior vaccination. The patient had Nasal Swab/Fast Test/PCR (for COVID) in Apr2021 with negative result. Information on the lot/batch number has been requested.

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1255740	4/25/2021	WI	39	F	1/27/2021	4/2/2021	Blood clot in injection arm; This is a spontaneous report from a contactable Other-HCP. A 39-years-old female patient received at hospital bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in Arm Left on 27Jan2021 (Batch/Lot Number: EI3249) as SINGLE DOSE for covid-19 immunisation . No other vaccine in fours weeks. Other medications in two weeks: Multivitamin.The patient received the first dose on 06Jan2021 at 10:30 AM (lot number=EI1284) on left arm via IM The patient medical history was not reported. The patient experienced blood clot in injection arm (vaccination site thrombosis) (life threatening) on 02Apr2021 15:15 with outcome of not recovered. The event was treated with Xarelto. No Covid prior vaccination; No Covid tested post vaccination; Sender's Comments: Based on chronological connection to the vaccine a causal relationship between event "blood clot in injection arm" and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1255703	4/25/2021			F			<p>Patient died; portal vein thrombosis; thrombocytopenia; This is a spontaneous report from a contactable physician. A 50-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on an unspecified date as SINGLE DOSE for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced portal vein thrombosis and thrombocytopenia 2 weeks after first Pfizer vaccine. Patient died. The patient died on an unspecified date. It was not reported if an autopsy was performed. The outcome of the events portal vein thrombosis and thrombocytopenia was unknown. The outcome of the event unknown cause of death was fatal. Information on the lot/ batch number has been requested.; Sender's Comments: The information available in this report is limited and does not allow a medically meaningful assessment of the case. Based on temporal association, a causal association between the reported events and BNT162B2 cannot be fully excluded. Case will be reassessed when additional information is available including medical history and concomitant drug information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and investigators, as appropriate. ; Reported Cause(s) of Death: Patient died</p>



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1255241	4/25/2021	TX	68	M	3/17/2021	3/27/2021	blood clot in lessor saphenous vein left leg; This is a spontaneous report from a contactable consumer (patient). A 68-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 17Mar2021 at 15:15 (lot number EN6207) as single dose for covid-19 immunization, administered at the hospital. The patient received the first dose on 24Feb2021 at 15:15 in the right arm (lot number EN6198) for covid-19 immunisation. The patient did not receive other vaccines in four weeks. Medical history included type 2 diabetes, deep vein thrombosis (DVT), and pulmonary embolism (PE). The patient has not had COVID prior to vaccination and not tested for COVID post vaccination. The patient's concomitant medications were not reported. The patient experienced blood clot in lessor saphenous vein left leg on 27Mar2021 at 18:00 with outcome of recovering. The patient's hematologist put the patient on Eliquis 5mg 2 BID and at the time of report, this medicine has started to dissolve the clot.

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1254326	4/25/2021	AZ	32	F	1/8/2021	2/19/2021	diagnosed with a superficial venous thrombosis in my lower extremity; This is a spontaneous report from a contactable Nurse (patient). A 32-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 08Jan2021 (Batch/Lot Number: EL0142) as SINGLE DOSE for covid-19 immunisation, at 32 years old. The patient's other medical history was not reported. Patient has no known allergies. The patient is not pregnant. The patient previously received the first dose of bnt162b2 on 18Dec2020, administered in left arm (Lot number LH9899) for covid-19 immunisation. The patient had no other vaccine in four weeks. The patient had no other medications in two weeks. Patient has no COVID prior vaccination. Patient was not tested for COVID post vaccination. There were no concomitant medications. The patient was diagnosed with a superficial venous thrombosis in the lower extremity on 19Feb2021. The patient has no known risk factor for the event. Therapeutic measures were taken which included ELIQUIS. The event resulted in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. Outcome of the event was recovered with sequelae (recovered with lasting effects) on an unspecified date.
1254584	4/25/2021	MN	59	M	3/13/2021	3/1/2021	3 days after the first dose I developed a blood clot in my right calf, never had one before, no trauma, i am very active; This is a spontaneous report from a contactable consumer (patient). A 59-year-old male patient received first received first dose of bnt162b2 (Pfizer, Formulation: Solution for injection, Lot Number: EP 7534b) via an unspecified route of administration, administered in left arm on 13Mar2021 11:00 at a single dose for covid-19 immunization. Medical history and known allergies were none. Concomitant medication included rivaroxaban (XARELTO). The patient developed a blood clot in his right calf 3 days after the first dose, never had one before, no trauma, he was very active on 16Mar2021 07:00. No covid vaccination was taken prior. No covid tested post vaccination. Blood thinner for the clot was given as the treatment. The outcome of the event was not recovered.

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1254599	4/25/2021	TX	43	F	3/3/2021	3/3/2021	Worsen neuropathic symptoms- pains on fingers, wrists, feet, toes, back.; migraine headache; Sore arm; fatigue; This is a spontaneous report received from a contactable consumer (patient herself). A 43-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection) via an unspecified route of administration in left arm on 03Mar2021 at 11:00 at single dose for COVID-19 immunization. Medical history included ovarian cancer, Blood clots, Hypertension and Sulfa: Allergies. Concomitant medications included duloxetine hydrochloride (CYMBALTA) 30 mg; warfarin 1mg and hydrochlorothiazide. On 03Mar2021, the patient experienced sore arm, Worsen neuropathic symptoms (existing side effects from chemo) - pains on fingers, wrists, feet, toes, back (medically significant), fatigue, migrain headache for 15 days after the first dose. No treatment received for AE. The outcome of events was not recovered. Information about lot/batch number has been requested.

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1254628	4/25/2021	CA	73	F	1/20/2021	1/20/2021	Blood and clots came out of nose and mouth, first vaccine.; Blood and clots came out of nose and mouth, first vaccine.; Blood and clots came out of nose and mouth, first vaccine.; Face felt tight, first vaccine.; Mouth and nose dry, first vaccine.; Mouth and nose dry, first vaccine.; Sore arm, first vaccine.; This is a spontaneous report received from a contactable consumer(patient). A 73-year-old female patient received first dose of BNT162b2 (Pfizer-BioNTech COVID-19 Vaccine), at the age of 73-years-old, via an unspecified route of administration, administered in Arm Left (in the back of the arm) on 20Jan2021 (maybe at 11:10 am) (Lot Number: EL3246; Expiration Date: Apr2021) as single dose for covid-19 immunisation. Medical history included ongoing Postural vertigo maybe 10 years ago for a day. No family medical history relevant to AE. The patient's concomitant medications were not reported. Patient got the Shingles vaccine years ago and the next day, she had a sore arm and tingles, up and down her arm. She didn't feel food for 7 days and felt achy. It was the first Shingles shot. No prior Vaccinations (within 4 weeks). The patient experienced blood and clots came out of nose and mouth on 21Jan2021 (the same time that she woke up) with outcome of recovered on 21Jan2021. She blew her nose and leaned over and noticed a drop of blood on the rug and grabbed a Kleenex. She blew her nose, easy, and all of a sudden blood and clots came out of her nose and mouth. It lasted for about 8 minutes. Sore arm on 20Jan2021 (started in the evening) with outcome of recovered on 21Jan2021. Face felt tight on 21Jan2021 (around 8:30 or 9:00 am) with outcome of recovered on 21Jan2021. Mouth and nose dry on 21Jan2021 (in the morning) with outcome of recovered on 21Jan2021.

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1254752	4/25/2021	IN	61	F	3/19/2021	3/19/2021	<p>Her platelets are 200, which is very low; Bell's palsy; Shot on the top of my shoulder; excruciating pain/shoulder pain/given high on the top of her shoulder. It hurt; sore arm; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose at the age of 61-years old via an unspecified route of administration on 19Mar2021 10:10 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included systemic lupus erythematosus from 1985 and ongoing, arthritis and osteoarthritis from an unknown date and unknown if ongoing (She has osteoarthritis throughout her body and her feet). Family history included stroke (husband died at the age of 59, he was having stroke upon stroke). The patient's concomitant medications were not reported. It was reported that when she received the shot, it was given high on the top of her shoulder and it hurt. She could not move her arm for 3 days. The pain was excruciating. On the 4th day, her arm was sore, but she could move it. She had no fevers, she didn't get sick, but she just couldn't move her arm. The shot was given at at 10:10 am, and by noon she could barely move her arm. Her left side of the mouth doesn't want to work properly. Her Bells Palsy started on 05Apr2021. She was in her car and driving to the store, when all of a sudden her left eye was watering. She got home and she didn't see anything wrong with her eye, except it was watering. She could tell a difference between the left and right side of face when she touched it. Something was wrong with her right side. Her eye was not opening all the way, it's been dropping, and her lip was down. She can't smile, and when she drinks water it's comes out. The patient clarified that it was her left side that is drooping. She went to the emergency room due to Bell's palsy. She could not move her arm within 2 hours of getting the shot. The patient mentioned her whole body aches from the Lupus and arthritis, but the shoulder pain was different after the vaccine. The shot itself hurt, and she thinks the one who administered the vaccine might have hit something. There's not a day that doesn't go by that she is not in pain. Her platelets are 200, which is very low. The patient underwent lab tests and procedures which included activated partial thromboplastin time: unknown result, blood glucose: unknown result, computerised</p>

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tomogram: unknown result, full blood count: unknown result, glomerular filtration rate: unknown result; all on 06Apr2021, magnetic resonance imaging: showed a darkened area in her brain that looks like its connected with Bells Palsy on an unspecified date, basic metabolic panel: unknown result on 06Apr2021, platelet count: her platelets are 200, which is very low on an unspecified date, prothrombin time: unknown result, troponin i: unknown result (High sensitive ); both on 06Apr2021. The patient did not recover from Bell's palsy, recovered from vaccination site pain on 23Mar2021, from sore arm on 19Mar2021 and the outcome of the remaining event was unknown. Information about Lot/batch number is requested.

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1254765	4/25/2021	NJ	66	F	2/26/2021		<p>blood clot in her right ankle; varicose vein in her right ankle and it started to hurt; varicose vein in her right ankle and it started to hurt; ankle on her right side started swelling; This is a spontaneous report from a contactable consumer (patient). A 66-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration on arm left on 26Feb2021 14:00 (Batch/Lot Number: EN6198) as SINGLE DOSE for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient previously took the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EM9809 and expiry date: 30Jun2021) on left arm on 05Feb2021 for covid-19 immunisation. The patient experienced blood clot in her right ankle, varicose vein in her right ankle and it started to hurt, ankle on her right side started swelling, all on an unknown date. All events caused patient physician office visit. Treatment received for all events. It is reported that she is calling about the Covid 19 vaccine. She wanted to report that she developed a blood clot in her right ankle. She went to the doctor yesterday on 06Apr2021. She would like to add she has no prior history of any type of blood issues. The doctor she saw thought that the blood clot and the Covid 19 vaccine could be related but would not commit to saying so directly. She started having issues about 6 days after the second Covid 19 vaccine. She doesn't exactly remember when, maybe the 04Mar2021 or 05Mar2021. She ignored the issues attributing them to over exercising. She reached a point where she couldn't ignore the issues anymore and went to the doctor. Caller clarifies she has a varicose vein in her right ankle and it started to hurt then her ankle on her right side started swelling. She only payed attention to her ankle when it got worse. The last 3 weeks have been awful. She would like it known that she does not lead a sedimentary lifestyle. She rides her bike 60 miles a week and walks 10 miles a week. She's always moving. This is unusual for her. The doctor she saw diagnosed her with a blood clot and he did a sonogram in his office. She has been prescribed Xarelto 15mg tablets. Take 2 tablets twice daily for the first 21 days then on the 22nd day start taking one 20mg tablet once daily. The patient underwent lab tests and procedures which included sonogram:</p>

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unknown result on 06Apr2021. The outcome of the all events was unknown.



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1254796	4/25/2021	CT	53	M	3/21/2021	3/22/2021	Blood clots in right leg below knee; he passed out from pain; pain in his right knee; he couldn't bend his knee at all; knee was swollen; couldn't walk/limping around; his knee more stiff; This is a spontaneous report from a contactable consumer (patient). A 53-year-old male patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number: EN6206), via an unspecified route of administration, administered in the right arm on 21Mar2021 at 10:00 as a single dose for COVID-19 immunization. Medical history included ongoing Factor V Leiden heterozygous, allergies to mushrooms from an unknown date and unknown if ongoing and a torn meniscus in his right knee and he had surgery 3 to 4 years ago. The patient's concomitant medications were not reported. The patient previously took Cephalexin and Percocet and experienced allergies. The patient did not have COVID prior to vaccination and has not been tested post vaccination. On 22Mar2021 at night around 2:30AM, the patient woke up and started walking to the bathroom and he passed out from pain. He had pain in his right knee. He thought he had torn his knee again. He had surgery 3 or 4 years ago for a torn meniscus in his right knee and he thought he had torn his meniscus again. He passed out, his wife found him and he went back to bed. In the morning, his knee was still very very sore, he couldn't bend his knee at all. He took an Advil between 6:30AM and 8:00AM. He hadn't taken any medications prior to the COVID-19 vaccine. His knee was swollen but the pain was manageable. He couldn't walk, he was on crutches for about 24 hours then the swelling started coming down and he put a brace on his knee. He could then walk without the crutches but it was still painful. The next day he had pain in the back of his knee. He thought the pain was caused because he had put the brace on and had been using the crutches. Like he had made his knee more stiff from not using it. He was limping around and the pain was bearable. At that point, the pain was maybe a 4 on a scale of 1-10 where his pain had been a 9 on a scale of 1-10. He took another Advil and he realized the pain in the back of his knee wasn't going away. He went to see his family doctor and his doctor was able to get him in that same day for an ultrasound. The ultrasound showed 2 blood clots behind his right knee. The patient had blood clots in right leg below knee. The week of the report, he got an

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appointment with a hematologist. The hematologist reviewed his case and the doctor isn't 100% sure the blood clots were from the Pfizer COVID-19 vaccine but the doctor isn't ruling it out either because it happened within 24 hours of receiving his first COVID-19 dose. He hadn't done anything strenuous before getting the COVID-19 vaccine, nothing that he thinks would have caused the blood clots. He would like to add, what he thinks is relevant, is that he is positive for Factor V. He reports he has one copy and Factor V only impacts about 3% of the population. The hematologist thought that he might be prone to developing blood clots. The hematologist reports that he has had patients who have had the COVID-19 virus who have developed blood clots. Maybe it's possible that the COVID-19 antibodies were trying to build up his immune system to COVID-19 and it created something similar to having the COVID-19 virus. If he is predisposed to blood clots then the COVID-19 vaccine may have precipitated the blood clots. His second COVID-19 vaccine is scheduled for Sunday, 11Apr2021. He had talked to both his family doctor and his hematologist and they both thought he should be ok in getting the second COVID-19 vaccine. He was prescribed blood thinners. If the second COVID-19 vaccine caused more blood clots the blood thinners would help him. He was asking if there is any additional information or guidance on receiving the second COVID-19 vaccine after his reaction. The pharmacist told him that the COVID-19 vaccine trials were all done in the left arm. He received his vaccine in his right arm and his right knee was affected. If he gets the second COVID-19 vaccine he's getting it in his left arm. He was prescribed Eliquis 5mg take one tablet twice daily. The outcome of the event blood clots in right leg below knee was recovering while the outcome of the other events was unknown.

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1255462	4/25/2021	PA		M		3/24/2021	Her husband got a heart attack a week after the first dose; there are blood clots on his legs; This is a spontaneous report from a Pfizer-sponsored program. A male patient of an unspecified age received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 24Mar2021 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The reporter stated that her husband got a heart attack a week after the first dose and there are blood clots on his legs on an unspecified date. Outcome of the events was unknown. Information on the Lot/Batch number has been requested.

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1255100	4/25/2021	TN	38	F	3/31/2021		Dvt and PE; Dvt and PE; This is a spontaneous report from a contactable other healthcare professional (patient). A 38-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date (at the age of 38-years-old) as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced deep vein thrombosis (DVT) and pulmonary embolism (PE) on 31Mar2021. The patient underwent lab tests and procedures which included SARS-COV-2 test: negative on an unspecified date. The event resulted in the Emergency room/department or urgent care. Therapeutic measures were taken as a result of both events [rivaroxaban (XARELTO). The outcome of the events was recovered on an unspecified date. Information on the lot/batch number has been requested.; Sender's Comments: Based on known drug profile and available information it is unlikely that the reported deep vein thrombosis and pulmonary embolism were causally related to BNT162B2. These are intercurrent medical conditions. Case will be reassessed if additional information is received. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1255567	4/25/2021	DC	70	M	3/12/2021	4/1/2021	COVID-19 test was positive; COVID pneumonia, COVID-19 test was positive; slight delirium; Arrhythmia; Abdominal pain; hypoxic; achy; myalgia; This is a spontaneous report from a contactable Physician reported in response to HCP letter sent via telephonic follow-up activity. A 70-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot number and expiry date were not reported) via unspecified route of administration on 12Mar2021 (age at vaccination 70-year-old) for COVID-19 immunization. Medical history included hodgkin's disease (HD) for 7 years, diabetes for 40 years/controlled, chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), non-responder to hepatitis B vaccine, dialysis on 05Apr2021 from 6 years, asthma in youth, arthritis, right hip replacement 1 month ago on 20Feb2021 and developed deep vein thrombosis (DVT) and cerebrovascular accident (CVA), atrial fibrillation (Afib) also started at that time in Feb2021. Concomitant medication included carvedilol (COREG) 6.25, furosemide sodium (LASIX) 40, APIXABAN (ELIQUIS) 5mg twice daily, multivitamin, iron twice a day, atorvastatin calcium (LIPITOR) 80 mg, insulin 18 u at night, calcium acetate 667 mg 2 tablets 3 times a day w/meal, famotidine 20mg daily, calcitriol (CALCITROL) took 3 times a week (was on dosing algorithm depending on phosphorous and vit D levels). Past drug history included amlodipine, ibuprofen, lisinopril with reaction allergies, metformin with contraindication to patient on dialysis, not a true allergy and patient previously took first dose of BNT162B2 on 17Feb2021 for COVID-19 immunisation. No prior vaccinations within 4 weeks. The patient experienced COVID-19 test was positive, COVID pneumonia, slight delirium, arrhythmia, shortness of breath, tachypnea, abdominal pain on an unknown date, hypoxic on 14Apr2021, myalgia and achy in Apr2021. It was reported that patient in her hemodialysis unit who were vaccinated with BNT162b2 but were recently diagnosed with COVID-19. Patient COVID results were sent to the local health department for genetic sequencing (pending) and SARS titers were drawn (pending). He presented to HD unit with SOB on 05Apr2021 and routine COVID-19 test was positive. He was hospitalized for COVID pneumonia and put on high flow oxygen, he was still in

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hospital. He came in for dialysis on 05Apr2021 and was very short of breath. Patient reported that the night before they felt myalgia and achy. No fever. Sent straight to the ER from the dialysis unit to check fluid levels and was admitted. He was tested for Covid and was found positive. His oxygen saturation was at 90. Required 2-3 liters of oxygen and next day on 06Apr2021 graduated to high flow oxygen for several days. on 14Apr2021, the patient became more hypoxic and was transferred to ICU. Patient had slight delirium and was not acting like himself. He underwent lab test included respiratory rate (RR) greater than or equal to 30 breaths per minute, heart rate (HR) greater than or equal 125 beats per minute, use of vasopressors to maintain BP, SpO2 less than or equal 93% on room air, PaO2/FiO2 less than 300 mm Hg on an unknown date, dialysis, chest X-ray showed bilateral fluffy infiltrates, covid test positive, CT scan had classic ground glass look for covid, CT of chest w/ contrast and no embolism, white cell count 6.2, hemoglobin 11.2, hemocrit 34.6%, platelet 110, sodium133, blood urea (BUN) 38, creatinine 3.7, brain natriuretic peptide (BNP) 1962, troponin 0.125, albumin 2.9, aspartate aminotransferase (AST) 49, alanine aminotransferase (ALT) 27, Pulse O2 low at 90 on 05Apr2021 and blood immunoglobulin G, blood immunoglobulin M (IgM /IgG) had unofficial result as a titer of 1 on 06Apr2021. He displays clinical signs at rest indicative of severe systemic illness. He came in slightly tachycardic about 120 bpm. Hypotension caused by hospital pulling too much fluid not by disease. No mechanical ventilation needed. Patient required oxygen because O2 saturation was at 90. Required 2-3 liters of oxygen initially and next day graduated to high flow. He was complaining of severe GI distress. Sonogram was negative. CT scan scheduled for tonight. He was on anticoagulation from prior DVT. Patient received treatment with remdesivir for COVID-19 and hydroxychloroquine/chloroquine, azithromycin, corticosteroids, decadron steroid for other events. No immunomodulating or immunosuppressing medications or received any other vaccines around the time of COVID-19 vaccination. Adverse events were resulted in emergency room, hospitalization and admitted to an Intensive Care Unit. The outcome of event COVID pneumonia was not recovered, whereas unknown for all

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other events. Information on the Lot/Batch number has been requested.; Sender's Comments: Based on the temporal association, there was a reasonable possibility that the vaccination with BNT162B2 played a contributory role in triggering the onset of the events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1255300	4/25/2021	OH	67	F	4/6/2021	4/6/2021	<p>sleeping for 3 days; weak; really thirsty; tired; Fever; real achy; terrible headache; left arm hot, red, and swollen at injection site; left arm hot, red, and swollen at injection site; left arm hot, red, and swollen at injection site; This is a spontaneous report from a contactable Nurse (patient). A 67-years-old female patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in Arm Left on 06Apr2021 09:00 (Batch/Lot Number: ER8734) as SINGLE DOSE (at the age of 67 years) for covid-19 immunisation. The patient had the first dose of BNT162B2 for COVID-19 immunisation in the left arm lot number EP7534 and the patient experienced peripheral swelling in left leg and blood clot. Medical history included ongoing thalassaemia beta Caller stated she was diagnosed with this in her later 20s or early 30s. The patient's concomitant medications were not reported. The patient experienced fever (disability) on 06Apr2021 20:00 with outcome of recovered, real achy (disability) on 06Apr2021 with outcome of recovered, terrible headache (disability) on 06Apr2021 with outcome of recovered, weak (disability) on 07Apr2021 with outcome of recovering, really thirsty (medically significant) on 07Apr2021 with outcome of recovered, tired (disability) on 07Apr2021 with outcome of recovered, sleeping for 3 days on an unspecified date with outcome of unknown, left arm hot, red, and swollen at injection site on 06Apr2021 with outcome of not recovered. The patient underwent lab tests and procedures which included body temperature: 102, body temperature: 101.9, body temperature: 106, body temperature: 101.6. Therapeutic measures were taken as a result of fever, real achy, terrible headache, weak. Treatment: Advil. The patient is not in a study or programme. No Additional vaccines administered within last 4 weeks. Events were considered related for real achy, terrible headache, weak, really thirsty, tired, and left arm hot, red, and swollen at injection site. Follow-up attempts completed: case closed.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for fever and other reported events. There is limited information provided in this report. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the</p>



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Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1255308	4/25/2021	OH	49	F	3/25/2021	3/25/2021	she thought she had a blood clot; maybe it is MS (multiple sclerosis); possible septal infarct; weakness in her left arm; losing her balance; vaccine was given up high on her arm, not 2 fingers down. She thought they had hit bone; less range of movement in her left foot; trouble walking; like someone who had a stroke; numbness; legs felt heavy climbing stairs; immediate pain when needle went all the way in and worse when vaccine went in; pain in shoulder joint; This is a spontaneous report from a contactable consumer (patient). A 49-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: Ep6955), dose 1 via an unspecified route of administration, administered in Arm Left on 25Mar2021 18:00 (at the age of 49years) as single dose for Covid-19 immunization. The patient is not pregnant at the time of vaccination. Medical history included anemia that is treated, living kidney donor, gastric bypass in 1999, gallbladder removal, hysterectomy, intussusception x2, migraines, high heart rate, and smoking. Concomitant medications included omeprazole (OMEPRAZOLE), amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), and albuterol [salbutamol] (ALBUTEROL [SALBUTAMOL]); all taken for an unspecified indication, start and stop date were not reported. The patient previously received Flu vaccine and Tetanus vaccine. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient has not been tested for COVID-19 since the vaccination. She got the shot on 25Mar2021 on Thursday evening at 1800. She is 49 years old and has had all the flu shots and tetanus shots. She has never had one hurt so bad. She stated that the vaccine was given up high on her arm, not 2 fingers down. She thought they had hit bone. It was reported that the patient experienced immediate pain when needle went all the way in and worse when vaccine went in. The whole time it hurt really bad and her arm hurt severely for 2 days from 25Mar2021. She still has pain in shoulder joint. That aside wasn't a big deal, it went away even though the joint is sore. The following Monday 29Mar2021 in the evening, her legs felt heavy and she had trouble going up the stairs. Then she had complete numbness of her left leg, from her hip or butt crack to the tip of her toes. It was

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on the same side she had the shot. It was further reported that the patient's legs felt heavy climbing stairs then she woke Thursday morning with her left leg numb. She couldn't feel herself starting to have a bowel movement because the numbness went all the way up to that area. She went to the ER (emergency room) on Saturday night (03Apr2021) because she was afraid of a blood clot. An ultrasound was done on her left leg, CT of head and neck, and blood work with nothing found. She has numbness and less range of movement in her left foot with trouble walking and have had no improvement with calf being numb. It was further clarified that when she was Easter shopping, there was numbness in her foot was causing her to drag her foot around the store. It was like someone who had a stroke, with slight impairment on one side. Her foot slaps the floor. She doesn't have control of it, she can't flex her foot up and down at all and she has little movement in her toes, even now. When she went to the emergency room, she thought she had a blood clot. She is a kidney donor and is healthy over all except for anemia that gives her tingly toes since she was 30, off and on. She never had a body part felt so numb, other than when she sits on her leg wrong. They did a bunch of tests there. They did a doppler, CT scan, and an EKG (unspecified date) which was abnormal. Her EKG has never been abnormal before. It said possible septal infarct undetermined time. The doppler showed no deep or superficial blockages noted from her groin down to her toes/ankle. The doppler was to check for blood clots. They referred her to her primary care provider who said that she will do a neurological exam. She has weakness in her left arm as well. The weakness in her left arm was only told by the neuro touch test. The patient further clarified that she doesn't have less range of motion, it is really just pain (arm). She can still move her arm all the way. Her left side is weaker or less sensitive as far as the neuro test. She wasn't aware she had less feeling on her arm until the nurse said she did. Her arm pain is nothing significant, it can hurt when moving her arm. She had no leg pain or anything like that until later in the week. She still had symptoms of losing her balance. Getting in and out of the chair she almost fell down. She didn't realize the numbness. Monday, she felt heaviness going up the stairs. For 2 days she had the worst pain ever in her arm.

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She had the tetanus shot and didn't have anything like that. It went away, when she raises her arm off from the side, she still has pain in the joint. She has migraines, it is nothing that is causing difficulty. She is more concerned something else happened. Patient thought maybe it is MS (multiple sclerosis) and asked if it is peripheral artery disease. She did smoke half a pack every other day. She is 49 but didn't start smoking till she was 36. It is a terrible habit and her doctor is aware. She also had her good and bad cholesterol which was just over 100. She is just reporting it because it happened on only the left side and she is a healthy person. She never had high blood pressure and never been treated for it, but she has had high heart rate before. It is not something that has ever caused any issue. She doesn't have something like peripheral artery disease, when she (software company name withheld) that is said plaque in the arteries. The doppler showed no signs of blockage superficial or deep on that side. She doesn't have an appointment until 29Apr2021. She doesn't know what to do to get more urgent care. The pain in her arm was better after the first 2 days. It is like a tooth ache, a dull ache. It is not all the time, just when moving her arm. Her legs were worse to where Thursday, she woke, and she was numb from the top of her leg to the tip of her toe. She can still lift her leg, but when she walks the tip of her second toe which is longer will drag on the ground. When she walks it is hard to hold her shoe on the left foot or put her shoe on. She can't maneuver her foot. When her foot hits the ground, the ball area of her foot smacks the floor because she doesn't have control over it. It is laboring to walk and is hard. She was kind of limping and pulling that leg on the left side. Her laboratory tests were BMP, CBC auto diff, CBC with diff, CT, angiogram of the head and neck, EKG 12 lead, and they did a venous doppler of the left lower extremity. It all came back good except the EKG which says septal infarct undetermined date, which has never come up on any tests before. The events resulted in Emergency room/department or urgent care, Disability or permanent damage. There was no treatment received for the adverse event. The patient has not been tested for COVID-19 since the vaccination. The outcome of events was not recovered.

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1255309	4/25/2021	VA	42	F	4/6/2021	4/7/2021	fever of 101; headache; muscle soreness and stiffness; muscle soreness and stiffness; extreme fatigue; Cannot hear out of it at all; have tinnitus in my left ear; This is a spontaneous report from a contactable consumer (who is also the patient). A 42-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8729), via an unspecified route of administration in the left arm, on 06Apr2021 15:00, as single dose, for COVID-19 immunisation. Medical history included blood clot. The patient had no known allergies. The patient was not pregnant at the time of vaccination. Concomitant medication included apixaban (ELIQUIS) taken for an unspecified indication, therapy dates not reported. The patient did not have COVID-19 prior to vaccination and had not tested for COVID-19 post vaccination. Historical vaccine included BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6208) received at age 42 years, via an unspecified route of administration in the left arm, on 12Mar2021 16:45, for COVID-19 immunization, and within 24 hours, the patient experienced tinnitus in left ear and cannot hear out of it at all which took two weeks to return after the first dose. The patient did not receive other vaccines in for weeks. On 06Apr2021, the patient received the second dose. On 07Apr2021 at 02:30, the patient had tinnitus in his left ear and could not hear out of it at all. On 07Apr2021 at 03:00, 12 hours after the injection, the patient had a fever of 101 along with headache, muscle soreness and stiffness, and extreme fatigue. No treatment was given for the events. The outcome of the events was not recovered.

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1255853	4/25/2021	FL	74	F	3/16/2021	3/20/2021	3/20/21: Pt bib Medical Center via helicopter with c/o headache/ seizure. Per FR, pt was driving when she was witnessed by friend having a possible seizure. Upon arrival to ED, pt had second episode of possible seizure. Pt given Ativan, Keppra and thiamine in ED. Pt is AAOx4 upon arrival, speech mildly delayed. VSS at this time. Pt reports drinking a bottle of liquor everyday and states a PMH of alcohol withdraw. Progress note from 3/25/21: Neurological examination at this time continues stable. Patient underwent DSA yesterday with findings of left frontal lobe cortical vein thrombosis with hemorrhagic conversion. Documented that given timing of events, a consideration should be given to possible COVID vaccine related thrombosis and may advise against second dose of vaccine. EEG with no evidence of epileptiform discharges. Continues with intermittent word finding difficulties/confusion, but continues following all commands consistently. Possible that some component is also related to longstanding ETOH abuse? Pending discussion of findings with NES, apparently patient was reported to have episodes of irregular heartbeat during DSA?

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1255460	4/25/2021	FL	60	M	4/3/2021	4/1/2021	<p>blood clot on the left side of neck; This is a spontaneous report from a contactable HCP (patient). The patient was a Respiratory Therapist. A 60-year-old male patient received his second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EN6206), via an unspecified route of administration on 03Apr2021 (at the age of 60-years-old) as single dose for COVID-19 immunisation. The patient took the first dose of BNT162b2 (lot number EN6199) on an unspecified date for COVID-19 immunisation. Medical history included high cholesterol and hypertension from an unknown date and unknown if ongoing. Concomitant medications included nebivolol hydrochloride (BYSTOLIC) taken for hypertension, start and stop date were not reported; rosuvastatin taken for blood cholesterol increased, start and stop date were not reported. The patient experienced blood clot on the left side of on an unspecified date in Apr2021. The event was treated with blood thinner. Patient thought it was called Xarelto because they called him on 07Apr2021. He was not sure how to spell that. Treatment was started on 07Apr2021. Consumer stated he first started having symptoms on the night of the injection. On an unspecified date in Apr2021 the patient did the ultrasound and that's when they found blood clot and he just got the results back. Recently, may be 2 weeks before reporting, patient had routine blood work and It was normal. It was nothing abnormal. The outcome of event was unknown.;</p> <p>Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Clot blood cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>

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1255463	4/25/2021			U			<p>Developed like a blood clot, black and blue in the arm;  Developed like a blood clot, black and blue in the arm;  This is a spontaneous report from a non-contactable consumer (patient). A patient of unspecified age and gender received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number and Expiration Date were not reported), via an unspecified route of administration, on an unspecified date, at a single dose, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously took the first dose of BNT162B2 for COVID-19 immunization. The patient was calling about the side effects of Pfizer COVID-19 vaccine and was wondering. The patient got the first and second vaccine of Pfizer for COVID-19. After the second dose of vaccine on an unspecified date, the patient developed like a blood clot, black and blue in the arm. The patient wanted to ask if this is a rare side effects or common. The outcome of the events was unknown. No follow-up attempts are possible; information about batch number cannot be obtained. No further information is expected.</p>



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1255545	4/25/2021			U			<p>I am bleeding heavily because I am getting blood clots and stuff like that; I am bleeding heavily because I am getting blood clots and stuff like that; Right side of face, my tongue inside is very swollen and irritated; Lot of pain in my joints and in my bones; Right side of face, my tongue inside is very swollen and irritated; Right side of face, my tongue inside is very swollen and irritated; Lot of pain in my joints and in my bones; This is a spontaneous report from a contactable consumer (patient) A patient of unspecified age and gender received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on an unspecified date (Lot number FN6200) as SINGLE DOSE for covid-19 immunisation; axitinib (INLYTA), via an unspecified route of administration from an unspecified date (Batch/Lot number was not reported) to an unspecified date, at 2 DF, 1x/day (two pills a day ) for renal cancer; pembrolizumab (KEYTRUDA), route of administration, start and stop date, batch/lot number and dose were not reported for renal cancer; zoledronic acid (ZOMETA), route of administration, start and stop date, batch/lot number and dose were not reported for bone disorder . The patient received the first dose of BNT162B2 on unknown date (Lot number CL9265). The patient medical history was not reported. The patient's concomitant medications were not reported. The patient stated "I got a clear cell renal cancer. And I am taking a combination Inlyta okay which is your drug and Keytruda and I also have also taken Zometa that is for the bones and I have had two Pfizer Vaccines (Unspecified Vaccines) for it.I am getting terrible side effects from either the Inlyta or the Keytruda. I am bleeding very heavily and the right side of face, my tongue inside is very swollen and irritated. I am getting a lot of pain in my joints and in my bones. I am bleeding heavily because I am getting blood clots and stuff like that. I just wonder if there is anything that I have been taking Inlyta two pills a day and I have taken probably 80 pills from the start. So, if there is anything to mitigate what's going on. The action taken with axitinib , and pzoledronic acid embolizumab was unknown.".The outcome of the event was unknown</p>

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1254969	4/25/2021	VA	42	F	3/12/2021	3/1/2021	Cannot hear out of it at all; have tinnitus in my left ear; This is a spontaneous report from a contactable consumer (patient). A 42-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 12Mar2021 16:45 (Batch/Lot Number: EN6208) as SINGLE DOSE for covid-19 immunisation, at 42 years old. Medical history included blood clot from an unknown date. Patient is not pregnant. Patient did not have COVID prior vaccination. Patient was not tested for COVID post vaccination. No other vaccine in four weeks. Concomitant medication included apixaban (ELIQUIS) taken for an unspecified indication, start and stop date were not reported. The patient experienced cannot hear out of it at all and have tinnitus in her left ear on Mar2021 (reported as 02:30), 24 hours after the first dose. Took 2 weeks to return after the first dose. Outcome of cannot hear out of it all was recovered on an unspecified date while unknown for tinnitus.
1257187	4/25/2021	TX	80	F	3/9/2021	4/19/2021	Patient family called on 4/23/2021 and reported that patient was hospitalized on April 9th and 13th , 2021 for blood clot in the lungs after taking the Johnson & Johnson covid-19 vaccine on 3/09/2021. During the time of the report patient's family state that patient was stable and she is doing okay.

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1255731	4/25/2021			M			Hot a fever then full blown covid; Hot a fever then full blown covid; blood clot; organ failure; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer reported that a male patient of an unspecified age received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Previously on an unknown date, the patient received the first dose of BNT162B2 vaccine. On an unspecified date, the patient experienced hot a fever then full blown COVID, blood clot and organ failure leading to patient death on an unknown date. It was not reported if an autopsy was performed. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected; Reported Cause(s) of Death: Drug ineffective; Covid-19; Blood clot; Organ failure
1255926	4/25/2021	TX	57	M	2/28/2021	3/13/2021	Blood clots, Hospitalization, Blood thinners
1257204	4/25/2021	MO	39	F	3/3/2021	3/23/2021	Patient began experiencing pain and difficulty walking on Tuesday, March 23. Later that afternoon she was taken to an Urgent care, who sent her to the ER for evaluation. She was diagnosed with a very large blood clot in her leg, spanning from just above the knee to her groin area. They admitted her and began treating her with blood thinners. While undergoing that treatment, her heart stopped 3 times and she had to be resuscitated. They discovered a pulmonary embolism. While removing a large clot from her lungs, the doctor found that her lungs were riddled with hundreds of tiny blood clots. They also said that she was bleeding internally, very heavily, from an unknown location. In all, they gave her 20 units of blood, and none of it stayed in her veins. The doctor said it seemed to just disintegrate. At that point, her brain and organs had begun shutting down and family made the decision to remove her from life support. She passed away Thursday evening, March 25, 2021.
1257145	4/25/2021	AR	65	F	4/25/2021	4/25/2021	Fever. Chills, hallucinations, renal failure, ischemic colitis, gi bleed, blood clot,, dehydration

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1257010	4/25/2021	AZ	51	M	4/14/2021	4/21/2021	Week after vaccine developed shortness of breath and pain breathing. Trip to ER and admitted to hospital. Diagnosed with Pulmonary Embolism. Blood clots both lungs.
1256966	4/25/2021		85	F	4/1/2021	4/16/2021	A stroke cause by blood clot 3 weeks after first dose.
1256826	4/25/2021	NY	61	M	3/8/2021	3/10/2021	shortness of breath, foot swelling, chills, body aches, dry mouth, fatigue, wheezing, eye burning sensation, joint pain, Blood clots in lungs, prescribed Xarelto
1256798	4/25/2021	WA	87	F	3/15/2021	3/1/2021	Patient's daughter came to the pharmacy on 04/24/2021 and stated that her mother, the patient, got the Janssen vaccine here and within a week, she had a blood clot and has been in the hospital ever since. This is all the information we received.
1256511	4/25/2021	WI	57	F	3/19/2021	4/2/2021	Left lower medial aspect swelling , warmth and thrombosis noted. Placed on Naproxen 500mg BID Compression stockings Heat and Cold compresses
1256737	4/25/2021	NC	75	M	2/1/2021	4/20/2021	Died blood clot in brain
1256715	4/25/2021	NY	34	F	3/20/2021	4/2/2021	During my menstrual cycle I usually have no symptoms other than tender breasts. So these symptoms were very unusual. Leg pains, pain and pressure in pelvis, clitoral pain, pain around vaginal opening, stinging like acid during urination that sent a shock through my entire body, uncontrollable bladder, nausea, large blood clots, lower stomach pain, flank pain, hot/cold chills, if I touch my belly button the pain radiated to my vagina, ovaries hurt, cervix pain, dryness, unable to get comfortable, crawling out of my skin, and constant urge to urinate, depression. I landed myself in the ER where they told me to take Tylenol and Motrin and sent me on my way. These medications were not able to control the amount of pain I was in. I have now reached out to a couple specialists.

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1256683	4/25/2021	NY	81	M	4/1/2021	4/14/2021	4/14/2021 Two weeks after the 2nd Covid-19 vaccine, about 11 PM. patient, developed a sudden numbness in his right are, hand & right side of the face. He had no sensation and could not feel anything. He immediately was taken to the emergency room at Hospital. They began testing and suspected a blood clot. They administered blood thinners, TPA by injection into the port, performed many tests including Ct scan, chest Xray, blood tests, EKG etc. He was being monitored & hooked up to various scanners. They decided to move him by Ambulance to the ICU Unit at Medical Center . He was in the neurology emergency room there for several hours & then moved the Neurology ICU. They kept him there, doing various testing, until Friday 4/16/2021 When they moved him to a regular Neurology floor. Staff neurologists continued to monitor his condition. On Saturday, 4/6/2021, an MRI showed a small blood clot in the Thalamus of the brain, which they believe caused the lack of sensation on the right arm, hand & face. He was discharged & went home on Monday 4/18/2021. New medication was prescribed, Physical therapy and was told to make an appointment with a Neurologist. On Thursday, 4/22/2021 patient had an appointment with his Cardiologist, Dr. the Dr gave him an examination & told him to proceed with the neurologist, etc. Patient has an appointment at PT in on Wed. April 28, 2021. He is waiting for an appointment with Dr. Neurologist at Neurology Group
1256680	4/25/2021	MN	50	F	4/10/2021	4/16/2021	Patient presented post-seizure. Reported 1 week of headache prior to presentation. Found to have cerebral venous sinus thrombosis, small areas of hemorrhage in the right frontal lobe, and bilateral pulmonary emboli, as well as thrombocytopenia (previously had normal platelet count). Per MD "Clinical picture is entirely consistent with VITT. See no other obvious explanation for this constellation of clinical findings. ~~

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1256512	4/25/2021	NH	60	F	4/7/2021	4/8/2021	Day one post vaccination - dull headache, leg pain, abdominal pain, back pain - these symptoms continued for a few days, I started to feel a bit better, did not take any pain reliever medications because I didn't want to mask symptoms. On 4/14/21, 7 days post vaccination, my leg pain in both legs worsened including numbness and a burning sensation in both feet. Back pain continued, arm pain started in both arms with numbness in both hands however the pain on my left side with legs and arms is worse. I've had intermittent shooting pains in my left ear, left jaw, left temple and across the left side of my face. I've also experienced shoulder and neck pain. The abdominal pain is intermittent and mild. On 4/15 - 4/18 the pain in my legs was so bad that it was waking me up at night and my arm pain was occurring more frequently. I decided to go to the ER on 4/18, day 11 post vaccination, due to my concern of a possible DVT or other type of blood clot. The ER physician's assistant did not look at my legs but did several blood tests and other tests.
1256268	4/25/2021		46	M	4/6/2021	4/12/2021	Iliac vein thrombosis pt started with right lower quadrant abdominal pain six days after vaccine. Persistent pain since then leading to hospital stay and diagnosis on imaging of right iliac vein thrombosis. no prior history of DVT, no family history of DVT, no inciting event/travel/change in activity level/surgery/illness
1256081	4/25/2021	NJ	58	F	4/8/2021	4/14/2021	April 14, my sister was transported to hospital feeling faint and numbness in her left leg. As a result, she was admitted and treated for: ? blood pressure readings as low as 82/43, 76/50 while standing ? blood clots on her heart that traveled to her brain that were causing multiple mini strokes ? 95% blockage in her right heart vessel which required a stent ? 50% and 60% blockage in other chambers that will require attention She was given heparin and then switched to a different blood thinner to dissolve the clots. she was discharged on April 23rd with instructions to followup with her cardiologist and neurologist.

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1256761	4/25/2021	NC	43	F	4/7/2021	4/25/2021	Janssen COVID-19 vaccine EUA Patient presented to hospital after crushing chest pain and syncopal event. Found to be hypotensive and hypoxic and echocardiogram revealed RV dilation and dysfunction with clot visualized in R atrium of heart. Patient received IV alteplase followed by start of IV heparin infusion. Currently intubated in ICU, on 3 vasopressors for shock.
1251620	4/24/2021	IL	73	F	4/5/2021	4/8/2021	Severe pain in left thigh groin & knee area. Went to ER, confirmed blood clot. Sent home w/blood thinners - Xarelto
1251583	4/24/2021	MD	33	M	3/31/2021	4/15/2021	4/15/21 woke up with severe pain in left upper thigh. Fatigue and headache began a few hours later. Needed to leave work. Early evening a rash developed in the left thigh and left foot swollen size of balloon and bright red. Went to the ER 10:30PM, admitted from ER on 4/16/21 for possible deep vein thrombosis and cellulitis of left leg. Shortly after admission, unable to obtain venous access, central line inserted for IV fluids and IV vancomycin and Zosyn. Foot swelling increased up to below knee with bright red skin color. No open wound noted on extremity. Ultrasound did not find a thrombosis but enlarged lymph nodes. 6 days later leg still swollen and red, repeat doppler ultrasound negative, but report stated could not compress to complete test due to severe swelling. He was also tachycardic and hypertensive during admission. Infectious disease doctor consulted and confirmed severe cellulitis but it was written in discharge summary the covid vaccine can not be ruled out as a cause of the infection and admission. Lasix was initiated to decrease swelling in lower extremity. He was on SQ heparin 3 times a day during the admission. He was discharged on Doxycycline and Augmentin. After discharge saw primary care physician who palpated large lymph nodes in neck. Mild headache persists. Ultrasound of neck to be completed on 4/27/21. Started on Tizanidine for pain.
1251532	4/24/2021	CT	19	F	4/10/2021	4/11/2021	Patient stated she needed to go to hospital for adverse reaction of pain in leg. After asking MD to check her leg, they discovered a blood clot per patient. She is now doing well per her.

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1249678	4/24/2021	GA		M	3/18/2021	4/15/2021	<p>Left lung is beginning to hurt again; chest is killing him; can barely walk; pain all over; the knot on the arm is blood clot; knot under the skin on his arm; painful knot under the skin; nauseated; kept vomiting all the next day, threw up about 20 times; This spontaneous case was reported by a patient and describes the occurrence of THROMBOSIS (the knot on the arm is blood clot) in a 45-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 007B21A and 027A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Broken bones. Concurrent medical conditions included Autoimmune disorder in September 2020. On 18-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 15-Apr-2021, the patient experienced NAUSEA (nauseated) and VOMITING (kept vomiting all the next day, threw up about 20 times). On 18-Apr-2021, the patient experienced SKIN MASS (knot under the skin on his arm) and PAIN OF SKIN (painful knot under the skin). On 19-Apr-2021, the patient experienced THROMBOSIS (the knot on the arm is blood clot) (seriousness criterion medically significant). On 20-Apr-2021, the patient experienced PULMONARY PAIN (Left lung is beginning to hurt again), CHEST DISCOMFORT (chest is killing him), GAIT DISTURBANCE (can barely walk) and PAIN (pain all over). On 17-Apr-2021, NAUSEA (nauseated) and VOMITING (kept vomiting all the next day, threw up about 20 times) had resolved. At the time of the report, THROMBOSIS (the knot on the arm is blood clot), PULMONARY PAIN (Left lung is beginning to hurt again), CHEST DISCOMFORT (chest is killing him), GAIT DISTURBANCE (can barely walk), SKIN MASS (knot under the skin on his arm), PAIN OF SKIN (painful knot under the skin) and PAIN (pain all over) outcome was unknown. No concomitant medications were reported. Treatment for the events included Elquis and I.V heparin. This case was linked to MOD-2021-081600 (Patient Link).; Sender's Comments: Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and</p>



*VAERS\_ID RECVDATE STATE AGE\_YRS SEX VAX\_DATE ONSET\_DATE SYMPTOM\_TEXT*

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onset of the reported events, a causal relationship cannot be excluded. Nausea and vomiting are consistent with the product safety profile.

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1249671	4/24/2021	TN	76	F	3/25/2021	4/12/2021	<p>they did ultrasound and found a blood clot in her right leg behind the knee; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (they did ultrasound and found a blood clot in her right leg behind the knee) in a 76-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031L20A) for COVID-19 vaccination. Concurrent medical conditions included Hypertension. Concomitant products included LIRAGLUTIDE (VICTOZA) and INSULIN GLARGINE (TOUJEO) for an unknown indication. On 25-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .5 milliliter. On 12-Apr-2021, the patient experienced DEEP VEIN THROMBOSIS (they did ultrasound and found a blood clot in her right leg behind the knee) (seriousness criterion medically significant). At the time of the report, DEEP VEIN THROMBOSIS (they did ultrasound and found a blood clot in her right leg behind the knee) outcome was unknown.</p> <p>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 12-Apr-2021, Ultrasound scan: found a blood clot in her right leg behind the knee (abnormal) found a blood clot in her right leg behind the knee. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment included xarelto 15mg. Concomitant medication included BP medicine. Her right leg started swelling and turned red a week ago(10Apr2021). She went to the doctor on 12Apr2021 and they did ultrasound and found a blood clot in her right leg behind the knee (12Apr2021). She is scheduled to get 2nd dose on 22Apr2021. She never had blood clot before so wanted to report it. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested</p>

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1249699	4/24/2021	NY	57	F	3/8/2021	4/10/2021	<p>Blood Clot in the Lower Left Lung; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Blood Clot in the Lower Left Lung) in a 57-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 008B21-2A and 010A21A) for COVID-19 vaccination. The patient's past medical history included Mastectomy bilateral on 20-Jan-2021 and Radiation therapy. Concurrent medical conditions included Breast cancer and Lung cancer (Has not been operated on as of yet). On 08-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 10-Apr-2021, the patient experienced PULMONARY EMBOLISM (Blood Clot in the Lower Left Lung) (seriousness criterion hospitalization). The patient was hospitalized on 10-Apr-2021 due to PULMONARY EMBOLISM. At the time of the report, PULMONARY EMBOLISM (Blood Clot in the Lower Left Lung) outcome was unknown. No concomitant medications reported. The patient developed a blood clot in the lower left lung, and was hospitalized. The doctor told her that because of cancer, radiation and recent mastectomy surgery she was at risk of developing blood clots. Treatment medication included apixaban for six months. The patient received both scheduled doses of mRNA-1273 prior to the event, therefore action taken with the drug in response to the event is not applicable. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Company Comment: Based on the current available information and temporal association between the use of the product and the onset date of the reported event, a causal relationship cannot be excluded. Patient's underlying cancer, radiation and recent mastectomy surgery were considered to be risk factors for developing blood clots.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported event, a causal relationship cannot be excluded. Patient's underlying cancer, radiation and recent mastectomy surgery were considered to be risk factors for developing</p>

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blood clots.

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1249676	4/24/2021	GA	45	M	3/18/2021	3/19/2021	<p>massive blood clot in the right lung; painful knot under the skin on his arm; threw up about 20 times in 6 hours, and kept vomiting all the next day; massive blood clot in the lung ended up in different parts of the lung causing extreme amount or pain\ Left lung is beginning to hurt again and his chest is killing him; next day when he got up and could barely walk; This spontaneous case was reported by a consumer and describes the occurrence of PULMONARY EMBOLISM (massive blood clot in the right lung), PULMONARY PAIN (massive blood clot in the lung ended up in different parts of the lung causing extreme amount or pain\ Left lung is beginning to hurt again and his chest is killing him) and THROMBOSIS (painful knot under the skin on his arm) in a 45-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 027A21A and 007B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Autoimmune disorder NOS in September 2020 and Broken bones. On 18-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 19-Mar-2021, the patient experienced GAIT DISTURBANCE (next day when he got up and could barely walk). On 26-Mar-2021, the patient experienced PULMONARY EMBOLISM (massive blood clot in the right lung) (seriousness criteria hospitalization, medically significant and life threatening). On 04-Apr-2021, the patient experienced PULMONARY PAIN (massive blood clot in the lung ended up in different parts of the lung causing extreme amount or pain\ Left lung is beginning to hurt again and his chest is killing him) (seriousness criterion medically significant). On an unknown date, the patient experienced THROMBOSIS (painful knot under the skin on his arm) (seriousness criterion medically significant) and VOMITING (threw up about 20 times in 6 hours, and kept vomiting all the next day). On 19-Mar-2021, GAIT DISTURBANCE (next day when he got up and could barely walk) outcome was unknown. On 28-Mar-2021, PULMONARY EMBOLISM (massive blood clot in the right lung) had not resolved. On 04-Apr-2021, PULMONARY PAIN (massive blood clot in the lung</p>

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							ended up in different parts of the lung causing extreme amount or pain\ Left lung is beginning to hurt again and his chest is killing him) had not resolved. At the time of the report, THROMBOSIS (painful knot under the skin on his arm) and VOMITING (threw up about 20 times in 6 hours, and kept vomiting all the next day) outcome was unknown. Not Provided Treatment information provided as blood thinners (IV heparin) and antibiotics were used to treat the events. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-081632 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-081632:2nd dose
1251659	4/24/2021	PA	71	M	1/27/2021	2/22/2021	Hospitalized with Pulmonary Thrombosis in both lungs. This occurred approximately 3 weeks after second injection. I had difficulty breathing so admitted myself to Hospital
1251752	4/24/2021	DC	39	F	4/16/2021	4/19/2021	I developed blood clots after receiving the first shot of Moderna resulting in PE
1251700	4/24/2021		60	F	3/23/2021	4/14/2021	Went into the er because I was shaking like I was having a seizure and I was delirious. During the testing they found a blood clot in my lung. I am being treated with anti biotics and blood thinners

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1251720	4/24/2021	NY	52	F	4/4/2021	4/5/2021	The day after I received the vaccin I experienced an extreme tension in my two eyes that I still have now but not as intense. My left eye is the most affected - The blood flows really fast in the eye and it is pulsing. I don't have the sensation every day now but still on and off. Both of my eyes feel tension not as much as it was at the beginning but still experiencing symptoms of pressure and pulsions. It feels like I am going to have an ophthalmic migraine. My eyes doesn't feel right either. Overall, I felt weak, highlighted and it felt like if I was experiencing feeling of "dissociation" - caused I think by my sight being affected. I couldn't do a lot as my energy was very low and it felt that my oxygen wasn't at its maximum. Every small activity required a lot of energy and I could barely walk around my block. It affected my work and I couldn't teach at the end of that first week. I wasn't feeling good. I went to my doctor on Monday, April 12th as I was concerned about blood clot or other neurological and pulmonary issues. My Doctor examined me and listened to me and concluded that the sides effects were taking longer than the average to go away. The following day I woke up reading about the blood clots due to J&J vaccin. I called back my doctor and we did a blood test. It came back negative and I got my eyes checked by my ophthalmologist too, and he didn't see anything.

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1249666	4/24/2021	MA	42	F	3/25/2021	3/30/2021	<p>This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of CEREBRAL VENOUS SINUS THROMBOSIS (Cerebral Venous Sinus Thrombosis) and HEADACHE (headache) in a 42-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 016B21A) for COVID-19 vaccination. Concomitant products included ETHINYLESTRADIOL, NORGESTREL (CONTRACEPTIVE HD) for Birth control. On 25-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 30-Mar-2021, the patient experienced HEADACHE (headache) (seriousness criterion hospitalization prolonged). On 02-Apr-2021, the patient experienced CEREBRAL VENOUS SINUS THROMBOSIS (Cerebral Venous Sinus Thrombosis) (seriousness criterion hospitalization prolonged). The patient was hospitalized from 02-Apr-2021 to 06-Apr-2021 due to CEREBRAL VENOUS SINUS THROMBOSIS and HEADACHE. At the time of the report, CEREBRAL VENOUS SINUS THROMBOSIS (Cerebral Venous Sinus Thrombosis) had not resolved, and HEADACHE (headache) outcome was unknown. Not Provided, DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Apr-2021, Computerized tomogram: abnormal (abnormal) Cerebral Venous Thrombosis in the brain. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment of the events included Pradaxa. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, the patient's recent history of starting back on oral contraceptives may remain a risk factor for this event.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, the patient's recent history of starting back on oral contraceptives may remain a risk factor for this event.</p>



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1249700	4/24/2021		61	F	1/20/2021	2/22/2021	<p>Deep vein thrombosis; Pulmonary embolism; Shortness of breath; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (Deep vein thrombosis) and PULMONARY EMBOLISM (Pulmonary embolism) in a 61-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 031L20A and 012220A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 on 03-Jan-2021. Concomitant products included PARACETAMOL (TYLENOL), MAGNESIUM and VITAMIN B3 for an unknown indication. On 20-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 22-Feb-2021, the patient experienced DEEP VEIN THROMBOSIS (Deep vein thrombosis) (seriousness criterion hospitalization) and PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced DYSPNOEA (Shortness of breath). The patient was hospitalized for 2 days due to DEEP VEIN THROMBOSIS and PULMONARY EMBOLISM. At the time of the report, DEEP VEIN THROMBOSIS (Deep vein thrombosis) and PULMONARY EMBOLISM (Pulmonary embolism) outcome was unknown and DYSPNOEA (Shortness of breath) had not resolved. Not Provided The patient received Xarelto and IV blood thinner at hospital. Company comment: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. This case was linked to MOD-2021-083811 (Patient Link).; Sender's Comments: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded</p>

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1251202	4/24/2021	AL	48	F	3/19/2021	3/27/2021	Events: Vaccine was given on 3/19/21; Hysterectomy on 3/25/21; blood clots diagnosed on 3/30/21 Left forearm was swollen, with a light reddish tint to it, and tender. After getting an ultra sound on my forearm a DVT was found and I was sent to the emergency room. I then had a CT scan done of my chest and it was discovered I had several pulmonary emboli. I was admitted to the hospital and put on a heparin drip. I am currently taking Eliquis and will be following up with a pulmonologist and a hematologist in a week or two.
1251690	4/24/2021	CO	57	M	4/3/2021	4/3/2021	My dad has been experiencing what seem to be definite blood clot symptoms since the vaccine but he refuses to go to the dr. Shortly after the vaccine he experiencing stabbing headaches that came on quickly and went away in an instant. I thought they were gone after that but he later told me the stabbing headaches continue, along with horrible pain in his legs, and ringing in his ears. He told me recently that the symptoms stopped exactly two weeks later but his legs are hurting again.
1249853	4/24/2021	NY	68	M	2/6/2021	2/7/2021	Anxiety the next day. It is Tuesday and still feel it; This is a spontaneous report from a contactable consumer. A 68-year-old male patient received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Lot number-UNKNOWN), via an unspecified route of administration in left arm on 06Feb2021 12.45 as single dose for covid-19 immunization. Patient was 68-years-old at the time of vaccination. The patient's historical condition included blot clots on warfarin. The patient's concomitant medication included duloxetine hydrochloride (CYMBALTA), mirtazapine, mirtazapine (REMERON) and atorvastatin. On 07Feb2021 12:00 the patient had anxiety and still feel it. Patient was not treated for the adverse event. The outcome of the event was reported as not recovered. Information on the lot/batch number has been requested.

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1250119	4/24/2021	PA	48	M	4/9/2021	4/9/2021	on 4/9/21 around 8pm extreme cold chills , headache , body aches fever all night , flu like feeling for 3 days body ache and little sleep , consistent headaches . Had out patient knee surgery on 4/14 . Continues nasty headaches and body aches after . on saturday 4/17 bad headaches all night , bones in upperbody and skin hurt , from waist up felt like i had sunburn including on top of head , little sleep again . Went to Emergency room on 4/18 am . Tested for blood clot in leg and was negative , they gave me something for headaches and i was dehydrated , tongue was white and continues to wake up everyday white and feeling like dehydration , continues head aches from front to back with some continues neck pain in back . Havent slept more than 2 hours at a time . wake up with headache everyday and at night headaches are bad . i drink plenty of fluids all day , should not be feeling dehydrated . its now 15 days since vaccine and have no answers , i need to be able to sleep to do my job , vaccine was a mistake
1250586	4/24/2021	FL	69	F	2/19/2021	3/2/2021	Severe pain in left leg, swelling, hot Sever pain in upper body-left side only--from jaw, to shoulder, to arm to side, front and back, all the way to the hip CT scan at hospital--pulmonary embolisms in both lungs, blood clot diagnosed in left leg at vascular surgeon's office before going to the ER Now on XARELTO for life.
1250826	4/24/2021		69	M	1/9/2021	1/20/2021	heart attack from blood clot
1250901	4/24/2021	MI	71	F	4/8/2021	4/21/2021	Blood clots in each lung and leg
1251010	4/24/2021	AZ	50	F	3/26/2021	3/28/2021	3/26 vaccination 3/28 slight swelling in both ankles. Over time, It started to spread into feet and heels 4/13 called PCM. Swollen to the size of softballs, hurt like crazy. 4/14 Ultra sound; no blood clots 4/19 Went to PCM. I wear compression socks and steroid pack per PCM. * dr stated it was 'more like swelling in the joints'.
1251068	4/24/2021	TN	61	M	4/2/2021	4/22/2021	PT STATED HE WENT TO THE CLINIC AND THEN THE ER WITH A BUMP ON THE BACK OF HIS LEG. PT WAS TOLD IT WAS A BLOOD CLOT.

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1251176	4/24/2021	WV	34	F	4/7/2021	4/21/2021	1) Bilateral acute appearing pulmonary embolism right greater than left, clot burden moderately large. 2) . Probable portal vein thrombosis with partial superior mesenteric vein thrombosis. 3) Changes of mild diffuse colitis are suspect. Potential etiologies for colitis includes infectious processes, inflammatory processes, as well as ischemic etiologies. 4) Splenomegaly. 5) Thrombocytopenia. Platelets of 39000
1251238	4/24/2021	OH	47	F	4/8/2021	4/16/2021	tia in right eye, on Friday morning on 4/16/ 21, between the hours of 8 am and 9:30 am, I went from feeling fine and sleeping to waking up not being able to hear in both ears, not being able to see anything out of my right eye, my left arm was completely numb all the way up to my shoulder and neck, the right side of my tongue was numb and my blood sugar was over 611. Initially they thought it was just a reaction to my high sugar levels, since the mri's showed I did not have evidence of a stroke. It wasn't until I saw a retina specialist the following Tuesday that she confirmed that yes I did have a stroke in my eye. I have not recovered my vision fully in my eye or the sensation in my tongue. I didn't connect it to the vaccination until I spoke with a friend whose sister also got pfizer 5 days before me and suffered a stroke 3 days before me, and two days after we spoke they announced Johnson& Johnson pause due to clots in women. The retina specialist says we will have to wait and see if the damage heals on it's own in the meantime I need to see her on a monthly basis.
1251780	4/24/2021	CA	50	F	4/16/2021	4/17/2021	4/16/21 Second Dose received. 4/17 and 4/18 noticed light swelling in ankles. No other effects. 4/19 - Emailed my Cardiologist about swollen ankles. Didn't think about the vaccine as a potential cause. He scheduled an Echocardiogram for May. 4/20 to 4/22 - Edema in ankles and lower legs with pain on bottom left. Tried heat and elevation with no relief. 4/23 - Called Advice Nurse with recommendation to go to ER. ER determined a blood clot in left leg at the left posterior tibial vein measured at 6.3cm.

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1251240	4/24/2021	CO	74	M	3/31/2021	4/13/2021	13th of April. I had a blood clot in my hand. My index finger on my left hand was numb and black and blue all around the knuckle area and into my hand area. I went to my primary care - I went to the acute center there. She said the hand was cold and could see the black and blue. They put me on Plavix for 30 days and I haven't had any reoccurrence of that. I think it was the 21st, I couldn't sleep all night, I had a kidney stone - the pain was so bad I got nauseous - around my back and side and in my front. I didn't have a fever. I went to the doctor office and they checked urine - and said there was blood in the urine. I was prescribed - Tamsulosin HCL. They thought I had passed most of it by the time I got there.
1252112	4/24/2021	TX	52	F	3/21/2021	3/21/2021	Transverse sinus thrombosis in the brain with severe headaches, nausea, dizziness, and blurred vision. Patient report headaches began within a week of receiving vaccine. She reports a electrical tingling sensation on the top of her head, which began on Tuesday 4/20/2021.
1251454	4/24/2021	OR	39	F	4/12/2021	4/22/2021	Headache== Found to have venous sinus thrombosis on CT and MRI
1251492	4/24/2021	CA	58	F	4/6/2021	4/11/2021	I delivered one baby in 1999 and one in 2002. Two miscarriages in between. I woke up 4/6/21 with a strange pain in my left leg. It felt circulatory, not muscular or skeletal. Swelling behind knee. I went to ER for ultrasound and they found a blood clot. Cat scan revealed pulmonary embolism. The nurses at the hospital confirmed that this was happening frequently. They said it wasn't rare. My PA at the clinic told me it was 1 in 5000 like me. Why doesn't the hospital report? I'm on bed rest for 10 days, compression stockings and Eliquis to thin my blood. I have halted all HRT, but have been told by my dr that it's clearly not related since i e been on them for over 6 years and never had a blood clots.
1251142	4/24/2021	IL	73	F	4/8/2021	4/22/2021	Blood clot in eye

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1254028	4/24/2021	PA		M			<p>Patient passed away; patient had blood clots in his brain/ Legs/ Lungs/ Arms; Severe hypotension; This spontaneous case was reported by a physician (subsequently medically confirmed) and describes the occurrence of DEATH (Patient passed away), THROMBOSIS (patient had blood clots in his brain/ Legs/ Lungs/ Arms) and HYPOTENSION (Severe hypotension) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced DEATH (Patient passed away) (seriousness criterion death), THROMBOSIS (patient had blood clots in his brain/ Legs/ Lungs/ Arms) (seriousness criterion death) and HYPOTENSION (Severe hypotension) (seriousness criterion death). The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment information was not provided. Company comment: This case concerns the death of a patient of unknown age and gender after administration of mrna-1273 (J)LOT UNKNOWN). Very limited information regarding this event/s has been provided at this time. Further information has been requested. Critical details such as the mRNA-1273 date of administration, onset of any signs and symptoms, and date of death is lacking.; Sender's Comments: This case concerns the death of a patient of unknown age and gender after administration of mrna-1273 (J)LOT UNKNOWN). Very limited information regarding this event/s has been provided at this time. Further information has been requested. Critical details such as the mRNA-1273 date of administration, onset of any signs and symptoms, and date of death is lacking.; Reported Cause(s) of Death: Unknown cause of death</p>
1251846	4/24/2021		59	M	4/1/2021	4/23/2021	Blood clot in left lower extremity, requiring TpA
1251880	4/24/2021	CA	60	M	4/19/2021	4/19/2021	Pulmonary Embolism (Blood Clot to the Lungs

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1254072	4/24/2021	VA	49	F	1/28/2021	1/30/2021	Mouth ulcers located inside of lip and under tongue; Thrush in mouth; This is a spontaneous report from a contactable consumer (patient). A 49-year-old (non-pregnant) female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: unknown), via an unspecified route of administration administered at left arm on 28Jan2021 09:00 PM at single dose for COVID-19 immunisation. Patient also received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: unknown), via an unspecified route of administration administered at left arm on 22Feb2021 04:30 PM at single dose for COVID-19 immunisation. The patient medical history included asthma and possible lupus. There were no known allergies. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine. Concomitant medications (medications the patient received within 2 weeks of vaccination) included cannabidiol (CBD OIL), montelukast sodium (SINGULAIR), montelukast (MONTELUKAST), colecalciferol (VITAMIN D [COLECALCIFEROL]). On 30Jan2021, the patient experienced mouth ulcers located inside of lip and under tongue, thrush in mouth. Occurred 2nd day after the first shot. Started medication and was under control. Flares up again 2nd day after 2nd shot. The patient was not diagnosed with COVID-19 prior to vaccination and patient was not tested for COVID-19 since the vaccination. Patient received clotrimazole 10mg tablets as treatment for event. Outcome of event for mouth ulcers located inside of lip and under tongue was not recovered and for thrush in mouth it was recovering. Information on the batch/lot number has been requested.

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1254022	4/24/2021	TX	80	F	3/3/2021	3/1/2021	<p>difficulty breathing; soreness after 1st dose left arm; Clot in Lung; chest pain; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY THROMBOSIS (Clot in Lung) in an 80-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 027A21A and 046A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Heart disorder. On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 29-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. In March 2021, the patient experienced PULMONARY THROMBOSIS (Clot in Lung) (seriousness criterion medically significant) and CHEST PAIN (chest pain). On 29-Mar-2021, the patient experienced VACCINATION SITE PAIN (soreness after 1st dose left arm). On an unknown date, the patient experienced DYSPNOEA (difficulty breathing). On 30-Mar-2021, VACCINATION SITE PAIN (soreness after 1st dose left arm) had resolved. At the time of the report, PULMONARY THROMBOSIS (Clot in Lung), CHEST PAIN (chest pain) and DYSPNOEA (difficulty breathing) outcome was unknown. <b>DIAGNOSTIC RESULTS</b> (normal ranges are provided in parenthesis if available): On 08-Mar-2021, Echocardiogram: normal (normal) Normal. On an unknown date, Computerised tomogram: abnormal (abnormal) Blood clot in Lung. On an unknown date, Pulmonary function test: normal (normal) came back perfect. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. On 08-Mar-2021 patient had an echocardiogram (results are not provided). Concomitant medications are not reported. No Treatment for events is provided. Based on the current available information which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, causal relationship cannot be excluded. Vaccination site pain is consistent with the known safety profile of the vaccine This case was linked to MOD-2021-084017 (Patient Link).; Sender's Comments: Based on the current available information which includes a strong temporal association between the use of mRNA-</p>



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							1273 vaccine and onset of the reported events, causal relationship cannot be excluded. Vaccination site pain is consistent with the known safety profile of the vaccine
1253221	4/24/2021	OR	65	F	4/3/2021	4/6/2021	CT of the abdomen and pelvis ordered on 4/20/21 revealed thrombosis of the right hepatic vein with heterogeneous enhancement of the right lobe of the liver compatible with Budd-Chiari syndrome.
1252537	4/24/2021			F		3/8/2021	BRUISING ON RIGHT THIGH; SWOLLEN RIGHT THIGH; TENDER RIGHT THIGH; BODY ACHES, PAIN; CHILLS; This spontaneous report received from a patient concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included blood clots in the neck. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose was not reported, administered on 08-MAR-2021 for prophylactic vaccination. The batch number was not reported. We are unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 08-MAR-2021, the subject experienced body aches, pain. On 08-MAR-2021, the subject experienced chills. On 13-MAR-2021, the subject experienced bruising on right thigh. On 13-MAR-2021, the subject experienced swollen right thigh. On 13-MAR-2021, the subject experienced tender right thigh. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from body aches, pain, and chills on MAR-2021, and the outcome of bruising on right thigh, swollen right thigh and tender right thigh was not reported. This report was non-serious.; Sender's Comments: MAC not required per standard procedure as the case assessed as non-serious.
1252400	4/24/2021	CA	30	F	4/10/2021	4/11/2021	The next day I was very fatigue and had body chills and mild fever. On monday I had chest tightness . I was still able to breathe and noticed that this was not normal. I presumed my day as usual. On Thursday I went to my local urgent care. They performed an EKG, Blood test to rule out infection and blood clots and a chest x ray. All of my test came back NORMAL. My Dr. stated that it was " CHEST WALL MUSCLE PAIN" The CHEST TIGHTNESS WENT AWAY ON SUNDAY. 1 week later from the day of the injection.

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1252018	4/24/2021	OH	71	F	3/28/2021	4/16/2021	On 4/16/2021 went to the emergency room with high blood pressure that was noted as a "hypertensive emergency". Was admitted into the hospital the next day where a CT scan confirmed that a blood clot in the brain occurred which led to a basal ganglia stroke. After a 5 day stay in the hospital, patient is now in a full time rehab facility to attempt to recover her cognitive and speech skills, while also attempting to regain use of her right hand which is currently not functioning due to the stroke.
1251851	4/24/2021	CA	58	F	4/12/2021	4/18/2021	Progressive headache, leading to ER admission, diagnosis of Left sigmoid sinus thrombosis accompanied by severe thrombocytopenia. Diagnosis confirmed as vaccine-induced immune thrombocytopenia and thrombosis (VITT)/vaccine-associated thrombosis and thrombocytopenia (VATT).
1247051	4/23/2021	AR	65	F	4/3/2021	4/4/2021	Patient called 4/23/21 reporting unilateral (left nostril) nosebleeds occurring each day since receiving the vaccine. She saw PCP and had blood pressure medications adjusted to control hypertension, however, nosebleeds have persisted. I have given her my personal cell phone number to call me immediately and to go to Emergency Room if bleeding worsens or other problems arise such as sudden, severe headache. (Patient states that blood flow contained clots for the first day or two, but has been flowing without clots each day at least and sometimes twice per day. She is able to stop blood flow within 5 minutes by packing nostril each time.) I have instructed patient to make appointment with ENT (Ear, Nose, Throat) Dr.

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1247493	4/23/2021	CA	32	M	4/8/2021	4/16/2021	<p>Covid-19 vaccine JJ: 32 y.o. male w/ no PMH presenting 2 weeks after receiving his Johnson &amp; Johnson COVID vaccine after having severe L calf pain found to have thrombocytopenia. From H&amp;P on 4/21, Patient reports that he had both fevers and aches after his vaccine (4/8/2021). Several days later developed low back pain radiating into his left leg which he initially attributed to sciatica. However, several days later, he went for a 6 mile hike, and felt that his left leg was hurting more. He went to PCP, where he received a blood test and was found to have a platelet count in the low 60s. This was initially thought to be a lab error, but he noticed that his left leg was swollen, somewhat red, and appeared that his blood vessels were swollen. This swelling resolves when he is lying down, and is worsened when he is standing. He received an US to r/o DVT, which was negative. However, after his repeat platelet count demonstrated thrombocytopenia, he was sent to the ED. He denies any recent leg trauma, though he has broken his leg before nearly 15 years ago. He denies weakness or issues going to the bathroom. Denies chest pain or shortness of breath. Denies chills, fevers, but did wake up last 2 nights drenched in sweat. He also reports a petechial rash on his legs. As of 4/22, medical team suspects Vaccine-induced thrombocytopenic purpura (VITT). VITT requires 1) thrombocytopenia, 2) documented clot, 3) positive PF4 Ab, and 4) recent AstraZeneca or J&amp;J vaccine. He meets criteria 1, 3, and 4. He has clinical signs of DVT but does not have a documented clot. Patient has L calf tenderness and prominent pooling of blood and vein engorgement of the L leg when he stands up. Possible that he had a DVT or multiple that cleared and now he has post-thrombotic syndrome. This is consistent with the pooling of blood with gravity and relief of symptoms with elevation. As he has had 2 negative US for DVT, unlikely that he has an unresolved DVT. abdominal and head CT are neg for thrombosis.</p>

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1247470	4/23/2021	AZ	55	F	4/5/2021	4/6/2021	4/5/2021--Received Janssen vaccine. Felt very hot during the day. 4/6/2021--Woke up with very bad headache and rash on the injected arm plus on my stomach. Went for a walk and felt pain in my left calf and achilles tendon. Went to work. 4/7/2021--Started my work day as a Personal Trainer/Fitness Instructor at 6am as usual. Taught cycling classes and trained a few clients. Went for walk. Still had a headache. When I got in my car to head home, my vision was super blurry and I felt very dizzy. I ate an orange and peanuts and hydrated more. I was not even sure I could drive home. I got home told my family how I was feeling. My husband noticed my eyes were very red and swollen. I took a shower, drank a smoothie and ate a salad. Used my aunt's BP cuff to check my BP and it was 148/99. I have NEVER had HBP. 4/8/21--Woke up feeling disoriented as if the left side of my face, body were off--neurological stuff. I went to reach for grapes in the refrigerator and could not grab them. I felt like I have never felt before and ask my husband to drive me to the ER. While at the waiting room at the ER, I felt chest tightness and pain and nauseous. My BP was 153/111. Again, I have never been diagnosed or been treated for hypertension. They did EKG, lab tests, chest X-ray. Once my BP came down, they sent me home. This is before all the JJ Janssen vaccine "news" came out and the reasons it was paused. I developed a very bad cough about two hours after I got home from the ER. 4/9/11--Made appointment with a brand new primary care doctor. Saw her on Monday 4/12/2021 as recommended by ER. I had never met her before. She prescribed a very low dose of BP medication, which I did not take because the number one side-effect is dry-cough. I was already coughing a lot, later on with blood. 4/11/2021--Still feeling pretty bad, I woke up to the news of the Janssen vaccine being paused. Frankly, I felt relieved that I was not going crazy. This truly has been one of the hardest things I have ever gone (and still am) going through. I became concerned about the pain in the left calf and heel could be a clot. Called primary care doctor. Had ultrasound of legs and chest x-ray the following day 4/12/2021--Had persistent cough with blood. Went to ER at 9pm. Had EKG, blood work, CT without contrast of chest, covid test--negative. Got home around 2am. 4/19/21--Followed up with primary care doctor who after

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1247460	4/23/2021	CA	41	F	4/3/2021	4/9/2021	<p>explaining to her I am extremely fatigued, still blurry vision, dizzy, cough better but not gone, chest discomfort on the left side, she referred me to an optamologist and cardiologist. My insurance and this poorly established referral system is very difficult to navigate. Up to now I am still waiting for the referral and pre-aurhtorization to the opthtamologist. (4/23/2021). I want to say, I am pretty healthy. I have worked in fitness and wellness for over 30 years. I have never drank alcohol, smoked or done any drugs. Prior to this no physician has told me I have HBP or any issues for which I have to be medicated. I take zero medications. Even when I had the bad headache from the vaccine I took nothing. I have not worked in two weeks and had not driven until last saturday. If I don't work, I don't get paid. I pay for almost \$600/month for my insurance in the marketplace. This has been another stressor of this storm. Getting providers to really listen and insurance companies to take situations like this seriously. I could not drive at night. This has been rough and I look forward to being myself soon. This reaction felt like a heart attack/stroke with extreme fatigue, acid reflux, cough with some blood, muscular pain. The rash and headaches were the least of my concerns. I am not yet recovered from all of this. I sure hope there is no permanent damage and that this too shall pass. It is important to note that I have tried reporting this event several times to the VAERS website online. I completed the 4-5 pages multiple times and it would not let me submit. I also called the VAERS 1-800 number to report and they told me to go back to the online form. I left several messages when I could not get it done online and to this date no one has called me back. I called to report my adverse reaction and they told me they do not take that info. I also called the health dept. After several phone calls to them a nurse called me back but did not take a formal report. When someone is feeling pretty sick, this is a lot to ask of. I persisted because I feel this is important to be reported.</p> <p>Left calf and thigh pain and swelling on the 6th day following vaccine which continued intermittently for a total of 12 days. I was seen at an urgent care, a left leg ultrasound was completed and I was diagnosed with deep venous thrombosis. I was prescribed Xarelto.</p>

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1247450	4/23/2021	LA	69	F	3/30/2021	4/5/2021	pt says on the 6th day she woke up w/ a headache and nauseated. She started vomiting and took Medizine which seem to help. On 4/11/21 she started having cramps in her stomachs like a spasm and SOB. She went to hospital ER. They did blood work and Chest X-Ray which came back negative results. She was told she did not have the same blood disorder as the other people who have had blood clots after taking the vax. She was told she had blood in her urine but had no infection. She will FU w/ PCP in June. Pt says her only symptoms now are some nausea and still does not feel normal.
1247546	4/23/2021	WV	32	F	4/12/2021	4/12/2021	I had very severe pain in both legs. This lasted for a few days before I ended up in the emergency room. They only drew labs and determined I did not have a blood clot. I'm taking ibuprofen and a baby aspirin but I do still have pain in both of my legs.
1247447	4/23/2021	NY	40	F	3/20/2021	4/3/2021	I have Had A MIGRAINE Along with HIGH BLOOD PRESSURE... It started 2 weeks after my 2nd Pfizer Shot... I was admitted into the hospital because after A Cat Scan, MRI, And A Spinal Tap looking for Menengitis They Couldn't Find ANYTHING WRONG... I was in the Hospital for 8 days... They where unsure WHAT WAS WRONG SO THEY TREATED ME WITH MANY DIFFERENT MEDICATIONS INCLUDING HEPRINE FOR BLOOD CLOTS... AS OF TODAY 4/23/2021.. I CONTINUE TO EXPERIENCE THESE UNBEARABLE HEADACHES... HAVEN'T SLEPT IN A MONTH.. AND I CONTINUE TO HAVE SUPER HIGH BLOOD PRESSURE... IF THIS CONTINUES I AM NOT SURE HOW I WOULD LIVE... THE PAIN IS HORRIBLE... SO SO BAD
1247287	4/23/2021	WV	56	F	2/12/2021	3/29/2021	bilateral pulmonary blood clots

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1247201	4/23/2021	NJ	44	F	4/1/2021	4/16/2021	Employee reported on 4/16 that after receiving the J&J vaccine she was having uterine contractions and pelvic pain. She went to her primary which put her on baby aspirin. Employee then called out for chest pain on 4/20. She went to the ER on 4/19/21 . ER stated she did not have a blood clot and it was muscle related. She was put on medication. She was put out of work for 3 days. Upon her return on 4/23 she returned to work and stated she was advised by her primary to get an MRI.
1247582	4/23/2021	LA	66	F	3/30/2021	4/5/2021	about 6 days after taking vax she had nausea and vomiting. On 4/11/2021 she had SOB and cramping in her stomach. She went to ER. They did blood work, EKG and Chest-X-RAY. She was told that she did not have the blood disorder that people with the blood clots have after taking the vax. She was released and told to FU w PCP. She still has some nausea that comes and goes and does not feel back to normal.

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1247125	4/23/2021	FL	31	F	4/10/2021	4/23/2021	<p>Saturday 4/10: 3:00 pm- first sign of headache -anxious and fatigued, series of falling asleep and waking up confused 10:41pm: First sign of chills and running ?hot and cold? Sleep was disturbed with intense vivid dreams and waking to sweat and running hot and freezing cold Sunday 4/11: 2:15 pm: Headache, sweating, diarrhea 6:51 pm: experienced confusion, brain fog, muscle tightness all over body Monday 4/12: 8:15 am: Woke up to muscle soreness, brain fog, and stuffy nose with green mucus. Left arm from at injection sight still sore. 8:53 am: Experienced disorientation and concern about safety driving to work 10:53 am: Dizziness and overall feeling of being unwell. Series of running hot and ?clammy? Expressed that everything seemed like a dream-like state. Experienced forgetfulness, confusion and uncertainty. 11:59 am: Ran hot and cold going from sweating to shivering cold. 12:02 pm: Questioned ?what?s real and what?s imagined?, hard to grasp reality. Fatigued, confused and trouble at work concentrating. 12:35- 1pm: Shivering cold, difficulty regulating body temp 2:30 pm: Starting feeling a little better, body temp started to go back to somewhat normal Tuesday 4/13 1:13 am: woke up sweating drenched and anxious, confused and achy. Experienced unusual amount of milky discharge not usually present in between menses. Throughout the day experienced less confusion as before, but still sore and not well overall in general Wednesday 4/14 4:15 am: woke up with major feet cramps, toes curling in without release for over an hour. Intense pain that had not been experienced before with the length of the duration of the cramp in both feet. 7:15 am: Feet cramped on and off, noticed left eye swollen (previously has happened before but not sure reason why). Took a Claritin and drank water to help with the cramping. Experienced immense anxiety about driving vehicle to work due to the muscle spasms now mostly on the left foot. 8:07 pm: Left foot was still cramping up sporadically throughout the day with lingering pain when muscle was relaxed Sleep throughout the night was accompanied by vivid intense dreams and waking up with more cramping in feet, more the left foot now Thursday 4/15 7am: Cramps in feet were still present, decided to check in to an urgent care to check it out 9:30 am: MD Now Urgent care visit- ran urine analysis and blood tests. 10:30 am: Discharged</p>



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1246983	4/23/2021	FL	58	F	4/5/2021	4/5/2021	<p>from Urgent care with following diagnosis: Acute cystitis without hematuria, abnormal urinalysis adverse effect of vaccine, initial encounter cyanosis of skin, shortness of breath and protein found in urinalysis. Instructed to immediately get CT angiogram to rule out blood clot. 12: pm Admitted to Mount Sinai Emergency Room-blood work, XRay and IV given. details below Discharged with the following diagnosis: Foot cramps - Primary Local reaction to COVID-19 vaccine Friday 4/16 Subtle and lingering muscle spasm on left foot. Experienced chills and consistent headache throughout the day Saturday 4/17 10 pm: Began to run a fever however did not check the temperature. Radiated heat and friend took care of me throughout the night as I sweated with confusion Sunday 4/19 Complete fatigue and tiredness, cramping in the foot seemed to have subsided. Still was running hot throughout the day. Monday 4/20 Took off work due to exhaustion and muscle ache and what seemed to be a fever Thursday 4/23 Followed up with General Practitioner Dr. Franco and was advised to report my experience with the Johnson and Johnson vaccine. Feeling better as of Friday 4/24 with slight fatigue but body temperature seems to be ok. No signs of the lingering cramping in the left foot but still slightly achy all over the body.</p> <p>After vaccination, at 10pm I started feeling flu like symptoms, fever chills shakes feeling miserable and this lasted 3 days straight, I also had diarrhea, nausea and vomiting. I woke up with a swollen jugular vein that ended up being a blood clot, 10 days later my arm was swollen up twice the size of my leg, the jugular was still swollen. I call the urgent care nurse they said to go to ER. I went to hospital got a CAT scan and ultrasound, I was given a shot of warfarin that was supposed to last for 12 hours. I went home and the next morning instead of going to the hospital, I went to hospital and they found 2 blood clots in brain, arm and leg and neck. I have had no history of blood clots and this all happened after the J&amp;J vaccine. They did a procedure where they tried to put a balloon to relieve the pressure. The blood clots in the brain cannot be removed because of their location and it would be dangerous to remove and I am on blood thinners for the rest of my life. Multiple blood clots in body brain, arm and shoulder.</p>

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1246956	4/23/2021	TX	73	F	4/9/2021	4/10/2021	Stroke and blood clot in right leg.
1247196	4/23/2021	FL	38	M	3/31/2021	3/31/2021	Patient states shortly after he received the vaccine, he developed intermittent bilateral upper and extremity numbness/tingling x 2 weeks. CTA/CTV head ruled out cerebral venous sinus thrombosis. MRI cervical, thoracic, and lumbar spines showed degenerative disk disease.
1247645	4/23/2021	WA	48	F	4/8/2021	4/8/2021	On the night of my J&J my vaccine , I felt very tired and sleepy but I could not sleep. The next morning I felt a burning sensation to my eyes as well to my right ear and that went away. I went to see my PCP that day as well because I was having a pressure sensation down my right calf and leg. On Wednesday I felt numbness sensation down my right arm and the right side of my body was weak. On Thursday, I called my PCP who advised me to go to the ER and to get monitored for thrombosis. I also began to have headaches and blurry vision. At the ER they performed an ultrasound and did lab work. The ultrasound exam did not show evidence of thrombosis or blood clots. The ER physicians told me to rest and elevate my legs. I also noticed that my BP was 130/90 which I never had before. To this day I still have throbbing sensation to my right calf and leg. I again went to the ER and they monitored me. They told me to take Ibuprofen for pain and again did an ultrasound which did not show any blood clots. I then started to have a burning sensation to my skull and scalp and also my left arm. I have not fully recovered from my symptoms.
1247700	4/23/2021	CO	45	F	4/7/2021	4/17/2021	Shortness of breath for several days, feeling fatigue and week, pain in right elbow Diagnosed Apr. 17 in ER setting: acute segmental and subsegmental pulmonary embolism without acute cor pulmonale Acute thrombosis of superficial vena basilica right arm
1247803	4/23/2021	OH	66	F	3/15/2021	4/19/2021	Patient received Moderna vaccine and was in her usual state of health. Developed shortness of breath and dyspnea of exertion for 2 weeks. Presented to her Physician's office who ordered a CT Angio which revealed multiple acute pulmonary emboli throughout both left and right main pulmonary arteries and lobar branches with ventricular strain. Patient underwent EKOS procedure to remove clot burden and was initiated on Xarelto. Patient is requiring 4L of oxygen at this time.

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1246863	4/23/2021	IL	62	F	3/24/2021	4/2/2021	Shortness of breath, blood clot in lungs
1247817	4/23/2021		52	F	3/10/2021	3/18/2021	52 yo female received J&J COVID-19 vaccination on 3/10. On 3/18, she presented to the ED with chief complaint of SOB and anemia. CT confirms bilateral submassive PE seen in segmental and subsegmental lobes. Symptomatic with tachypnea, pleuritic CP, tachycardia. Patient has history of PE 3 years ago as well, and was on warfarin for 6 months. Only family history of clots is elderly grandmother with DVT's. No sudden death in family. Age-appropriate cancer screening up to date. Patient is wheelchair bound and was dehydrated 2/2 gastroenteritis which made her high risk for VTE. Less likely due to hypercoagulable disorder. At discharge, she is hemodynamically stable...Tachypnea and pleuritic chest pain resolved. Myeloproliferative neoplasm panel negative. She was started on apixaban (will finish loading doses 3/26, and continue 5mg BID indefinitely). Will be referred to hematology as outpatient for PE + anemia.
1246575	4/23/2021	WI	27	F	4/8/2021	4/17/2021	Patient presented on 4/17 to urgent care afer significant vaginal bleeding (soaking through a pad every 1 hour to 1.5 hours) and petechia on multiple extremities. She also had a nose bleed and bleeding in mouth earlier in the day that resolved spontaneously. After obtaining CBC, platelets were <1000. She was on oral contraceptives. She is a non smoker. She received work up for thrombosis, not indication of thrombosis. She did have some muscle aches and fever and fatigue the day after vaccine. Histroy notable for mild diffuse petechiae on all 4 extremities. As inpatient received solumedrol 125 mg (then switched to prednisone 80 mg daily), IVIG 1 g/kg x 2 doses. she was discharged on 4/19 d/t rising platelets, Vaginal bleeding slowing and Petechia much fainter.

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1247838	4/23/2021		89	F	3/9/2021	4/18/2021	89 yo female received J&J COVID-19 vaccination on 3/9/21. Patient with history of SMA thrombosis presenting with 1 month history of abdominal pain, nausea, and vomiting, found to have SMA stent thrombosis. Stopped antiplatelet therapy several months prior to admission without consulting vascular team. Admitted and stable on heparin drip. GI was consulted, as her symptoms are not a classic presentation of mesenteric ischemia. On 4/21 she underwent EGD. EGD was read as normal stomach and duodenum, Schatzki ring (widely patent) and regular Z-line. After this patient was able to resume PO intake in increasing volumes without nausea, vomiting or abdominal pain. Pt discharged on 4/23 with prescription for apixaban.
1247844	4/23/2021	AL	20	F	3/6/2021	4/13/2021	Onset of period was delayed by 8 days - this is highly unusual as periods are normally very regular. When period began, it was incredibly heavy and contained clots of blood. Accompanied by significant abdominal pain and cramping with nausea. Also, the blood was bright red (normally it is dark brownish red).
1247921	4/23/2021	MD	80	M	3/11/2021	4/15/2021	4/15/2021 approximately 1030 am client found to be AMS, non-responsive, aphasic, aphagic, left-sided facial droop, teeth clenched, left eye closes, right eye with deviated gaze. 911 called, client to hospital ER, work up/evaluation, admission for stroke related to blood clots found left frontal and right temporal lobes, per spouse. Client discharged 4 days later to home s/p CVA, bed-bound, remains aphasic, aphagic, non-communicative, no response to verbal stimuli. PLEASE NOTE: hospital admission. Unable to complete section 21. Admit for 4 days.
1247969	4/23/2021	MO	55	M	4/10/2021	4/17/2021	patient received second dose of Moderna vaccine on 4/10/2021, and he developed his first symptoms 7 days after. He ultimately came to hospital with SOB, diagnosed with bilateral PTE. no clots noted in his legs bilaterally. He did well, was on Room Air throughout his stay, which was less than 24 hours and went home on Eliquis for Anti-coagulation.

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1247999	4/23/2021	MN	66	F	3/31/2021	4/1/2021	On 04-01-2021, I started to experience fever, chills and terrible headaches. I also developed pneumonia. A chest x-ray was done which demonstrated ground glass opacities. My breathing was also bad. I also have an enlarged heart. I also do not have any blood clots. I did not have problems before the J&J vaccine. To this day I still have headaches that come and go. I do not know if the J&J vaccine attributed to my symptoms and my doctor is till monitoring me.

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1248045	4/23/2021	IL	39	F	4/10/2021	4/11/2021	<p>J&amp;J COVID Vaccine EUA J&amp;J Vaccine 4/10/2021 4/13/21: Believes she is having a reaction to her Johnson and Johnson COVID-19 vaccination. This vaccination was given on 04/10/2021. Patient is 39-year-old female with a past medical history significant for ulcerative colitis that has been in remission since the patient was 21 years of age, epileptic seizures on Vimpat and clonazepam. Patient comes in as a transfer with a chief complaint of possible reaction to Johnson and Johnson COVID-19 vaccine. Patient presents with multiple complaints. The patient states that upon receiving the vaccine on 04/10/2021 she suddenly developed presyncopal episodes where she felt like she was about to pass out but that subsided later on. 12 hours following the shot she had intense headache which was frontal and then later on travel to the back of her head and traveled down her spine. Patient described the headache to be the worse headache of her life, stated that it was worse than going through labor. Patient stated that she received morphine which helped her with the headache. Patient also complained of chest pain which was left-sided with no radiation, constant. No history of previous myocardial infarctions. Her troponins that were conducted were negative. Patient also complained of experiencing blood in her stool. She stated that when she wiped herself on the morning of 04/13/2021 she experience blood on the toilet paper and blood in the bowel. However, her stool occult blood that was conducted was negative. Patient is being followed by Neurology, she contacted her neurologist and they recommended to come to the ED with concerns of thromboembolism. Patient's D-dimer was negative. Patient denied any recent travel anywhere or coming into contact with anyone sick. She denied developing any fevers cough shortness of breath abdominal pain nausea vomiting or any urinary concerns. 4/15/21: Patient is a 39-year-old female with a past medical history significant for ulcerative colitis that has been in remission since the patient was 21 years of age, epileptic seizures on Vimpat and clonazepam. Patient comes in as a transfer with a chief complaint of possible reaction to Johnson and Johnson COVID-19 vaccine. Headache: MRI brain and MRI venogram was ordered. MRI brain did show concerning signed for idiopathic intracranial hypertension. Neurology was consulted. Patient had high volume LP. Patient</p>

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responded well post LP. Patient will be discharged on topiramate with a taper instructions per neurology. Patient will make appointment with Ophthalmology. Patient will follow up with Neurology as well. Chest pain concerning for ACS: Negative troponin. EKG normal sinus rhythm. Concern for vaccine reaction: Patient has J&J vaccine. No clots were noted. Patient's symptoms are most likely are secondary to idiopathic intracranial hypertension and history of migraines. 4/16/2021: 39-year-old female presents emergency room with chief complaint of headache. Onset this morning. Headache is generalized. Headache is constant. Headache is worth with position change. Such as moving head side to side or with changing from lying to sitting and sitting to standing. Headache improves with lying supine. To has tried pushing fluids, taking over-the-counter medication, and also increasing her caffeine intake to offset the headache. She denies any of these helping with her symptoms. Patient's pain is right an 8 out of 10. The patient denies anything additional alleviating and or aggravating factors to chief complaint. Today when the patient's headache started. She contacted her neurologist. She was told to come to the emergency department for a blood patch. The patient added that her neurologist felt that she needs a blood patch not only because of the recent lumbar puncture but because there was at minimum 25 mL of spinal fluid removed at the time of her lumbar puncture. This lumbar puncture occurred under fluoroscopy. However, they had difficulty getting the pressure gauge on thus, more than 25 mL was removed.. Pain Pain Scale: 8 /10. Timing: constant. gradual. Character: mild. 4/19/21: patient reports intense headaches she attributes to the spinal tap. Ketorolac, DHE, ondansetron given.

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1248051	4/23/2021	VA	72	F	4/5/2021	4/12/2021	Patient was admitted with ischemic colitis and hypoglycemia. She also tested positive for C.diff during her hospitalization, unclear if this was from prior antibiotics in March. She did not receive DVT prophylaxis for 2 days. She developed a nonocclusive DVT in the right internal jugular and subclavian veins and a Nonocclusive superficial thrombosis in the right basilic vein on 4/18. She went into PEA and was revived, intubated, and transferred to the ICU. She went into PEA again and was revived after 5 rounds of CPR. The family decided to make the patient comfort care and expired on 4/19
1248189	4/23/2021	IL	38	F	3/13/2021	4/1/2021	Blood clot in superficial vein in right heel of foot
1247811	4/23/2021	NY	33	M	4/8/2021	4/16/2021	Severe thrombocytopenia (Platlet Count of 18) HPI: 33 y.o. male with no PMH coming in now w/ progressive thrombocytopenia to 18. He received the J&J covid vaccine on 4/8 and felt well afterwards. Last Friday (4/16) he began to experience constitutional symptoms (fever to 100.4, chills, night sweats feeling drenched, decreased appetite) so decided to get his labs drawn as an outpatient for further evaluation. Symptoms progressed until Tuesday, when they began to subside slightly. At that point, his labs resulted and were notable for thrombocytopenia. He got his labs redrawn the day before admission and it was noted that his thrombocytopenia was worsening, so he was directed to the ED for further evaluation. Patient seen by hematology, started on dexamethasone 40 mg PO daily as well as IVIG treatment x2. MRV of brain without evidence of dural venous sinus thrombosis ***PATIENT CURRENTLY HOSPITALIZED***



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1245460	4/23/2021	FL	73	F	2/10/2021	2/13/2021	I had a stroke; Blood clot; Speak was bad, couldn't form words, speak was impaired; Missed her dose due to the decision not to get it; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of CEREBROVASCULAR ACCIDENT (I had a stroke) and THROMBOSIS (Blood clot) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 010M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was reported.). On 10-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Feb-2021, the patient experienced CEREBROVASCULAR ACCIDENT (I had a stroke) (seriousness criterion hospitalization). On an unknown date, the patient experienced THROMBOSIS (Blood clot) (seriousness criterion medically significant), SPEECH DISORDER (Speak was bad, couldn't form words, speak was impaired) and INTENTIONAL DOSE OMISSION (Missed her dose due to the decision not to get it). On 16-Feb-2021, CEREBROVASCULAR ACCIDENT (I had a stroke) had resolved. At the time of the report, THROMBOSIS (Blood clot) and SPEECH DISORDER (Speak was bad, couldn't form words, speak was impaired) outcome was unknown and INTENTIONAL DOSE OMISSION (Missed her dose due to the decision not to get it) had resolved. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not provided. The patient was receiving treatment with clopidogrel (Plavix) 75mg since the stroke (which is a stronger blood thinner TPA drug that resolve the blood clot). Reportedly, the patient was hospitalized for 3 days. Patient also stated that she was nervous about getting her 2nd dose so she missed her dose due to the decision not to get it with regards to the fear of having another stroke. Company comment Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked; Sender's Comments:

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1245238	4/23/2021	TX	52	F	4/8/2021	4/15/2021	The back of my left leg hurting all of a sudden on 04/15/2021. The pain on the leg is getting worse each day. Went to the ER on 04/20/2021. Per the doctor no swelling and no redness. I said something is really wrong please check. They did blood work and everything came back good. They did a sonogram and that's where they saw a Blood Clot. Was given Eliquis.
1245284	4/23/2021	MO	24	F	4/7/2021	4/7/2021	In addition to the five main side effects (fever, chills, headache, nausea, and muscle pain), I also had severe lower body pain in my legs. I couldn't walk. It felt like my limbs were cut off from the rest of my body. I had an intense sensation of knives stabbing me in different places all over my body. I couldn't sleep the night of the shot due to the pain. Today marks 15 days since getting it, and I still have fatigue, radiating pain down my left arm and leg, and brain fog. I had a pretty bad migraine the other night. I have not received any treatment. I called my doctor who told me to go to the ER to get checked for a blood clot using a Doppler. I haven't gone yet because it's expensive and I'm still functioning. I'm considering going if I don't get better.
1245306	4/23/2021	NY	68	M	2/13/2021	3/10/2021	I got a blood clot, venous, in my upper right leg. Started on or about March 3rd, 2021

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1245371	4/23/2021	MD	95	F	3/10/2021	3/11/2021	<p>irritated her heart condition; Clot blood; weakness in legs, couldnt walk with legs; Coma; couldn't breathe; stroke/massive stroke in left side of her brain; Irritated her heart condition, rapid heart beat; Headache; Tiredness; This spontaneous case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (stroke/massive stroke in left side of her brain), CARDIAC DISORDER (irritated her heart condition), DYSPNOEA (couldn't breathe), THROMBOSIS (Clot blood), COMA (Coma) and MUSCULAR WEAKNESS (weakness in legs, couldnt walk with legs) in a 95-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for Covid-19 Vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Heart disease, unspecified, Hypertension and AFib. Concomitant products included APIXABAN (ELIQUIS) for Anticoagulant therapy, SACUBITRIL VALSARTAN SODIUM HYDRATE (ENTRESTO) for Hypertension, METOPROLOL for an unknown indication. On 10-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Mar-2021, the patient experienced HEADACHE (Headache) and FATIGUE (Tiredness). On 12-Mar-2021, the patient experienced MUSCULAR WEAKNESS (weakness in legs, couldnt walk with legs) (seriousness criterion hospitalization). On 13-Mar-2021, the patient experienced CARDIAC DISORDER (irritated her heart condition) (seriousness criterion hospitalization), THROMBOSIS (Clot blood) (seriousness criterion hospitalization) and HEART RATE INCREASED (Irritated her heart condition, rapid heart beat). On 15-Mar-2021, the patient experienced CEREBROVASCULAR ACCIDENT (stroke/massive stroke in left side of her brain) (seriousness criteria death and medically significant). On 16-Mar-2021, the patient experienced DYSPNOEA (couldn't breathe) (seriousness criterion hospitalization prolonged) and COMA (Coma) (seriousness criterion hospitalization prolonged). The patient was hospitalized on 13-Mar-2021 due to CARDIAC DISORDER, COMA, DYSPNOEA, MUSCULAR WEAKNESS and THROMBOSIS. The patient died on 17-Mar-2021. The reported cause of death was massive stroke in left side of her brain. It is</p>

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unknown if an autopsy was performed. At the time of death, CARDIAC DISORDER (irritated her heart condition), DYSPNOEA (couldn't breathe), THROMBOSIS (Clot blood), COMA (Coma), MUSCULAR WEAKNESS (weakness in legs, couldn't walk with legs), HEART RATE INCREASED (Irritated her heart condition, rapid heart beat), HEADACHE (Headache) and FATIGUE (Tiredness) outcome was unknown. Action taken with mRNA-1273 in response to the events was not Applicable. This case concerns an 95 year old female patient, with medical history of A Fib, Heart disease, Hypertension who experienced a serious unexpected event of Death 8 days after receiving 1st dose of mRNA- 1273 . Very limited information regarding these events has been provided at this time. However, the patient's advance age, multiple co-morbidities, may remain as risk factors. Further information is requested. This case was linked to MOD-2021-074814 (Patient Link).; Sender's Comments: This case concerns an 95 year old female patient, with medical history of A Fib, Heart disease, Hypertension who experienced a serious unexpected event of Death 8 days after receiving 1st dose of mRNA- 1273 . Very limited information regarding these events has been provided at this time. However, the patient's advance age, multiple co-morbidities, may remain as risk factors. Further information is requested.; Reported Cause(s) of Death: massive stroke in left side of her brain

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1245380	4/23/2021	NC	64	M	4/1/2021	4/9/2021	<p>Patient urinated blood clot in urine; Patient urinated blood in urine; This spontaneous case was reported by a consumer and describes the occurrence of HAEMORRHAGE URINARY TRACT (Patient urinated blood clot in urine) in a 64-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Lymphoma. Concomitant products included ACALABRUTINIB (CALQUENCE) for Lymphoma, CYANOCOBALAMIN (VITAMIN B-12), CALCIUM and FOLIC ACID for an unknown indication. On 01-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .5 ml. On 09-Apr-2021, the patient experienced HAEMORRHAGE URINARY TRACT (Patient urinated blood clot in urine) (seriousness criterion medically significant) and HAEMATURIA (Patient urinated blood in urine). On 10-Apr-2021, HAEMORRHAGE URINARY TRACT (Patient urinated blood clot in urine) and HAEMATURIA (Patient urinated blood in urine) had resolved. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient recovered (clarified as the patient's urine was clear and did not have blood clots) on 10 Apr 2021. Patient self treated by drinking lots and lots of fluids (not further clarified). Company comment: Based on the current available information and the temporal association between the product use and the start sate of the events a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and the temporal association between the product use and the start sate of the events a causal relationship cannot be excluded.</p>

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1245398	4/23/2021	CO	32	M	3/22/2021	3/28/2021	DVT; armpit turned purple with no sensation; armpit turned purple with no sensation; excruciating pain; axillary swelling in the right arm pit; body aches; headache; chills; brain fog; lightheadedness; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (DVT), SKIN DISCOLOURATION (armpit turned purple with no sensation) and SENSORY LOSS (armpit turned purple with no sensation) in a 32-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 003B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. Concomitant products included APIXABAN (ELIQUIS), OXYCODONE HYDROCHLORIDE, OXYCODONE TEREPHTHALATE, PARACETAMOL (PERCOCET [OXYCODONE HYDROCHLORIDE;OXYCODONE TEREPHTHALATE;PARACETAMOL]), PARACETAMOL (TYLENOL), OXYCODONE, DOCUSATE SODIUM (COLACE) and HYDROCODONE BITARTRATE, PARACETAMOL (NORCO) for an unknown indication. On 22-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 28-Mar-2021, the patient experienced FEELING ABNORMAL (brain fog), DIZZINESS (lightheadedness), MYALGIA (body aches), HEADACHE (headache) and CHILLS (chills). On 29-Mar-2021, the patient experienced SWELLING (axillary swelling in the right arm pit). On 31-Mar-2021, the patient experienced DEEP VEIN THROMBOSIS (DVT) (seriousness criteria hospitalization and medically significant), SKIN DISCOLOURATION (armpit turned purple with no sensation) (seriousness criterion hospitalization) and SENSORY LOSS (armpit turned purple with no sensation) (seriousness criterion hospitalization). On 02-Apr-2021, the patient experienced PAIN (excruciating pain). On 30-Mar-2021, SWELLING (axillary swelling in the right arm pit) had resolved. At the time of the report, DEEP VEIN THROMBOSIS (DVT), SKIN DISCOLOURATION (armpit turned purple with no sensation), SENSORY LOSS (armpit turned purple with no sensation), FEELING ABNORMAL (brain fog), DIZZINESS (lightheadedness), PAIN (excruciating pain),

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1245405	4/23/2021	NY		F		2/4/2021	<p>MYALGIA (body aches), HEADACHE (headache) and CHILLS (chills) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment medication - Eliquis</p> <p>blood clot on spleen; This spontaneous case was reported by a consumer and describes the occurrence of SPLENIC THROMBOSIS (blood clot on spleen) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event (No relevant medical history provided). On 04-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced SPLENIC THROMBOSIS (blood clot on spleen) (seriousness criterion medically significant). At the time of the report, SPLENIC THROMBOSIS (blood clot on spleen) outcome was unknown. Not Provided Treatment information was not provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. This case was linked to MOD21-076398, US-MODERNATX, INC.-MOD-2021-078083 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. MOD21-076398: US-MODERNATX, INC.-MOD-2021-078083:</p>

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1245407	4/23/2021	WA	32	M	2/1/2021		<p>a blood clot right below his lung on the left side; his chest was hurting; he couldn't breath; Second shot three weeks later; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (a blood clot right below his lung on the left side) in a 32-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history reported). In February 2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (a blood clot right below his lung on the left side) (seriousness criterion medically significant), CHEST PAIN (his chest was hurting), DYSPNOEA (he couldn't breath) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Second shot three weeks later). At the time of the report, THROMBOSIS (a blood clot right below his lung on the left side), CHEST PAIN (his chest was hurting) and DYSPNOEA (he couldn't breath) outcome was unknown and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Second shot three weeks later) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered THROMBOSIS (a blood clot right below his lung on the left side), CHEST PAIN (his chest was hurting) and DYSPNOEA (he couldn't breath) to be related. No further causality assessment was provided for INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Second shot three weeks later). Patient was taken to the ER (Emergency Room). Treatment Xarelto was started. Patient has Cardiologist appointment on 28-APR-2021. Company comment:Limited information regarding the blood clot, chest pain and difficulty breathing has been provided at this time and a causal relationship cannot be excluded. Inappropriate schedule of vaccine administered is unrelated to the vaccine and is not reported as specifically resulting in adverse events. This case was</p>



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linked to MOD21-076660 (E2B Linked Report).; Sender's Comments: Limited information regarding the blood clot, chest pain and difficulty breathing has been provided at this time and a causal relationship cannot be excluded. Inappropriate schedule of vaccine administered is unrelated to the vaccine and is not reported as specifically resulting in adverse events. MOD21-076660:

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1245419	4/23/2021	CA	62	F	4/2/2021	4/3/2021	found several blood clots in her lungs; it (difficulty breathing) became worse; difficulty breathing; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (found several blood clots in her lungs) in a 62-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 039AZ1A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history reported.). Concomitant products included APIXABAN (ELIQUIS) for an unknown indication. On 02-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Apr-2021, the patient experienced DYSPNOEA (difficulty breathing). On 05-Apr-2021, the patient experienced CONDITION AGGRAVATED (it (difficulty breathing) became worse). On 07-Apr-2021, the patient experienced PULMONARY EMBOLISM (found several blood clots in her lungs) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 07-Apr-2021 to 11-Apr-2021 due to PULMONARY EMBOLISM. On 15-Apr-2021, DYSPNOEA (difficulty breathing) and CONDITION AGGRAVATED (it (difficulty breathing) became worse) had resolved. At the time of the report, PULMONARY EMBOLISM (found several blood clots in her lungs) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Apr-2021, COVID-19: negative (Negative) Test results came back negative on 06Apr2021. On 07-Apr-2021, X-ray: abnormal (abnormal) Blood clots in lungs. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. After x-ray at urgent care on 07-Apr-2021 showed several blood clots in lungs, the patient was taken to the ER (emergency room) and was subsequently admitted to the hospital. Treatment information was not provided. On 12-Apr-2021 the patient went to their PCP (primary care physician) who stated that the clots most likely were not due to the vaccination and that the 2nd dose was safe for her to receive. At the time of this report on 15-Apr-2021, the patient reported feeling fine. Company Comment: Based on the current available information and temporal

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association between the use of the product and the start date of the events 1-3 days after the vaccination, a causal relationship cannot be excluded. Very limited information regarding these events has been provided at this time. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events 1-3 days after the vaccination, a causal relationship cannot be excluded. Very limited information regarding these events has been provided at this time. Further information has been requested.

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1245440	4/23/2021	FL		M	3/24/2021	4/8/2021	<p>blood clots; his arm felt sore, almost like he had just received the vaccine; doctor thinks it has something to do with the heart; low blood pressure; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (blood clots) in a 64-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 24-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Apr-2021, the patient experienced THROMBOSIS (blood clots) (seriousness criterion hospitalization), PAIN IN EXTREMITY (his arm felt sore, almost like he had just received the vaccine), CARDIAC DISORDER (doctor thinks it has something to do with the heart) and HYPOTENSION (low blood pressure). The patient was hospitalized on 08-Apr-2021 due to THROMBOSIS. At the time of the report, THROMBOSIS (blood clots), PAIN IN EXTREMITY (his arm felt sore, almost like he had just received the vaccine) and CARDIAC DISORDER (doctor thinks it has something to do with the heart) had not resolved and HYPOTENSION (low blood pressure) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not provided. On 08 Apr 2021, the patient's arm felt sore, "almost like he had just received the vaccine". He went to urgent care, and they sent him to the hospital and he was admitted. The patient said his doctor thinks the blood clots had something to do with the heart. The patient thought it had to do with the vaccine because he has "always been healthy" and never had any heart problems. The patient was still in the hospital at the time of this report. Treatment information was not provided. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Doctor thinks "thrombosis" has something to do with the heart</p>

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1245443	4/23/2021	FL	67	M	3/11/2021	4/14/2021	extremely high blood pressure; severe headache; DVT to right leg starting at the groin and going down to the foot; worsen edema with 4+and 5+ pitting edema in right leg; This spontaneous case was reported by a nurse (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (DVT to right leg starting at the groin and going down to the foot) in a 67-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 031B21A and 030A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was provided.). Concomitant products included DUPILUMAB (DUPIXENT) from 09-Mar-2021 to 06-Apr-2021 and DULOXETINE HYDROCHLORIDE (CYMBALTA) for an unknown indication. On 11-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 14-Apr-2021, the patient experienced DEEP VEIN THROMBOSIS (DVT to right leg starting at the groin and going down to the foot) (seriousness criterion medically significant) and OEDEMA PERIPHERAL (worsen edema with 4+and 5+ pitting edema in right leg). On an unknown date, the patient experienced HYPERTENSION (extremely high blood pressure) and HEADACHE (severe headache). At the time of the report, DEEP VEIN THROMBOSIS (DVT to right leg starting at the groin and going down to the foot), OEDEMA PERIPHERAL (worsen edema with 4+and 5+ pitting edema in right leg), HYPERTENSION (extremely high blood pressure) and HEADACHE (severe headache) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Apr-2021, Ultrasound Doppler abnormal: abnormal (abnormal) Causative extensive occlusive thrombus", DVT in the right leg starting from the groin going down to the foot. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient had an ultrasound of the leg performed. The diagnosis showed "causative extensive occlusive thrombus". Patient reported taking heparin and

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acetaminophen(Tylenol) ad treatment for the symptoms.  
This case was linked to (E2B Linked Report).; Sender's  
Comments: Based on the current available information  
and temporal association between the use of the product  
and the start date of the events, a causal relationship  
cannot be excluded. MOD-2021-079102:1st dose

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1245447	4/23/2021	OH	56	F	12/12/2020	2/21/2021	<p>had another stroke; blood clots in brain; Difficult to control right hand; difficult to speak; had a stroke and went to the hospital; This spontaneous case was reported by a nurse (subsequently medically confirmed) and describes the occurrence of CEREBROVASCULAR ACCIDENT (had another stroke), CEREBRAL THROMBOSIS (blood clots in brain), TRANSIENT ISCHAEMIC ATTACK (had a stroke and went to the hospital), DYSKINESIA (Difficult to control right hand) and DYSARTHRIA (difficult to speak) in a 56-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 012M20A and 039A20A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No reported medical history). On 12-Dec-2020, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Jan-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 21-Feb-2021, the patient experienced TRANSIENT ISCHAEMIC ATTACK (had a stroke and went to the hospital) (seriousness criterion medically significant). On 23-Feb-2021, the patient experienced CEREBROVASCULAR ACCIDENT (had another stroke) (seriousness criteria hospitalization and medically significant), CEREBRAL THROMBOSIS (blood clots in brain) (seriousness criterion hospitalization), DYSKINESIA (Difficult to control right hand) (seriousness criterion hospitalization) and DYSARTHRIA (difficult to speak) (seriousness criterion hospitalization). The patient was hospitalized from 23-Feb-2021 to 26-Feb-2021 due to CEREBRAL THROMBOSIS, CEREBROVASCULAR ACCIDENT, DYSARTHRIA and DYSKINESIA. At the time of the report, CEREBROVASCULAR ACCIDENT (had another stroke), CEREBRAL THROMBOSIS (blood clots in brain), TRANSIENT ISCHAEMIC ATTACK (had a stroke and went to the hospital), DYSKINESIA (Difficult to control right hand) and DYSARTHRIA (difficult to speak) outcome was unknown. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication use was not reported. Treatment for the events included Plavix.; Sender's Comments: Although a temporal association exist,</p>

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1246686	4/23/2021	IN	52	F	3/8/2021	3/17/2021	critical details such as the patient's medical history, list of concomitant medication are lacking . Pending additional information, causality with mRNA-1273 administration cannot be confirmed for all events.
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1245459	4/23/2021			M			Ischaemic stroke; This spontaneous case was reported by a consumer and describes the occurrence of ISCHAEMIC STROKE (Ischaemic stroke) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event (No medical history was provided.). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced ISCHAEMIC STROKE (Ischaemic stroke) (seriousness criterion medically significant). At the time of the report, ISCHAEMIC STROKE (Ischaemic stroke) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. Reporter mentioned that diagnosis from hospital which included magnetic resonance imaging (MRI), computed tomography (CT scans), and echocardiogram (EKG) did not reveal any signs from where the blood clots were originated. No treatment information was provided by the reporter. Very limited information regarding this event/s has been provided at this time. Further information has been requested
1246817	4/23/2021	IL	53	M	3/26/2021	4/16/2021	Blood clot in each lung. Started in legs, spread through heart and settled in lungs. This occurred about 3 weeks AFTER J&J/Jansen vaccine. Immediate symptoms were painful leg cramps on both sides back pain, fever sweating, nausea, clammy skin, headache, neck pain.

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1245476	4/23/2021	IL	82	M	2/3/2021	3/1/2021	Blood clots; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Blood clots) in an 82-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 013A21A and 031L209) for COVID-19 vaccination. Concurrent medical conditions included Cancer (The patient was in recovery from cancer). On 03-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. In March 2021, the patient experienced THROMBOSIS (Blood clots) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood clots) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In March 2021, Computerised tomogram: blood clots (abnormal) Blood clots. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not provided. Description: The patient developed blood clots (medically significant) two weeks after receiving his second dose of the vaccine . The patient was in recovery from cancer and was required to have computerized tomography (CT) scans. He had a computerized tomography (CT) scan within two weeks of taking his second dose and the blood clots were discovered. The patient had never had blood clots before. The patient had already been in contact with his oncologist and was prescribed apixaban. The patient received both scheduled doses of mRNA-1273 prior to the event, therefore action taken with the drug in response to the event is not applicable.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
1245770	4/23/2021	NH	45	F	4/18/2021	4/22/2021	Blood clot in right arm

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1245965	4/23/2021	MD	29	F	3/25/2021	4/21/2021	My menstrual cycle came a lot heavier than it has ever been, including large blood clots. Additionally, my premenstrual symptoms were much more painful and intense
1246172	4/23/2021	VA	78	M	3/8/2021	4/1/2021	PATIENT EXPERIENCE A BLOOD CLOT IN LEG AND HAD TO BE HOSPITALIZED
1246262	4/23/2021	MI	49	M	1/9/2021	1/26/2021	I had a massive stroke at work a few weeks after the 1st vaccine shot. Rushed to hospital for emergency surgery to remove blood clot in right side of brain. My paralysis was reversed after surgery but lingering headaches exist.
1246442	4/23/2021	NY	53	F	3/26/2021	4/14/2021	Muscle aches started about 12 hours after the injection. First my legs and back but after another 12 hours it was mostly my legs. Legs felt like the muscles were being pulled. (It felt like the beginnings of the extreme reaction I had to ampicillin 2 decades earlier, though not nearly as severe.) My arm swelled slightly, was warm at the injection site and ached about 12 hrs after the injection. The leg aches lasted about 2 days, the arm ache lasted about 1 day and the slight arm swelling lasted about 6 days... Reason for my reporting: I had an annual eye exam 4/14/21 where a retinal scan was done. The optometrist saw some blood spots in my left eye and referred me to an ophthalmologist. Ophthalmologist performed additional scans and tests including a Fluorescein angiography and determined I have BRVO (Branch Retinal Vein Occlusion) which is a series of blot clots in small vessels of the eye's main vein. He did not say it could be a result of the vaccine but I have no risk factors associated with getting BRVO. Since it is not affecting my vision yet, the doctor wants to monitor it in 3 months to make sure it has not worsened. Since the Janssen vaccine was put on hold for causing other types of blot clots in women in my age group, I am wondering if the vaccine caused the blood clots in my eye.
1246568	4/23/2021	UT	51	M	2/1/2021	3/16/2021	I had a pulmonary embolism on 3/17/2021. Prior to that a blood clot in my left calf.

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1245430	4/23/2021	CT	77	M	2/11/2021	3/12/2021	<p>Veins was outside and sore; really big and sore red area; really big and sore red area; all the veins in his R leg was protuberate; two blood clot; DGThrombosis; Felt terrible; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (two blood clot) and THROMBOSIS (DGThrombosis) in a 77-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 016M20A and Unknown) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Leg injury (severe damage to right leg, hit by "protellier" small airplane.) in 1977, Surgery ("many surgeries") and Clot blood. On 11-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 12-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 12-Mar-2021, the patient experienced MALAISE (Felt terrible). On 13-Mar-2021, the patient experienced THROMBOSIS (two blood clot) (seriousness criterion medically significant), THROMBOSIS (DGThrombosis) (seriousness criterion medically significant), VASCULAR PAIN (Veins was outside and sore), ERYTHEMA (really big and sore red area), PAIN IN EXTREMITY (really big and sore red area) and VEIN DISORDER (all the veins in his R leg was protuberate). At the time of the report, THROMBOSIS (two blood clot), THROMBOSIS (DGThrombosis), MALAISE (Felt terrible), VASCULAR PAIN (Veins was outside and sore), ERYTHEMA (really big and sore red area), PAIN IN EXTREMITY (really big and sore red area) and VEIN DISORDER (all the veins in his R leg was protuberate) outcome was unknown. Not Provided Concomitant medication included unspecified statin for high cholesterol. The patient reported that he is retired. He reported that his leg is functioning well, he has only one of the three arteries in the legs and many damaged veins. Treatment medication included Seroto to treat the blood clots. Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. This case was linked to MODERNATX, INC.-MOD-2021-077978 (E2B Linked Report).; Sender's Comments: Based on the information</p>

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provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. MODERNATX, INC.-MOD-2021-077978:

1246591	4/23/2021	IL	32	F	4/20/2021	4/22/2021	Heavy, clotty period
1248235	4/23/2021	CA	51	M	4/9/2021	4/21/2021	Pain and swelling in Left Calf muscle. Treating the blood clot with Xeralto
1246721	4/23/2021	FL	73	F	1/31/2021	2/16/2021	Fever over 100, 3 blood clots discovered in hospital where I was sent by the Hematologist after fever started.
1246807	4/23/2021	TX	55	F	3/21/2011	4/3/2021	Blood clot in left leg and phnomia

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1245454	4/23/2021	AR	44	F	3/15/2021	3/23/2021	Small amount of blood clots; Potassium levels dropped; Increased hypertension; dizziness; Arm pain from her elbow to shoulder; Shortness of breath; Blood pressure increased; fatigue; chills; Hear arm was hot to touch; Itchiness; Red circle near injection site the size of a quarter; not to take the second dose; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Small amount of blood clots) and HYPOKALAEMIA (Potassium levels dropped) in a 44-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 026A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse reaction. On 15-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, the patient experienced VACCINATION SITE ERYTHEMA (Red circle near injection site the size of a quarter). On 24-Mar-2021, the patient experienced VACCINATION SITE WARMTH (Hear arm was hot to touch) and VACCINATION SITE PRURITUS (Itchiness). On 25-Mar-2021, the patient experienced PAIN IN EXTREMITY (Arm pain from her elbow to shoulder), DYSPNOEA (Shortness of breath), BLOOD PRESSURE INCREASED (Blood pressure increased), DIZZINESS (dizziness), FATIGUE (fatigue) and CHILLS (chills). On 01-Apr-2021, the patient experienced THROMBOSIS (Small amount of blood clots) (seriousness criterion medically significant), HYPOKALAEMIA (Potassium levels dropped) (seriousness criterion medically significant) and HYPERTENSION (Increased hypertension). On an unknown date, the patient experienced PRODUCT DOSE OMISSION ISSUE (not to take the second dose). At the time of the report, THROMBOSIS (Small amount of blood clots), HYPOKALAEMIA (Potassium levels dropped), PAIN IN EXTREMITY (Arm pain from her elbow to shoulder), DYSPNOEA (Shortness of breath), BLOOD PRESSURE INCREASED (Blood pressure increased), HYPERTENSION (Increased hypertension), VACCINATION SITE WARMTH (Hear arm was hot to touch), DIZZINESS (dizziness), VACCINATION SITE PRURITUS (Itchiness), FATIGUE (fatigue), VACCINATION SITE ERYTHEMA (Red circle near injection site the size of a quarter) and CHILLS (chills)

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outcome was unknown and PRODUCT DOSE OMISSION ISSUE (not to take the second dose) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. On 01-Apr-2021 patient went to the ER for 2 hours. The HCP at the ER stated she had increased hypertension, potassium levels dropped and there was a small amount of blood clots. Her primary care physician said not to take the second dose. Patient inquired about what she can do to manage her symptoms. Concomitant drugs were not reported. Treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Further information is requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Further information is requested.

1249567 4/23/2021 FL

40 F

3/29/2021

4/12/2021 My first period after the vaccine arrived 6 days early, which is quite abnormal for me. The day before I couldn't work at my desk due to pain in my low back and hip flexors, which is also abnormal. Then the period was heavier than normal lasted 3 days longer than normal. It looked like there were clots in the blood. I mentioned this experience to a friend, who said several of his female friends also experienced bizarre periods after receiving the JJ vaccine. Was this drug tested on women of reproductive age before being released?

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1249277	4/23/2021	OH	53	F	4/7/2021		NOSE BLEED WITH BIG CLOT WHEN BLOWING NOSE; SINUS TYPE HEADACHE; TIREDNESS; STOMACH CRAMPS; This spontaneous report received from a patient concerned a 53 year old female. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included patient had no history of headaches. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 201921A, expiry: UNKNOWN) dose was not reported, administered on 07-APR-2021 for prevention of covid-19. No concomitant medications were reported. On 07-APR-2021, the subject experienced stomach cramps. On 07-APR-2021, the subject experienced tiredness. On 09-APR-2021, the subject experienced sinus type headache. On 10-APR-2021, the subject experienced nose bleed with big clot when blowing nose. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from nose bleed with big clot when blowing nose on 10-APR-2021, stomach cramps, and tiredness on 08-APR-2021, and sinus type headache on 11-APR-2021. This report was non-serious.; Sender's Comments: V0: This 53-year-old male patient sho reported nose bleeding with big clot of blood when eh blew his nose 3 days after receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. The patient also reported stomach cramps and tiredness on the day of vaccination and sinus type of headache 2 days after vaccination. The patient denies any history of headache. The patient recovered from the events. No other details reported. Based on the information that is available, the event is assessed as plausible with the causal association to immunization, per WHO causality classification of adverse events following immunization based on a lack of a definitive plausible biological mechanism. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information is requested



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1249278	4/23/2021	MO		F			<p>BLOOD CLOT IN LEFT LUNG; This spontaneous report received from a consumer concerned a female of unspecified age (in late 40's or early 50's) and ethnicity unspecified. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, Expiry: UNKNOWN) dose, 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient was diagnosed with blood clot in her left lung after receiving the vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This female patient of unspecified ethnicity, in her late 40's or early 50's, was reported to have blood clot in her lungs after an unspecified duration from receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. No other details was reported. Based on the information that is available, the event is assessed as indeterminate with the causal association to immunization, per WHO causality classification of adverse events following immunization based on a lack of a definitive plausible biological mechanism. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information will be requested once contact information is obtained</p>

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1249280	4/23/2021	FL		M			HEART ATTACK FROM BLOOD CLOT; This spontaneous report received from a patient via a company representative concerned a Not Hispanic or Latino and Asian male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient experienced heart attack from blood clot and the patient died. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0: This is an Asian male, unspecified age, who experienced a heart attack from a blood clot on an unspecified date after receiving the covid-19 vaccine ad26.cov2.s also on an unspecified date. No other details given. The information provided precludes a meaningful medical assessment. Additional information will be requested.; Reported Cause(s) of Death: DEATH

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1249321	4/23/2021	NY		F			<p>SUPERFICIAL LEG THROMBOSIS; CHEST CONGESTION; TERRIBLE HEADACHE; LEGS WERE FROZEN; BRUISES ON HER LEGS; This spontaneous self-report was received from a patient and concerns a 68 year old female of unspecified race and ethnicity. Initial information received from the patient on 13-APR-2021 was processed with additional information received from the patient on 14-APR-2021 and telephone follow up with the patient on 20-APR-2021. The patient's weight and height were not reported. The patient had tuberculosis and had completed TB medication course. The patient does not have hypertension or diabetes. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration, date, vaccination site, and batch number were not reported) for prophylactic vaccination. The batch number will be requested in follow up. The patient was not taking any concomitant medications. On the third day after vaccination, the patient experienced terrible headache. Two days later, both her legs were frozen, and she had bruises on her legs. She went to a physician who advised her to go to the Emergency Room (ER), where they did an ultrasound on her legs. The physician told her that she had superficial leg thrombosis and asked her to take aspirin. No labs or any other diagnostic tests were performed. On the fifth day post-vaccination, the patient had chest congestion for 1 day. At the time of report, the patient was feeling better, and her bruises were disappearing. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from chest congestion and terrible headache, and was recovering from superficial leg thrombosis, legs were frozen, and bruises on her legs. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This 68-year-old female patient of unspecified ethnicity was found to have superficial blood clots in both legs 5 days after receiving COVID-19 VACCINE AD26.COV2.S intramuscularly for the prevention of symptomatic SARS-CoV-2 virus infection. The patient reported "terrible" headache 3 days after vaccination, "chest congestion" and that both her legs were "frozen" and with bruises 5 days after vaccination. Ultrasound on both legs showed superficial leg thrombosis during emergency room consultation and was advised to take aspirin as treatment. The event is</p>

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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1249328	4/23/2021	MI					
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recovering. Based on the information that is available, the event is assessed as plausible per the causality classification for adverse events. Considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information has been requested for further assessment.

BLOOD CLOT; This spontaneous report was received from a female patient of an unspecified age. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine Ad26.COV2.S (suspension for injection, route of administration, and batch number were not reported) dose, vaccination site, and start therapy date were not provided, for prophylactic vaccination; and was treated with XARELTO (rivaroxaban; film-coated tablet, oral, batch number was not reported) dose, frequency, and therapy dates were not provided, for an unknown indication. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient experienced a blood clot. The patient reported she got a blood clot after receiving her vaccine, and that she had just started taking rivaroxaban. Action taken with Covid-19 vaccine Ad26.COV2.S was not applicable, and action taken with rivaroxaban was not reported. The patient outcome for the event of blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: v0 This report involves a female patient of unspecified age who experienced a blood clot on an unspecified date after receiving the Janssen COVID-19 Vaccine Ad26.COV2. Concomitant medications included rivaroxaban (recently started). The patient's past medical history and details of the event were not reported. The recent starting of rivaroxaban infers a recent clot or a condition that would predispose the patient to develop a clot, however this case has insufficient information to make a meaningful medical assessment.

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
1249336	4/23/2021			U	3/16/2021		<p>THROMBOSIS IN MY RECTAL AREA; ARM VERY SENSITIVE TO THE TOUCH; SEVERE HEADACHE; CHILLS; SORE ARM; This spontaneous self-report was received from a patient of unspecified sex, age, race and ethnicity. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration, dose, vaccination site, and batch number were not reported, ) administered on 16-MAR-2021 at 13:00 for prophylactic vaccination. The batch number will be requested in follow up. No concomitant medications were reported. On 16-Apr-2021 in the evening post vaccination, the patient had severe headache and chills. The headache continued the whole next day, but was not as bad as the first evening. Her arm was very sore, and it hurt to move it the first day, and then very sensitive to the touch the next day, and continued for a whole week. On 29-Apr-2021 (13 days post vaccination), " thrombosis (according to my doctor) appeared in my rectal area that still hasn't gone away". The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from arm very sensitive to the touch, severe headache, and sore arm, had not recovered from thrombosis in my rectal area, and the outcome of chills was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This patient of unspecified age, gender, and ethnicity reported to have "thrombosis (according to my doctor) appeared in my rectal area that still hasn't gone away" 13 days after receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. The patient also reported severe headache and chills on the day of vaccination that persisted until the following day, as well as arm soreness that persisted for a whole week. No other details was reported. Based on the information that is available, the event is assessed as indeterminate with the causal association to immunization, per WHO causality classification of adverse events following immunization based on a lack of a definitive plausible biological mechanism. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information is requested</p>

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1249343	4/23/2021			M			<p>CLOT OF ABOUT 3-4 INCHES; LOWER LEG PAIN; This spontaneous report received from a patient via a company representative concerned a 35 year old male. The patient's weight, height, and medical history were not reported. The patient had no history of blood clots and is active. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: unknown) dose was not reported, 1 total administered on 23-MAR-2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date in 2021, the patient experienced lower leg pain. About a week after that, on an unspecified date in 2021, the patient experienced clot of about 3-4 inches confirmed by ultrasound. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the lower leg pain and clot of about 3-4 inches was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This 35-year-old male patient of unknown ethnicity was reported in social media to have "clot of about 3-4 inches confirmed by ultrasound" after an unspecified duration from receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. This was preceded by symptom of lower leg pain 1 week prior. No other details was reported. The information available precludes a complete and meaningful assessment. The case will be re-assessed once additional information is received.</p>

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
1249274	4/23/2021	TX		F	4/8/2021		<p>BLOOD CLOT IN LEFT LUNG; SHORTNESS OF BREATH; DIARRHEA; LEG PAIN; INJECTION SITE PAIN; HEADACHE; SWEATING; DIZZINESS/FEELING FAINT; This spontaneous self-report was received from a patient and concerned a 29 year Black Mexican, White (Hispanic or Latino) old female. The patient's height and weight were not reported. The patient's concurrent conditions included hypertension, latex allergy, allergic to banana, and non smoker. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: 205A21A expiry: UNKNOWN) dose was not reported, 1 total dose on left arm administered on 08-APR-2021 (Thursday) for prophylactic vaccination. Concomitant medications included labetalol and nifedipine for hypertension. On 08-APR-2021, when patient received a vaccination it hurt at the time of injection. Later, she developed a headache. At night, she woke up with sweating. She went down to the kitchen and felt shortness of breath and felt faint. On 09-Apr-2021 (Friday), after she woke up, she developed diarrhea all day. On 10-APR-2021 (Saturday), her symptoms were continuing included diarrhea, sweating, dizziness, legs hurting, headache, and feeling shortness of breath. On 11-APR-2021 (Sunday), she felt better, however headache was ongoing. At night, she started feeling bad again. On 12-APR-2021, she woke up with diarrhea and sweating, no symptoms have resolved. On 13-APR-2021, her legs continued to be in pain. At night, she went to emergency room (ER) and have blood work done, showing it was positive for a blood clot. Her computerized axial tomography (CAT) was performed and blood clot in left lung was found. Her doctor said that all other blood work came back normal, and he did not see anything else wrong with her, and that the blood clot was related to the vaccine. He wanted to put her on a blood thinner and prescribed Eliquis (apixaban). Doctor mentioned that if she felt shortness of breath or started feeling dizzy, she must go to the hospital. It was reported that she was hospitalized for 1 day, and both admission and discharge dates were reported 13-APR-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from blood clot in left lung, injection site pain, headache, sweating, shortness of breath, dizziness/feeling faint, leg pain, and diarrhea. This report was serious (Hospitalization Caused</p>

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1249409	4/23/2021	TN		F			<p>/ Prolonged, and Other Medically Important Condition).; Sender's Comments: This is a 29 year old male patient, who experienced leg pain and noted to have blood clot in the left lung 1 day and 5 days, respectively, after receiving the COVID-19 vaccine ad26.cov2.s on the left arm. Height and weight not reported. Patient has hypertension and is taking Labetalol and Nifedipine. Patient has history of allergy to latex and banana. Patient is not a smoker. Few hours after receiving the vaccine, patient developed headache, sweating, dizziness and shortness of breath. The following day, patient had diarrhea and experienced leg pain, laterality not reported. The symptoms were persistent and, 5 days after the vaccine, patient sought consult at the Emergency Room (ER) where the CAT scan showed blood clot in left lung. Patient was prescribed with Apaxiban. The information provided precludes a meaningful medical assessment. Additional information requested.</p> <p>SPONTANEOUS HEADACHE; This spontaneous report received from a health care professional concerned a 63 year old female. The patient's height, and weight were not reported. The patient's past medical history included abdominal aortic aneurysm, ascending aortic aneurysm, atrial fibrillation, degenerative disc, heart issue, stroke, drug allergy, blood clot behind eye, smoker, and overweight, and other pre-existing medical conditions included patient had medical history of naturally throwing clots and short term memory. The patient was previously treated with promethazine. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1802029, and batch expiry: UNKNOWN) dose was not reported, administered on 18-MAR-2021 for prophylactic vaccination. Concomitant medications included apixaban for atrial fibrillation, hydrocodone, levothyroxine, and lisinopril. On an unspecified date, the subject experienced spontaneous headache. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of spontaneous headache was not reported. This report was non-serious.</p>



<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1249401	4/23/2021	TX		M		4/8/2021	<p>BLOOD IN URINE WITH CLOTS; BODY ACHES/WHOLE BODY HURT; MUSCLE ACHES; This spontaneous report received from a patient concerned a 73 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included high blood pressure. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808980, expiry: UNKNOWN) dose was not reported, frequency 1 total, administered on 07-APR-2021 to left arm for prophylactic vaccination. Concomitant medications included medication for high blood pressure. On 08-APR-2021, the patient's "whole body hurt" with muscle aches and body aches. On 16-APR-2021, the patient experienced "blood in urine with clots", sometimes the clots were dry and other times they were wet. Patient experienced blood in urine each time he urinated having started on 16-APR-2021 and he had never experienced this prior to receiving the vaccine. Patient stated that he did not experience any other side effects such as fever, abdominal pain or leg pain. Patient had not yet sought medical attention and had not taken any medications to treat his adverse effects. Patient stated that he had planned to reach out to a healthcare professional on 19-APR-2021 (tomorrow). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the muscle aches, body aches/whole body hurt and blood in urine with clots was not reported. This report was serious (other medically important condition).; Sender's Comments: V0:20210436909-Covid-19 vaccine .Ad26.Cov2.S-Blood in urine with clots. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1249568	4/23/2021		30	F	3/11/2021	4/5/2021	blood clot on the left leg; blood clot on the right leg; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (blood clot on the right leg) and THROMBOSIS (blood clot on the left leg) in a 30-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 038321A) for COVID-19 vaccination. The patient's past medical history included No adverse event (no medical history reported). On 11-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 05-Apr-2021, the patient experienced THROMBOSIS (blood clot on the right leg) (seriousness criterion medically significant). On 12-Apr-2021, the patient experienced THROMBOSIS (blood clot on the left leg) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (blood clot on the right leg) and THROMBOSIS (blood clot on the left leg) outcome was unknown. Not Provided The patient has not provided with any concomitant medication. No treatment medications are listed. Company Comment Based on the current available information which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-043122 (E2B Linked Report). Reporter did not allow further contact; Sender's Comments: US-MODERNATX, INC.-MOD-2021-043122:1st dose

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1249614	4/23/2021	LA	59	F	12/22/2020	1/19/2021	Thrombosis of inferior mesenteric and splenic vein/Severe Abdominal pain; Thrombosis of inferior mesenteric and splenic vein/ severe abdominal pain; Headache; Nausea; This spontaneous case was reported by a nurse (subsequently medically confirmed) and describes the occurrence of SPLENIC VEIN THROMBOSIS (Thrombosis of inferior mesenteric and splenic vein/ severe abdominal pain) and MESENTERIC VEIN THROMBOSIS (Thrombosis of inferior mesenteric and splenic vein/Severe Abdominal pain) in a 59-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 025L20A and 011B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No recorded medical history). On 22-Dec-2020, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Jan-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 19-Jan-2021, the patient experienced HEADACHE (Headache) and NAUSEA (Nausea). On 27-Jan-2021, the patient experienced SPLENIC VEIN THROMBOSIS (Thrombosis of inferior mesenteric and splenic vein/ severe abdominal pain) (seriousness criteria hospitalization prolonged and medically significant) and MESENTERIC VEIN THROMBOSIS (Thrombosis of inferior mesenteric and splenic vein/Severe Abdominal pain) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 1 day due to SPLENIC VEIN THROMBOSIS. At the time of the report, SPLENIC VEIN THROMBOSIS (Thrombosis of inferior mesenteric and splenic vein/ severe abdominal pain), MESENTERIC VEIN THROMBOSIS (Thrombosis of inferior mesenteric and splenic vein/Severe Abdominal pain), HEADACHE (Headache) and NAUSEA (Nausea) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Jan-2021, Computerised tomogram: thrombosis of inferior mesenteric and splenic vein (abnormal) Thrombosis of inferior mesenteric and Splenic vein. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. The

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patient experienced severe abdominal pain and went to Emergency room and CT Scan and lab investigations were done. She was given. The patient stayed for 24 hours in Emergency room. The patient received 1st dose of Moderna vaccine on 22 Dec2021 and no symptom after vaccine administration. Treatment for the event included prescribed apixaban for 6 months and heparin. The patient received both scheduled doses of mRNA-1273 prior to the event; therefore, action taken with the drug in response to the event is not applicable.  
Company Comment: Based on the current available information and temporal association between the use of the product and the start dates of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start dates of the events, a causal relationship cannot be excluded.

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1249630	4/23/2021	KS	63	F	4/19/2021		<p>Hemorrhoid; Minor bleeding issues/ hemorrhoid; Clot of blood in stool; This spontaneous case was reported by a consumer and describes the occurrence of RECTAL HAEMORRHAGE (Minor bleeding issues/ hemorrhoid) and HAEMATOCHYZIA (Clot of blood in stool) in a 63-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Rectal bleeding (10 years ago). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Apr-2021, the patient experienced RECTAL HAEMORRHAGE (Minor bleeding issues/ hemorrhoid) (seriousness criterion medically significant) and HAEMATOCHYZIA (Clot of blood in stool) (seriousness criterion medically significant). On an unknown date, the patient experienced HAEMORRHOIDS (Hemorrhoid). At the time of the report, RECTAL HAEMORRHAGE (Minor bleeding issues/ hemorrhoid), HAEMATOCHYZIA (Clot of blood in stool) and HAEMORRHOIDS (Hemorrhoid) had not resolved. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment information was not provided. On unknown date, the evening after receiving the Moderna COVID-19 vaccine, the patient reported seeing a blood clot in the toilet. The patient stated it looked like hemorrhoids. The patient denied seeking medical care. The patient stated the bleeding is minor but at the time of this report, ongoing. The patient stated having similar minor bleeding approximately 10 years ago. This case concerns a 63-year-old female with PMH of rectal bleeding had serious unexpected events of Rectal hemorrhage, hematochezia and non serious unexpected hemorrhoids. Event onset with unknown latency. after first dose mRNA-1273. Events ongoing. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: This case concerns a 63-year-old female with PMH of rectal bleeding had serious unexpected events of Rectal hemorrhage, hematochezia and nonserious unexpected hemorrhoids. Event onset with unknown latency. after first dose mRNA-1273.</p>

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Events ongoing. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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1249644	4/23/2021	NV	69	M	3/23/2021	3/26/2021	leg hurting; Leg was completely clotted; 10 days was blowing blood clots out of his nose; blowing blood clots out of his nose; This spontaneous case was reported by a consumer and describes the occurrence of PAIN IN EXTREMITY (leg hurting), DEVICE OCCLUSION (Leg was completely clotted) and DEVICE OCCLUSION (10 days was blowing blood clots out of his nose) in a 69-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 003B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Coronary artery disease since an unknown date, Blood pressure (controlled blood pressure) since an unknown date, Diabetes (controlled diabetes) since an unknown date, Cholesterol (controlled cholesterol) since an unknown date and Stent placement (history of 7 stents in heart) since an unknown date. Concomitant products included CLOPIDOGREL BISULFATE (PLAVIX), METOPROLOL, LOSARTAN, ATORVASTATIN and EMPAGLIFLOZIN, LINAGLIPTIN (GLYXAMBI) for an unknown indication. On 23-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Mar-2021, the patient experienced PAIN IN EXTREMITY (leg hurting) (seriousness criterion hospitalization), DEVICE OCCLUSION (Leg was completely clotted) (seriousness criteria hospitalization and disability), DEVICE OCCLUSION (10 days was blowing blood clots out of his nose) (seriousness criterion hospitalization) and EPISTAXIS (blowing blood clots out of his nose). At the time of the report, PAIN IN EXTREMITY (leg hurting), DEVICE OCCLUSION (Leg was completely clotted), DEVICE OCCLUSION (10 days was blowing blood clots out of his nose) and EPISTAXIS (blowing blood clots out of his nose) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In February 2021, Ultrasound scan: (abnormal) 85% plaque Plaque build up in main artery of leg. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient have allergy to denies and had a history of PAD Patient given Xarelto as treatment. Please update the narrative by replacing

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Thrombus with Device Occlusion. Please delete the wording Occult Blood and add Epistaxis. Company comment: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.



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1249658	4/23/2021	IL	36	F	1/26/2021	2/26/2021	<p>blood clot in left leg; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of VENOUS THROMBOSIS LIMB (blood clot in left leg) in a 36-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 013L20A and 013L20A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No medical history reported.). Concomitant products included ASPIRIN [ACETYLSALICYLIC ACID] for an unknown indication. On 26-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 26-Feb-2021, the patient experienced VENOUS THROMBOSIS LIMB (blood clot in left leg) (seriousness criterion medically significant). At the time of the report, VENOUS THROMBOSIS LIMB (blood clot in left leg) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Feb-2021, Fibrin D dimer: positive (Positive) positive. On 26-Feb-2021, Ultrasound Doppler: abnormal (abnormal) showed a clot in left leg.. Treatment was with Eliquis prescribed by her doctor. However the patient only took an aspirin daily. The blood clot resolved. The patient reported she was very healthy, runs daily, does not smoke, is not pregnant and is not on birth control pill (all of which are risk factors for DVT/blood clots). Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-081281 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-081281:1st dose event</p>

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1249741	4/23/2021	GA	55	M	4/10/2021	4/10/2021	04/12 - Palpitations early morning and couple of times during day 04/13 - Palpitations early morning and bed time 04/14 - Palpitations on and off - severe early morning and bed time 04/15 - Mild to moderate headache (mostly left side) throughout the day, palpitations early morning and few long lasting during the day and bed time 04/16 - Continued mild headache, early morning and night time palpitations. Went to see Dr. Did bloodiest and EKG (normal) 04/17 - Continued mild headache. Dr. called with abnormal D-dimer (875). Prescribed Eliquis 2.5mg and ordered Ultrasound and CT scans of head and chest 04/19 - Continued mild headache. Did Ultrasound (lower extremities), CT scans of head and chest 04/21 - Mild headache most of the day. Received rest of blood tests - (normal Plates, PT, INR, Fibrinogen). CT scans of head and chest results show no signs PE or thrombosis 04/22 - Very light head during day. Mild headache evening. 04/23 - Mild headache (Tylenol provided temp relief but not completely) - Ultrasound is clear - no DVT
1248311	4/23/2021	TX	43	F	4/10/2021	4/11/2021	constant back pain that started on April 11 presented to ER on April 19 for back pain and abdominal pain, afraid that she has a clot a few days ago, started having shortness of breath and left leg pain that radiates to the left groin

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1245413	4/23/2021	IN		F	2/26/2021	4/2/2021	<p>Blood clot in left leg and moved down to bottom of her heel; Hard Time Walking due to blood clot; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Blood clot in left leg and moved down to bottom of her heel) in a 59-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was provided.). Concomitant products included ACETYLSALICYLIC ACID (ASPIRIN 81) for an unknown indication. On 26-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 02-Apr-2021, the patient experienced THROMBOSIS (Blood clot in left leg and moved down to bottom of her heel) (seriousness criterion medically significant) and GAIT DISTURBANCE (Hard Time Walking due to blood clot). At the time of the report, THROMBOSIS (Blood clot in left leg and moved down to bottom of her heel) and GAIT DISTURBANCE (Hard Time Walking due to blood clot) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Patient reported that doctor prescribed prednisone to treat the symptoms. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1249385	4/23/2021	TX	49	F		3/21/2021	<p>HAD BODY ACHE; HAD HEADACHE; PULMONARY EMBOLISM IN BOTH LUNGS; SHORTNESS OF BREATH; CHARLIE HORSE IN LEGS IN MIDDLE OF NIGHT; LOWER EXTREMITIES HURTING AND SWELLING; HAD FLU-LIKE SYMPTOMS; TIRED/LETHARGIC; This spontaneous report received from a patient concerned a 49 year old female. The patient's height, and weight were not reported. The patient was a non alcohol user and non smoker, and he took vitamins. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029, expiry: unknown) dose was not reported, administered on 19-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On an unspecified date progressively 4 days after receiving vaccine the patient had headache and had body ache. On 21-MAR-2021, the patient had flu-like symptoms and felt tired/lethargic. On 24-MAR-2021, the patient had lower extremities hurting and swelling. On 26-MAR-2021, the patient felt charlie horse in legs in middle of night. On 01-APR-2021, the patient had shortness of breath and he could not catch her breath. At that point patient went to emergency room. In emergency room the patient underwent CT scan and revealed with small clots in lower lobe of both lungs. The patient was treated with 40 mg Eliquis for treatment. The emergency room doctor advised consumer to saw pulmonary specialist and follow up with him primarily. On 15-APR-2021, the patient had pulmonary embolism in both lungs. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from had flu-like symptoms, and had not recovered from pulmonary embolism in both lungs, lower extremities hurting and swelling, shortness of breath, tired/lethargic, charlie horse in legs in middle of night, headache, and body ache. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This is a 49 year old female patient, African American, who experienced pain on lower extremities and was noted to have small clots in the lower lobes 5 days and 13 days, respectively, after receiving the the COVID-19 vaccine ad26.cov2.s. Patient's height and weight were not reported. Patient is a non smoker and non alcoholic beverage drinker. Past medical history not reported and patient denied taking medications, except vitamins. Four (4) days after</p>

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receiving the vaccine, patient experienced flu like symptoms. lethargy, headache and body ache which were noted to resolve. Five (5) days after receiving the vaccine, patient developed pain on the lower extremities and patient noted to fell charley horse (muscle spasm and pain). Thirteen (13) days after receiving the vaccine, patient experienced shortness of breath, which prompted consult at the emergency room. CT Scan done revealed small clots in the lower lobe of both lungs. Patient was noted to have pulmonary embolism. The temporal relationship may be consistent but there is insufficient evidence for the vaccine to cause the events; hence this is assessed as indeterminate per causality classification of adverse events following immunization. Additional information requested.

VENOUS CLOT AND THROMBOSIS; This spontaneous report received from a physician via a company representative concerned a patient of unspecified age, ethnicity, and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced venous clot and thrombosis, and was hospitalized (date unspecified). It was reported that the patient was currently hospitalized and the physician was asking for information in regards to anticoagulation therapy. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of venous clot and thrombosis was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: A patient of unspecified age, ethnicity, and sex experienced venous clot and thrombosis an unknown time after vaccine. This was reported by a physician to a company representative. No laboratory values are reported. No clinical history, medical history, medications, or details are reported. There is insufficient information to make a meaningful medical assessment. Additional information has been requested including attempted contact with the treating physician.

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1248317	4/23/2021	TX	44	F	3/13/2021	3/14/2021	The day after her first Moderna COVID-19 shot (3/14/2021) she developed groin pain that lasted for about 2 days before going away, but then on 3/16/2021 she developed Chest Pain in her mid-chest and associated shortness of breath which did not go away, so she went to the emergency room on 3/17/2021 and was diagnosed with a Pulmonary Embolism. (I assume the groin pain was caused by a blood clot in her upper leg that moved up into her lungs.)

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1249414	4/23/2021	FL	64	F	3/17/2021		<p>CLOTS ON RIGHT LEG; HEADACHE; PRESSURE ON BOTH LEGS; PRESSURE ON HANDS; This spontaneous report received from a patient via a company representative concerned a 64 year old Hispanic or Latino female. The patient's height, and weight were not reported. The patient's concurrent conditions included high blood pressure and diabetes. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029 expiry: UNKNOWN) dose was not reported, 1 total administered on 17-MAR-2021 at left arm for prophylactic vaccination. No concomitant medications were reported. On 17-MAR-2021, the patient had experienced headache after vaccination. On 27-MAR-2021, the patient began to experience intermittent pain on right leg. On 30-MAR-2021, she experienced headache again and was still having leg pain; she visited the Emergency Room (ER) and was admitted on 30-MAR-2021. On 02-APR-2021, the patient experienced clots on right leg. On APR-2021, a catheter was placed in catheterization procedure and her right leg vein was unclogged of a clot. A second clot did not require removal because the vein had already unclogged itself after medication. The patient was administered unspecified anticoagulants. She was discharged on 5-APR-2021 and was prescribed ticagrelor which was then changed to clopidogrel. On 18-APR-2021, the patient experienced a headache again and feeling of pressure on legs and hands. Patient was advised to visit ER. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from clots on right leg and intermittent pain on right leg on 02-APR-2021, recovered with sequelae from headache on 19-MAR-2021, and had not recovered from pressure on both legs and pressure on hands. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: This 64 year-old Hispanic or Latino female with history of high blood pressure and diabetes was hospitalized for clots in her right leg 13 days after receiving the Janssen Covid-19 vaccine. Concomitant medications were not reported. On the day of her vaccination, she experienced a headache. Ten days later, she began to experience intermittent leg pain. Three days later (ie, 13 days post vaccination), she went to the emergency room (ER) and</p>

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was admitted to the hospital. During the hospitalization, a clot was removed via catheterization and she was administered unspecified anticoagulants. A second clot resolved on its own without surgical intervention. After 6 days in the hospital, she was discharged with ticagrelor which was later changed to clopidogrel. She recovered from the clots. Thirteen days after discharge, she began to experience headache and "pressure" in both legs and hands. She was advised to go to the ER; no further information was provided. Based on the limited information, the relationship of the serious events with Janssen Covid-19 vaccine is considered indeterminant. Additional information is being sought.



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1249273	4/23/2021			M		4/8/2021	<p>BILATERAL BLOOD CLOTS IN LEFT AND RIGHT LOWER LUNGS; This spontaneous report received from a patient via a company representative concerned a 46 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: unknown) dose was not reported, 1 total administered on 05-APR-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 08-APR-2021, the patient experienced mild chest pain and dyspnea. On 14-APR-2021, the patient visited to emergency room and diagnosed with bilateral blood clots in left and right lower lungs. The patient had no prior medical history of blood clot and pulmonary issues. On 14-MAR-2021, treatment medications included: rivaroxaban. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of bilateral blood clots in left and right lower lungs was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This is a 46 male patient, unspecified ethnicity who was noted, at the emergency room (ER), to have bilateral blood clots in left and right lower lungs 9 days after receiving the covid-19 vaccine ad26.cov2.s. Weight and height were not reported. Medical history, smoking history and concomitant medications were not reported. Six (6) days prior to the visit to the emergency room, the patient experienced mild chest pains and dyspnea. Patient was sent home from the ER with Rivaroxaban. Based on the available information and considering the temporal causality, this is assessed as indeterminate per WHO causality classification of adverse reaction following immunization.</p>

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1248394	4/23/2021	WA	61	F	4/6/2021	4/9/2021	received the vac on 4/6, starting aprox 8th -9th I start to not feel good... just thought is was a mild reaction to the shot... by the 12th I felt terrible, very short of breath and unable to walk with out thinking I was going to die..... waiting as long as I could then I went to urgent care on the 14th and was told I probably have asthma and was given a few medications... on the 18th things were not any better and I no longer could take the pain and not being able to breathe... so I went to the hospital and was admitted to the PPC floor of the hospital after being in the ER. the next morning I had to have a procedure to break up BLOOD CLOTS in my lungs... I spent 4 days in the PPC ward and now home trying to recover from this... I was told my condition was very serious and was lucky I came in... Of course the doctors will not say this was a direct link to the shot ... i never had any problems before and never any blood clots. The doctor who did the procedure told me to make sure I REPORTED IT.... I was released from the hospital on the afternoon of the 21st.. 4 days!
1248534	4/23/2021	PA	64	F	4/5/2021	4/8/2021	I became confused and unsteady. I then fell. My husband helped me up but he knew something was wrong. He called 911 an ambulance took me to the hospital but I was transferred to another hospital. In case I needed surgery. It was touch and go. I was suffering a stroke. A blood clot was also found. I was in the hospital ICU for 3 days then transferred to another room. For another day.
1248592	4/23/2021	WA	70	M	3/13/2021	4/7/2021	I experienced a mini-stroke (TIA) in which my speech was affected and which resulted in me being hospitalized. For about 5 minutes, I was unable to find words and properly communicate. I went to the ER and was admitted and had a battery of tests, kept overnight, and discharged the following day. My statin dose was increased, and I was put on a baby aspirin, in addition to Pradaxa blood thinner. i believe that I may have had a vascular thrombi related to the effect of the medicine/spike protein.
1248330	4/23/2021	LA	65	F	3/9/2021	4/19/2021	Patient has leg cramps starting on Monday, April 19th. She went to the hospital at later date. Doctor diagnosed her with leg clot.

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1248713	4/23/2021	NY	47	M	4/6/2021	4/12/2021	patient presented to emergency room with severe headache and blurry vision. diagnosed with cavernous sinus thrombosis
1248862	4/23/2021	NC	58	M	3/15/2021	3/16/2021	Patient flew from city to city through another city on Tuesday 3/16/21. He had a reaction on the flight where he coughed for 1.5 hrs and was hot in the airplane. He could not go to work and was required to get Covid tested on 3/18. Still coughing and having trouble sleeping (laying down). Rapid Covid test negative on 3/18. PCR test results negative on 3/21 from hospital. He continued to grow weak and cough from 3/16-3/21. At 3am on 3/22 he called and said that his feet were 2X their size and having difficulty breathing. Taken to hospital via ambulance. When transferred to ER bed, Dr said that he lost pulse. They intubated and got his pulse back. Died at 5:15am. Autopsy said cardiac arrest. Dr said that they could not maintain a heart beat. He asked me if the patient had a history of blood clots? No he did not ever have a blood clot that I know of. He had a chest xray post mortem showing fluid in his lungs from low circulation of blood.

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1249245	4/23/2021			M	3/26/2021		<p>PASSED OUT; COULD HARDLY GET UP; TROUBLE WITH LEFT HIP OR KNEE; LIGHT HEADED; NOT FEELING UP TO PAR; This spontaneous report received from a patient concerned an 85 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: unknown) dose was not reported, 1 total administered on 26-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 26-MAR-2021,(on the night of vaccination) patient could hardly get up while he was putting some beer in refrigerator. Since then patient had trouble with his left hip or knee. Few days before 10-APR-2021, patient was light headed and not felt up to par. On 10-APR-2021, the patient was passed out which he never experienced before. On the same day, the patient was hospitalized and checked everything including blood clots in his leg. They did not found anything that could be causing problem. The patient was admitted to the hospital for 3 days. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the could hardly get up, trouble with left hip or knee, not feeling up to par, light headed, passed out was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: This 85-year-old male patient of unknown ethnicity was admitted in a hospital after "passing out" 15 days after receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. The patient noted difficulty standing up on h the day of vaccination but attributed it to his hip or knee "trouble". On the day of hospitalization, the patient complained of light headedness and was rushed to the hospital when he was found passed out. The patient reported that the hospital checked everything including clots in his leg but did not found anything that could cause the problem. No laboratory/diagnostic test results were reported; the treatment and outcome was not reported. Based on the information that is available, the event is assessed as indeterminate with the causal association to immunization, per WHO causality classification of adverse events following immunization based on a lack of a definitive plausible biological mechanism. However,</p>

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considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information will be requested for further assessment once contact information is available.

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1249271	4/23/2021	VA	72	F	3/14/2021		FAST HEART RATE; BLOOD CLOT IN BOTH LUNGS; ACHY; LOW ENERGY; VERY WEAK; HEADACHE; FEVER; This spontaneous report received from a patient concerned a 72 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included fibromyalgia. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805022, and expiry: UNKNOWN) dose was not reported, administered on left arm on 13-MAR-2021 for prophylactic vaccination. Concomitant medications included pregabalin(Lyrica) for fibromyalgia and bad back. The patient reported pregabalin makes her gait off. On 13-MAR-2021, the patient felt okay. On 14-MAR-2021, the patient experienced achy, low energy, very weak, headache, fever of 100 degrees fahrenheit. Laboratory data included: Body temperature (NR: not provided) 100 F. On 13-APR-2021, she had wellness visit. The patient had a fast heart rate. Laboratory data included: Heart rate (NR: not provided) 144 (units unspecified). So immediately her electrocardiogram was taken and she was hospitalized for 2 days in emergency room by ambulance and started running tests. The patient had a computer tomography with dye contrast and it showed blood clots in both lungs. She had many tests, echocardiogram and X-rays. Treatment medications (dates unspecified) included: continuous oxygen via nasal prong (3.2 litre down to 2 litre), warfarin sodium(Coumadin), blood, whole, and rivaroxaban(Xarelto). The patient stated once she had rivaroxaban she felt "free". Currently also had 2 intravenous and taking blood regular. She was also on physical therapy. The therapist came in and made her walk across her room twice according to therapist she did not need oxygen. The patient currently had 2 IV's and taking blood regular. The patient will be discharged with or without the oxygen. The patient has machine on her chest with all kinds of wires. She don't know about her oxygen saturation. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from achy, low energy, very weak, headache, and fever on 15-MAR-2021, had not recovered from fast heart rate, and the outcome of blood clot in both lungs was not reported. This report was serious (Hospitalization Caused / Prolonged and Life Threatening).; Sender's Comments: V0: This is a 72 year old female, unspecified

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							ethnicity, who experienced tachycardia and was noted to have blood clots in both lungs 32 days (around 1 month) after receiving the COVID-19 vaccine ad26.cov2.s on the left arm. Patient had Fibromyalgia and is maintained on Pregabalin (Lyrica). Patient's height and weight were not reported as well as history of smoking, allergies or drug abuse. One day after receiving the vaccine, the patient experienced fever, headache, weakness and pain, which resolved. During a wellness visit after a month from the vaccine, tachycardia was noted and an EKG was done. Patient was immediately brought to the ER, where the CT Scan (with contrast) showed blood clots in both lungs (detailed result not reported). Other tests done were also not reported. Patient was subsequently admitted in the hospital and was discharged after 2 days. The information provided is insufficient to show that the vaccine is causing the event; hence, this is assessed as indeterminate per WHO causality classification of adverse event following immunization. Additional information requested.
1248552	4/23/2021	MA	95	F	4/12/2021	4/23/2021	Developed severe right leg pain within two days after the vaccine. She had confirmed deep venous thrombosis on ultrasound confirmed on 4/23/21 without other known provocation.

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1249270	4/23/2021			F		4/1/2021	D DIMER POSITIVE; DIZZY; FEELS TERRIBLE; This spontaneous report received from a company representative via media post and concerned an adult female (age approximately 30). The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose was not reported, administered on APR-2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date in APR-2021, the patient reported dizzy and felt terrible. On an unspecified date, the patient went to urgent care and tested positive for D-Dimer (PT of Fibrin D dimer increased). The patient went to emergency room for full body ultrasound to look for clots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the dizzy, feels terrible and d dimer positive was not reported. This report was non-serious.
1248863	4/23/2021	FL	53	F	4/1/2021	4/8/2021	PATIENT STATED SHE FELT BACK PAIN, LEG PAIN, AND CHEST PAIN IMMEDIATELY AFTER GETTING THE VACCINE, PATIENT WAS OBSERVED FOR 15 MINUTES AND FELT WELL ENOUGH TO GO HOME; HOWEVER, PATIENT CALLED PHARMACY TODAY 4/23/21 FOR THE FIRST TIME SINCE 4/8/21 STATING HER CHEST PAIN AND LEG PAIN HAVE INCREASED SINCE GETTING THE VACCINE. PATIENT WAS COUGHING ALOT WHILE TALKING ON THE PHONE AND CRYING DUE TO THE CONCERN OF JENSSSEN VACCINES IN THE NEWS. I ADVISED THE PATIENT THAT SHE SHOULD GO TO THE EMERGENCY ROOM FOR FOLLOW UP DUE TO CONCERNS OF HER EXPERIENCING CHEST PAIN AND LEG PAIN IN ORDER TO ELIMATE THE POSSIBILITY OF ANY CLOTS.



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1249240	4/23/2021	NC	40	F	4/12/2021		CHEST TIGHTNESS; INTERMITTENT HEADACHES; This spontaneous report received from a patient concerned a 40 year old female. The patient's height, and weight were not reported. The patient's past medical history included basilar artery thrombosis, and vertebral artery thrombosis, and concurrent conditions included non-smoker, and other pre-existing medical conditions included no illicit use of drugs. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose was not reported, administered on 10-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. Concomitant medications included . On 12-APR-2021, the subject experienced chest tightness. On 12-APR-2021, the subject experienced intermittent headaches. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from intermittent headaches, and chest tightness. This report was non-serious.; Sender's Comments: V0; MAC Comment is not required for non serious case as per standard protocol.
1249239	4/23/2021			U			BLOOD CLOTS; This spontaneous report received from a company representative via social media post and concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported, one total dose is administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow up will be requested. No concomitant medications were reported. On an unspecified date, the subject experienced blood clots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clots was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This patient reported via social media to have blood clots and to have received the COVID-19 vaccine ad26.cov2.s. No other information provided. There is insufficient information to make a meaningful assessment. Additional information will be requested.

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1249227	4/23/2021	WV		M		4/7/2021	LEG PAIN; This spontaneous report received from a patient concerned a male of unspecified age. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included does not take blood thinner. patient's father lost legs to blood clot. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose was not reported, administered on 07-APR-2021 for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch number. No concomitant medications were reported. On 07-APR-2021, the subject experienced leg pain. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from leg pain on APR-2021. This report was non-serious.; Sender's Comments: V0: Medical Assessment comment was not required as per standard procedure as the case assessed as non-serious
1249224	4/23/2021	LA		M		4/1/2021	BLOOD CLOT IN CORONARY REGION; This spontaneous report received from a patient via a company representative concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose was not reported, administered on 10-APR-2021 for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On APR-2021, the patient experienced blood clot in coronary region. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot in coronary region was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This is a male, unspecified age, unspecified ethnicity, who experienced blood clot in coronary region after he received the COVID-19 vaccine ad26.cov2.s on an unspecified date. No other details given. The information provided precludes a meaningful medical assessment. Additional information requested.

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1249220	4/23/2021	NC		F	4/6/2021		<p>ELEVATED CLOT LEVELS; DIZINESS/LIGHTHEADED; NAUSEA; BRUISE ON LEG; SWELLING; WISDOM TOOTH PULLED; This spontaneous report was received from a consumer and concerned a female of unspecified age and sex, White, Hispanic or Latino. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number and expiration date: Unknown) dose was not reported, 1 total administered on 11-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. The patient's father reported that on 06-Apr-2021, in urgent care patient's wisdom tooth was pulled. On 08-APR-2021, the subject experienced dizziness/lightheaded, nausea, bruise on leg, swelling 4x4 inches on lower right calf. The next day, the patient's bruise/swelling move to inside of right knee, she had new bruise on leg and went to urgent care; the doctor told her she hit it. On 09-APR-2021, the bruise moved to inside of knee, and the patient was taken to emergency room (ER) where "clot test" showed elevated clot levels and rivaroxaban (Xarelto) was prescribed for treatment. On 10-APR-2021 (Saturday morning), ultrasound was done; result not reported. At the time of report there was decreased in swelling. The patient's father stated that, the event's might be related to wisdom tooth pulled. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from elevated clot levels, dizziness/lightheaded, nausea, bruise on leg, and swelling. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This is a female patient, unspecified age, unspecified ethnicity, who experienced elevated clot levels 29 days after receiving the Janssen COVID-19 vaccine and 3 days after the patient's wisdom tooth was pulled out. The patient had her wisdom tooth pulled out 26th day post vaccination. 2 days later (28 days after the vaccination), the patient experienced dizziness and nausea and was noted to have bruise and swelling (around 4x4 inches) on the right lower leg. The next day, bruise/swelling was noted to reach the area of the right knee, probably the medial side, which prompted consult at the ER. The "clot test" done as was noted to be elevated (no actual results</p>

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							provided). An ultrasound was also done but the result was not reported. Long periods of immobility (sitting in the dental chair) and the temporal plausibility from the dental procedure to the event of elevated clot levels confounds the temporal plausibility of the elevation of clot level and the vaccine; hence this is assessed as indeterminate per WHO classification of adverse event following immunization. Additional information requested.
1242233	4/22/2021	CA	37	M	3/11/2021	3/26/2021	Blood clots in the Liver and Kidney also Pulmonary Embolism. went to ER was admitted and spent 6 days there. was put on Heparin as well as antibiotics. currently on Warfarin to maintain proper blood INR numbers.
1241679	4/22/2021	NJ	24	F	2/25/2021	4/19/2021	Acute cerebral venous sinus thrombosis
1241867	4/22/2021	NC	62	M	4/10/2021	4/10/2021	Received the vaccine approximately 12:22 PM on Saturday, April 10, 2021. At approximately 6:55 pm that same day (Saturday, April 10, 2021) my husband collapsed in our living room. I called 911 and the operator talked me through how to do chest compression CPR on my husband until the paramedics arrived. My husband was then taken by ambulance to hospital where doctor performed an emergency procedure wherein he removed the blood clot in one of my husband's stints (he has three) that he had put in in 2017. Doctor was able to eventually stabilize my husband's heart. My husband spent 5 days in the hospital as a result of this.
1241684	4/22/2021	CA	25	F	4/8/2021	4/9/2021	admitted to hospital that evening with acute intracerebral hemorrhage felt to be from a cerebral venous thrombosis with dense left hemiplegia. one week later, developed bilateral upper extremity cephalic vein thrombosis that the following week, 4/21/21, continued to propagate
1241940	4/22/2021	TX	65	F	4/8/2021	4/18/2021	I currently have swelling in my hands, pain in my vaccinated arm, bone pain, a bump in my hand like thrombi, burning sensation in my stomach, taste of blood in my throat, leg and joint pain. After I was vaccinated.
1241957	4/22/2021	FL	59	M	4/10/2021	4/18/2021	Thrombosed Hemorrhoid (blood clot). Rapid onset of initial pain. Still experiencing pain.

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1241986	4/22/2021	CA	50	F	3/15/2021	3/15/2021	I had 2 adverse reactions to the Janssen Covid-19 Vaccine EUA: AE #1) Roughly 15 minutes after receiving the vaccination, the lower half of my face went numb for approximately 3 hours. The people who administered the vaccine made me stay at the site for about an hour and a half to make sure that the reaction did not get worse. AE #2) 10 days after receiving the vaccination, the lower part of my left leg began to swell significantly. I went to the emergency room on 4/13/2021. When I was there, they did tests and confirmed that I have a blood clot behind my knee. To treat the blood clot, the emergency room doctor gave me lovenox 110mg and warfarin 5mg. Since then, I have followed up with my primary doctor who has me taking warfarin 10mg ( 1x daily) and lovenox (as needed).
1242013	4/22/2021	NY	73	M	2/20/2021	3/7/2021	8 Days after my 2nd Moderna Shot, Fatty Blood Clots started pouring out of my mouth(about 50 over a 24 hour period) . There was No cause or affect to it- meaning No cough or Nose Bleeding,etc. I went to emerency room on 03/09/2021 and was admitted for testing. While there they ALSO noticed my heart was Pausing. A 3 day ZIO Test was done. It came back extreme with 39 Pauses and a pulse as low as 35 BPM. A Heart Pace Maker had to be placed in me at Medical CTR on 04/20/2021.
1242195	4/22/2021	SC	63	M	4/10/2021	4/12/2021	Took my last shot of Pfizer on 4/10/2021 at 10:00 AM and on4/12/2021 started having shortness of breath,tiredness, and chest pains this continue on until 4/15/2021 while I was at work at 6:15 PM my wife had to be called to come pick me and take me to the hospital where they did a Cat scan and discovered that I had Blood Clots In both Lungs and had to remove them at that time in order to save my life
1241772	4/22/2021	NC	60	M	3/26/2021	3/31/2021	I have severe swelling in both legs from knee to my feet, severe itching and hives, legs have blistered and burst open. I also have a Blood clot in my lower left leg. Have tried 2 kinds of antibiotics, I am on Xarelto 10 mg tab for the blood clot
1242237	4/22/2021	OK	59	M	2/4/2021	4/11/2021	DVT BLOOD CLOT

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1242314	4/22/2021	TN	52	F	3/28/2021	4/5/2021	Started to have body aches and return of arm soreness on 4/5 (eight days after the vaccine) Left flank intermittent pain, eventually traveling to the left back on 4/9 (interrupted sleep) 4/10 Continued pain, intensifying but manageable with Naproxen (assumed it was a kidney stone) Pain moved to right back and flank on 4/11, supplement NSAID with Tylenol to control the pain but pain grows severe (message PCP) 4/12 See PCP in afternoon, elevated heart rate + pain, suspects kidney stone, suggests ER for quicker CT scan, but ER is a 5+ hour wait, so I scheduled appt. with urologist for 4/13. Get CT scan for stone, lungs present with ground glass opacities like Covid. 4/14 Covid test (plus my partner is Partner is also tested. Isolate at home awaiting results. Pain is now only on the right side, experiencing shortness of breath, assume it's related to the pain. 4/15 get negative Covid results around midnight, message PCP. 4/16 PCP insists on ER, CT scan with contrast reveals pulmonary embolism, clots in both lungs, admitted to hospital for observation, ultrasound of legs reveals no problems with the veins, etc. Start Lovenox 4/17 released that evening with Xarelto, follow up with doctor 4/22
1242429	4/22/2021	FL	64	M	3/27/2021	4/3/2021	developed swelling and pain left arm within 1 week of administration Janssen Covid -19 vaccine IM left arm on 3/27/2021, on 4/16/21 left upper extremity venous sonogram demonstrated left axillary vein thrombosis
1242450	4/22/2021	IL	67	F	3/15/2021	4/20/2021	4/20/21 ER HPI: 67 y.o. female who presents with complaint of shortness of breath since yesterday night when she went to bed and describes it as heaviness associated with lower chest pain both back and front. Patient says shortness of breath is worse with lying down and with activity. Patient also complained of cough that is nonproductive. No fever or chills, no nausea vomiting and no abdominal pain. Patient has been off her Coumadin is since for 04/09/2021 for back injection for back pain. Patient said the the shortness of breath is similar to the last time she had blood clot.

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1242493	4/22/2021	IA	45	M	3/13/2021	3/16/2021	On March 13, I received the Johnson & Johnson vaccine at the clinic. The pharmacist monitored me for symptoms but there were none right away. I did have a fever and some body aches in the two or three days that followed but those were short-lived. While driving on March 16, I started experiencing some irregular breathing and periods of shortness of breath about three hours after leaving home. I stopped at the emergency room at the Health Center where Dr diagnosed me with an acute pulmonary embolism after discovering a small blood clot in one of my lungs. He prescribed me with Eliquis, which I am still taking today. Their phone number is provided if you have questions. I haven't had too many shortness of breath episodes lately but do not know if the blood clot is still there. I am scheduled to see my hematologist on April 27 to get further updates on this. My hematologist Dr is located in clinic number provided While it has not yet been proven that the vaccine caused the blood clot in my lung, I feel the need to report this in the wake of recent news about the Johnson & Johnson vaccine. My hematologist and primary care physician are both aware that I have received the vaccine but I have not received any further communication from them.
1242553	4/22/2021	OH	71	F	3/9/2021	3/30/2021	~~I received the Johnson and Johnson Covid vaccine on March 9th. On March 30 I was admitted to the hospital with excessive blood clots in my right leg and right lung. My Pulmonary Dr felt I should report this to you. I did have blood clots last year and recently ( February 8th) had back surgery both circumstances could of contributed to the issue. If you need any further information or have questions please do not hesitate to contact me.
1242561	4/22/2021	OH	69	F	3/30/2021	4/19/2021	Patient presented for the outpatient procedure of a cataract extraction. Found to be hypertensive and very short of breath. Sent to primary care physicians office who in turn ordered a CT scan. Found to have Pulmonary Embolism and Deep Vein Thrombosis

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1242683	4/22/2021		53	M	4/9/2021	4/21/2021	Deep Vein Thrombosis- occlusive and non-occlusive in R axial and R brachial veins at level of PICC line. Pt admitted to hospital on 4/18/21 with acute basal ganglia hemorrhagic CVA, with PICC line placement on admission. DVTs identified on 4/21 via ultrasound. Pt currently admitted to Hospital
1241646	4/22/2021	IL	50	F	3/31/2021	3/31/2021	High fever (102/103), chills, severe muscle aches, splitting migraine headache. A week later I had my period and experienced heavy bleeding and passing large blood clots not normal to my usual period. Still having headaches and its been 3 weeks.



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1240530	4/22/2021	CA	53	F	4/9/2021		<p>SHORTNESS OF BREATH; OUT OF BODY FEELING; EPIGASTRIC PAIN; POSSIBLE RHEUMATOID ARTHRITIS FLARE; STINGING IN THE RIGHT ARM; This spontaneous report received from a patient concerned a 53-year-old not Hispanic or Latino white female. The patient's height, and weight were not reported. The patient's concurrent conditions included rheumatoid arthritis, gastroesophageal reflux disease (GERD), hashimoto's thyroiditis, possible sjogren's, penicillin allergy and sulfa drugs (sulfonamide) allergy, and other pre-existing medical conditions included opiates allergy causing rash. The patient experienced drug allergy when treated with Azithromycin, Ciprofloxacin and Levofloxacin for an unknown indication. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 043A21A, expiry: UNKNOWN) dose was not reported, administered on 09-APR-2021 in right deltoid for prophylactic vaccination. Concomitant medications included Acetylsalicylic acid (Aspirin) to prevent blood clot, and Prednisone for an unknown indication. On 09-APR-2021, the patient experienced stinging in the right arm for a few seconds while getting the vaccine shot, then pain in left arm, stomachache in the night, profound weakness in the legs, heaviness in both legs and both arms, shortness of breath, out of body feeling, severe pain in the epigastric area. It was reported that vaccine could have triggered a rheumatoid arthritis reaction in legs hands, feet and arms. The feeling of weakness and heaviness in the arms and legs were still on going, and the reaction with Aspirin occurred about 30 minutes ago but became better once she took a liquid antacid. The patient took the Aspirin to prevent clots because she was on prednisone, which was read on the news that blood clots may form after getting the vaccine. She attributed the heaviness of the arms and legs as a possible rheumatoid arthritis flare. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from stinging in the right arm, and epigastric pain on an unspecified date in APR-2021, was recovering from out of body feeling, and had not recovered from shortness of breath, and possible rheumatoid arthritis flare. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210421350-covid-19 vaccine ad26.cov2.s-possible</p>

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1242594	4/22/2021	MN	21	F	3/22/2021	4/14/2021	Left Transverse and sigmoid Cerebral Venous Sinus Thrombosis in a patient with Chronic left Mastoiditis and previous Hx of VTE. I do not believe this was likely an AE from vaccine

rheumatoid arthritis flare. This event is considered not related. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event than the drug. Specifically: MEDICAL HISTORY, UNDERLYING DISEASE.

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1241021	4/22/2021	FL	63	F	4/1/2021		HEADACHES/PAIN AT THE BACK OF THE HEAD AND BASE OF THE SKULL 3 EPISODES; MILD NAUSEA EXPERIENCED IT 4 TIMES LAST WEEK AND LAST NIGHT; INCREASED SALIVA/MEDIUM AMOUNT OCCURS DURING NAUSEA EPISODE ONLY; SWEATINESS OCCURRED ONLY AT NIGHT, STATED THAT SHE WOKE UP WITH A WET T-SHIRT IN A COLD SWEAT; CHILLS OCCURRED ONLY AT NIGHT AT THE SAME TIME AS THE FEVER; RIGHT ARM SORENESS; FEVER/FELT HOT; This spontaneous report received from a patient concerned a 63 year old female. The patient's height, and weight were not reported. The patient's past medical history included blood clot in leg, and concurrent conditions included hypertension, and other pre-existing medical conditions included the patient was not pregnant at the time of reporting. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029, and batch number: 1805029 expiry: UNKNOWN) dose was not reported, administered on 31-MAR-2021 for prophylactic vaccination. Concomitant medications included diazepam, and fluoxetine hydrochloride. On APR-2021, Laboratory data included: Pain scale (NR: not provided) 5-6/10. On 01-APR-2021, the subject experienced increased saliva/medium amount occurs during nausea episode only. On 01-APR-2021, the subject experienced sweatiness occurred only at night, stated that she woke up with a wet t-shirt in a cold sweat. On 01-APR-2021, the subject experienced chills occurred only at night at the same time as the fever. On 01-APR-2021, the subject experienced right arm soreness. On 01-APR-2021, the subject experienced fever/felt hot. On 01-APR-2021, the subject experienced mild nausea experienced it 4 times last week and last night. On 03-APR-2021, the subject experienced headaches/pain at the back of the head and base of the skull 3 episodes. Laboratory data included: Pain scale (NR: not provided) 8/10. Treatment medications (dates unspecified) included: acetylsalicylic acid. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from sweatiness occurred only at night, stated that she woke up with a wet t-shirt in a cold sweat, chills occurred only at night at the same time as the fever, right arm soreness, and fever/felt hot on 03-APR-2021, had not

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							recovered from mild nausea experienced it 4 times last week and last night, and increased saliva/medium amount occurs during nausea episode only, and the outcome of headaches/pain at the back of the head and base of the skull 3 episodes was not reported. This report was non-serious.
1240236	4/22/2021	NY	52	M	3/25/2021	3/27/2021	Blood clot in mouth on day 2, 9, and 16 from first injection

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1240479	4/22/2021	FL	63	F	3/19/2021		FATIGUE; FELT HORRIBLE; SKIN BURNING AND HURTS TO TOUCH/SKIN ON FIRE/PAINFUL SKIN; NAUSEA; CHILLS; DIARRHEA; VOMITTING; LEG HEAVINESS; LEG PAIN/INTERMITTENT PAIN IN HIPS, BACK, DOWN TO MY KNEES; WEAKNESS; This spontaneous report received from a patient concerned a 63 year old female. The patient's height, and weight were not reported. The patient's past medical history included covid infection, double lung pneumonia, leg pain, and leg heaviness, and concurrent conditions included arthritis, and fatigue, and other pre-existing medical conditions included patient second shingles shot begins in february. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1802070 expiry: UNKNOWN) dose was not reported, administered on 19-MAR-2021 13:30 for prophylactic vaccination. No concomitant medications were reported. On 2021, the subject experienced leg heaviness. On 2021, the subject experienced leg pain/intermittent pain in hips, back, down to my knees. On 2021, the subject experienced weakness. On 19-MAR-2021, the subject experienced diarrhea. On 19-MAR-2021, the subject experienced vomiting. On 19-MAR-2021, the subject experienced chills. On 19-MAR-2021 16:00, the subject experienced nausea. On 19-MAR-2021 23:00, the subject experienced skin burning and hurts to touch/skin on fire/painful skin. On 20-MAR-2021, the subject experienced felt horrible. On 25-MAR-2021, Laboratory data included: Diagnostic ultrasound (NR: not provided) No clots found. On an unspecified date, the subject experienced fatigue. Treatment medications (dates unspecified) included: calcium chloride dihydrate/fructooligosaccharides/glucose/magnesium chloride hexahydrate/potassium chloride/sodium chloride/sodium lactate. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from vomiting, and nausea on 20-MAR-2021, was recovering from diarrhea, had not recovered from chills, skin burning and hurts to touch/skin on fire/painful skin, leg pain/intermittent pain in hips, back, down to my knees, weakness, fatigue, and leg heaviness, and the outcome of felt horrible was not reported. This report was non-serious.; Sender's Comments: V1:Medical assessment comment not required as per standard

*VAERS\_ID RECVDATE STATE AGE\_YRS SEX VAX\_DATE ONSET\_DATE SYMPTOM\_TEXT*

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procedure as case assessed as non-serious.

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1242735	4/22/2021	NE	28	M	4/10/2021	4/20/2021	ED NOTE is as follows...from 4/21/21 @ 21:47 a 28 y.o. male who to the emergency room with reports of a headache for the last 48 hours. He reports this as being one of the worst headaches he has ever had. He was seen at urgent care and given Toradol, Zofran and Benadryl and still rates his pain an 8 out of 10. He does feel pressure behind his eyes. And reports vomiting in the parking lot at urgent care. He denies abdominal pain back pain, neck pain, shortness of breath, chest pain, numbness or tingling or any other worsening concerns. Reports that he did receive a recent Johnson & Johnson vaccination. Patient states he does vape. He occasionally drinks alcohol he denies any illicit drugs. Patient denies any head trauma. Diagnosis management comments: This is a 28-year-old male arrives to the emergency room with reported migraine headache for the last 48 hours. He did report that he was go to urgent care in which he received a migraine cocktail of Zofran, Benadryl and Toradol. Patient reported that his headache was not resolved so urgent care sent him on for further evaluation. Patient upon arrival had a negative neurological exam however he did report that he had pressure behind his eyes. Was unable to see any papilledema on fundoscopic exam. Check patient's pressures bilaterally and they were 21 and 18. Patient did report to me that this was the worst headache of his life. I did administer IV fluids here as well as Tylenol and morphine. Patient did report some improvement. Patient did report in his past medical history had a recent Johnson & Johnson vaccination. A CBC and CMP was obtained. Did have thrombocytopenia with a count of 66. Since my exam was PERRL with normal extraocular movements. He had no eye redness or eye pain. Of low concerns for any iritis or uveitis. Patient's patient CT of his head did show a abnormal CT that had a dense appearing superior sagittal sinus that was representing a venous thrombosis. Radiologist did recommend a MRI MRV. An MRI and MRV was ordered. Patient MRI MRv did show findings are consistent with a venous thrombosis involving the right jugular right transverse sinus and superior sagittal sinus there is also a patchy edematous change within the subcortical white matter areas bilaterally and symmetrically. There was no CVA. With patient's reported migraine headache. Reported blurred

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1240565	4/22/2021	MI		M	4/13/2021		<p>vision, low platelets, recent vaccination I do believe patient has vaccine induced thrombotic thrombocytopenia. With this finding I did converse with my overseeing physician Calls were made out to neurology and then a call out did prefer to have patient started on IVIG at 1 g/kg daily for 2 days and blood thinner Xarelto 15 mg p.o. twice daily. These orders were initiated. Internal med services was consulted and with conversations of family, internal med services out possible transfer that an interventionalists could be available if patient needed it. Report was given at 2100 upon my end of shift.</p> <p>BLOOD CLOT; This spontaneous report received from a male patient of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, frequency 1 total administered on MAR-2021(2weeks ago from date of reporting) for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. The patient wanted to know about the blood clots with the JNJ shot and was thinking that he had a blood clot on 13-APR-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: A consumer of unknown age or gender called company to inquire what is going on with blood clots after vaccine. The subject stated that he thinks he has a blood clot 2 weeks after vaccine, but did not provide details, did not see a doctor or have an any diagnosis, and refused to see a doctor despite encouragement. He did not share any contact information or other information stating he would "wait for our lies to come out about clots." This case is confounded by a lack of meaningful history, a lack of diagnosis, a lack of workup, and a lack of contact information for any follow up. A meaningful medical assessment can not be made.</p>



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1240708	4/22/2021	CA	41	F	4/8/2021	4/19/2021	Delayed menstrual cycle by 4 days, when started very painful and heavy. Much more clots than usual and lasting longer than usual. Uncomfortable enough to require rest. Still going heavy when it should be tapering off.?
1240746	4/22/2021	SC		F		3/1/2021	BLOOD CLOTS; BACKACHE/BACK PAIN; This spontaneous report received from a patient concerned a 72 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included backache. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. Concomitant medications included oxycodone for backache/back pain. On MAR-2021, the subject experienced blood clots. On MAR-2021, the subject experienced backache/back pain. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clots, and the outcome of backache/back pain was not reported. This report was non-serious.

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1240868	4/22/2021	NC		M		4/1/2021	ANKLE SWELLING; BRUISING TO THE RIGHT LOWER LEG; This spontaneous report received from a patient concerned a male of unspecified age. The patient's height, and weight were not reported. The patient's concurrent conditions included deep vein thrombosis in lower extremity, animal allergy, seasonal allergy/tree allergy, no alcohol use, and non smoker, and other pre-existing medical conditions included the patient had no history of drug abuse or illicit drug use. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1802070, expiry: UNKNOWN) dose was not reported, administered on 14-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 01-APR-2021, the subject experienced bruising to the right lower leg. On 06-APR-2021, the subject experienced ankle swelling. On 12-APR-2021, Laboratory data included: Diagnostic ultrasound (NR: not provided) Negative. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from bruising to the right lower leg, and ankle swelling. This report was non-serious.; Sender's Comments: V0 Medical assessment comment not required as per standard procedure as the case was assessed as non-serious.

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1240887	4/22/2021	CA	21	F	3/18/2021		PAIN IN BOTH ARMS; HEADACHE; CHILLS; PAIN IN INJECTION ARM; FEVER; PAIN IN VEINS; This spontaneous report received from a patient concerned a 21 year old female. The patient's height, and weight were not reported. The patient's past medical history included thrombosis, and concurrent conditions included penicillin allergy, and other pre-existing medical conditions included the patient was not pregnant at the time of report. The patient was previously treated with rivaroxaban for thrombosis. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805031 and expiry: UNKNOWN) dose was not reported, administered on 18-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 2021, the subject experienced pain in veins. On 18-MAR-2021, the subject experienced chills. On 18-MAR-2021, the subject experienced pain in injection arm. On 18-MAR-2021, the subject experienced fever. On 19-MAR-2021, the subject experienced headache. On 25-MAR-2021, the subject experienced pain in both arms. Treatment medications (dates unspecified) included: paracetamol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from chills, pain in injection arm, fever, and headache on 19-MAR-2021, had not recovered from pain in both arms, and the outcome of pain in veins was not reported. This report was non-serious.; Sender's Comments: V0: Medical assessment comments not required as per standard procedure as the case is considered non serious.

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1240954	4/22/2021	TX		F		4/8/2021	<p>PAIN IN WHOLE RIGHT ARM AND BOTH LEGS; PAIN AT INJECTION SITE; FATIGUE; PAIN IN LEFT HIP; SHOOTING PAIN IN HEAD; SWELLING OF BOTH LEGS; PAIN OVER EYES; PAIN IN BRIDGE AND SIDE OF NOSE; STOMACH ACHE; NAUSEA; SEVERE HEADACHE; INSOMNIA; BLEEDING AT INJECTION SITE; This spontaneous report received from a patient concerned a 74 year old female. The patient's height, and weight were not reported. The patient's past medical history included superficial blood clot, and concurrent conditions included no alcohol user, and non smoker, and other pre-existing medical conditions included no known drug allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 042A21A, and expiry: 17/JUN/2021) dose was not reported, administered on 08-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 08-APR-2021, the subject experienced insomnia. On 08-APR-2021, the subject experienced bleeding at injection site. On 11-APR-2021, the subject experienced severe headache. On 11-APR-2021, the subject experienced nausea. On 11-APR-2021, the subject experienced stomach ache. On 15-APR-2021, the subject experienced pain at injection site. On 15-APR-2021, the subject experienced fatigue. On 15-APR-2021, the subject experienced pain in left hip. On 15-APR-2021, the subject experienced pain in whole right arm and both legs. On 15-APR-2021, the subject experienced shooting pain in head. On 15-APR-2021, the subject experienced swelling of both legs. On 15-APR-2021, the subject experienced pain over eyes. On 15-APR-2021, the subject experienced pain in bridge and side of nose. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from nausea, and stomach ache on 11-APR-2021, insomnia on 09-APR-2021, and bleeding at injection site on 08-APR-2021, recovered with sequelae from severe headache on 11-APR-2021, and had not recovered from pain at injection site, fatigue, pain in left hip, shooting pain in head, pain over eyes, pain in bridge and side of nose, pain in whole right arm and both legs, and swelling of both legs. This report was non-serious.</p>

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1240654	4/22/2021	NY		F		4/9/2021	DIZZY; CHILLS; TIRED; NAUSEA; INJECTION SITE PAIN; This spontaneous report received from a patient concerned a 53 year old female. The patient's height, and weight were not reported. The patient's past medical history included genetic blood clot history, supraventricular tachycardia, and covid-19 infection, and concurrent conditions included penicillin allergy, non alcoholic, and non smoker. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808980, and expiry: UNKNOWN) dose was not reported, administered on 09-APR-2021 12:00 for prophylactic vaccination. No concomitant medications were reported. On 09-APR-2021, the patient experienced dizzy, chills, tired, nausea, injection site pain. Patient took Tylenol for chills and Pepcid for nausea. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from chills on 10-APR-2021, was recovering from tired, dizzy, and nausea, and had not recovered from injection site pain. This report was non-serious.
1240989	4/22/2021	FL	31	U		4/9/2021	PAIN IN ARM; ANXIETY ABOUT BLOOD CLOTS; FEVER; INJECTION SITE SORENESS; This spontaneous report received from a consumer concerned a 31 year old of unspecified sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 043A21A, expiry: UNKNOWN) dose was not reported, administered on 09-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 09-APR-2021, the subject experienced injection site soreness. On 10-APR-2021, the subject experienced fever. On 12-APR-2021, the subject experienced anxiety about blood clots. On 13-APR-2021, the subject experienced pain in arm. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fever on 11-APR-2021, was recovering from injection site soreness, and had not recovered from pain in arm, and anxiety about blood clots. This report was non-serious.

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1241572	4/22/2021	NY	41	F	4/9/2021	4/13/2021	My period was supposed to start on 04/09 the day I got the vaccine. It was delayed until 04/13 when it began to bleed BLACK clotty sticky sludge. It had the appearance and consistency of vegemite or molasses. Black sludge. At first it was extremely heavy with very large black clots. Then it became tiny little black clots suspended in a brown sludge. This continued for 6 days until 04/18. Then on 04/19 my menstruation turned bright red with no clots, but has not abated at all for another 4 days. I am currently today on Thursday 04/22 still bleeding almost 2 weeks after taking the J&J shot. I cannot believe I am still bleeding after 10 full days!!! Never in 30 years of menstruating have I had a 10 day period. I am very scared and upset.

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1241054	4/22/2021	PA		F		4/14/2021	<p>BLOOD CLOT IN LEFT CALF; This spontaneous report received from a patient and concerned a female of unspecified age. The patient was called to obtain additional information on 21-APR-2021 and message was left on a voicemail. The patient's height, and weight were not reported. The patient has no family history of thrombosis. The patient does not have any underlying conditions. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose was not reported, administered on 13-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 14-APR-2021, the subject experienced blood clot in left calf. The patient noted that she did not have any underlying conditions or family history that may have made her more predisposed to this diagnosis. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clot in left calf. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This spontaneous report concerns a female patient of unspecified age who experienced a blood clot one day after Janssen COVID-19 vaccine was administered for prevention of symptomatic SARS-CoV-2 virus infection. The patient's height, and weight were not reported. The patient has no family history of thrombosis and has not reported any underlying conditions. No concomitant medications were reported. The patient did not provide details related to the blood clot, except it was not resolved at the time of the report. Given lack of alternative explanation and temporal plausibility the event is considered possibly related to Janssen COVID-19 vaccine.</p>

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1241062	4/22/2021	NY	43	F		4/1/2021	EXHAUSTION; PAIN IN ARM; SCABBY RASH/RASH ON BACK/UPPER AND LOWER ARM/LEG; ITCHY RED RASH ON BACK/UPPER AND LOWER ARM/LEG; This spontaneous report received from a consumer concerned a 43 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included asthma, and tiny clot in lung. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 042A21A expiry: UNKNOWN) dose was not reported, administered on 09-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On APR-2021, the subject experienced itchy red rash on back/upper and lower arm/leg. On APR-2021, the subject experienced scabby rash/rash on back/upper and lower arm/leg. On 09-APR-2021, the subject experienced pain in arm. On 10-APR-2021, the subject experienced exhaustion. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from exhaustion on APR-2021, was recovering from scabby rash/rash on back/upper and lower arm/leg, and the outcome of pain in arm and itchy red rash on back/upper and lower arm/leg was not reported. This report was non-serious.
1241112	4/22/2021	CA	51	M	4/1/2021	4/9/2021	I experienced "Moderna Arm" on the day following the injection, but it subsided after a couple of days. Eight days later, though, it returned (swelling/redness/milder pain) -- accompanied by swelling in my right ankle and tightness/some tingling/mild pain in my right ankle/upper calf. I suffered a blood clot for the first time in each leg in early November; the more serious of the two was in the vicinity of my upper calf in my right leg. In December, I began to experience sensations in my right ankle that were similar (albeit more intense) to what I later experienced after my vaccine; the post-vaccination symptom in my right calf was also similar (but milder) to what I had experienced from the DVT.



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1241143	4/22/2021	MI		F			<p>BLOOD CLOT; This spontaneous report received from a consumer via a company representative concerned a female (consumer's wife) of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported, for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced blood clot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This is a spontaneous report of a female patient of unspecified age, who developed a blood clot an unspecified time after receiving the Janssen COVID-19 vaccine. No medical history or concomitant medications were provided. There is insufficient information to make a meaningful medical assessment. Additional information is being sought.</p>

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1241185	4/22/2021	NJ		M	3/28/2021		<p>BLOOD CLOT IN LEFT LEG; LEFT LEG CALF PAIN; This spontaneous report received from a patient concerned a 78 year old Asian, Not Hispanic or Latino male. The patient's weight was 220 pounds, and height was 67 inches. The patient's past medical history included stent (unknown where stent was placed), and concurrent conditions included non alcohol user, and non smoker. The patient had no known drug allergies and no any drug abuse / illicit drug use. The patient was previously treated with Clopidogrel bisulfate for drug used for unknown indication. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805031, and expiry: UNKNOWN) dose was not reported, 1 total administered on 18-MAR-2021 to left arm for prophylactic vaccination. Concomitant medications included amlodipine, metformin, metoprolol, and vitamin b complex all for drug used for unknown indication. On 28-MAR-2021, the subject experienced left leg calf pain. Patient reported that he experienced left leg pain below calf muscle and went to hospital and was further diagnosed with blood clot in left leg on 16-APR-2021. He was on Plavix and asked to stop Plavix on 16-APR-2021 by physician and placed on Eliquis 10 mg for the first 7 days twice a day and then 5 mg once a day for blood clot in left leg as treatment administered and with further concern to physician. He had appointment to hematologist for further follow up on 26-APR-2021. Laboratory data included: Diagnostic ultrasound (NR: not provided) Blot clot to left lower leg on 16-APR-2021. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from left leg calf pain, and blood clot in left leg. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This is a 78 year old male patient, who experienced left leg calf pain 10 days after receiving the Janssen COVID-19 vaccine on his left arm. 29 days after receiving the vaccine, patient sought consult for the left leg pain and was further diagnosed with blood clot on the left leg by diagnostic ultrasound. Patient's weight is 220 pounds and has a height of 67 inches. Patient is non smoker and does not take alcoholic beverages. Patient has no known history of drug allergies or drug abuse. Past medical history include having stent placed on him but he could not recall where the stent was placed.</p>

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Patient was on Clopidogrel bisulfate but was asked to stop on the day he was diagnosed with the blood clot. Other concomitant medications include: amlodipine, metformin, and vitamin B complex,. Indication for all medications being taken is unknown. Age and obesity (BMI = 34.5 per weight and height provided) are known risk factors for developing blood clot in the lower leg. Having a stent and concomitant medication suggest a cardiac problem. Based on the available information and considering the temporal relationship, the events of left leg calf pain and blood clot are assessed as indeterminate per WHO causality classification of adverse events following immunization.

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1241226	4/22/2021	MI	52	F			<p>CEREBRAL INTRACRANIAL HYPERTENSION WITH FREE FLUID IN BRAIN BEHIND EYE; FLARED UP ARTHIRITIS; This spontaneous report received from a patient and concerned a 52 year old, White, not Hispanic or Latino, female. Initial information was received on 16-APR-2021 from the patient, with additional information received on 20-APR-2021 from the patient. The patient's weight was 170 pounds, and height was 65.5 inches. The most recent body mass index was 27.9. The patient's family history included rheumatoid arthritis in father, and concurrent conditions included arthritis (possibly rheumatoid arthritis), chronic back pain, and hip pain. The patient was due for a surgery, but it was cancelled due to pandemic. She had no history of headaches or migraines. Patient received several unspecified vaccines (had several vaccines 3 years ago before trip ) with no problems. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805020 expiry: UNKNOWN) dose was not reported, administered on 15-MAR-2021 on right arm for prophylactic vaccination. Concomitant medications included acetylsalicylic acid 81 mg, daily, ascorbic acid, ergocalciferol, metaxalone, oxycodone, and zinc. The patient concurrently receives spinal/epidural pain injections every two to three months. Approximately 16-30 hours after the vaccination, she had a flare up of her arthritis (left hip, L3, L4, L5, sciatic pain on the left side going all the way down to her knee, ankle, and foot, where her normal arthritis hurts daily). Pain medication did not help. She also developed migraines which caused pain behind the left eye similar to severe sinus infection, light sensitivity, her face felt tingly and numb in her temples and cheeks (left side). She was concerned about a stroke, but did not have droopiness and could smile on both sides. On 29-MAR-2021 (day 14 post vaccination), the patient went to her pain specialist to receive her spinal/epidural pain injection because she was in a lot of pain and she was "overdue". In retrospect, the patient wondered if she should have waited longer after having received the vaccine before doing so. On 30-MAR-2021 (day 15 post vaccination), she awoke and was blind for several (12 - 14) hours. She thought she had a stroke and took 4 baby aspirins. She was rushed to the hospital and was hospitalized on 30-MAR-2021. After the initial 2-3 hours that she was completely blind, it</p>

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would come back within minutes. The vision came back in halos. It was blurry but if she moved or bent down, it would go again and then it would come back very quickly. Several tests were performed. The MRI (Magnetic resonance imaging) did not show clots, stroke, or tumors, but showed intracranial hypertension. After the CT and MRI, a lumbar puncture was performed (results not provided). The patient said that the hospital noted cerebral intracranial hypertension with free fluid in her brain behind her eye. In the hospital, bloodwork was normal except for her triglycerides which were high. Patient reported that her platelet levels which were "perfect" and provided "318" as a specific example. She was discharged on 01-APR-2021. Corrective treatments included: steroids in the hospital for the intracranial hypertension and prescription strength aspirin 325 mg. The patient was not certain if injectable blood thinners were given to her in the hospital. She was discharged with methylprednisolone, alprazolam, twice a day prn to treat her headaches, aspirin 325 mg daily, and rosuvastatin 5 mg, daily, for high triglycerides. After patient was discharged, she had 2 episodes of lightheadedness with the blindness. The first one lasted about 5 minutes maximum and the second one on 12-APR-2021 lasted approximately 30-40 minutes. She had to be sitting down and her vision returned in halos with a lot of fireworks like bright stars. The patient had ringing in the ears, especially the left ear and when she had these episodes. On 14-APR-2021, the patient patient went to PCP (primary care provider). She stated that alprazolam helps her headaches. On 20-APR-2021, she had a "good day", did not experience headaches, and did not take alprazolam. She will follow up with a neurologist and an ophthalmologist. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the cerebral intracranial hypertension with free fluid in brain behind eye and flared up arthritis were not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: This 52 year-old White female was hospitalized for intracranial hypertension 15 days after receiving the Janssen Covid-19 vaccine. Medical history includes an unspecified arthritis with chronic left hip and back pain for which she receives epidural injections every 2-3 months, and a body mass index of 27.9. She

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has no history of migraines or other headaches and has tolerated multiple vaccinations previously. Concomitant medications include acetylsalicylic acid 81 mg daily, metaxalone, and oxycodone. Approximately 16 hours after vaccination, she experienced a flare of her arthritis which her pain medications did not relieve. The next day, she began to experience migraine headaches which were associated with pain behind her left eye and sinuses, left-sided facial tingling and numbness without weakness, and light sensitivity. Fourteen days post-vaccination, she received an epidural injection because she was in a lot of pain. The following morning, she awoke and experienced visual disturbance, described as "complete" blindness. then return of vision with halos and blurriness, and intermittent loss and return of vision depending on her body position. She took 4 baby aspirins, went to the hospital, and was admitted. MRI showed intracranial hypertension but no clots, stroke, or tumors. A lumbar puncture and CT scan were also performed. Blood tests, including platelet counts (e.g. 318), were normal except for high triglycerides. She was treated with steroids and aspirin 325 mg and was discharged 2 days later. She was given methylprednisolone, oxycodone-acetaminophen and alprazolam prn for headaches, aspirin 325 mg, and rosuvastatin for high triglycerides to continue at home and will follow up with a neurologist, ophthalmologist and her primary physician. Based on the available information, the relationship of intracranial hypertension with Janssen Covid-19 vaccine is considered inconsistent.

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1241321	4/22/2021	AR		M			GASTRO PROBLEMS; SEVERE ABDOMINAL PAIN; BODY ACHE; WATER/SLUDGE/BILE DIARRHEA; FEVER; HEADACHE; INJECTION SITE PAIN; LITTLE RED DOTS AROUND THE INJECTION AREA; NO ENERGY; This spontaneous report received from a patient concerned a male of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included congested heart failure, and concurrent conditions included blood clot problem, and diabetes. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808978, expiry: UNKNOWN) dose was not reported, administered on 09-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, the subject experienced gastro problems, severe abdominal pain, body ache, water/sludge/bile diarrhea, fever, headache, injection site pain, little red dots around the injection area, and no energy. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from little red dots around the injection area, and the outcome of gastro problems, fever, headache, severe abdominal pain, water/sludge/bile diarrhea, body ache, no energy and injection site pain was not reported. This report was non-serious.

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1241351	4/22/2021	NJ	60	M	4/1/2021	4/11/2021	10 days after the shot, my blood pressure rose to 198/112 and my pulse went to 161. and i called 911 and went to hospital. i had a severe headache for 3 days leading up to calling 911. finally on the April 1st, i went to hospital. i had a lump on my right shoulder never there before and i felt like the lump was causing my right side of my face to be numb. The hospital refused to believe me that i had some blood clot, they downplay the incident and instead gave me a brain CT SACN and brain MRA which was negative, they kept me for observation overnight and let me go noon the next day. since i have had follow ups with my regular doctor, a cardiologist and my nephrologist. I know that reaction was due to medication, either way glad i got the shot. BUT Since this time, I am retaining water, i know this because my rings do not fit anymore, rings i had for 20 years, never ever once had a hard time to put on or remove. I know my body, thats not the worse of it. i test my blood pressure every day at requesting of my kidney doctor, since the incudent of my pressure 198/112 my diastolic on average is raised 20 points. I log this daily. here are some examples from before the medication 111/67 , 109/63 , 129/64 , 105/62 120/81. now my pressure is totally different for example, 155/88 150/91 157/90 , 134/88. nothing else changed in my life, I am exactly the same as before only now i have covid shot.. yesterday i saw the 4th doctor since i am shot up and she gave me a new pill olmesartan medoxomil, only on it one day but my diastolic pressure is still much higher than before. i dont want to die, i dont want a stroke, or a heart attach, i have a lot to live for still. nobody is helping me, doctors are just throwing pills at me and not treating root cause which i feel strongly to beleive it is from covid shot.



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1241379	4/22/2021	MN	43	F	2/27/2021	2/27/2021	left neck spasm; felt uneasy; slight pain under sternum; fatigue; pain in her left knee; trembling in her upper body; face became a bright red; heat in her body; weakness in arms and hands; bed bound; pain in her lower back over kidney area; her body would be drenched in sweat mostly around heart and sternum area, she could splash; injection site started having pain; her injection site started having pain, it swelled up; Had skin eruptions like a boil on her right uper buttock; the boil was thought to be cellulitis and she was given a topical antibiotic; vomiting; racing heart; facial numbness and tingling; nausea; hard time breathing; shortness of breath; hives were on her upper back and under hips; she was covered in hives from, they covered her chest in a "Vshape; cough; burning sensation in her mouth; mouth was dry, tongue was thick and full, no salivation; Disoriented; began to feel very very thirsty; drinking 1 liter of water; felt pins and needles down her arms; numbness like pins and needles on injection site and neck; and while laying in bed, she felt like she was driving a race card; could not sleep; was going to pass out; high blood pressure; "She had a spot appear on her right leg and a ultrasound of her leg was performed to verify if a blood clot had developed (clot was not diagnosed)"; twitches in her abdomen, where her abdomen would cramp up; fallen down a short flight of stairs; felt like she could not move her limbs (elbow to fingers, knees to toes),limbs felt like they were frozen and paralyzed; dizzy; vertigo; migraine, lightheadedness, ringing ears, cloudy vision and headache; felt like as if someone was sitting on her chest; had a crawling sensation; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PRESYNCOPE (was going to pass out), CELLULITIS (Had skin eruptions like a boil on her right uper buttock; the boil was thought to be cellulitis and she was given a topical antibiotic), PERIPHERAL PARALYSIS (felt like she could not move her limbs (elbow to fingers, knees to toes),limbs felt like they were frozen and paralyzed) and DYSPNOEA (hard time breathing; shortness of breath) in a 43-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 025A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Bradycardia and Hives (Patient recalls

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20 years ago; she had hives.) in 2001. Concurrent medical conditions included Migraine. Concomitant products included RIZATRIPTAN for Migraine. On 27-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Feb-2021, the patient experienced PERIPHERAL PARALYSIS (felt like she could not move her limbs (elbow to fingers, knees to toes),limbs felt like they were frozen and paralyzed) (seriousness criterion disability), DIZZINESS (dizzy), VERTIGO (vertigo), MIGRAINE (migraine, lightheadedness, ringing ears, cloudy vision and headache) and CHEST DISCOMFORT (felt like as if someone was sitting on her chest; had a crawling sensation). On 01-Mar-2021, the patient experienced ABDOMINAL PAIN (twitches in her abdomen, where her abdomen would cramp up) and FALL (fallen down a short flight of stairs). On 02-Mar-2021, the patient experienced PRESYNCOPE (was going to pass out) (seriousness criterion medically significant), RASH MACULAR ("She had a spot appear on her right leg and a ultrasound of her leg was performed to verify if a blood clot had developed (clot was not diagnosed)"), HYPERTENSION (high blood pressure), INSOMNIA (could not sleep), PARAESTHESIA (felt pins and needles down her arms; numbness like pins and needles on injection site and neck) and RESTLESSNESS (and while laying in bed, she felt like she was driving a race car). On 03-Mar-2021, the patient experienced DISORIENTATION (Disoriented) and THIRST (began to feel very very thirsty; drinking 1 liter of water). On 04-Mar-2021, the patient experienced ORAL DISCOMFORT (burning sensation in her mouth; mouth was dry, tongue was thick and full, no salivation). On 05-Mar-2021, the patient experienced DYSPNOEA (hard time breathing; shortness of breath) (seriousness criterion medically significant), URTICARIA (hives were on her upper back and under hips; she was covered in hives from, they covered her chest in a "Vshape), COUGH (cough), HYPOAESTHESIA (facial numbness and tingling) and NAUSEA (nausea). On 07-Mar-2021, the patient experienced PALPITATIONS (racing heart). On 10-Mar-2021, the patient experienced VOMITING (vomiting). On 11-Mar-2021, the patient experienced CELLULITIS (Had skin eruptions like a boil on her right uper buttock; the

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boil was thought to be cellulitis and she was given a topical antibiotic) (seriousness criterion medically significant). On 12-Mar-2021, the patient experienced HYPERHIDROSIS (her body would be drenched in sweat mostly around heart and sternum area, she could splash), VACCINATION SITE PAIN (injection site started having pain) and VACCINATION SITE SWELLING (her injection site started having pain, it swelled up). On 13-Mar-2021, the patient experienced BACK PAIN (pain in her lower back over kidney area) and BEDRIDDEN (bed bound). On 15-Mar-2021, the patient experienced MUSCULAR WEAKNESS (weakness in arms and hands). On 17-Mar-2021, the patient experienced PYREXIA (heat in her body). On 21-Mar-2021, the patient experienced ERYTHEMA (face became a bright red) and TREMOR (trembling in her upper body). On 30-Mar-2021, the patient experienced FATIGUE (fatigue) and ARTHRALGIA (pain in her left knee). On 01-Apr-2021, the patient experienced CHEST PAIN (slight pain under sternum). On 02-Apr-2021, the patient experienced MUSCLE SPASMS (left neck spasm) and MALAISE (felt uneasy). At the time of the report, PRESYNCOPE (was going to pass out), CELLULITIS (Had skin eruptions like a boil on her right uper buttock; the boil was thought to be cellulitis and she was given a topical antibiotic), PERIPHERAL PARALYSIS (felt like she could not move her limbs (elbow to fingers, knees to toes),limbs felt like they were frozen and paralyzed), DYSPNOEA (hard time breathing; shortness of breath), RASH MACULAR ("She had a spot appear on her right leg and a ultrasound of her leg was performed to verify if a blood clot had developed (clot was not diagnosed)'), DIZZINESS (dizzy), VERTIGO (vertigo), MIGRAINE (migraine, lightheadedness, ringing ears, cloudy vision and headache), CHEST DISCOMFORT (felt like as if someone was sitting on her chest; had a crawling sensation), ABDOMINAL PAIN (twitches in her abdomen, where her abdomen would cramp up), FALL (fallen down a short flight of stairs), HYPERTENSION (high blood pressure), DISORIENTATION (Disoriented), ORAL DISCOMFORT (burning sensation in her mouth; mouth was dry, tongue was thick and full, no salivation), URTICARIA (hives were on her upper back and under hips; she was covered in hives from, they covered her chest in a "Vshape), COUGH (cough), HYPERHIDROSIS

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(her body would be drenched in sweat mostly around heart and sternum area, she could splash), BACK PAIN (pain in her lower back over kidney area), MUSCULAR WEAKNESS (weakness in arms and hands), ERYTHEMA (face became a bright red), MUSCLE SPASMS (left neck spasm), INSOMNIA (could not sleep), BEDRIDDEN (bed bound), PARAESTHESIA (felt pins and needles down her arms; numbness like pins and needles on injection site and neck), RESTLESSNESS (and while laying in bed, she felt like she was driving a race car), THIRST (began to feel very very thirsty; drinking 1 liter of water), PALPITATIONS (racing heart), TREMOR (trembling in her upper body), CHEST PAIN (slight pain under sternum), MALAISE (felt uneasy), VACCINATION SITE PAIN (injection site started having pain), VACCINATION SITE SWELLING (her injection site started having pain, it swelled up), FATIGUE (fatigue), VOMITING (vomiting), PYREXIA (heat in her body), ARTHRALGIA (pain in her left knee) and NAUSEA (nausea) outcome was unknown and HYPOAESTHESIA (facial numbness and tingling) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Mar-2021, Blood pressure measurement: increased (High) increased. On 02-Mar-2021, Electrocardiogram: unknown (Inconclusive) unknown. On 02-Mar-2021, Heart rate: increased (High) increased. On 02-Mar-2021, Ultrasound Doppler: unknown (Inconclusive) result unknown. On 06-Mar-2021, Blood pressure measurement: increased (High) increased. On 06-Mar-2021, Electrocardiogram: normal (normal) Tests came back fine. On 06-Mar-2021, Heart rate: 110 (High) increased. On 06-Mar-2021, Oxygen saturation: 90 (Low) decreased. On 06-Mar-2021, Ultrasound scan: normal (normal) The tests came back fine. On 07-Mar-2021, SARS-CoV-2 test: negative (Negative) negative. On 18-Mar-2021, Blood pressure measurement: normal (normal) normal. On 18-Mar-2021, Electrocardiogram: unknown (Inconclusive) unknown. On 18-Mar-2021, Heart rate: 85 (High) Pulse was a bit higher than her normal.. On 01-Apr-2021, Fibrin D dimer: unknown (Inconclusive) result unknown. On 01-Apr-2021, Ultrasound Doppler: unknown (Inconclusive) result unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown.

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1240985	4/22/2021	NJ		F		4/10/2021	<p>Per report, the patient had a skin eruption which was thought to be cellulitis at the clinic. Treatment included intravenous infusion with epinephrine, naltrexone, diphenhydramine, rizatriptan, naproxen sodium, TEA, a nerve supplement, and topical antibiotics. She was discharged home with EpiPen, prednisone, and famotidine. On 01 April 2021, the patient felt like she had a blood clot and received an EKG, D-dimer test, and ultrasound of the heart and lower limbs. On 07 April 2021, the patient reported feeling energetic. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> <p>ELEVATED BLOOD PRESSURE; SEVERE HEADACHE; FATIGUE; This spontaneous report received from a patient concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 08-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 10-APR-2021, the subject experienced severe headache. On 10-APR-2021, the subject experienced fatigue. On 12-APR-2021, the subject experienced elevated blood pressure. Laboratory data included: On 12/Apr/2021, computerized tomography scan was done to rule out blood clots. computerized tomography scan (CT scan) (NR: not provided) normal. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from severe headache, elevated blood pressure, and fatigue. This report was non-serious.</p>

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1244950	4/22/2021	NC		F		3/17/2021	CONSISTENT PAIN WHILE WAKING RESTING IN RIGHT CALF MUSCLE; This spontaneous report received from a consumer concerned a 44 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included dairy allergy, wheat allergy, and gluten allergy, and other pre-existing medical conditions included the patient had give birth 4 times with healthy delivery. The patient never got a clot before, not overweight. The patient was not pregnant at the time of report. The patient was non-smoker and alcohol user. The patient did not have any drug abuse/illicit drug use. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 1802072 expiry: UNKNOWN) dose was not reported, administered on 11-MAR-2021 on left arm for prophylactic vaccination. No concomitant medications were reported. On 17-MAR-2021, the patient experienced consistent pain (pain to touch ) while waking and resting in right calf muscle. She did not take anything for that pain. The patient had no swelling. She had normal temperature. On 13-APR-2021, the patient went to MD for D-dimer to be measured because her physician recommended to do so since she was going to have a long flight on 14-APR-2021. The physician had a concern for having a blood clot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from consistent pain while waking resting in right calf muscle on 23-MAR-2021. This report was non serious..
1242711	4/22/2021	UT	57	F	4/8/2021	4/12/2021	Soreness in my legs - I have blood clot history in my family and was worried. I went to see my doctor. - 14th. He did a visual exam. He said I was developing immunity because the vaccine was working. On the 19th, in the middle of the night, I had diarrhea and wasn't feeling well at all. I had diarrhea for 18 hours - and I was sleeping and running a fever but it didn't go over 101: It was at 99 - 100.5. Diarrhea stopped yesterday -I was eating BRAT (bananas, rice, applesauce, toast) - no caffeine - diet. But this morning, I work up with diarrhea again and I have had diarrhea three times already today. I've had a ringing in my ears that started two days ago and it's still there.

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1242694	4/22/2021	KY	51	F	3/8/2021	4/19/2021	03/19/21 woke up with numbness on whole right side of body (head to toe). Referred to ER by Family Physician on 03/20/21. admitted to hospital for testing. MRI confirmed a blood clot caused a Lacuna Infarcts Event (type of mini stroke) The patient continues to have numbness and difficulty walking, driving and has affected her normal daily activities. The patient will be required to start Plavix and baby aspirin. Waiting for requirement for Prolong numbness which affects her daily activity.
1245230	4/22/2021	WA	46	F	4/9/2021	4/22/2021	Patient received J&J COVID vaccine on 4/9/21 at pharmacy . Today (4/22/21), patient is admitted to our facility with VTE, submassive, unprovoked, with bilateral high-burden PE and LLE DVT, and right heart strain / acute cor pulmonale; in patient with H/o R PE, provoked 2014 after transcontinental flight, s/p Warfarin x 6 months, reportedly negative hypercoagulable panel; with strong family history of venous thrombosis in mother and sister. Heparin drip started, plan to start DOAC tomorrow. Anticipate hospital admission for at least 2 nights.
1245227	4/22/2021	IA	84	F	3/26/2021	4/5/2021	My Mom received the J&J Vaccine. Apprx 10 days later fell, fractured hip, Surgery April 3rd - On April 5th doctor at medical center said she has a blood clot and low platelets. Was in Hospital from April 2 to April 12th

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1245071	4/22/2021	NV		F		4/1/2021	HEAVIER MENSTRUAL FLOW WITH VISIBLE CLOTTED BLOOD; MENSTRUAL CRAMPING; FATIGUE; This spontaneous report received from a patient concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose was not reported, administered on 06-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On APR-2021, the subject experienced heavier menstrual flow with visible clotted blood. On APR-2021, the subject experienced menstrual cramping. On APR-2021, the subject experienced fatigue. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the menstrual cramping, heavier menstrual flow with visible clotted blood and fatigue was not reported. This report was non-serious.; Sender's Comments: V0: Medical assessment comment is not required as per standard procedure as case assessed as non-serious.



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1244951	4/22/2021	CA		F	4/1/2021		SEVERE BRUISING ON BILATERAL LEGS STARTED OFF DARK RED, BLUE GREEN AND PURPLE; FULL BODY NIGHT TIME SWEATING; FEVER; POUNDING HEADACHES THAT COME AND GO; BLOOD CLOTS ALL OVER MY LEGS; This spontaneous report was received from a patient and concerned female of unspecified age. The patient's height, and weight were not reported. The patient's concurrent conditions included non alcoholic, non smoker, no known allergies, and born with slight thalassemia. The patient had no drug abuse or illicit drug usage. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number and expiry date: unknown) dose was not reported, administered on 02-APR-2021, at left arm for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. The patient had a fever of 102 Fahrenheit on 02-APR-2021. On 07-APR-2021, the patient noticed severe bruising on her bilateral legs, and stated that they were each about the size of a half dollar they started off dark red, turned blue, purple and noted they kept popping up. She stated that they were now blue and green in color. The patient felt that if she did not do something both her legs would be covered. She stated they were blood clots all over her legs. The patient had a visit to emergency room for the severe bruising on bilateral legs started off dark red and turned blue, green and purple. She also reported full body night time sweating every night and pounding headaches that come and go, especially upon standing.. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fever on 03-APR-2021, had not recovered from severe bruising on bilateral legs started off dark red, blue green and purple, and full body night time sweating, and the outcome of blood clots all over my legs and pounding headaches that come and go was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: A female of unspecified age experienced fever the day of vaccine and 5 days later experienced bruising on bilateral legs the size of a half dollar. They varied in color. The patient visited the emergency room but details of diagnosis and treatment were not provided. There was no confirmation of a diagnosed thrombotic event. Based on the

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							information provided, a meaningful medical assessment can not be made. Additional information will be requested, including contact with the patient and/or treating physician for further assessment.
1244754	4/22/2021	LA	49	F	4/1/2021	4/4/2021	On the 4th day following the vaccine I woke up with swelling in my left armpit about the size of a golf ball. Achiness on the left side of my face, neck and shoulders that lasted till the 8th day. By the 14th day, the swelling in my left armpit had shrunk to the size of a large acorn with an enlarged vein like tissue protruding down my inner armpit. This area was still sore. On Day 21st I saw a doctor who suspected a blood clot and ordered an ultrasound at the hospital and blood work. After an ultrasound for approximately an hour the technical did not detect a blood clot and sent me home. The doctor phoned me to tell me they did not find anything and that if the pain and swelling continues I could see a surgeon to have the enlarged area surgically removed.
1244714	4/22/2021	OH	33	F	4/10/2021	4/10/2021	by 4:45 pm I felt off. By 6:30 pm I felt like I couldn't move very well. It affected all the bones I have ever broken or sprained before. Had cold chills, my temperature was 95.1. I felt like my blood pressure was high. I had a bad headache and took advil. April 11th I still felt off and had a headache. Around 4:30 pm I had rectal bleeding. Wednesday April 14th I had very bad leg pain in my right leg. Friday April 16th I went to urgent care for Leg pain and slight chest pain. They sent me to the ER. I had a chest Xray and ekg done and both came back normal. I was able to have a vascular ultrasound Monday April 19th in right leg and it showed no blood clots. I still have leg pain April 22nd.
1244382	4/22/2021	IL	51	M	3/8/2021	3/25/2021	Blood clot causing heart attack
1244088	4/22/2021	CO	57	F	3/24/2021	3/26/2021	Blood clots and related severe pain
1244061	4/22/2021	MI	54	M	3/29/2021	4/10/2021	Hospitalized for acute blood clot in each leg

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1242748	4/22/2021	ME	41	F	4/8/2021	4/8/2021	I took the vaccine at 2:10pm on 4/8/21 and 20 minutes later at 2:30pm on 4/8/21 my cycle started a whole week early, which is very abnormal for me. I am bleeding clots of blood for 5 days now with weakness and pains. My normal cycle is very regular and lasts 3 days, the first day is heavy then moderate, then light on the third day i barely need a liner. This has been heavy bleeding with sizable blood clots.
1242802	4/22/2021	AR	57	M	2/8/2021	2/23/2021	On 2/23/2021 patient had to have carotid endarterectomy to remove a clot from his aortic arch to his carotid siphon. Patient also had several mini strokes per wife and now has neurological deficits. He received his second Moderna vaccine on 3/8/2021 at another pharmacy and 5 days after he had another series of mini strokes.
1245000	4/22/2021	SD	71	M	3/10/2021	3/30/2021	Blood clots in the lungs, pulmonary embolism
1243975	4/22/2021	TX	49	M	4/2/2021	4/12/2021	Pulmonary embolism symptoms felt April 12, 13. Pulmonary infarction felt night of April 15th forward. Blood test was positive for possible clots done April 16th. CT/CTA chest scan done at hospital (also April 16th) confirmed the above embolism and infarction. Blood thinner via shots, then via tablet (Xarelto) until discharge on April 17th. Continuing on Xarelto.
1242841	4/22/2021		70	F	3/19/2021	4/21/2021	large saddle PE with large clot burden and scattered pulmonary emboli throughout all lobes.
1243087	4/22/2021	MA	66	F	3/1/2021	4/22/2021	Cortical sinus thrombosis with intracerebral hemorrhage, seizures. Admitted to ICU.
1243194	4/22/2021	MN	63	M	3/10/2021	3/23/2021	Patient had the Janssen vaccine as noted. He presented with significant superficial clot in the lower leg. Ultrasound read Mixed partially occlusive and occlusive superficial venous thrombosis in the right greater saphenous vein. This originates 2.2 cm from the junction with the right common femoral vein. He presented with 2 days of leg swelling without clear trigger such as travel, trauma etc.

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1243207	4/22/2021	MA	105	F	3/26/2021	4/14/2021	pts granddaughter says she was not feeling well and a couple of weeks after taking the vax and had to call 911 on 4/16/2021. Paramedics took her to Hospital ER, in same city and state as patient, where she was admitted. She called her granddaughter 4/18/2021 and told her she had tested positive for Covid Virus while at the hospital and that she had a blood clot on her lung. She is being treated w/ a blood thinner.
1243337	4/22/2021	NY	64	F	3/27/2021	3/29/2021	1st occurrence: After 1st vaccination on March 6th, 2021- intense pain in left leg, passed out, went to urgent care 2nd occurrence: After 2nd dose on March 27th, 2021 - on the 28th flu like symptoms- on the 29th intense leg pain, passed out, transported to hospital by ambulance, doppler revealed blood clot, blood work normal, placed on Eliquis I have since been to the hematologist and had a work up... blood tests are normal
1243390	4/22/2021	FL	34	F	4/13/2021	4/17/2021	Patient experienced a headache that lasted for a few days prior to admission, relieved with ibuprofen. On 4/17/21, patient had two seizures at home and subsequently brought to the ER, started on levetiracetam. CT brain on admission showed dural venous sinus thrombosis, heparin drip initiated. Hypercoagulable workup was negative.
1243646	4/22/2021	MO	65	F	4/8/2021	4/11/2021	On Sunday night, 04/11/2021 around 7:00pm, patient stated she started getting sick to her stomach. She complained of headaches and fatigue. At midnight she vomited, couldn't lay down and symptoms lasted all night. She complained of back pain too. she noticed blood in her urine with a clot of blood in it and had shortness of breath. She vomited twice. In contact by phone with her daughter at the time. Patient refused to go the the emergency room or call her physician. She has a cardiologist who is her primary care physician.
1243888	4/22/2021	NH	35	F	4/1/2021	4/16/2021	Patient received the vaccine at her home. She was straight cathed by a home health nurse and there was a blood clot and a large amount of blood noted to her urine. She was monitored over the weekend, but her urine remained clear. She has been in her usual state of health and has had no other symptoms since then

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1242878	4/22/2021	NY	62	M	4/8/2021	4/15/2021	Bleeding in my urinary tract for which they found a clot in my bladder the catheterized me to clear up blood
1236733	4/21/2021	WI	48	M	3/17/2021	3/24/2021	PER PATIENT REPORT, PAIN A WEEK LATER MY LEG WAS ACHING. I USED ICY HOT, MASSAGER. STARTED SWELLING, WENT TO WALK IN. THEY DID AN ULTRASOUND AND SAID I HAD A BLOOD CLOT IN MY LEG AND IT WAS TRAVELING TO MY LUNGS. THERE WERE A COUPLE SPECKS ON LUNG PER XRAY.
1236234	4/21/2021	WI	47	F		3/16/2021	BLURRY VISION; WEAKNESS; FELT SICK; TIRED; COULDN'T MOVE; DIZZY; This spontaneous report received from a patient concerned a 47 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included non-alcoholic, non-smoker, no cholesterol, and varicose veins, and other pre-existing medical conditions included no known drug allergies and had a watch on eating. family history of varicose veins, thrombosis and blood clots. patient is healthy and exercise regularly. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805031, and expiry: UNKNOWN) dose was not reported, administered on 15-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 16-MAR-2021, the subject experienced couldn't move. On 16-MAR-2021, the subject experienced dizzy. On 16-MAR-2021, the subject experienced felt sick. On 16-MAR-2021, the subject experienced tired. On 18-MAR-2021, the subject experienced blurry vision. On 18-MAR-2021, the subject experienced weakness. Treatment medications (dates unspecified) included: ascorbic acid/ergocalciferol/folic acid/nicotinamide/panthenol/retinol/riboflavin/thiamine hydrochloride. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from couldn't move, felt sick, and tired, had not recovered from dizzy, and the outcome of blurry vision and weakness was not reported. This report was non-serious.
1236676	4/21/2021	OH	64	M	3/23/2021	4/17/2021	Developed a blood clot in his right leg, inner thigh, up toward groin area. ER diagnosis on 4/20/21 at healthcare facility.

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1236718	4/21/2021	OH	64	M	3/23/2021	4/1/2021	patient reports he spent many days in hospital after 2nd Moderna vaccine with severe blood clots. Informed he did not tell hospital that he had the 2nd Moderna shot but informed the other hospital. It was the other hospital that instructed the patient to contact the Health Department to inform of the same
1236681	4/21/2021		61	F	4/7/2021	4/12/2021	RLE DVT--Acute, occlusive deep vein thrombosis in the right gastrocnemius vein--started on anticoagulant--apixaban
1236650	4/21/2021	MA	52	F	3/6/2021	3/8/2021	I began having pain in my lower left leg later on Sunday (felt like a pulled muscle) but by Monday it was more painful. Since I had surgery (see above) my doctor sent me fir an ultrasound where a clot was found. Went to emergency room to further evaluate and get treated. Was given elequis and am taking for 3 months. Was told clot was likely related to immobility from injury, but wanted to report just for your consideration
1236620	4/21/2021	IN	83	M	2/1/2021	2/25/2021	patient is currently on study for melanoma and has routine MRIs for monitoring. At his last MRI on 2/25 an asymptomatic cerebral venous thrombosis was incidentally found.
1236563	4/21/2021	FL	56	F	4/1/2021	4/17/2021	CEREBRAL VEIN THROMBOSIS 3 WEEKS AFTER RECEIVING PZIZER VACCINATION

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1236404	4/21/2021	NJ		M		4/9/2021	<p>VENOUS THROMBOSIS; PAIN IN LEFT LEG; This spontaneous report received from a consumer concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 06-APR-2021 for prophylactic vaccination. Frequency was 1 total. Vaccination site was unspecified. No concomitant medications were reported. Batch number is not reported and has been requested. On 09-APR-2021, the patient experienced pain in left leg. On 16-APR-2021, he was diagnosed venous thrombosis, and he was hospitalized (date unspecified). Consumer told that currently patient was admitted when she called. Treatment to treat adverse event was not reported. Hospital name and address was not reported. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from venous thrombosis, and pain in left leg. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: This is a spontaneous report of a male of unspecified age who developed a venous thrombosis and was hospitalized 10 days after receiving the Janssen COVID-19 vaccine. No medical history, concomitant medications or additional details were reported. Additional information has been requested. The case will be assessed further when additional information is received.</p>

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1236381	4/21/2021	TX	59	F		4/8/2021	FEELING CLAMMY; FEELING WARM; HYPERVENTILATION; FATIGUE; This spontaneous report received from a patient concerned a 59 year old female. The patient's weight was 160 pounds, and height was 160 centimeters. The patient's past medical history included blood clot on both lungs, and blood clot on legs, and concurrent conditions included alcohol user, cigarette smoker, seasonal allergy, penicillin allergy, and sulfa drugs allergy, and other pre-existing medical conditions included patient had no drug abuse and drug illicit usage. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, and batch number: 203A21A expiry: UNKNOWN) dose was not reported, administered on 08-APR-2021 for prophylactic vaccination. Concomitant medications included acetylsalicylic acid for prevention of blood clot. On 08-APR-2021, the subject experienced feeling clammy. On 08-APR-2021, the subject experienced feeling warm. On 08-APR-2021, the subject experienced hyperventilation. On 08-APR-2021, the subject experienced fatigue. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from hyperventilation on 08-APR-2021, and had not recovered from feeling clammy, feeling warm, and fatigue. This report was non-serious.
1236759	4/21/2021	FL	76	F	3/21/2021	3/25/2021	Foot and ankle swelled and went to doctor - found blood clot in right leg
1237398	4/21/2021	OH	65	F	1/23/2021	2/1/2021	Hospitalized (inpatient) with May-Thurner Syndrome, resulting in thrombectomy and prescribed year-long course of blood thinners. Hospitalized after second vaccination but vascular surgeon noted that some of the removed clot appeared to be about one month old or originating soon after the first vaccination. remain under care of PCP and vascular surgeon until full resolution.



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1236386	4/21/2021	PA	49	F		4/10/2021	CRAMPS IN BOTH THIGHS; ACHY; TIRED; This spontaneous report received from a consumer concerned a 49 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included stroke (3x clot in brain), latex allergy, alcohol use, and nonsmoker. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose was not reported, administered on 09-APR-2021 10:30 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 10-APR-2021, the subject experienced achy. On 10-APR-2021, the subject experienced tired. On 11-APR-2021, the subject experienced cramps in both thighs. Treatment medications (dates unspecified) included: paracetamol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from cramps in both thighs, achy, and tired on 14-APR-2021. This report was non-serious.
1236770	4/21/2021	GA	48	M	4/13/2021	4/15/2021	Heart Attack, 100% blockage with blood clot. I had to have three stents put in, but survived. I was in hospital for 2 days,
1236773	4/21/2021	MN	77	M	2/25/2021	3/18/2021	Patient had COVID infection in 12/2020. Had 1st moderna vaccine 1/31/21. developed new headaches 2/12/21. 2nd dose of moderna COVID vaccine on 2/25/21. on 3/18/21 admitted to the hospital with right sided weakness, expressive aphasia, left gaze preference and right hemineglect found to have a left posterior parietal intracranial hemorrhage with vasogenic edema and extensive venous sinus clot involving the superior sagittal sinus, bilateral transverse sinus and sigmoid sinus to the level of the jugular veins. He stabilized and was airlifted from one place to another to have hospice care.
1236791	4/21/2021	NC	31	M	4/8/2021	4/9/2021	Client awoke with chest pain and visited local ER for suspect M.I. Transferred to Hospital for angioplasty, related to thrombosis in R) coronary artery. Treated for 3 days and released to home with 3 months of follow-up cardiac rehab. Scheduled to return back to work as an auto mechanic on 4/26/2021.

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1236887	4/21/2021	TX	82	M	4/8/2021	4/10/2021	Extreme lower extremity swelling and pain. Evaluated in PCP office on 04/22/21, ultrasound of right LE was negative for blood clot. Patient's symptoms worsened and PCP referred patient to ER on 04/16/21 and CT of chest revealed 3 clots in the lungs. Patient was admitted to hospital and stated on heprin therapy. Still currently inpatient awaiting approval to transfer for inpatient rehab due to decreased endurance and bilateral lower extremity pain which is affecting ability to ambulated without assistance.
1236952	4/21/2021	AZ	62	F	4/14/2021	4/15/2021	18 hours after my 2nd moderna vaccine, I experienced slurred speech. When I arrived by car at my destination, I checked into a motel, looked into the mirror and noticed my left side of my face was drooping. I knew this was sign of stroke. I called 911 right away. I was taken to hospital. They did a CBC the night I arrived and the next day as well. They did 2 cat scans with and without contrast. Dr. in the ER determined that I had suffered a Transient Ischemic Attack which was brought on in less than 24hours of the 2nd Modern vaccine shot, and that the TIA was from the vaccine. The cat scans did not reveal any blood clots at the time of the scans. Dr. concluded that they had broken up quickly and that was why he diagnosed me with TIA.
1236988	4/21/2021	VA	55	F	4/6/2021	4/14/2021	Acute deep vein thrombosis (DVT) of popliteal vein of left lower extremity
1237011	4/21/2021	FL	68	F	4/7/2021	4/7/2021	Upon receiving injection, I became dizzy due to blood pressure drop. For 4 days following injection I had a severe headache. I called my Dr and they ordered a CT scan of my brain and sinuses. I developed nausea and a low grade fever which developed into a higher grade fever {100 degrees). As of the 20th of April I am still experiencing these symptoms. The CT scan came back negative for blood clot. I'm 5'3" and 118lbs. and in excellent health prior to this experience. I feel like the dosage for my size was too much for my body to handle. I need recommendations on how to counteract the adverse effects and/or how long can I expect to feel like this. I am due for the second shot on 4/28/21 and will NOT be taking it. Thank You

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1237045	4/21/2021	WI	39	F	1/27/2021	4/14/2021	In the first week of April, patient developed bruise-like markings on her left upper arm where she received the vaccine. The following week she noticed swelling and discoloration of her left arm. She went to Urgent care on April 14th where bloodwork and an ultrasound came back normal. Over the weekend of April 17-18, the swelling got worse and she called her PCP on April 19th, who advised her to go to the Emergency Dept. At the ED, bloodwork, an ultrasound and CT of the chest was ordered and she was diagnosed with a blood clot. Acute deep vein thrombosis of axillary vein of left upper extremity. She was given a prescription for rivaroxaban.
1237051	4/21/2021	OH	46	F	3/25/2021	3/27/2021	central retinal vein thrombosis
1237164	4/21/2021	FL	61	F	4/1/2021	4/21/2021	PATIENT PRESENTED TO OUR EMERGENCY ROOM WITH COMPLAINTS OF DIZZINESS, VERTIGO, AND VOMITING WHICH ONSET WAS ONE DAY. PATIENT REPORTS RECEIVING JOHNSON & JOHNSON COVID VACCINE 2 WEEKS AGO . CTA OF HEAD SHOW POSSIBLE TRANSVERSE VENOUS SINUS THROMBOSIS ABOUT 7MM, PATIENT IS ADMITTED TO ICU FOR FURTHER WORK UP .

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1236198	4/21/2021	AZ	57	F		4/9/2021	MUSCLE TIGHTNESS IN THE ARM; SWELLING OF THE LYMPH NODES; FELT TIRED; HEADACHE; This spontaneous report received from a patient concerned a 57 year old female. The patient's height, and weight were not reported. The patient's past medical history included neck injury, and car accident, and concurrent conditions included hashimoto's disease, overweight, sinus infection, and blood clot. The patient was previously treated with ibuprofen. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 09-APR-2021 for prophylactic vaccination. The batch number was not reported and it has been requested. Concomitant medications included acetylsalicylic acid for blood clot, curcuma longa rhizome for drug use for unknown indication, zingiber officinale rhizome for drug use for unknown indication, amoxicillin trihydrate/clavulanate potassium for sinus infection, ergocalciferol, magnesium, and . On 2018, Laboratory data included: Platelet aggregation test (NR: not provided) negative. On 09-APR-2021, the subject experienced felt tired. On 09-APR-2021, the subject experienced headache. On 10-APR-2021, the subject experienced muscle tightness in the arm. On 10-APR-2021, the subject experienced swelling of the lymph nodes. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from felt tired, headache, muscle tightness in the arm, and swelling of the lymph nodes. This report was non-serious.
1237397	4/21/2021	WI	81	F	4/9/2021	4/10/2021	CLIENT HURT HER ANKLE COMING OUT OF HER BED ON 4/10/21 AND DEVELOPED A BIG BRUISE, SWELLING, AND COOL TO TOUCH THAT DIDN'T HEAL AND REQUIRED A URGENT CARE VISIT ON 4/21/21. SYMPTOMS HAVE STAYED THE SAME , NOT PROGRESSIVELY GETTING WORSE. CLIENT WENT TO SEE HER PRIMARY AND HE SAID IT WAS 'ANGRY' AND NEEDED A VISIT TO URGENT CARE FOR AN ULTRASOUND TO RULE OUT A BLOOD CLOT.

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1235517	4/21/2021		82	M			blood clot in his pulmonary artery and several others in his legs; blood clot pulmonary artery; shortness of breath; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (blood clot in his pulmonary artery and several others in his legs) and PULMONARY EMBOLISM (blood clot pulmonary artery) in an 82-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Family history included Factor V deficiency, Factor II deficiency and MTHFR deficiency. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (blood clot in his pulmonary artery and several others in his legs) (seriousness criteria hospitalization prolonged and medically significant), PULMONARY EMBOLISM (blood clot pulmonary artery) (seriousness criterion medically significant) and DYSPNOEA (shortness of breath). At the time of the report, THROMBOSIS (blood clot in his pulmonary artery and several others in his legs), PULMONARY EMBOLISM (blood clot pulmonary artery) and DYSPNOEA (shortness of breath) outcome was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided. Action taken with mRNA-1273 in response to the event was not applicable. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
1237452	4/21/2021	MI	21	F	4/7/2021	4/10/2021	Acute deep vein thrombosis (DVT) of right peroneal vein
1237232	4/21/2021	NE	35	M	3/20/2021	3/28/2021	Swollen spleen, blood clot in spleen, splenic infarct.

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1235521	4/21/2021	TN	73	F	2/3/2021	3/24/2021	After the vaccination, and while in the hospital, she was diagnosed with a blood clot in the left atrium the size of a golf ball; Reported she was diagnosed with a spontaneous peptic ulcer bleed; Stated that she feels like she is "sitting on a powder keg"; This spontaneous case was reported by a patient (subsequently medically confirmed) and describes the occurrence of ATRIAL THROMBOSIS (After the vaccination, and while in the hospital, she was diagnosed with a blood clot in the left atrium the size of a golf ball) and PEPTIC ULCER HAEMORRHAGE (Reported she was diagnosed with a spontaneous peptic ulcer bleed) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 022M20A and 211M28-9) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Heart failure (7 years ago-consumer reported it resolved on its own but was placed on Entresto at that time) in 2014 and Arterial stent insertion (Left atrial appendage closure device to treat atrial fibrillation and prevent clots) in 2019. Concurrent medical conditions included Arthritis, Cardiac disorder NOS (Body aches), Headache, Fluid imbalance (Fluid in feet), High cholesterol, Hypotension and Pain. Concomitant products included CARVEDILOL (COREG), HCTZ, VITAMIN C [ASCORBIC ACID], ATORVASTATIN CALCIUM (LIPITOR), ACETYLSALICYLIC ACID (BABY ASPIRIN) and PARACETAMOL (TYLENOL) for an unknown indication. On 03-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 24-Mar-2021, the patient experienced ATRIAL THROMBOSIS (After the vaccination, and while in the hospital, she was diagnosed with a blood clot in the left atrium the size of a golf ball) (seriousness criteria hospitalization prolonged and medically significant). On an unknown date, the patient experienced PEPTIC ULCER HAEMORRHAGE (Reported she was diagnosed with a spontaneous peptic ulcer bleed) (seriousness criterion medically significant) and FEELING ABNORMAL (Stated that she feels like she is "sitting on a powder keg"). The patient was hospitalized from 24-Feb-2021 to 12-Mar-2021 due to

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ATRIAL THROMBOSIS. At the time of the report, ATRIAL THROMBOSIS (After the vaccination, and while in the hospital, she was diagnosed with a blood clot in the left atrium the size of a golf ball), PEPTIC ULCER HAEMORRHAGE (Reported she was diagnosed with a spontaneous peptic ulcer bleed) and FEELING ABNORMAL (Stated that she feels like she is "sitting on a powder keg") outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 06-Feb-2021, Echocardiogram: results are not mentioned (Inconclusive) Results are not mentioned. The patient stated that she initially was being cared for by a small, local hospital but was transferred to a larger hospital. The patient reported that she has never had any blood clots until now. Treatment for the event included apixaban (twice daily). The patient received both scheduled doses of mRNA-1273 prior to the event; therefore, action taken with the drug in response to the event is not applicable. This case was linked to MOD-2021-075865 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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1235792	4/21/2021	TX	43	F	3/24/2021	3/24/2021	Worsen neuropathic symptoms; migraine headache; Sore arm; fatigue; low grade fevers; chilled; This is a spontaneous report from a contactable consumer(patient). This is the 1st of 2 reports, for the Second dose. A 43-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 on 24Mar2021 (at age of 43 years old) 11:45AM, via an unspecified route of administration, administered in Arm Left (Batch/Lot number was not reported) at single dose, for covid-19 immunisation. Medical history included Ovarian cancer, blood clots, hypertension. known allergies Salfa. The patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 on 03Mar2021 (at age of 43 years old) 11:00 AM, via an unspecified route of administration, administered in Arm Left (Batch/Lot number was not reported) at single dose, for covid-19 immunisation and experienced Sore arm, Worsen neuropathic symptoms (existing side effects from chemo) - pains on fingers, wrists, feet, toes, back# fatigue, migraine headache for 15 days. Concomitant medication(s) in two weeks included duloxetine hydrochloride (CYMBALTA) 30 mg, warfarin 1mg and hydrochlorothiazide, all taken for an unspecified indication, start and stop date were not reported. Sore arm, Worsen neuropathic symptoms (existing side effects from chemo) - pains on fingers, wrists, feet, toes, back# fatigue, migraine headache for 15 days after the first dose. For second dose, same symptoms continuously for 11 days now and low grade fevers, chilled for first 4 days after the vaccine and on the 11th and 12th days after the second dose. No treatment received for events and The patient was not diagnosed with COVID-19 prior to vaccination, and Since the vaccination, the patient has not been tested for COVID-19. Outcome for events was not recovered. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021377679 Same patient/drug, diff event sep for different doses.



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1235790	4/21/2021	CA	50	M	3/16/2021	3/19/2021	pulmonary embolism; shortness of breath; This is a spontaneous report from a contactable consumer (patient). A 50-year-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot ep7534), via an unspecified route of administration, administered in right arm on 16Mar2021 15:00 as single dose for covid-19 immunisation. Medical history included high blood pressure. Concomitant medication included verapamil. The patient previously took lisinopril and experienced allergies. The patient received first dose of bnt162b2 on 23Feb2021, 13:00 for Covid-19 immunization. On 19Mar2021, the patient started having challenges with shortness of breath. On 31Mar2021, after the challenge continued to grow he was checked into the hospital and was diagnosed with pulmonary embolism. Despite no travel nor history of family blood clots, nor was he was genetically dispositioned. The events resulted in emergency room/department or urgent care. Therapy for the events included Blood thinner. The patient had no other vaccine in 4 weeks, and no Covid prior vaccination. The patient was Covid tested post vaccination. The patient underwent lab tests and procedures which included nasal swab was negative on 31Mar2021. Outcome of events was recovering.

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1235767	4/21/2021	MD	20	F	3/20/2021	3/20/2021	small clot behind my left knee; left foot had swollen; This is a spontaneous report from a contactable consumer (patient). A 20-year-old female patient received BNT162B2 (lot number: ER2613) first dose on 20Mar2021 10:15 on left arm at single dose for COVID-19 immunisation. Medical history and concomitant medications were none. Patient is not pregnant. No other vaccine in four weeks. No Covid prior vaccination, No known allergies. She took the vaccine around 10:00am and around 6:00pm (also reported as 06:30 PM) she noticed that her left foot had swollen. She consulted with her general physician and he requested that patient did an Ultra Sound exam of her left leg. The result of the exam reported a small clot behind her left knee. Therefore, doctor suggested that she reported these events to Pfizer so an evaluation is made to identify if similar events have occurred with other patients. She was concerned if she should take the second shot on 17Apr2021. AE resulted in Doctor or other healthcare professional office/clinic visit. Patient received Eliquis 5mg (two times daily) as treatment. Patient had Nasal Swab on 01Apr2021 and tested negative. The outcome of the events was not recovered.
1235740	4/21/2021	CA	60	F	3/4/2021	3/4/2021	I fainted; blood clots; light headed; I lost all color and my skin was wet and clammy; I lost all color and my skin was wet and clammy; This is a spontaneous report from a contactable consumer. A 60-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) lot number: EN6199, via an unspecified route of administration, administered in right arm on 04Mar2021 15:00 as single dose for Covid-19 immunisation. Medical history included known allergies to Atovaquone/proguanil. Concomitant medications were not reported. On 04Mar2021, approximately 10 minutes post vaccine, the patient fainted in the waiting area. She was told by a witness that she fainted two times. EMTs administered an IV and did a simple EKG. The patient lost all color and her skin was wet and clammy. EMTs were concerned about her heart and transported her to the ER where she had a full EKG and lab work for D-Dimer to consider blood clots. The patient has remained lightheaded for weeks after the vaccine. The outcome of the events was recovered with sequelae.

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1235719	4/21/2021	CA	35	F	4/12/2021	4/18/2021	left arm swelling started from 4/18, extended from upper arm to lower arm in the afternoon. went to Urgent care on 4/19 morning, the NP reviewed my blood report and referred me to do ultrasound and also ask me to go to ER if the swell extend. as the swell extend, i went to ER in the afternoon. blood test shows high D-dimer and then ultrasound finds blood clot in the vessel near left neck. diagnosed to be Deep Vein Thrombosis. no family history of such problem. in the hospital, they gave me a shot of blood thinner and also prescript oral blood thinner to be take at home.

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1235690	4/21/2021	MA	40	F	4/2/2021	4/2/2021	<p>Blood clots; Kind of bleeding; arm began being extremely itchy; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clots) and HAEMORRHAGE (Kind of bleeding) in a 40-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 02-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Apr-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced PRURITUS (arm began being extremely itchy). On 05-Apr-2021, the patient experienced THROMBOSIS (Blood clots) (seriousness criterion medically significant) and HAEMORRHAGE (Kind of bleeding) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood clots) and HAEMORRHAGE (Kind of bleeding) outcome was unknown and PRURITUS (arm began being extremely itchy) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In April 2021, Pregnancy test: Negative. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided. Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, excluding other etiologies causal relationship cannot be excluded; Sender's Comments: Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, excluding other etiologies causal relationship cannot be excluded</p>

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1235687	4/21/2021	AL	49	M	3/12/2021	4/10/2021	Memory lapse, difficulty with memory recall; Confused; Blood clots; Cerebral Ischemic Attack; Brain Fog; Headache; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of MEMORY IMPAIRMENT (Memory lapse, difficulty with memory recall), CONFUSIONAL STATE (Confused), THROMBOSIS (Blood clots) and TRANSIENT ISCHAEMIC ATTACK (Cerebral Ischemic Attack) in a 49-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 046A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Heart valve operation. Concomitant products included WARFARIN SODIUM (COUMADIN) for an unknown indication. On 12-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 10-Apr-2021, the patient experienced MEMORY IMPAIRMENT (Memory lapse, difficulty with memory recall) (seriousness criterion hospitalization), CONFUSIONAL STATE (Confused) (seriousness criterion hospitalization), THROMBOSIS (Blood clots) (seriousness criterion hospitalization) and TRANSIENT ISCHAEMIC ATTACK (Cerebral Ischemic Attack) (seriousness criterion hospitalization). On 15-Apr-2021, the patient experienced FEELING ABNORMAL (Brain Fog) and HEADACHE (Headache). The patient was hospitalized from 10-Apr-2021 to 12-Apr-2021 due to CONFUSIONAL STATE, MEMORY IMPAIRMENT, THROMBOSIS and TRANSIENT ISCHAEMIC ATTACK. At the time of the report, MEMORY IMPAIRMENT (Memory lapse, difficulty with memory recall), FEELING ABNORMAL (Brain Fog) and HEADACHE (Headache) had not resolved and CONFUSIONAL STATE (Confused), THROMBOSIS (Blood clots) and TRANSIENT ISCHAEMIC ATTACK (Cerebral Ischemic Attack) had resolved. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Apr-2021, Computerised tomogram: abnormal (abnormal) revealed blood clots. On 10-Apr-2021, International normalised ratio: low (Low) Low. On 10-Apr-2021, Magnetic resonance imaging: abnormal

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(abnormal) revealed blood clots. On 15-Apr-2021, International normalised ratio: low (Low) Low. It was reported that the patient still has difficulty with memory recall, brain fog, headache, and still having trouble with low INR. The patient did not have any side effects after the first dose. Treatment for the events included Levonox injections and Coumadin (increased dose). Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, excluding other etiologies causal relationship cannot be excluded. Headache is consistent with the product known safety profile.;

Sender's Comments: Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, excluding other etiologies causal relationship cannot be excluded. Headache is consistent with the product known safety profile.

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1235672	4/21/2021	IA	88	M	2/4/2021	2/5/2021	<p>blood clots in his right leg and left leg; Emergency Room at 4am because he had trouble breathing and walking; found blood on both his lungs; chills especially at night that lasted 2 nights; He states he is still in misery; Patient was supposed to get second dose on 04-Mar-2021, but he is not going to get it; shoulder pain/hip pain; Pain in arms, leg; trouble walking due to his pain; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (blood clots in his right leg and left leg), DYSPNOEA (Emergency Room at 4am because he had trouble breathing and walking), HAEMOPTYSIS (found blood on both his lungs) and CHILLS (chills especially at night that lasted 2 nights) in an 88-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 004M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Asthma since an unknown date. Concomitant products included MONTELUKAST and FLUTICASONE FUROATE, VILANTEROL TRIFENATATE (BREO ELLIPTA) for Asthma, METOPROLOL and APIXABAN (ELIQUIS) for an unknown indication. On 04-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-Feb-2021, the patient experienced THROMBOSIS (blood clots in his right leg and left leg) (seriousness criteria hospitalization and life threatening), DYSPNOEA (Emergency Room at 4am because he had trouble breathing and walking) (seriousness criterion hospitalization), HAEMOPTYSIS (found blood on both his lungs) (seriousness criteria hospitalization and medically significant), PAIN IN EXTREMITY (Pain in arms, leg), GAIT DISTURBANCE (trouble walking due to his pain) and ARTHRALGIA (shoulder pain/hip pain). On 04-Mar-2021, the patient experienced INTENTIONAL DOSE OMISSION (Patient was supposed to get second dose on 04-Mar-2021, but he is not going to get it). On an unknown date, the patient experienced CHILLS (chills especially at night that lasted 2 nights) (seriousness criterion hospitalization) and FEELING ABNORMAL (He states he is still in misery). The patient was hospitalized on 20-Feb-2021 due to DYSPNOEA, HAEMOPTYSIS and THROMBOSIS, and then for 2 days due to CHILLS.</p>

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At the time of the report, THROMBOSIS (blood clots in his right leg and left leg), DYSPNOEA (Emergency Room at 4am because he had trouble breathing and walking), HAEMOPTYSIS (found blood on both his lungs), PAIN IN EXTREMITY (Pain in arms, leg), GAIT DISTURBANCE (trouble walking due to his pain), FEELING ABNORMAL (He states he is still in misery) and ARTHRALGIA (shoulder pain/hip pain) had not resolved and CHILLS (chills especially at night that lasted 2 nights) and INTENTIONAL DOSE OMISSION (Patient was supposed to get second dose on 04-Mar-2021, but he is not going to get it) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Chest X-ray: (abnormal) Found blood on both of his lungs. On an unknown date, SARS-CoV-2 test: (Negative) Negative. On an unknown date, Ultrasound scan: (abnormal) Found blood clots in his right leg and left leg. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Patient was taken to the ER (Emergency Room) on 20-Feb-2021 at 4 AM. Several tests including Chest X-Ray, MRI, Blood work, Ultrasound (groin and legs) were performed. Only few tests results were reported. Received treatment including Oxygen, Eliquis and Antibiotics. Patient has been on oxygen full time until 7Apr2021 Company comment: Based on the current available information and temporal association between the use of the product and the start date of these event, a causal relationship cannot be excluded. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these event, a causal relationship cannot be excluded. Further information has been requested.



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1235666	4/21/2021	GA		M	3/16/2021	3/31/2021	<p>Patient got scared and did not get his second dose; tried to urinate and could not; passed a clot with some drops of blood; This spontaneous case was reported by a consumer and describes the occurrence of URINARY RETENTION (tried to urinate and could not) and HAEMORRHAGE URINARY TRACT (passed a clot with some drops of blood) in a 73-year-old male patient who received mRNA-1273 (batch no. 024M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Tumor (Malignancy in the tubular tumor in Penis) and Bladder operation (in past 3 months). Concurrent medical conditions included Diabetes and Hypertension. Concomitant products included METFORMIN, LISINOPRIL, AMLODIPINE and ESCITALOPRAM for an unknown indication, PRAVASTATIN SODIUM (PRAVASTATIN NA). On 16-Mar-2021, the patient received first dose of mRNA-1273 (Intramuscular) 1 dosage form. On 31-Mar-2021, the patient experienced URINARY RETENTION (tried to urinate and could not) (seriousness criterion medically significant) and HAEMORRHAGE URINARY TRACT (passed a clot with some drops of blood) (seriousness criterion medically significant). On 13-Apr-2021, the patient experienced PRODUCT DOSE OMISSION ISSUE (Patient got scared and did not get his second dose). At the time of the report, URINARY RETENTION (tried to urinate and could not), HAEMORRHAGE URINARY TRACT (passed a clot with some drops of blood) and PRODUCT DOSE OMISSION ISSUE (Patient got scared and did not get his second dose) outcome was unknown. The action taken with mRNA-1273 (Intramuscular) was unknown. Treatment medication was not reported. Based on the current available information and the temporal association between the product use and the start of the events a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and the temporal association between the product use and the start of the events a causal relationship cannot be excluded.</p>

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1235627	4/21/2021		58	M	3/1/2021	3/3/2021	Could not walk; Leg was swollen; Nurse told him his leg was hot; blood clot in both his lungs; Blood clot in both his legs; Fast heartbeat; Soreness in left calf; Ultrasonography NOS abnormal; CT abnormal; Ankle and foot still swollen; This spontaneous case was reported by a patient and describes the occurrence of PAIN IN EXTREMITY (Soreness in left calf), GAIT DISTURBANCE (Could not walk), PERIPHERAL SWELLING (Leg was swollen), FEELING HOT (Nurse told him his leg was hot), PULMONARY EMBOLISM (blood clot in both his lungs), DEEP VEIN THROMBOSIS (Blood clot in both his legs), HEART RATE INCREASED (Fast heartbeat) and ULTRASOUND SCAN ABNORMAL (Ultrasonography NOS abnormal) in a 58-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 013a21a) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. Concomitant products included IRBESARTAN and LEVOTHYROXINE for an unknown indication. On 01-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 03-Mar-2021, the patient experienced PAIN IN EXTREMITY (Soreness in left calf) (seriousness criterion hospitalization). On 17-Mar-2021, the patient experienced GAIT DISTURBANCE (Could not walk) (seriousness criterion hospitalization), PERIPHERAL SWELLING (Leg was swollen) (seriousness criterion hospitalization), FEELING HOT (Nurse told him his leg was hot) (seriousness criterion hospitalization), PULMONARY EMBOLISM (blood clot in both his lungs) (seriousness criterion hospitalization), DEEP VEIN THROMBOSIS (Blood clot in both his legs) (seriousness criterion hospitalization) and HEART RATE INCREASED (Fast heartbeat) (seriousness criterion hospitalization). On 14-Apr-2021, the patient experienced JOINT SWELLING (Ankle and foot still swollen). On an unknown date, the patient experienced ULTRASOUND SCAN ABNORMAL (Ultrasonography NOS abnormal) (seriousness criterion hospitalization prolonged) and COMPUTERISED TOMOGRAPH ABNORMAL (CT abnormal). The patient was hospitalized from 17-Mar-2021 to 20-Mar-2021 due to DEEP VEIN THROMBOSIS, PAIN IN EXTREMITY and PULMONARY EMBOLISM. At

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							the time of the report, PAIN IN EXTREMITY (Soreness in left calf), GAIT DISTURBANCE (Could not walk), PERIPHERAL SWELLING (Leg was swollen), FEELING HOT (Nurse told him his leg was hot), PULMONARY EMBOLISM (blood clot in both his lungs), DEEP VEIN THROMBOSIS (Blood clot in both his legs), HEART RATE INCREASED (Fast heartbeat), ULTRASOUND SCAN ABNORMAL (Ultrasonography NOS abnormal), COMPUTERISED TOMOGRAM ABNORMAL (CT abnormal) and JOINT SWELLING (Ankle and foot still swollen) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Computerised tomogram: abnormal (abnormal) Abnormal. In 2021, Ultrasound scan: abnormal (abnormal) Abnormal. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route) was unknown. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Reporter did not allow further contact; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
1235625	4/21/2021	IN	22	F	4/16/2021	4/16/2021	Consistent headache - Tylenol or Excedrine relieved Heavy period - began 4 days early. Excessive blood clots and amount of blood. Left arm pain- unable to move arm without pain x 3 days. Tylenol relieved Fever- began 2 days after. Tylenol reduces fever.
1235593	4/21/2021	IA	46	F	3/5/2021	3/21/2021	I received the Janssen vaccine on 3/5/2021. My first menstrual cycle after the vaccine, which started on 3/21/21, was significantly different than any other period. I woke in the middle of the night to extreme pain in my abdomen and bled along the floor as I walked to the bathroom. There were clots in the blood in addition to extraordinarily heavy blood flow. The period was so significantly different from any other that I scheduled an appointment with a nurse practitioner that works with my primary care doctor. I asked her to "run" all tests that were available and approved by insurance, which she did. All came back normal. Due to the significant difference in my period this month, the ARNP requested an inner-uterine ultrasound which found the below:

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1237463	4/21/2021	MA	52	F	3/9/2021	3/16/2021	Right ankle swelling upward to knee; diagnosed with blood clot per patient; treated with Eliquis.

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1235544	4/21/2021	MT	57	M	4/2/2021	4/2/2021	<p>Acute pulmonary embolism/two blood clots in lung; Chest pain; Pain over left arm; pain all over joints; Nausea; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Acute pulmonary embolism/two blood clots in lung) in a 57-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 038A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was provided). On 02-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Apr-2021, the patient experienced PAIN IN EXTREMITY (Pain over left arm), ARTHRALGIA (pain all over joints) and NAUSEA (Nausea). On 12-Apr-2021, the patient experienced CHEST PAIN (Chest pain). On 13-Apr-2021, the patient experienced PULMONARY EMBOLISM (Acute pulmonary embolism/two blood clots in lung) (seriousness criterion medically significant). At the time of the report, PULMONARY EMBOLISM (Acute pulmonary embolism/two blood clots in lung), CHEST PAIN (Chest pain), PAIN IN EXTREMITY (Pain over left arm), ARTHRALGIA (pain all over joints) and NAUSEA (Nausea) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Apr-2021, Computerised tomogram: abnormal (abnormal) diagnosed acute pulmonary embolism.. Two blood clots in lung. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. Description: The patient experienced pain over left arm, pain all over joints, nausea after vaccine administration. On 12 Apr2 021, the patient experienced chest pain and went to Emergency. Room where blood test and D-dimer was done. The treatment information included apixaban. Company Comment: Based on the current available information and the temporal association between the product use and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and the temporal association between the product use and the start date of the events a causal relationship cannot be excluded.</p>

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1236190	4/21/2021	NJ		F		4/13/2021	MILD HEADACHE; HYPERVENTILATION; STRESSED OUT; This spontaneous report received from a parent concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included blood clots. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose was not reported, administered on 29-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 13-APR-2021, the subject experienced hyperventilation. On 13-APR-2021, the subject experienced stressed out. On an unspecified date, the subject experienced mild headache. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the hyperventilation, stressed out and mild headache was not reported. This report was non-serious.

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1235520	4/21/2021	CA	55	F	3/17/2021	3/19/2021	<p>blood clots in the heart; had no energy, very weak, extremely weak; irregular heartbeats; couldn't walk very good; shortness of breath; coughing; chills; nausea; vomiting; This spontaneous case was reported by a consumer and describes the occurrence of INTRACARDIAC THROMBUS (blood clots in the heart), ASTHENIA (had no energy, very weak, extremely weak) and HEART RATE IRREGULAR (irregular heartbeats) in a 55-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Tumor and Arrhythmia. Concurrent medical conditions included Heart disease, unspecified in 2020. On 17-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Mar-2021, the patient experienced DYSPNOEA (shortness of breath), COUGH (coughing), CHILLS (chills), NAUSEA (nausea) and VOMITING (vomiting). On 01-Apr-2021, the patient experienced ASTHENIA (had no energy, very weak, extremely weak) (seriousness criterion hospitalization) and GAIT DISTURBANCE (couldn't walk very good). On 09-Apr-2021, the patient experienced HEART RATE IRREGULAR (irregular heartbeats) (seriousness criterion hospitalization). On 12-Apr-2021, the patient experienced INTRACARDIAC THROMBUS (blood clots in the heart) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 05-Apr-2021 to sometime in April 2021 due to HEART RATE IRREGULAR, then from 05-Apr-2021 to sometime in April 2021 due to INTRACARDIAC THROMBUS, and then from 09-Apr-2021 to sometime in April 2021 due to ASTHENIA. On 25-Mar-2021, CHILLS (chills) and VOMITING (vomiting) had resolved. At the time of the report, INTRACARDIAC THROMBUS (blood clots in the heart), ASTHENIA (had no energy, very weak, extremely weak), HEART RATE IRREGULAR (irregular heartbeats), GAIT DISTURBANCE (couldn't walk very good), DYSPNOEA (shortness of breath), COUGH (coughing) and NAUSEA (nausea) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. Patient was placed on unknown medication to</p>

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1236127	4/21/2021			U			<p>help dissolve blood clots for one or two months.  Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded</p> <p>BLOOD CLOTS IN MY LEFT LUNG; GOT SERIOUSLY SICK; This spontaneous report received from a patient via a company representative and concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received Janssen COVID-19 Vaccine (ad26.cov2.s) (suspension for injection, intramuscular, batch number: Unknown) dose was not reported, administered on 20-MAR-2021 for prophylactic vaccination. The batch number was not reported, and has been requested. No concomitant medications were reported. On an unspecified date, the patient got seriously sick and was hospitalized for blood clots in left lung on unspecified date. Patient reported blood clots in left lung that caused to be hospitalized for two days. Patient reported being on blood thinners (unspecified) and oxygen. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the got seriously sick and blood clots in my left lung was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: A patient of unspecified age and sex experienced blood clots in the left lung an unspecified time after vaccine. The patient reported being on blood thinners and oxygen. No further details were provided. There is insufficient information to make a meaningful medical assessment. Additional information has been requested.</p>



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1235808	4/21/2021	IL		F		3/10/2021	Brain clot: acute thrombosis of the Left transverse sinus, left sigmoid sinus and upper left internal jugular vein cerebral sinus venous thrombosis; This is a spontaneous report from a contactable nurse. A 39-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in Arm Left on an unspecified date (reported as 19Mar2021; pending clarification). (Batch/Lot Number: EL9266) as single dose for covid-19 immunization. The patient's medical history was not reported. The patient was not pregnant at the time of vaccination. Concomitant medication included desogestrel, ethinylestradiol (PIMTREA) taken for an unspecified indication, start and stop date were not reported. The patient previously took diflucan and experienced allergy. The patient experienced brain clot: acute thrombosis of the left transverse sinus, left sigmoid sinus and upper left internal jugular vein cerebral sinus venous thrombosis (hospitalization, disability, life threatening) on 10Mar2021 12:45. The patient was hospitalized for brain clot: acute thrombosis of the left transverse sinus, left sigmoid sinus and upper left internal jugular vein cerebral sinus venous thrombosis for 6 days. The patient was treated with Heparin and Coumadin. The event resulted in: doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event), disability or permanent damage. The patient received the second dose of bnt162b2 on an unspecified date (reported as 18Mar2021; pending clarification), lot number: EN6204, on right arm. The patient was recovering from the event. The patient was not diagnosed with COVID prior to vaccination. Patient has not been tested for COVID post vaccination.; Sender's Comments: Based on the current available information, the events occurred prior to BNT162B2 administration (this information need be clarified). The reported events are considered as an intercurrent or underlying condition which is not related to the suspected drug at this time. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of

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aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

1235815 4/21/2021 FL

53 M

3/11/2021

3/25/2021

stroke; Brain bleed; Brain blood clot; This is a spontaneous report from a contactable consumer via a Pfizer sponsored program named Corporate (Pfizer) Social Media Platforms. A 53-years-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 11Mar2021 13:15 as single dose for covid-19 immunisation. Medical history reported as none. The patient's concomitant medications were not reported. The patient experienced brain blood clot on 25Mar2021 08:00 , stroke and brain bleed on an unspecified date. The patient was hospitalized for brain blood clot, stroke, brain bleed for 7 days. Therapeutic measures were taken as a result of brain blood clot, stroke, brain bleed included Ventilator. The patient died on 02Apr2021. An autopsy was not performed. The outcome of events was fatal. No other vaccine in four weeks; No covid prior vaccination. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Brain blood clot; stroke; Brain bleed

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1235823	4/21/2021	TN	68	M	1/20/2021	1/24/2021	DVT in right leg from calf to thigh; small blood clots; swollen right leg; This is a spontaneous report from a contactable consumer (patient). A 69-year-old male patient received bnt162b2 (BNT162B2; lot unknown: Not available/provided to reporter at the time of report completion), dose 1 via an unspecified route of administration, administered in Arm Left on 20Jan2021 14:00 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunization, at the age at vaccination of 68 years old. Medical history included high blood pressure from an unknown date and unknown if ongoing. No other vaccine in four weeks. Patient had no known allergies. Concomitant medications included losartan taken for an unspecified indication, start and stop date were not reported. The patient experienced dvt in right leg from calf to thigh on 25Jan2021 with outcome of not recovered, small blood clots on 25Jan2021 with outcome of not recovered, swollen right leg on 24Jan2021 10:00 AM with outcome of not recovered. Reported four days after the first vaccine, swollen right leg. Five days after the first vaccine, diagnosed with DVT in right leg from calf to thigh. Small blood clots. Events resulted in: Doctor or other healthcare professional office/clinic visit, Life threatening illness (immediate risk of death from the event). No Covid prior vaccination. No Covid tested post vaccination. Therapeutic measures were taken as a result of events included: Eliquis. Information on the lot/batch number has been requested.
1235824	4/21/2021	CA		U			blood clot; This is a spontaneous report from a contactable consumer (patient) from a Pfizer-sponsored program. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date (Lot number was not reported) at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced blood clot (life threatening) on an unspecified date. Event as reported: Patient had a blood clot due to our vaccine. The outcome of the event was unknown. Information about lot/batch number has been requested.

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1235838	4/21/2021	MN	54	F	3/21/2021	3/24/2021	<p>Extreme inflammatory response. In ER/hospitalized 5 days post vaccine; Had Angiogram, found clot in Obtuse Marginal; This is a spontaneous report from a contactable consumer (patient). A 54-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 21Mar2021 12:00 (Lot Number: EN6207), age at vaccination of 54-years-old, as single dose for covid-19 immunisation. Medical history included cardiac failure from an unknown date and unknown if ongoing, connective tissue disorder from an unknown date and unknown if ongoing. Patient was not pregnant. Concomitant medications included hydroxychloroquine sulfate (PLAQUENIL [HYDROXYCHLOROQUINE SULFATE]) taken for an unspecified indication, start and stop date were not reported; isosorbide mononitrate (IMDUR) taken for an unspecified indication, start and stop date were not reported; metoprolol (METOPROLOL) taken for an unspecified indication, start and stop date were not reported; rosuvastatin calcium (CRESTOR) taken for an unspecified indication, start and stop date were not reported; furosemide (FUROSEMIDE) taken for an unspecified indication, start and stop date were not reported. The patient previously took codeine and experienced hypersensitivity. The patient experienced extreme inflammatory reaction on 24Mar2021 at 04:00 AM and clot blood on 24Mar2021; events were serious as resulted in Emergency room/department or urgent care, hospitalization (for 5 days), life threatening illness (immediate risk of death from the event). The patient had extreme inflammatory response; in ER/hospitalized 5 days post vaccine. Angiogram was performed and clot in obtuse marginal was found; unable to remove clot, surgeon was able to break it apart and balloon the vessel open. It was unknown if patient had COVID prior vaccination. Patient had no other vaccine in four weeks. Sars-cov-2 test was negative on 15Apr2021. The patient was considered to be recovering from the events.</p>

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1236051	4/21/2021	OR	67	M	4/9/2021		DIZZINESS; FEELING HIGH; WEAKNESS; This spontaneous report received from a patient concerned a 67 year old male. The patient's weight was 167 pounds, and height was not reported. The patient's past medical history included blood clots, and concurrent conditions included flu shot and weed smoker. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 042A21A, expiry: UNKNOWN) dose was not reported, administered on 09-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 09-APR-2021, the subject experienced dizziness. On 09-APR-2021, the subject experienced feeling high. On 09-APR-2021, the subject experienced weakness. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from dizziness, and weakness, and the outcome of feeling high was not reported. This report was non-serious.

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1236116	4/21/2021			M			IN ICU WITH CLOTS; This spontaneous report was received from social media via a company representative and concerned a male patient of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose, start therapy date were not reported, for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient was hospitalized in the intensive care unit (ICU) with clots (date unspecified). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome for the event of clots was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: v0 This report involves a male patient of unspecified age who received the Janssen COVID-19 Vaccine Ad26.COV2 and, after an unspecified period of time, was hospitalized in the intensive care unit (ICU) with "clots" (site unspecified). Medical history, concomitant medications, and details of the event were not reported. This case has insufficient information to make a meaningful medical assessment. The case will be assessed further when additional information is received.

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1235798	4/21/2021			F			Blood clots in legs where old injury was; This is a spontaneous report from a contactable consumer (patient). A 83-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. Medical history included patient had an old leg injury several times in the past, which was fine. The patient's concomitant medications were not reported. The patient experienced blood clots in legs where old injury was on an unspecified date with outcome of unknown. Received call from consumer who stated she had a speech impediment. She was calling about the Pfizer COVID vaccine. She had the 1st shot. She had an old leg injury several times in the past, which was fine. This time it had big blood clots that appeared since the vaccine. She was afraid to go for second shot. She would like some guidance about getting second shot because she was afraid to go get it. Unable to confirm if speech impediment was prior to receiving vaccine or after. No further details provided. Information on the lot/batch number has been requested.

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1236146	4/21/2021	OH	22	F		4/7/2021	ELEVATED D-DIMER; SHORTNESS OF BREATH; COLD; GOT SICK; This spontaneous report received from a parent concerned a 22 year old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 205A21A expiry: UNKNOWN) dose was not reported, administered on 07-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, the subject experienced shortness of breath. On 07-APR-2021, the subject experienced cold. On 07-APR-2021, the subject experienced got sick. On 09-APR-2021, the subject experienced elevated d-dimer. Laboratory data included: Fibrin D dimer (NR: not provided) elevated levels of 0.6. On 09-APR-2021 15:30, Laboratory data included: CT scan (NR: not provided) negative for blood clots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the cold, got sick, shortness of breath and elevated d-dimer was not reported. This report was non-serious.; Sender's Comments: V0: Medical assessment comment not required as per standard procedure as case assessed as non-serious.



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1236188	4/21/2021	AZ		F			LUMP AT THE INJECTION SITE (QUARTER SIZE OR BIGGER LUMP); DISCOMFORT AT INJECTION SITE; ARM/HAND NUMBNESS; This spontaneous report received from a patient concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's concurrent conditions included factor v leiden mutation. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805020, expiry: UNKNOWN) dose was not reported, administered on 22-MAR-2021 for prophylactic vaccination. Concomitant medications included rivaroxaban for pulmonary embolism bilateral lungs, and deep vein thrombosis right side. On an unspecified date, the subject experienced lump at the injection site (quarter size or bigger lump), discomfort at injection site, and arm/hand numbness. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the lump at the injection site (quarter size or bigger lump), discomfort at injection site and arm/hand numbness was not reported. This report was non-serious.

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1235566	4/21/2021	MT	67	M	3/30/2021	3/31/2021	<p>Suffered an anaphylactic reaction and I was taken by ambulance to the Emergency Room; Diarrhea; Nausea; Headache; Myalgia; Fever; Fatigue; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of ANAPHYLACTIC REACTION (Suffered an anaphylactic reaction and I was taken by ambulance to the Emergency Room) in a 67-year-old male patient who received mRNA-1273 (batch no. 002A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 (Was hospitalized with Covid in February 2021) on 01-Feb-2021, Deep venous thrombosis NOS (Ended up with Deep Venous Thrombosis in the hospital) and Thrombophlebitis. On 30-Mar-2021, the patient received first dose of mRNA-1273 (Intramuscular) 1 dosage form. On 31-Mar-2021, the patient experienced HEADACHE (Headache), MYALGIA (Myalgia), PYREXIA (Fever) and FATIGUE (Fatigue). On 07-Apr-2021, the patient experienced DIARRHOEA (Diarrhea) and NAUSEA (Nausea). On 13-Apr-2021, the patient experienced ANAPHYLACTIC REACTION (Suffered an anaphylactic reaction and I was taken by ambulance to the Emergency Room) (seriousness criteria medically significant and life threatening). On 01-Apr-2021, PYREXIA (Fever) had resolved. On 12-Apr-2021, NAUSEA (Nausea) had resolved. At the time of the report, ANAPHYLACTIC REACTION (Suffered an anaphylactic reaction and I was taken by ambulance to the Emergency Room), DIARRHOEA (Diarrhea), HEADACHE (Headache), MYALGIA (Myalgia) and FATIGUE (Fatigue) outcome was unknown. Not Provided The action taken with mRNA-1273 (Intramuscular) was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company comment: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.</p>

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1239004	4/21/2021	MD	74	M	2/27/2021	4/13/2021	deep vein thrombosis (DVT) and pulmonary embolus (PE)
1238678	4/21/2021	MI	25	F	3/25/2021	3/27/2021	Adverse event: Ischemic Colitis most likely from a blood clot Symptoms: stomach pain -> severe diarrhea -> diarrhea of only blood, no stool for 24 hrs Symptoms began Saturday after vaccination (which was administered Thursday afternoon) Treatment: hospitalization, steroids, antibiotics
1238703	4/21/2021	AZ	53	F	4/4/2021	4/6/2021	Severe headache that persisted for 10 days following vaccine. CT Venogram was negative for sinus thrombosis.
1238821	4/21/2021	WA	74	F	2/17/2021	2/25/2021	Breathing problems starting Feb 25th, approx 2PM, escalating until Mar 1st when patient went to Walk-In Clinic for immediate care. Her oxygen saturation level was found to be in the upper 80's percentage. Was then taken by ambulance to Hospital and given oxygen. At hospital she was given a blood thinner drip. Also performed CT scan and found blood clots in her lungs. She was released to return home approx 24 hrs later with blood thinner pills (Eliquis) and at-home oxygen generation. These were necessary for approx two weeks until her O2 levels returned to normal without supplemental O2.
1238905	4/21/2021	GA	56	F	4/14/2021	4/16/2021	right upper extremity partially occlusive subclavian deep venous thrombosis
1238916	4/21/2021		60	F	3/6/2021	4/14/2021	Pt has a history of DM2, HTN, HLD, HCV cirrhosis (sp treatment, Child Pugh A), CKD3 with baseline Cr 1.5 who presented to the ER after a syncopal episode and with headaches. She has no history of a positive COVID test. She reported receiving the J&J vaccine on 3/6 and reports headaches since then. She also had a syncopal episode that prompted her presentation to the ED. She underwent MRV of the brain looking for sinus thrombosis. The brain portion was normal but she was found to have a LIJ thrombus. She denies prior history of VTE. It is overall unclear if this thrombus is related the her symptoms, to the vaccine, or completely incidental. Pt was started on a heparin drip in the hospital...

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1238918	4/21/2021	VA	33	F	4/10/2021	4/18/2021	Patient developed unexplained bilateral bruising behind both knees eight days following vaccination. Does not have a history of bruising so visibly nor a history of blood clots. Bruises started off very red, slightly itchy and scattered. Over the next few days, the bruises darkened purple and merged closer together. Bruising was much more severe on the left leg than the right. Bruising has become less apparent over time.
1238925	4/21/2021	NC	47	M	3/16/2021	4/15/2021	Pt experienced pain/cramping in his right leg on or about 4-15-21. Thought this was due to new work shoes. Pain continued through the weekend and on Monday 19th visited his PCP where a scan was preformed confirming a clot in his right leg between his thigh and ankle. Pt started on therapy and has a follow up with his physician on Friday 23rd. Pt doing well and in good spirits.
1238583	4/21/2021	MS	70	F	3/31/2021	4/6/2021	States she developed leg pain 6 days after shot and didn't think it was anything to worry about until she saw the J&J blood clot news and decided to get checked. Had appt and ultrasound on 4/19/2021 with NP. Found to have two non-occlusive, small blood clots in the right leg.
1239001	4/21/2021	CO	57	M	3/22/2021	4/21/2021	Day following shot it felt flu like, days following shortness of breath, stopped to rest and catch breath. 04/04/21 after getting coffee in hotel I could not regain my breath, became pale, sweaty and chilled. Was taken to emergency room, given oxygen and CT was taken of lungs, CT showed numerous blood clots throughout lungs with two larger at the bridge between, one on either side. Was give oxygen to help breathing, given Heparin to stop clot growth and T___ (something) to dissolve clots. Morning 04/05 was taken off oxygen and that evening clot medication was removed. Discharged morning 04/06 and put on Eliquis and to be reevaluated in three months by PCP. Sometime in the spring of 2020 I was asymptomatic for COVID, it was not until June last year until I knew after donating blood and it was test for COVID antibodies and I was positive.

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1239026	4/21/2021	CA	51	F	4/9/2021	4/9/2021	Felt slightly dizzy or "woozy." It came and went for about 45 minutes as I sat in my car in the parking lot after vaccination. After about an hour, it completely subsided and I didn't feel dizziness anymore. I did not receive any treatment for this. Also, on the fourth day after vaccination (April 13), I felt pressure/tightness in my chest. Because the blood clot cases had been publicized, I called my doctor, who advised me to go to the emergency room of our local hospital. They gave me an EKG, which looked fine, and said they thought the tightness might be related to my asthma (although that is not a symptom I have ever felt with my asthma before, which usually manifests as slight wheezing). The chest tightness lasted about two days and then went away completely without treatment.
1239051	4/21/2021	NM	63	F	3/1/2021	4/1/2021	2 weeks and 2 days after receiving the vaccination I had a blood clot blown from my nose no before issues with a bloody nose and not after it was a large blood clot there was not any continued bleeding before or after. Also where the shot was given is still sore in that area and does not seem to get better this is my right arm I am exercising and not any improvement.
1237543	4/21/2021	OR	37	F	4/7/2021	4/7/2021	Patient developed palmar digital vein thrombosis in 4th digit of left hand
1239125	4/21/2021	NE	67	M	4/12/2021	4/21/2021	Patient admitted with DVT, acute occlusive venous thrombosis in the left posterior tibial and peroneal veins.
1239231	4/21/2021	FL	54	M	4/7/2021	4/17/2021	I went to the ER on 4/17/21. Had Pulmonary Embolism in both lungs. I was in the hospital 3 days. I have no personal history of blood clots and no family history of blood clots. Now I must be on blood thinners the rest of my life, because the science does not know? I understand from the doctors that 4 out of 1,000,000 cases are happening with the Pfizer vaccine. Why is this information not being released to the public? I almost died from the Pfizer vaccine and am not permanently disabled by it.
1239772	4/21/2021	WA	67	F	1/30/2021	4/9/2021	After an arterial catheterization, a blood clot developed in my forearm, about an hour later.

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1239782	4/21/2021	IL	60	M	3/10/2021	4/13/2021	Tues 4/13/21- Headache and dizziness started about 4p. Wed 4/14/21- Could not go to work because of headache and dizziness. Made appt for 4/15 at 6:45a with Dr Thur 4.15/21- Awoke with intense headache and dizziness. Ready to go to appt but emergency room called at 6:37 to switch to a Virtual appt. I never received a call so I walked to the office. They told me they would not see me as I had Covid 19 symptoms. Went to airport and received a Negative Covid test. Went o Clinic and was diagnosed with fluid in the ears and a sinus infection. Went to work and only stayed 2 hours. Drove myself to the emergency room with weakness, shortness of breath and intense pain under the sternum. Diagnosed with a blood clot in the right ventricle. The cardiac cath lab removed it. Was in intensive care Thur-Sat.
1240013	4/21/2021	MN	80	M	2/9/2021	2/11/2021	not feeling well and short of breath on 2/11/21, 2/12/21 more short of breath ambulance came. Went into PEA in ambulance with CPR. They gave TPA for suspected blood clot. He initially improved. He did not recover and died 4/4/21. He spent the entire time in hospital or TCU with complications. We brought him home 4/2 to die at home.

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1236057	4/21/2021		53	F		4/10/2021	BLOODY NOSE WITH CLOTS; COULD NOT SLEEP WELL; FLU LIKE SYMPTOMS; INJECTION SITE DID NOT LOOK NORMAL; EXCRUCIATING SHARP PAIN AT BOTTOM OF FEET; BREATHING CHALLENGES; This spontaneous report received from a patient concerned a 53 year old female. The patient's weight was 110 pounds, and height was 155.448 centimeters. The patient's past medical history included influenza virus, and suspected covid-19. The patient was previously treated with influenza vaccine for prophylactic vaccination. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 203A21A expiry: UNKNOWN) dose was not reported, administered on 09-APR-2021 18:00 for prophylactic vaccination. No concomitant medications were reported. On 10-APR-2021, the subject experienced breathing challenges. On 10-APR-2021, the subject experienced flu like symptoms. On 10-APR-2021, the subject experienced injection site did not look normal. On 10-APR-2021, the subject experienced excruciating sharp pain at bottom of feet. Laboratory data included: Body temperature (NR: not provided) 101 unit unspecified, 102.3 unit unspecified. On 11-APR-2021, the subject experienced bloody nose with clots. On 11-APR-2021, the subject experienced could not sleep well. Treatment medications (dates unspecified) included: naproxen sodium, and paracetamol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from breathing challenges, flu like symptoms, and injection site did not look normal, had not recovered from could not sleep well, and the outcome of bloody nose with clots and excruciating sharp pain at bottom of feet was not reported. This report was non-serious.; Sender's Comments: V.0 Medical assessment comment not required as per standard procedure as case was assessed as non-serious.
1238958	4/21/2021	MD	67	M	3/29/2021	4/2/2021	acute deep vein thrombosis (DVT) and pulmonary embolus (PE)
1237936	4/21/2021	CO	46	F	4/8/2021	4/13/2021	Blood clot in right arm , SOB, CHEST PAIN, arm pain,

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1239122	4/21/2021	NV	47	M	3/31/2021	4/17/2021	Chief complaint of worsening lower leg pain. Initially the patient thought that he had pulled a muscle however he had complaints of claudication upon ambulation. Patient reports having J&J COVID vaccination approx 2.5 weeks prior. Patient reported his friend informed him that he might potentially have a blood clot and that he should come to the emergency department. Imaging consistent with acute DVT and patient taken to IR for tPA direct catheter infusion.
1238513	4/21/2021	WA	37	M	3/10/2021	4/16/2021	Bilateral pulmonary thrombosis; hospitalized 2 day, given IV anticoagulant;
1237550	4/21/2021	MI	43	F	4/5/2021	4/16/2021	Cavernous sinus thrombosis per CT
1237551	4/21/2021	GA	65	F	2/3/2021	4/2/2021	Blood clot in Right leg and bilateral lungs. Patient also reported headache for >1 week, fatigue, shortness of breath and blood pressure that elevated above 210 systolic.
1237632	4/21/2021	GA	48	M	3/15/2021	3/19/2021	Foot and ankle swelling 4 days after 1st injection, which is ongoing. Visit to vein doctor on 4/15 and diagnosed with blood clot in left ankle. Put on blood thinners and told to wear compression socks.
1237704	4/21/2021	MT		F	3/10/2021	3/25/2021	Death, blood clots in liver
1237947	4/21/2021	CA	65	F	4/1/2021	4/12/2021	Patient admitted 4/12/21 with fatigue and abdominal pain. Found to have UTI but no definite sepsis, and acute renal failure. Treated with iv antibiotics and iv fluids. Over next 48 hours developed worsening encephalopathy and thrombocytopenia. MRI/MRA/MRV showed no acute findings. Hyperammonemia noted, with no known Hx of cirrhosis; US did not show portal vein or hepatic vein thrombosis. Encephalopathy worsened, no clear etiology; EEG just showed generalized encephalopathy. Renal function worsened. Patient became obtunded and was intubated 4/16/19. Platelet nadir of 31k. Dialysis started. Left common femoral DVT developed. Patient had DIC type picture. Respiratory failure worsened, hypotension developed, patient passed away 4/20/21. No clear etiology of encephalopathy and thrombocytopenia identified, unclear if related to J&J vaccine received 2 weeks prior.



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1237959	4/21/2021	ID	62	M	3/12/2021	3/19/2021	Superficial vein thrombosis in left thigh that was reported to a primary care provider on 3/19, 6 days after the vaccine was given.
1238060	4/21/2021	NV	62	F	4/9/2021	4/9/2021	4-9-21 vaccination Later that evening, I basically feeling 'outside of myself' like my 'spirit left my body'. Took me a week to feel like myself. I had the headaches, felt sluggish, lethargic for a week. I was unable to do normal daily activities. I went to see my PCM on 4-12-21. He did some medical tests / labs. Results were negative for clots. They said I have a cyst on the back of my leg. Waiting on results of my MRI. *HA are ongoing.
1238450	4/21/2021	MN	37	F	4/9/2021	4/12/2021	Thrombosed Hemorrhoids. Extreme pain, bleeding. Went in to urgent care after 3 days and they cut them open to remove blood clots. There was no clear event that triggered these to appear.
1238510	4/21/2021	WI	26	F	4/9/2021	4/11/2021	On Sunday morning i woke up to my left arm being swollen, red, hot to the touch. Over the course of the next few days the swollen part got bigger to the size of a baseball Tuesday I called my doctor and they wanted me to get seen right away at the ER. They did an ultrasound right away and they ruled out a blood clot and an abscess. They figured it would just be an infection. They put me on an antibiotic for 7 days up to 4x a day. Today 4/21 I took my last dose of the 7 days. Called my doctor and they are starting me on another 5 days of antibiotic to get rid of this infection in my arm. It is now down to a quarter size or a little bigger. Hoping that in the next 5 days it will be completely gone. I don't have the redness and heat anymore just a smallish lump.
1237651	4/21/2021	ID	53	M	3/26/2021	4/14/2021	Possible cerebral venous sinus thrombosis
1238488	4/21/2021	MD	81	F	3/14/2021	3/28/2021	Patients daughter reported her mother had a stroke (cerebral thrombosis). Patient was admitted to hospital on 3/28/21. Patient has surgery and was admitted to the ICU. Patient also has rehabilitation. Patient is currently recovering at home .
1238061	4/21/2021	PA	39	F	3/18/2021	4/21/2021	Blood clot

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1238403	4/21/2021	MI	78	M	2/6/2021	3/1/2021	Paitent had a stroke for no identifiable reason. They saw little bloodclots in his brain. Because he has heart stints, the doctors at the hospital said everything that prevents strokes was already being done for him. They had a heart monitor placed in his chest and today the cardiologist read the results. There is nothing in his heart that would cause the clots. Blood clots are not part of his family health history. The only thing "different" during the time previous to the stroke was the covid shots. Just reporting in case it is part of a trend. He hd mobility issues and had to be in physical therapy for a few weeks. His balance is still weak.
1238361	4/21/2021	GA	79	F	1/19/2021	3/1/2021	Blood clots

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1238341	4/21/2021	FL	64	F	4/7/2021	4/17/2021	<p>Patient claims "3 days" after vaccination she developed headache that worsened over the next two days to include dizziness, photophobia, scotomata. However, the state tracking system lists her date of vaccination 10 days prior to the symptom onset. Below is a more detailed description: This is a 64-year-old female nurse practitioner with coronary artery disease, uncontrolled (untreated) type 2 diabetes, obesity, and remote history of kidney donation who presented yesterday with a 5-day history of nausea and frontal headache with new recent dizziness /lightheadedness when standing. She describes her headache as starting out as temporal and periorbital and then persisting as a frontal discomfort radiating to the back and down the neck. Associated with this were complaints of blurry vision, photophobia and scotomata. She denies any focal weakness or numbness/tingling. There was no vomiting or reports of seizures. She denies no recent problems finding words or bouts of confusion. She denies a history of arrhythmia or palpitations. Patient received the first dose of the Moderna COVID-19 vaccination on 4/14/2021 into her right arm, 5 days prior to admission (But state records list 4/7/2021 as the date). She did not take any medication to pre-empt side effects such as NSAID, aspirin, H2 blocker, or Tylenol. Initially she developed a sore arm the night of the vaccination. Three days later the headache developed that did not respond to Tylenol PM although it helped her sleep. She noted taking more than the recommended dose and had mouth dryness. Patient denies any past history of COVID exposure and any illness c/w COVID where she was not tested. She has never had her antibody titer checked. She recently had a dental procedure for an exposed nerve and had a temporary filling placed. No antibiotics were given and denies having a dental abscess. She described that one of her sisters developed "blood clots from her heart due to atrial fib" after her Pfizer vaccination. She denies rashes or stigmata of endocarditis, no fevers, chills, or night sweats. She describes vaginal itching a few days ago and self treated with an anti-yeast cream (Monistat) that relieved symptoms and does not currently have dysuria, frequency or urgency. On admission, her UA was abnormal and culture is pending but she received one dose of Rocephin and is still without urinary symptoms. After admission CT scan and MRI of the</p>

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brain revealed focal areas of likely small subacute embolic infarcts. (See report) Since admission she had a reassuring ECHO and no further worsening. No evidence for A flutter or fib Review of Systems Constitutional: no fever, no chills, no sweats, mild General weakness Skin: no Jaundice, no rash, no lesions, no petechiae ENMT: no ear pain, no sore throat, moderate congestion, no hoarseness Respiratory: no shortness of breath, no cough, no orthopnea, no wheezing Cardiovascular: no chest pain, no palpitations, no edema Gastrointestinal: mild nausea, no vomiting, no diarrhea, no GI bleeding Genitourinary: no dysuria, no hematuria, no discharge, no pain Musculoskeletal: no back pain, no trauma; Some neck discomfort bilaterally R>L Neurologic: moderate headache, mild dizziness, no numbness, mild weakness Psychiatric: mild sleeping problems, no irritability, Describes herself as high strung type A Heme/Lymph: no bleeding tendency, no bruising tendency, no petechiae, no swollen nodes Allergy/Immunologic: moderate seasonal allergies, no food allergies, no recurrent infections, no impaired immunity Additional ROS info: Except as noted in the above Review of Systems and in the History of Present Illness all other systems have been reviewed and are negative or noncontributory Problem List/Past Medical History 1) Uncontrolled diabetes with a hemoglobin A1c greater than 11; She stopped metformin and has tried to control it with diet alone. She does not have a PCP 2) Coronary artery disease with 4 stent placements in 2017; noncompliant with aspirin 3) Hyperlipidemia on Crestor 4) History of kidney donation to her late husband. She reports a stable creatinine 5) Obesity with a BMI of 34.8 Physical Exam Vitals & Measurements T: 36.4 °C (Oral) TMIN: 36.4 °C (Oral) TMAX: 36.5 °C (Oral) HR: 86(Peripheral) RR: 18 BP: 115/72 SpO2: 92% WT: 92.4 kg General: alert, no acute distress Skin: warm, dry Head: no trauma, normocephalic Neck: Trachea midline, no adenopathy, no tenderness; No bruits Eye: normal conjunctiva, sclera clear Cardiovascular: regular rate and rhythm, normal peripheral perfusion. No carotid bruits Respiratory: Lungs CTA, respirations non labored Chest wall: no deformity Gastrointestinal: non distended, Extremities: no deformity, no trauma Neurological: oriented x 4, LOC appropriate for age, CN

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1238230	4/21/2021	OR	46	F	4/12/2021	4/12/2021	<p>II-XII intact, motor strength equal &amp; normal bilaterally upper extremity, sensation equal &amp; normal bilaterally, speech normal Psychiatric: cooperative, affect appropriate for age, normal judgement, normal psychiatric thoughts Assessment/Plan This Visit Diagnosis 1. ASB (asymptomatic bacteriuria) R82.71 - No antibiotic treatment recommended - Do not act on pending urine culture 2. Embolic cerebral infarction I63.40 - Unclear source as echo was clear; no stigmata of endocarditis - No carotid study as of yet - She has multiple risk embolic stroke (DM, age, hyperlipidemia, smoking, obesity) - Unclear if COVID vaccine initiated this process (has a low threshold for a cerebral event) - There are no national reports regarding this type of side effect in an mRNA vaccine 3. Adverse effect of viral vaccines T50.B95A - Received COVID Moderna vaccine and symptoms developed 3 days later - Unclear if vaccine cause symptoms 4. Diabetes mellitus E11.9 - Poorly controlled with Hbg over 11 5. Body mass index (BMI) of 38.0 to 38.9 in adult Z68.38 - Current weight 92.4 kg 6. Tobacco use Z72.0 - Small amount 7. H/O unilateral nephrectomy Z90.5 - Creatinine is currently 6.0 Plan: * I will report the possible vaccine adverse event to the national system (VAERS) - This was shared with the patient and she can also file a report - Recommend that the sister also file a VAERS report * Await neurology opinion regarding carotid studies * No further antibiotics since she has no symptoms</p> <p>I had reaction right away five minutes afterwards drowsy and metallic taste in mouth and :30 observation and extremely fatigue and a neck pain and 4-5 pain level issue 04/12/2021 04/13/2021. Doctor phone and recommended ER and next day tired and off and fatigue and felt off and went to urgent care 04/16/2021 and fever and blood pressure electro cardio gram and for stroke and heart and stroke and clots and no symptoms for clots results was good and not able to sleep and Friday was extremely exhausted and neck pain and fever and medication. Fatigue and fatigue come and Motrine or Tyler. Still have neck pain and fatigue that comes and go not recovered.</p>

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1238201	4/21/2021	TX	42	F	2/4/2021	4/7/2021	On 4/7/21 patient was unable to go to work due to fatigue. She was sent home from a free-standing ER who reported she most likely had a viral illness. She passed out getting into the bathtub and presented to Hospital. At this hospital her chief complaints were excessive fatigue, myalgia, fever, chills. She was diagnosed with TTP with portal venous thrombosis. She was refractory to high dose steroids, plasmapheresis, and rituximab x2. She is now set to begin treatment with caplacizumab and is currently on day 12 of hospitalization.
1233380	4/20/2021	MN	61	M	3/4/2021	3/9/2021	Client's wife called and reported that client had a heart attack 5 days after receiving the vaccine. He also had blood clots.
1233671	4/20/2021	FL	75	F	2/1/2021	3/1/2021	Developed increased weakness and was admitted to Hospital. Was treated with plasmapheresis and during treatment developed acute psychosis and paranoid delusions. Was transferred to the Geriatric Psychiatry Unit at Hospital in for further treatment. Around a week into that admission, she had a dramatic neurologic change and was found to have extensive dural vein thrombosis with ischemic and hemorrhagic events. She was started on heparin drip and sent to Unit for thrombectomy that was unsuccessful. She is currently intubated and comatose with plans for compassionate withdrawal of care soon. Family wanted this sequence of events to be related to the appropriate authorities to investigate if there is any link to the initial vaccination.

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1233094	4/20/2021	FL	75	M	4/8/2021	4/8/2021	It started with a familiar reaction and that was I had tingling and pain in my feet it started with both feet and it was significant, like when the feet goes to sleep and it is coming back and you feel the pins and needles feeling, and it was exactly what I get with CIDP. It moved from both feet up to both hands and I was not really afraid because that is what happens with CIDP when your auto immune system is stimulated. I get numbness on my feet and in my hands. I thought that the vaccine stimulated my immune system. The CIDP has been in remission and maybe the shot has stimulated my nervous system. The other day I noticed that when taking the hot plate from the microwave it was hot but I did not feel it at all. I thought the food has not heated up, when my wife touched the plate she said it was very hot and I did not feel the plate hot at all. I also felt pain in my left foot to a point that I am not ambulatory. The pain is so extreme in my left foot if I try to stand up. I have been in my bed for the last 2 days. I am not sure if it is the CIDP or GOUT that is attacking my foot but it has been triggered by the vaccine. I also have severe pain in my left leg. I called my cardiologist and I have a phone consultation with him today to check for clot formation. The pain has subsided a bit today, but yesterday the pain in my leg was very intense. I also had pain at the injection site and felt a little feverish since yesterday around 3PM and it went to 101F and this morning I am fine again. I did not take anything for it and this morning I woke up and I felt well (in regards to the fever). I did not have fever before then.
1233017	4/20/2021	NC	29	F	3/8/2021	3/27/2021	Patient developed a cerebral venous sinus thrombosis diagnosed on 3/27/21 after receiving the moderna covid vaccine on 3/8/21
1233121	4/20/2021	MN	58	M	3/12/2021	3/22/2021	Received shot on 3/12. Starting having pain in chest on 3/22. Was diagnosed with blood clots in the lungs on 3/26 via blood test and CT scan.
1233144	4/20/2021	NH	48	F	3/28/2021	4/1/2021	Blood clot in the Right arm, s/s started 48 hours after first shot in the series.

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1233196	4/20/2021	MA	20	M	3/12/2021	3/20/2021	Admission HPI: Right-sided chest pain began 2 days prior to admission (3/19) after getting out of car, without identifiable trigger. Pain was sharp, pleuritic, and worst with movement; didn't feel it when still. Pain not responsive to ibuprofen or heating packs. Reported 30-60 seconds of self-resolving heart racing during ocular migraine which has been his baseline for years. Not associated with SOB (at rest or with exercise), palpitations, presyncope, or syncope. No viral URI symptoms, N/V, or rash. He did receive his 2nd Moderna COVID vaccine about 1 week PTA, followed by 36hrs of fevers, chills, and body aches. Given persistence of pain, Patient asked his parents to present to urgent care. In UC, he was noted to tachycardic with CXR with bibasilar atelectasis and b/l effusions, per report. Given continued tachycardia, decision was made to transfer to ED to r/o PE. In ED, tachycardic to 104-116 and tachypneic 22-26. Had one episode of tachycardia to 182 iso ocular migraine. Endorsed chest pain but points to R middle abdomen when asked where worst. Exam was unremarkable. He received 1 dose of morphine which reduced pain from 10/10 to 0/10. Labs notable for leukocytosis (14.61), thrombocytopenia (422), elevated d-dimer (1.56), and elevated CRP (5.6). Otherwise normal chem and coags. COVID/RVP negative. CXR unremarkable. CTPA showed scattered PEs in b/l lower lobes with small pulmonary infarct in RML. No evidence of right heart strain. Heme was consulted who recommended starting him on lovenox and sending lupus anti-coagulant. Cardiology was consulted who recommended EKG, BNP, and troponin, all of which were normal and reassuring against right heart strain. ECHO was therefore deferred to the AM. The decision was made to admit. Upon arrival to the floor, Patient was tachycardic 114 and tachypneic to 22, otherwise stable vitals. He denied any pain since morphine. Denied any unexpected weight loss; reports that car ride was short. Mom reports that Patient has been less active d/t cold weather and baseball being on hold. Denies family or personal history of clots. Last seizure ~13 years ago. Hospital Course: (3/21 - 3/22) Patient was admitted to the hematology service. He was therapeutically anticoagulated with LMWH injections and his anti-Xa level prior to discharge was 0.92. (goal 0.5-1.0) Lower extremity ultrasound with Doppler showed patent veins



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							and no evidence of DVT and upper extremity ultrasound showed no evidence of DVT, though there was potential evidence of collateralization seen in mid and distal third of right subclavian vein and left internal jugular vein. Since this was an unprovoked PE, a full thrombophilia workup was sent and will be followed up by the outpatient hematology clinic. Cardiology consulted regarding possibility of right heart strain and the tachycardia during migraine episodes. Echocardiogram performed on 3/22 was technically limited but showed no gross abnormalities. The cardiology team requested a repeat echo scheduled outpatient for 1-2 months after discharge.
1233202	4/20/2021	KY	54	F	3/10/2021	4/1/2021	Patient states that while vacationing, 3 weeks and 1 day after receiving her Janssen vaccine, she woke up at 8:30am with numbness in her left foot. When attempting to stand she fell to floor. After checking her blood pressure and blood sugar she took 2 tylenol and sat down to rest. Around 10:30am she began to have numbness in her left hand and on the left side of her face. She was taken by ambulance at that time to Hospital. While there they ran a number of tests and scans diagnosing her with have a stroke caused by a small blood clot in right side of her brain. She was admitted to the hospital and was not discharged until 4/3/2021. Upon returning home, she has been seeing her PCP, APRN and a neurologist. She has since been released on 4/19/2021 to go back to work and has no residual side effects from stroke. She states she is now on blood pressure and cholesterol medication and is taking a daily baby Aspirin.
1233280	4/20/2021	AL	35	M	3/25/2021	4/12/2021	left calf pain , swelling and redness, patient reports stating one week prior to being seen in the clinic on 19April2021, Patient was diagnosed with acute Embolism and Thrombosis of left popliteal Vein and started on Eliquis

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1233331	4/20/2021	GA	68	F	3/19/2021	4/3/2021	Client reported shortness of breath and chest pain 2 weeks after receiving second Pfizer COVID vaccine. She was transported to the hospital and received an EKG and a CT Scan of the chest. Patient reported that the scan showed large blood clots in both lungs. She reports that she was given high dose TPA and admitted to the ICU. Per client she had ultrasound of legs, arms, and groin which was negative. She is currently taking Eliquis and was discharged from the hospital on 4/6/2021. #Hospital for 3 days
1233356	4/20/2021	NE	50	F	4/19/2021	4/20/2021	Blood clot in left nasal cavity
1233116	4/20/2021	CT	36	M	4/6/2021	4/11/2021	Leg pain, pressure headaches and chest tightness resulting in ER visit 4/12. Attending physician noted no visible signs of clots. Occasional shortness of breath and brief bursts of dizziness and nausea (not necessarily together) persist, as do minor headaches.
1233450	4/20/2021	MS	50	M	3/19/2021	4/1/2021	A week and a half after taking the Janssen COVID shot I had a knot and pain come up in my lower back. After going to the chiropractor two times the knot and pain ended up in my right leg. I then went to Urgent Care where they diagnosed me with a large blood clot. They sent me to imaging and after scanning the area confirmed that there was a blood clot in my right leg. Urgent Care then set me up with a specialist.
1233469	4/20/2021	OH	51	F	3/16/2021	3/21/2021	About 5 days after initial vaccine I began a period that was the heaviest I had ever had. After 10 days I contacted my Dr. who ordered blood work. Did blood work on 4/5, by this time period had finally slowed to spotting. Had 2nd vaccine on 4/6 and immediately started bleeding heavily again and about 4 days in had four or five clots the size of half dollars or larger. Saw Dr. on 4/14 and ordered another blood test and was prescribed iron pills for anemia. As of the date 4/20, I am still bleeding with no signs of stopping.
1233502	4/20/2021	CO	63	M	3/12/2021	4/10/2021	Abdominal pain, Portal Vein Thrombosis (Blood clots in veins to the Liver, Spleen and Large Intestine) Treatment - Heparin drip and then converted over to the blood thinner Xarelto Recommended that I follow up with my primary care physician and seek the advice of a Hematologist

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1233510	4/20/2021	MN	46	F	4/8/2021	4/19/2021	Death. Multiple pulmonary thrombi.
1233528	4/20/2021	NJ	45	F	4/9/2021	4/13/2021	I had a deep purple bruise the size of a quarter on my right arm a few days after taking the Janssen vaccine. I did not injure myself or bump into my right arm so I was baffled about how I got the bruise. I also experienced weird sensations in the muscle of my left calf on two occasions a few days within my vaccine. They felt like muscle contractions and the muscles quivered and I thought I was getting a charlie horse, but they were not painful or unbearable. The quivering lasted about 10-30 seconds. I've never had any sensation like this in my calf before. All of this coincided with me hearing news about the blood clots and deaths associated with the J&J vaccine shortly after I took the jab. Initially, I brushed it off and talked myself out of any connection between the vaccine and my symptoms. I was talking with family & friends recently and they suggested I report my symptoms so that's I why I'm reporting now 11 days after my vaccine.
1233567	4/20/2021	CA	70	F	2/11/2021	2/19/2021	I was diagnosed with Covid-19 on 12/02/2020 which was six weeks before my first dose of the vaccine on 01/21/2021. I also tested positive on 12/16/2020. I started to have a lot of problems with my legs. I had a lot of pain in my right leg. I was also very short of breath. It was excruciating pain at the top of my right thigh. I have been a runner in the past so this is unusual for me. I have a blood clot that was found on a scan with contrast. I have seen an ENT, Neurologist, Cardiologist, Orthopedist and Hematologist. I am also a cancer survivor of Non-Hodgkin's Lymphoma. I have been prescribed Eliquis and taking it for one week and the pain has improved.
1233582	4/20/2021	WA	43	M	2/16/2021	2/18/2021	The same day, I was exhausted. It lasted 2 days. After that, on the 2nd or 3rd day after my shot, my right calf began to hurt. I knew it was connected to the vaccine, but I figured it would go away. Once the information came out about blood clots and my calf still hurt and didn't get better, I decided to go and get it checked out.

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1233627	4/20/2021	NY	57	F	4/2/2021	4/4/2021	Deep vein thrombosis was the diagnostic from the after effects of the second vaccination. Blood cot caused leg swelling and pain They did a cat scan & MRI Treatment was being given Eliquis (4 pills a day for 7 days) (2 pills after) It is a blood thinner and must follow up with my doctor.
1233630	4/20/2021	RI	63	F	4/2/2021	4/12/2021	In the morning I noticed a pinching feeling in my lower right leg. I called my doctor to check on this. She sent me for an ultrasound of the leg on 04/15/2021. During a follow-up visit she informed me that it was a superficial blood clot and set up a second ultrasound on 04/28/2021 for confirmation that it had cleared.
1231348	4/20/2021	CA	30	M	4/7/2021	4/10/2021	Bruises on my right leg. Possible blood clot. Right leg has noticeable pain when bending and feels heavier/ different compared to my left leg.
1232940	4/20/2021	AL	53	F	3/23/2021	3/23/2021	patient had a headache, weak arm, slept a lot more, experienced pain in arm as well, and a "funny feeling" in her chest. Patient went to the ER and said they found a blood clot.
1231434	4/20/2021	CA	46	F	4/14/2021	4/15/2021	Light headedness an hor after receiving. Fatigue in same time line. Premenopausal but had just completed typical light, short menses cycle 3 days prior to vaccine. The next night memses retumed and was very heavy , clotty and accompanied by cramps. I usually dont havr cramps, and i havent had a heavy period like that for several years. Still occurring on day 5 after vaccination. Typical periods are 3 days of minimal show.
1233646	4/20/2021	TX	61	F	3/27/2021	4/8/2021	On 04/08/2021, I noticed a blistering rash on the back of my right thigh. About 4? x 2?. I went to the Dr. on 04/09/2021; diagnosis Shingles. I was given a steroid shot, Valacyclovir tablets, and Clotrimazole and Betamethasone Dipropionate Cream (1%). On 04/18/2021 I noticed new rash patches; the fronts of both thighs (6? x 4?), on my back (3? x 1?) and the backs of my hands. I returned to the Dr. on 04/19/2021 and was prescribed another round of Valcyclovir, Prednisone 20 mg tablets, Hydroxyzine HCL 50mg, Gabapentin 300 mg capsules. The rash seems to have stopped spreading as of 04/20/2021.

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1232423	4/20/2021	MA	33	M	3/28/2021	3/28/2021	03/28: At 9 PM (9 hours after shot), I rapidly experienced fatigue, fever (101 degrees), chills, aches, and slight nausea. I took my vitals during this time: SPO2 of 98-99%, BP was 123/80, and heart rate was in the mid-to-high 80s. By midnight, I felt much better and assumed everything was over. 03/29: Woke up feeling fairly tired. As I was trying to do my normal morning routine of cleaning up, taking out trash, etc. I noticed a shortness of breath. No fever or other symptoms from the night before. I checked my SPO2 levels with 3 different oximeters, and all gave readings in the 93%-94% range. My heart rate, which is usually in the 80s and 90s when moving about, was in the low 70s, bottoming at 72. This was nerve racking. This along with intermittent dizziness persisted for 24 hours. I got COVID tested and it came back negative. Flu came back negative, too. A consult with a doctor inferred that "everyone has different vaccine side effects." Not helpful. This shortness of breath/fatigue/low blood oxygen saturation continued persistently for the next 48 hours. I was essentially advised to stay home and rest. I noticed some lymph node swelling, too. By day 4, I was feeling much better. My heart rate had gone back up into the 80s, and my blood oxygen sat. had increased to 96-97%. I was still somewhat tired and got winded very, very easily. It's been over two weeks since my second shot upon writing this. I didn't want to report, but I can't make heads or tails as to why this happened. The only change in my health was taking the vaccine. I don't have any blood clots, asthma, or underlying issues. However, these side effects, if they are as such, need to be discussed. I know others who got the Moderna vaccine with similar anecdotes. The difference is, living with a clinician, I monitor my vitals all the time and knew enough to take measurements.
1231366	4/20/2021	MA	40	F	3/19/2021	3/20/2021	Migraine High blood pressure Bruises Blood clot Dizziness Nauseous Fatigue Itching Chills Muscle aches
1231390	4/20/2021	MI	93	M	2/25/2021	2/27/2021	After first shot some swelling in lower leg, after shot 2 severe swelling and blood clots both legs

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1231406	4/20/2021	CA	50	M	3/19/2021	4/12/2021	About 3 weeks after the vaccine I started having severe chest and belly aches on the right side. CT scan showed a blood clot on my lungs and pneumonia
1233670	4/20/2021	UT	81	F	3/16/2021	3/22/2021	Patient is a 81-year-old woman who last Tuesday received her second vaccination shot in her left arm. Several hours after the procedure she developed pain and discomfort in her left arm. The left arm discomfort gradually increased over the past 3 to 4 days and she began to experience symptoms of claudication in her left forearm and hand. She had a difficult time performing her daily tasks. The pain significantly worsened today to the point that she had constant pain in her hand and developed numbness in her fingers. She presented to the urgent care clinic and was subsequently transferred to the emergency room where CT angiogram demonstrates thrombus in her left brachial artery. She denies a history of heart palpitations. She has no history of hypercoagulable state. She has no history of blood clots or easy bleeding. She has no history of infection and denies fevers chills or night sweats. She has no significant history of peripheral vascular disease and can walk over a mile without difficulty. She denies symptoms of transient ischemic attacks. Left brachial ulnar and radial artery thrombectomy due to inflammation of the brachial artery and thrombus in the brachial artery extending into the origin of the radial and ulnar arteries done on 3/22/2021. Discharged on aspirin 81 mg daily and Lovenox. Has transitioned to Eliquis now. Complication of left arm wound dehiscence. Debrided by wound clinic on 4/9/2021. Taken for washout/wound closure on 4/13/2021. Continues to f/u in our clinic.
1231692	4/20/2021	NC	26	F	3/10/2021	4/6/2021	5 Blood clots coming from right nostril, headache, fatigue, stomach pains. Nose bleed with clots lasted 15-20 minutes. Headache, fatigue, stomach pains lasted throughout the day.
1233682	4/20/2021	PA	53	F	4/8/2021	4/15/2021	Blood clots developed in leg following week on Thursday. Went for treatment Monday.
1231985	4/20/2021	PA	58	M	4/7/2021	4/19/2021	pt developed symptoms on 4/19/2021 after receiving shot on 4/7/2021. Patient was admitted to hospital and discovered to have a clot in left leg. Patient is receiving Lovenox.

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1231997	4/20/2021	OK	67	M	4/1/2021	4/14/2021	He developed a blood clot in his right arm.
1232042	4/20/2021	DC	55	F	4/5/2021	4/5/2021	I received the covid vaccine at 1:30pm. That same night while lying in bed, I had a sudden sharp pain in my right ankle. It felt like a vein exploded. It was warm and red the next day. I followed up with my primary nurse practitioner, who sent me to have a duplex ultrasound. There were no clots.
1232091	4/20/2021	NJ	75	F	2/25/2021	3/9/2021	I was diagnosed with a Central Retina Vein Occulsion or eye stroke (left eye) due to blood clot obstructing blood flow through central vein.

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1231727	4/20/2021	NC	58	F	4/9/2021		BIG KNOT LIKE BUG BITE OR A BEE STING ON ARM AROUND THE INJECTION SITE; HOT SKIN AROUND THE INJECTION SITE; SLIGHTLY ITCHY AROUND THE INJECTION SITE; HARD SKIN ON ARM/TOUGH SKIN ON ARM; SORE ARM AROUND THE INJECTION SITE; SWELLING AROUND THE INJECTION SITE; This spontaneous report received from a patient concerned a 58 year old female. The patient's height, and weight were not reported. The patient's past medical history included blood clots. The patient was previously treated with warfarin for blood clots. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 043A21A, and expiry: UNKNOWN) dose was not reported, administered on 09-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 09-APR-2021, the subject experienced big knot like bug bite or a bee sting on arm around the injection site. On 09-APR-2021, the subject experienced hot skin around the injection site. On 09-APR-2021, the subject experienced slightly itchy around the injection site. On 09-APR-2021, the subject experienced hard skin on arm/tough skin on arm. On 09-APR-2021, the subject experienced sore arm around the injection site. On 09-APR-2021, the subject experienced swelling around the injection site. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from sore arm around the injection site on APR-2021, was recovering from big knot like bug bite or a bee sting on arm around the injection site, swelling around the injection site, hot skin around the injection site, and slightly itchy around the injection site, and the outcome of hard skin on arm/tough skin on arm was not reported. This report was non-serious.



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1232271	4/20/2021	CT	65	F	4/14/2021	4/14/2021	I had no symptoms except a very sore arm the first shot . After 2nd shot I had Unexplained severe pain in my foot for hours and then it went away the next day. I could not walk as I could not bear any weight on it. Also with the 2nd shot I had fever, chills, sweats, head ache, body aches, exhaustion and nauseous for a good 36 hours. My husband was afraid the pain in the foot was a blood clot and wanted me to go to the hospital but I was honestly just to sick to go to the hospital. I was too sick to move. After 36 hours most symptoms disappeared leaving just fatigue for the next 24 hours.
1232919	4/20/2021	ND	56	M	4/14/2021	4/18/2021	Blood clot in lower leg. After ultrasound, Doctor gave treatment protocol. Still undergoing treatment course.
1232427	4/20/2021	FL	34	F	4/14/2021	4/14/2021	She got her vaccine, initially she had bruising on her forearm that was blue/yellow with a swollen vein connected running down to her hand. She had tingling and numbness in her fingers in a select few on the left hand. She also had drooping of her left eye for a short period and a sensation on her left leg, swelling and pain. She went to the urgent care on 4/15/21, they told her to go home and monitor it. She knew that somewhat was not right and called a nurse at Hospital and went to the ER shortly thereafter and confirmed that she had a blood clot in her jugular vein IJ-DVT. In the ER they gave her a shot of Lovenox in the ER into her stomach and run several tests. They also gave her an anti-inflammatory in her right arm. She was sent home with Eliquis for the next 3 months. She has extreme exhaustion, and in addition to that she has had a lot of swelling on the left side of her leg, and visited the ER again on 4/17/21. Her left foot became blue, very swollen, so they ran a number of tests which all came back negative. She thinks these are side effects in relation to the previous. She is still continuing with stiffness in her neck as well. She also has a severe headache, fever of about 100, and severe achiness. She has not been able to work due to these symptoms since 4/15/21. The ER told her to have a lot of rest, no heavy listing/straining due to the clot.

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1232464	4/20/2021	FL	65	F	3/11/2021	3/11/2021	pt says one of her toes on her left foot went completely numb. Within a couple of days she started swelling between her left big toe and the toe next to it. Her entire left foot started swelling and then her leg started swelling. She went via ambulance to ER. They did an US of her leg and found 2 blood clots in the back of calves. She was given a RX for blood thinner. She went to 3 pharmacies and could not find it so she went home. She went home and then her right foot swelling as well. She went back via ambulance to ER. She was given blood thinner injection, and IV and took blood work. Pt was admitted where she stayed for 5 days. She was released and prescribed Eliquis. She has to take 20 mg a day for first week and then 10mg a day the following week for 3 months. She still has constant pain and her left foot continues to swell. Pt will have to have another US in 3 months.
1232476	4/20/2021	FL	53	F	3/25/2021	4/12/2021	Patient presented to Emergency Department on 4/17/21 with a severe headache that started 5-7 days prior. CBC and Chem-8 were normal with platelets of 314. Findings from CT head venogram showed irregularities of the left transverse sinus with possible sinus thrombosis. Patient was admitted for further work-up and treatment. Patient was followed by Neurology. On 4/18 MRI revealed no cavernoma seen and no stroke or hemorrhage. Per Neurology, the areas of filling defects seen on CTV are still present which could be nonocclusive thrombus vs stenosis with prominent arachnoid granulations, but given history and risk factors, would treat as cerebral sinus venous thrombosis. Patient was treated with heparin then transitioned to apixaban, which she was discharged on. Patient was instructed to follow up with neurology in 3 months for a repeat CTV. Patient was discharged 4/19/21.
1232500	4/20/2021	MA	75	F	4/7/2021	4/10/2021	Blood clot causing swelling, pain, redness in left leg from groin to ankle--sent for ultrasound from Vascular surgeon's office at.

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1232513	4/20/2021	GA	36	M	4/10/2021	4/15/2021	Spoke with patient via telephone on 4/20/21. Patient reports brief syncopal episode 4/15/21 at 6pm; reports he went to urgent care then to hospital. Reports he had CT scan and that multiple blood clots and pulmonary embolism were diagnosed. Reports he was transferred via ambulance early am on 4/16/21 to more advanced hospital. States thrombectomy was performed and he was discharged home on 4/17/21. States he is recovering at home and was advised he still has a blood clot in the leg. Reports he is on blood thinning medication at this time.
1232585	4/20/2021	WI	55	M	4/2/2021	4/5/2021	Patient was diagnosed with deep venous thrombosis 11 days after receiving Pfizer Covid-19 vaccine. Patient developed L leg pain and swelling 3 days after vaccine. First notice pain with swimming when he felt a cramp. Over next few days leg became painful while walking on it. He had no shortness of breath or trouble breathing except for a brief time while he was swimming and felt as if he was slightly shorter of air than normal. He has had no injury to the leg that he can remember. He has not been immobilized or gone on long trips lately. Patient was diagnosed with DVT on 4/13. Patient was started on Xarelto
1232607	4/20/2021	MO	46	M	2/24/2021	2/25/2021	Developed left arm pain and swelling after 1st vaccine in left shoulder. Persisted longer than previous reactions. Found to have blood clot in left brachial vein on 4/15/21 on ultrasound after evaluation by me
1232655	4/20/2021	SC	53	F	4/12/2021	4/20/2021	patients PCP office called to inform us that patient was positive for a DVT today. She was calling to inform us of the adverse event following her vaccination 04/12/2021. Blood clots were the reason that was reported for this vaccine to be pulled from the market the very next day 04/13/2021. Called the office back and left message with them to report as well since they have lab work and other patient information

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1232686	4/20/2021	MN	34	F	3/30/2021	3/31/2021	Spotting (light bleeding) for 3 days turned into shedding huge blood clots vaginally from 4/3 - 4/5. I bled though pads in just 5-10 minutes. Clots ranged from the size of a quarter to the size of the palm of my hand. They were very large, very frequent, and very painful. I never experienced this before in my life. The bleeding lasted 12 days total.
1232784	4/20/2021	CO	45	F	1/2/2021	3/29/2021	2 Ischemic strokes on right side of brain due to blood clots
1232173	4/20/2021	OH	41	F	4/1/2021	4/14/2021	Superficial venous thrombosis of left arm Start 2 days after shot, heat, ibuprofen
1234500	4/20/2021	MD	38	M	3/22/2021	4/10/2021	Blood clot leading to stroke

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1234262	4/20/2021	OH	71	F	3/13/2021	3/16/2021	<p>Patient with questions /concerns-said she had to get vaccine because of recent dx/tx for breast cancer. She said received vaccine on 3/13- then on 3/16 she was seen for one of her breast cancer therapy sessions- they have been treating her for lymphedema - she said she has been going for breast cancer in July- no chemo just radiation- surgery of breast with removal of seven surrounding lymph nodes. She was advised to wear a compression bra- on 3/16 and ever since then her left side of neck has been sore- thought it was likely related to compression bra not fitting correctly b/c too tight &amp; was professionally fitted on her- the straps seem very tight over the collar bone area that was damaged/irritated by the radiation she received on that side up through Oct 2020 for cancer. Now when she saw story today in news she got concerned could the neck soreness really be from a blood clot? She as been going the week for tightness in neck to physical therapy which started yesterday for lymphedema. Again her radiation ended Oct 2020 but she has had persistent swelling in breast &amp; fluid in lymph nodes on the left side. She still has pain in on collar bone- on same side of radiation- blisters, sore, red. As well as this new compression bra having two tight straps on each side. Her COVID vaccine shot in right arm but left side where breast surgery was She went on 3/16 for consultation on breast lymphadema - that was when told her to wear tighter bra for compression on 3/16. She is going today to be fitted for new one that is not so tight. She is approx. 4 weeks post vaccination &amp; post when started wearing that tighter bone- maybe three inches from where had radiation injury is located.</p>
1234286	4/20/2021	KS	44	F	3/20/2021	4/13/2021	<p>pt said she had isolated pain above her left elbow around 4/13/2021. the pain is now from her elbow to mid bicep. (she had given blood on 3/4/2021) pt saw a provider on 4/19/2021 regarding her symptoms. She was referred for a US. Results were superficial thrombosis left cephalic vein at the level of the mid upper arm extending into the forearm. She had blood work and was told to take Ibuprofen for pain and to stop taking her birth control. Pt will have a FU appt to discuss blood work results.</p>

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1234287	4/20/2021	OH	71	F	3/13/2021	3/16/2021	Calling with questions /concerns-said she had to get vaccine because of recent dx/tx for breast cancer. She said received vaccine on 3/13- then on 3/16 she was seen for one of her breast cancer therapy sessions- they have been treating her for lymphedema - she said she has been going for breast cancer in July- no chemo just radiation- surgery of breast with removal of seven surrounding lymph nodes. She was advised to wear a compression bra- on 3/16 and ever since then her left side of neck has been sore- thought it was likely related to compression bra not fitting correctly b/c too tight & was professionally fitted on her- the straps seem very tight over the collar bone area that was damaged/irritated by the radiation she received on that side up through Oct 2020 for cancer. Now when she saw story today in news she got concerned could the neck soreness really be from a blood clot? She as been going the week for tightness in neck to physical therapy which started yesterday for lymphedema. Again her radiation ended Oct 2020 but she has had persistent swelling in breast & fluid in lymph nodes on the left side. She still has pain in on collar bone- on same side of radiation- blisters, sore, red. As well as this new compression bra having two tight straps on each side. Her COVID vaccine shot in right arm but left side where breast surgery was She went on 3/16 for consultation on breast lymphadema - that was when told her to wear tighter bra for compression on 3/16. She is going today to be fitted for new one that is not so tight. She is approx. 4 weeks post vaccination & post when started wearing that tighter bone- maybe three inches from where had radiation injury is located.

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1234420	4/20/2021	WV	56	M	3/17/2021	3/19/2021	I began to feel numb around my mouth and nose. It spread to most of my face, then chest, then arms, mainly left arm and leg, then to both legs. General weird feeling / numbness, no pain. I had trouble with limb control, not bad, but enough to notice. Mainly left side, but noticeable on both sides. From the onset on face numbness to the chest leg spread was just a matter of a few, maybe 5 minutes. I looked at my face in the car mirror, and appeared to have facial control. I was driving to a relatives house, and it worried me. On the way, I also noticed a lump in my right neck, about the size of a pea. When I got to my relatives house I told them I thought I had a small stroke, but wasn't sure. The numbness lasted until the next day, then slowly went away. It took about 2 days before the numb twitchy feeling went away from my left eye/upper cheek area. The lump in my neck also went away. rubbing on it actually made the numbness slightly go away. I did not go to a hospital, or seek any treatment. I think I should have. I do believe that I had a small stroke / blood clot, and that it should be reported. I think I am OK now,
1234466	4/20/2021	SD	63	M	4/9/2021	4/10/2021	Patient came to pharmacy today w/ his wife to pick up Rx for XARELTO. He has developed multiple DVT's in his leg. He reported symptoms started the day after (Saturday) his second dose of Moderna COVID 19 vaccine on Friday 4.9.21. His leg was swollen by Sunday 4.11.21. Symptoms would get worse and then get better. He finally went to see Dr. today 04.20.21. They found several blood clots in the leg via doppler. Patient was therefore prescribed Xarelto. Pt wife advised that Dr said clots were due to Moderna vaccine and they should let pharmacy know also. Their next appointment will be in 2 weeks.

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1234475	4/20/2021	VA	48	F	4/12/2021	4/13/2021	<p>On Monday, 4/12/21, I was given the 2nd dose of the vaccine. There were no immediate symptoms other than a sore arm (from injection site) later that day. Tuesday morning, my left arm was swollen and I experience joint pain in my fingers and wrist. The following afternoon, I began to feel extremely tired and had vertigo. I laid down and slept the entire evening; still feeling the joint pain. The following Wednesday morning, I woke up to a swollen arm with a knot at the injection site, blisters, body rashes, and wheals under my breast and wheals on my shoulder, legs, and feet. I was even more exhausted. I took Benadryl for the rash and Advil for the pain. Thursday, I continued to develop rashes that would come and go on the left side of my body and upper chest. Friday, still experiencing the inflammation and pain, I visited my doctor who told me to continue taking the Benadryl and OTC pain meds. For good measure, we ordered a d-dimer test. Over the weekend, in addition to the other symptoms, I began to have a lot of ringing in my ears, a backache (throbbing sensation), and my hands began to painfully swell with blisters. I could only taste the salt or sugar in foods and was extremely tired. Monday morning, I received a call from my doctor advising me that the d-dimer test came back extremely high (1.23) and needed to have a vascular ultrasound to check for blood clots. I visited an ER and had the test done. No clots were found but I continue to experience ringing in my ears, severe pain in my back that limits my ability to walk and breathe, swelling of various extremities, a rash (and itching), and overall inflammation. The Benadryl isn't working nor is the OTC pain medication. My doctor has prescribed Prednisone.</p>



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1234257	4/20/2021	CA	27	F	4/5/2021	4/16/2021	a 27 y.o. female with a history of Covid infection December 26, 2020, positive covid test December 29, 2020. She had approximately 2 weeks of symptoms including generalized body ache and generalized weakness. Fatigue and some headache. Had some persistence of symptoms after that time. Had some benefit from ibuprofen. Was seen at emergency room on January 27, 2021 stating that she felt that all her symptoms of Covid had resolved except for some chest pain which awoke her on January 27. She presented to the emergency room. Had sinus tachycardia at 113 but otherwise unremarkable physical exam, laboratory studies with white blood count elevated 16,004-20, hemoglobin 13.7 g hematocrit 41.8%, MCV 87.1, RDW 12.7%, platelet count 329,000, segs 72.8%, lymphs 20.6%, monocytes 4%, eosinophils 1%, basophil 0.6%. BUN 10.1, creatinine 0.8, AST 24, ALT elevated 56, alkaline phosphatase 68, total protein 7.6, total bilirubin 0.3, albumin 3.6, globulin by subtraction 4.0, troponin less than 0.02, D-dimer quantitative 0.22, urine pregnancy test normal. Chest x-ray normal. Chest pain appears to be musculoskeletal and was reproduced by palpation of her chest wall. No evidence of deep venous thrombosis or pulmonary embolism. D-dimer was normal. Heart rate returned to normal after some intravenous fluids. Patient discharged on Zithromax 500 mg day 1 and then to 50 mg days 2 through 5. Also continued on ibuprofen. Received Johnson and Johnson vaccine April 5, 2021. Over the next week patient started having increasing soreness. Her joints hurt more than usual and her headache was worse. She had a sensation that her legs were "numb and tingly" starting at her buttocks and extending down her leg. Because of reported incidence of cerebral sinus thrombosis or cerebral vein thrombosis patient appropriately presented for screening in the emergency room and was sent for appropriate imaging. April 16, 2021 CT scan of head with and without contrast no acute intracranial hemorrhage, no mass-effect or midline shift. On contrast-enhanced images there appears to be a lobular nonocclusive filling defect in the far lateral right transverse sinus. Lobular occlusive filling defect is also likely present in the mid to central right transverse sinus. Short segment filling defect in the medial left transverse sinus. Remainder of sinuses and internal cerebral veins

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are patent. Focal lobular filling defect within the confluence of the right and transverse sinus most likely related to arachnoid granulation. No edema hemorrhage of the cerebellum or cerebrum. No other significant findings. April 16, 2021 confirmatory MRI angiogram of head without contrast with no restricted diffusion to suggest acute or subacute infarct. Contrast void in the middle to central right transverse sinus consistent with occlusive thrombus. Nonocclusive thrombus in the far lateral right transverse thrombus. Narrowing of the medial left transverse sinus without complete occlusion. April 16, 2021 2345 hrs. initial hematology consultation. D-dimer and fibrinogen levels have been requested stat and are still pending. If fibrinogen level is low will replace with cryoprecipitate. If D-dimer is elevated barely confirms diagnosis of possible vaccine related thrombosis. The fact the patient is not thrombocytopenic at this time is encouraging, however despite the lack of thrombocytopenia she still has clearly documented symptomatic nonocclusive and occlusive thrombus in her cerebral sinus. From UPToDate.com Ad26.COV2.S (Janssen COVID-19 vaccine, also referred to as the Johnson & Johnson vaccine) ? On April 13, 2021, the US Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) recommended pausing administration of AD26.COV2.S to further investigate rare cases of cerebral venous sinus thrombosis and thrombocytopenia [33]. As of that date, six cases had been reported, all in females aged 18 to 48 years with onset 6 to 13 days after vaccination; during this period, 6.8 million doses were administered (with 1.5 million doses in females of that age range) [121-123]. Since some vaccine recipients have not been followed for longer than the time frame over which these symptoms develop, the incidence may change with additional follow-up. Initial symptoms included headache, backache, chills, and fatigue, and progressed to focal neurologic deficits. Intracerebral hemorrhage and thromboses at other sites were also seen in some patients. All of the five patients who were tested for the anti-PF4 HIT antibody tested positive. Another case, in a young male who was a vaccine recipient in one of the pre-emergency use authorization efficacy trials, had been previously reported. These cases appear similar to those reported following ChAdOx1 nCoV-19/AZD1222, another

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adenovirus-vector vaccine. Although rare, the observed number of events exceeded the expected rate among females <50 years old. Given the extreme rarity of these events, the FDA and CDC acknowledge that they recommended the pause out of an abundance of caution and to ensure awareness of these rare events.

?Evaluation and management of possible thrombotic complications ? Recipients should be aware of the possible association and seek immediate care for signs and symptoms suggestive of thrombocytopenia (eg, new petechiae or bruising) or thrombotic complications (including shortness of breath, chest pain, lower extremity edema, persistent severe abdominal pain, unabating severe headache, severe backache, new focal neurologic symptoms, and seizures) [117]. In such cases, some experts suggest evaluation with complete blood count and differential (including the platelet count), quantitative D-dimer, HIT testing, and imaging of any suspected site of thrombosis [113,114,125]. Onset 4 to 20 days after vaccination, platelet count <150,000/microL, elevated D-dimer, and a positive anti-PF4 antibody (HIT antibody) suggest the diagnosis. Treatment with a non-heparin/non-warfarin anticoagulant (eg, argatroban or direct oral anticoagulant) and intravenous immune globulin has been suggested. The CDC recommends not using heparin in individuals with thromboses following receipt of Ad26.COV2.S unless HIT testing is negative [126]. (See "Cerebral venous thrombosis: Etiology, clinical features, and diagnosis" and "Clinical presentation and diagnosis of heparin-induced thrombocytopenia", section on 'Terminology and HIT variants' and "Management of heparin-induced thrombocytopenia", section on 'Role of IVIG'.) As stated above all the 6 cases were "all in females aged 18 to 48 years with onset 6 to 13 days after vaccination" this would certainly fit the timeframe that we are seeing in this case. Recommendations from national guidelines would be to start treatment with dexamethasone immediately while awaiting intravenous gammaglobulin. To pursue intravenous gammaglobulin treatment at 1 g/kg over 1 to 2 days. It is recommended to avoid heparin and instead use direct factor X inhibitor such as Eliquis, which this patient is already been started on. There is unfortunately considerable risk that even though patient's symptoms appear mild at this time, that she may

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deteriorate in the very near future and I would recommend treating her aggressively at this time with dexamethasone and intravenous gammaglobulin while we are awaiting further testing. Patient clearly has had unusual thrombosis, especially in a 27-year-old. With the fact that she had headache dating back to January, it is impossible to determine the acute versus chronic nature of her venous sinus thrombosis. Covid infection does cause increase in coagulation as well. However, given the small risk of tragic outcome with cerebral vein and sinus thrombosis in the setting of Covid vaccinations, we will proceed aggressively with treatment starting tonight with intravenous gammaglobulin and intravenous dexamethasone. Will require rapid fasting glucoses to evaluate possible hyperglycemia from high-dose dexamethasone. Will consider stopping dexamethasone at 48 hours. Current recommendation for gammaglobulin would be single 1 g/kg or 500 mg/kg over 2 days. No recommendations for treatment beyond this point. Current recommendations for gammaglobulin dosing would recommend using an adjusted dose for patients with greater than 125% of their ideal body weight. This patient at 122 kg on a 5 foot 2 inch frame does qualify for adjusted dose and her orders reflect that. I appreciate the opportunity see this patient this evening and consultation requested by Dr. We will follow patient in hospital. Hopefully she will have gradual improvement and avoid any serious or tragic complications of her cerebral sinus thrombosis. We will have pharmacy report possible adverse reaction to Johnson & Johnson vaccine to the FDA as required by law. April 17, 2021 follow up. No new events. Laboratory studies remained excellent. White blood count is further elevated, however, this may be secondary to high-dose dexamethasone with a white blood count of 16,060. Hemoglobin 14.0 g hematocrit 42.8%, MCV 86.8, RDW 12.9%. Platelet count is actually increased slightly at 374 as of 9:10 AM this morning. Differential shows left shift as expected with dexamethasone. Results from yesterday showed fibrinogen normal at 369 (180?415) pro time normal at 10.4 seconds with INR of 0.97, PTT 26.7. D-dimer 0.23 (0.19?0.50). With platelet count, fibrinogen and D-dimer normal I am inclined to believe that this is not an acute post vaccination HIT-like phenomena. If it were I would still expect to see some

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degree of thrombocytopenia elevated D-dimer and perhaps low fibrinogen. The other explanations for her cerebral venous sinus thrombosis are either idiopathic spontaneous and merely coincidentally associated at the exact same time as her Covid infection or more likely, cerebral venous sinus thrombosis secondary to hypercoagulable state secondary to her Covid infection from December 2020. Unfortunately there is no way to accurately date the acuity of the venous thrombosis in her cerebral sinus. HIT Testing is still pending and most likely will not be available for 3-4 more days despite being ordered stat. Have called the laboratory and asked them to check with our outside reference lab what the expected return time is on this test. (LabCorp says "Tuesday April 20, 2021). Patient refused intravenous gammaglobulin infusion which has been ordered last night. Patient has been receiving dexamethasone which was a bridge until intravenous gammaglobulin could be administered. Current guidance from the expert hematology panel (EHP) on Covid vaccine induced thrombosis dated April 7, 2021 from the public health would state that a patient who has a reduced platelet count without thrombosis with a D-dimer normal and normal fibrinogen or thrombosis with a normal platelet count and D-dimer normal and normal fibrinogen are "unlikely cases". They recommend for probable cases who have D-dimers that are elevated to send HIT assay and then give immediate intravenous gammaglobulin while awaiting results. They recommend fibrinogen supplementation, if needed. They recommend a direct acting antithrombin agents such as the Eliquis this patient is receiving. They recommend steroids particularly if there is a delay in getting intravenous gammaglobulin delivered. With the fact that we now have 24 hours in the hospital with no evidence of thrombocytopenia, no evidence of increased fibrinolytic activity or active thrombosis, and no evidence of hypofibrinogenemia, I would argue that her presentation is subacute. In this setting, I do not feel intravenous gammaglobulin would be necessary and does involve a small risk as well as considerable cost. Dexamethasone also involves small risk and negligible cost. I have discontinued both of these medications. My overall impression would be that this was not related to her Johnson & Johnson vaccination which was recent, but

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rather her more distant Covid infection. It is impossible to definitively answer the question however. The next question is duration of anticoagulation. Risk of recurrent cerebral sinus venous thrombosis is relatively small but the morbidity can be high. Studies have been performed showing medications in the same class as Eliquis have been associated with a decrease in incidence of the recurrence. Most hematologist recommend 3 months of anticoagulation for provoked venous thrombosis including cerebral sinus venous thrombosis. I feel this patient's thrombosis is "provoked", with her association at the same time of her Covid infection (and possibly vaccination). I would recommend Eliquis (apixaban) 5 mg twice daily or Xarelto (rivaroxaban) 20 mg daily with food. I would feel comfortable in discharging patient for outpatient follow up IF Dr and other speciality services agree. Plan 3 months of full dose anticoagulation with direct factor X inhibitor. Circulation 2010 Jun 29;121(25):2740-6 "Long-term evaluation of the risk of recurrence after cerebral sinus-venous thrombosis", Background: The clinical course of cerebral sinus-venous thrombosis (CSV) is largely unknown because prospective studies with a long follow-up and with the goal to assess thrombosis recurrence rate and predisposing factors for recurrence are lacking. Methods and results: One hundred forty-five patients with a first CSV were followed up for a median of 6 years after discontinuation of anticoagulant treatment. End points were recurrent CSV or other clinical manifestations of venous thromboembolism. CSV recurred in 5 patients (3%) and other manifestations of venous thromboembolism (deep vein thrombosis of the lower limbs or pulmonary embolism) were seen in 10 additional patients (7%), for a recurrence rate of 2.03 per 100 person-years (95% confidence interval, 1.16 to 3.14) for all manifestations of venous thromboembolism and 0.53 per 100 person-years (95% confidence interval, 0.16 to 1.10) for CSV. Nearly half of the recurrences occurred within the first year after discontinuation of anticoagulant therapy. Risk factors for recurrent venous thrombosis were male sex (adjusted hazard ratio, 9.66; 95% confidence interval, 2.86 to 32.7) and, for thromboses other than CSV, severe thrombophilia resulting from antithrombin, protein C, protein S deficiency, antiphospholipid antibodies, or combined abnormalities

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							(adjusted hazard ratio, 4.71; 95% confidence interval, 1.34 to 16.5). Conclusions: The risk of recurrent CSVT is low and is higher in the first year after discontinuation of anticoagulant treatment and among men. Mild thrombophilia abnormalities are not associated with recurrent CSVT, but severe thrombophilia entails an increased risk of deep vein thrombosis of the lower limbs or pulmonary embolism. April 19, 2021 Follow up, no change in condition. Discussed case with Dr. will order Factor V Leiden, prothrombin gene mutation, anti phospholipid and anti cardiolipin antibodies, if she will allow draw. Expect Heparin Induced Thrombosis testing result tomorrow, but with no thrombocytopenia after given heparin, expect will be normal. Will await result. If discharged, would recommend 3 months direct thrombin inhibitor (Eliquis/Xarelto/Pradaxa) at full anticoagulation dose. Then stop, no taper. Overall still feel "provoked" thrombosis due to December Covid, unrelated to J&J Covid vaccine, but can not definitively prove that..
1234495	4/20/2021	AR	18	F	4/8/2021	4/20/2021	I had other symptoms earlier on that I reported using v safe but today I started my period (while on birth control) two weeks and one day early. I normally have a very light bleed in day one and it is very heavy and has lots of clots. My first spot of blood appeared around 3 pm and I have bled about 15 ml since then. I know the volume as I use a menstrual cup. My first bleed day I normally don't bleed but one small clot ~2 ml in volume.
1235108	4/20/2021	NM	83	F	3/3/2021	3/7/2021	Patient developed pain in her left calf 4 days after the 1st Pfizer COVID-19 vaccine. She was sent for venous doppler and found with an extensive superficial venous thrombosis in the left great saphenous vein that was only cm from the deep system. The clot extended from the upper calf to the thigh. She was and is being treated for DVT as the clot was so extensive. She has no history of clots. She does have varicose veins and has not been as active as usual. She is currently still in treatment .

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1234509	4/20/2021	AL	62	M	2/22/2021	3/4/2021	On 3/4/21 noticed my left calf was swollen. I did not think much of it at first. A week later the swelling had progressed to include my ankle. Saw Dr. and ordered an ultrasound on both of my legs. Right leg was normal & left lower leg had a clot(s) in it. Dr. ran blood work then prescribed Eliquis. Saw him in follow-up on April 14. Swelling down but not gone. Renewed the prescription for Eliquis and set a followup visit for Friday June 18. He ordered additional blood work to be drawn on Wednesday June 16 to have results at the next visit.
1234526	4/20/2021	CA	60	M	3/13/2021	3/29/2021	Blood clot in left leg on 3/22/2021 and 3/29/2021
1234907	4/20/2021	FL	65	M	4/12/2021	4/15/2021	On April 16 patient came home fatigue, pale and legs hurting. The next day complained of right knee pain, Fatigue and looked pale. He woke up in the middle of the night complaining of right calf tightness and pain. On Sunday 18th he started to limp and when we looked at his calf it was double in size, warm to touch, and redness. We then went to the ER and had an ultrasound and CT scan . We were told he has multiple blood clots in the right leg and clots in both lungs. He was then transported to a hospital and given blood thinner shots in stomach. He was released from the hospital 4/20 and given blood thinners and assigned a hematologist. He'll be on blood thinners 6-12 months, out of work a month and tested regularly to check platelets.



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1235447	4/20/2021	MN	33	F	3/22/2021	4/17/2021	Patient presented to the ER on 4/20/21 with headache. On Saturday (4/17/2021), the patient had "the worst headache I have ever had" along with severe inner left ear pain. Patient took an ibuprofen which helped with the pain for about an hour then the pain came back. Pain got worse 2 hours later when she drove home from work. She called the RN line and was told to take ibuprofen and follow up in the AM. The next day 4/18/2021, patient went to urgent care and received Toradol and was told it was a migraine. Today 4/20/21, patient still had pain and noted feeling left sided facial numbness and blurry vision that correlated with when she got the headache. Patient went to an urgent care today and CT scan revealed a blood clot. She was then sent to the ED for evaluation. In the ED, she has no headache and facial numbness and has minimal left ear pain. Her headache is localized to the left side of her head. Patient denies fever, chills, and COVID symptoms. Patient was started on argatroban drip per hematology recommendation.
1233706	4/20/2021	GA	45	M	3/17/2021	4/3/2021	DVT - Left leg. Three separate clots in three different veins. Placed on Eliquis for 3-6 months.
1233645	4/20/2021	PA	33	F	3/19/2021	3/20/2021	The day after my first vaccine dose (3/20/2021), my menstrual cycle started and I had large globs. Some looked like large blood clots, while others looks like they might contain tissue almost like what you would expect in the event of a miscarriage. I know for certain I was not having a miscarriage. No treatment. Symptoms subsided until next menstrual cycle on (3/17/2021), when I again experienced the same symptoms. Symptoms the second time were not as prevalent as the first time but still noticeable.
1234477	4/20/2021	CA	29	F	4/11/2021	4/12/2021	Experienced these symptoms within 12-24 hours: Chills, fever, headache, body ache, nausea, vomiting, confusion, memory loss. Went to hospital 22 hours after receiving shot. Blacked out for 7 hours that day at the hospital. Was tested for meningitis and did MRV scan for brain clots but all came back clear / negative. Likely experienced dehydration and drop in sodium levels. Was hospitalized from 4/12-4/16.

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1234059	4/20/2021	MO	56	M	3/19/2021	4/11/2021	Less than 1 mo following injection pt developed DVT RLE. He presented with rt foot/ankle pain 3/29. The pain improved then around 4/10 he developed significant pain/swelling to rt calf. Venous US confirmed DVT. Pt started on Eliquis. Pt has h/o superficial thrombosis, not h/o DVT.
1234231	4/20/2021	CA	46	F	4/7/2021	4/13/2021	6 days after I got the vaccine, I noticed a large rash across my torso. I am unsure if the rash was developing prior to when I noticed, but the rash is on my stomach and part of my lower back. I finally visited my primary doctor today and was told the rash is a drug reaction - it is not itchy nor painful. **I am supposed to be on baby aspirin indefinitely due to my heart condition. I have not taken baby aspirin in a few years. But after there were reports of women getting blood clots after getting the JNJ vaccine, I started taking baby aspirin 6 days after I got the vaccine. The rash may have happened before or after I took my first dose of baby aspirin. I stopped taking baby aspirin the following day. Today, my doctor advised me to stop taking all Vits and Supplements. I will be taking Zyrtec and Tagamet for next 10 days, hoping the rash will go away.
1233818	4/20/2021	NY	55	F	4/7/2021	4/17/2021	Purple , looking like blood clots on the back of her leg
1233715	4/20/2021	NJ	38	M	4/9/2021	4/14/2021	Event: Blood clot in right leg (superficial thrombosis) Treatment: Rest, elevation, heat and ibuprofen Outcomes: TBD

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1234044	4/20/2021	OH	72	F	3/4/2021	3/24/2021	<p>Patient called c/o shortness of breath on exertion, slight cough, runny nose, weakness and fatigue. States O2 sitting 97 and P 79-80 and O2 walking &lt;88 and P 100's. States had covid vaccine # 1 on 3/4/2021. Completed viral/travel screen which was negative. Patient is a 72 y.o. female with chronic diastolic heart failure, hypertension, hyperlipidemia, hypothyroidism, vitamin D deficiency, depression with anxiety, who presented with shortness of breath on exertion. CTA chest was performed, showing filling defects in secondary and tertiary pulmonary arterial branches in bilateral lower lobes as well as right upper lobe. Patient was admitted for management of acute bilateral pulmonary emboli. Patient was started on Lovenox 1 mg/kg twice daily; transitioned over to oral apixaban for discharge. TTE obtained, without evidence of right heart strain. Patient is a 72 y.o. female who presents to the office today stating "I do not feel so good". She mentions noting blurry vision over the past 1 week right eye only with decreased vision. Denies any eye pain. Thinks her vision is worse outside in the sun. In addition, today she states she was up moving around getting ready for today's appointment when all of a sudden she felt a brief slight low light shock pointing to left anterior chest wall. Denies any chest pain or pressure but reports noting her heart rate was elevated up to 150. She states her O2 sat at home was 97% on room air. She checked her blood pressure which was not abnormal but cannot recall the number. She was recently diagnosed with a PE for which she was hospitalized, see previous note. She is concerned as she feels perhaps her Covid vaccine initially received on 3/4/2021 could have caused her blood clot. Her second dose was received on 3/31/2021 and has since not been feeling well EKG in the office with new onset A. fib relation noted, rapid ventricular rate with a pulse of 152 bpm. 911 was called and patient transferred to the ER for further evaluation and recommendations. Patient currently on Eliquis for PE. Patient, with a past medical history of essential hypertension, mixed hyperlipidemia and grade 1 diastolic dysfunction, as well as acute bilateral pulmonary emboli 3/2021 diagnosed a few days after her first dose of the Pfizer Covid vaccination, now anticoagulated on Eliquis who presented to KMC emergency room on 4/14/2021 from her primary care provider's office after being found in newly diagnosed</p>

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atrial fibrillation with RVR, rate in the 150s. Of note, patient had received her second dose of the Pfizer Covid vaccine on 4/10/2021. She had scheduled this primary care provider appointment due to waxing and waning blurred vision of her right eye, with associated right-sided headache that had been ongoing over the last week. Patient reports that on the day of arrival she had not felt well, felt slightly weak and fatigued, but denied shortness of breath, chest pain or heart palpitations. Per ER notes, patient was instructed on vagal maneuvers while she was in the ambulance, and had converted to sinus rhythm by the time of her arrival to the emergency room. Per review of her telemetry on the day of discharge, patient did have one short episode of PAF on 4/15/2021, spontaneously converting to sinus rhythm, as well as intermittent PACs. Her home lisinopril was changed to Coreg, without further episodes of RVR and with good blood pressure control. In regards to her headache, patient underwent an MRI of the brain, which was negative for acute findings; she had no temporal tenderness, and ESR was within normal limits. She did improve symptomatically with administration of Tylenol and Zofran for her corresponding nausea/vomiting. On the day of discharge, patient was feeling much better, and stable for discharge. An appointment with doctor of ophthalmology was offered to patient for 4/16/2021, however due to transportation issues, this was rescheduled for 4/20/2021. She was instructed on changes in her medication, as well as encouraged to schedule an appointment with her established cardiologist. All questions and concerns were addressed.

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1234046	4/20/2021	MI	103	F	4/7/2021	4/13/2021	Received a Janssen vaccination on 4/7/21 from a home visiting nurse from the County Health Department. On approximately 4/13/21, the family noticed slight signs of an issue, with patient slumping towards the right, and showing some signs of weakness on right side of body. Family contacted the PCP, who advised to take her to the ED. Family was hesitant to do that because patient had been bedridden for past few years. She seemed to improve somewhat on 4/15/21. Then the morning of 4/16/21, the family found her on the floor of her bedroom. She appeared to have had a moderate to severe stroke. Right side of body paralyzed, cannot speak. Uncertain whether mental faculties further deteriorated. PCP ordered a hospice facility for care. Stroke likely caused by blood clot but unsure if related to JJ vaccine. She has not been evaluated in person by her health care providers.
1234034	4/20/2021	KY	53	F	2/12/2021	3/24/2021	Stroke from a blood clot that went to the left side of my brain causing the right side of my body to be numb , weak and to lose a range of motion. Event date: 3/24/2021; hospitalized 3/24/21, 3/25/21, and 3/26/21.

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1234070	4/20/2021	MI	34	F	4/8/2021	4/10/2021	4/10/21 Patient presented to Urgent Care with Arm Pain (left arm painful and tingly since COVID shot 4/8; now pain is different and there is a lump on her forearm she can feel). 4/13/21 Contacted the office to schedule an appointment regarding worsening symptoms. Scheduled appointment. 4/14/21 cont. Seen in office by PA for: 1. Left arm pain - tender nodule L forearm, will get US due to recent birth, Johnson and Johnson vaccine, FH of DVT, to r/o DVT causing the lump, await results. Symptomatic care in the interim, may use warm compresses. - USV VENOUS UPPER EXTREMITY DUPLEX LEFT; Future 2. Paresthesia of left arm - site of reported injection and superficial induration 1.5cm from acromion process, suspect SIRVA due to sit of administration of vaccine, recommend symptomatic care with warm compresses, gentle massage if benefit noted, pt is breastfeeding so recommend local care at this time, consider PT, pt declines at this time as she will be on vacation next week. Discussed possible cortisone injection but deferred due to recent COVID vaccine 6 days ago, pt agrees as there is some recommendation to avoid steroids in close proximity to vaccinations to avoid blunting the immune response 3. Family history of DVT - see #1 4/15/21 After speaking with the DVT clinic Dr contacted the patient and recommended she take an 81mg low dose daily aspirin, until symptoms resolve, around one month. And repeating venus duplex in 7-10 days. Determined she would go prior to her leaving for her trip as she planned to be out-of-town during that time frame. (Per provider result notes.) 4/16/21 Patient was seen in emergency department for: Patient presents for evaluation of multiple concerns. Following the Johnson & Johnson COVID-19 vaccine she was recently diagnosed with superficial thrombophlebitis in the left forearm by ultrasound, has been taking aspirin and symptoms have not worsened. Left upper extremity exam is quite reassuring today, I see no clinical evidence for DVT and she is neurovascular intact. I did not feel that repeat ultrasound was necessary at this time, but she does have this scheduled next week so I advised her to keep that appointment. She has a very slight headache which has been present since the day she received the vaccine, currently 2/10 without vision or other neurologic concerns. No abdominal pain. I have low clinical suspicion for CVST or PVT at this time.

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Advised return if she develops worsening headache or new neurologic symptoms. Patient complained of new onset left lower lateral breast pain and lump starting today. She is currently breastfeeding and notes decreased milk production today. She does have a tender fullness on exam but no redness or visible swelling, she is nontoxic and well-appearing without fever. She has history of mastitis in the past, but she states her PCP recommended she be evaluated for possible blood clot in the breast. Advised the patient that I have very little concern for that at this time, if anything it would be superficial and not amenable to anticoagulation but I did not feel that imaging was necessary at this time. I will cover her with antibiotics for lactational mastitis, she has cephalosporin allergy but states she had formal testing for penicillin allergy and tolerated this well so I prescribed Augmentin. She will use a warm compress and continue nursing, I did recommend she start on the right side to initiate let down on the left. 4/20/21 patient was seen in the office for: Patient presents for follow up of recent ED visit. She was seen here last week for left arm pain/nodule/paresthesia following her Johnson & Johnson vaccine. She also reported a slight headache that was present since day of vaccine. An US was performed and showed a left cephalic vein thrombus of LUE. She was advised to start ASA 81mg daily for the next month and get repeat US in 7-10 days. She then called in with left breast pain/swelling and was directed to the ED for evaluation of possible blood clot. She does have hx of mastitis several weeks ago. The ED did not pursue additional imaging of breast, they told her it was likely lactational mastitis and they did prescribe augmentin and warm compresses for this. Today, patient presents states he feels "a lot better". Regarding the left breast lump, redness, swelling she states this has completely resolved. She did not start the augmentin as she was worried about this potentially causing thrush for her daughter; she explains she had mastitis 7-8 weeks ago and was on antibiotics and then her and her daughter continually passed thrush back/forth to each other 3x so she was hoping to avoid this. She did treat with frequent feeding/pumping, and warm compresses and symptoms resolved. She was told to see us for elevated blood pressure in the ER, per review of EMR and her DC papers, her blood pressure in the ED

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was 130/75. Today her blood pressure is 122/78. Regarding her left arm symptoms, she states the numbness/tingling has nearly resolved; she will occasionally get a very mild tingling in her 4th/5th fingers that resolves after a few seconds. She denies pain or swelling of the arm. She no longer can palpate the clot and thinks that it is gone. She no longer feels swelling or tenderness in her left axilla. She stopped the ASA and started motrin/warm compresses as was advised by the ED. Her mild headache continues since the vaccine but is somewhat improved. She denies worsening or severe headache; denies vision changes, dizziness, lightheadedness, speech difficulty, etc. Phone encounter also from 4/20/21: Phone call placed to DVT clinic to get their guidance as Dr had talked with them last week. Reached RN, who reviewed with Dr. After review of patient's history/chart/growth of superficial clot, Dr recommended that patient not travel as planned and continue on 81mg ASA daily. They would like us to place a referral so they can see her later this week or early next week. They also want us to place order for repeat US either this coming Friday or Monday and they will coordinate to get this done at their office/same time as appointment. I did place phone call to patient to discuss and give their advice. They had just left this morning by car. I reviewed Dr advice to not travel and she will discuss with her husband if they are going to run around or not. She was agreeable to continuing on the 81mg ASA Daily and repeat US/visit with DVT clinic in 5-7 days as recommended.



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1234080	4/20/2021	MI	34	F	4/8/2021	4/10/2021	4/10/21 Patient presented to Urgent Care with Arm Pain (left arm painful and tingly since COVID shot 4/8; now pain is different and there is a lump on her forearm she can feel). 4/13/21 Contacted the office to schedule an appointment regarding worsening symptoms. Scheduled appointment. 4/14/21 cont. Seen in office by PA for: 1. Left arm pain - tender nodule L forearm, will get US due to recent birth, Johnson and Johnson vaccine, FH of DVT, to r/o DVT causing the lump, await results. Symptomatic care in the interim, may use warm compresses. - USV VENOUS UPPER EXTREMITY DUPLEX LEFT; Future 2. Paresthesia of left arm - site of reported injection and superficial induration 1.5cm from acromion process, suspect SIRVA due to sit of administration of vaccine, recommend symptomatic care with warm compresses, gentle massage if benefit noted, pt is breastfeeding so recommend local care at this time, consider PT, pt declines at this time as she will be on vacation next week. Discussed possible cortisone injection but deferred due to recent COVID vaccine 6 days ago, pt agrees as there is some recommendation to avoid steroids in close proximity to vaccinations to avoid blunting the immune response 3. Family history of DVT - see #1 4/15/21 After speaking with the DVT clinic Dr contacted the patient and recommended she take an 81mg low dose daily aspirin, until symptoms resolve, around one month. And repeating venus duplex in 7-10 days. Determined she would go prior to her leaving for her trip as she planned to be out-of-town during that time frame. (Per provider result notes.) 4/16/21 Patient was seen in emergency department for: Patient presents for evaluation of multiple concerns. Following the Johnson & Johnson COVID-19 vaccine she was recently diagnosed with superficial thrombophlebitis in the left forearm by ultrasound, has been taking aspirin and symptoms have not worsened. Left upper extremity exam is quite reassuring today, I see no clinical evidence for DVT and she is neurovascular intact. I did not feel that repeat ultrasound was necessary at this time, but she does have this scheduled next week so I advised her to keep that appointment. She has a very slight headache which has been present since the day she received the vaccine, currently 2/10 without vision or other neurologic concerns. No abdominal pain. I have low clinical suspicion for CVST or PVT at this time.

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1234081	4/20/2021	TN	69	F	3/5/2021	4/2/2021	Took first Pfizer Covid 19 vaccine on March 5, 2021, second dose on March 19, 2022. Suffered stroke from blood clot on April 2, 2021.
1234108	4/20/2021	GA	56	M	3/13/2021	4/19/2021	Went to the hospital with chest pain. They performed a catheter to check for blockages and instead found an extremely rare blood clot that ultimately caused a mild heart attack.
1234130	4/20/2021	FL	61	M	4/15/2021	4/16/2021	Hematuria. Severely thickened urinary bladder with blood clots in organ and urine . Please note 1st Doze of Covid-19 vaccine was on 03/25/2021 and 2nd doze was on 04/15/2021.

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1234132	4/20/2021	NY	43	M	4/1/2021	4/15/2021	Blood clot in left leg , Found out on April 15 2021

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1234152	4/20/2021	MA	47	M	3/12/2021	3/18/2021	<p>Pt. had (what we think) a small seizure on Thursday, March 18th and then again on Saturday, March 20th. On Sunday, March 21st, 911 had to be called as his seizure did not end. He had a grand male. He was seizing for several hours. At the time this was all occurring he has been on anti seizure meds for a few years Divalproex 1000 mg am and 1000 mgs pm daily). He passed 1 week later, March 28 at approx 6:45pm at the Clinic. I am unable to get any information on his medical report for that week. Statement from his Nurologists is on second page. Additional information for Item 18: Statement: 47 year old gentleman who passed away on March 28 from aspiration pneumonia secondary to status epilepticus and on a history of multiple sclerosis / additional leukoencephalopathy of unknown etiology (both treated with rituximab), prior seizures (on valproic acid) and pulmonary embolism (on apixaban). The key reason for reaching out is in light of the announcement about the side effects of the Johnson &amp; Johnson vaccine specifically cerebral venous sinus thrombosis. While he had a known history of seizures, he had no clear trigger for these seizures; including that his valproic acid level was therapeutic (83.0 mcg/mL) at time of presentation. He had, however, received the Johnson &amp; Johnson vaccine on March 12 before having what in hindsight appeared to be repeated seizures between March 18-21; he had a more significant one on March 21 that hospitalized him. This time frame appears consistent with the reported cases of central venous sinus thrombosis associated with the Johnson &amp; Johnson vaccine. Equally, he was taking apixaban at that point in time and his PLT (173) / INR (1.1) / PTT (36.6) at time of presentation were all normal and stable. He did have an elevated ProBNP (552.0) at presentation; nasopharyngeal swab was negative for COVID / Influenza A/B / RSV and non-contrast head CT did not show any clear new abnormalities. His only D-dimer was obtained on March 23 and was 226. He did not have a CT angiogram or venogram. Overall the link between the vaccine and pt. seizures is not definite. At the same time, the similarity with the reported cases has led to me wanting to report it in case of the possible link. If you require further information then please don't hesitate to email me Pt. med list at the time of this incident Modifinil - 100 mg/1per day/AM Sertraline - 100 mg/1per day/AM</p>

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							Vitamin D3 - 50 mg/1per day/AM Divalproex - 500 mg/2per day/AM Eliquis - 5 mg/1per day/AM Furoseminde - 20 mg/1per day/AM Metoprolol - 100 mg/1per day/AM Lisinopril - 10 mg/1per day/AM Divalproex - 500 mg/2per day/PM Eliquis - 5 mg/1per day/PM Metoprolol - 100 mg/1per day/PM Melatonin - 5 mg/1per day/PM Quetiapine - 50 mg/3per day/PM
1234170	4/20/2021	CA	46	F	4/9/2021	4/20/2021	We got a call from Doctor from ER to inform us that this patient came to the ER today & got swollen arm @ the injection site (left arm). They did the ultra sound & found there's a clot in brachial vein on the opposite arm (right arm). Doctor said they'll give pt Eliquis today.
1234219	4/20/2021	NC	52	F	4/14/2021	4/16/2021	On Friday 4/16/21 evening, I had my left tonsil spontaneously rupture without any provocation. I was not eating or drinking but felt like I had something in my throat. I coughed it into a tissue, and it was a blood clot the size of a nickel. My tonsil had 2 places that it was oozing blood and continued to bleed for about 1.5 hours. It eventually tapered off and the redness/bruising disappeared over the next 48 hours. There was no pain, no warning - just a mouth full of blood. The tonsil that ruptured was on the same side as where I received the injection and I had swollen lymph nodes under my arm on that same side until Sunday 4/18. I can't help but think it was related to the vaccine as I had no other cold/hay fever/allergy symptoms of any kind to explain a bleeding tonsil.
1228845	4/19/2021	MD	56	F	4/8/2021	4/18/2021	pain in lower left lung under breast. hurt to breathe, prescribed steroids and pain patch. was told no sign of clot, possible pleurisy.

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1228999	4/19/2021	WA	69	M	3/13/2021	4/6/2021	On April 6th at 8:30am, wife noticed her husband had facial drooping and slurring of speech, and left hand weakness. He was taken to Good Hospital.. Upon arrival a CT was performed, in which it was confirmed a right middle cerebral infarction. He was then transfered priority to a Trama Hospital for a thrombectomy by Dr. This was successful in removing the clot. He spent 3 days in ICU and then moved to progressive care. Pt is on his 13 day in the hospital where he is no longer able to care for himself. He now has behavioral disturbances, aggitation, confusion, delium, halluciantions. He is under Psychiatric care, physical, occupational, and speech therapy.
1228968	4/19/2021	TX	28	F	3/6/2021	3/13/2021	Started with chest pain, a couple of days after the shot. Fainted on 3/13/21, transported by EMS to emergency room. CT scan was done, Dr. said she has blood clots in her lungs. Was given a prescription for Eliquis 5 mg twice daily.
1228903	4/19/2021	CA	75	M	4/6/2021	4/9/2021	patient had massive intracerebral hemorrhage 3 days after vaccination. family claims patient was doing well until vaccination. there is a suspicion that patient might have had sinus venous thrombosis that lead to the the ICH.
1228874	4/19/2021	CA	70	M	4/14/2021	4/15/2021	At about 10:09 AM on Wednesday, April 14, 2021 I received my second dose of the COVID-19 Pfizer Vaccine. At about 5:06 AM, the next morning of Thursday, April 15, 2021 I awoke with a swollen, reddish and painful big toe and upper foot with the pain centered around the lower joint of the big toe of the right foot. I did not know what caused the condition. Origninally, I guessed that I had somehow sprained my foot or had a blood clot. After searching the internet, I found informaton regarding gout - The symptoms exactly matched my symptoms. Additionally, afterwards, I discovered an article in Podiatry Today that reported gout attacks after vaccinations.

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1229047	4/19/2021	IA	43	F	1/7/2021	1/18/2021	Hospitalized with cerebral venous sinus thrombosis from 1/26/2021-1/29/2021. Presented with severe headache. Treatment included anticoagulation initially with heparin infusion, followed by oral anticoagulation with Eliquis. She required prescription medications for management of headache. Discharged home with ongoing headache.
1228783	4/19/2021	TN	50	F	2/26/2021	3/1/2021	Patient received her 1st dose of Pfizer COVID vaccine on 02/26/2021. She noted some wheezing and slight shortness of breath and shared this information with her PCP at her regularly scheduled visit on 03/01/2021. PCP refilled inhaler at that time. Her shortness of breath progressively worsened, and she was seen by another provider as a walk-in at the office of her PCP on 03/13/2021. At that time, she was prescribed prednisone for 5 days, noting some improvement after a few days. She received her 2nd Pfizer COVID vaccine on 03/19/2021. The patient woke up on the morning of 03/20/21 with a swollen and painful leg and by 03/22/21 called PCP and was seen in the office. PCP ordered D-Dimer and LE ultrasound. Per the patient, the D-dimer was abnormal and the LE U/S showed a blood clot. PCP sent the patient to the ER, where a chest CT was ordered and showed a pulmonary embolus. She was admitted overnight and started on Eliquis, and discharged the next day after seeing a hematologist.
1228716	4/19/2021	TX	48	F	4/9/2021	4/10/2021	THE DAY AFTER VACCINATION, PATIENT HAD BURING SENSATION AND PAIN IN BILATERAL LOWER EXTREMITIES. REFERRED TO ER. ULTRASOUND SHOWED NO EVIDENCE OF CLOTS
1228712	4/19/2021	AR	70	M	2/10/2021	3/24/2021	Patient had blood clots in right leg and in each lung.
1228697	4/19/2021	WV	31	F	4/14/2021	4/15/2021	The next day after I received vaccine, I noticed bruise on my left thigh (about 1 inch). I did not hit or do anything else to have a bruise, so, I think it is a blood clot.
1228694	4/19/2021	OK	39	M	3/24/2021	3/26/2021	Blood clot developed on mechanical heart valve, managed with inpatient anticoagulation



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1228670	4/19/2021	NC	55	F	4/6/2021	4/6/2021	Excruciating side effects. It started with a headache, and now the intense pain has progressed behind my ear, neck and I am unable to swallow, open my mouth etc. I went to my general doctor on 04/15/21 where he thought I might have blood clot, which was ruled out negative by performing CT Scan. I was given pain killer medicine last Thursday. On Friday the 16th the pain got even worse with medicine, my Doctor told me to go to Emergency Department. I was given a stronger cocktail for drugs and a second CT scan of my throat was done. ED physician Dr. Winter verified that it was reaction to COVID vaccine as your body is trying to reject/cope with this substance (?Your nerves are angry with you?)
1229291	4/19/2021	AL	58	F	3/30/2021	3/30/2021	Vaccine #1 taken at 9:45am; first 12 hours tiredness; next 12 hours nausea, diarrhea, fever (elevated 2.5-3 degrees from normal); body aches; difficulty breathing; next 9 hours body aches, fever and difficulty breathing intensified; went to ER at 5:30pm; blood oxygen at 72%; Rapid Covid test negative; chest xray presented as "white cracked glass"; 2nd covid test negative; admitted to hospital at 11:30pm as non-covid patient; on BiPAP machine at 100% oxygen for next 36 hours; weaning off oxygen over nine days in hospital; small blood clot in lungs found via CT Scan; treated with IV broad spectrum antibiotics and steroids; Section 21: Ascension ; 9-day hospital stay;
1228668	4/19/2021	FL	66	F	3/17/2021	4/1/2021	My symptoms i had sever headache! Once April 1st Hit! Thats Was the day I Had a Heart stroke at store, i don?t remember anything and once i woke up i was at the hospital, and they told me that i had a heart stroke because i had lots of blood clots in my body. And they told me i vomit and peed myself during the whole situation i went in store
1228672	4/19/2021	VA	61	M	3/30/2021	4/12/2021	Approximately 12 days after vaccination, he developed a soft tissue growth at the area of injection. No signs of induration, infection, or inflammation. No signs of clot. Presents as a lipoma, but was not present previously. It does cause him to have some discomfort.
1229299	4/19/2021	IA	28	M	3/11/2021	3/17/2021	Blood Clot diagnosed at Hospital.

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1229596	4/19/2021	MI	67	M	3/1/2021	3/1/2021	Blood clot in left arm caused a stroke

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1227915	4/19/2021	MN	58	F		3/30/2021	<p>PULMONARY EMBOLISM; FEVER; SLIGHT COUGH; FEELING ACHY; CHILLS; This spontaneous report received from a patient concerned a 57 year old female. The patient's height, and weight were not reported. The patient's past medical history included right leg deep vein thrombosis (2011), arthroscopic meniscus surgery (2011), and superficial thrombophlebitis on left leg from mid-calf up to mid-thigh (AUG-2020), and concurrent conditions included factor V Leiden mutation. (2011). The patient was not on oral contraceptive pills. No immediate family had history of clots. A family member on mom's side has had clots. She had right leg deep vein thrombosis in 2011 after arthroscopic meniscus surgery on right knee, followed by long car ride. She was diagnosed with Factor V Leiden mutation in 2011 at the time of that clot. She was on warfarin for about 4 months then taken off. She did well for almost a decade. In last AUG-2020 had a superficial thrombophlebitis in left leg from mid-calf up to mid-thigh. She was Xarelto (rivaroxaban), monitored with ultrasound, taken off on 15/17-JAN-2021. The patient was previously treated with warfarin for right leg deep vein thrombosis, and rivaroxaban for superficial thrombophlebitis on left leg from mid-calf up to mid-thigh. The patient received COVID-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808980), administered on 30-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 30-MAR-2021, the patient felt good with slight cough on the day. She experienced achy by 7 PM, went to bed, then started getting the chills. At 2 AM on 31-MAR-2021 she had fever of 102 F. The laboratory appointment on Thursday, 01-APR-2021 unrelated laboratory was ordered. On 01-APR-2021, she was walking from parking lot to a building and was very short of breath. On 03-APR-2021, she was going up one flight of stairs, and felt severely short of breath and had dry cough. On 4-APR-2021, she experienced pain between shoulder blades in back. Oxygen saturation at home was 93-94% on RA while resting. On 4-APR-2021, she went to emergency room at a computerized tomogram (CT) of chest with contrast around at 6:30 PM showed massive pulmonary embolism. The right chamber the heart was enlarged due to the blockage from the embolism. Blood levels for "stress on heart" came back high. The patient</p>

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went to cath lab for pulmonary angiogram on 4-APR-2021 and had EKOS catheter direct thrombolysis. She was started on heparin and transitioned to Xarelto (rivaroxaban) on 5-APR-2021. She was on blood thinners and the left lung was cleaned up and removed. The clot was still on the right lung, unable may or may not be cleared. The patient was discharged on 06-APR-2021. The patient was hospitalized for 2 days. On 04-APR-2021, Platelet count was 181 (normal range 140-440), on 5-APR-2021, Platelet count was 160 (normal range 140-440), on 6-APR-2021 Platelet count was 154 (normal range 140-440). At the time of this massive PE event, the patient was not on any anticoagulation and since the event, had been restarted on Xarelto, and she was told she needs to continue for life. The action taken with COVID-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from pulmonary embolism, and the outcome of feeling achy, chills, fever and slight cough was not reported. This report was serious (Hospitalization Caused / Prolonged, and Life Threatening).; Sender's Comments: V0: A 57-year-old woman with a history of Factor V Leiden deficiency (off anticoagulation for several months) and previous DVT 10 years ago was hospitalized for pulmonary embolism four days after vaccine. The same day after vaccine, the patient reported chills and a 102 F fever. Two days after vaccine she experienced shortness of the breath and four days after vaccine, the shortness of breath became worsened with pain in the back between the shoulder blades. The patient went to the hospital and was diagnosed with massive pulmonary embolism with enlargement of the right side of the heart. She underwent direct catheter thrombolysis in the cath lab and was started on Xarelto. The patient was hospitalized for 2 days and is doing well. Although there is a close temporal relationship, the history of Factor V Leiden with previous DVT provides plausible alternate explanation for the event.

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1228665	4/19/2021	UT	66	F	3/8/2021	3/14/2021	It started with flu like symptoms, upset stomach, not feeling well according to my husband who was present, fast onset of vomiting and continued to vomit for 24 hours many times, complete loss of memory for 24 hours, this started around 3:00 p.m. on 3/14/21, started to feel better about 24 hours later. Next event, 4/19/21, 7:30 a.m. had a very bad nose bleed with two large clots coming out of my nose. Nose bleed stopped after about 15 minutes.
1229471	4/19/2021	IL	86	F	3/13/2021	3/19/2021	Patient had 1st Pfizer vaccine on 3/13/21. She states she went to ER on 3/19/21 and was found to have a blood clot behind her left knee (found by ultrasound). She was put on Eliquis. Patient had 2nd Pfizer vaccine on 4/3/21. Patient did not mention blood clot at time of 2nd vaccine. Patient was admitted to hospital on 4/13/21 for stroke. It was attributed to bleeding in brain and patient was taken off Eliquis and put on a new blood thinner. She will be discharged on 4/20/21 to rehab.

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1229461	4/19/2021	MO	30	F	4/5/2021	4/7/2021	I had my first dose of Covid 19 Pfizer vaccine on the 5th of April, 2021 at 1pm. I had sore arm and was fatigued which was expected. However, the day I had my vaccine was also the day my menstrual cycle started and just to assure myself I informed the pharmacist and asked if that was okay and they said it shouldn't be a concern. I was doing fine until toward the end of day 3. I was expecting my period to stop as it always does on 3rd day but I started bleeding heavier that day there after. It didn't worry me much until I started discharging huge blood clots as big as an apple 2 times every after 30 mins from that moment. I rushed to the ER later that night(still bleeding heavily with blood clots every now and then) but I was not admitted since my vitals and the blood counts were normal at that moment. I went back home and hoped the bleeding would stop but again with on pain or fever what so ever I kept bleeding all day. This is my 5th day of bleeding. Then on Sunday morning, I still kept bleeding heavy and I was too weak that I went back to the ER again. This time , (day 6) I got admitted because I have had lost a lot of blood and I needed blood transfusion. My HB dropped from 11.3 to 6.7 and it went further down to 5 something. I got 3 units of blood transfusion in the ER. They did ultrasound, CT scans(with and without contrast) and still couldn't figure out the cause of the bleeding. My uterus showed no problems but my body was not even responding to Tranexamic acid to stop the bleeding. So the doctor proceeded with an angiogram and did an emergency uterine artery Embolization to stop the blood supply to the uterus. The bleeding stopped there after and I started regaining my vitals. However, the cause of the bleeding still remains unknown.
1229416	4/19/2021	CA	53	F	3/17/2021	4/5/2021	Patient diagnosed with a left arm deep vein thrombosis that extends from the forearm to the lateral part of the subclavian vein- nonocclusive in some areas.

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1229175	4/19/2021		61	M	4/1/2021	4/15/2021	Starting about 2 weeks after vaccine administration in left deltoid, patient started having a blotchy rash on left inner forearm. It looks like a giant bruise or almost like bleeding under the skin. Dark round circles. No pain, swelling, itchiness, or fluid. No pain on applying pressure to it. Was worried it was a blood clot but we think it is associated with receiving the vaccine as it is only in the left forearm. Patient states that it is "clearing up".
1229402	4/19/2021	SC	85	F	3/31/2021	4/10/2021	Patient was hospitalized due to multiple blood clots, including jugular, brachial, and others. Patient was hospitalized for treatment on 4/10/21 and is still there.
1229055	4/19/2021	TX	33	F	3/10/2021	3/29/2021	I found out about my pregnancy the day I got the vaccine (which was after I got the vaccine). After that I proceeded to get a pregnancy test confirmation (march 26) and it came back positive from the doctors office. On March 28 I began to have bleeding and I passed a blood clot the size of a baseball. I called the nurse line that next day and they told me they could not give me any medical advice because I had not been seen by a doctor for this pregnancy. During that week I began to experience a rash that began in the middle of my chest and proceeded to spread All over my stomach and back. It is now April 19 in the rash has continue to spread all over my limbs. On April 5 I went to the pregnancy clinic and was also getting a ultrasound and they were unable to locate the embryo in the uterus. On April 15 I got an ultrasound transvaginal and they were unable to locate an embryo or in a heartbeat. I then went to the hospital the next day on April 16 the hospital that I received my vaccine at and they did not give me any care and told me that my rash was a possible contact to something I may have come in contact recently. I try to express to the doctor that I've been experiencing issues since I received the vaccine and he did not connect any of the dots to my experiences. As of today April 19 I have come across several Different websites that state that red spot is a part of the symptoms an adverse reaction to the vaccine or should be of concern.
1229208	4/19/2021	CO	76	M	3/11/2021	3/21/2021	Patient urinated and passed a small blood clot. Happened once ten days after vaccination and then resolved. Patient had another episode 4/9/2021, passed small blood clot with urination, and again, resolved

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1229499	4/19/2021	FL	81	M	1/11/2021	1/24/2021	Multiple blood clots, bleeding, hematoma, bleeding events after heparin, swelling in lower body, gangrene in both feet, double below knee amputation, situation ongoing, still in hospital.
1229161	4/19/2021	MI	67	F	4/6/2021	4/7/2021	Fever between 103 and 104 f, dizziness, nausea, black outs for several days. Lost consciousness fully 1 week after shot and was admitted to the hospital and told she was covid positive. Dangerously low blood pressure. Given steroids and fluids, and meds to prevent blood clots and sent home the next day. Continued to pass out & vomit for a few more days. Went back to ER for fluids and nausea medication. 13 days since shot, and still running fever. Still very sick.
1229128	4/19/2021	FL	52	F	4/5/2021	4/16/2021	Presented with heahache Head CT showed dural sinus venous thrombosis currently treated with argatroban
1229095	4/19/2021	TX	76	F	2/27/2021	3/5/2021	Blood Clot in Lung, diagnosed March 27, 2021



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1229080	4/19/2021	CO	41	F	3/8/2021	3/19/2021	<p>Patient is a 41 yo woman with no PMH who presented to an outside urgent care with left flank pain found to have a wedge-like defect in the posterior left lower renal pole suggestive of a renal infarct. She underwent CTA which did not show any embolism, thrombus, dissection. The radiologist did note mild beading of the bilateral renal arteries, however the radiologist at Valley View reviewed the images as well and was not as convinced. Left renal infarct: Given suggestion of mild feeding of the bilateral renal arteries, patient underwent CTA of the chest, head and neck which did not show any other signs of fibromuscular dysplasia. Echocardiogram did not have any thrombus or decrease in function. Patient did not have any arrhythmias on telemetry. Blood cultures were ordered and pending on discharge, but patient did not have any of endocarditis. A hypercoagulable work-up including factor V Leiden, protein C, protein S, Antithrombin, lupus anticoagulant, beta-2 microglobulin, anticardiolipin antibodies were all sent and are pending at the time of discharge. Discussed the case with hematology at hospital: Most experts treat with 3 months of anticoagulation other evidence is not entirely clear and aspirin 81 mg may be a reasonable choice. In light of the patient's lack of insurance, decision was made to treat with 1 month of apixaban followed by 81 mg of aspirin daily indefinitely. Discharged with a short course of oxycodone 5 mg #15.</p>
1229407	4/19/2021	TX	50	F	4/6/2021	4/6/2021	<p>04/06/2021 -5pm redness that looked like a sunburn on both arms, 04/14or 04/15/2021 7pm worst leg cramp I've had since I was pregnant over ten years ago in right leg, 4/18/2021 about 3pm, all of a sudden there was a blood clot next to my eye (between my eye and my nose). No pain, just appeared.</p>

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1227932	4/19/2021	NJ	54	F	3/1/2021		<p>BILATERAL DEEP VEIN THROMBOSIS TO LOWER EXTREMITIES; PULMONARY EMBOLISM IN BOTH LUNGS; BODY ACHE; CHILLS; This spontaneous report received from a consumer concerned a 54 year old female. The patient's weight was 190 pounds, and height was 66 inches. The patient's past medical history included cancer, and concurrent conditions included no alcohol use, and non-smoker, and other pre-existing medical conditions included the patient was not pregnant at the time of reporting. The patient had no known allergies and drug abuse/illicit drug usage. The patient received JANSSEN COVID-19 VACCINE (covid-19 vaccine ad26.cov2.s) (suspension for injection, route of admin intramuscular, batch number: 1805031, and expiry: not reported) dose was not reported, 1 total, administered in left arm on 05-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 03-MAR-2021, the patient experienced chills. On 06-MAR-2021, the patient experienced body ache. Since 09-APR-2021, patient started experiencing leg pain and was admitted to a hospital on 10-APR-2021. The patient was diagnosed with 2 deep vein thrombosis (DVTs) to the lower extremities with pulmonary embolism. The patient was on therapeutic Lovonox (enoxaparin sodium) and was prescribed Lovonox injection twice a day for 6 months. The patient had visited emergency room and hospitalized for 5 days. The patient was discharged from hospital on 13-APR-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from body ache, and chills on 10-MAR-2021, and was recovering from bilateral deep vein thrombosis to lower extremities, and pulmonary embolism in both lungs. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: This 54-year-old obese female with BMI of 30.7 was hospitalized due to bilateral deep vein thrombosis (DVT) to lower extremities and pulmonary embolism (PE) in both lungs 35 days after receiving JANSSEN COVID-19 VACCINE (covid-19 vaccine ad26.cov2.s) in left arm for prophylactic vaccination. The patient's past medical history included cancer. The subject had chills 2 days prior to the vaccination and body ache 1 day post vaccination. The symptoms resolved 5 days post vaccination. She started experiencing bilateral leg pain 33 days post vaccination and chest pain 34 days post vaccination. The patient</p>

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1227919	4/19/2021			U			<p>visited emergency room and was hospitalized. She was diagnosed with bilateral DVTs to the lower extremities and PE in both lungs. Details of the hospitalization were not reported. She was discharged after 5 days of hospitalization with prescription of enoxaparin injection twice a day for 6 months. The patient was recovering from bilateral DVT to lower extremities and PE in both lungs. Based on the available information, with risk factors of obesity and cancer, DVT and PE are assessed as indeterminate with causal association to immunization, per WHO causality classification for adverse events following immunization. Company causality is considered not related to JANSSEN COVID-19 VACCINE. Additional information has been requested for further assessment.</p> <p>BLOOD CLOT IN LEG; BLOOD CLOT IN LUNG; This spontaneous self-report was received from a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029, expiry: unspecified) dose and therapy start date were not reported for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, 2 weeks after getting vaccination, the patient experienced blood clot in leg and blood clot in lung. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the thrombosis leg and thrombosis pulmonary was not reported. The patient also reported to VAERS (no reference number provided). This report was serious (Other Medically Important Condition).; Sender's Comments: A patient of unspecified age and sex experienced thrombosis leg and thrombosis pulmonary 2 weeks after vaccine. No concomitant medications were reported. No additional history, diagnostics, treatment, or other information was reported. There is insufficient information to make a meaningful medical assessment. Additional information has been requested.</p>

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1227921	4/19/2021	TN		F	3/1/2021		DVT; HEADACHE; UNCONTROLLED SHAKING; TROUBLE BREATHING; FEVER; This spontaneous report received from a company representative concerned a 29-year-old female. The company representative heard the information on the local news. The patient's height, and weight were not reported. The patient was taking estrogen-based birth control pills. The patient received COVID-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 19-MAR-2021 for prophylactic vaccination. Concomitant medications included estradiol for birth control. On an unspecified date in MAR-2021, one-week post-vaccination, patient developed uncontrolled shaking, had trouble breathing and fever. She went to the emergency room for her symptoms and was sent home (no time frame was reported). One week later, she developed swollen legs and couldn't walk, and she was diagnosed with a deep vein thrombosis (DVT). On an unspecified date she was hospitalized and admitted in the intensive care unit (ICU). Patient was out of the ICU on 11-APR-2021 (Sunday). Patient was still under treatment. It was also reported that patient had headache that persisted for 2 weeks. The report was from the local news and follow-up was not possible. The action taken with COVID-19 vaccine ad26.cov2.s was not applicable. The outcome of the uncontrolled shaking, trouble breathing, fever, headache and DVT was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: This is a spontaneous report of a 29-year-old female who developed a deep vein thrombosis two weeks after receipt of the Janssen COVID-19 vaccine. She also reported uncontrolled shaking, trouble breathing, and fever one week after vaccine administration, and a headache which had persisted for two weeks. No medical history was reported; she was taking estrogen-based birth control pills. Estrogen-based birth control pills place the patient at risk for thrombosis, but there are insufficient other details to make a meaningful medical assessment regarding the events in the case.

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1227922	4/19/2021	PA		F			<p>BLOOD CLOT; BROKE TAIL BONE; VACCINE EXPOSURE DURING PREGNANCY; This spontaneous pregnancy report was received from a pharmacist via a company representative, and concerned an approximately 40 year old female. The patient's height, weight, and medical history were not reported. The patient received Covid-19 vaccine Ad26.COV2.S (suspension for injection, route of administration not reported, batch number: unknown) dose and vaccination site were not reported, administered in 2021 for prophylactic vaccination. No concomitant medications were reported. In 2021, the patient experienced vaccine exposure during pregnancy. The date of the patient's last menstrual period and expected delivery date were not provided. In 2021, the patient experienced broke tail bone during labor and gave birth (live birth). On an unspecified date in 2021, the patient experienced a blood clot and died. It was noted that she was at high risk for clots because she was 4 weeks post partum (gravida 1, para 1). Action taken with Covid-19 vaccine Ad26.COV2.S was not applicable. The patient died of a blood clot and broke tail bone in 2021; the outcome of vaccine exposure during pregnancy was not reported. It was unspecified if an autopsy was performed. This report was serious (Death). This case, from the same reporter is linked to 20210430297.; Sender's Comments: V0: The case concerns a pregnant female subject around age of 40, who developed thrombosis, skeletal injury and exposure during pregnancy an unspecified time after Janssen COVID-19 vaccine was administered intramuscularly for prevention of symptomatic SARS-CoV-2 virus infection. The subject's past medial history, last menstrual period, estimated date of delivery and concomitant medications were not provided. Per the reporter (pharmacist) the patient was at a high risk for blood clots because she was 4 weeks post-partum. The patient broke her tail bone during the labor, gave a birth, and later died of a blood clot. No additional information was provided. It is not known whether the autopsy was performed. Given alternative explanation and risk factors of pregnancy, labor and skeletal injury (trauma) the event of thrombosis is considered inconsistent with the causal association to immunization, per the WHO causality classification for adverse events following immunization. Events of skeletal injury was result of an accident and</p>

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1227926	4/19/2021	NJ		M			<p>therefore not considered related. Company causality for event of thrombosis is considered not related to Janssen COVID-19 vaccine (Level 4 -Insufficient information available to confirm a possible, probable or a definitive case of venous thrombosis, per the Brighton Collaboration case definition); Reported Cause(s) of Death: BLOOD CLOTS; BROKE TAIL BONE</p> <p>BLOOD CLOT; This spontaneous report received from a consumer via a company representative and concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, a week or so after the Covid-19 vaccination the patient passed away in his sleep. The patient had no underlying condition. An autopsy was performed on an unspecified date and the patient was found to have blood clot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0: A male patient of unspecified age passed away in his sleep an unspecified time after receiving the Janssen COVID-19 vaccine for prevention of COVID-19 infection. It stated that the patient had no underlying condition. A blood clot was found by autopsy; no further details are provided. There is insufficient information to make a meaningful medical assessment. Additional information is being sought.; Reported Cause(s) of Death: BLOOD CLOT; Autopsy-determined Cause(s) of Death: BLOOD CLOT</p>

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1227928	4/19/2021	FL	64	F		3/17/2021	POTENTIAL DEEP VEIN THROMBOSIS; SMALL BLOOD CLOT; ANKLE CALF BOTH SWOLLEN; This spontaneous self-report was received from a patient and concerned a 64 year old female. The patient's height and weight were not reported. The patient's concurrent conditions included no known allergies and smoker. Other relevant history included no alcohol intake, nor any drug abuse/illicit drug use. The patient received COVID-19 VACCINE AD26.COV2.S (suspension for injection, route of administration and dose not reported, batch number: 1805029, and expiry: unknown) administered on 14-MAR-2021 on the left arm for prophylactic vaccination. No concomitant medications were reported. On 17-MAR-2021, the patient had "ankle calf both swollen" indicating potential deep vein thrombosis. She went to hospital emergency room, and "HCP confirmed small clot". The action taken with COVID-19 VACCINE AD26.COV2.S was not applicable. The patient was recovering from "ankle calf both swollen" and had not recovered from potential deep vein thrombosis and small blood clot. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This is a spontaneous report of a 64 year old female who developed a swollen calf and ankle swelling indicating a potential deep vein thrombosis 3 days after receipt of Janssen COVID 19 vaccine. Patient was seen in the emergency room by HCP, who confirmed a small clot. No other medical history was reported but patient was noted to be a smoker, reported as 2x a year. Age increases the risk of deep vein thrombosis, but the there is insufficient other details to make a meaningful medical assessment.
1227467	4/19/2021	PA	31	M	3/1/2021	4/18/2021	Deep venous thrombosis

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1227931	4/19/2021	TN		M	3/16/2021	3/16/2021	EAR BLEED; BLOOD IN SEMEN; NOSE BLEED WITH CLOT; CHEST PRESSURE; This spontaneous report received from a patient concerned a 56 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805031, expiry: 26-MAY-2021) dose was not reported, 1 total, administered on 16-MAR-2021 at right arm for prophylactic vaccination. No concomitant medications were reported. On 16-MAR-2021, the subject experienced chest pressure. On 23-MAR-2021, the subject experienced nose bleed with clot, ear bleeding and blood in semen within first week after the vaccine, blood in semen lasted around a week that reduced gradually and resolved. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from nose bleed with clot on 11-APR-2021, ear bleed on 26-MAR-2021, and blood in semen on 02-APR-2021, and had not recovered from chest pressure. This report was non-serious.



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1227818	4/19/2021			F			<p>BLOOD CLOT; This spontaneous report received from a consumer via media by a company representative concerned a female of unspecified age. The patient's height, and weight were not reported. The patient was prone to blood clots her entire life, but managed it. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration and batch number were not reported) dose (1 total), start therapy date were not reported, for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient developed a blood clot. A day after the vaccination, the patient died from the blood clot. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death, and Other Medically Important Condition).; Sender's Comments: This anecdotal report from media involves a female patient of unspecified age who was prone to blood clots her entire life and on an unspecified date developed a blood clot and died from the blood clot a day after received the Janssen COVID-19 Vaccine Ad26.COV2. Concomitant medications, and details of the event were not reported. This case has insufficient information to make a meaningful medical assessment. The case will be assessed further when additional information is received.; Reported Cause(s) of Death: BLOOD CLOT</p>

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1227933	4/19/2021	MS	59	U	3/22/2021		<p>THROMBOSIS ARM; SHORTNESS OF BREATHE; ARM BURNING; ARM DISCOMFORT; SWOLLEN ARM; This spontaneous report received from a patient concerned a 59 year old of unspecified sex. The patient's height, and weight were not reported. The patient's past medical history included blood clots treated with Eliquis. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805020, and expiry: UNKNOWN) dose was not reported, 1 total administered on 08-MAR-2021, left arm for prophylactic vaccination. No concomitant medications were reported. On 22-MAR-2021, two weeks after vaccination the patient experienced swollen arm and arm discomfort. On 29-MAR-2021, the patient experienced shortness of breathe and arm burning. On 30-MAR-2021, the patient experienced thrombosis arm. Laboratory data (dates unspecified) included: Scan (NR: not provided) Right Arm Occluded. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from swollen arm, and shortness of breathe, and had not recovered from thrombosis arm, arm discomfort, and arm burning. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This 59-year-old of unspecified gender, currently on Eliquis for history of blood clots noted swelling of arm with discomfort and burning (described as "like from a match") as well as shortness of breath 14 days after receiving COVID-19 VACCINE AD26.COV2.S on left arm. Scan showed right arm was occluded. Treatment for the events was not reported; the patient is recovering from swelling of arm and shortness of breath; the patient have not recovered from thrombosis of arm and arm discomfort/burning. The event is confounded by the underlying history of blood clots that is being treated medically. However, the events are assessed as indeterminate with a causal association to immunization, per the causality classification for adverse events following immunization based on a lack of a definitive plausible biological mechanism. Considering temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information has been requested for further assessment.</p>

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1227934	4/19/2021	IL	20	M	4/14/2021		FEMORAL DEEP VEIN THROMBOSIS; This spontaneous report received from a physician concerned a 30-40 year old male. The patient's height, and weight were not reported. The patient's pre-existing medical conditions were unknown. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose was not reported, administered on 25-MAR-2021 for prophylactic vaccination. The batch number was not reported. the company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 14-APR-2021, approximately 20 days after the patient received vaccination, he experienced femoral deep vein thrombosis. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from femoral deep vein thrombosis. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: A 30-40 year-old man experienced femoral deep vein thrombosis approximately 20 days after vaccination. No past medical history or concomitant medications were reported. There were no details provided, including diagnostic workup. There is insufficient information to make a meaningful medical assessment.

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1227937	4/19/2021	NV		F		4/2/2021	GAGGING; SHORTNESS OF BREATH; BACK HURTING; NOSEBLEED; GETTING HOT AND COLD; LEG PAIN / SORE ARM; CHILLS; HEADACHE; This spontaneous report received from a patient concerned a 56 year old female patient. The patient's weight, height, and medical history were not reported. The patient received COVID-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805025, expiry: not reported) dose was not reported, administered on 01-APR-2021 to the left arm as prophylactic vaccination. No concomitant medications were reported. On 02-APR-2021, the day after vaccination, the patient experienced chills, hurting back, feeling hot and cold, headache and sore arms. The patient administered TYLENOL (acetaminophen) for headache. She stated the lower part of back was hurting so that she increased her water intake but the pain did not go away. On 03-APR-2021, third day after vaccination, the patient experienced blood clot came out of nose and nose started bleeding, described as dark red (subsumed under nosebleed). At the same time on 03-APR-2021, patient experienced gagging, pain in legs, and shortness of breath. Treatment medications (dates unspecified) included: paracetamol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from headache, nosebleed, leg pain / sore arm, and shortness of breath, and the outcome of chills, back hurting, gagging and getting hot and cold was not reported. This report was non-serious.

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1227958	4/19/2021	MO	47	F	3/25/2021	4/4/2021	Blood Clots; Pulmonary Embolisms; DVT (Deep vein thrombosis); This is a spontaneous report from a contactable consumer (patient). A 47-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: ENG207), dose 2 via an unspecified route of administration, administered in Arm Left on 25Mar2021 10:00 (at the age of 47years) as single dose for Covid-19 immunization. The patient received the dose 1 of BNT162B2 via an unspecified route of administration, administered in Arm Left on 04Mar2021 08:30 (Batch/Lot Number: ENG203) as single dose for Covid-19 immunization. The patient is not pregnant at the time of vaccination. Medical history included essential tremor, insulin resistance, and anxiety; all from an unknown date and unknown if ongoing. Concomitant medications included propranolol, metformin, bupropion, and citalopram; all taken for an unspecified indication, start and stop date were not reported. The patient was not diagnosed with COVID-19 prior to vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced blood clots, pulmonary embolisms, and a DVT (deep vein thrombosis) on 04Apr2021 (11:00AM). The patient was hospitalized due to the events for 4 days. The patient was treated with Heparin and Eliquis. The patient was tested for Covid-19 post vaccination via Nasal Swab on 03Apr2021 with Negative result. The outcome of events was recovering. The adverse events resulted in Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event).

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1227960	4/19/2021	FL	72	F	1/4/2021	2/24/2021	Suffered a stroke; blood clots in the brain; This is a spontaneous report from a contactable consumer (patient). A 72-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number and expiration date not reported) via an unspecified route of administration, administered on the left arm on 04Jan2021 14:00 at a single dose for COVID-19 immunisation. Medical history included heart valve replacement, thyroid issues and headache. Concomitant medications included medications in the last two weeks (unspecified). The patient previously received first dose of BNT162B2 on an unknown date for COVID-19 immunization. On 24Feb2021 12:00 PM, the patient suffered a stroke - blood clots in the brain. Had brain scans earlier in the year for headaches but nothing found. The events resulted to doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event)]. The patient was hospitalized for the events for 7 days. Therapeutic measures were taken as a result of the events which included surgery to break and remove the clot. Prior to vaccination, the patient was not diagnosed with COVID-19. Post vaccination, the patient has not been tested for COVID-19. No known allergies. The facility where the vaccine was administered was in a Public Health Clinic facility. Patient was not pregnant. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Outcome of the events was recovered on an unspecified date. Information about lot/batch number has been requested.
1229600	4/19/2021	KY	32	F	1/27/2021	1/28/2021	Extremely heavy periods since vaccination. Four cycles since first vaccination and all are much heavier and closer together than normal, and now containing clots which I have not experienced before.

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1227930	4/19/2021	NH		F	4/5/2021		<p>BLOOD CLOT; ARM SORENESS; TIREDNESS; This spontaneous report received from a patient and concerned a 36 year old female. The patient's weight was 177 pounds and height was 165 centimeters. The patient's past medical history included fibroid surgery (fibroid was taken out 2 months), and concurrent conditions included alcohol drinker (once a week - occasionally), non-smoker, no drug abuse or illicit drug use, no known allergies. The patient received COVID-19 vaccine ad26.cov2.s (suspension for injection, intramuscular (right deltoid), batch number: 043A21A) dose was not reported, administered on 05-APR-2021 for prevention of covid-19 disease. No concomitant medications were reported. On 05-APR-2021, an unspecified amount of time after vaccination, the patient experienced arm soreness and tiredness that resolved within 3 days. On 15-APR-2021, 10 days after vaccination, the patient experienced calf pain and blood clot. It was reported the patient felt a very sharp pain on her right calf while walking, pain scale was 8/10, and it was so painful that she could not put pressure on it. Therefore, she decided to go to the hospital to have it checked. Her attending physician confirmed based on ultrasound that she has a blood clot on her right leg. She was prescribed blood thinner Eliquis (apixaban) however she was still undecided because her insurance denied to cover it and it was out of pocket. Once she returned home, she stated that the sharp pain was gone and it was just achy. After conversation with her physician, her physician postponed the medication for now because he wanted to make sure that her blood was not already thin before prescribing a blood thinner. She will go to the hospital again on 16-APR-2021 to see a hematologist for blood works and her physician advised her not to work until 20-APR-2021 as a preventive measure. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from arm soreness, and tiredness on 08-APR-2021 and had not recovered from blood clot. This report was serious (Other Medically Important Condition, and Life Threatening).; Sender's Comments: V0: a 36-year-old female experienced a blood clot in her right leg, 10 days after receiving the Janssen COVID-19 vaccine for prevention of COVID-19 infection. The patient is a non-smoker, her BMI is 34.5; she has no other relevant medical history and reported</p>

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							no concomitant medications. Ten days after receiving the vaccine, she felt a sharp pain, graded 8/10, in her right calf while walking. Ultrasound showed a blood clot on her right leg. She was prescribed Eliquis but did not fill the prescription and the pain subsided; she was to have further blood tests and see a physician the following day. Additional information is being sought.
1228271	4/19/2021	IL	30	F	3/20/2021	4/16/2021	Patient has been having left arm pain. Developed acute, partially occlusive left subclavian deep vein thrombosis found on duplex on 4/16/21. She was started on lovenox and will have further work-up.
1228553	4/19/2021	KY	65	F	4/5/2021	4/18/2021	The patient presented to the emergency department with altered mental status, dry heaving, and body aches. She was found to have a partially occluding thrombus of the right cephalic vein consistent with venous thrombosis, as well as findings of thrombosis in the anterior segment branch of the right portal vein. She had a d-dimer of 25.77 increased to 35.2, and was thrombocytopenic with a platelet count of 92, which dropped to 36 the following morning. Platelets to present were: 92-36-32-23-19-28. The patient received the Johnson & Johnson COVID-19 vaccination two weeks prior to presentation.
1228515	4/19/2021	VA	68	M	3/19/2021	3/20/2021	I had a blood clot on right side of brain resulting in stroke and not being able to use left side of body.



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1228508	4/19/2021	TX	42	M	3/10/2021	3/31/2021	Pt was found in severe distress in the bathroom by his wife. He couldn't walk or stand, complained of being dizzy with slurred speech and was throwing up a lot. 911 was immediately called. The EMTs during their assessment said his BP was normal but when he was asked his name, he started saying the alphabet"ABC... XYZ". He was transported by ambulance to ER. Cat scan showed he had a bleed on the brain. The doctors told us it was because he had very high blood pressure, however where the bleed was, they said he wouldn't need surgery and that the body would reabsorb it over time. He was admitted to the ICU and has been there ever since. Several days later, he started having difficulty breathing and they discovered several blood clots in his right leg that had broken off into his heart and lungs. He had emergency surgery to remove the clots in his heart (approximately 10) and was given heparin in small doses over an 8 hour period so that it wouldn't cause the bleed in his brain to increase. The doctor should fill in the rest.

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1228483	4/19/2021	PA	58	M	3/31/2021	4/4/2021	He got his vaccine, and on Sunday he thought that he had a cramp in his leg, and asked his wife and told her that he had this. By that afternoon he still had the cramping feeling, and started drinking water as his wife is a nurse and felt that he may be dehydrated. Throughout the week he had a Charlie Horse pain in his left calf, and felt that it was getting worse and not going away. The whole week he went to work and on the 7th day it started swelling and went to Hospital after he got off of work, and he saw a resident Dr. who said that his leg was swollen and told him that she was going to schedule an ultrasound. He had that on Friday on 4/16/21, and was scheduled for 4:00 but due to the pain went to the ER and gave him IV and checked his blood work. The ultrasound showed that he did have a blood clot and prescribed Eliquis and gave him a dose while in the ER. He told him that he would be on that for a while. He is supposed to see the resident this afternoon for recheck. He is still having pain and wanting to know where he is going to do from this point. He does work out every day at his home gym and has not smoked, and now wanting to know how this is going to affect his life from this point into the future. He also jumps rope 3 times a day and now not able to do this.

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1228468	4/19/2021	PA	58	M	3/30/2021	4/4/2021	He got his vaccine, and on Easter he thought that he had a cramp in his leg, and asked his wife and told her that he had this. By that afternoon he still had the cramping feeling, and started drinking water as his wife is a nurse and felt that he may be dehydrated. Throughout the week he had a Charlie Horse pain in his left calf, and felt that it was getting worse and not going away. The whole week he went to work and on the 7th day it started swelling and went to Hospital after he got off of work, and he saw a resident who said that his leg was swollen and told him that she was going to schedule an ultrasound. He had that on Friday on 4/16/21, and was scheduled for 4:00 but due to the pain went to the ER and gave him IV and checked his blood work. The ultrasound showed that he did have a blood clot and prescribed Eliquis and gave him a dose while in the ER. He told him that he would be on 2 a day for 7 days and then 1 a day, but did not tell him how long. He is supposed to see the resident this afternoon for recheck. He is still having pain and wanting to know where he is going to do from this point. He does work out every day at his home gym and has not smoked, and now wanting to know how this is going to affect his life from this point into the future. He also jumps rope 3 times a day and now not able to do this.
1228406	4/19/2021	KS	48	F	3/29/2021	4/5/2021	A week after receiving the shot, I started experiencing severe pain in my left calf. On Friday, April 9, I was diagnosed with 2 blood clots in my left leg (Thrombus in the posterior tibial vein on the left.).

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1227917	4/19/2021	NJ		M		4/4/2021	<p>BLOOD CLOT IN LEG; This spontaneous report received from a patient concerned a 72 year old male. The patient's height, and weight were not reported. The patient was reported to be over 6 feet tall and not overweight. The patient's past medical history included cataract surgery (in his 60s); and concurrent conditions included former smoker (ex-smoker who quit 1 year ago). The patient had no chronic medical conditions and had no history of recent travel or trauma. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose was not reported, administered on 01-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. The patient was not taking any concomitant medications. On 04-APR-2021, the patient's leg felt abnormal and on 05-APR-2021, the patient went to urgent care center, where an ultrasound found a blood clot. The patient was prescribed Eliquis (apixaban) and was since feeling better, however, still had leg discomfort. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from blood clot in leg. This report was serious (Other Medically Important Condition). Additional information was received from consumer (daughter of patient) via telephone follow up on 16-APR-2021. The following information was updated and incorporated into the case narrative: patient details, medical history, concurrent conditions, medical story including treatment, and event details.; Sender's Comments: V1: Follow up from the patient's daughter provided additional clinical details. This case concerns a 72 year-old male without significant medical history who was diagnosed with a blood clot in his leg 4 days after receiving the Janssen Covid-19 vaccine. He is not overweight, is not taking chronic medication, and had no recent trauma or travel. He quit smoking one year ago. Three days after vaccination, his leg felt abnormal. The following day, he went to an urgent care center where an ultrasound revealed a lower extremity blood clot. He was sent home with apixaban. No information regarding blood testing was provided. As of the time of the report (i.e. 11 days after his diagnosis), he is feeling better but still has leg discomfort. Based on the limited information, the relationship with Janssen Covid-19 vaccine is considered inconsistent. Additional information is being sought.</p>

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1228304	4/19/2021	PA	62	F	3/16/2021	3/19/2021	I was ill with diarrhea, sick to stomach, blood clots coming out of my rectum for 24 hrs., body aches.
1227916	4/19/2021	PA		F		3/1/2021	BLOOD CLOTS IN BRAIN; This spontaneous report was received concerning a female patient of unspecified age. The patient's weight, height, and medical history were not reported. The patient received COVID-19 VACCINE AD26.COV2.S (suspension for injection, route of administration not reported), administered on an unspecified date in MAR-2021. The batch number was not reported. No medical history or concomitant medications were reported. On an unspecified date in MAR-2021, the patient was ill for a few weeks with a headache and was subsequently hospitalized with blood clots in her brain. The outcome of blood clots in brain was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: 20210425372 V0: This is a spontaneous report of a female of unspecified age who experienced a headache and reportedly blood clots in her brain (cerebral thrombosis), a few weeks after receipt of the Janssen COVID-19 vaccine. No medical history, concomitant medications or additional details were reported. No laboratory results were provided. Additional information has been requested. The blood clot could represent cerebral venous sinus thrombosis (to be clarified). The case will be assessed further when additional information is received.

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1227980	4/19/2021	TX	51	M	3/27/2021	3/1/2021	Blood Clot/The Blood clot was in the legs and went to his lungs; Blood Clot/The Blood clot was in the legs and went to his lungs; fell; Leg pain; This is a spontaneous report from a contactable consumer. A 51-year-old male patient received his first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 27Mar2021 (Batch/Lot Number: EP6955) as single dose for covid-19 immunisation. Medical history included thrombosis from 2020 to an unknown date, it was Months ago in 2020, He was prescribed a medicine for blood clots, but since then he has had no issues, anxiety from an unknown date and unknown if ongoing. Her brother in law had anxiety about even getting the vaccine. The patient experienced leg pain on Mar2021 , pulmonary thrombosis, leg thrombosis and fall on an unspecified date. The patient died on 02Apr2021. An autopsy was not performed. The clinical course was the following: The Blood clot was in the legs and went to his lungs, his leg never got red or anything and it was a blood clot. He was having such bad leg pain, it's too bad, had there been some sort of warning, he would have thought to wait till next year. There was nothing the day he got vaccine, but that night his leg started hurting, his girlfriend said let me go get a cold wrap and she wrapped it, he's a farmer. He wakes up the next day and his leg is still hurting, the 3rd day it goes on, his leg still hurting and no one is thinking it a blood clot, he calls the doctor and tells the doctor his leg is hurting, they suggest ibuprofen for inflammation, the next day thought maybe it's better, by Friday he was making breakfast, fell and died. With his girlfriend she said what's going on, and he went straight to hospital, they said the clot in his leg went to the lung. The Blood clot when it was in the leg it never got hot, red, or anything like that. He had the vaccine in the morning and on that same day the leg pain started later that night. It Started out with Leg Pain, she does not know if it was right or left but it was just one leg.; Reported Cause(s) of Death: Thrombosis pulmonary; Thrombosis leg; Fall; Leg pain

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1227979	4/19/2021	TX		M		3/1/2021	got clots all over the body; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced got clots all over the body in Mar2021 and he passed away. Pfizer has not been reporting any effects of blood clot. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: got clots all over the body

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1227978	4/19/2021		23	M	1/25/2021	1/25/2021	Nodule on both forearm; swelling along veins and they became painful; swelling along veins and they became painful; 2 superficial venous thromboses, one in my arm and another in my leg; 2 superficial venous thromboses, one in my arm and another in my leg; Deep vein thrombosis leg; This is a spontaneous report from a contactable consumer (patient). A 23-year-old male patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration in arm left on 25Jan2021 (Lot Number: EL3247), as single dose, for COVID-19 immunisation. Patient was vaccinated in the hospital. Medical history and concomitant medications were none. Patient did not have known allergies. Patient did not have COVID-19 prior to vaccination. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech, lot# EL0142) on 04Jan2021 at 11:30 AM in left arm and experienced nodule on extremity and vaccination site nodule. The patient experienced deep vein thrombosis leg (medically significant, life threatening) in 2021 with outcome of not recovered, nodule on both forearm (life threatening) on 25Jan2021 with outcome of not recovered, swelling along veins and they became painful (life threatening) in 2021 with outcome of not recovered, swelling along veins and they became painful (life threatening) in 2021 with outcome of not recovered, 2 superficial venous thromboses, one in arm and another in leg (life threatening) in 2021 with outcome of not recovered. It was reported that within hours from second dose the nodules reappeared. At this time, patient was told to take Allegra and did so for 4 weeks. A month later, patient began to see some swelling along his veins and they became painful. This developed into a DVT, deep venous thrombosis, in leg and 2 superficial venous thromboses, one in arm and another in leg. all the events required physician office visit. None of the events occurred at vaccination site, but physician believed they were triggered by receiving the vaccine. Treatment of Eliquis was initiated the day before report. Patient was not tested for COVID-19 post vaccination. Follow-up attempts are completed. No further information is expected.



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1227977	4/19/2021	IN		M	3/24/2021	3/26/2021	<p>Pulmonary embolism/ blood clot/ passed out; This is a spontaneous report from a contactable consumer (patient's daughter). A male patient of an unspecified age received BNT162B2 (Pfizer COVID-19 vaccine), dose 1 via an unspecified route of administration, administered in arm, side unknown, on 24Mar2021 14:30 (Lot Number: EN6208) as single dose for COVID-19 immunisation. Vaccination facility type was clinic. Medical history included colon cancer in 2011. He had cancer in 2011 but resolved that year without chemotherapy or radiation. His lab work was good. There were no concomitant medications. No prior vaccinations (within 4 weeks). No family medical history relevant to AE. The patient experienced pulmonary embolism on 26Mar2021 with fatal outcome. The reporter was reporting on the Pfizer COVID vaccine that her father received. She stated he died from a blood clot after receiving the first dose. Stated she needs help because he had no health issues and he died. She just wanted this information to be out there and for people to be aware. This morning they had been reading on the news that the Johnson and Johnson vaccine is on hold. It seems to be put on the market without research. She felt like her father was a guinea pig. Her mother didn't want to get her second dose. Stated there seems to be an issue with Pfizer too. Her father had no issues whatsoever. His death certificate stated the cause of death was a pulmonary embolism, but he had no history of blood clots. Passed away Friday 26Mar2021 at 11:33 am. The reporter stated when he went to Emergency Room they thought he was having a heart attack. All physicians were wondering what happened because he had no health issues. The event required a visit to the emergency room that day because he passed out at his job. The patient underwent lab tests and procedures which included lab work: good in 2011. The patient died on 26Mar2021. An autopsy was performed that revealed pulmonary embolism.; Reported Cause(s) of Death: Pulmonary embolism; Autopsy-determined Cause(s) of Death: Pulmonary embolism</p>

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1227968	4/19/2021	NY	30	F	1/27/2021	1/29/2021	DVT (Phlegm Asia Cerulean Dolmens); This is a spontaneous report from a contactable health care professional (patient). This 30-year-old female patient (not pregnant) received 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL9262) at single dose via an unknown route in left arm on 27Jan2021 12:00 PM for Covid-19 immunization. Medical history included urinary tract infection. Family history included chronic kidney disease (CKD). No other vaccine in four weeks. No Covid prior vaccination. Other medications in two weeks included spironolactone 50 mg, daily. Historical vaccine included 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL3248) at single dose via an unknown route in left arm on 06Jan2021 17:30 for Covid-19 immunization. The patient experienced DVT (Phlegm Asia Cerulean Dolans) on 29Jan2021 05:00 AM. AE resulted in Emergency room/department or urgent care, and was serious due to hospitalization and life threatening illness (immediate risk of death from the event). The event resulted in 2-day hospitalization. Known allergies included and had reaction (hives) to apixaban (ELIQUIS) upon discharge from hospital after thrombectomy. Covid tested (saliva) post vaccination on 13Feb2021 was negative. The event treatment included thrombolysis, thrombectomy. Outcome of the event was resolved with sequel (reported as recovered with lasting effects).; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event deep vein thrombosis occurred in a plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Committees and Investigators, as appropriate.

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1228608	4/19/2021	CA	59	F	3/13/2021	3/13/2021	She got the vaccine and immediately she got the headache, loss of appetite, dizziness. The next day she had the aches and pains, nausea, loss of appetite, vomiting and she is still going through it on 4/19/21 and this is her first day back to work. She did have brain fog, nose was bleeding everyday and was put on antibiotics as her arm swelled up. Her arm swelled up, and went to the ER who said that she had an infection in it, and gave her antibiotics and anti-inflammatories. The infection did go away but the inflammation and swelling are still present. She started getting numbness in her arms and legs, and had a CT scan which did not show any blood clots. She is waiting on a referral to a neurologist to see what is going on with that. She also has been having problems with her lungs, asthma has been acting up and gave her a shot to open her throat as it was slowing closing and gave her a steroid shot to stop the swelling as she was having difficulty speaking. If she talks too much her throat gets irritated and starts to lose her voice. She has been in and out of the ER and UC due to this. She never had a fever, rash, or anything else. She does still have a lot of weakness.
1228364	4/19/2021	PR	68	F	4/9/2021	4/16/2021	On Monday April 12, my mother reported leg pain which she thought was related to a flare up of her knee (surgery 4 years ago). She described her pain as a strong sharp pain, that spread throughout her calf area. She reported it as increasing in pain and worsening daily. By Friday April 16th I asked her to report to Emergency Department. At which time she was told she had a blood clot in her right leg.
1231003	4/19/2021	WI	39	F	1/6/2021	4/1/2021	Blood clot left arm, arm swelling
1230416	4/19/2021	NY	85	F	4/7/2021	4/8/2021	Presented with right hand/arm pain, numbness, and weakness since morning after receiving injection on ipsilateral side. Workup and imaging confirmed acute arterial thrombosis of the right upper extremity requiring surgery and thrombectomy.
1230513	4/19/2021	VA	55	F	3/7/2021	3/14/2021	Approximately a week after vaccine, I began to have Claudication pain in right leg that progressed to critical limb ischemia with 4 weeks requiring surgery to remove serial clots in right lower extremity.

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1230555	4/19/2021	FL	85	F	3/17/2021	3/28/2021	Vaccination was on Wednesday, March 17, 2021 at 3 PM. Symptoms began 8 days later, and Emergency Room admission 3days later on Sunday, March 28, 2021, for Blood Clots in legs and lungs,(critical in Pulmonary Artery). Blood thinner started immediately was Zarelto, and continues daily. Pain, nausea, shortness of breath, and fatigue were the symptoms. The patient was admitted to hospital for 5 days and sent home to recuperate. 3 days later, on Sunday she was back into the emergency department with intestinal bleeding that had gone on for 2 days. She was admitted again and had a colonoscopy. Bleeding stopped and she went home after 3 more days. She is currently getting home health care.
1230622	4/19/2021	OH	57	M	3/18/2021	3/19/2021	Had a blood clot and a stroke and blind in right eye, and some paralysis in face. Happened day after first vaccine.
1230771	4/19/2021	MN	57	M	4/7/2021	4/15/2021	Deep Vein Thrombosis in lower right leg
1230832	4/19/2021	PA	62	F	4/3/2021	4/4/2021	4/4 2021 - Red raised Rash at the injection site about the size of a quarter 4/5 2021 _ Itchy raised rash, sore to the touch about the size of a dollar piece 4/6 2021 - Itchy raised, hard and hot. sore to the touch about 3" round 4/7 2021 - Itchy raised, hard, sore to the touch about 3 1/2" round Called Dr. Was told to take Benadryl, Tylenol, compress If no improvement the next bay then I had to come in to the office. I started to see some improvement- not as red. over the next two day it continued to itch less, redness was fading, still itchy and hard. By the 11th they swelling was down to the size of a quarter and redness was gone but still itchy. 4/18 it was about the size of a pea still a little itchy but doesn't hurt and no redness. However, on 4/13 around 6:30 pm I had to be rushed to the hospital couldn't breath, vision and speech was declining . was admitted for blood clot that cut the oxygen to brain causing a mini stroke
1230841	4/19/2021	FL	83	F	3/19/2021	4/13/2021	Blood clot, stroke

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1230848	4/19/2021	AZ	64	F	4/5/2021	4/12/2021	Exactly a week after receiving the J&J vaccine, I was out on my morning walk when my head became very fuzzy and my vision was altered (seeing jagged zigzags-fuzzy ones with my left eye). The vision issue persisted when I closed my eyes. The fuzzy head issue continued during a very difficult walk home and when I arrived and things didn't clear, my husband ended up taking me to the emergency room. I got in quickly because the symptoms I described sounded to them like a stroke. But, I didn't have a stroke. They did a CT scan. It was fine. The vision thing they thought sounded like the effect of a migraine. But, I've never experienced migraines. (Note: this incident occurred the day before the news of the J&J blood clots became public). Anyway, after a couple of hours in the emergency room, I was fine and went home. So, I don't know what happened and it probably didn't have anything to do with the vaccine. I'm not prone to being alarmist and I would only consent to go to the emergency room if I thought I were in a serious situation. The blood work indicated my platelets were in the normal range. And, I'm too old to be in the category of the six women who experienced blood clots. However, I just thought I should report this in case anyone else experiences something similar.
1230912	4/19/2021	CO	40	F	4/1/2021	4/6/2021	Cavernous Sinus Thrombosis, Right Jugular Thrombosis, Pulmonary Embolism, thrombocytopenia (20K)
1230412	4/19/2021	OH	60	F	4/13/2021	4/15/2021	Deep Vein Thrombosis right leg, superficial femoral vein to popliteal vein and distal

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1230972	4/19/2021	FL	74	F	2/27/2021	4/13/2021	<p>Blood Clot in the Left leg; Pain in the Left Leg; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Blood Clot in the Left leg) in a 74-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 007B21A and 007B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Blood pressure high. Concomitant products included LISINOPRIL and HCTZ for Blood pressure high. On 27-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 2 dosage form. On 13-Apr-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced PAIN IN EXTREMITY (Pain in the Left Leg). On 14-Apr-2021, the patient experienced THROMBOSIS (Blood Clot in the Left leg) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood Clot in the Left leg) and PAIN IN EXTREMITY (Pain in the Left Leg) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Apr-2021, Ultrasound joint: ultrasound (abnormal) Blood Clot in the Left leg. Patient did not have a history of Blood Clots. She was Not taking any hormones (Estrogen, Progesterone) Treatment for event included Eliquis for blood clot. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. Based on the current available information and temporal association between the use of the product and the onset date of the reported event a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported event a causal relationship cannot be excluded.</p>
1230559	4/19/2021	AZ	53	M	3/30/2021	4/2/2021	<p>pateint reported he had blood clot 3 days after receiving moderna vaccine</p>

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1231007	4/19/2021	NY	70	F	2/21/2021	2/22/2021	The day after I received the vaccine I felt pain in my right leg. I went to a pain mangagement doctor and he ordered an ultrasound. It revealed that it was negative for a blood clot but it was an psuedo aneurism. I then had a CTA scan that revealed that it was a Popiteal aneruism. The doctor does not know the cause of this but said that it could be a reaction from the vaccine.
1231017	4/19/2021	NV	63	M	3/11/2021	3/18/2021	ultrasound found first blood clot behind left knee on 3/18/21....Another clot on left ankle on 4/08/21.... Another clot on left shin on 4/16/21.... Doctor prescribed Xarelto on 3/18/21... Since that date the 2 later blood clots have formed... I have NEVER had a blood clot before receiving Jansen vaccine at a community church on 3/11/21
1231037	4/19/2021	NM	61	U	4/15/2021	4/15/2021	Patient experienced leg pain with first vaccine that continued and only worsened with second shot. He also had 4-5 episodes of headaches that went away and SOB episodes when talking. Cramps in left leg: He went to the hospital. The ultra sound lady said she saw a small clot. The PA he saw reported the radiologist did not diagnose a clot. The PA cautioned from prescribing any blood thinners for fear of interacting with DM medications (metformin and lisinopril). The PA gave the green-light for the second shot. Symptoms worsened after booster.
1231133	4/19/2021	MT	76	M	2/18/2021	3/10/2021	Severe blood clots on both lungs
1231186	4/19/2021	TN	18	M	4/5/2021	4/16/2021	Approximately 11 days after receiving my first dose, I began feeling dull pain in my left calf. By Saturday, 4/17, the pain was severe enough to warrant a trip to the emergency room. After receiving an ultrasound of my leg, two blood clots were found in my left calf. One fully occluded a vein and another partially occluded a different vein.

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1231210	4/19/2021	IN	57	M	3/12/2021	3/15/2021	I received the vaccine on 3-12-21 and woke up 3-15-21 with pain in the bottom of my left foot. I scheduled an apt with my PCP on 3-16-21. My PCP scheduled an ultrasound on 3-24-21 where the nurse discovered blood clots in my lower left leg. I started taking Eloquis later that afternoon. I then had an apt with a blood dr. on 4-9-21 where she drew blood for tests. I was experiencing my heart racing and she scheduled me an apt with a cardiologist on 4-13-21 where the cardiologist suspected that the clots had moved into my lungs. The cardiologist did an EKG on the same day. I have a heart echo scheduled for 5-7-21. I am experiencing side effects from Eloquis so 4-19-21 I switched to Xeralto.
1231267	4/19/2021	MA	21	F	4/16/2021	4/17/2021	The day following the injection, I had vaginal spotting that was bright red, not clots, and severe cramping. Note that this was not during the menstruation portion of my cycle. It lasted for about 2 hours.
1229630	4/19/2021	WA	64	M	3/28/2021	4/7/2021	Pain in lower left bicep in first week, experiencing fatigue/tiredness. After 10 days I experienced severe pain at the site of injection, very small red spot appeared around injection site. Pain was so severe, I took one capsule hydrocodone 5-325 TB at 2 AM. The medication did not cure the pain, and I slept less than two hours. I called my nurse practitioner's office, and they offered an appoint late in the morning. And I couldn't wait that long so I drove to urgent care. Prompt care examined and saw no swelling, ruling out possible blood clot. Prompt care did not have ultra sound. They told me to use ice, heat, and pain medication. Extreme pain continued for about three more days, pain medication did very little to help. Unable to speak directly to the Nurse Practitioner on the phone, due to my disability and alexia, communicating online is very difficult without an assistant present. The pain slowly subsided over the next week.



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1229905	4/19/2021	NJ	51	F	3/23/2021	3/23/2021	3/23 & 3/24 - Sore arm 3/23 & 3/24 - Severe diarrhea which did make me weak 3/23 - 3/26 -My Sjogrens Syndrome had a flare but I previously never had such dry hands and dry legs. - I did have fatigue 4/1 & 4/2 - I had COVID arm -> I can share a picture of my left arm 4/9 thru 4/11 - Bulging temple on my left side just above my left eye appeared -- I took aspirin from 4/9 thru 4/12 to reduce chance of a blood clot -- This never happened like this in my life before and I had no headache and I was not dehydrated -- I can share a picture of the temple by my eye. I did feel fatigue. 4/7 thru 4/17 - The left side of my upper lip twitched for about a minute; it usually occurred in the morning when I woke up. 3/23 thru 4/17 - My Sjogrens Syndrome dry eye inflammation and dryness increased in my left eye but has since gone back to pre-vaccine limited dryness

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1231266	4/19/2021	NV	30	F	4/6/2021	4/6/2021	Around 5:30 pm in the evening following my vaccine I started having chills, headache, nausea, and fever of 101. Chills got worse, whole body was shaking and shivering. Nausea progressed into constant dry heaving. Head was pounding with the worst pain I have ever felt in my life, worse than natural child birth and worse than running marathons. The nausea was so bad and I could feel my fever burning and getting worse. I was about to vomit so got out of bed to go to the toilet to vomit and the whole room started spinning completely out of control. My heart was racing and I could hear it and feel it pounding rapidly through my ears. I couldn't walk and was so disoriented I crawled to the bathroom to throw up in the toilet. My husband heard me and came and picked me up off the bathroom floor and carried me to our bed. As the night progressed fever got worse, head was in almost unbearable pain, severe body aches over my whole body, heart racing and horrible nausea and dry heaving. I made it through the night. For two days after I had a headache and fever and nausea and body aches and couldn't get out of bed to care for my children. By the third and fourth day I was able to get out of bed at times and still felt fatigue, nausea, headache and body aches. Anytime I would stand up for 10 days after the vaccine it felt like I was rocking on a boat. I am almost at 2 weeks and still feel fatigue and dizziness at times. On April 15th, 9 days after my vaccination I had symptoms of a blood clot in my leg. I went to the Emergency Room and was diagnosed with a superficial blood clot of the leg as well as swelling in the vein. I am thankful to be alive!
1230927	4/19/2021	VA	37	F	2/15/2021	2/20/2021	Extremely heavy period bleeding started on February 20th out of no where. Bleeding contained big clots and was very heavy. Went to my GYN on March 15th who prescribed a five day supply of Tranexamic acid. On March 20th, my bleeding finally stopped.

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1229690	4/19/2021	CO	34	F	3/23/2021	4/3/2021	Janssen COVID-19 Vaccine EUA: patient presents to the emergency department (ED) reporting headache (10 out of 10 pain, difficult to keep eyes open) with neck pain, blurred vision, nausea, and photophobia for two weeks prior to arrival. Patient is four month post partum and breastfeeding. Patient diagnosed with cerebral venous sinus thrombosis and intraparenchymal hemorrhage. Admitted and underwent venous sinus thrombectomy. Currently still hospitalized.
1230405	4/19/2021	GA	60	F	4/10/2021	4/16/2021	Six days after receiving the Johnson & Johnson/Janssen vaccine, the patient complained about strong pain in the right arm (same as vaccination arm). She went to the ER on the 7th day after receiving the vaccination and after doing EKG, ultrasound, and CT scan, they found multiple blood clots in her right arm where she received the vaccine.
1229685	4/19/2021	GA	40	F	3/19/2021	4/1/2021	On 04/01/2021 I had a random nose bleed and passed a clot the size of half of a bean.
1229697	4/19/2021	MD	34	F	3/16/2021	3/16/2021	After the first dose the patient started to bleed (uterine bleeding) couple hours after the vaccine administration. Ultrasound located the source in uterine ? possible blood clot (the bleeding has stopped by itself after 6 days. After the second dose it happened again, the bleeding has not stopped on day 8 (and counting). Diagnosis: uterine bleeding ? unknown nature.
1229713	4/19/2021	CA	42	F	3/10/2021	4/4/2021	Menstrual flow has been heavier, lasting longer and with more clots, and more intense cramps. Has continued spotting since the end of menstrual flow, which is also unusual for her.
1229724	4/19/2021	OH	62	M	3/10/2021	4/1/2021	Patient started with Left lower leg pain and redness on 4.1.21. Went to Emergency dept on 4.4.21 and diagnosis of Left leg cellulitis and prescribed Doxycycline. Patient came to PCP office on 4.6.21 with worsening left lower leg pain and swelling. Order L lower leg doppler. Diagnosis of L lower leg deep vein thrombosis of tibial vein on 4.7.21 and prescribed Apixaban 5mg 2 BID x 7 days on 4.7.21

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1229745	4/19/2021	CA	39	M	4/11/2021	4/14/2021	is a 39 yo M with no significant PMH. He presents for symptoms following Johnson and Johnson vaccine. PMH: none PSH: Right knee surgery, Lasik Family Hx: Denies any family history of HTN, clots, heart disease Patient received the Johnson and Johnson COVID-19 vaccine on 4/11/21, he began feeling tired, headache and bilateral leg pain on 4/12/21. He had one dose of Tylenol 4/12/21. At around 4pm on 4/14/21 he reports that he had SOB, more bilateral leg pain, and dizziness. He states he went home and slept. Woke up Thursday and all his symptoms had resolved. Denies chest pain, numbness, tingling, swelling in his legs. Patient does endorse that he does have a stressful job working for airport and he had 3-4 cups of coffee daily. He also endorses that after the new of the side effects of the Johnson and Johnson vaccine appeared, he did notice he had more anxiety. Occupation: Works at airport, 12 hours shifts, on-call Social: no drinking, no drugs, smokes 1 cigarette per day for past 8 years
1229812	4/19/2021	VA	41	F	1/27/2021	4/3/2021	Prior to Covid vaccine, no periods in 25 months. After vaccine, 4/3/21, started with heavy bleeding, abdominal cramping and passing clots. Bled for 13 days, with the heaviest bleeding of my life and passing large clots. On 4/13/21, placed on Megestrol Acetate 40mg daily to treat for 20 days, currently on day 6 of treatment.
1229829	4/19/2021	OH	22	F	3/20/2021	4/5/2021	In addition to the typical expected reaction to the Pfizer vaccine (fever, sore arm, etc.), I have been suffering from abnormal menstrual bleeding since the vaccination. I felt as though it was necessary to report because my doctors have no idea what is causing this, and nothing else could be affecting it. I have been bleeding for 2 weeks now (starting April 5), with clots around 5". I had a full CBC in January and found nothing abnormal that could explain this, including no history of extended bleeding (historical max of 7 days).
1229890	4/19/2021	AK	57	M	3/12/2021	4/5/2021	Vet states he is having right-sided chest pain under his right breast. It started about 2 weeks ago which was two weeks after getting the Janssen vaccine. he heard the vaccine was causing lung clots and he wanted to notify us.
1229894	4/19/2021	CA	62	F	4/2/2021	4/3/2021	blood clots in lungs

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1229975	4/19/2021	TX	70	M	2/24/2021	2/28/2021	Reported by patients wife. She Reports blood clot in left leg "from thigh to calf". Treated with blood thinners since beginning of March 2021. Has taken Enoxaparin Sodium 100mg bid since onset and recently started on Xarelto by hematologist 04/16/2021.
1230337	4/19/2021	FL	41	F	2/9/2021	4/19/2021	I developed a rash 3 weeks after my second shot on my legs arms stomach and back. Not going away does not itch red spots doctor treated with ABx didnt help gave me prednisone no help. Today noted blood when I wiped saw blood and clots in toilet my period just went off last week now I'm bleeding again this has never happened before. I am very concerned please contact me asap
1230389	4/19/2021	VA	65	F	3/8/2021	3/15/2021	High fever, severe night sweats, blood clots in lungs
1229680	4/19/2021	MO	46	F	4/6/2021	4/7/2021	Received Janssen vaccine 4/6. Started menstrual cycle 12 hours after vaccine even though had just completed last cycle 1 week prior. Normally cycles are 28-30 days apart. They have not been quite as regular since Covid and has had some shorter periods between normal cycles. After the vaccine bleeding was heavier than normal with large clots but by end of last week had changed color and looked like it was ending. Today had no discharge upon awakening but again has a small amount of bright blood. Of course, there is concern for coagulopathy related to the vaccination. No leg pain, no shortness of breath. Has had HA off and on since had Covid but no worse now than in previous weeks. Left ear pain has been painful since Covid but now has pain in both ears when that occurs. Quit taking ibuprofen last week for discomfort and switched to Tylenol.
1230006	4/19/2021	AZ	44	F	4/12/2021	4/12/2021	Patient's husband reported that patient has been feeling nauseated since she received the vaccine and that she has started having stomach cramps. He reported that they are concerned about her having blood clots and he was informed to take her to the her primary care if that is a concern. He bought OTC aspirin and reported that he will have patient take it for the new two weeks. He was advised to take patient to the doctor is nausea and cramping persist.

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1230341	4/19/2021	PA	44	F	3/16/2021	4/18/2021	According to patient, she woke up at 2:00 a.m. to use the restroom and noticed she had a very dry mouth and was thirsty. She passed out and when she came to she experienced decreased vision. She was taken to the emergency room via ambulance for tests. She was diagnosed with a blood clot to her lungs after CT scans. She also had additional scans and blood work and stayed at Hospital in town (I am having trouble adding this to the shaded area in question 21).
1230388	4/19/2021	MO	45	F	2/19/2021	3/1/2021	Blood clot in right subclavian vein on March 1.
1230273	4/19/2021	TX	69	M	3/1/2021	4/2/2021	Partially occlusive peroneal blood clot that developed the week after he received the second Pfizer COVID vaccine
1230215	4/19/2021		59	F	4/6/2021	4/15/2021	59 Y old female was admitted to hospital after 1 day of severe diarrhea and lower abd pain, followed by 1.5 days of BRBPR, all resolved on 4/12 morning. Lower abd pain improved but did not resolved. She had a normal BM the next day. She was seen by her PCP and CT scan of abd was ordered (on 4/15/21), which showed thrombosis of inf mesenteric vein and 2 small branches of right portal vein. She denies any personal or Fhx of thromboembolic dz. She is exsmoker and is not on any hormone replacement therapy. she had no recent trauma or surgery. She received her first dose of Covid 19 moderna vaccine on 4/6/21. She was treated with IV heparin. The exact time of the thrombosis is unknown.

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1230189	4/19/2021	LA	35	F	4/10/2021	4/12/2021	I received the vaccine on day 5 of my period. I take no hormones of any kind and my periods are regularly 5-7 days in length. My period began on 4/6. Instead of beginning to wane, my period started to get extremely heavy and I started passing clots again about 24hr after the injection. On the night of 4/12 I passed an unusually large clot, roughly the size of a hockey puck and felt very faint and weak. I continued to bleed quite heavily until this morning (4/19), for a total of 14 days. I called my obgyn on Tuesday of last week to report the excessive bleeding and that my cervical lymph nodes had become so swollen that it was bothersome to swallow. My Dr said to go to ER if I experienced typical blood clot/PE symptoms and had received no guidance about the effects of this vaccine on menstruation. I have had mild headaches, sore throat, mild fevers and fatigue as well since the injection
1230142	4/19/2021	CA	57	F	4/11/2021	4/11/2021	5 minutes after injection my forearm and hand began to tingle and have pressure, nerve type pain. No breathing issues so was sent home. Reported the continued arm pain the next day to the doctor and she ordered an ultrasound. Report negative on blood arm clot. Got a fever, body aches, headache, tired, triggered a migraine per doctor, localized reaction of 2 3/4" at injection site with redness, swelling, pain. Almost passed out at a store - Became dizzy, tingling hands and sweating and taken to ER by ambulance. ER ruled out blood clot but found I had a UTI without any symptoms-prescribed an antibiotic. Continue to have minor headache and minor discomfort at injection site. Awful experience and adverse reactions!
1230134	4/19/2021	DC	44	F	3/28/2021	3/31/2021	Started to feel chest pain and shortness of breath 3 days after the vaccine. Ended up in the hospital 5 days after the vaccine and diagnosed with blood clots in the lungs.

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1230114	4/19/2021	WA	29	F	4/6/2021	4/6/2021	Headache that night of the shot (within an hour or two of the shot). That lasted until Thursday evening and going into Friday. I didn't wake up with it. I took 600 mg of Ibuprofen at bedtime on Wednesday. Didn't wake up with the headache Thursday. I started getting body aches all over my body on Wednesday and they got worse until about 2:30 and I took a 15 min nap and woke up and felt a little better but I had them all the way to bedtime. And I was cold. That was until 1:00 PM on Wednesday. Wednesday night at 06:00 pm, on my left foot from arch to my toes I had a hot sensation. I thought one of my pets had pidd on my foot - hot and wet feeling. But they didn't. That has been happening frequently and intermittently and I am still experiencing them. The level of heat has decreased - it is warm and wet instead of hot and wet feeling. Happens frequently throughout the day. On Friday, I noticed, I had a rash on my left forearm. I noticed it on Friday evening and that went away on Thursday of last week after I was able to be hydrocortisone ointment on it for a few days. The rash was really itchy. Patient portal - messages to doctor: She ruled out deep vein thrombosis - Naturopathic Oncology .
1225680	4/18/2021	MO	43	F	4/6/2021	4/6/2021	Approximately 6-8 hours after the vaccine experienced chills, body aches and developed 100.3 fever. The night was miserable with fever, chills and dizziness when walking to the bathroom. The next day low grade fever and chills that began to subside around 24 hours post vaccination. For the next 48 hours had residual aches and fatigue. Began feeling significantly better after the 72 hour mark. However, after learning about blood clot issue has been having anxiety and some left sided pain that I'm not sure if it's anxiety or migraine related or possibly something worse.
1225652	4/18/2021	CO	40	F	4/2/2021	4/13/2021	Approximately 11 days s/p 2nd vaccination, patient developed calf pain. After the pain persisted for two days she went to the local emergency room and was diagnosed with a DVT. No personal or family history of blood clots. No precipitating life events. No culprit medications. Age appropriate cancer screening up to date.



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1225573	4/18/2021	FL	29	M	4/8/2021	4/11/2021	Patient had to have surgery for blood clot removal in rectum, within 1 week of receiving Janssen vaccine. No prior health issues leading up to this event.
1225687	4/18/2021	AZ	42	F	12/23/2020	1/21/2021	Hospitalized for what was determined with Guillain Barre - Miller Fischer Syndrome. Symptoms slowly started a couple weeks after the vaccine and eventually worsened to the point of not being able to open my mouth. Symptoms included facial paralysis, Muscle weakness, fatigue, vision issues, Neuropathy issues. I was transfused with multiple doses of Immunoglobulin and IV steroids. Still currently in Physical therapy I have lost 3 months of not being able to work. Also had a blood clot
1225529	4/18/2021	NY	63	F	4/13/2021	4/13/2021	Caused a huge dip in my phone results. Meaning I was more likely to clot
1225437	4/18/2021	NY	48	M	4/8/2021	4/11/2021	4/11/21 generalized fatigue 4/14/21 shortness of breath and chest pain 4/15/21 right lower extremity Deep vein thrombosis and bilateral Pulmonary emboli 4/16/21 mechanical thrombectomy of pulmonary emboli 4/15/21 - 4/18/21 treatment with heparin infusion which was transitioned to eliquis
1225330	4/18/2021	IL	69	M	3/4/2021	3/14/2021	Patient was admitted on 4/14/21for work up of complaints of dizziness, lightheadedness, one episode of syncope, balance and gait issues, blurred vision, tinnitus that has been present for a little over a month. Patient underwent a CTA 4/14/21: intraluminal filling defects within the superior sagittal sinus and draining dural veins to the right and left of midline near the vertex. There are findings consistent with chronic thrombosis of the left transverse and sigmoid sinus with partial recanalization of the sigmoid sinus and jugular bulb at the skull base. Still in hospital today

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1225290	4/18/2021	NY	66	F	3/30/2021	3/30/2021	Immediately upon receiving the shot I had a severe headache in the back of my head and in my upper back. It reminded me of the pain I had with the TIA several years ago. I told the pharmacist that gave me the shot and she said that it was something she had not seen before so quickly sat there for 30 minutes. The pain continued but was not quite as severe. I left with my son and almost when to the hospital but decided to come home and monitor. It lasted three days and I still get random pains there in the back of my head. I suffer from anxiety so I had thought at the time that it possibly could have been nerves. But now in light of the reported cases of blood clots and the fact that I have had at least one TIA...maybe two, I thought that I should report this incident. It was an immediate severe pain!!
1225926	4/18/2021	MI	35	F	4/8/2021	4/17/2021	Dural venous sinus thrombosis.
1225184	4/18/2021	AR	56	F	4/7/2021	4/13/2021	On April 7th received Janssen COVID vaccine at pharmacy. On April 13 started developing shortness of breath and dizziness/light headed. Had knee surgery at hospital the 14th on right knee to remove cyst (scheduled surgery). On 15th still short of breath and felt like had cold. Worsening SOB on 16th. On 17 was SOB walking from bathroom. Talked to daughter on phone and she said to go to ER. Went to ER about 8pm and Was diagnosed with bilateral blood clots in lungs and admitted to step down on heparin drip. Getting Echo TEE on Monday 19th and bilateral leg ultrasounds today on 18th

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1224928	4/18/2021	MA	48	F	4/1/2021	4/2/2021	Blood clot DVT in left leg.; Blood clot DVT in left leg.; This is a spontaneous report from a contactable consumer. A 48-year-old non -pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), at the age of 48 years, via an unspecified route of administration, administered in the left arm on 01Apr2021 10:45 (Batch/Lot number was not reported) as a single dose for covid-19 immunization. The patient has no medical history. Patient has not had Covid prior to vaccination. The patient has no known allergies. The patient's concomitant medications were not reported. The patient experienced blood clot DVT in left leg on 02Apr2021 at 09:00. Treatment for the event includes blood thinners. It was reported that the AE resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event). The patient underwent lab tests and procedures which included nasal swab for covid test on 02Apr2021 which had a negative result. The outcome of the event was not recovered. Information about Lot/batch number is requested.
1225320	4/18/2021	IN	56	F	4/1/2021	4/16/2021	Hives over most of body. Extremely itchy. Started on day 15 after vaccine. Went to urgent care on day 16. Put on Hydroxyzine, famotidine, clotrimazole/betamethasone topical ointment. Day 17 woke up and am 75% better on itchiness. Welts are still there but puffiness is mostly gone.
1225703	4/18/2021	NC	68	M	2/13/2021	3/18/2021	ON 3/18/2021 I had a massive stroke due to several blood clots in the caratid artery and in the brain. I survived and am now in the process of rehab to regain full mobility.

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1225799	4/18/2021	FL	53	F	4/3/2021	4/11/2021	4/11/2021 830PM I NOTICED MOISTURE IN MY UNDERWEAR. WENT INTO BATHROOM , PANTIES BLOODIED, BRIGHT RED AND A QUARTER SIZED CLOT WAS IN THE TOILET. I SUFFERED NO PAIN. HOWEVER I HAD A TOTAL HYSTERECTOMY IN 1997, AND SHOULD NOT HAVE ANY BLEEDING WHATSOEVER. TOOK A SHOWER, ADVISED MY HUSBAND OF THE INCIDENT. WENT TO BED , 230AM 4/12/2021 SAME THING HAPPENS, ONLY NOW I AM WIPING BRIGHT RED BLOOD AND I FELT A LARGER SIZED CLOT LEAVE MY BODY. I WENT TO THE ER IMMEDIATELY.
1225816	4/18/2021	MS	75	M	4/5/2021	4/12/2021	Almost exactly seven days after my second Moderna shot, I had a urination which was dark blood red. It included a small blood clot, which by my estimate was at most 1/2" long by 1/8" in diameter. There was no pain or burning on discharge, either with that urination, or before, or after. My next urination after that had a very small amount of dark red discoloration; and there has been no dark red in my urine after that [now six days]. Following that bloody urination, I did have a slight discomfort in the area below my belly button for several hours, but then it stopped. Since that incident, I have increased my intake of water and decreased my intake of acidic and carbonated drinks. I have not smoked in more than 45 years; and the occasional urinary dribbling I had experienced for some years before that incident has decreased noticeably. All else is OK. As a non-healthcare professional, I concluded the outcome to date is good. I have an appointment to see my doctor, on April 22.
1225906	4/18/2021	PA	45	M	4/9/2021	4/10/2021	Patient received his second Pfizer vaccine on Friday. Saturday he came down with symptoms that we considered were like the stereotypical second dose. Fever, cough, shortness of breath, coming and going. It lingered until Tuesday, at which time he got a Covid test-negative. Went to dr, and he said there was a possibility of blood clots. Tests showed that he had severe pulmonary embolisms in both lungs- the main and 3 secondary arteries.

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1225942	4/18/2021	WI	16	F	3/19/2021	3/28/2021	Patient was a 16yr female who received Pfizer vaccine 3/19/21 at vaccine clinic and presented with ongoing CPR to the ED 3/28/21 after cardiac arrest at home. Patient placed on ECMO and imaging revealed bilateral large pulmonary embolism as likely etiology of arrest. Risk factors included oral contraceptive use. Labs have since confirmed absence of Factor V leiden or prothrombin gene mutation. Patient declared dead by neurologic criteria 3/30/21.
1225955	4/18/2021	OH	70	F	4/5/2021	4/13/2021	Mother in hospital with blood clots in both lungs on a ventilator. She has been hospitalized since 4/16/21
1225999	4/18/2021	IL	40	F	4/2/2021	4/14/2021	Repeated, extreme nosebleed with large clots. I was unable to stop it and had to go to the ER on 4/16. They had to cauterize the site of the bleed. I do have a history of mild nosebleeds but this was unusual. I do not take any blood thinning medications. The silver nitrate did stop the bleeding. The ER ductus was not concerned that this was vaccine related but I thought it was unusual enough to report.

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1224924	4/18/2021	NY	67	F	3/17/2021	4/3/2021	I had emergency surgery to remove a femoral blood clot from my groin to the bottom of my left leg; This is a spontaneous report from a contactable consumer (patient). A 67-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in left arm on 17Mar2021 12:00 (Batch/Lot Number: EP6955) as single dose for covid-19 immunisation at a Pharmacy or Drug Store. Medical history included known allergies to sulfa drugs, latex, animal dander, dairy, wheat, mold, mildew, ragweed and other wildflowers; and clot once before in the same leg-left inner thigh in 1974. Concomitant medications included thyroid (ARMOUR THYROID) and apixaban (ELIQUIS). The patient previously had a pneumonia vaccine on 24Feb2021 in the left arm. The patient does not know if her first dose of Pfizer vaccine caused this, but on "04Mar2010" (as reported) she had an emergency surgery to remove a femoral blood clot from her groin to the bottom of her left leg which started on 03Apr2021 at 12 AM (as reported). The event resulted in emergency room/department or urgent care visit, hospitalization for 2 days and was considered life threatening illness (immediate risk of death from the event). She had a clot once before in the same leg-left inner thigh in 1974. The patient was on Eliquis 5 mg 2 pills 2 X day for two more days, then 1 pill in am and 1 pill in evening for rest of her life. The patient had the second dose of BNT162B2 (lot: ER8732) on 07Apr2021 in the left arm. The patient has no covid prior vaccination and was not tested for covid post vaccination. The event recovered with lasting effects.

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1224406	4/18/2021	NC	35	F	3/26/2021	3/29/2021	Abnormal bleeding / Menstrual cycle began 4 days early; heavy blood clots / Menstrual cycle began 4 days early; This is a spontaneous report received from a contactable consumer. A 35-year-old female consumer (patient) reported for herself that she received the second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot #ER8730) via an unspecified route of administration in arm left on 26Mar2021 05:00 PM at single dose for COVID-19 immunisation. Relevant medical history was not reported. Concomitant medications included levothyroxine sodium (SYNTHROID). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, was the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. On 29Mar2021 the patient experienced abnormal bleeding with heavy blood clots and menstrual cycle began 4 days earlier (less than 72hours after second vaccine). Adverse event start time was 10:00 AM. The events were resolving at the time of report. No treatment was received.
1226060	4/18/2021	OH	50	F	3/21/2021	4/6/2021	About a week and a half after 1st vaccine pt had a pain in her knee that eventually spread up and down to ankle and thigh area. On 3/21 she went to urgent care and was referred to the emergency room because she was also having a pain in her chest. She had a stress test, EKG, chest xray, and Doppler and was diagnosed with a large DVT in the thigh and a small clot near the ankle. She was given Lovenox injections inpatient for 3 days and sent home on Xarelto 15/20mg starter pack and Aspirin 81mg. She was also started on metoprolol tartrate 25mg and atorvastatin 40mg. She saw her PCP 4/6 and sees a cardiologist and hematologist within the next couple of weeks for follow-up.
1226073	4/18/2021	FL	51	F	3/31/2021	4/9/2021	Swollen left leg, shortness of breath, painful upper left thigh diagnosed with blood clots
1225905	4/18/2021	WI	32	F	4/7/2021	4/16/2021	ADVERSE EVENT: DEEP VEIN THROMBOSIS SYMPTOMS: RIGHT INNER THIGH PAIN TIME: 9 DAYS POST VACCINATION

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1224396	4/18/2021	NY	72	F	3/29/2021	3/1/2021	<p>hoped she wasn't having a heart attack; Elevated Pulse/high pulse/pulse was 165 beats per minute/climbed up to 195; Drenched in sweat/sweating/sweating like a dog in the middle of the night; Wasn't feeling well; Tightness in chest; Cough; Sinuses congested; Sore; Puffy, bubbled up arms, inflamed; Puffy, bubbled up arms, inflamed; Feverish/felt hotter than usual; Really, really tired/wiped out tired; so sleepy; Sore Arm/her arm started to hurt; Nauseous; Sore Throat/throat hurts; eyes half closed/eyes closing; Puffy Face; blood clot; This is a spontaneous report from a contactable consumer (patient). A 72-year-old female patient received the first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number ER8733, expiry date: unknown), via an unspecified route of administration, on 29Mar2021 11:45, as single dose, for COVID-19 immunisation. Medical history included ongoing latex allergy (developed welts where the straps met the skin) diagnosed 20-30 years ago; ongoing dye allergy (developed warm soreness to leg, tightness in the chest, could not breathe) diagnosed many years ago; sulphite allergy (diagnosed about 1975-1980; cannot eat processed foods, bleached foods, frozen pre-made foods; tries to eat only single item foods; last anaphylactic reaction after eating olive oil at a restaurant because it had sulphites in it; Mother was possibly allergic to sulphites; Son also allergic to sulphites); and blood pressure that runs low. The patient previously took epinephrine and experienced epinephrine allergy; ciprofloxacin (CIPRO) and experienced Cipro Allergy (eyes closed, got puffy, couldn't breathe); amoxicillin for abscessed tooth and had a reaction because of the sulphites in it; epinephrine (EPIPEN) and experienced epinephrine allergy (does not use it anymore); plantago ovata (METAMUCIL) which she then found out the orange one had sulphites. Historical vaccine included flu shot for immunization and she experienced 104-degree temperature and was sick as a dog and she went to the emergency room (she had flu shot maybe 3 times). Ongoing concomitant medication included multivitamins. The patient got her first dose of BNT162B2 on 29Mar2021 at 11:45. On the same day, once she got home, she became really, really tired/wiped out tired; was so sleepy; experienced sore arm/her arm started to hurt; was nauseous; had sore throat/throat hurt; eyes half</p>



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closed/eyes closing and puffy face. On 30Mar2021, the patient experienced elevated pulse/her pulse got too high/pulse was 165 beats per minute/climbed up to 195. Her heart rate was 194 at some point for a couple of minutes then stayed at 165 for a long time. She hoped she wasn't having a heart attack. She had tightness in her chest, wasn't feeling good and was coughing. She stayed in her bed to wait out her symptoms. These lasted for 10 minutes (as reported). She started meditating hoping her heart rate would decrease and it did after about 15-20 minutes. The patient also felt feverish/felt hotter than usual. Before she took the vaccine on 29Mar2021, her temperature was at 96. She stated that her temperature usually runs low as 95-06 degrees. She also felt like her sinuses were congested; was sore; had puffy, bubbled up arms, inflamed. The patient hoped it was not a blood clot she developed. At the time of the report, the patient stated that her heart rate was 61 beats per minute, earlier it was in the 70s; and her temperature was at 96.3. Her second dose is scheduled on 19Apr2021 and mentioned that if these were her reactions with the first dose, she is questioning getting the second dose. The outcome of "blood clot", "hoped she wasn't having a heart attack", "Wasn't feeling well", "Tightness in chest", cough, and sinuses congested was unknown. The patient recovered from "Drenched in sweat/sweating/sweating like a dog in the middle of the night", and "Elevated Pulse/high pulse/pulse was 165 beats per minute/climbed up to 195" on 30Mar2021; and was recovering from "Sore Arm/her arm started to hurt", and "eyes half closed/eyes closing". The outcome of the remaining events was not recovered. Information on the lot/batch number has been obtained. Additional information is expected.

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1226090	4/18/2021	SC	33	F	4/13/2021	4/14/2021	Shortness of breath when doing regular low effort activities. Elevated heart rate at all times. Went to ER Thursday 15 APR, had an EKG and chest X-Ray. X-ray came back normal, lungs fine. EKG confirmed the elevated heart rate some arrhythmia. Was told to follow up with regular doctor. Had follow up appointment friday 16 APR remotely, doctor recommended returning to ER to check for blood clots/pulmonary embolism. Had another EKG, same as day before. Had CT scan, no blood clots. Sent home for rest, told was having an adverse reaction to the COVID Vaccine.
1227239	4/18/2021	CT	33	F	4/15/2021	4/15/2021	Shot 2- 4/15/21- Thursday 6 hours after- nausea started 9 PM ? extremely nauseous, uncontrollable chills, 102 fever and skin hurt to touch (that didn't last long) (Friday)Next morning- low-grade fever, mild headache, no appetite 2 pm- still no appetite, headache, neck pain and chills Bedtime- chills, low-grade fever Saturday- 4/17- woke up completely soaked- I'm thinking I must've spiked a fever during the night. I also woke up with sharp painful chest pain. Went to the ER my D dimer blood tests were slightly elevated so they did a CAT scan and didn't find any evidence of blood clots. Saturday Evening- still no appetite, headache and neck pain Today -4/18- still no appetite,neck pain,headache and fatigue

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1224644	4/18/2021	FL	77	F	3/28/2021	3/29/2021	back to having blood in her stools/ still bleeding/ numerous large volume stools; she did not have blood on the toilet paper, any rectal bleeding/ had no bleeding or anything for the rest on the day on 29Mar2021; This is spontaneous report from a contactable consumer (patient). A 77-year-old female patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration at the age of 77-years-old, administered in Arm Left on 28Mar2021 (Lot Number: ER2613) as single dose for COVID-19 immunization. Medical history included ongoing irritable bowel syndrome for a good part of her life, over 50 years, High level of hormones, Testosterone (Problems for the last couple of years, 2-3 years), Losing hair, Rectal bleeding from Jan2021 to an unknown date (Rectal bleeding, noticed blood on toilet paper, and rectal bleeding, in the beginning of Jan2021), that her stools were thin and maroon color/that her stools had specks in them, clots, that looked like blood. She started complaining about this. Concomitant medication included spironolactone taken as Diuretic or for Hormones from Jan2021 and ongoing. The patient previously received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration at the age of 77-years-old, administered in Arm Left on 28Feb2021 (Lot Number: EL9267) as single dose for COVID-19 immunization and experienced bleeding, blood in her stools, she did not have blood on the toilet paper, any rectal bleeding and she had volumes of regular stool like normal people stool. She stated she had no bleeding or anything for the rest on the day, aching arm, and Volumes of regular stool/ went to the bathroom 20 times. The patient has had Irritable Bowel Syndrome for a good part of her life, over 50 years, and since the pandemic and being house bound the Irritable Bowel Syndrome was worse. She wanted to get the vaccines but wanted to address the bleeding first that started in Jan2021 the day she started her spironolactone medication. She stated her and her husband wanted to get the vaccines but it was so hard to get in. Her doctor suspects Hemorrhoids. She believed it is not Hemorrhoids because she doesn't hurt or itch. She believes she has blockages in her bowels. That her stools were thin and maroon color. That her stools had specks in them, clots, that looked like blood. She started complaining about this, and noticed blood on toilet paper, and rectal bleeding, in the

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beginning of Jan2021. Then they were finally able to get their vaccines. The day after receiving the vaccine, 29Mar2021, she did not have blood on the toilet paper, any rectal bleeding, and she had volumes of regular stool, like normal people stool. She had numerous large volume stools on 30Mar2021. She stated she had no bleeding or anything for the rest on the day on 29Mar2021. She told her husband and sister. She thinks there may be something in the vaccine that could help her Irritable Bowel Syndrome. She wanted to report her experience in case it could help someone and help down the road for Irritable Bowel Syndrome patients. On 30Mar2021 she was back to having blood in her stools. She stated she is still bleeding in Mar2021. The side effects said some may have diarrhea but not her. She was scheduled to have a blood test in the next 2 weeks to check her hormone levels and see if the medication was helping her. The patient underwent lab tests and procedures which included colonoscopy: results not reported on 27Apr2020, computerised tomogram: results not reported on 27Apr2020. Numerous large volume stools resolved on 30Mar2021. Outcome of the rest of the events was unknown.

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1224636	4/18/2021	NY	73	M	2/14/2021	2/1/2021	Blood clots after the 2nd dose; Blood clot split and some went into side of lung; This is a spontaneous report from a contactable consumer (patient). A 73-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the right arm, on 14Feb2021 at 15:45 (Lot Number: EL3247) (at the age of 73-years-old) as a single dose for COVID-19 immunisation. The patient had no medical history, family history, or concomitant medications. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: E10142 (as reported)), in the right arm, on 24Jan2021 at 15:45 (at the age of 73-years-old) for COVID-19 immunisation. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced blood clots after the 2nd dose and blood clot split and some went into side of lung in Feb2021, which required hospitalization from 27Feb2021 to 28Feb2021. The clinical course was reported as follows: The patient stated he did not know what date the blood clots occurred and can't tell when that happened, but it was maybe a few weeks after the second dose of the vaccine. He stated that one blood clot is in the right leg near the calves and the blood clot broke and split some and went up into the side of his lung as it was detected in a doppler on 27Feb2021. The patient was hospitalized from 27Feb2021 to 28Feb2021. The doppler was performed as soon as he went into the emergency room and they went through a series of tests with unknown results on 27Feb2021 and 28Feb2021. The patient stated that the right leg is bigger than the other leg and they told him it might stay that size and may not go down. The patient is now on apixaban (ELIQUIS) 5 mg for the rest of his life. In the beginning, they gave him an unspecified shot in his stomach, then after that he began taking apixaban at two pills in the morning and two pills at night, then they cut him down to 1 pill in the morning and 1 pill in the evening, and he started it right when he went into the hospital immediately. Therapeutic measures were taken as a result of the event as aforementioned. The clinical outcome of blood clots after the 2nd dose and blood clot split and some went into side of lung was unknown.

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1224608	4/18/2021	ME	57	F	3/31/2021	4/1/2021	tip of left ring finger turned white and numb/finger was completely white and the rest of her hands were blue and red and white and yellow; tip of left ring finger turned white and numb; her finger felt funny; Reynauds phenomenon; sore arm; fever; chills; headache; swollen lymph node in the armpit of the arm she got her Covid 19 vaccine in; swollen lymph node started with a sharp pain and it's very sore; left foot, it was pulsing and throbbing all night; feet were modeled red, blue; feet were modeled red, blue; very sick; needed her glasses trying to give her primary care doctor's phone number; has something like gout in her foot; The swollen lymph node started with a sharp pain and could be a blood clot as far as she knows; This is a spontaneous report from a contactable consumer (patient) via the medical information team. A 57-year-old female patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot: EW0150; expiry: 31Jul2021), via an unspecified route of administration in left arm on 31Mar2021 01:30 as single dose for covid-19 immunisation. The vaccination facility type was a warehouse. The vaccine was not administered at a military facility. No previous immunization with the Pfizer vaccine considered as suspect. No vaccines administered on same date with the Pfizer vaccine considered as suspect. No prior vaccinations (within 4 weeks) and no following prior vaccinations. Medical history included covid-19 in Nov2020. The patient had no concomitant medications. The patient had the first dose of bnt162b2 on 31Mar2021 and 12 hours later (on 01Apr2021), sore arm, fever, chills and headache. Got a swollen lymph node in armpit, same arm as injection left side, today tip of left ring finger turned white and numb. She thinks it was Reynauds phenomenon. The patient called and told nurse in her doctor's office and they said if it was painful, it could be a pain clot. It was painful at first, that lymph node started 24 hours later with a sharp pain, and then she just assumed it could be a lymph node. Swollen lymph node started with a sharp pain and it was very sore. The nurse told the patient to call Pfizer. The patient was fine until the tip of her finger happened. The patient said If it was painful it could be a blood clot, would need an x ray and asked if did the shot cause this. The complete ring finger left hand, the patient looked it up and it said it could happen to her feet and she looked,

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and her feet were modeled red, blue it was bizarre. Never happened before. The patient was not happy about getting the vaccine, she already had covid in November of last year (2020). The patient wouldn't have called if it wasn't for her finger. Not just her feet, her hands got like this too. The patient didn't want to get the second shot. The patient asked if there was any information or mandate on timing information for the second dose, should she needed to postpone it. The patient asked if what was the efficacy after first dose as she felt like she was immune because she had the virus and now the vaccine. She was very hesitant to get the Covid 19 vaccine. She thinks her body created Covid 19 antibodies. A couple days ago she was very sick. The swollen lymph node started with a sharp pain and could be a blood clot as far as she knows (in 2021). Even putting on deodorant she can tell it's there, it was very sore and there's a lump. Today (on 01Apr2021), she noticed the tip of her finger got white it was numb. She looked it up online and she thinks it was Reynaud's phenomenon. She has a picture if Pfizer needed it. The finger was on the same arm that she received her vaccine in. It was the ring finger on left hand. Once it started happening her finger felt funny and felt numb. She put her finger under warm water. She reported that the white color was maybe a third of the way down towards her knuckle. She was asking if this was normal or has this been reported. She had called her doctor today and spoke with the nurse who told her to call the CDC and report her symptoms. She needed her glasses trying to give her primary care doctor's phone number. The patient wanted to add that she has something like gout in her foot and on that side too, the left foot, it was pulsing and throbbing all night. She's had this pain in her left foot, she thinks its gout because it was all the symptoms of gout and she had it for a while, it hurts off and on but that night it was hurting and throbbing. She has not been diagnosed with gout in that left foot. She still has a headache but today she felt good except for her finger turning white and going numb. The lymph node in her armpit hurts. Her doctor's nurse told her if its painful to the touch it could be a blood clot so she was nervous about that. The tip of her finger was completely white and the rest of her hands were blue and red and white and yellow. She reported that her finger was back

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to normal now. She didn't want to get too inoculated since she also had the Covid 19 virus. The events did not require visit to emergency room nor physician office. The outcome of the events was unknown for thrombosis, Raynaud's phenomenon, erythema, cyanosis, illness, visual impairment, and gout while for the remaining events was recovering.



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1224548	4/18/2021	MA	67	M	2/25/2021	3/15/2021	found down unconscious; unwitnessed fall; oxygen was in the 60s; submassive bilateral pulmonary emboli; right femoral vein emboli/ occlusive thrombus visualized in the right proximal femoral vein; some degree of right heart dysfunction; blood sugar very high; A1C elevated; Haptoglobin elevated; elevated troponin; This is a spontaneous report from a contactable nurse. A 67-year-old male patient received second dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; Lot number was not reported) via an unspecified route of administration, at the age of 67-year-old, on 25Feb2021, as SINGLE DOSE for covid-19 immunisation. Medical history included Traumatic brain injury at the age of 29 which resulted in a CVA (right sided stroke)because the hospital did not know how to give Mannitol, behavioral problems in 2008, run over by a train in 2008, wears two AFOs (one on the left leg from having a right sided stroke, he also wears one on his left leg from having a stroke with right sided weakness, the right AFO was worn since he was 29, and then the other one he started wearing in 2008 when he was run over by a train and almost had his leg severed and he wears a left AFO), dementia diagnosed 4-5 years ago, head surgeries, depression, affective disorder, anxiety. The patient had multiple hospitalizations, and he has hyper reflexivity like all brain patients have. The patient has no history of blood clots or emboli. Concomitant medications included olanzapine (ZYPREXA) taken for depression and oxcarbazepine (TRILEPTAL) taken for affective disorder and anxiety. The patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number not reported) single dose for covid-19 immunisation, pneumonia and flu vaccine in 2008 for immunization and has no reaction. The patient received his second dose of the vaccine on 25Feb2021 and two weeks later he was found down/ was found down unconscious at the nursing home and his oxygen was in the 60's on 15Mar2021. The nursing home did not know if her brother hit his head because it was unwitnessed. The patient was found down, not responsive, and it was an unwitnessed fall. The patient was treated as a trauma patient and that this occurred around 10 oclock on 15Mar2021. At that time, he was transferred to a local hospital to the emergency room and put on oxygen. They transferred him within 4 hours

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because they did not know what to do. Caller adds that the hospital thought that he had a subdural hematoma but the hospital does not have a neuro radiologist, so the hospital transferred to the other hospital that somebody with head knowledge can look at his CAT scan. The patient was misdiagnosed with a subdural hematoma because there were changes in his CT scan from his 3 previous brain surgeries. The patient had a traumatic brain injury when he was 29, and experienced changes. The patient was found to have submassive bilateral pulmonary emboli on 15Mar2021 described as central lobar sub segmental PEs in both lungs, PE was within the distal right main artery, pulmonary artery distal left main, left middle lobe, middle right lobe / upper right lower lobe and middle lobar, segmental and sub segmental pulmonary arteries. The patient also had pulmonary emboli in the distal left main pulmonary artery of left middle lobe and left lower lobe, pulmonary arteries. There was also some degree of right heart dysfunction which was diagnosed by contrast. On 15Mar2021, the patient also had right femoral vein emboli/ occlusive thrombus visualized in the right proximal femoral vein. The patient is in a nursing home, the doctor did not want to listen to the reporter because her brother is a nursing home patient and they just assume he is immobile but he is not. The patient underwent lab test and procedures which included Blood sugar very high (they think it was because of heart strain and acute injury because then it came down down down), A1C elevated, Haptoglobin elevated, elevated troponin. These results were all elevated and from acute injury. At the time of the report, the patient is feeling better and needs less oxygen. The events found down unconscious, unwitnessed fall and oxygen saturation low, pulmonary embolism, right femoral vein emboli/ occlusive thrombus visualized in the right proximal femoral vein, and some degree of right heart dysfunction caused hospitalization from 15Mar2021 to 18Mar2021. The reporter absolutely does believe the events and the suspect drug are correlated. Outcome of found down unconscious, unwitnessed fall and oxygen saturation low, pulmonary embolism was recovered on 18Mar2021 while it was unknown for the other events.

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1224538	4/18/2021	WY	59	M	3/11/2021	3/18/2021	<p>Bell's palsy; eye sight in that eye is getting worse every day; right eyelid was sticking on his eye and wouldn't shut; he couldn't move his face on the left side and he can't control it at all; blood got really thin and wouldn't clot; left hand got really swollen; entire arm bruised; edema in his hand; edema in his hand got to the point where his skin was cracking; blood got really thin and wouldn't clot; face went numb; This is a spontaneous report from a contactable consumer (patient). A 59-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; lot number: EN6207, Expiration Date: Jul2021), via an unspecified route of administration, administered in Arm Right on 11Mar2021 (at the age of 59 years old) as single dose for covid-19 immunisation. Medical history included lupus from 2020 and ongoing, ongoing High Blood Pressure, Spinal Surgeries from 1999, Chronic Pain, Retention water, blood clot issue. The patient previously had tetanus shot. Concomitant medications included losartan potassium; allopurinol; hydroxychloroquine; methocarbamol; morphine sulfate (MS CONTIN); oxycodone; furosemide. Caller states he is calling about the Pfizer Covid 19 Vaccine. Seven days later the dose of vaccine (18Mar2021), patient developed Bell's Palsy which he has never had before and has never had any other problem with. He has seen an ENT, his pain doctor, and his medical doctor and they all say the Covid vaccine has caused the problem he is having. He was told by his ENT this is very possibly permanent. Emergency Doctors are who he went to because he thought he was having a stroke, because half of his face went numb. He has been to the doctor 10 times in the last 7 days, it has not been fun at all. He didn't put it together until he saw the ENT, who said Bell's Palsy is caused from a virus. States he had no idea until he said that, that it could possibly be from the injection. States he has never had Bells Palsy before and it started 8 days after the initial shot. His right eyelid was sticking on his eye and wouldn't shut and he couldn't move his face on the left side and he can't control it at all. Clarifies he couldn't shut his right eye all of the way. Since then they have told him he needs to tape his eye shut for 12 hours a day to keep from going blind. The thing that bothers him is his eye sight in that eye is getting worse every day even though he uses the cream and tapes it shut. His wife told him even with both</p>

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eyes shut, it will not completely shut because his lower eyelid is hanging down too far. The ENT told him he needs a hearing test today at 2:00p.m. to see if this is going to be a permanent problem. He is getting ready to go to the ear doctor to find out more. At the same time he developed the Bells Palsy, his blood got really thin and wouldn't clot which seems really weird. Also on 18MAR2021, his left hand got really swollen and the entire arm bruised and they said the edema in his hand got to the point where his skin was cracking because his blood got so thin that it couldn't clot at all. He had a blood clot issue in the past. States his arm and hand have improved, he can move his hand again finally. The ENT said that since he has been on Prednisone, for recovery for Bells Palsy, for over a week and gotten worse instead of better, it may be permanent. Prednisone is not working, it has actually gotten worse. Prednisone 10mg for 7 days and to decrease by one tablet every day until gone but states he has gotten worse. Treatments (assessed as for all events): Prednisone. States that it has been two weeks since this happened and the doctor told him the only other option is skull surgery. The bones in his head would be drilled out to make room for the nerves in hopes he would be able to work his mouth again, so not a good thing. Eye cream. He is on disability and his house payment is 3/4 of what he makes, so he can't take care of the medical bills himself otherwise he wouldn't worry about it. It is very depressing. His medical doctor said he hadn't seen any cases of Bell's Palsy for 2 years, and he has seen 4 in the last week so that doesn't give him a lot of confidence even though he is still encouraging people to get the vaccine because it is safer than not. He has multiple visits to the ER 3 times between 18MAR2021 and 19MAR2021 within 24 hours; states he was in the ER for hours and hours but no admission. States they did a CT Scan, MRI, CT with contrast and then after that ended up 22 saw ENT who confirmed the fact that Covid Vaccine that gave Bells Palsy and on 22-23 saw his GM again. Prior Vaccinations (within 4 weeks): None within 4 weeks; states 9 months ago he had a Tetanus Shot. No AE(s) following prior vaccinations. The outcome of the event Bell's palsy, Visual acuity decreased, Eyelid disorder, Orofacial dyskinesia, numbness in face was not recovered; other events was recovering. All events happened on

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1224525	4/18/2021	CA	77	F	2/4/2021	2/6/2021	<p>she and they thought she was having a heart attack; she must have passed out because she didn't remember all the tests; she got a sharp pain underneath her left rib cage/pain was number10/still had pain off and on, periodically; broke out in sweat, real bad, number 10, she broke out in a clammy sweat; hard to breath, she got a sharp pain underneath her left rib cage; the muscle that goes around her heart, it was having like a charley horse; heart rate, She says 102, 103, it went up to 200 in the ambulance.; chest pain; Nausea; hard to breath, she got a sharp pain underneath her left rib cage; This is a spontaneous report from a contactable consumer (patient). A 77-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EL3246), via an unspecified route of administration, administered in left arm on 04Feb2021 09:00 as single dose for COVID-19 immunization. Medical history included ongoing atrial fibrillation for a about 6 years , ongoing anemic for the last 20 years, glaucoma from 1998, had both eyes operated on and in 2016 she was operated on again, cataract had this 4 years ago in she says, in 1918, 1919, she clarifies 2018, Cardiac pacemaker insertion which pacemaker that controls her heart so the pulse does not drop below 65. She says that pacemaker was implanted, she thinks, 2014 maybe, blood pressure, arthritis throughout her body and had 30 operations, body doesn't absorb what she eats, anxiety, asthma, muscle spasms; she reported she has had a lot of surgeries, both of her ankles have had triple fusions, these were in 2005, 2010, 2014, 2018, both her ankles were fused, she had 5 surgeries on her feet; she has had both of her knees replaced because of arthritis, 2012 and 2015 she believes, had numerous other surgeries and she doesn't want to go through all of them, a right shoulder reverse rotator cuff repair, she had a rotator cuff put in, she doesn't have a rotator cuff, this happened in 2019, her left shoulder, because of an automobile accident, rotator cuff was so damaged that they couldn't repair it, she has minimum use of her left arm and has had operations on her left shoulder in 2005; had a pacemaker put in about 6 years ago, the next morning they kept her overnight, they came in, they took an Xray, she had to go back 2 days later because the lead had come of the heart, they had to go back in an reattach the lead to the heart; 2 years ago her</p>

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pacemaker was going all over her chest, the doctor did not believe her and it landed under her armpit, it was the size of an orange, the doctor thought it was a lump, she went to the hospital, her pacemaker started falling apart, they took it out and put a new one in, it was about 4 years ago; a lump in her breast, she has been put under 30 times, they were all necessary, nothing for glamorizing; had surgeries in her left arm and some fingers than were numb. There was no prior vaccinations within 4 weeks, no events prior vaccinations and no family history. Ongoing concomitant medication included baclofen taken for muscle spasms for about 2 years, calcium for arthritis and her bones degenerate for 30 years, ergocalciferol (CALCIFEROL VIT D) taken for gets anemic real easy for 20 years, duloxetine taken for anxiety, taking this about 3 years ago; ferrous sulfate taken for anemic real easy for about 20 years; folic acid taken to rebuild cells taking this she thinks in 2015, furosemide taken for a diuretic to get rid of fluid for 2 years, metoprolol tartrate taken for atrial fibrillation, and blood pressure, taking this since she had her pacemaker put in; montelukast for asthma for 20 years; hydrocodone bitartrate, paracetamol (NORCO) taken for arthritis for 20 years, and warfarin taken for blood thinner/thin the blood out so she doesn't get blood clots; and adults vitamins for bone supplement and metabolism for 20 years as her body doesn't absorb what she eats. She says she takes a lot of medications and when she does blood bloodwork she was low so they make her take them. The patient previously took rivaroxaban (XARELTO). On 06Feb2021, the patient experienced she thought she was having a heart attack. The patient reported that she had to call an ambulance at 11:30 at night, she thought she had a massive heart attack. She had chest pain, nausea, it was hard to breath, she got a sharp pain underneath her left rib cage. She stated that when the ambulance got here they thought she was having a heart attack, they did nitroglycerin, when they got to the house, when in the ambulance on the way to the hospital they did another pill of nitroglycerin when they got to the hospital. The pain was a number 10. She stated she broke out in sweat, once they got her all hooked up they got to the hospital 6 miles away to the hospital. She was there for 2 full days, they did Xrays, dye in her, checked her hears, and did bloodwork. When she had chest pain, she reported they

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gave the morphine, it lasted about 6 hours; she still had problems breathing, they took her, she must have passed out because she didn't remember all the tests, she was in and out of it, the severe pain stopped after 6 hours, still had pain off and on, periodically. When she got pain in the ambulance then the nausea went away. After the hospital nitro and another shot for the pain, the nausea stopped. After the hospital after this they gave morphine and the pain subsided a little but didn't totally go away until 6 o'clock in the evening, she still had problems breathing because every time she breathed she got pain under her left rib cage. She says the sweat was at home, real bad, number 10, she broke out in a clammy sweat, on the 6th when she was having pain. She says that after the hospital, a couple days after that, she saw her cardiologists, he told her what happened, it was related to vaccine, it was the muscle that goes around her heart, it was having like a charley horse, he says it felt like you're having a heart attack, her tests said her heart was good. She talks about her blood pressure and heart rate, and says 102, 103, it went up to 200 in the ambulance. She says they thought it was a heart attack, her blood pressure was usually low blood pressure and all the symptoms she was having was because of her muscle having a charley horse that felt like it was coming from the heart, if they had contacted him, he said she would have just needed a massive amount of anti-inflammatory and it would have stopped the pain. The events required an emergency room visit. She wanted to know if anybody else has been hospitalized for massive heart attacks and says that's what she was having. The patient had her second shot on 22Feb2021. Outcome of event nausea was recovered on an unspecified date; and outcome of the rest of events was unknown.



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1224468	4/18/2021	TN	63	M	3/15/2021	3/15/2021	multi focal pneumonia; atrial fibrillation/the second worst feeling he has ever had since he had his first heart surgery; arm started hurting real bad/a severe pain that radiated down to elbow, arm, chest; This is a spontaneous report from a contactable consumer (patient). A 63-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 15Mar2021(Lot Number: EN6204; Expiration Date: 30Jun2021) as single dose for covid-19 immunisation. Medical history included acute diabetes, acute thyroid disease, covid like in 2021 (10 weeks before), 3 heart surgeries with 12 stents, ongoing chronic obstructive pulmonary disease (COPD)slight case diagnosed in 2016-2017, bad thyroid from 2006 and ongoing and told he had full blown Hashimotos in 2017, bad diabetic from 2015 and ongoing and went into diabetic type coma on 18Dec2015 (sugar when got him out of the parking lot cause he had to drive there was 738 or 768 put him in ICU from 18Dec2015-25Dec2015. Had to give him shots like every 2 hours. Started giving him insulin there but insurance wouldn't approve it so kept him on Metformin. Like 5th or 6th day got it under control), bad heart from 2007 and ongoing (In 2017 he had a heart attack they call 'widowmaker', he was told he hemochromatosis like his brother and sister. Caller stated they got it from his parents, but the doctors can't find it now. He had 3 different heart surgeries and has 12 stents in him. 9 weeks before (2021), he went to the hospital because of his heart, got a real bad heart, been put on a heart transplant list, they told him his blood tries to flow backwards and all of it's going over to the right chamber; after 2 hours after he had been admitted to the hospital they told him he had had a heart attack, level 3- they knew from blood tests they'd done. About 1 hour later said test was positive for COVID. He had no symptoms. While in hospital they gave him Zinc, Vitamin D3, Vitamin B1 and that was it. They kept him 5 days at the hospital. Also reported that went to the hospital for triple bypass heart surgery when he got in said somethings wrong, watch everything on the monitors wouldn't tell him nothing; said your widow maker is completely blocked up 99% had to go in and unblock that up so they can't do any kind of bypass on him again. The only thing they can do was heart transplant or heart graft

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where they take part of the left chamber and he didn't have but like 18% of that left, take it come over whatever they're talking about, he doesn't know it's a heart graft whatever they're talking about there), 2 hernia operations, hemochromatosis (little sister and older brother has hemochromatosis-patient got hemochromatosis (too much iron in the blood) from 1 gene from his mother and 1 gene from his father. Brother doesn't have it anymore; but patient's and his sisters mutated); ongoing blood pressure abnormal; anxiety; ongoing wheezing; ongoing chronic Atrial fibrillation. Concomitant medications included aspirin (ASPIRIN [ACETYLSALICYLIC ACID]) taken to help blood to be thin from 2007 and ongoing; levothyroxine taken for Bad thyroid from 2006 and ongoing; metoprolol succinate taken for blood pressure from 2015 and ongoing; clonazepam taken for anxiety from 2012 to an unspecified stop date; fluticasone propionate taken for sinuses from 2015 and ongoing; insulin glargine (LANTUS) taken for diabetes from 2019 and ongoing; insulin aspart (NOVOLOG) taken for diabetes from 2019 and ongoing; salbutamol (ALBUTEROL HFA) taken for wheezing from 2018 and ongoing; budesonide, formoterol fumarate (SYMBICORT) taken for COPD from 2018 and ongoing; amiodarone (AMIODARONE) taken for atrial fibrillation from 22Mar2021 and ongoing; amoxicillin, clavulanate potassium (AUGMENTIN) taken for an unspecified indication from 22Mar2021 to 29Mar2021; apixaban taken for prevent blood clots and chronic Atrial fibrillation from 22Mar2021 and ongoing. The patient had pneumonia shot and flu shot took that in Sep2020. The was no vaccinations within 4 weeks prior to the BNT162B2. The patient previously received Xanax for anxiety from unknown date to 2012; received Humalog , Glipizide and Metformin for Diabetes. The patient got his first Pfizer COVID-19 Vaccine shot on Monday 15Mar2021 at sometime between 15:30-16:00. Not even an hour after he got the Pfizer COVID-19 Vaccine shot his arm started hurting real bad, felt like a hot ice pick was in his arm-described as it started locally just in one spot, then started getting worse going down to his elbow. About 30-45 minutes after got out of there, he was sick, didn't know what was wrong with him. Also reported as by 16:30 he felt bad and pulled up to a friends house. He would say it was an allergic reaction;

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starting in his arm, a severe pain that radiated down to elbow, arm, chest, it was hard to breathe since 18Mar2021. He went to a friends house after getting the shot, and by the time he got to the friend's house, he felt sick and laid down for about two hours and just kept feeling worse and worse. After that he went home and went to bed. He stayed in bed Tuesday, 16Mar2021, Wednesday, 17Mar2021 and was able to drag himself out of bed to at least go to the bathroom on Thursday morning, 18Mar2021. When he got out of bed, he couldn't breathe. When he got up Thursday morning he couldn't even move his whole left side, had to grab nightstand and pull himself up to stand up out of the bed; stumbled to the bathroom about 3 feet away. He made his way to the phone and called his sister to tell her to call an ambulance because he couldn't breathe. When he got to the emergency room he was told he was in atrial fibrillation. He stayed in the hospital with primary diagnosis as multifocal pneumonia with atrial fibrillation. Feeling like heart beating out of his chest, machine going off every 2-3 minutes. It took about 9-10 hours to get the atrial fibrillation under control. He stayed in Hospital for 4 days-admitted 18Mar2021-discharged 22Mar2021. He spoke to his heart doctor who said it was hard to breathe due to the Atrial fibrillation and all his doctors say they did not know whether it was a reaction to the covid vaccine. He heard the doctors talking and they were saying they didn't think he was going to make it. His heart rate was going between 80 and 200. He had 3 different IV's going in each arm shooting different heart medications in him and the doctor explained that the medications didn't mix well, could not go in the same IV at the same time. The patient shared that this was the second worst feeling he has ever had since he had his first heart surgery. He meant they thought he was dead or dying he lost feeling of everything. His arm felt better, but every now and again felt like a little knot or something was in there. He was breathing better, they gave him inhalers, albuterol. He thought that his heart doctor was going to start him on oxygen. He went to his Cardiologist on 01Mar2021 on Monday, 2 weeks before getting his first Pfizer COVID-19 Vaccine: cardiologist told him his triglycerides raised up about 15 was about 268. All his Cardiologist did was change his blood pressure medicine. Went to his Endocrinologist on 08Mar2021

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1224392	4/18/2021	SC	72	M	1/18/2021	3/22/2021	<p>Monday, 1 week before he took the Pfizer COVID-19 Vaccine: Endocrinologist raised his Lantus SoloStar U-100 insulin 100 units/mL (3mL) from 60 units nightly to 64 units nightly then. All his other blood tests were good, they just said keep doing what you're doing. The outcome of all the events was resolving. Follow-up attempts are completed. No further information is expected.</p> <p>Developed a blood clot behind the left knee; This is a spontaneous report from a contactable consumer. A 72-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in Arm Left on 18Jan2021 16:00 (Batch/Lot Number: EL3246) as SINGLE DOSE, dose 2 via an unspecified route of administration, administered in Arm Left on 17Feb2021 (Batch/Lot Number: EN6200) as SINGLE DOSE for covid-19 immunisation. Medical history included Known allergies: Feathers. Concomitant medication included cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]) taken for an unspecified indication, start and stop date were not reported. On 22Mar2021 18:00, the patient Developed a blood clot behind the left Knee. Ae resulted in : [Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care]. The patient received treatment for the event: Blood Thinner Meds and Compression Stocking. The outcome of the event was not recovered. The patient did not have covid prior vaccination, and the patient was not COVID tested post vaccination.</p>

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1224436	4/18/2021	NE	72	M	3/17/2021	3/19/2021	deep vein thrombosis on Sunday; Extreme fatigue on Friday; This is a spontaneous report received from a contactable consumer. A 72-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6208) via unspecified route on left arm single dose for COVID-19 immunization on 17Mar2021, 10:45 AM, at 72-year-old. Medical history was not reported. The patient had not had COVID prior vaccination. Concomitant medications in two weeks included: fluoxetine 20 mg; atorvastatin 10 mg. The patient had not had other vaccine in four weeks. The patient previously took morniflumate (FLOMAX) and had allergy to it. The patient was extreme fatigue on Friday 19Mar2021 and deep vein thrombosis on Sunday 21Mar2021 06:00 PM. I was hospitalized for two days including a veinogram to remove the blood clots from my left leg. I'm now taking rivaroxaban (XARELTO) 15 mg twice a day and were wearing a compression sock for my left leg. Treatment also received as IV heparin. Emergency room/department or urgent care involved and reported as serious due to hospitalization for 2 days. The patient had not had COVID tested post vaccination. Outcome of the events was resolving.
1224902	4/18/2021	TX	63	F	3/17/2021	3/27/2021	developed blood clots in lungs; This is a spontaneous report from a contactable consumer (patient). A 63-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: CP6955), via an unspecified route of administration into the left arm on 17Mar2021 as a single dose for COVID-19 immunisation. Medical history included allergies to sulfa. Patient was not pregnant. There were no concomitant medications. The patient previously took amoxicillin and experienced drug allergy. The patient developed blood clots in lungs on 27Mar2021 09:45. The patient was brought to the emergency room and was hospitalized for 3 days. The event was reported as life threatening. It was also reported that the patient was given treatment (unspecified). The patient underwent lab tests and procedures which included SARS-CoV-2 test: negative on 27Mar2021. Outcome of event was recovering.

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1224670	4/18/2021	IN	54	M	3/18/2021	3/1/2021	<p>This is a spontaneous report received from a contactable consumer (patient). A 54-year-old male patient (height: 193cm, weight: 99.79kg) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: EN6207) via an unspecified route of administration at right upper arm on 18Mar2021 18:00 (54-year-old at time of vaccination), at single dose, for COVID-19 immunization. The patient's medical history included blood pressure, teeth cleaned (Shortly before the shot, went to the dentist to have teeth cleaned. Directly from Dentist went to pharmacy. Went to pharmacy's Drive Thru to pick up a little antibiotic from the dentist. It was 4 capsules of Amoxicillin. He was supposed to take the Amoxicillin before the dentist office visit, but he forgot to do that. Therefore, soon as he left the dentist office he went to pharmacy to pick it up so he could take it. While he was there, was offered the COVID 19 vaccine and that it was the last shot). Concomitant medications included atenolol tablet from 2016 (been taking for 5 years) and ongoing for blood pressure, and ascorbic acid/ cyanocobalamin/ ergocalciferol/ nicotinamide/ pyridoxine hydrochloride/ retinol/ riboflavin/ thiamine mononitrate (ONE-A-DAY). No additional vaccines administered on same date. No history of all previously immunizations. No prior vaccinations within 4 weeks. He got the shot Thursday and by Sunday, many different side effects were coming in. He has had side effects from the COVID VACCINE, but initially he does not want to file report, just thinks that everyone needs to get the shot. He does not have complaints. He is wondering how long the side effects will last, and when they go away. States that he is being treated as he has gone to the doctor's. Also states that he made an appointment with the doctor and almost went to the emergency room a couple of times. Right after the shot, he was getting in the car and his right leg started hurting (on 18Mar2021). It didn't go away for a couple of days. It went away but then noticed his shoes started feeling funny. He wasn't looking at his feet, put his shoes on they felt tight. Then he started to look at feet more. Below his knees, his legs are swollen. Swelling started within 2 to 3 days after the vaccine. The swelling is really severe when standing. Everybody at work has seen how sick he is and his legs. Swelling in the legs has him concerned, thinking maybe it's a blood clot. He was given medicine and</p>

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would like to see it go away. He keeps his legs up. He has other side effects (all in Mar2021) and is having flu like symptoms. He basically has the flu. He has never had the flu shot. This is the first flu shot (He referred to the COVID vaccine as the flu shot as documented. However, confirmed suspect product as Pfizer covid vaccine) he has had that he knows of. He is questioning if he should get the second shot. He feels a little dizzy. Quick questions get him confused and that it comes and goes. Lungs felt full, gasping for air: not now but, since the doctor gave him antibiotics (unspecified injections, he was given 2 shots at the doctor's office, one in each arm), his lungs felt full. At times he was gasping for air. It went away but thought he was going to die. Now when he gets winded, it feels like he has a dry cough. Gets winded easily. The doctor ordered him an inhaler, Symbicort, but it was very expensive, so he did not get it at that time. He never picked it up because it was too much money. The fluid is not there anymore and he does not feel like he needs this as does not feel like it needs to be cleared. He is having wheezing. He can now take deeper breaths. Fatigue: initially, that he was feeling tired within 1 or 2 days, but he did not recall the next day feeling that way (later stated it was within 2-3 days he started to feel tired). He is still tired. Unable to clarify time frame of fatigue further. He feels bloated and full. Hasn't really eaten but feels real full and bloated. Hot and cold flashes started occurring about the same time as the other symptoms. He had these last evening. He does not get the flu very often and doesn't take the Flu shot. This is the closest thing he can remember having a pretty good episode with the flu. He was also given prescriptions for 2 new medications: Triamterene 37.5mg daily, for leg swelling; Clindamycin, 300mg, twice a day, an antibiotic. The odd thing is that it seems like his eyes are big, like really, really big, like they are really open. It is like big eye balls. States that he is just sick and his body is reacting to getting better. He has not been to work in the last 3 days. States that he is fine, just worried about work. Patient asked for personal advice about going back to work. The outcome of "his right leg started hurting" was recovered; outcome of "below his knees, his legs are swollen/ swelling in the legs/ put his shoes on they felt tight" and Fatigue/feeling tired was not recovered; outcome of other events was unknown.

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1224262	4/18/2021	CA	19	F	3/28/2021	3/30/2021	strange pain on her left collar bone; going to see someone just in case it's a blood clot; lump on her collar bone, left collar bone; does hurt a little bit; This is a spontaneous report from a contactable consumer or other non hcp (patient herself). A 19-years-old female patient received bnt162b2 (BNT162B2, Formulation: Solution for injection), dose 1 intramuscularly administered in Arm Left (like the shoulder area) on 28Mar2021 09:00 (Lot Number: ER8734 and Expiry date: unknown) as single dose for covid-19 immunisation. The patient medical history was not reported. There were no concomitant medications. No additional Vaccines administered on same date of the Pfizer suspect. On 30Mar2021, the patient experienced going to see someone just in case it's a blood clot, lump on her collar bone, left collar bone, does hurt a little bit and on unspecified date strange pain on her left collar bone. 19-year-old female got the first Pfizer Covid vaccine at 9 am on Sunday, March 28 and this morning, she woke up with a strange pain on her left collar bone and there was a lump there, states when she woke up, she noticed a pain, checked in the mirror, she saw on the left side she saw a bump and checked on the right side and didn't see anything and that's when she got worried. Caller states she was just calling to report it, she's worried that it's a blood clot or something else. Why was the patient taking Pfizer BioNTech COVID Vaccine (Verbatim): she wanted to be vaccinated to protect herself and her community. Caller states she would not like to provide her last name at this time. However, provided her last name initial. She also reports she would not like to provide her address, height, or weight right now. She states she used to volunteer at a hospital. She does not see expiration or NDC number on card she received when she got her vaccine. Caller states she does know that one of her family members has the Factor 5. She is not sure if she has it but would like to be tested for it. The outcome of the event going to see someone just in case it's a blood clot was recovered, lump on her collar bone, left collar bone and does hurt a little bit was not recovered and strange pain on her left collar bone was unknown. Information on batch/Lot number has been requested.



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1224239	4/18/2021	GA	39	F	3/10/2021	3/10/2021	Had blood clot in left leg. Blood in eyes. Sinus sore throat short breath congested headache vision problems. Tested positive for strep one month after receiving one vaccine been taking antibiotics for 6 days but I'm getting worse.
1224177	4/18/2021	GA	29	F	2/24/2021	3/12/2021	Blood clot blocking blood flow to brain - 1st episode: (3/12/21) stabilized, minor limited movement left side - 2nd episode: (3/24/21) no blood flow to brain, death (maintained on life support for organ donation)

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1224690	4/18/2021	NE	64	M	2/3/2021	3/27/2021	not sleeping on that shoulder; Sinus infection/Head Congestion; Bronchitis; Positive Covid Test; Positive Covid Test; This is a spontaneous report from a contactable consumer. A 65-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in left arm on 03Feb2021 (Batch/Lot Number: EL9262) as single dose for covid-19 immunisation. Medical history included raynaud's phenomenon from 1992 and ongoing, chronic obstructive pulmonary disease from 1998 and ongoing, anaemia from 1986 and ongoing, renal transplant from 2014 to an unknown date, stated it started during chemo in 1986 and comes and goes but he never gets better than borderline; states since his kidney transplant it happens less, lymphoedema from 2010 and ongoing, hypertension from 2000 and ongoing, ongoing dry mouth, stated he has had his whole life because of Sjogren's, mycobacterium chelonae infection from 2014 to an unknown date, stated it was a cousin to Leprosy and a type of TB. Stated the infectious disease doctors presented his case to the CDC and he was on antibiotics for 2 months to get rid of that, one cost \$5000/day. States he was getting cellulitis in both legs every week until they took care of that, sleep apnoea syndrome from 1998 and ongoing, ongoing peripheral venous disease, blood clot in lung and DVT in leg, stated he has thrown blood clots that lodged in his lung and had a DVT in his right leg--during chemotherapy, gout from 2005 and ongoing, advanced neuropathy and ongoing, advanced neuropathy all over his body for 25 years. Stated he has had finger nails torn out and it doesn't hurt. Leg ulcer from: 1987 and ongoing, reoccurring leg ulcers mainly around his ankles. Stated his skin was so thin that it breaks open and forms ulcers. States he got out of the hospital in Nov 1986 and they showed up next summer 1987. States he has been wearing compression support hose since 1988 all the time, ongoing Sjogren's syndrome, Sjogren's Syndrome which is a lesser degree of Lupus. States he has had it for 6 years. States the clinic missed it on him. States he was diagnosed in the air force and it has advanced now to the point that they are calling it Lupus like. State he is a 100% disabled. Caller states he had a kidney transplant in 2014 and he has been on immunosuppressant drugs for 18 years.

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Mainly Prednisone, CellCept and Tacrolimus. Historical vaccine included BNT162B2, Lot: EK4176, on 13Jan2021 for COVID-19 immunization. Concomitant medication(s) included prednisone taken for transplant suppression and sjogren's from 1998 and ongoing; allopurinol taken for gout and ongoing; amlodipine taken for raynaud's phenomenon; bisacodyl (DULCOLAX [BISACODYL]) taken for an unspecified indication and ongoing; hydrofluoric acid (HYDROFLUORIC ACID) taken for moisturizing legs for skin and ongoing; losartan taken for hypertension and ongoing; magnesium oxide taken for supplement magnesium levels are low and ongoing; mycophenolate mofetil (CELLCEPT [MYCOPHENOLATE MOFETIL]) taken for Kidney Transplant Suppression and Sjogren's for 18-20 years and ongoing; rosuvastatin taken for blood cholesterol abnormal and ongoing; tacrolimus taken for kidney suppression anti rejection and ongoing; tiotropium bromide (SPIRIVA) taken for lung problems copd; states he has had 8 pneumonias and bronchitis and ongoing; valaciclovir (VALACICLOVIR) taken for outbreaks of shingles in mouth herpes simplex and ongoing; vitamin d ongoing; vitamin b12 taken for supplementation, ongoing. The patient experienced positive covid test on 27Mar2021 11:00 with outcome of recovering, not sleeping on that shoulder on an unspecified date with outcome of unknown , head congestion on an unspecified date with outcome of unknown, sinus infection on an unspecified date with outcome of recovered, bronchitis on an unspecified date with outcome of unknown. Stated he had his second shot on 3Feb2021 and on 27Mar2021, he was diagnosed with Covid. Caller stated on Saturday 27Mar2021, when they found out, the emergency room was really startled [that he tested positive for Covid after being fully vaccinated] and the hospital is a good size. Stated he was the first person that has been fully vaccinated that has caught Covid at the hospital. States he may have caught the virus earlier. States it started with head congestion that lead to a sinus infection and he was put on a Z-pack. States the sinus infection went away but he started having lung trouble so he went back and they said he had bronchitis, his lungs looked fine, and they put him on a different antibiotic. States they said lets do a Covid swab to make sure but they really doubt he would have it

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and the Covid test came back positive and boy were they surprised. Clarifies the antibiotic didn't work on the Covid. States it was Levofloxacin, dosage unknown. States the Hospital is normally good about putting the dose on there but they didn't put the dosage and they kept the bottle at the emergency room on Saturday. Caller states that he is also on these other medications; however he doesn't think they were taken within the 2 weeks before the vaccines. Acetaminophen as needed, albuterol as needed, Refresh Eye Drops as needed, Guaifenesin as needed uses when he gets a chest cold and gets them fairly often, and Sudafed as needed. States a surgeon once told him he had the worst bronchitis that he has seen in his career. States he has had a collapsed lung. States during therapy they were putting in a subclavian line and nicked his lung. States boy does that hurt getting a line put in. Caller states he had a kidney transplant in 2014 and he has been on immunosuppressant drugs for 18 years. Mainly Prednisone, CellCept and Tacrolimus. Treatment was giving him a boost of dexamethasone, simply relying on the vaccine to help him get better. States he had no adverse reactions, other than not sleeping on that shoulder, that is all he had. Emergency Room visited on Saturday 27Mar2021 and 23Mar2021. States they did X-rays and blood tests and that is when they told him on 23MAR2021 that he had Bronchitis and sent him home on the antibiotic. The patient underwent lab tests and procedures which included blood test: unknown result on 23Mar2021, sars-cov-2 test: positive, x-ray: unknown result on 23Mar2021. Therapeutic measures were taken as a result of positive covid test, sinus infection, bronchitis.

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1224703	4/18/2021			F			Some blood clot on both of her legs; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced some blood clot on both of her legs on an unspecified date. It was reported that patient would have a procedure on Friday and then she was going to go for the vaccination on Saturday. they would like to known if there was any problem for her to have the vaccination done. The outcome of the event was unknown. No follow-up attempts are possible; information about batch number cannot be obtained.

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1224724	4/18/2021	OH	29	F	1/22/2021	3/1/2021	pre-eclampsia; blood pressure remains somewhat elevated; heart rate is severe, intermittently/heart rate remained very elevated; the end of January for the first shot and three weeks later for second shot and at the time, she was pregnant; protein in the urine; weighed a little more; This is a spontaneous report received from a contactable healthcare professional (HCP) (patient) via the medical information team. This healthcare professional reported information for both mother and fetus/baby. This is a mother (patient) report. A 29-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), first dose (batch: EL9262) on 22Jan2021 (at the age of 29-years-old) then second dose (lot: EN6201) on 18Feb2021 (at the age of 29-years-old); both via an unspecified route of administration as single dose for covid-19 immunisation. The patient was pregnant at the time of vaccination. Medical history included blood clot (during her previous pregnancy); pulmonary embolism (during her previous pregnancy) and pregnancies (previous pregnancies were kind of close together). Concomitant medication included enoxaparin sodium (LOVENOX) for blood clot prophylaxis/pulmonary embolism prophylaxis (patient had a blood clot, a pulmonary embolism, during her previous pregnancy and so they make her prophylactically take it, always has been on it. The patient had a blood clot and was breastfeeding so she did enoxaparin sodium and she got pregnant again and was still on enoxaparin sodium). The patient received first dose of bnt162b2 on 22Jan2021, and the second dose on 18Feb2021. She was pregnant at the time, subsequently developed pre-eclampsia on 22Mar2021, and delivered on 25Mar2021, 7 weeks before her due date. The patient's seriousness for preeclampsia was hospitalization from 22Mar2021 to 28Mar2021 and life threatening. The patient stated that they delivered the baby and the overall preeclampsia has resolved. The patient's blood pressure remains somewhat elevated and heart rate was severe, intermittently in Mar2021 with seriousness of medically significant and hospitalization from 22Mar2021 to 28Mar2021. The patient had a doctor appointment at a maternal fetal medicine on 22Mar2021 then from there she was delivered because her blood pressure and heart rates continued to worsen. The patient still has increased

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blood pressure, but she never had any blood pressure issues, just mild. The patient's blood pressure remained somewhat elevated and heart rate remained very elevated, but she couldn't say there was still protein in the urine (in 2021). The patient stated that her heart rate and blood pressure improved, and were medically significant. The patient remained on the dose and then her heart rate went up, not her blood pressure, just her heart rate went up really high starting in February, beginning of March and they increased her dose to, maybe in March, beginning of March, her heart rate went up, had her on enoxaparin sodium at 100mg once daily as her prophylactic dose and changed and went up from that to 100mg twice daily by injection. The patient stated that she may have weighed a little more (in 2021). The last weight was with pregnancy and pre-eclampsia. The patient weighed 205 (unspecified date). The patient was pregnant so she was seeing more of her maternal/fetal medicine and OB, but had seen her primary care throughout, maybe once. The patient stated that they didn't have enough data on pregnancy and neonatal and she wanted to contribute and advance knowledge in her area by providing information. The patient got the vaccination just on her own, just wanted to protect herself and her baby, the benefits outweighed the risks so she proceeded to get the vaccine. The outcome of the events blood pressure increased and heart rate abnormal was recovered in 2021; for pre-eclampsia was recovered with sequel on 25Mar2021 while for the remaining events was unknown. The patient did not believe the pre eclampsia had anything to do with the vaccine. The patient was not indicating that the vaccination led to the pre-eclampsia, that's for Pfizer to determine. No follow-up attempts are needed. No further information is expected.; Sender's Comments: Based on the current available information, the events Pre-eclampsia, Blood pressure increased, and Heart rate increased are most likely related to an intercurrent or underlying condition which is not related to the suspected drug. The patient was pregnant at the time of vaccination may provide a plausible explanation for the events. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of

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aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021374536 Same reporter/drug/event for different patients (for baby)



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1224818	4/18/2021	NJ	48	M	1/27/2021	1/28/2021	Heart stopped 6 times; unresponsive; soreness; felt like unwell; vomiting; Body aches; achiness; passed out 7 times; fever; chills; Left arm soreness at injection site and up back of shoulders; Left arm soreness at injection site and up back of shoulders; This is a spontaneous report from a contactable consumer.A 48-years-old male patient received second dose of bnt162b2 (Pfizer-Biontech Covid-19 Vaccine, Formulation: Solution for injection, Lot Number: EN5318), intramuscular, administered in left arm on 27Jan2021 11:00 at single dose for covid-19 immunisation. Medical history included asthma, myocarditis and allergies to Fruit or nut that grows on trees. Concomitant medication included esomeprazole magnesium (NEXIUM). The patient's heart stopped 6 times on 29Jan2021, he had a low grade fever, achiness and chills at 01:30, but they were gone the next day. Basically, at first, he took the shot and got the reactions that everyone else does, right arm soreness 01:30. On 07Jan2021 17:00, patient took the first dose of bnt162b2 (Pfizer-Biontech Covid-19 Vaccine, Formulation: Solution for injection, Lot Number: EL1042), intramuscular, administered in left arm. No prior vaccination was given within 4 weeks. He fell in the shower and passed out and hit his head at 18:00. He was not hooked up to a machine. About 18:30, his wife got him to the couch. He drank carrot juice and ate a granola bar. At 18:30 his eyes were wide open, but he was unresponsive. About every 30 minutes, he was going down. The third one came about 18:45-19:00. The pass outs lasted 15-20 seconds. and all he remembers was waking up to her screaming at him. The next one came at 19:15 and was in the ambulance on the way to the hospital and that is when he vomited in the ambulance and on the couch. Pass out number 3 was at home and 4 was in the ambulance. There was vomiting with both of them. Pass out number 5 was in the hospital when she was getting in the bed and was not hooked up in the room yet. Finally, they got him hooked up to a machine at 20:30 and into a room. They said if you feel dizzy, press the button. He found out his heart rate went from 80's down to 30's. That was the 6th pass out. This was the first time he was on a machine. His heart did not actually stop, it just went down to 30's and would come back. Then, it happened one more time on the machine and at that point, they were hooking him up to an IV and giving him medication to

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1224855	4/18/2021	CA					
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1224855	4/18/2021	CA		M			
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keep him from vomiting. He does not have the name of that medication or the dose or lot or expiration. He got stabilized but they had him hooked up shockpads in case anything happened. They recorded his heart stopping 6 times during the night and of those 6 times, he does not have the times. 2 seconds was the longest time of all of the stops. He does not know how many each were. This was when he woke up on 30Jan2021. He later stated he was hospitalized 28Jan2021 at 7pm and those 6 stops occurred 29Jan2021 through the night previously. The patient was hospitalized for heart stopped 6 times from 29Jan2021 and discharged on 01Feb2021. The patient underwent lab tests and procedures which included body temperature was low grade fever, echocardiogram, brain scan and electrocardiogram shows normal, heart rate: 80 beats, heart rate was down to 30 on his heart beat. They gave shot in the leg for blood clots, nausea medication and a bunch of pills given as treatment. The outcome of heart stopped 6 times was recovered with Sequel, patient passed out 7 times, body aches, fever and chills, left arm soreness at injection site and up back of shoulders was recovering, unresponsive and soreness next day felt like unwell and vomiting was unknown, achiness was recovered. No follow-up attempts are possible. No further information is expected

Bells Palsy; This is a spontaneous report from Pfizer - General Company Information received from contactable consumer reporting for himself (patient). A male patient (Age: 49; Unit: Unknown) received bnt162b2 (Lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunization. Medical history included DVT (deep vein thrombosis). Concomitant medication included ongoing rivaroxaban (XARELTO) taken for DVT. The patient developed Bell's Palsy after receiving vaccination shot on an unspecified date. The outcome of the event was unknown. Information about lot/batch number has been requested.

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1224898	4/18/2021	IL	67	F	3/17/2021	3/25/2021	Stroke due to a large blood clot to the brain; Stroke due to a large blood clot to the brain; Widespread blood clots in both of her arms; This is a spontaneous report from a contactable consumer (daughter). A 67-year-old female patient received the 2nd single dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration, in the left arm, on 17Mar2021 (at the age of 67 years old, not pregnant at time of vaccination) (Lot number was unavailable since unable to locate or read the details), for COVID-19 immunisation. The patient's medical history included ongoing atrial fibrillation, high blood pressure, and scoliosis. Concomitant medications included ongoing acetylsalicylic acid (ASPIRIN) for atrial fibrillation, naproxen, pregabalin, tramadol, and metoprolol. The patient never had a history of blood clots. There were no allergies to report. The patient had not received any other vaccines in the four weeks prior to receiving BNT162b2. The patient had received the first single dose of BNT162b2 on an unspecified date, in the left arm. The patient's daughter stated that her mother suffered a stroke due to a large blood clot to the brain on 25Mar2021 at 12:30 am, requiring hospitalization. During hospitalization, a surgery to remove blood clot from the brain was needed. Hospitalization lasted 12 days. The reporter added that in the week prior to the reporting, the mother 'passed' (as reported) but had widespread blood clots in both of her arms. The patient required unspecified treatment due to the events and had not recovered at the time of the reporting. The events were considered also serious since life threatening and due to disability. The patient did not have COVID-19 prior to the vaccination and had not tested positive post vaccination. Information on lot/batch number has been requested.

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1224438	4/18/2021	DE	57	F	2/16/2021	2/18/2021	Post menopausal bleeding; vaginal bleeding; This is a spontaneous report from a contactable physician (patient) reported for herself. A 57-year-old female patient received 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, LOT number: EL9266, expiration date unknown) via unspecified route of administration at arm right on 16Feb2021 16:15 at age of 57-year-old at single dose for COVID-19 immunisation. Patient was not pregnant at time of vaccination. Medical history included hypertension, allergic to Cipro. Patient previously received 1st dose of BNT162B2 on 21Jan2021 at 02:00 PM (Lot number: EL3246) at single dose for COVID-19 immunisation. Concomitant medications included lisinopril, biotin/ cyanocobalamin/ folic acid (MVI 3), vitamin D3. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. LMP 7/2018 No significant gynecological history other than pregnancies/childbirth. No prior abnormal vaginal/uterine bleeding. No known history of uterine fibroids. No h/o bleeding/coagulation disorder. On 18Feb2021, patient experienced vaginal bleeding began with light flow and gradually increased with use of pads and tampons. There was no clots. Menstrual period lasted until 23Feb2021. (This appeared to be similar to menstrual periods in the past except there was no cramping on the first day and in the past would have expected to end on 22Feb2021. No further vaginal/uterine bleed or spotting since 23Feb2021. On 19Feb2021, platelet was 349 (normal range: 150-450). On 16Mar2021, endometrial biopsy was negative. On 16Mar2021, Pap (Smear cervix) was negative. On 16Mar2021, ultrasound showed endometrial thickness within normal range 4 mm, 2 small fibroids 1 cm, 2 cm, normal ovary sizes, small L ovarian cyst. Prior to vaccination, the patient wasn't diagnosed with COVID-19. Since the vaccination, the patient been tested for COVID-19 by COVID-19 PCR (SARS-CoV-2) saliva with unknown results. It was reported that patient experienced Post menopausal bleeding on 18Feb2021 at 12:30 and vaginal bleeding on 18Feb2021 at 12:30. Outcome of events was recovered on 23Feb2021. Events resulted in doctor or other healthcare professional office/clinic visit. There was no treatment for the events.; Sender's Comments: Based on the information provided, reported events are not related to suspect product. Case

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will be reassessed when additional information is available. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1227272	4/18/2021	MD	83	F	3/8/2021	3/9/2021	<p>massive stroke; massive blood clot in brain next day; This is a spontaneous report from a contactable healthcare professional. An 83-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 08Mar2021 10:00 (Batch/Lot number was not reported) as a single dose for COVID-19 immunization. There were no medical history and concomitant medications. Patient is not pregnant at the time of vaccination. Patient did not receive any other vaccines within 4 weeks and no other medications within two weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. Patient has not been tested for COVID-19 since the vaccination. Patient has no known allergies. On 09Mar2021 19:00, patient had massive blood clot in brain and stroke. AE resulted in: emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event). Patient died on 13Mar2021 with cause of death: massive stroke. Outcome of the event "massive blood clot in brain next day" was unknown. Autopsy was not performed. Treatment received for AEs include anticoagulant. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Stroke and Thrombosis cerebral cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: massive stroke</p>

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1227130	4/18/2021	OH		M	3/12/2021		<p>PNEUMONIA; BLOOD CLOTS; This spontaneous report received from a consumer concerned an 89 year old male. Initial information was received on 13-APR-2021 and processed with additional information received on 15-APR-2021. The patient's height, and weight were not reported. The patient's past medical history included congestive heart failure (ejection fraction 20%), large lower left groin hernia, atrial fibrillation, and dementia. No known drug allergies was reported. There was no history of blood clots. The patient received vaccination with covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose was not reported, administered on 04-MAR-2021 for prophylactic vaccination. Vaccination site was not reported. Batch number was not reported, will be requested. Concomitant medications included apixaban twice a day for atrial fibrillation. On 11-MAR-2021, the patient was taken to Emergency Room (ER) and diagnosed with pneumonia. Patient was awake over 48 hours 'felt due to dementia and illness'. On 14-MAR-2021, the patient was taken back to hospital and X-ray and CAT scan showed saddle pulmonary embolism. On 15-MAR-2021, the patient was discharged to a home with hospice. On 23-MAR-2021, the patient deceased. It was unknown if autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death, Hospitalization Caused / Prolonged).; Sender's Comments: V0: An 89-year old man experienced fatal saddle pulmonary embolism 10 days after vaccine. Relevant medical history included congestive heart failure with ejection fraction 20%, atrial fibrillation (A Fib), and dementia. Relevant concomitant medication (others not reported) included Eliquis for A fib. The patient was diagnosed with pneumonia in the Emergency Department 7 days after vaccine, and 3 days later was brought back to the hospital and diagnosed with saddle pulmonary embolus. He was discharged home on hospice the next day and died 19 days after vaccine. There was no reported thrombocytopenia. The patient's age, concurrent pneumonia, and complicated past medical history are confounders. There is insufficient information to make a meaningful medical assessment. Additional information has been requested, including attempts to contact the patient's treating physicians.; Reported Cause(s) of Death: PNEUMONIA; BLOOD</p>

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1227131	4/18/2021			F		4/14/2021	<p>ARACHNOID GRANULATION; This spontaneous report was originally received from the patient's husband and concerned a 45-year-old female patient. Initial information was received and processed with additional information received in discussion with treating physician on 15-APR-2021. The patient's weight 69 kg and height 178 cm. Patient's medical history included smoking for 10 years and quit 10 years ago. Subject's concurrent conditions included insomnia. The patient was reported to be in good health, Body Mass Index (BMI) reported as 21.7. The patient had no family history of blood clots. On 08-APR-2021, the patient received vaccination with Janssen COVID-19 vaccine Ad26.CoV2.S (suspension for injection, route of administration not reported; batch number not reported and requested), dose unspecified, for COVID-19 vaccination. Batch number was not reported, will be requested. Non-company suspect drug included unspecified contraceptive pill (unknown, oral) for unspecified indication. Concomitant medications included cannabis sativa for insomnia. On an unspecified date 'just following' vaccination, the patient had influenza-like symptoms. On 10-APR-2021, patient started experiencing headaches. On 14-APR-2021 (6th day post-vaccination), the patient presented to Emergency Room (ER) with four days of worsening headache and diagnosed with suspected right transverse sinus thrombosis (later ruled out.) The patient was transferred to a second hospital's intensive care unit (ICU) on an unspecified date. On 15-APR-2021 (7th day post-vaccination), a magnetic resonance imaging (MRI) scan of the brain showed suspected cerebral venous sinus thrombosis (CVST). No other symptoms or neurologic deficits reported, and her platelet count was reported as normal at 268,000 on admission (units and normal range not reported). The admitting physician initiated argatroban whilst closely following the patient's platelet count. Testing for a panel for heparin-induced thrombocytopenia including anti-platelet factor 4 (anti-PF4) antibodies and other unspecified workup were also planned. On an unspecified date, MRV of brain showed an absence of flow in right transverse sinus highly suggestive of thrombosis, sluggish flow in sigmoid sinus and superior IJ. MRA showed non-visualized of A1 segment of right ACA, more distal segment supplied by Left ACA, this is a normal anatomic variant. Also non</p>

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visualization of R vertebral artery which is felt to be a normal anatomic variant as well. This read was reviewed on 15-APR with neuro-interventionalist physician and 3 radiologist who were all in agreement that this was instead a normal variant (arachnoid granulation.) Report was addended to clarify that there was never any thrombosis. Patient's blood pressure was 120/86 and heart rate 88. Patient was fully anticoagulated with argatroban. No heparin was received. Heparin induced thrombocytopenia (HIT) panel was sent and lab was requested to urgently process. Platelet count remained normal from 268 to 227 on 15-APR-2021. On 15-APR-2021, a CT venogram was performed which again confirmed no thrombosis; rather there was arachnoid granulation (normal variant). All imaging was confirmed with neuro-interventionalist physician and 3 radiologist who were all in agreement. Treatment with agratroban was discontinued on 15-APR-2021. As of 15-APR-2021, patient was clinically improving. Headache was resolved and neurologically intact. Patient was eating and was planned to discharge home later in the day. The action taken with COVID-19 vaccine Ad26.CoV2.S was not applicable. Action taken with contraceptive pill was unknown. The event arachnoid granulation was recovering This report was serious (hospitalization/prolonged hospitalization).; Sender's Comments: V0: A 45-year-old female experienced headache 2 days after vaccine and was hospitalized for suspected transverse venous sinus thrombosis (which was ruled out) 6 days after vaccine. There was no secondary hemorrhage, and after the imaging was reviewed with a neuroradiologist, it was determined that there was no thrombosis at all, but rather an arachnoid granulation (normal anatomic variant.) This was confirmed on follow up CT venogram the following day. Relevant concomitant medications included oral contraceptives. Platelet count was normal (268,000) on admission. No heparin was received, but a panel for heparin-induced thrombocytopenia, including ELISA for anti-PF4 antibodies is pending. The patient was initially anticoagulated on argatroban and symptoms improved one day after admission; the headache is resolved, she is neurologically in tact, and discharge is planned to home. Although the use of oral contraceptives is a risk factor for thrombosis, there was no thrombosis in this

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1227158	4/18/2021	CO	61	M	3/17/2021	3/17/2021	<p>case.</p> <p>found a deep blood clot.; my calf, foot, and knee swelled up by evening./It stayed swollen for a week; my calf, foot, and knee swelled up by evening./It stayed swollen for a week; This is a spontaneous report from a contactable consumer (patient). A 61-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 61-years of age), dose 1 via an unspecified route of administration, administered in arm right on 17Mar2021 12:00 (Batch/Lot number was not reported) as a single dose for COVID-19 immunisation. Medical history included blood clot after a back fusion about 16 years ago (2005), and had a knee replacement 3 months before the vaccine (Dec2020). The patient's concomitant medications were not reported. The patient previously took ANCEF [cefazolin sodium] and had allergies; and oxacillin which the patient had allergies and hepatitis. The patient was not diagnosed with Covid prior to vaccination nor was he tested for covid since vaccination. The patient did not receive any other vaccine within 4 weeks prior to Covid vaccine. It was reported that the day the patient received the first vaccine his calf, foot, and knee swelled up by evening. It stayed swollen for a week and he went to see his doctor. He did an ultrasound on his calf and found a deep blood clot. He was now on blood thinners. He mentioned that he had a knee replacement 3 months before the vaccine but it was progressing fine. Usually blood clots occur after surgery within a 2 week period. He had a blood clot after a back fusion about 16 years ago. He was reporting this because his doctor was not sure why he got the blood clot and it coincided with the vaccine. The patient underwent lab tests and procedures which included ultrasound scan: found a deep blood clot in Mar2021. The events started on 17Mar2021 18:30 with outcome of recovering. The events resulted to doctor or other healthcare professional office/clinic visit. Therapeutic measures were taken as a result the events with LOVANOX and PRADAXA. Follow-up attempts are completed. No further information is expected.</p>

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1227231	4/18/2021	PA	29	F	3/25/2021	3/28/2021	cerebral venous sinus thrombosis; CT scan that revealed the clot; horrible headache after intercourse; vomiting; This is a spontaneous report from a contactable consumer (patient). A 29-years-old non-pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot Number: EP7534), second dose via an unspecified route of administration, administered in left arm on 25Mar2021 09:45 as single dose for COVID-19 immunisation. Patient was 29 year old at the time of vaccination. Medical history included asthma, gastrooesophageal reflux disease, peanut and treenut allergy, all from an unknown date. Patient had estrogen allergy. Patient was not diagnosed with COVID-19 Prior to or after the vaccination. Concomitant medications included cetirizine hydrochloride (ZYRTEC ALLERGY), medroxyprogesterone acetate (DEPO PROGESTIN), beclometasone dipropionate (QVAR), OMEPRAZOLE, SERTRALINE HYDROCHLORIDE, all taken on an unspecified date and for unknown indication. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient had her first dose of bnt162b2 on 04Mar2021 at 9:45 am in left arm for COVID-19 immunisation. On 28Mar2021 at 09:45 the patient was diagnosed with cerebral venous sinus thrombosis a few days after receiving the second dose of the vaccine. She had a horrible headache after intercourse, went to the ER after vomiting, and had a CT scan that revealed the clot. The patient was hospitalized for cerebral venous sinus thrombosis. The patient underwent lab tests and procedures which included computerised tomogram: revealed the clot. Patient received Heparin and Eliquis as treatment for the events. Outcome of the events was recovering. No follow-up attempts needed. No further information expected.
1226093	4/18/2021	NH	72	M	3/27/2021	4/5/2021	DVT blood clot in left leg

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1227129	4/18/2021			U			<p>BLOOD CLOT; RIGHT LEG PAIN; HEADACHE; This spontaneous report received from a patient concerned a patient of unspecified age and sex. The patient's height, and weight were not reported. The patient's concurrent conditions included COVID-19. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805022, and expiry: UNKNOWN) dose was not reported, administered on 06-MAR-2021 at 02:19 for prophylactic vaccination. No concomitant medications were reported. The patient reported that she had a blood clot/pain in right leg 2-3 days after she received the vaccine. She reported that she used compression socks for a week. The patient also reported that she experienced headaches (date unspecified), which still come and go every other day. The patient stated that she had the same blood clot pain in the same leg as when she had COVID-19 infection in MAR-2020. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from headache, and the outcome of blood clot and right leg pain was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: A patient of unspecified age and sex reported a "blood clot/pain" in right leg 2-3 days after vaccine. The patient had a history of "blood clot pain" in the same leg when she had COVID infection one year ago. History of thrombosis would provide a plausible alternative explanation for the event, although there are insufficient details to make a meaningful medical assessment. The patient was contacted and could not be immediately reached. Additional information has been requested for further assessment.</p>

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1227269	4/18/2021	MI	64	F	3/19/2021	3/1/2021	possible pinched nerve; TIA; heart rate is low anyways from the medications but it dropped to 35 when she was in the hospital/heart rate dropped; her right arm, the right side of her face, and her right knee were numb/ she has numbness in her right finger and right thumb; face feels like its burning; her vision was kind of blurry; sensational loss in her right hand; caller's sclera looked like her eye was bleeding and her pupil started turning a different color.; caller's sclera looked like her eye was bleeding and her pupil started turning a different color.; eye was super red; rupture of a blood vessel in her eye; blood clot in eye; This is a spontaneous report from a contactable nurse (reported for herself). A 64-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Solution for injection, Lot Number: ER2613, expiry date not reported), via an unspecified route of administration, administered in left arm on 19Mar2021 09:00 at a single dose for covid-19 immunisation. Medical history included ongoing hypertension from 1900 wherein blood pressure was high prior to her atrial fibrillation medications; A fib (atrial fibrillation) from 2016 and ongoing; and ongoing heartrate low. As a child the caller had the vaccine in the sugar cube (unspecified) and her mouth was swelling from it; and stated that patient's sister was hospitalized after receiving the same vaccine. Family medical history included mom has hypertension. Concomitant medications included apixaban (ELIQUIS) taken for A fib (atrial fibrillation) from an unspecified start date and ongoing at 5 mg twice a day; sotalol taken for A fib (atrial fibrillation) from an unspecified start date and ongoing at 80 mg, twice a day; and diltiazem taken for A fib (atrial fibrillation) from an unspecified start date and ongoing at 180 mg, once a day. The patient was a healthcare worker and she has had friends who have died from covid. The patient had no previous immunization with the Pfizer vaccine considered as suspect and no additional vaccines administered on same date of the Pfizer suspect. Patient had no prior vaccinations (within 4 weeks). The patient stated she had the first dose of the vaccine and had a TIA (Apr2021) and rupture of a blood vessel in her eye 20Mar2021. The TIA was on Monday (Apr2021) and she was supposed to have her second dose tomorrow (09Apr2021). She stated she may get it but she is not taking it tomorrow because she is still

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having residual symptoms. She asked what the length of time she can wait to get it before she has to restart. Patient reported that after she got her first vaccine she had a ruptured blood vessel in her eye the next day (20Mar2021). She put warm and cool compresses on her eye then the ruptured blood vessel subsided. The ruptured blood vessel came back again a few days later and this time it was the entire sclera. She developed blood clots in her eye and the doctor said it probably wasn't from the vaccine (Mar2021). She was supposed to get her second dose of the vaccine tomorrow 09Apr2021 but she was going to hold off for now. She then had a TIA (Mar2021) and became hospitalized because of it from 06Apr2021 to 07Apr2021. The patient has ongoing atrial fibrillation but has been taking her medication religiously. She believed that the TIA was from the vaccine as there was no explanation as to why it happened. Her heart rate was low anyways from the medications (dates unspecified) but it dropped to 35 when she was in the hospital (Apr2021). The patient's primary care provide was not the attending in the hospital when the caller was hospitalized. Furthermore, it was reported that on 21Mar2021, patient's eye was super red but only on one side of her left eye. On Tuesday, 22Mar2021, caller went to see her primary care provider and they told the patient to put a warm compress and no eye drops in her eye, that helped. Then that Friday, 25Mar2021, the patient's sclera looked like her eye was bleeding and her pupil started turning a different color. Then last Monday (Apr2021), the patient woke up and her right arm, the right side of her face, and her right knee were numb she got up and went to see if she had a facial droop and did not. The patient thought it was from her sleeping wrong, but these symptoms did not go away. The patient went to the Emergency Room where they did a CT of her head and neck, with and without contrast which was negative. The patient was admitted on 06Apr2021 to the observation unit where they did an MRI and ECHO, which were both negative and she was diagnosed with a TIA and possible pinched nerve (Apr2021). The patient denied any heavy lifting prior to this event other than normal day to day things. The patient was discharged on Wednesday 07Apr2021. The patient's face felt like its burning, she has numbness in her right finger and right thumb. Physical therapy and occupational therapy said

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the patient should be okay but to be careful with things that were hot because she was at risk of burning herself. The second time the patient's eye became red, her vision was kind of blurry (Apr2021) and she didn't know if the blood was in her pupil. The only deficit that the patient has now is sensational loss in her right hand (Apr2021) and that should improve per the occupational therapist at the hospital. The caller was supposed to get the second dose of the vaccine on 09Apr2021 but she doesn't want to take it while she is having these symptoms. Results of tests and procedures for investigation of the patient included: head ct with and without contrast: negative on 06Apr2021; MRI brain: negative on 06Apr2021; Echocardiogram: negative on 07Apr2021; speech evaluation: passed on 07Apr2021. The patient asked what the efficacy is after one dose and if a booster will be needed since she is only protected for 6 months. Patient asked if she needed to restart the series of vaccinations if she doesn't get the second vaccine tomorrow 09Apr2021. The events ruptured blood vessel in eye, blood clot in eye, sclera looked like her eye was bleeding, eye was super red were reported as serious medically significant, and heart rate dropped as life-threatening. As reported, the events required emergency room and physician's office visit. Therapeutic measures were taken as a result of the events rupture of a blood vessel in her eye, and eye was super red. The outcome of the events reported was unknown. As per reporter, the events ruptured blood vessel in eye, blood clot in eye, and heart rate dropped were related to the covid BioNTech vaccine.; Sender's Comments: Based on the temporal relationship, the association between the reported events with BNT162b2 use can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.



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1227369	4/18/2021	NJ	60	M	3/31/2021	4/6/2021	2 lower- left leg Superficial blood clots; ~ a DVT Deep Vein Thrombosis per Ultrasound on 4/12/21, was diagnosis ; ER Dr. on 4/12/21 prescribed Eliquis 60 day Treatment.
1227273	4/18/2021	MA	44	F	3/15/2021	3/30/2021	massive clots; Pulmonary Embolisms; Occluded Left Lung, Right Ventricle; Occluded Left Lung, Right Ventricle; This is a spontaneous report from a contactable consumer (parent). A 44-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported) via an unspecified route of administration administered in the right arm on 15Mar2021 13:45 as a single dose for COVID-19 immunisation. Medical history included multiple sclerosis. The patient is not pregnant at the time of vaccination. The patient has no known allergies and has not had COVID prior to vaccination. Concomitant medications included gabapentin, carbamazepine (TEGRETOL), fluoxetine, colecalciferol (VITAMIN D), fish oil, and baclofen. The patient did not receive any other vaccine in 4 weeks prior to the COVID vaccine. On 30Mar2021 06:00, the patient experienced Pulmonary Embolisms, Occluded Left Lung, Right Ventricle and had emergency open heart surgery to remove massive clots. He coded for 4 minutes and was in ICU for 9 days. The patient was hospitalized due to the events on an unspecified date for 12 days. The events resulted in Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event), and Disability or permanent damage. Treatment for the events included open heart surgery. The patient underwent COVID test post vaccination via nasal swab on an unspecified date with unknown results. The outcome of the events was recovered with sequelae on an unspecified date. Information about lot/batch number has been requested.

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1227284	4/18/2021	WA	74	F	3/30/2021	4/6/2021	She almost died from pulmonary edema; Lungs have blood clots in them; This is a spontaneous report from a contactable consumer (patient's husband). 74-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), dose 2 intramuscular, administered in left upper arm muscle at age 74 years on 30Mar2021 (Batch/Lot Number: EP6955) as single dose, for COVID-19 immunisation. The patient medical history was reported as no. There were no concomitant medications. The patient historically took the first shot of BNT162B2 on an unspecified date for COVID-19 immunisation. It was reported that the patient took the shot of second dose of Pfizer BioNTech COVID Vaccine (Lot number: EP6955) shot on 30Mar2021 in her left upper arm muscle. Patient was in the hospital at the time of reporting hanging on to life. Patient got pulmonary edema and she almost died, her lungs are, have blood clots in them from 06Apr2021 then she went to the hospital on 07Apr2021, has to stay in the hospital for 4 days. Patient was not experiencing symptoms anymore, she has had blood thinners they administered blood thinners (treatment), she was improving. She has to stay 2 more days in the hospital taking the blood thinners. Laboratory test was done on 08Apr2021 which is in the hospital where she almost died. Vaccine was administered at a hospital. Patient was recovering at the time of report.
1227295	4/18/2021	NY	30	F	4/3/2021	4/13/2021	On April 16, 2021 (Day 13 after Vaccine) I was diagnosed with acute deep vein thrombosis (DVT) of my femoral vein in my left leg by Hospital. In other words, I was diagnosed with a blood clot in my upper left leg. Pain in both my legs had started on April 13, 2021 (Day 10 after Vaccine). On April 16, I had a virtual appointment with my doctor, Dr. , who prescribed an ultrasound to rule out DVT. I went to an ultrasound appointment at Radiology at 3:30pm where a blood clot was found in my left leg. I was admitted into the emergency room at Hospital and prescribed medication and follow ups from there. These adverse symptoms developed after I submitted other adverse symptoms to VAERS on April 13, 2021 (Temporary VAERS E-Report Number: 435841).
1227316	4/18/2021	PA	44	F	4/14/2021	4/18/2021	Spotting between periods in the form of clots. Day 16 of cycle. Cramps.

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1227320	4/18/2021	CA	71	M	1/16/2021	1/18/2021	about 2 days after the 1st dose of the moderna vaccine, felt very tired and unwell for several days. He felt okay for about 2 weeks then on January 29, 2021 he felt intense chest pain. Concerned it was a heart attack, he was brought to the hospital. He stayed one night and the hospital ran several tests like EKG, stress test and others. Found his results to be normal and was released on January 20, 2021. Even the moment he was released, he felt very dizzy but hospital was not concerned and thought maybe side effect of medication. He continued to feel dizzy, fuzzy brain and hard time staying awake during the day and sleeping through the night for the rest of the week. He passed sometime in the early hours of February 6, 2021. Doctor's suspicion is a blood clot. He has no history of blood clots, heart problems or any health issues.
1227376	4/18/2021	TN	46	F	3/15/2021	3/25/2021	Shortness of breath, nausea, headache, incident of blurred vision in one eye. Had visit with PCP on March 26th with follow-up testing on March 30th and 31st. Condition worsened and went to emergency room on April 4th and was admitted to ICU. EKOS procedure performed on April 5th. Discharge diagnosis on April 7th: 1) Acute bilateral PE (Pulmonary Embolisms/Blood Clots) with significant right heart strain status EKOS cath directed thrombolytics on April 5th. 2) Extensive bilateral deep vein thrombosis. 3) Significant right heart strain confirmed on the echo 4) Mild anemia 5) Metabolic acidosis with mild hyponatremia 6) Hypercoagulable workup, most results pending at discharge 7) Acute hypoxic respiratory failure
1227242	4/18/2021	CA	31	M	4/18/2021	4/18/2021	I felt numbness in my right leg, the numbness went up to my right arm and then I started slurring. This happened within a few minutes. I laid down and called a nurse adviser. I was recommended to go to ER, so my wife took me to ER. They did CT scan of my head, then CT scan of my head and neck with contrast, then MRI of my head, then MRI of my head and neck with contrast. It was confirmed that I had an ACUTE ISCHEMIC STROKE. It was decided to perform carotid endarterectomy surgery to remove a clot in the neck carotid artery. The clot was removed.

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1226242	4/18/2021	NC	59	F	4/2/2021	4/10/2021	Eight days after receiving the vaccine, my wife developed shortness of breath, headache, fatigue, and unusual vision problems. She was taken to the emergency room on 4/15 where she underwent a battery of tests (see details below). She was admitted to the hospital (where she currently is) and was diagnosed with blood clots in the lungs and two strokes in the area of the brain that affects vision. She then underwent ultrasound tests of her legs and carotid artery, which were negative for signs of blood clots. Although my wife's symptoms are different than the symptoms of others that led to the vaccine pause, her doctors strongly encouraged us to report it to the VAERS. My wife had no underlying or pre existing conditions that would lead to blood clots in her lungs, and stroke. After extensive testing there is no evidence that the blood clots in her lungs as well as the clot/clots that went to her brain initiated in her legs. They believe that some sort of "event" would have had to happen to cause these blood clots, and the only unusual thing in the time frame of this condition is the vaccine. As I mentioned earlier, my wife is still hospitalized.
1226112	4/18/2021	TX	36	F	3/6/2021	4/13/2021	Pt presents to the ED with c/o right leg/calf pain and swelling. She also had a headache last week. She is concerned she may have a blood clot related to the Johnson & Johnson COVID vaccine, as the vaccine is currently on hold.

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1227128	4/18/2021	TX		F		4/11/2021	THREE BLOOD CLOTS IN THE LUNG; TWO BLOOD CLOTS IN THE LEG; HEART ENLARGEMENT OF LOWER CHAMBERS; This spontaneous report received from a consumer concerned an 86 year old female patient. Initial information received on 13-APR-2021 and processed with additional information received on 15-APR-2021. The patient's weight was 161 pounds, and height was 67 inches. The patient's past medical history included hip fracture in 2015, and uncomplicated hip replacement surgery in 2015. Patient's concurrent conditions included non-smoker and no alcohol use. No recent travel or trauma was reported. No varicose veins or known cancer was reported. Patient saw her doctor for annual checkups and cancer screening. She is an active person who lives alone, still drives, and performs activities of daily living independently. The patient received vaccination with covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029) dose was not reported, administered on 08-MAR-2021 for prophylactic vaccination. Vaccination site was not reported. No concomitant medications were reported as it was reported that the patient denied HRT and chronic medications. Approximately 1 week later, on or about 15-MAR-2021, she began to feel fatigue, tiredness, and shortness of breath which she thought might be due to the start of a heavy pollen season. On 11-APR-2021, the patient's fatigue, shortness of breath, and tiredness did not improve, so her son took her to the Emergency Room (ER), where CT scan found 3 clots in her lungs and duplex scan found 2 clots in her legs (patient's son was not certain if bilateral or unilateral). Patient's oxygen saturation was in 80s. On 11-APR-2021, a test also revealed that the lower chambers of her heart were enlarged. On 12-APR-2021, patient underwent EKOS procedure to treat lung clots. Tissue Plasminogen Activator (TPA) had been put into the lungs via EKOS procedure 'with ultrasound inserted into blood clot in the lung'. Patient initially was treated with heparin but was stopped. Patient was treated with unspecified anticoagulant as patient's son did not know. Pulse rate was 139. On 12-APR-2021, patient was admitted to Intensive Care Unit (ICU) (no beds were available on 11-APR-2021). He had no information regarding lab results. On 15-APR-2021, patient was transferred out of ICU to a

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room on regular floor. Patient was still very tired. Oxygen saturation was in 90s. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from three blood clots in the lung, two blood clots in the leg, and heart enlargement of lower chambers. This report was serious (Hospitalization Caused / Prolonged, and Life Threatening).; Sender's Comments: V0: This 86 year-old active, independent female was hospitalized for 3 blood clots in her lungs and 2 blood clots in her legs 5 weeks after receiving Janssen Covid-19 vaccination. Medical history includes hip surgery after a hip fracture with uncomplicated course 6 years prior; she is a nonsmoker, does not have varicose veins, no known cancer, no history of recent trauma or travel and takes no chronic medications. Approximately 1 week after vaccination, the patient began to feel fatigue and shortness of breath. She initially thought her symptoms were due to the start of heavy pollen season. When symptoms did not improve 4 weeks later, she went to the emergency room where CT scan found 3 clots in her lungs and duplex scan found 2 clots in her legs. Oxygen saturation was in the 80s at that time. The following day she underwent EKOS procedure to treat the lung clots and was initially treated with heparin. The anticoagulant was subsequently changed after a public health announcement. She was admitted to the ICU and transferred to a regular room 3 days later. She was told the lower chambers of her heart were enlarged. She still feels very tired but her O2 saturation has improved to the 90's. No laboratory results were available to the reporter. Based on the limited information, the event is inconsistent with the causal association to immunization, per the WHO causality classification for adverse events following immunization.

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1226180	4/18/2021	OR	52	F	4/7/2021	4/14/2021	52-year-old previously healthy female who received first dose of Janssen COVID-19 vaccine on 4/7/2021. She started having periorbital right headaches starting on or about 4/14/2021. Headaches were alleviated with OTC Advil. On the morning of 4/18/2021, she awoke with RIGHT arm weakness which, over the course of several hours, progressed to include right-sided leg weakness and aphasia. Initial CT head showing multifocal hemorrhage within the LEFT frontal lobe. Course complicated by epileptic seizure. MRI brain with and without contrast and CT venogram brain notable for superior sagittal sinus thrombosis involving the mid and anterior segments of the superior sagittal sinus. Patient found to have new thrombocytopenia on admission with platelet level 78k; previously had normal platelets 6/4/2019. D-dimer elevated > 4.00 mcg/ml FEU. Started on Argatroban gtt, nicardipine, and IVIG.
1226099	4/18/2021	MS	79	F	3/23/2021	3/27/2021	Had blood clots in my brain 4 days later resulting in a stroke
1226244	4/18/2021	OH	47	F	3/23/2021	4/2/2021	Roughly 7 to 10 days after injection I presented with raised, red and itchy injection site. Roughly 13 days after the injection I presented with a tight right calf muscle that felt similar to a constant "charlie horse". It continued to worsen over the next 5 days until my right foot went numb and cold on Sunday April 4. I called my doctor the next day (Mon April 5) and they got me in that day and I went to the hospital the same day for an ultrasound. The hospital confirmed I had a blood clot in my lower leg.
1226348	4/18/2021	NJ	48	M	4/2/2021	4/2/2021	Shortness of breath, pulmonary emboli, deep vein thrombosis (DVT) in leg
1226448	4/18/2021	RI	78	F	3/9/2021	3/9/2021	Blood clot leading to heart attack
1226678	4/18/2021	GA	66	M	1/14/2021	1/27/2021	deep vein thrombosis, blood clot in left leg and 2 clots in lung, pneumonia, in hospital 3 days, released 2 days and back in for 3 days with gastrointestinal hemorrhage with melena
1226722	4/18/2021	KY	64	F	4/8/2021	4/9/2021	Vomiting and Diarrhea day after vaccine. 6 days after shot blood clot and stroke, currently in ICU.

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1226730	4/18/2021	UT	65	M	3/5/2021	3/8/2021	Big blood clots following Prostate Surgery 3 days after Vaccine applied Please see attached explanation and pictures
1226935	4/18/2021	VA	56	F	1/1/2021	1/21/2021	I am post menopause. I began menstrual cramps on the 1/20/2021. My period started a day later. The flue was heavy and with clots. My hot flashes stopped for 2 months. My hot flashes resumed at the end of March 2021.
1226954	4/18/2021	CA	82	F	2/14/2021	2/28/2021	Blood clot in left arm on 2/28/2021 (2 weeks after 2nd dose of Moderna). Diagnosed at Emergency Room.
1226955	4/18/2021		62	M	3/24/2021	3/29/2021	Extensive DVT requiring surgery. Received second Moderna vaccine approximately one week prior to admission, presented with acute onset of left leg swelling and pain. Left lower extremity ultrasound demonstrated an extensive deep venous thrombosis extending from the common femoral vein into the peritoneal and posterior tibial vein with a patent IVC. He was given a treatment dose of enoxaparin and admitted to the hospitalist service. Overnight he developed diminished sensation in his toes and vascular surgery was consulted. On 3/31/2021 he underwent mechanical thrombectomy of the left superficial femoral and common femoral veins as well as stenting of the left common iliac vein stent. Of note he was noted to have May Thurner physiology with compression of the left common iliac vein by the external iliac artery on the right. Post procedurally the patient's swelling and edema was significantly improved. He did not have any significant pain or difficulty ambulating. On postoperative day #1 he was evaluated and found to be hemodynamically stable with improvement of his symptoms and stable for discharge home. Prior to discharge it was discussed with the patient that he will need to be on a loading dose of Eliquis for 7 days, followed by a maintenance dose of 5 mg twice daily. No h/o COVID.



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1226125	4/18/2021	TX	44	F	4/12/2021	4/13/2021	4/13/2021 1am shortness of breath, chest tightness, 10:30 am Dr Visit (X-ray, EKG, Blood clots lab done) 12:00pm Sent to Hospital, Again everything done(X-Ray,EKG,Blood work, CT scan) They gave me an albuterol treatment which alleviated some chest tightness. I was released around 4pm from hospital. Once home I took some Benadryl 25mg
1222394	4/17/2021	SC	68	M	4/3/2021	4/12/2021	Bilateral pulmonary embolism, clot in leg, pneumonia developed after the vaccine. Patient was hospitalized for 3 nights.
1222465	4/17/2021	PA	41	F	3/20/2021	3/22/2021	The first two days I had a normal reaction with fatigue and soreness. On the second night I developed a severe sinus issue that caused my tongue to turn white/gray and be dry and sore. Frequent diarrhea, headache, sore throat, soreness, low grade fever for half a day and a resulting acid reflux condition. (I have never had acid reflux before) I was tested for Covid and Strep, both negative. Continued lymph node sensitivity for two weeks. 3.5 weeks in, I developed muscle tension, unrelenting, from the back of my head all the way down my spine. I had continued chest pressure and some numbness on my left side in my arm, leg and later my face. No home remedies worked and rarely do I get back/neck/shoulder pain. I was not doing anything strenuous. I went to the ER where they tested me for blood clots (J&J news had just come out and I have a family history) and prescribed valium for the muscle tension which has somewhat helped. I fully recognize that this might be bad luck, a series of unfortunate events after I received my shot. However, I have not been sick all year, I have never had acid reflux issues or pain like this in my neck/back/shoulders previously. The fact that in the 4 weeks after the shot I have not had a single day where I felt normal is a red flag to me. I feel like it is worth reporting in case anyone else has had a similar experience.
1222480	4/17/2021	TX	35	F	4/14/2021	4/15/2021	DVT (blood clot) in right leg below knee; leg cramps with sharp pain in calf with pressure, dull pain throughout leg and up to arm and shoulder when seated or laying down; prescribed blood thinners and scheduled follow up with primary care on Monday.

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1222578	4/17/2021	CA	69	M	2/28/2021	3/11/2021	3/11/2021 Blood clots both lungs, CT scan diagnosis, Xarelto blood thinner prescribed, 3/23 admitted again plural effusion both lungs and pericarditis , hospitalized five days
1222753	4/17/2021	NY	53	F	4/7/2021	4/16/2021	Pain and blood and small blot clots in urine/bladder
1222930	4/17/2021	VA	60	F	4/12/2021	4/16/2021	Patient woke up to get ready for work and noticed blood coming out of right ear. Clots were in the blood that came out of the ear.
1222969	4/17/2021	KY	72	M	2/6/2021	2/7/2021	Blood Clot that resulted in a stroke 25 hours after the shot. My heart went into A-Fib (first time ever)
1223056	4/17/2021	IL	62	F	2/26/2021	3/14/2021	My wife started to fall and pass out had no strength to get up this happened two to three times cinch she got the shot the last time she past out in the shower and i rushed her to hospital were she pasted away from blood clots to the right side of the neck and stated bleed on the brain
1223098	4/17/2021	ME	56	M	4/1/2021	4/14/2021	Headache for the last 36 hours and I don't get Headaches,it's not severe but medium like I'm on Plavix so I don't think I can get blood clots
1223111	4/17/2021	PR	63	M	3/9/2021	3/14/2021	Patient had severe pain in one leg since 03/14/2021 Went to the emergency room on 03/21/2021 where he was notified that he had a clot in his lung. It caused a bilateral pulmonary embolism.
1223220	4/17/2021	VA	62	M	3/30/2021	4/6/2021	On 4/6/2021 woke up with severe left muscle cramp in left leg. Next 3 to 5 days tried massage, ice, compression and Motrin - no relief. Did no treatment for the next couple of days. Went to primary care doctor and then got an ultra-sound on 4/14/2021 at clinic - by Doctor. Results showed had three blood clots in left leg. Started on Eliquis that day.

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1223301	4/17/2021	TX	53	F	3/16/2021	3/24/2021	Patient reports tear in esophagus on 3/24/21 in the evening whenever she felt sick to her stomach. She did not feel well, drank one beer, and ate a packet of tuna. She continued to not feel well and felt the food did not go down correctly, so she reached into her throat and noticed blood. She called her doctor and the doctor recommended monitoring for increased bleeding. Later that night, she reports not feeling well again, made herself throw up, and noticed the vomit was all blood. The patient then called 9-1-1, and presents to the hospital. During the hospital visit she noticed that she saw 'blood clots about the size of a quarter' when she went to the bathroom. Patient reports the hospital gave her 4 pints of blood, 4 bags of 'yellow stuff' (patient assumes its plasma), protonix, antibiotics, and NS. Patient was in the ICU and reports being in the hospital for about 5 days total, whenever the doctor recommended being put on hospice. The patient did want to be put on hospice and wants to be treated, so she contacted her heart doctor and is waiting on an appointment with him on the 28th of April. Patient reports that doctor told her that she 'needs a new heart', but that she is not a good candidate, and that the Dr. told her this just a day or two ago. Patient reports that she did not know it was a tear in her throat (esophagus) until they "stuck a scope down there".
1222372	4/17/2021	UT	88	F	4/5/2021	4/10/2021	SMV thrombosis; CT scan of the head WO IV contrast shows no e/o CSVt
1223432	4/17/2021	NC	47	F	4/9/2021	4/14/2021	CVA and cerebral venous sinus thrombosis

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1221916	4/17/2021	MA	83	M	2/27/2021	3/29/2021	<p>blood clot in his brain; Patient collapsed on the floor at night 2 days after receiving 2nd dose; brain was dead; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of BRAIN DEATH (brain was dead), CEREBRAL THROMBOSIS (blood clot in his brain) and LOSS OF CONSCIOUSNESS (Patient collapsed on the floor at night 2 days after receiving 2nd dose) in an 83-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 0021B21A and 001821A) for COVID-19 vaccination. The patient's past medical history included No adverse event (no medical history reported). On 27-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 29-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Patient collapsed on the floor at night 2 days after receiving 2nd dose) (seriousness criterion hospitalization prolonged). On 30-Mar-2021, the patient experienced CEREBRAL THROMBOSIS (blood clot in his brain) (seriousness criteria death and hospitalization prolonged). The patient died on 08-Apr-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, LOSS OF CONSCIOUSNESS (Patient collapsed on the floor at night 2 days after receiving 2nd dose) outcome was unknown. Not Provided</p> <p>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Mar-2021, X-ray: blood clot (Positive) x-rays revealed blood clot in his brain. No concomitant medications were reported. After the 2nd dose, On 29Mar2021, at night, he collapsed on the floor and was taken at the hospital on same night by ambulance. So he was hospitalized on 30Mar2021 and upon doing tests and x-rays, they found blood clot in his brain. He stayed in hospital through out and transferred to hospice center on 06Apr2021 where he passed away on 08Apr2021. His brain was dead and never recovered from the clot. Unknown treatment medications were given at the hospital. Very limited information regarding these events have been provided at this time. No further information is expected.; Sender's Comments: Very limited information regarding these events have been</p>

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							provided at this time. No further information is expected.; Reported Cause(s) of Death: Unknown cause of death
1223364	4/17/2021	IL	50	F	2/16/2021	3/8/2021	I received vaccine doses on 2/16/21 and second on 3/16/21. Trying to complete good deeds for Lent, I donated Plasma for the first and only time on 3/7/21. On 3/8/21 my right calf starting seizing up and I was experiencing calf pain. I was advised to do stretches and use a heating pad. It persisted for over a week and I went for a Doppler ultrasound scan on 3/17/21. Blood clots were found. The Plasma donation center screening led me to believe that they were concerned with other vaccines but not the Covid19 vaccine. Writing report because I think there is a possible connection to the blood clots, vaccine and plasma donation. I had to "do nothing" for three weeks and have been placed on Eliquis, a blood thinner for four months. Follow-up with Dr. for blood work and Doppler in July.
1221993	4/17/2021	IL	82	F	4/8/2021	4/9/2021	4/9/21 before 8am - coughed up large amounts of blood, went to ER at hospital several hours later. Admitted to the hospital for 4 days after finding blood clots in the lungs.
1223282	4/17/2021	WA	72	F	3/6/2021	3/9/2021	Noticed painful right calf 3/09/2021. Went to urgent care at hospital on 3/10/2021. Was given an ultrasound and it was determined that I had a blood clot in my calf vein. Was given heparin treatment for seven days followed by xarelto. I have had 2 dvts in the past associated with surgery. This dvt was listed as unprovoked, however I believe it was caused by the second shot of modern. Was told by doctors to report this to veers.

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1223443	4/17/2021	WA	55	F	4/6/2021	4/9/2021	On April 9th, I developed a headache at 9pm while watching tv. About 15 minutes later I noticed my vision was changing so I called my daughter to come stay with me and took tylenol fast release capsules. I went to bed and woke up the next morning with the same headache so I asked my daughter to take me to urgent care. Upon arrival they did a Covid test. I told them about my previous stroke in July 2020 and that I had a PFO closure done in October and have been on Plavix (clopidogrel) since then so I wasn't worried about stroke. The dr sent me to the ER immediately and they performed an MRI scan and told me I had suffered a new stroke due to blood clot.
1221593	4/17/2021	MI	44	F	4/7/2021	4/16/2021	Day 8 began having nagging headache that will not go away. It is not the most severe headache I have ever had, but, with the pause due to clots and my age group, I am worried. Has not ended after 24hrs. Pain is in back of my neck.
1221619	4/17/2021	OR	66	M	3/15/2021	3/26/2021	Pain increased in left calf, clot found in left calf at medical center, rushed to different medical center, 6-1/2 hour surgery to remove clot in lower left leg. 100% blocked. Hospital diagnosis found left leg ischemia (199.8). Procedures performed, popliteal artery patch repair, Angiogram, fasciotomy calf.
1221630	4/17/2021	OR	48	F	4/3/2021	4/16/2021	Accute deep vein thrombosis of popliteal vein of right lower extremity.
1222006	4/17/2021	MN	24	F	3/30/2021	3/31/2021	Flu like symptoms- Fever (102 degrees) started ~ 10 hours post shot lasted 48 hours, chills, body aches, headache Rash resembling Livedo, or blood clots of the skin first notices 2 days after shot was received but may have started earlier. Condition has not worsened but livedo is still present as of 4/17/2021. Went to doctor about it and was told as long as it does not get worse not to worry.
1221715	4/17/2021	OR	64	M	4/3/2021	4/11/2021	Had shot 4/3 Bad Headache 4/11 Blood clot / lungs 4/14

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1222355	4/17/2021	PA	64	F	4/12/2021	4/12/2021	The patient received vaccine at the pharmacy and stayed for an observational period of 15 minutes. The patient left the pharmacy seeming fine but then reported on 4/17 that she had fainted at her residence and she was taken in an ambulance to a hospital. Patient said that the hospital ruled out a blood clot.
1221552	4/17/2021	WA	45	M	4/15/2021	4/16/2021	Noticed a feeling of pressure around bend in arm the day after vaccine. Took off sweatshirt to find a cause unknown but noticeable spot that was not previously there. It looks like a small blood clot. We can provide pictures. The pain subsided, no tingling or numbness by end of day. Concern is mostly whether pt should take a second dose with this reaction. Pt has severe varicose veins in his legs, not sure if its related.
1222039	4/17/2021	VA	41	F	1/19/2021	1/1/2021	Short Summary: DVT followed by Multiple Bilateral Pulmonary Embolisms (significant blood clots in both lungs). Context: After the first vaccine (about a week before my second vaccine), I self diagnosed myself with a calf injury due to extreme pain in my calf that felt like a continuous cramp. The extreme pain lasted until my second shot (about a week). When going for my second shot, I reported a rash with hives on my lower abdomen that had appeared within five hours of my first shot, so they requested I stay a little longer for observation. That night I began having some breathing difficulties, but assumed they were to be expected. The breathing difficulties continued to get worse until my nurse practitioner told me to go directly to the nearest ER (2/16/21), where I was officially diagnosed with multiple bilateral pulmonary embolisms. I was admitted to healthcare facility for 24-48 hours, until an EKG revealed heart abnormalities that caused them to use a physician's transport to move me to another unit. I was discharged from the hospital on 2/2/21 after I stabilized from heparin shots, avoiding more invasive procedures. I have been in ongoing recovery since then, receiving ongoing care from a hematologist and pulmonologist. A little extra context for you - I arrived to the hospital with diabetic ketoacidosis and have an endocrinologist since hospitalization that has diagnosed me with Type 1 Diabetes (previously misdiagnosed as type 2 - I'm now on insulin which is controlling my blood glucose well).

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1222143	4/17/2021	WA	73	M	4/8/2021	4/9/2021	Acute superior mesenteric venous thrombosis and portal venous thrombosis
1222152	4/17/2021	FL	50	F	4/11/2021	4/11/2021	Patient's husband called about reactions after the vaccine as patient does not speak english. She experiencing trouble breathing for the whole week and feels very tired. Also reports swelling and pain in the legs and hand, significant enough to prevent her from removing her wedding ring. I recommended them to go to the emergency room as soon as possible as her symptoms resemble a possible clot. She does not have a PCP to refer her to nor does she has insurance. He agrees to take her to the emergency room.
1222295	4/17/2021	PA	49	F	4/6/2021	4/10/2021	Potential Blood Clot
1222322	4/17/2021	FL	45	M	3/29/2021	4/7/2021	Blood clots developed in the 3 arteries in my lower right leg, cutting off all blood flow below my ankle. Extreme pain in my calf, my foot immediately lost its color and no pulses could be detected in my ankle or foot. Rushed to ER by ambulance. Vascular surgeon diagnosed it as simultaneous arterial thrombosis in the posterior tibial artery, anterior tibial artery, and fibular artery of the lower right leg. Admitted to the ICU, treatment was heparin drip for 3 days until all 3 clots cleared and all foot pulses were detectable.
1221632	4/17/2021	MO	34	F	4/9/2021	4/9/2021	Unusual Heavy menstrual bleeding with clots starting hours after receiving shot. Headache and fatigue day after shot. Menstrual heavy bleeding continued for 6 days outside of normal cycle. Day 7 having moderate leg pains and stomach pains and occasional headaches.
1223890	4/17/2021	AR	41	F	4/16/2021	4/17/2021	Severe inflammation in legs. Seen in ER D-dimer high. No evidence of clot in leg which was where the main complaint of pain and swelling. Pain in both legs but right greater than left. Elevated blood pressure 153/61. Headache. Nausea with vomiting. Dizziness. Fatigue. Global joint pain > 24 hours after injection. Chest pain dominant left side.
1223445	4/17/2021	VT	40	F	3/20/2021	4/3/2021	Superficial Thrombosis in right leg began to present 2 weeks after first injection. Worsened over next two weeks until I visited my doctor who sent me for an ultrasound.



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1223212	4/17/2021	WA	47	F	3/9/2021	3/24/2021	03/24/2021 Blood clot appeared on left arm area of mid forearm. Blood clot raised skin and was painful to touch. Treated with hot pack for approximately 20 min. Blood clot remained for approximately 8 hours and then broke the vein and I was bruised for approximately 5 days.
1223996	4/17/2021	MI	77	F	3/8/2021	3/17/2021	Developed massive Pulmonary Blood Clots in both lungs. First symptom was shortness of breath and feeling I would faint. Went to Hospital Emergency room and was admitted immediately spent 2 1/2 days in ICU for treatment to dissolve blood clots (TPA) Was discharged on third day as oxygen level, heart beat, breathing and blood pressure appeared normal. Took second COVID19 (Pfizer-BioNTec) shot on Monday, March 29, 2021 at 1:00 p.m. (Lot ER8732) No adverse reaction to second shot except some muscle pain in left leg (calf).
1223892	4/17/2021	MD	49	F	4/12/2021	4/12/2021	101.3 fever developed around 9 pm. Headache lasted about 24 with onset around 7 pm. Tylenol reduced fever, headache, vaccine paused next day caused anxiety. Anxiety is what caused me to call dr. Dr was more concerned about fever. He explained what to look for with clots. Reaffirmed rareness.
1223874	4/17/2021	MO	37	M	4/16/2021	4/17/2021	5 hours after the shot body aches and fatigue set in. That last through the night. This is not a concern as everything indicates this is normal. However, the next day on 4/17/2021 I have pain in my right leg calf. The pain is to the right of the calf and feels like a dull pain. The area is not warm or swollen so I don't expect it to be a blood clot, but thought it might be worth reporting just in case.
1223855	4/17/2021	MS	26	F	3/24/2021	3/25/2021	Chills 12 h after receipt of vaccine followed by low grade fever (101 F) and body ache with minor headache. Symptoms subsided by the end of the following day. 1st menstrual period post-vaccination was noticeably heavier with more clots than usual.
1223833	4/17/2021	CO	46	M	3/26/2021	4/11/2021	Bilateral pulmonary embolism, Left Brachial artery clot, abdominal clots

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1223789	4/17/2021	MA	61	F	3/5/2021	3/6/2021	My sister, received the J & J vaccine on March 5th. I now know that she was not feeling well for a few days afterwards. She then felt better until day nine after the vaccine. On the evening of the ninth day, she began having abdominal pain, vomiting & diarrhea, headache. This was Sunday evening. Unfortunately I wasn't aware of how she was feeling and she didn't go to the emergency rm. until Tuesday morning. Tests determined her platelet level was low and abdominal CT showed bleeding from her adrenal glands. She was given platelets, pain meds and admitted into the hospital. Later that night staff felt she wasn't responsive and a head CT was performed. It was determined she had a brain hemorrhage and emergency surgery was performed. It is my understanding that there was brain damage at that point. During the early morning hours of the 10th day, post surgery, a repeat CT scan was done showing more hemorrhaging and blood clots. She also developed a DVT and PE and was kept on a respirator until the 13th day post vaccine to allow family to say their goodbyes. On the morning of the 13th day patient was removed from life support and she passed.
1223595	4/17/2021		43	F	3/20/2021	3/21/2021	The day after patient received vaccination, she experienced severe and unusual vaginal bleeding that lasted one month. Bleeding contained clots, which is not typical of her menstrual cycle.
1223729	4/17/2021	CA	60	M	4/12/2021	4/15/2021	On Thursday around noon, pt. had a headache, chest pains, numbness in left arm, the ER checked his heart rate and it was 215, they did blood work which came back normal & took more blood 4 hours later to check for heart damage, They admitted him to the hospital and did an EKG the next day that did not show any negative results (you'd have to get that from the hospital) They completed an Angiogram and found no blockage. Today, April 17th, I believe they did a cat scan of his lungs to check for blood clots and I am not sure of the results.
1223667	4/17/2021	FL	73	M	3/1/2021	4/1/2021	Blood clots - minor stroke
1223638	4/17/2021	MD	34	F	4/1/2021	4/16/2021	Severe period cramps starting on 4/16, continued to get worse 4/17. Passing blood clots (does not normally happen).

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1223736	4/17/2021	PA	50	F	2/24/2021	3/20/2021	sudden pain in right leg, leg began turn blue and toes white within 15 minutes. excruciating pain called for an ambulance and was taken to ER primary diagnosis was ischemia of right lower extremity emergency surgery for large blood clot in right leg and a small one in the left leg hospitalized for 3 days prescribed blood thinners and adjusted other meds
1223502	4/17/2021	NC	49	M	4/7/2021	4/8/2021	received Janssen J & J shot 9:15 am on April 7th approx, 24 hours later had to leave work for home because I became incredibly weak, tired and without energy. struggled at driving home had to repeatedly slap my face to stay awake. checked my temp. when arrived home, had a low fever (100.1) went to bed slept for 4 hours, checked temp (100.1) went back to sleep. woke 9 am on 4/9/2021 checked temp. (normal) fever broke on 4/9/2021 used restroom at 11:01 am 4/9/2021 large amount of bleeding from rectum LARGE AMOUNTS of blood clots in stool (shaped like Candy) Contacted medical provider. Spoke to a triage nurse, explained my concerns about bleeding from rectum and blood clots in stool... she dismissed that my restroom issues were related to the vaccine,
1223961	4/17/2021	WA	43	F	4/17/2021	4/17/2021	Probably unrelated but I am on day 3 of my normal menstrual cycle (typically 5-7 days). Approximately 2 hours after receiving the vaccination I began passing large clots and my flow went from regular to heavy. I do have heavy cycles from time to time but found the abrupt change in cycle interesting. Other than being sore in the arm and tired I feel fine.
1219160	4/16/2021	OH	72	M	2/4/2021	2/15/2021	Felt fine after vaccination. Estimating that around February 15th is when he began not feeling well. Stated he had abdominal pain and a general feeling of un wellness. He went to medical center on February 22nd and was then transferred to medical center. Patient stated that several tests were ran and he had blood clots in his heart and spleen. Upon further scans and testing including a heart catheterization nothing could be found as the cause for the clots. Patient had not had history of clots before. Permanent damage to the heart and spleen.

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1219057	4/16/2021	OH	22	M	2/26/2021	2/26/2021	My son Fell out at work after shot was given. He had a seizure, he lay unresponse on floor until medics were called. He noe has a blood clot in brain & has had 3 more seizures.Patient drives a fork lift & drives a truck he is nolonger able to do either.
1219055	4/16/2021	WV	72	F	4/3/2021	4/3/2021	On April 3, 2021 the patient received the first dose of the Moderna COVID vaccine. The patient's husband states that "crashed an hour and a half after she got the shot." He defines this "crash" as decreased blood sugar, decreased responsiveness, and the seizures. She presented to the Hospital for evaluation and was subsequently transferred to the Medical Center on April 4th for further workup. She was intubated on April 4th and subsequently self-extubated on April 8th. Nursing staff and documentation indicate that the patient has had no further seizures since her presentation to the medical center. On April 14th she was found to have an acute lower extremity DVT. She was placed on a heparin drip and her platelet's dropped to 35. The heparin drip was discontinued, a HIT panel was ordered, and argatroban was started. Heamtology was consulted and the patient was found to have thrombotic thrombocytopenia. An MRI of the brain was ordered to rule out CNS thrombosis given recent seizures. The MRI has not been performed yet and the patient is still hospitalized.

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1218973	4/16/2021	MD	37	F	3/23/2021	4/2/2021	Per hospital chart notes, known timeline of events is pieced together as follows: 2021-03-23 - patient received J&J COVID-19 vaccine at Drug Store 2021-03-24 - patient developed myalgias, headache, shortness of breath, and chills - resolved within 24 hours 2021-04-02 - patient developed headache intermittent from right to left side of head for which patient was seen at an urgent care. Patient was prescribed Fioricet (butalbital/acetaminophen/caffeine). 2021-04-05 - patient developed right-sided neck pain 2021-04-06 - patient got tested for COVID-19, resulted negative on 2021-04-07 2021-04-08 - patient seen at Medical Center emergency department for headache and right-sided neck pain that shoots to (2021-04-08 cont.) the head and shoulder, for which patient self-medicated with ibuprofen. Patient reported to ED provider that using ibuprofen nearly relieves headache and makes her functional and had the most improvement the day she visited the ED prior to her visit. Patient received a CT scan of the head without contrast that was unremarkable. Patient was diagnosed with headache and neck sprain and was prescribed ibuprofen 600 mg, take 1 tablet by mouth every 8 hours, and diazepam 5 mg, take 1 tablet by mouth 3 times a day as needed for muscle spasm. 2021-04-12 - patient developed left lower extremity pain 2021-04-14 - patient followed up with Neurologist outpatient as directed by ED provider and was advised to get an MRV and left lower extremity doppler. Patient was prescribed tramadol 50 mg and butalbital/acetaminophen/caffeine (Fioricet) by the Neurologist. 2021-04-15 - patient presented to Medical Center ED before outpatient MRV and LLE doppler could be done due to worsening right-sided neck pain and inability to ambulate comfortably due to lower extremity pain that had been worsening over several days. Upon examination, there is subtle swelling to left lower extremity and doppler revealed multiple DVTs in left lower extremity. CT head without contrast was unremarkable, however, CT venogram of the brain reveals thrombi of the right transverse sinus and sigmoid sinuses, as well as IJ. Patient was initiated on argatroban and admitted to inpatient at the time of this report. "Heparin induced platelet antibody" and "lupus anticoagulant evaluation" tests are ordered and pending.

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1218940	4/16/2021		85	F	1/21/2021	1/26/2021	Small bowel obstruction History of DVT (deep vein thrombosis) History of anticoagulant therapy NAUSEA VOMITING BACK PAIN Leg Pain Abdominal Pain
1218939	4/16/2021	CA	68	F	2/10/2021	2/16/2021	I am on Warfarin daily and prior to my first Moderna vaccine, my INR was 2.2. It jumped to 3.4, 3.8, then 3.9 and I have not changed anything in my diet, nor have I changed any medication routine. I have heard about blood clots, but was wondering if there is an interaction with warfarin or similar meds. I have no symptoms other than bruising more easily.
1218850	4/16/2021	NH	43	F	4/11/2021	4/12/2021	Received the J&J Covid Vaccine shoot on Sunday, April 11th at the Clinic. The night of receiving my shot, I had a migraine and neck pain which resulted in trouble sleeping. When I got up in the morning, I started having severe muscle pain in my thighs and in my calf, mild cramps in the abdomen. The leg pain lasted the entire day with exhaustion, which interfered with my ability to work a full day. When I went to bed later that night, I still had pain behind my left knee and I was worried about if there was a blood clot. I got up the next morning and my legs were still cramping but improved from the prior day. When I saw the news discussing the blood clot issue associated with the J&J vaccine, I felt it was important to contact my Dr. to discuss the leg pain. They did an ultrasound (vascular scan) on my left leg and follow up with my doctor's office walk-in clinic after the scan. My legs were examined and no clots were identified. We discussed things to watch for.

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1218790	4/16/2021	MO	49	M	4/5/2021	4/7/2021	Swollen lymph nodes and abdominal pain from right hip bone down to scrotum. Pain on 4/7 was such that i though i was suffering a hernia. Couldn't get out of car or move my right leg across my body. Could put right leg into pants leg. Hurt to bend over and do much of anything on 4/7. Initially thought pain was in testicle but doesn't hurt at all to the touch. Realized it more a swollen area in the groin between hip bone and scrotum. Nothing hurts to the touch at all in that area either which lead my to believe it was swollen lymph nodes. The Feeling is as if i got hit in the right groin and my testicle has been hit and discomfort is 8 inches above right testicle in my groin area. It has been improving every day since then, the more i walk the better it is. It only hurts when i sit now and it seems to aggravate it pretty well but once i start moving the pain goes away. It has been 9 days now and the i don't notice it all day until i come back to the office and sit at my desk and again it gets aggravated and the discomfort feels like my right testicle is near my appendix Since this all started my legs feel heavier in the calf and have little nerve sensations when i sit too, which concerns me about the blood clot possibility and so i have been emailing with my doctor. I am going to make appt for Monday 4/19
1219249	4/16/2021	NY	47	M	4/5/2021	4/7/2021	2 days after receiving the vaccine I have been diagnosed with Deep vein thrombosis and pulmonary embolisms.
1218587	4/16/2021	ND	55	M	3/31/2021	4/3/2021	Patient received Johnson & Johnson (J&J) Janssen COVID 19 vaccination on 3/31/21. Follow up telephone call was done to patient to assess for warning signs of blood clots. Patient reports new onset of shortness of breath 3 days after receiving the J&J COVID 19 vaccination and severe headaches. Patient denies any other symptoms of abdominal pain, leg pain or swelling, backache, petechiae, or new or easy bruising. Patient was given the following recommendations to seek medical care at the nearest emergency department. Patient states he is going to make a medical appointment with his primary care doctor at a local clinic in the town he lives in. Patient was advised due to the symptoms he is experiencing that he should seek medical attention for the symptoms he is having due to the warning signs of a type of blood clot that is occurring in the J&J COVID 19 vaccination.

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1219720	4/16/2021		58	M	4/7/2021	4/9/2021	patient received vaccine on 4/7 and developed N/V on 4/9. Presented to hospital on 4/15 with portal vein thrombosis.
1218742	4/16/2021	TX	36	M	4/10/2021	4/10/2021	Johnson & Johnson Vaccine on Saturday, April 10, 2021 - 1 p.m. 11 p.m.: Sharp pain inside of L thigh Sweats, Chills, escalating fever All night, fever increasing to 103 High blood pressure 160/130 Sweats Lymph nodes very swollen No sleep overnight Sunday, April 11, 2021 Aches and pains both legs Fever continued through Sunday 100F Migraine started at daybreak, lasted all day (Lots of Tylenol and Advil, alternating) Arm with shot started to hurt Few hours of sleep was interrupted again by inside thigh sharp pain in L leg Monday, April 12, 2021 Running fever 100 Blood pressure high Arm started to show rash in the evening Woken up with sharp pain in L leg. Caused limp all day Monday. Fever broke Monday evening. Tues., April 13, 2021 Sharp pain in L leg Leg felt hot Called physician, no return call Called pharماسist, told me to go to ER due to J&J Blood clot potential issue and my symptoms Went to the ER, long wait to get an ultrasound on L leg to make sure blood flow normal Released Didn't sleep well. Continued to have leg pain took advil to get rest Wednesday - Thursday, April 14-15, 2021 Felt sore on leg, went about my day normally Was in Bed at 11 p.m. Friday, April 16, 2021 Was woken by sharp pain under L armpit 1 a.m. and left arm hurt/sore Took Tylenol and Heartburn meds had trouble falling back asleep Fell asleep 4 a.m. Woke up 8:30 a.m. with sharp pain under armpit still Blood pressure 145/112, ten minutes later 145/108 Called my physician again and they told me to drop everything and goto a different ER to get an angiogram done - The first ER did almost nothing that needed to be done according to the physician.
1218930	4/16/2021		77	F	3/31/2021	4/8/2021	NA Lung cancer - developed a cerebral thrombosis
1219629	4/16/2021	GA	74	U	3/31/2021	4/14/2021	EXTENSIVE BLOOD CLOT ,DVT AND PE



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1220068	4/16/2021	MT	36	F	4/6/2021	4/15/2021	Pt had right sided chest pain x3 days starting 4/12/21, had a week of cough, fever, "general not feeling well" prior to ER admission 4/15/21. Had CT scan in ER on 4/15/21 - per radiology report a clot and pneumonia noted in RUL of lung. WBC count >22, elevated D Dimer, T Max in ER was 102.2. Was given PO Tylenol, 100mg Lovenox Subq, and IV antibiotics and flown to hospital.
1220036	4/16/2021	NC	27	M	3/27/2021	3/28/2021	I had intense stomach pains, muscle pains for 4 days. Could not get out of bed. Also had a fever. I thought these were regular side effects and eventually got better. Then, about a week later I started getting nose bleeds with blood clots coming out of my nose. These lasted a few more days. This never happened to me before, and must have been a side effect from the vaccine.
1219954	4/16/2021	NY	75	F	3/11/2021	4/4/2021	Day of vaccine I didn't feel bad, just felt queasy later, I was tired the next day. I don't know when the SOB started but it continued through the month of March. I thought it was an exacerbation of my chronic issues, by Sunday 4/4/2021 I coughed up blood, and on Monday I went to the hospital and had a CT scan and was told I had a pulmonary embolism and a clot in my leg. Now I'm on an injectable blood thinner for the rest of my life and I was told it would take 3-4 months to resolve the blood clots.
1219828	4/16/2021	NC	94	M	3/19/2021	3/1/2021	Patient received his first Moderna vaccine 3-19-21. He was due for his 2nd dose 4-16-21. We followed up with his sister due to missed appointment and was informed that he passed away 4-15-21 due to a blood clot.
1219798	4/16/2021	AR	79	F	3/14/2021	3/24/2021	Patient was in store and top of chest started hurting and down left arm. Patient states that they called 911 and ambulance took her to the hospital. She was tested and found to have mild heart attack with blood clot in vein of her heart. Had procedure to remove clot was put on blood thinner and is now wearing a heart monitor for the next 30 days. Is on Brelinta for the next 30 days as well. Patient went back to ER on Tuesday night (4/13/21) due to SOB spent 12 hours at ER before being transferred back to hospital. She spent another day and half before discharge diagnosed with fluid buildup.

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1219390	4/16/2021	MI	48	F	4/10/2021	4/13/2021	Pt states she noticed Tues left leg cramping in calf back and knee and thigh that feels like a charlie horse. denies hx of blood clots or long travel Left calf swollen cool to touch. Pt states her foot is more swollen to her. Patient found to have an indeterminate age deep vein thrombosis. Discharged home from the emergency department with a prescription for Apixaban.
1218200	4/16/2021	PA	29	M	4/12/2021	4/12/2021	Patient is a 29-year-old male with no significant past medical history. Presents emergency room for a syncopal event. Patient was upstairs in this facility receiving a COVID vaccine. A few minutes after receiving the vaccine he began to feel lightheaded, asked for assistance and had a syncopal episode. Patient was eased to the ground there was no trauma. States he has had previous near syncopal events associated with seeing blood or having needles injected into him in the past. He is without complaint. Denies any chest pain or headache prior to event. Denies any previous history of blood clots or other coagulopathies.

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1216640	4/16/2021	MI	73	M	2/21/2021	3/19/2021	My father received the first dose of the moderna vaccine on February 21, 2021. On March 19, 2021 my father exhibited stroke-like symptoms and was admitted into the hospital for a medical emergency. The doctors ran multiple tests and determined that he suffered a transient ischemic attack (TIA). His symptoms subsided and he was discharged on March 20, 2021. He received his second dose of the moderna vaccine on March 21, 2021 and, on the same day, suffered the same stroke-like symptoms which the doctors determined was another TIA. My father had no previous history of strokes, seizures or stroke-like symptoms prior to receiving the moderna vaccine. My father was re-admitted into the hospital on March 21, 2021 and over the course of two weeks was subject to a number of tests which revealed that his platelet count had significantly decreased to the point where his blood began to clot. They diagnosed him with a sudden onset of thrombotic thrombocytopenic purpura (TTP). The doctors explained that TTP was very serious and life-threatening disease if left untreated. Since this discovery, my father has needed to receive multiple plasma exchanges and rituximab treatments. I have written records asking the doctors about the link between the moderna vaccine and his TTP. The doctors recommended that I report this information. I believe it's critical for others to be made aware about the serious side effects of the moderna vaccine. I am willing to share my father's medical records which proves the drastic decrease in his platelet count following his receiving the moderna vaccine.

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1218531	4/16/2021	FL		M		4/5/2021	DEEP VEIN THROMBOSIS; This spontaneous report received from a patient concerned a 46 year old male. Initial information was received and processed with additional information received on 15-APR-2021. The patient's weight and height were not reported. Patient's medical history included insomnia for which he took klonopin occasionally. Patient was non-smoker. Patient's body fat was reported as 6% The patient received vaccination with Janssen COVID-19 VACCINE (covid-19 vaccine ad26.cov2.s) (suspension for injection, route of admin intramuscular, batch number: Unknown) dose was not reported, administered on 14-MAR-2021 13:00 in left arm for prophylactic vaccination. Batch number was not reported, will be requested. No concomitant medication was reported as patient reported not taking any medication at the time of the event. Patient' did not have any blood work done since taking the vaccine. On 23-FEB-2021, platelet count was 206. On 05-APR-2021, the patient was diagnosed with deep vein thrombosis. Patient reported that after 2 weeks of vaccination, he experienced pain in left calf muscle for 2-3 days. Physician sent the patient for doppler scan for his leg. Patient was diagnosed with deep vein thrombosis. Treatment medications included: Eliquis (apixaban). Patient was prescribed apixaban 20 mg a day for a week and continue with it 10 mg a day for 2.5 months. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of deep vein thrombosis was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: A 46-year-old man was diagnosed with deep venous thrombosis (DVT) in his left leg 21 days after vaccine. There was no relevant medical history or concomitant medications, he is a nonsmoker, and there is no family history of thrombosis. Nineteen days before vaccine his platelet count was normal at 206,000 and no laboratory work has been performed since then. The patient was treated with Eliquis. Idiopathic DVTs often are followed by an extensive workup to identify the cause, and the patient is reaching out to his physician to discuss further. Based on information currently available, company causality is considered possibly related.

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1219387	4/16/2021	ND	47	M	3/31/2021	4/2/2021	Patient received Johnson & Johnson COVID 19 vaccination on 3/31/21. Follow up telephone call made to screen patient for warning signs of blood clots. Patient reports new onset symptoms of severe headache that started occurring on 4/2/21 at 4:pm. Patient was given the recommendation to seek medical attention at the nearest emergency department for medical evaluation for blood clots due to reported symptoms. Patient denies any abdominal pain, leg pain or swelling, or shortness of breath. Patient states he does not plan to be evaluated in emergency department but will make an appointment to be seen by primary care provider. Patient educated and informed that the severe headache symptom is a warning sign of a blood clot and should seek medical evaluation at the nearest emergency department. Patient verbalizes understanding. Patient also given Nurse COVID line number.
1219386	4/16/2021	PA	76	F	2/17/2021	2/26/2021	On 02/26/2021, 10 days after given the vaccine I was admitted to the hospital with a blood clot in my left leg and in both lungs. I was given Heparin, admitted, started on Xarelto, released on 02/28/2021. I will be on blood thinners for a at least 90 days.
1219345	4/16/2021	NY	66	F	4/2/2021	4/6/2021	Received second shot on April 2@ 1130am. Started with diarrhea and vomiting's on April 6 at 3:30 am. Continued to 4:30 am on April 10. Slight elevated temperature at 99.1 . On morning of April 11 couldn't put pressure on right side, leg and arm, facial numbness. Went to er and they said I was having a stoke, transferred to hospital. MRI done verified Stroke with blood clot to Left thalamus Sent home and will be receiving PT and OT.

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1216619	4/16/2021	NV	27	F	3/17/2021	3/18/2021	On 03/18/2021 at 03:30AM I had a lot of arm pain from my shoulder to my elbow in my left arm. This lasted until 03/31/2021. On 03/18/2021 I woke up with a headache that would not go away. Next, at about 03:15PM I was not able to walk for about 10 minutes. Then, at about 05:00PM I started menstruating. At 07:00PM I had severe pain in my pelvic area for an hour and a half. At approximately 08:30PM I passed a softball sized blood clot vaginally. I bled heavily through the night. On 03/19/2021 I still had a headache and no energy at all. I continued to bleed heavily all day as well. 03/20/2021 was the exact same as the days prior. 03/21/2021 I was still bleeding heavily throughout the day with no energy. I still had the headache as well. I started feeling dizzy while walking on this day. 03/22/2021 I went to work like normal. I was cold all day. I was still bleeding, headache and dizziness. It was hard to stand for 30 minutes. While climbing the stairs I got very light headed and dizzy. I could not go up the stairs at a normal pace. 03/23/2021 I had the same symptoms all day but I was getting short of breath walking short distances. I still had very little energy and a headache. I also lost all color in my face and hands. I was still cold all day. I noticed some slight swelling in my ankles. 03/24/2021 The symptoms were getting more intense. I was still cold. I finally took some aspirin for the headache because it was very severe. The medication didn't help with it. This routine went on for the next week and the symptoms intensified with each day. Throughout this time I was still passing clots that ranged in size from golf/ping pong ball to baseballs. They were very painful when they passed. The days from 03/25/2021 to 04/01/2021 were all the same as far as how I felt. On 04/02/2021 I woke up with the same symptoms but now I could not stay awake for anything. I slept on and off all day. I only ate one meal a day because I was so tired and I had no appetite. The headache was getting worse as the days went on. The bleeding was still happening. It was not as heavy as the weeks before, but enough to be painful still. I also started having abdominal pain. On 04/03/2021 I was seeing stars when I moved too quickly. My heart rate was elevated with shortness of breath along with the rest of the previous symptoms. My headache however was very intense. 04/04/2021 I still couldn't stay awake on top of all the other symptoms. The dizziness and stars were

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							more frequent. I couldn't move my head without seeing stars. 04/05/2021 I couldn't get warm and I still felt the same way. I called and made a doctor's appointment for Wednesday the 7th. I had all the same symptoms still and they were getting worse. I had to move in slow motion so I could try to function. 04/06/2021 I woke up drained of all my energy and color. I couldn't shower because of the pain in my body. I couldn't stand because I felt like I was going to fall down. I could barely stand up straight let alone walk very far. I was shaking from being so cold. I had all the same symptoms from the days prior. I was in severe pain. I couldn't sit because of the pain in my abdomen I couldn't stand because of the weakness in my legs. I could barely see anything because of the stars I was seeing. At this point I had no color and I was barely conscious. That is when my family took me to the emergency room.
1219326	4/16/2021	AZ	77	F	4/12/2021	4/15/2021	Body aches night of injection. Extreme bloody nose with clots on 3rd day after injection. Swollen and very itchy right wrist 3rd day after injection. Was able to stop bloody nose after 1 hour, did not need medical help. Have not experienced a bloody nose in over 50 years so this was quite unusual.
1219778	4/16/2021	TX	60	F	4/1/2021	4/3/2021	38 hours after injection the patient experienced severe dizziness, vomiting. Couldn't walk. Moving slowly. Went to ER on Monday, and was diagnosed with Left Subclavian Thrombosis causing cerebellar infarction and requiring a subclavian thrombectomy.

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1217229	4/16/2021	NC	50	F	4/8/2021	4/8/2021	After I drove up and got my shot, the people had me drive to the next parking lot and park. We had to park every other space. By the time I got parked, I started to feel dizzy. I was afraid to tell anyone because I didn't want to go to the hospital. At first, I felt extremely dizzy so that I would not have driven if I had been allowed. Then, My heart then started to race for about 5 minutes before it started to calm down. The person who gave me my shot wrote on my paper on my dashboard that I had to sit for 20 minutes after my shot. I sat there for the whole 20 minutes and by the time I left, I felt much better, but it scared me it a bit. I was told to beep my horn if I had a reaction, but I was afraid too. I sat in my truck and waited to see if it got better or worse. It did get better. I was told by friends that I should report it so I am. I have been fine this week since that happened after the vaccination, without any dizziness or heart racing. But, I am having pain in my left leg and I'm a little worried about that because people are reporting blood clots. I think I have a vein that is bad in that leg, although I have never been diagnosed with it. That area has caused me pain in the past but I am so used to it that I normally just ignore it. There's just a spot on my left thigh that hurts where I think the veins are bad. Since the vaccination, I have had more pain in that area. I don't know if I need to be concerned with that. I have been trying to wait that out too.



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1220939	4/16/2021	CO		F	3/6/2021	3/28/2021	Acute cor pulmonale; problems breathing; experienced heart strongest beat; dizziness; Saddle embolism pulmonary art; This spontaneous case was reported by a consumer and describes the occurrence of PULMONARY EMBOLISM (Saddle embolism pulmonary art), COR PULMONALE ACUTE (Acute cor pulmonale), DYSPNOEA (problems breathing), PALPITATIONS (experienced heart strongest beat) and DIZZINESS (dizziness) in a 57-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 003A21A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No reported medical history). Concomitant products included LEVOTHYROXINE SODIUM (SYNTHROID) and ERENUMAB (AIMOVIG [ERENUMAB]) for an unknown indication. On 06-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Mar-2021, the patient experienced PULMONARY EMBOLISM (Saddle embolism pulmonary art) (seriousness criteria hospitalization and life threatening), DYSPNOEA (problems breathing) (seriousness criterion hospitalization), PALPITATIONS (experienced heart strongest beat) (seriousness criterion hospitalization) and DIZZINESS (dizziness) (seriousness criterion hospitalization). On an unknown date, the patient experienced COR PULMONALE ACUTE (Acute cor pulmonale) (seriousness criteria hospitalization and life threatening). The patient was hospitalized from 28-Mar-2021 to 31-Mar-2021 due to COR PULMONALE ACUTE, DIZZINESS, DYSPNOEA, PALPITATIONS and PULMONARY EMBOLISM. On 31-Mar-2021, PULMONARY EMBOLISM (Saddle embolism pulmonary art) outcome was unknown. At the time of the report, COR PULMONALE ACUTE (Acute cor pulmonale), DYSPNOEA (problems breathing), PALPITATIONS (experienced heart strongest beat) and DIZZINESS (dizziness) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. After 2 weeks of vaccination, the patient started to experienced heart strongest beat, problems to breathing and dizziness. On 28 MAR 2021 she felt this symptom

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and she thought "something is going bad" and has to be hospitalized on intensive care unit (ICU) from 28MAR2021 to 31MAR2021 (4 days). They diagnosticated "saddle embolism pulmonary art with acute cor pulmonale". They found several clots in both lungs and one big clot/ one large clot in the pulmonary artery. Pulmonary embolism between lungs. Treatment information was not provided. Vaccination second dose was recommended. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

1220095 4/16/2021 OR

60 F

3/24/2021

4/2/2021

Felt sick with covid like symptoms beginning 4/2, Shortness of breath began 4/3, received negative covid test on 4/7, went to ER on 4/12, CT scan showed MASSIVE bilateral Pulmonary embolism, Angiogram of heart showed right side under stress at 50%. 4/13 Surgery - catheterized directed thrombosis to dissolve clots. Discharged from hospital 4/15

1218142 4/16/2021 VA

52 F

4/2/2021

4/4/2021

Nausea. Heavy bleeding including clot

1218061 4/16/2021 CT

40 F

4/9/2021

4/9/2021

Later that day I started getting pain in the hip/groin area of my left leg preventing me from putting pressure on it or walking. The acute pain diminished after about 3 hr and I could walk again but the hip flexor area remained tender and felt like a sore muscle had been pulled for about 3 days. About 5pm I developed really bad chills which lasted about 24 hrs and was really intense about the first 6hr. About 11pm I developed a severe headache preventing me from sleeping which lasted about 9hrs. 4/10 I had occasional chills, the headache had subsided a little but had a nagging tension feeling and I was really fatigued and really wiped out the remainder of that day. My Gynecologist advised I stopped taking my Birth Control for the next month to lower my risk of blood clots.

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1218010	4/16/2021	MI		F			ARM IN A KNOT; This spontaneous report received from a patient concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included blood clot. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose, start therapy date were not reported for prophylactic vaccination. The batch number was reported. Per procedure, no follow up will be requested for this case. No concomitant medications were reported. On an unspecified date, the subject experienced arm in a knot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of arm in a knot was not reported. This report was non-serious.
1218000	4/16/2021	NY		F	3/1/2021		HEADACHE; This spontaneous report received from a patient concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's concurrent conditions included blood clots in her leg. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 06-MAR-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On MAR-2021, the subject experienced headache. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of headache was not reported. This report was non-serious.

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1217976	4/16/2021	IN	51	F		3/15/2021	HEADACHE; TIRED; INJECTION SITE PAIN; This spontaneous report received from a patient concerned a 51 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included cerebral venous sinus thrombosis, diabetic, and non smoker, and other pre-existing medical conditions included the patient was not pregnant at the time of reporting. The patient experienced drug allergy when treated with estradiol, and progesterone. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029, and expiry: UNKNOWN) dose was not reported, administered on 15-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 15-MAR-2021, the subject experienced injection site pain. On 16-MAR-2021, the subject experienced headache. On 16-MAR-2021, the subject experienced tired. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from injection site pain on 19-MAR-2021, and tired on 26-MAR-2021, and was recovering from headache. This report was non-serious.
1217960	4/16/2021			F		4/8/2021	THROAT SWELL; This spontaneous report received from a patient concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included blood clots. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808982 expiry: UNKNOWN) dose was not reported, administered on 08-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 08-APR-2021, the subject experienced throat swell. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from throat swell on 08-APR-2021. This report was non-serious.

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1217874	4/16/2021	MI	45	F	3/29/2021	4/11/2021	Per client self report: Experienced LLE extremity pain beginning on 4/11/2021, but thought nothing of it at the time. Client was previous scheduled for testing/procedure for asthma with pulmonologist on 4/15/2021, with pre-test/procedure lab work scheduled for Monday, 4/12/2021. Client presented for lab work on 4/12/2021 as scheduled and shortly thereafter received phone call from pulmonologist's office stating that the labs showed and elevated D-dimer and that she would be scheduled for a follow-up CT Scan of the chest and ultrasound of the lower extremities, which was scheduled on 4/14/2021. Client presented for CT scan of chest and ultrasound of lower extremities as directed and returned home on 4/14/2021. Client reported in conversation that she "didn't feel right" and noticed some SOB, and had planned to rest outside of going in for scheduled tests. Client received a phone call on 4/14 from pulmonologist's office advising her to go immediately to the emergency room due to a blood clot being found in the left lung as per CT scan report. Client presented to Emergency Room and was started on Eliquis 5mg tablets - 2 tablets by mouth twice daily X1 week and then 1 tablet by mouth twice daily and discharged to home. Client remains at home at the time of interview with no additional or worsening symptoms.
1217866	4/16/2021	AZ	51	M	4/1/2021	4/15/2021	Systemic: Blood Disorder (diagnosed by MD)-Severe, Additional Details: Patient hospitalized for blood clot (called pharmacy @ 835pm on 4/15/21). Asked by hospital to contact pharmacy. Patient called from personal phone number.
1217814	4/16/2021	NJ	63	F	3/7/2021	3/15/2021	Starting on about 3/15/21 I started ?getting very uncomfortable pain in my calf on both legs and it lasted 2 weeks. . I do walk 4-5 5 days a week and never experienced this feeling prior. I put heat on my legs massaged the and also used a rolling pin. I never called my dr did not think of it. Just though it was cramping but blood clots did enter my mind but I thought can?t be I am so active.

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1217752	4/16/2021	TN		F			<p>SHORTNESS OF BREATH; CHEST PAIN; SEVERE BLOOD CLOTS; This spontaneous report was received from a female patient of unspecified age. The patient's weight, height and medical history were not reported. The patient received COVID-19 vaccine Ad26.CoV2.S (suspension for injection, route of administration not reported), dose not reported, on 29-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, within a week of receiving the vaccine, the patient reported that she began experiencing shortness of breath and increasing chest pain. On 11-APR-2021, the patient was admitted to the hospital and a diagnosis of severe blood clots was made. After a full work-up, no etiology was determined. The action taken with COVID-19 vaccine Ad26.CoV2.S was not applicable. The outcomes of the shortness of breath, chest pain and severe blood clots were not reported. This report was serious (caused hospitalization).; Sender's Comments: V0:This female patient of unspecified age was hospitalized due to shortness of breath and increasing chest pain an unspecified time after blinded COVID-19 VACCINE Ad26.COV2.S was administered intramuscularly for prevention of symptomatic SAR-CoV-2 virus infection. No concomitant medications, past medical history has been reported. On an unspecified date, within a week of receiving the vaccine, the patient reported that she began experiencing shortness of breath and increasing chest pain. the patient was admitted to the hospital and a diagnosis of severe blood clots was made. After a full work-up, no etiology was determined. At the time of the report the outcome of the event is unknown. Based on the limited information the event is inconsistent with the causal association to immunization, per the WHO causality classification for adverse events following immunization. The event is considered not related to the blinded study vaccine. Additional information has been requested for further assessment.</p>

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1218255	4/16/2021	MN	36	F	3/19/2021	3/20/2021	Received Janssen COVID vaccine on 3/19/2021 around 8 am. Was in ER on 3/20/21 around 3 pm. Was found to have acute occlusive deep venous thrombosis of the left popliteal vein, peroneal veins and one of the paired left posterior tibialis veins proximally.
1217463	4/16/2021	CA	86	F		3/12/2021	BODY PAIN ESPECIALLY BACK PAIN, NECK PAIN AND JOINT PAIN; This spontaneous report received from a patient concerned an 86 year old female. The patient's weight was 180 pounds, and height was 153.67 centimeters. The patient's past medical history included history of arthritis, heart attack, double hernia surgery, left knee fracture, right leg artery clot, and right toe gangrene, and concurrent conditions included shortness of breath, blood pressure, non alcohol user, non smoker, hay fever allergy, and sticky tape allergy, and other pre-existing medical conditions included no history of drug abuse. the patient had no history of vaccine allergy and no pre-existing acute illness 30 days prior to vaccination. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029 expiry: UNKNOWN) dose was not reported, administered on 11-MAR-2021 17:30 for prophylactic vaccination. Concomitant medications included metoprolol tartrate for blood pressure, venlafaxine hydrochloride for blood thinner, calcium for drug used for unknown indication, clopidogrel bisulfate for drug used for unknown indication, losartan potassium for drug used for unknown indication, and oxybutynin hydrochloride for drug used for unknown indication. On 12-MAR-2021, treatment medications included: acetylsalicylic acid. On 12-MAR-2021 00:30, the subject experienced body pain especially back pain, neck pain and joint pain. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from body pain especially back pain, neck pain and joint pain. This report was non-serious.

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1218520	4/16/2021	TX		F	3/31/2021		<p>LOW VITAMIN D LEVEL; FELT VERY SHORT OF BREATH, THINKS IT MAY BE DUE TO BLOOD CLOT; This spontaneous self-report was received from a patient and concerned a 32 year old female. Initial information received on 11-APR-2021 was processed with additional information obtained from telephone follow up with the patient on 15-APR-2021. The patient's weight was 200 pounds and height was 65 inches. The patient's past medical history included COVID-19 infection last year with minimal symptoms and not hospitalized, and concurrent conditions included protein C and protein S deficiencies with "many previous clots" with most recent in 2019, alpha 1 antitrypsin deficiency, low iron, low ferritin, low vitamin D, and contrast dye allergy. The patient was previously treated with warfarin for anticoagulation for 13 years, and 8 months ago was switched to XARELTO. The patient received COVID-19 VACCINE AD26.COV2.S (suspension for injection, route of administration, dose, vaccination site, and batch number were not reported) administered on 31-MAR-2021 at 10:30 for prophylactic vaccination. The batch number would be requested in follow up. Concomitant medications included rivaroxaban for anticoagulation. On 31-MAR-2021 around 19:30, the patient felt very short of breath, had a hard time breathing and "thought it may be due to a blood clot" and felt "like it maybe getting worse". She saw hematologist on 14-APR-2021, who, at her request, stopped XARELTO effective 15-APR-2021, and started a 2 week course of Lovenox, with plan to start warfarin after that. This was not medically indicated, but requested by patient, and physician agreed. Her oxygen saturation at that visit was normal. On 14-APR-2021, laboratory data included: platelet count (NR: not provided) 470 (units unspecified), and vitamin D (NR: not provided) low at 19 (units unspecified); as treatment "mega dose" was ordered to her pharmacy. Her hematologist scheduled a VQ scan for 19-APR-2021 to evaluate for pulmonary embolism. The patient reported the event felt very short of breath, thinks it may be due to blood clot related to COVID-19 VACCINE AD26.COV2.S. The action taken with COVID-19 VACCINE AD26.COV2.S was not applicable. The patient had not recovered from the events. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This 32 year-old female with medical</p>



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							<p>history significant for obesity (BMI 33), Protein C &amp; S deficiencies with "many previous clots" (most recent in 2019) began to feel very short of breath approximately 9 hours after receiving Janssen Covid-19 vaccination. Other medical history included alpha 1 anti-trypsin deficiency, low ferritin, low vitamin D, allergy to contrast dye, and mild Covid-19 infection last year which did not require hospitalization. Concomitant medications included rivaroxaban which was started 8 months ago; warfarin had been used for 13 years prior to rivaroxaban. She felt her difficulty breathing could be a blood clot and went to see her hematologist 2 weeks after vaccination. Rivaroxaban was stopped at her request, not because it was medically indicated, and enoxaparin was started with a plan to start warfarin 2 weeks later. Platelet count was 470, vitamin D level was low, and oxygen saturation was normal at that time. A VQ scan is scheduled 5 days later since she is allergic to dye. While the cause of the dyspnea has not yet been determined, a new blood clot would most likely be related to the patient's underlying hypercoagulable state and not the vaccine. Based on insufficient information, the causal association of serious shortness of breath to immunization is assessed to be indeterminate per the WHO causality classification for adverse events following immunization.</p>
1217054	4/16/2021	CA	21	F	4/13/2021	4/15/2021	Painful cramps, heavier period on first day with clots. Not my usual period, heavier.

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1217053	4/16/2021	CA	30	M	4/15/2021	4/15/2021	<p>Client was vaccinated with the Pfizer Covid vaccine with lot #EW0162 at 11:59am on 04/15/2021. EMT observed client standing at the facility exit speaking to the interpreter. EMT noted upon approach client appeared alert, tracking with his eyes, in no apparent distress. Client had a chief complaint of numbness at his injection site. Client stated that he had completed his 15 minutes and had exited the site but began to experience numbness at his injection site while exiting. This was the client's first dose of the Pfizer vaccine. Client states he has a history of a deep vein thrombosis and hypertension. Client is not on any medications and denies any known allergies. Assessment revealed that client's left arm/injection site was clean, dry and bandage remained intact. Client was negative for hives, swelling, severe sweating, shortness of breath or other signs of anaphylaxis. Client was alert and oriented to person, place, date, and event; and airway, breathing and circulation were intact. Client had full range of motion of his arm and denied any tingling. Client denied any pain upon palpation of the injection site and stated that his numbness was strictly localized to injection site and did not spread to rest of arm. Client's vital signs upon entering EMT station for further evaluation revealed: blood pressure 180/140, respirations 18, pulse 68, 98% on room air; lung sounds clear bilaterally, temp 98 degrees F, eyes remained equal, round, and reactive to light at 5 mm. Client stated that he had his blood pressure taken last week and that his systolic was approximately 160. Client agreed to remain for an additional 30 minutes of monitoring per site lead nurse and was stable throughout observation. Vital signs at 1220: blood pressure of 180/140, respiratory rate of 18, heart rate of 68, and oxygen saturation of 98% on room air. Vital signs at 1235: blood pressure of 160/124, respiratory rate of 18, heart rate of 76, and oxygen saturation of 99% on room air. Vital signs at 1250: blood pressure of 158/118, respiratory rate of 18, heart rate of 76, and oxygen saturation of 99% on room air. At the completion of the client's observation, client stated that numbness was "better" and stated that it was "almost gone." Client's blood pressure improved upon reassessments, and all other vitals were remained within normal limits. Client was provided with vaccine information packets and encouraged to seek follow-up</p>

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							care or emergency care if symptoms become more severe later in the evening. EMS was denied by client, no medication or other interventions were indicated or administered. Client departed facility by ambulation to private care at 1253 in positive disposition. EMT reported to lead nurse about client's status after client left facility already. Lead nurse educated EMT regarding high blood pressure referral to EMS. But EMT stated client denied EMS.
1216642	4/16/2021	IL	35	M	12/31/2020	2/17/2021	In the 3 weeks leading up to February 10th, I became progressively more bloated with fluid in my stomach area, with an increasing feeling of fullness. By the 10th, I felt so full that I had only eaten one meal in two days. I had also been sleeping upright for days to attempt to clear what I perceived to be a stomach blockage and therefore was quite tired. I walked in to the ER and the x-ray revealed the blood clot in my portal vein. The physician immediately had enoxaparin administered to me and I was admitted. I received another enoxaparin dose the next morning. I was discharged on Xarelto 15mg twice a day in the afternoon of Feb 11th. I am continuing on Xarelto as my hematologist runs various tests and I have an EGD on 4/16 due to a possible stomach ulcer. I was diagnosed with: Mesenteric venous thrombosis Elevated transaminase measurement Fatty liver
1218182	4/16/2021	DC	31	F			Asthma flair up, abdominal pain, blood clot, headache, and lack of sleep.
1218187	4/16/2021	WA	41	F	4/9/2021	4/13/2021	Six days after my second shot of Pfizer I got a DVT Clot in my left leg behind the knee. Started with Severe pain felt like a charlie horse in my left calf and foot that would not go away for more than 24 hours. My Blood pressure spiked and i got a migraine from the pain , My left leg and food felt like stone.. The next day I called the nurse from my insurance company and she advised I go in to the hospital. Went to ER got a Ultrasound, blood tests and the ultrasound came back positive for a DVT clot. Treatment is Xarelto and follow up with my primary. Lab Results came back normal.

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1218197	4/16/2021	ND	44	F	3/31/2021	4/6/2021	Follow up telephone call to patient after receiving the Johnson & Johnson (J&J) Janssen vaccination on 3/31/21 was made 4/15/21. Patient was screened for warning signs of blood clots and patient answers yes to having severe headache and shortness of breath. Denies any abdominal pain and leg pain. Patient states symptoms began 4/6/21 at around 6pm in the evening and continue to the day of telephone call. Transportation arrangement was made for patient due to lack of transportation to go seek medical attention in ER. Patient was transported to ER for medical evaluation. Upon review of patients chart, patient was seen 4/15/21 in ER. Patient did not report any symptoms of severe headache and shortness of breath. Patient complains of having common cold in ER.
1218240	4/16/2021	NC	78	F	2/4/2021	3/4/2021	Extensive DVT(blood clots) involving both legs-- initially with tachycardia dyspnea. Now on 10a meds. Likely to have disability or permanent damage. History of post-op DVT with PEs following shoulder surgery, subsequent placement of IVC filter.
1218318	4/16/2021	NC	34	F	4/1/2021	4/15/2021	I have a history of heavy periods which resulted in the need for an ablation in October 2018. Since the ablation my periods have been much more manageable. I got my period 13 days after receiving the shot and it started out much heavier than normal, by the second day I was bleeding extremely heavily, soaking an overnight pad in less than 2 hours with bright red blood and passing clots the size of dimes and pennies. Day 3 has started out the same as day 2. Prior to my period starting my back hurt and I had much worse than normal abdominal cramps. Nothing in my life has changed besides the vaccine, I am certain there is a connection between the two. I am not sure how long this will last, I was instructed to go ahead and report the adverse event.
1218327	4/16/2021	MI	56	F	3/27/2021	3/27/2021	Cerebral venous sinus thrombosis with venous infarct. Was also found to have antithrombin III deficiency and elevated factor 8. She had uncontrolled HTN and DM at the time and untreated OSA.

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1218378	4/16/2021	TX	55	F	3/31/2021	4/2/2021	I would like to amend my first report to add that 2 days after I received the vaccine I noticed bruises in my hands and one in my leg. 2 bruises on my knuckles and also 2 on the side of my hands. They are symmetric, I did not hit my hands anywhere. My husband also noticed a small bruise on my right leg. They were very prevalent the first week I received the vaccine and they are slowly fading away. The ones in my hands are almost gone, the one in my leg is very small now. You can still see it though. After seeing about the Janssen vaccine being associated with blood clots I had a virtual visit with my doctor, and he does not seem very concerned about blood clots but asked me to come in for some blood work. I did not go yet because I would like to wait for at least 28 days after the vaccine to go in and have the blood work done. I also remember I had a very bad headache one day soon after I got the vaccine but I was battling some sinus issues before the vaccine, so I am not sure if that was related to sinuses or not. I took an Advil and it went away. And my arm still hurts a little, not as often as before. The pain comes and goes. Before it would happen several times during the day now it is more like once a day and once it goes away it just comes back the next day.
1218422	4/16/2021	WY	67	M	4/5/2021	4/6/2021	DEATH! About 24 hours after getting his 2nd Moderna Covid-19 shot, patient got deathly ill with explosive vomiting and diarrhea. Not long later he was passing out. Paramedics were called, and he was taken to the hospital where he passed away from a massive heart attack. The doctors gave him clot-busting drugs in an attempt to save him. He has never had problems with blood clots in his life. He was the healthiest one of us all, and was almost never sick. The doctor said that it was probably no coincidence that he died so soon after receiving his Covid shot. I am convinced that they are connected. A healthy man suddenly gets blood clots in his heart 24 hours after getting his shot? Not a coincidence!!!!!!!!!!!!!!1

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1218425	4/16/2021	OH	53	F	3/18/2021	4/5/2021	Patient received the COVID 19 vaccine on March 18, 2021 @6:00pm. On April 5, 2021 @8:00am the patient began to feel pain in L leg which progressed to area red and tender to touch and increased in pain with each day. Patient went to the ER on April 9, 2021 and an ultrasound revealed a 10 cm blood clot in left leg. Patient was not admitted but sent home on Zarelto 15 mg 2x daily. Patient did see physician as a follow up.
1217613	4/16/2021	CA	35	F	3/9/2021	3/19/2021	Site: Pain at Injection Site-Mild, Systemic: see below - Medium, Additional Details: Patient states that 10 days after vaccination, started to get swollen legs and pain which went away a week later. She was concerned due to blood clot warning and I advised her to seek additional medical assistance which she said she would seek. She did state in addition, she experienced swollen lymph nodes and breast tenderness which occurred right after vaccination and lasted 2 weeks.
1221210	4/16/2021	CA	39	F	4/2/1981	4/3/2021	On the day after vaccination I had extreme dizziness and faintheadedness, and heavy brain fog. I could not drive or stand up for long periods of time. I was having issues expressing thoughts and having my normal conversations. This was accompanied by strong headache on right side of my head and slightly stuffed sinuses. The day afterwards all symptoms disappeared. However, they reappeared at milder levels intermittently through the next several days. I am now at day 14 with the dizziness and brain fog still occurring intermittently and last night had short episode of abdominal pain. I decided to call the doctor's office this morning when the dizziness started again, for advice and to schedule a brief exam. They told me to go straight to the ER instead, so I went and had blood drawn. Blood came back normal and likelihood of clot very low, so was released but referred to my primary doctor and a neurologist for follow up over the next week. The intermittent dizziness and brain fog persist ever since my shot 2 weeks ago. Additional symptoms that I believe to be normal are dull leg pain behind the knees, slight tightness in chest sometimes, and recurring mild headache.

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1221044	4/16/2021	TX		M	1/6/2021	2/1/2021	<p>Blood clot in the right leg; Blood clot in the lungs; Blood clot in the hip; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clot in the hip), THROMBOSIS (Blood clot in the right leg) and PULMONARY EMBOLISM (Blood clot in the lungs) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. Unknown and 015L20A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No reported medical history). On 06-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. In February 2021, the patient experienced THROMBOSIS (Blood clot in the hip) (seriousness criteria hospitalization and medically significant). In March 2021, the patient experienced THROMBOSIS (Blood clot in the right leg) (seriousness criteria hospitalization and medically significant) and PULMONARY EMBOLISM (Blood clot in the lungs) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 16-Mar-2021 due to PULMONARY EMBOLISM, THROMBOSIS, THROMBOSIS At the time of the report, THROMBOSIS (Blood clot in the hip), THROMBOSIS (Blood clot in the right leg) and PULMONARY EMBOLISM (Blood clot in the lungs) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Patient states that 2-3 weeks after receiving the second shot they had a blood clot in the hip and a week later they had a blood clot in the right leg and in the lungs. Patient reports they had to be hospitalized for two nights, in the Medical City Fort Worth Hospital. Patient states they do not have any history of blood clots. Patient mentioned reading online, in forums, that people had taken Pfizer and Moderna vaccines and two weeks after had blood clots and ended in the hospital. Based on the current available information and temporal association between the use of the product and the start dates of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start</p>

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							dates of the events, a causal relationship cannot be excluded.
1221061	4/16/2021	CO		M	3/14/2021	3/14/2021	DBD blood clot in leg; Arm got little sore; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (DBD blood clot in leg) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was reported.). Concomitant products included RIVAROXABAN (XARELTO) for an unknown indication. On 14-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 14-Mar-2021, the patient experienced PAIN IN EXTREMITY (Arm got little sore). On 05-Apr-2021, the patient experienced THROMBOSIS (DBD blood clot in leg) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (DBD blood clot in leg) outcome was unknown and PAIN IN EXTREMITY (Arm got little sore) had resolved. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Reportedly, the patient's sore arm went away pretty fast. The patient received treatment with Xarelto (Rivaroxaban) for blood clot in his leg. Company Comment Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Reporter did not allow further contact
1221080	4/16/2021	MT	47	M	1/6/2021	1/9/2021	Lower left leg pain, swelling and redness 3 days after 2nd dose of Pfizer Covid vaccine. Ultrasound confirmed superficial blood clot from ankle to knee.



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1221095	4/16/2021	TX	55	F	3/26/2021	3/27/2021	possible stroke; small clot that went through and resolved on its own; Loss use of left leg/couldn't use her leg; tingling in left arm; This spontaneous case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (possible stroke), THROMBOSIS (small clot that went through and resolved on its own), MONOPLÉGIA (Loss use of left leg/couldn't use her leg) and PARAESTHESIA (tingling in left arm) in a 55-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 046A21A) for COVID-19 vaccination. The patient's past medical history included Familial hypercholesterolemia, Peripheral arterial disease and Stent placement (has stents in her iliac ery). Concomitant products included ATORVASTATIN CALCIUM (ATORVASTATIN [ATORVASTATIN CALCIUM]), ACETYLSALICYLIC ACID (BABY ASPIRIN) and SERTRALINE for an unknown indication. On 26-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Mar-2021, the patient experienced CEREBROVASCULAR ACCIDENT (possible stroke) (seriousness criterion hospitalization), THROMBOSIS (small clot that went through and resolved on its own) (seriousness criterion hospitalization), MONOPLÉGIA (Loss use of left leg/couldn't use her leg) (seriousness criterion hospitalization) and PARAESTHESIA (tingling in left arm) (seriousness criterion hospitalization). The patient was hospitalized from 27-Mar-2021 to 28-Mar-2021 due to CEREBROVASCULAR ACCIDENT, MONOPLÉGIA, PARAESTHESIA and THROMBOSIS. At the time of the report, CEREBROVASCULAR ACCIDENT (possible stroke), THROMBOSIS (small clot that went through and resolved on its own), MONOPLÉGIA (Loss use of left leg/couldn't use her leg) and PARAESTHESIA (tingling in left arm) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In March 2021, Computerised tomogram: Inconclusive. In March 2021, Magnetic resonance imaging: Inconclusive. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No treatment information was provided. Patient reports an MRI and CT scan was done, and she was informed that they suspected she had a small cot that went through and resolved on its own.

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							Company Comment: Based on the temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However patient's hx of familial hypercholesterolemia, peripheral arterial disease and stent placement are confounding factors that may play a possible contributory role.
1221124	4/16/2021	MN	66	F	3/5/2021	4/2/2021	Sudden onset left calf pain 4/2, increasing swelling and pain, presented for evaluation 4/9, SVT and DVT noted on ultrasound same day, started on Eliquis to manage clot.

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1221127	4/16/2021	TX		F	1/22/2021	1/29/2021	<p>Died of clots in brain; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of BRAIN STEM THROMBOSIS (Died of clots in brain) in a 76-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event (No medically reported history). On 22-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 29-Jan-2021, the patient experienced BRAIN STEM THROMBOSIS (Died of clots in brain) (seriousness criteria death and medically significant). The patient died on 30-Jan-2021. The reported cause of death was Brain stem thrombosis. It is unknown if an autopsy was performed. This is a 76 year-old, who received mRNA-1273 Vaccine) and died 8 days after receiving first dose of vaccine and subsequently experienced brain stem thrombosis. No medical hx or conmeds were provided. The reported cause of death was brain stem thrombosis. Very limited information has been reported at this time. Further information is expected. This case was linked to MOD21-075103, US-MODERNATX, INC.-MOD-2021-075124 (Linked Report).; Sender's Comments: This is a 76 year-old, who received mRNA-1273 Vaccine) and died 8 days after receiving first dose of vaccine and subsequently experienced brain stem thrombosis. No medical hx or conmeds were provided. The reported cause of death was brain stem thrombosis. Very limited information has been reported at this time. Further information is expected. MOD21-075103: US-MODERNATX, INC.-MOD-2021-075124:Patient's brother in law case; Reported Cause(s) of Death: brain stem thrombosis</p>

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1221137	4/16/2021	FL	93	F	1/22/2021	1/22/2021	My my grandma got them a derma vaccine on January 22 she died on February 11 she was admitted to the hospital with a blood clot in her leg they tried to do surgery but when they put her under the anesthesia she never woke back up. She was 93 years old and had many other health conditions but when I called the doctors office to ask them if they reported my grandma they just kept giving me the runaround I tried to call hospital as well and I got the same thing they told me to go back to the doctor. I think someone should know and I think it?s way too difficult for family members to try to report adverse side effects it took me all day to find someone that could help me get to this website. I think there may be a lot more adverse side effects but people don?t know how to report them.
1221028	4/16/2021	RI	22	F	4/7/2021	4/15/2021	Started about 11:30am on April 16th, shortness of breath, heart rate in the 120s, chest pain, and headache I called my campus health services and they instructed me to go to the ER. I had a positive d dimer and was given a contrast CT scan which turned out negative for blood clots. Still experiencing the same symptoms as of 8:30pm April 17th.

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1221191	4/16/2021	UT		M	2/6/2021		<p>pulmonary fibrosis; heart hurt; hearing and eyes are no good and he is old; COPD; hearing and eyes are no good and he is old; arm sore; lungs felt funny and airy but could breathe real good; real bad frontal headache and the top of the head that were two real strong headaches that lasted quite a while; change in smell for several days; he is in terrible pain lying in the bed due to dirty things wrong with him; terminally ill; neck pain; This is a spontaneous report from a contactable consumer or other non-health care professional via PPDI. An 80-years-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Lot number: en5318) via unspecified route of administration on 06Feb2021 as single dose for COVID-19 immunization. Medical history included twelve chronic conditions that he has been treated for, for years. Patient mentioned on an unspecified date, he already died once, clarified, it was very sudden and he had a heart attack in his sleep. He had central sleep apnea and he stopped breathing. He has atherosclerosis, his arteries are clogged and he has chronic inflammation, stated it is a can of worms. He has polycystic kidney disease, stated his kidneys are headed that way. He has chronic insomnia, Cerebrovascular accident from 2008, had mini strokes and had heart surgery for blood clots to his brain in 2008. The patient concomitant medications were not reported. On an unspecified date, the patient experienced pulmonary fibrosis, heart hurt, arm sore, lungs felt funny and airy but could breathe real good, real bad frontal headache and the top of the head that were two real strong headaches that lasted quite a while, change in smell for several days, he is in terrible pain lying in the bed due to dirty things wrong with him, terminally ill, hearing and eyes are no good and he is old, copd, hearing and eyes are no good and he is old and neck pain. AE for second dose transmitted. Patient also stated that after the second shot, his arm was sore at the site, swelling and pain more profound and sooner, knot in the arm, arthritic knees and joints became more painful, illusion of a spider walking on the wall, pain in the left arm bicep, lower left back got painful and went down in to the hip and left thigh muscles and had headaches. Patient mentioned his heart and lungs heart a few days after the second shot and had a strange feeling in his lungs. Patient stated he had night</p>

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							sweats and got drenched but this is a symptom of a heart problem which he has. Patient stated his heart beat was skipping around 68-78 and his oxygen was skipping around. Patient stated that he has PVC. Patient stated he had a headache on the top of his head. Outcome of the events was unknown.
1221434	4/16/2021	PA	49	F	3/20/2021	3/21/2021	On March 21, 2021 at around 5:30 I had fever, headache, nausea, fatigue, dizziness. The next day, March 22, I had heart palpitations, dizziness and still fever. On March 24, 2021 at approximately 8:00 pm, my right leg became heavy and felt numb. On March 25 I woke up to my mouth locked with Bell's Palsy like drooping on the right side of my face. My mouth remained unable to open fully for the next day and the numbness and pain in my leg increased. On March 26 I went to the ER because I was afraid I was having a stroke. They gave me tests and said I did not have a stroke. They gave me steroids and they helped with my jaw but the pain in my leg increased. The pain in leg continued with more pain in my knee. I followed up with my family doctor and they sent me to have an ultrasound of my leg to check for a blood clot on April 9th No blood clot was found. Pain continued and increased so the doctor sent me for an MRI on April 14. MRI showed moderate effusions to the knee joint and I have an appointment with a orthopedic doctor on Tuesday April 20th. I continue to have stabbing pain in my knee and swelling and discomfort.
1221214	4/16/2021	PA	42	F	2/22/2021	3/9/2021	I woke up in the middle of night with chest pain and trouble breathing. I had a pulmonary embolism. The pain and difficulty breathing lasted several days. Since then, I have experience a flare of the antiphospholipid syndrome - low platelets (blood work), splinter hemorrhages, clots, and the like. Whether from the embolism or other, the pulmonary hypertension has gotten drastically worse - with increased shortness of breath, irregular heart beats, dropping pulse ox.

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1221237	4/16/2021	NJ	34	F	4/10/2021	4/10/2021	Fever (102), body chills, body aches, headache, abdominal pain, water retention, nausea, insomnia. Most of the symptoms occurred on the first night. Nausea took 4 days to subside. I'm on day 6 and I had an ultrasound done to my leg as my left leg has started to hurt. Ultrasound showed no blood clots. Pending blood work results. Water retention is still present however it does seem to be subsiding today, day 6.
1221315	4/16/2021	LA	55	F	4/7/2021	4/14/2021	Patient started noticing left arm swelling and pain about 2-3 weeks after the vaccine. She then presented to the hospital 4/16/21 and was found to have a deep vein thrombosis in her left brachial vein as well as a thrombosis in her right internal jugular vein. She is currently being further worked up and will be admitted to the hospital for anticoagulation.
1221387	4/16/2021	CT	67	F	2/20/2021	3/14/2021	Approximately 3 weeks after 1st vaccine, on March 14, 2021, I developed a film over my right eye and experienced jagged multi colored lines. Experienced this every few days for anywhere from 15 minutes to 1 hour in length. Again 3 weeks after my second vaccine, I woke up with the same eye problem which has been constant now for 1 week. I am unable to see clearly out of my right eye. This is still ongoing and my retinal specialist believes a blood clot may have traveled to my eye and burst causing this problem.

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1221428	4/16/2021	NE	53	F	2/24/2021	2/26/2021	Ended up in healthcare facility on 3-1 dehydrated and released Back to healthcare facility on 3-4 stayed until 3-7 Started hallucinating and given meds. very dehydrated Released and then family came to pick her up. Hallucinating on drive back to where she would be staying. 3-8 back to healthcare facility because she was slurring words ---gave fluids and released 3-9 Unit had to come to get her very weak and fragile. Couldn't move her ourselves. Ended up admitting her until 3-12 At house she was supervised the whole time, weak, needed assistance, slurring words off and on. 3-22 Eye doc appt found blood clot behind eye. Sent her to healthcare facility to be examined by Neugolist. Did CT Scan and MRV/MRI found. They found clots and ended up sending her to healthcare facility. Was in city where they run tons of tests. mini strokes lead to the Thrombosis which caused the blood clots. Released on 4-2 into the care of a home where she started to hallucinate even more. Back to healthcare facility on 4-9 still currently there where they are treating her hallucinations, memory loss and more.
1221447	4/16/2021	IN	47	F	3/31/2021	4/1/2021	Started having headache, chills and body aches on 4/1/2021. On 4/2/2021 I had major fatigue. On 4/4/2021 my right leg began to swell terribly and then on 4/6/2021 it was discovered that I had one big and many small blood clots in my right leg.
1220129	4/16/2021	PA	63	M	4/6/2021	4/12/2021	PATIENT DEVELOPED BLOOD CLOT IN EYE. WENT TO RETINA SPECIALIST. WENT TO ER. COROTID ARTERY HAS 80% BLOCKAGE



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1220901	4/16/2021	IL		F	3/26/2021	3/26/2021	spitting out blood and blood clots; sluggish; Dizziness; chills; low grade fever; Bad headache; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of HAEMATEMESIS (spitting out blood and blood clots) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event since an unknown date. On 26-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Mar-2021, the patient experienced HAEMATEMESIS (spitting out blood and blood clots) (seriousness criterion medically significant), SLUGGISHNESS (sluggish), DIZZINESS (Dizziness), CHILLS (chills), PYREXIA (low grade fever) and HEADACHE (Bad headache). On 26-Mar-2021, HAEMATEMESIS (spitting out blood and blood clots) outcome was unknown. At the time of the report, SLUGGISHNESS (sluggish), DIZZINESS (Dizziness), CHILLS (chills), PYREXIA (low grade fever) and HEADACHE (Bad headache) outcome was unknown. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Mar-2021, Pyrexia: low (Low) Low. This case was linked to -MOD-2021-068465 ( Linked Report). Reporter did not allow further contact; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded..-MOD-2021-068465:Dose 1

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1221175	4/16/2021	TN	73	F	2/3/2021	2/3/2021	Spontaneous Peptic ulcer bleed; Left arm became sore; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PEPTIC ULCER HAEMORRHAGE (Spontaneous Peptic ulcer bleed) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 211M28-9 and 022M20A) for COVID-19 immunization. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Heart failure (Heart failure 7years ago has resolved by its own but was placed on entresto at that time), Cardiac disorder, Headache since an unknown date, General body pain and Left atrial appendage occlusion (to treat atrial fibrillation and prevent clots.) in 2019. Concurrent medical conditions included Edema legs (Fluid in feets), High cholesterol and Hypotensive (Mild hypotensive). Concomitant products included CARVEDILOL (COREG), HCTZ, ASCORBIC ACID, ROSA CANINA FRUIT (VITAMIN C & ROSEHIP), ATORVASTATIN CALCIUM (LIPITOR), ACETYLSALICYLIC ACID (BABY ASPIRIN) and PARACETAMOL (TYLENOL) for an unknown indication. On 03-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 03-Feb-2021, the patient experienced PAIN IN EXTREMITY (Left arm became sore). On an unknown date, the patient experienced PEPTIC ULCER HAEMORRHAGE (Spontaneous Peptic ulcer bleed) (seriousness criterion hospitalization). The patient was hospitalized from 24-Feb-2021 to 12-Mar-2021 due to PEPTIC ULCER HAEMORRHAGE. On 04-Feb-2021, PAIN IN EXTREMITY (Left arm became sore) had resolved. At the time of the report, PEPTIC ULCER HAEMORRHAGE (Spontaneous Peptic ulcer bleed) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Consumer reported that she had a TEE (Transesophageal echocardiogram ) on around 06 feb (exact date unknown). Treatment medication included Eliquis twice a day. Based on the current available information and temporal association between the use of the product and the start date of the

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							events, a causal relationship cannot be excluded. This case was linked to MOD-2021-075255 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
1220693	4/16/2021	TX	44	F	4/3/2021	4/4/2021	patient called on 04/16/2021 and stated that ever since she received the second dose of the moderna vaccine on 04/03/2021, she has been having pain in the arms, hips, thighs, and calves and feeling of muscle spasms. the pain in the thighs and calves lasted about 24 hours, but eh pain in her arm, shoulder blades, and fingertips are still there. the pain feels like a dull, thrombing pain, and sometimes it hurts her to the point where she's not able to type. she went to next level urgent care on 04/12/2021 and they gave her ibuprofen 800mg, but she's still having the pain. she is scheduled to see her primary care physician on monday 4/19/2021. upon further questioning her case, rph on duty found out she was cut by a chicken wire that was rusted on her left thumb and had received a tetanus vaccine on 03/20/2021 and was seen at an urgent care. rph on duty said she will follow up with patient on monday after she returns from seeing her md.
1221455	4/16/2021	IN	28	F	4/7/2021	4/16/2021	Abnormally heavy menstrual cycle with large clots noted on day three of cycle.
1220442	4/16/2021	GA	44	F	3/31/2021	4/3/2021	Developed a 7mm Blood Clot
1220191	4/16/2021	CA	54	M	3/6/2021	3/18/2021	Left leg pain, swelling, and tingling. Patient was found to have DEEP VEIN THROMBOSIS of LEFT LOWER EXTREMITY - POPLITEAL VEIN.

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1220623	4/16/2021	WI	19	F	4/9/2021	4/9/2021	Patient claims she felt dizzy after vaccination and lost consciousness near checkout lane approximately 10 minutes after vaccination. She was assisted by asset protection staff and pharmacy staff. She left the store under her own power. She reported that she has had headaches and dizziness after the vaccination and was seen at an urgent care that did not provide her with a diagnosis, but felt her symptoms may have been caused by a concussion. She was advised by clinical team to contact her primary care doctor to follow-up, especially with recent reports of thrombosis linked with the J&J vaccine.
1221024	4/16/2021	SC	71	F	2/11/2021	2/25/2021	Extreme bruising at allergy shot site Nose bleed and blood clot
1220652	4/16/2021	NJ	34	F	4/2/2021	4/3/2021	Blood clots (i started heavy menstrual cramps a day after the shot and I saw exceeding amount of blood clots which has never happened this excessively before) Fever, chills, headache, nausea (all very severe level)
1220558	4/16/2021	CA	62	M	4/8/2021	4/12/2021	-Nausea, Vomiting, Memory loss, headache, seizure - 4/12/2021 at 4 am -Seen in ED on 4/12/2021 and had a negative non-contrast brain CT -MRI 4/15/2021 showed a Nonpyogenic thrombosis of intracranial venous system
1220696	4/16/2021	UT	70	F	3/7/2021	4/9/2021	vaccine 3/7/21. 4/9/21 presented in ER with leg pain. dx with dvt. has no prior hx or fam hx of clots. is not a smoker. is on hrt. treating dvt with eliquis.
1220846	4/16/2021	MA	34	F	4/7/2021	4/7/2021	1) threw up 3x at 8 pm the night of the injection (4/7/21). Felt malice for 48 hours afterwards. 2) heavier than normal period (blood clots coming out). Cycle started on 4/11 which is my expected timing.

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1220994	4/16/2021	NY		M	3/16/2021	3/16/2021	<p>tested positive for COVID- 19; Trouble breathing; blood clots in lungs; Chills; fever; body aches; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (blood clots in lungs) and COVID-19 (tested positive for COVID- 19) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 038A21A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No medical history reported). On 16-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Mar-2021, the patient experienced THROMBOSIS (blood clots in lungs) (seriousness criteria hospitalization prolonged and medically significant) and COVID-19 (tested positive for COVID- 19) (seriousness criterion hospitalization prolonged). At the time of the report, THROMBOSIS (blood clots in lungs) and COVID-19 (tested positive for COVID- 19) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No treatment information was provided. Based on the current available information which includes a strong temporal association between the use of the product and onset of the reported events, and excluding other etiologies, a causal relationship cannot be excluded. Fever, chills and myalgia are consistent with the product known safety profile. Reporter did not allow further contact; Sender's Comments: Based on the current available information which includes a strong temporal association between the use of the product and onset of the reported events, and excluding other etiologies, a causal relationship cannot be excluded. Fever, chills and myalgia are consistent with the product known safety profile.</p>

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1220884	4/16/2021	KS		M	3/9/2021	3/9/2021	Minor surgery on foot that caused blood clot; Sore arm; This spontaneous case was reported by a consumer and describes the occurrence of POSTOPERATIVE THROMBOSIS (Minor surgery on foot that caused blood clot) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was reported.). On 09-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Mar-2021, the patient experienced VACCINATION SITE PAIN (Sore arm). On 18-Mar-2021, the patient experienced POSTOPERATIVE THROMBOSIS (Minor surgery on foot that caused blood clot) (seriousness criterion medically significant). At the time of the report, POSTOPERATIVE THROMBOSIS (Minor surgery on foot that caused blood clot) and VACCINATION SITE PAIN (Sore arm) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medication were not provided. Treatment medications included blood thinner, rivaroxaban for blood clot. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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1220899	4/16/2021	MO		M	2/25/2021	4/1/2021	blood clots in both legs; severe pain in both his legs; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (blood clots in both legs) in a 67-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 008D21A and 011A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was reported.). On 25-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 01-Apr-2021, the patient experienced THROMBOSIS (blood clots in both legs) (seriousness criterion medically significant) and PAIN IN EXTREMITY (severe pain in both his legs). At the time of the report, THROMBOSIS (blood clots in both legs) and PAIN IN EXTREMITY (severe pain in both his legs) outcome was unknown. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided. Treatment included Eliquis (apixaban) for three months. Reportedly, the patient was put on apixaban 2 tablets every morning and evening for 14 days and will then take 1 tablet every morning and evening for a total of 3 months. He does think that the medicine is helping. Patient stated that he never had blood clots before and suspects that it was from the shot.; Sender's Comments: Very limited information has been provided at this time. Further information has been requested. Based on the current information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded

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1220922	4/16/2021	WI		F		3/11/2021	Blood clot; Pain; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clot) in a 30-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 11-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clot) (seriousness criterion medically significant) and PAIN (Pain). At the time of the report, THROMBOSIS (Blood clot) and PAIN (Pain) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Company comment: Limited information regarding the events has been provided at this time and a causal relationship cannot be excluded



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1220961	4/16/2021	NY	56	F	4/8/2021	4/8/2021	Thrombosis on left arm and chest; "you can see all of the veins"; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Thrombosis on left arm and chest) in a 56-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 037B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Neuralgia. On 08-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 08-Apr-2021, the patient experienced THROMBOSIS (Thrombosis on left arm and chest) (seriousness criterion medically significant) and VASODILATATION ("you can see all of the veins"). At the time of the report, THROMBOSIS (Thrombosis on left arm and chest) and VASODILATATION ("you can see all of the veins") had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Concomitant product include an unspecified neuralgia medication. No treatment information was reported. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.

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1220980	4/16/2021	GA	78	F	1/11/2021	3/9/2021	<p>Blood clot; Left leg pain; Discoloration (blue-purple); Swelling; This spontaneous case was reported by an other health care professional and describes the occurrence of THROMBOSIS (Blood clot), PAIN IN EXTREMITY (Left leg pain), SKIN DISCOLOURATION (Discoloration (blue-purple)) and SWELLING (Swelling) in a 78-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 011J20A and 013L20A) for COVID-19 vaccination. The patient's past medical history included Clot blood in 2010. Concurrent medical conditions included Drug allergy (Dalaudid, Ambien and Demerol) and Hypertension. Concomitant products included DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE (FARXIGA), GLIMEPIRIDE (AMARYL), ACETYLCARNITINE HYDROCHLORIDE (NEUROTIN [ACETYLCARNITINE HYDROCHLORIDE]), COLECALCIFEROL (CALTRATE VITAMIN D DAILY), MINERALS NOS, VITAMINS NOS (CENTRUM A TO ZINC) and VITAMIN D NOS for an unknown indication. On 11-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Mar-2021, the patient experienced PAIN IN EXTREMITY (Left leg pain) (seriousness criterion hospitalization), SKIN DISCOLOURATION (Discoloration (blue-purple)) (seriousness criterion hospitalization) and SWELLING (Swelling) (seriousness criterion hospitalization). On an unknown date, the patient experienced THROMBOSIS (Blood clot) (seriousness criterion hospitalization). At the time of the report, THROMBOSIS (Blood clot), PAIN IN EXTREMITY (Left leg pain), SKIN DISCOLOURATION (Discoloration (blue-purple)) and SWELLING (Swelling) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient was sent to hospital to remove clots. The patient stated that the clot was 2/3 size of thigh. The patient scheduled to have a second procedure in May to remove blockages from iliac. Action taken with mRNA-1273 was not applicable. Based on the current available information and temporal association between the use of the product and the onset date of the reported events, a causal relationship cannot</p>

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be excluded. Prior medical history of blood clot is considered a significant risk factor.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported events, a causal relationship cannot be excluded. Prior medical history of blood clot is considered a significant risk factor.

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1220987	4/16/2021	FL	71	F	4/6/2021	4/7/2021	<p>blood in her urine with clots; urine was dark like the color of syrup and it was a brown thick stream; sharp severe headache; chills; fatigue; This spontaneous case was reported by a non-health professional (subsequently medically confirmed) and describes the occurrence of HAEMORRHAGE URINARY TRACT (blood in her urine with clots) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 030A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 06-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 07-Apr-2021, the patient experienced HEADACHE (sharp severe headache), CHILLS (chills) and FATIGUE (fatigue). On 08-Apr-2021, the patient experienced HAEMORRHAGE URINARY TRACT (blood in her urine with clots) (seriousness criterion medically significant) and CHROMATURIA (urine was dark like the color of syrup and it was a brown thick stream). On 09-Apr-2021, HAEMORRHAGE URINARY TRACT (blood in her urine with clots) and CHROMATURIA (urine was dark like the color of syrup and it was a brown thick stream) had resolved. At the time of the report, HEADACHE (sharp severe headache), CHILLS (chills) and FATIGUE (fatigue) outcome was unknown. Not Provided No relevant concomitant medications were provided. The patient received acetaminophen for symptoms. She is currently seeking help from her health care provider regarding this situation and is undergoing some tests in the meantime such as a renal ultrasound. Action taken with mRNA-1273 in response to the events was not applicable. Based on the current available information and temporal association between the use of the product and the start date of the event (headache, chills, and fatigue), a causal relationship cannot be excluded. Very limited information regarding the events (Haemorrhage urinary tract, chromaturia) has been provided at this time. The subject's medical history and concomitant medications are required for analysis. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event (headache, chills, and fatigue), a causal</p>

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1220880	4/16/2021	OH	71	F	3/2/2021	3/5/2021	<p>relationship cannot be excluded. Very limited information regarding the events (Haemorrhage urinary tract, chromaturia) has been provided at this time. The subject's medical history and concomitant medications are required for analysis. Further information has been requested.</p> <p>Stroke due to a blood clot on the left side of my brain; had a dizzy spell; felt very tired; This spontaneous case was reported by a patient (subsequently medically confirmed) and describes the occurrence of CEREBROVASCULAR ACCIDENT (Stroke due to a blood clot on the left side of my brain) in a 71-year-old female patient who COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 02-Mar-2021, the patient received first dose (Intramuscular) at an unspecified dose. On 05-Mar-2021, the patient experienced DIZZINESS (had a dizzy spell) and FATIGUE (felt very tired). On an unknown date, the patient experienced CEREBROVASCULAR ACCIDENT (Stroke due to a blood clot on the left side of my brain) (seriousness criteria medically significant). At the time of the report, CEREBROVASCULAR ACCIDENT (Stroke due to a blood clot on the left side of my brain), DIZZINESS (had a dizzy spell) and FATIGUE (felt very tired) outcome was unknown. No concomitant medications were reported. Treatment information was not provided. Based on the current available information and temporal association between the use of the product and the onset date of the reported events, a causal relationship cannot be excluded. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported events, a causal relationship cannot be excluded. Further information has been requested.</p>

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1220641	4/16/2021	CO	52	M	4/9/2021	4/9/2021	Per pt report: Pt started having body aches within a couple hours of vaccine, developed severe 9/10 pain over the next several days. L shoulder pain radiating to ribs and neck w/ muscle spasms, causing HA, R hip and sacral pain, flank pain radiating down R leg. Pt reports that vision in L eye is blurry, R eye vision intact, numbness to L arm and hand, able to move. Pt reports 1in x 0.5 in blood clot when blowing nose Thursday morning, small clot subsequently about 1/2 the size, smaller clots later.

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1221012	4/16/2021	CO	73	M	2/13/2021	2/13/2021	<p>small intestine got blocked and due to blockage blood supply stopped; started having blood clot thrombosis both in his right leg as well as left leg; Missed the 2nd dose; Blocked small intestine; This spontaneous case was reported by a nurse and describes the occurrence of SMALL INTESTINAL OBSTRUCTION (Blocked small intestine), INTESTINAL ISCHAEMIA (small intestine got blocked and due to blockage blood supply stopped) and THROMBOSIS (started having blood clot thrombosis both in his right leg as well as left leg) in a 73-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 030M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse effect (No relevant medical history reported) and Surgery. Concomitant products included thyroid medication for an unknown indication, cholesterol medication. On 13-Feb-2021 at 10:30 AM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Feb-2021, the patient experienced SMALL INTESTINAL OBSTRUCTION (Blocked small intestine) (seriousness criterion medically significant). On 13-Mar-2021, the patient experienced INTESTINAL ISCHAEMIA (small intestine got blocked and due to blockage blood supply stopped) (seriousness criterion medically significant), THROMBOSIS (started having blood clot thrombosis both in his right leg as well as left leg) (seriousness criterion medically significant) and PRODUCT DOSE OMISSION ISSUE (Missed the 2nd dose). On 13-Mar-2021, PRODUCT DOSE OMISSION ISSUE (Missed the 2nd dose) had resolved. At the time of the report, SMALL INTESTINAL OBSTRUCTION (Blocked small intestine), INTESTINAL ISCHAEMIA (small intestine got blocked and due to blockage blood supply stopped) and THROMBOSIS (started having blood clot thrombosis both in his right leg as well as left leg) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications included thyroid medication and cholesterol medication. Patient called in to report that he received his 1st dose of Moderna vaccine on</p>

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							13Feb2021 in left arm at 10.30 am and his 2nd dose of Moderna vaccine was scheduled on 13Mar2021. On 13Mar2021he went to Emergency Room (ER) and he had major surgery on small intestine, patient mentioned that his small intestine got blocked and due to blockage the blood supply was stopped and the intestine started to die. On that day, the patient underwent a surgical procedure which the doctor had to take out 12 inches of small intestine and stapled back. He was hospitalized for five days. Five to seven days after his surgery, he developed blood clot thrombosis in his right and left legs. Treatment for the event included blood thinner, which he has been on for 45 days. It was reported that the second dose of Moderna vaccine was missed due to hospitalization for the events and the blood thinner that he was on. Most recent FOLLOW-UP information incorporated above includes: On 13-Apr-2021: reporter added, product indication added, event added(missed dose), event assessment done, additional info added( Source Document and mail document added); Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
1213273	4/15/2021	KS	41	F	4/3/2021	4/12/2021	Very very heavy periods with huge clots and super painful. Never had that kind of periods and pain before . Soaking large pad 1 an hour for hours
1213276	4/15/2021	IN	75	M	1/1/2021	4/8/2021	Patient had headache after each dose of vaccine. As this is a common reaction to vaccine, patient was not concerned. However, after headache worsened/did not resolve, patient you went to doctor, and doctor ordered MRI. Patient received phone call to go to ER d/t MRI results of blood clots in brain on 4/8/2021. Patient was hospitalized for one day and placed on high dose eliquis. Patient then went home. Patient woke up with rapid heart beat and chest pain on 4/12/2021 and was readmitted to the hospital for an additional day.
1213298	4/15/2021	OH	65	M	3/11/2021	3/19/2021	I started having migraine headaches on 3-19-2021 , this lasted for 3 days. On 3-23 started coughing up blood , that progressively became worse. Went to emergency room and was admitted CAT scan of lungs showed that I had 3 blood clots.



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1213311	4/15/2021		81	F	2/21/2021	2/24/2021	Pt was diagnosed with cerebral venous sinus thrombosis on 3/25/21 after having severe HA x 3 days. Looing back, she had a cbc for other reasons on 2/24/21 (3 days after her 2nd Covid vaccine) that showed a drop in platelets to 126,000 (although platelets in 2020 were 150,000)
1213399	4/15/2021	TX	65	F	3/19/2021	4/11/2021	On April 11, 2021, patient passed a sizeable blood clot and has experienced labored breathing.
1213393	4/15/2021			U			Lost consciousness and speech, blood clot to the brain caused a stroke
1213227	4/15/2021	NY	37	F	3/2/2021	3/2/2021	mesenteric venous thrombosis, symptoms began around same time as vaccine
1213174	4/15/2021	CA	41	F	3/17/2021	3/18/2021	Superficial blood clots in both upper legs; each leg had one in the front and one in the back. They were very painful and tender with bruising around the area. The clots could be seen and felt.
1213131	4/15/2021	FL	69	F	3/11/2021	3/29/2021	PATIENT DIED FROM BLOOD CLOT 3/29/2021 - AUTOPSY PERFORMED AND CONFIRMED

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1213036	4/15/2021	MI	42	M	3/24/2021	4/10/2021	Received vaccine 3.24.21. Had been incarcerated / in prison system until 4.7.21. Complex past medical history. 4.10.21: Went to ED on 4.10.21 - for hematuria. CHIEF COMPLAINT: BLOOD IN URINE (patient reports hematuria an hour prior to arrival along with spitting up a large clot (hemoptysis). denies rectal bleeding at this time. denies being on a blood thinner. c/o back pain starting a few hours ago. HX aortic aneurysm and scheduled to get surgery in a few weeks. )Urinalysis returned showing moderate amount of blood was 73 RBCs. Patient did not have frank hematuria on specimen. Patient's laboratory work otherwise remains unremarkable. Electrolytes within normal limits. Patient has a stable hemoglobin of 13.8. CT scan showed evidence of acute aortic dissection. There were scattered faint ground-glass opacities along the right upper lobe as well as left upper lobe. COVID-19 testing was added on after results. At this time I do not have a great explanation for the patient's hematuria. I did instructed to follow up with Urology for further evaluation of this. He is hemodynamically stable I do not believe further testing is warranted at this time. Return precautions were discussed including urinary retention, large volume bleeding or any other concerning symptoms. He voiced understanding of this and was discharged stable condition. He was provided a work note as he is on probation and it is for her of his hospitalization at this time. 4.13.21: Went to ED on 4.13.21: CHIEF COMPLAINT: LEG PAIN (pt c.o. right leg swelling/pain that started 3 days ago; had johnson&johnson vaccine on 3/24 and is concerned for blood clots; supposed to have surgery at the end of the month; recently seen for blood in urine; c.o. generalized body aches)42-year-old male presents with right calf pain and reported swelling. On presentation patient is well-appearing and nontoxic, afebrile, hypertensive 134/113 with otherwise normal vital signs. On exam, the patient has no swelling in the bilateral lower extremities, he does have very mild tenderness to palpation in the right posterior proximal calf just below the knee. Remainder of physical examination is otherwise unremarkable. Given history of blood clot and reported right calf pain, right lower extremity duplex venous ultrasound ordered to evaluate for DVT. EKG was obtained on arrival, and showed normal sinus rhythm with no evidence of ST

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							segment elevated for depression, no dysrhythmia, no comparison when compared with prior EKG from July 2019. Right lower extremity ultrasound showed no evidence of DVT. I shared results of the workup with the patient and told him that there is no indication for further workup or treatment at this time. I recommended Tylenol or Motrin as needed for right leg pain. I recommended compression stockings as needed for right leg swelling. I encouraged him to follow up with all specialists physicians as previously scheduled and with his primary care physician as needed. Office visit 4.14.21: Subjective: a 42 yr.. male evaluated with a video visit on 4/14/2021 Currently he complains of headache, hot/cold flashes (no fever), nasal congestion, and Bilat ear pain. R leg is swollen. The symptoms have been present for 2 day(s). Was incarcerated - has been out for about week. He denies a history of chills and fevers He has tried acetaminophen, Flonase for his symptoms. Sick Contacts: none known History is provided by patient There is history of asthma or recurrent respiratory infections. Went to the ER yesterday and 4/10 Had his J&J vaccine: 3/24 COVID19: negative 4/10
1213024	4/15/2021	TX	64	F	4/10/2021	4/10/2021	Call rec'd from pt; she wants to report a reaction to the J & J vaccine which she got this past Saturday 4/10 at 10am; her symptoms began that night at 9pm , primarily nausea and vomiting. she could not keep anything down, finally she remembered a past txment from her childhood, pepto bismol and milk; ( she had IBS as a child); her sxs persisted for about 3 days, finally on Wednesday she felt better and has been tolerating a bland diet; she is better now; pt feels that there is a strong correlation between her diabetes and the vaccine; she is asking that this be reported via the VAERS system; pt did not experience anaphylaxis nor rashes/urticaria, nor any classic blood clot sxs; m
1213016	4/15/2021	NY	55	F	3/19/2021	3/28/2021	10 days after receiving Janssen COVID-19 vaccine I suddenly developed severe pain to my right leg. Pain was so severe I could not walk, I dragged myself into the medicine pantry and believing it could possibly be a thrombosis, I instantly took 2 baby aspirins. Although I wanted to call for help, I was too far from my phone therefore I began to massage the area and remained in place until the pain subsided enough to regain movement.

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1213415	4/15/2021	NH	56	M	4/10/2021	4/13/2021	56 year old gentleman with only medical history being COVID-19 infection in October. Admitted on 4/13/2021 for a cerebral vascular accident due to thrombosis of right posterior cerebral artery hemorrhagic conversion (I63.331). Has left-sided weakness. Patient also tested positive by PCR (Panther Aptima) on 4/14/2021.
1212971	4/15/2021	AZ	46	F	4/3/2021	4/15/2021	I had bloodwork showing increased D-Dimier and that I may have a blood clot.
1213979	4/15/2021	TX	48	F	3/15/2021	4/12/2021	HOSPITALIZED FOR BLOOD CLOTS, UNRESPONSIVE AND TAKEN TO HOSPITAL
1212939	4/15/2021	NY	48	F	2/16/2021	3/21/2021	3-4 weeks after the vaccination I developed a ovarian vein thrombosis and was hospitalized on 3/15/21 . I am concerned based on new reports of blood clots in women with the Johnson & Johnson vaccination that this is related to my first injection. I was a healthy individual prior to this with no history of blood clots.
1212978	4/15/2021	TX	38	F	4/6/2021	4/12/2021	Pt states that on Monday she noticed that she couldn't put pressure on her leg to walk. (04-12-21) Pt called and made an appointment on 04-13-21 and saw her PCP. Ultrasound was ordered and was dx with near occlusive vein thrombosis in the distal right femoral vein. Pt was prescribed Lovenox 100mg to take now and was also prescribed eliquis 5 mg twice daily, and acetaminophen-codeine to help with the pain.
1214025	4/15/2021	CT	53	M	3/21/2021	3/22/2021	Received the first shot of Pfizer Covid Vaccine at 10:00 AM on 3/21/21. Aside from some drowsiness I felt fine the entire day. Then that night I woke up at 2:30 AM with severe pain in my right knee. I was unable to bend the knee or walk for the next 36 hours. After that the pain transitioned to the back of my calf muscle for the next few days. The pain then went back to my knee for a day and then returned to the back of my calf muscle. On 3/30/21 I saw my primary care physician who then sent me to get an ultrasound which determined that the pain in my knee and calf were caused by blood clots (DVT). I was then prescribed Eliquis 5 mg blood thinners.

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1212435	4/15/2021	OH	78	M	3/17/2021	4/1/2021	He got the vaccine, was not able to breath real good and didn't think about it. It got to the point within 2 weeks that he was not able to get up from the chair due to the shortness of breath. By 4/1/21 he was not able to breath very well, but continued to stay home. Then by 4/12/21 he was not able to breath well at all and his wife took him to the ER. In the hospital they did x-rays and found out that his lungs are full of blood clots and both legs have blood clots in them. He was admitted and gave him Heparin drip for the 2 days to get the blood clots dissolved and was also on oxygen for 2 days. He was discharged home yesterday with Xarelto, and was told that he would be on that for the rest of his life, and is on oxygen for sleep and when he's up and around, but if he's resting and feels he's breathing okay he can remove it. They informed him that it would take approximately 2 months for all the blood clots to dissipate, and that he was full of blood clots, and had both legs and both lungs which are quite full.
1212931	4/15/2021	GA	78	M	4/6/2021	4/7/2021	Stroke caused by blood clot - Vision Impairment and memory impairment
1214295	4/15/2021	IL	64	F	3/15/2021	4/13/2021	blood clot in arm
1214279	4/15/2021	AR	60	F	3/1/2021	4/15/2021	Patient's daughter called on her behalf to translate from Spanish. She reported that her mother was having "flu-like" symptoms approximately 3 weeks after receiving the J&J vaccine. She also mentioned that she was having a headache in the back of her head and neck which are known to be possible indication of a cerebral venous sinus thrombosis which has been rarely associated with the J&J vaccine. I advised the daughter to take the mother to the emergency department for further evaluation and she agreed that she would take her right away.

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1214246	4/15/2021	MO	43	F	4/6/2021	4/7/2021	Pt called LPHA to report she was seen in the ER on 4/8/21 for a potential blood clot in her left leg. Pt reported she awoke from sleep late 4/7/21 early 4/8/21 with severe pain in her left leg. She reported it hurt so bad she was "screaming". She stated it felt like a "charley horse" and her husband noted a knot in her leg. She went to the ER on 4/8/21 due to the inability to put pressure on her leg and/or walk on her leg. She reports having a CT scan of her chest at the ER and no clots were noted. She stated they did not image her leg at that time and scheduled an ultrasound/doppler for around 4/27. She was prescribed some oral blood thinner, but could not recall the name. She stated she stopped the blood thinner on 4/12/21 after the new reports regarding the J & J vaccine and not using blood thinners to treat. Today she states her leg is purple, black and blue and is swelling more when she is up on it at work. RN instructed pt to call her primary provider regarding stopping the blood thinner and to see if re-evaluation of her leg is needed. Pt also instructed to seek emergency treatment for increased swelling or pain to her leg, headache, abdominal pain, shortness of breath or any other concerns. Pt plans to speak with or see her primary provider today.
1214158	4/15/2021	VT	33	F	4/2/2021	4/3/2021	Sharp, painful cramp in right rib cage that was provoked by certain movements. Blood clot? Resolved within 24 hours.
1213493	4/15/2021	NY	43	M	3/28/2021	3/28/2021	Had COVID on 2/7/21- Feverish feeling x 1 day, fine after. Tested negative 2/17/21. One half hour after receiving the vaccine, onset of hoarseness. Severe hoarseness persists until today. Eyelids pink, swollen slightly, persisted 2 weeks. Did not feel well. 4/15/21 - Hospital Emergency Room. Chest pain. Elevated blood pressure. COVID test positive. Discharged with azithromycin, zinc sulfate 220mg, ProAir. High blood pressure, new onset. On 4/6/21 BP 160/120 both arms. 4/7/21 Hospital ER. MRI, CT brain showed Dural Venous Thrombosis. To ICU for anti coagulation, until 4/14/21. MRV done. Now on floors, started coumadin. 9 days hospitalization so far. CT done again 4/15/
1214095	4/15/2021	NY	67	M	4/8/2021	4/14/2021	patient had pain and swelling in left leg - sent for doppler - positive for thrombophlebitis

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1213429	4/15/2021	UT	54	M	3/8/2021	3/22/2021	DIAGNOSIS: 1. Superficial thrombophlebitis MEDICAL DECISION MAKING/DIFFERENTIAL DX: Differential diagnosis includes DVT, superficial thrombophlebitis, muscle strain, tendinitis. The patient presented to the emergency department with atraumatic left leg pain. An ultrasound reveals a fairly large blood clot in the greater saphenous vein. Although this is a superficial clot, given its extent, I think it warrants anticoagulation. Per the trial, the patient would benefit from 45 days of 10 mg Xarelto treatment. The patient was given good precautions regarding bleeding risk while on a blood thinner. He will schedule follow-up appoint with his primary care doctor. He will also use Tylenol and warm packs to help with the discomfort from the superficial thrombophlebitis. He was discharged in satisfactory condition.
1213504	4/15/2021	OH	70	F	3/24/2021	3/27/2021	Deep Vein Blood Clot
1213492	4/15/2021	LA	61	F	3/18/2021	3/27/2021	on Saturday, March 27th, patient noticed swelling in left lower leg with Shortness of breath, and heart racing. on 3/39, the patient presented to the ED and was admitted and diagnosed with a blood clot from left groin to left ankle, with "clot in heart and lungs". heparinized and discharged home on Coumadin currently taking 5 mg on Sunday, Monday, Wednesday, and Saturday and 2.5 mg on Tuesday and Friday each week.
1213487	4/15/2021	SC	53	F	4/12/2021	4/13/2021	Patient reports they injected Humira on Sunday 4/11, then they got their J&J COVID vaccine on Monday 4/12. Patient reports they developed a fever of 103°F for 2 days and could not get out of bed the first day. Patient has also had a migraine for 3 days that is improving, and today it comes-and-goes. Patient also takes estrogen, so they are concerned for thrombosis risk. Patient denies blurred vision, fainting or loss of consciousness, or other changes in mental status. Patient also denies swollen or redness in their calves and ankles.

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1213440	4/15/2021	OH	27	F	4/9/2021	4/11/2021	Friday evening I had what I thought was normal reaction: chills, aches, headache, nausea. Saturday it was mostly aches. Sunday was dizziness, aches, nausea and cramping in left leg. Monday was nausea, aches, tingling in hands and feet, headache, brain fog. Tuesday I woke up with major imbalance and needed to use walls to walk without falling over. Dizziness subsided after some time to only rapid movements. I had a warm burning sensation in left leg with tingling hands and feet. Moderate headache. Reports came out of stopping the Janssen vaccine so I contacted my doctor with my symptoms and they ordered blood tests for clots.
1213431	4/15/2021	NY	47	F	3/1/2021	3/16/2021	Patient admitted with massive portal vein thrombosis and low plt in setting of infection. Symptoms started one week prior
1213430	4/15/2021	OH	58	F	3/19/2021	4/5/2021	Patient reports being hospitalized April 8-10 with blood clots in her legs and lungs
1214146	4/15/2021		44	M	3/12/2021	3/14/2021	March 14 2021 - 2 days after first vaccine shot, leg pain, 1-3 days later diagnosed with superficial blood clot in left leg via ultrasound, treated with baby aspirin for 3 days and heat pad, symptoms slowly lessened till 2nd dose of vaccine on April 2nd, after second dose symptoms worsened again, both legs still fatigue very quickly to this day (April 15 2021) when I'm sitting down on chairs, seats etc. April 8 2021, 12:30pm - heart pain for 30 minutes, felt very weak, similar to light heart attack, ER visit later that day couldn't find any explanation
1211576	4/15/2021	NY	56	M	3/16/2021	3/29/2021	Swelling in left leg around calf and ankle. After a blood test and sonogram a Deep Vein Thrombosis was found in my left leg. Determined "unprovoked" by Dr. after subsequent blood test results came back negative.
1215421	4/15/2021		33	F	4/1/2021	4/2/2021	abdominal pain since vaccine, found to be pregnant. headache 1 week after vaccine. normal exam. no change in vision. no personal or family history of clots. better with reglan



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1212394	4/15/2021	FL	64	M	3/2/2021	4/3/2021	Day after the shot (March 3) he started having shortness of breath and then continued up until March 16 started running fever of 102.9 and still having difficulty breathing- went to ER and then diagnosed with blood clots in lung "acute pulmonary emboli" and pulmonary infarct and his heart was enlarged-by CAT scan. In ICU for 3 days and discharged at that time out of ICU to home.
1212142	4/15/2021	OH	53	M	3/9/2021	3/15/2021	Started with swelling of Rt. lower leg with pain, pain went to Rt. and Lt. side of upper leg, had appointment with Fam. Doctor was sent to get Ultra sound of Rt. upper leg was then advised to go straight to emergency room, started on cores of blood thinners after a blood clot was found.
1212127	4/15/2021	PA	24	F	3/12/2021	4/11/2021	Site: Pain at Injection Site-Mild, Systemic: Blood Disorder (diagnosed by MD)-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: blood clots in stool-currently under care of primary care physician for clot formation investigation-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Headache-Medium, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Systemic: Unable to Sleep-Medium, Systemic: Weakness-Medium, Additional Details: patient reported blood clots in stool on 4/11/21 and 4/12/21. Patient was flushed, dizzy and faint after clot was found. Patient has no significant history of hemorrhoids or colorectal conditions.
1212090	4/15/2021	AL	50	M	3/8/2021	3/15/2021	Systemic: Visual Changes/Disturbances-Severe, Additional Details: patients wife called to say that around 1 week after vaccine pt experienced vision issues. dr say he had a blood clot in eye which lead to partial blindness in one eye.
1211991	4/15/2021	WI	72	F	3/17/2021	3/22/2021	Clots Ongoing
1214358	4/15/2021		57	M	4/1/2021	4/14/2021	1. Acute left deep venous thrombosis in the popliteal, posterior tibial, peroneal, one branch of gastrocnemius veins. 2. Acute left superficial venous thrombosis in the great saphenous prox thigh to knee extending into a varicose vein at the proximal calf. 1. Pulmonary embolism with large thrombus burden bilaterally, right greater than left ASA/heparin gtt started

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1211831	4/15/2021	SC	56	F	4/1/2021	4/6/2021	Have blood clot in right leg now on blood thinners
1212458	4/15/2021	OH	67	F	3/6/2021	3/20/2021	2 weeks 8 days after vaccine, patient suffered which sent pt to emergency room. Husband states she had a "blood clot" to brain with skull fracture and traumatic brain injury. Transferred to Medical Center, then to long term facility. Has not recovered to date. Husband states unable to speak or move.
1211219	4/15/2021	TX	62	F	4/6/2021	4/6/2021	Back Spasms (ongoing). Makes me wonder about blood clots as my back was the first thing to hurt when I had a PE.
1211014	4/15/2021		51	F	4/5/2021	4/6/2021	c/o persistent headache, abd pain, low appetite, and L leg on/off pain since J&J vaccine on 5 Apr. denies n/v/d/, chest pain or SOB. states BP is higher than usual. concerns for blood clot. last Tylenol 1000. 51 yo f c/o MEG pain/"knot" w/ongoing decreased appetite and nausea w/o vomiting x7d w/additional new HA w/o visual changes x2-3d approx 10d s/p J&J covid vaccine; Pt states concerns for ulcer vs. other etiology; Pt denies any fevers/nausea/chills, urinary sx's, back pain, vaginal bleeding/discharge, recent hx of trauma/inj distant hx of 1x hysterectomy

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1211008	4/15/2021		61	F	4/5/2021	4/12/2021	vaccine reaction-passed out. c/o worsening headache and feels tire. states broke out sweat, stomach pain, HA, leg cramping and passed out (for about 30sec according to husband) on Mon. took Advil several days. last Advil 0600. J&J vaccine on 5 Apr. 61 yo f w/spouse c/o ongoing headache w/concerns for single episode of 'passing out' approx 48hrs pta approx 30-45 sec per spouse at bedside; Pt states nighttime episode w/preceding leg crampings, sweating, dizziness, sat on footstool and per spouse passed out but caught by spouse and avoided injury; spontaneous recovery w/o further issue from that episode, spouse denies any post-syncope seizure-like activity/urinary incontinence/tongue biting; Pt and spouse concerned. for cerebral venous thrombosis; Pt has sig hx of prior neurosurgery for posterior/occipital schwannoma around 2017, successfully removed, w/o further findings or complications on f/u (last DEC 2020) to include repeat imaging at that time Pt states has been taking advil OTC for ha but no sig relief at this time; Pt defers need for medications at time of provider evaluation; Pt denies any fevers/ns/chills, cp, sob, palpitations, dyspnea, abd pain/cramping, current nvd, prior syncope, fam hx of MI/SCD/dysrhythmias.
1211001	4/15/2021	AZ	66	F	3/22/2021	3/28/2021	Patient is deceased. Had a blood clot travel to her brain and causes an un recoverable stroke
1210977	4/15/2021	OR	42	F	2/1/2021	2/22/2021	Lower right leg blood clot. Currently on Xarelto blood thinner.
1210966	4/15/2021	NJ	86	F	4/2/2021	4/10/2021	My mother was found unconscious on the kitchen floor. She was taken to the hospital. She had different test including a Cardiac stress test and it was found to be okay. However, my mother developed a blood clot in her left leg. She still been under medical observation in the hospital.
1211949	4/15/2021	GA	44	F	4/6/2021	4/7/2021	At first I had diarrhea sleeping a lot. Then I started to have pain on my arms and on one of my legs . Went to the doctor's and they draw blood to see if I have any blood clots . Waiting on results.

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1212659	4/15/2021	FL	86	M	3/13/2021	4/12/2021	pt came into the office with symptoms of left lower extremity swelling/edema. Ultrasound was done that determined patient is Positive for acute deep vein thrombosis of the left femoral and left popliteal veins. Pt placed on Eliquis right away.
1212787	4/15/2021	LA	61	F	3/23/2021	4/10/2021	On April 10, 2021, patient reported losing vision in right eye. Saw primary physician on 4/14/2021 and had ultrasound of the neck done on 4/14/2021. Patient reported per phone on 4/15/2021 that she was told that she had a stroke in her right eye. Was placed on ASA 325mg and Clotidogrel 75mg.
1212770	4/15/2021	VA	67	F	3/6/2021	3/30/2021	CT chest scan found blood clots in the vessels of the lungs and inflammation in the lymphatic area outside of the lung lobes.
1212726	4/15/2021	OH	62	M	3/6/2021	3/23/2021	Received vaccine 3/6/21, had Right Hip replacement surgery on 3/23/21 and had arterial blood clot post surgery with revascularization. Surgery performed by Dr. at a Medical Center
1212715	4/15/2021	MD	38	M	4/7/2021	4/10/2021	Developed pain in right calf and hamstring. No improvement over the next few days. Went to Vein specialist and they performed an ultrasound. A blood clot was found in my right calf.
1212707	4/15/2021	MA	48	M	2/17/2021	2/24/2021	Day after had severe gum bleeding at dentist cleaning, on February 24th had a blood nose hemorrhage, needed to go to emergency department. They had to insert a nasal balloon because I wouldn't clot for about 4 hrs.

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1212681	4/15/2021	NY	82	F	3/17/2021	3/21/2021	In the middle of the night, I AWAKENED to the MOST SEVERE PAIN in my left arm. Thought perhaps a clot or a heart attack. ALTHO IVE NEVER HAD EITHER SO I DIDNT KNOW WHAT WHAT HAPPENING. I just lay there in place. I was awake and alert so I figured neither of the above. However, when I tried to use my arm, in a number of directions, It was extremely painful. I could not put this arm behind my back as tho to scratch my back. I am not sure if it was an attack on a MUSCLE or TENDON. I do know that in December 2019 I was given a 3-day dose of CIPRO anti-Biotics WHEN in the middle of the THIRD night I awakened with exactly the same reaction to the COvid vaccine BUT IN MY RIGHT LEG. In both instances it has taken me months to heal. I did go for therapy for my right leg event. Not for the left arm. I can only conclude that there is a connection between the medications.
1212437	4/15/2021	TX	76	F	3/7/2021	3/22/2021	Right leg swelling below knee , feels like needles around right ankle, call heart doctor had a scan of both legs found no blood clots have tried using a extra water pill to bring down swelling but it comes back the next day.
1212661	4/15/2021	OH	45	M	3/29/2021	4/7/2021	DVT in calf that turned in to substantial pulmonary embolisms in both lungs with no prior blood clot history. Treatment included a TPA to dissolve clots as well as vascular surgery to remove clots not dissolved in the left lung.
1212913	4/15/2021	AZ	36	F	3/1/2021	4/7/2021	Menstruation: I received my vaccine late night March 30 and was fatigued and slept most of the next afternoon and through the night. I began my period on April 1, which is around the usual time. Everything seemed fine for that first week (flow, discomfort levels, mood, etc.). but I still haven't stopped bleeding (as of April 15), which is completely abnormal; today marks two straight weeks of menstruating. Within this second week, there is significantly more cramping and back pain than usual, and my flow is very heavy with frequent large, thick clots passing in the blood, some globules the size of quarters or even half-dollars (though amorphously shaped). I go back for my second dose on April 22, and have a scheduled doctor's appointment on April 28.
1212599	4/15/2021	OH	65	M	2/15/2021	4/5/2021	Blood clot resulting in stroke in left brain

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1212582	4/15/2021	MN	36	F	4/7/2021	4/9/2021	I did not receive treatment other than a prescription for a headaches. I ended up having a bad headache after my J&J vaccine. My headache developed at the base of my skull and radiated to the top of my neck. I had another headache above my eye as well. I also had intense joint pain from my upper leg all the way to my right ankle. I also experienced nausea along with my headache. An ultrasound of the right groin was performed to check any clots in my right leg. The doctor who saw me prescribed Emetrex for the headaches and there has been no follow up since then. I still have a headache today but is a lot less in intensity.
1212565	4/15/2021	MA	45	M	4/9/2021	4/14/2021	Developed acute severe abdominal pain and found to have splenic infarct, splenic artery thrombosis, celiac artery stenosis on morning of 4/14/2021 on CT abd/pelvis with IV contrast and presented to ED for symptoms. Started on apixaban.
1212549	4/15/2021	WI	57	F	3/31/2021	4/6/2021	Client reports having onset of pain to back of right knee, bruising, and swelling on 4/6/2021. She called teledoc on 4/9/2021, provider diagnosed her with superficial blood clot. Treating with applying warm compress to area. Client had onset of headache, dizziness, nausea, light headed, unsteady gait, vomiting, chills and sweats on 4/10/2021. Patient called teledoc on 4/14/2021, they recommended COVID-19 testing, results are negative on 4/12/2021. Symptoms ongoing since 4/14/2021, recommended she call provider regarding symptoms.
1212529	4/15/2021	GA	40	F	3/14/2021	3/15/2021	I went on Sunday March, 14, 2021 to get the Johnson and Johnson shot offered through the school system. I noticed that my blurred vision intensified. I went to the eye doctor 3/16 and that is where they found blood clots behind my right eye close to my center. I was referred to a Retinol specialist 3/26/21 and sent me to get a physical to check for diabetes. It had started to heal a little. There was not clear diagnosis on what could have been causing the the blood behind my eye. 4/2/2021 Went for physical at PCP and results of physical was good with no Diabetes.

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1212461	4/15/2021	VA	50	F	3/12/2021	4/14/2021	On 4/15/2021 patient presented with chest pain and left lower extremity pain, which started about 2 days prior to admission. CTA showed large volume multifocal bilateral pulmonary emboli throughout numerous right lower lobe, right middle lobe, right upper lobe, left upper lobe, and left lower lobe segmental branches. Left lower extremity venous ultrasound showed no evidence of deep or superficial vein thrombosis; the right lower extremity was not scanned. Patient denies personal or family history of VTE. She states that she does not smoke and has no history of smoking. Patient was treated with apixaban 10 mg po BID x7 d followed by 5 mg po BID. Platelets were 295 on admission.
1212673	4/15/2021	MI	44	M	4/6/2021	4/7/2021	Blood Clot and bruising on lower backside of leg, I noticed leg Pain (just uncomfortable) in the right leg at the location of clot. A time frame in relationship to the time of shot is unknown. Estimated within 24 hours. Bruising appeared morning of 04/14/21, PCP recommended in person visit. I went to urgent care, they had me drive to emergency Room at local hospital. Evaluation, blood testing and imaging concluded a blood clot in the lower right leg. Blood thinners was prescribed Eliquis 5 mg, discharged same day. It may be possible the hospital had submitted this form on my behalf.
1216042	4/15/2021	AZ	49	M	3/22/2021	3/29/2021	Swelling left leg. Femoral vein DVT identified on ultrasound on April 5, 2021 (partially occluded clot). hematologist switched me from Eliquis to starter pack of Xarelto.
1214422	4/15/2021	WI	63	M	3/10/2021	3/29/2021	Blood clots in left leg, hip, bilateral lungs; treated with blood thinners; was admitted to hospital from 4/1-4/3; discharged to home, stable

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1215435	4/15/2021	DE	60	M	3/7/2021	3/18/2021	Patient began experiencing back pain on March 14 and on or around March 18 he started coughing up blood clots according to a coworker. Patient lived alone and was unable to be reached on Sunday March 21. I went over to his house and found him deceased in his bed. Patient had a trashcan beside his bed and it appeared to have some blood in it. Patient had thick mucus coming out of his mouth and blood coming out of his nose. According to paramedics he had passed a few hours before finding him. Unfortunately Patient has been cremated so there is no way to say that this was related to the Covid 19 shot from Johnson and Johnson, however there are new reports that blood clots have been a side effect. I would like to speak with someone from the Department of Health to discuss this further. I feel this could be related to the vaccination and I would to know how long the Health Department knew about this possible side effect. If patient would have known sooner that the blood clots were a side effect I feel he would have gone to the Emergency Room. Patient had no health insurance and he was trying to prevent getting Covid. This has caused our family so much heartache and we are all very apprehensive about getting the Covid Vaccine ourselves. Please contact me as soon as possible, I am also patient's executor so I am able to speak to you on behalf of patient and our family. Thank you.
1215502	4/15/2021	MO	53	F	3/26/2021	4/2/2021	7 DAYS AFTER VACCINATION PATIENT FELT NUMBNESS AND LOSS OF TASTE IN HER TONGUE. THE FOLLOWING MORNING SHE WOKE AND ONE SIDE OF THE FACE WAS DROOPING. PATIENT RECEIVED CARE AT AN URGENT CARE FACILITY. A CT SCAN WAS PERFORMED TO RULE OUT BLOOD CLOT. PATIENT WAS DIAGNOSED WITH BELL'S PALSY
1215510	4/15/2021	CA	52	M	4/3/2021	4/4/2021	Woke up Sunday the day after and couldn't walk. Waited to see if it would wear off the next day was admitted into emergency with a minor stroke caused by a blood clot



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1215513	4/15/2021	WA	49	F	4/5/2021	4/6/2021	The usual arm soreness and feeling of fatigue for a few days after. Not sure the following is related, but mentioning here due to the small number of women who experienced severe issues related to blood clots. Light nose bleeds - mostly when blowing nose - chunks - persists. Also, have been menopausal but am now having a cycle - thin and light bleeding.
1215528	4/15/2021	MI	34	F	4/8/2021	4/8/2021	Patient noticed a small lump at the injection site almost immediately after vaccine given. That night patient developed 'pins & needles' down her left arm, arm/hand tremors, chills/fever (102.3), nausea, body aches, fatigue and shoulder pain. Patient took ibuprofen at 4 am on 4/9. Saturday (4/10) patient noticed a lump on her left forearm. She went to the doctor and an ultrasound was done on 4/14 which revealed a superficial venous thrombosis in the cephalic vein of the left forearm. Patient was told to start on aspirin 81mg on 4/15. Dr also measured injection site identified by patient as 1.5 cm below acromion process. Physical therapy will also be set up.
1215572	4/15/2021	OK	39	F	3/8/2021	4/1/2021	My period started on the expected day, April 1st 2021 and it has not stopped (15 days as of now) and is excessively heavy with extremely large clots every day. I have not yet seen a doctor as I do not currently have health insurance.

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1215648	4/15/2021	CA		M	2/1/2021	3/27/2021	bruises are darker than normal since he has started Eliquis; Constipation; swollen index finger and swollen toe/determined to be gout; felt lousy; This is a spontaneous report from a contactable consumer, based on information received by Pfizer. This spontaneous case was reported by a physician and describes the occurrence of GOUT (swollen index finger and swollen toe/determined to be gout), FATIGUE (felt lousy), CONTUSION (bruises are darker than normal since he has started Eliquis) and CONSTIPATION in 92-year-old male patient who received apixaban (Eliquis) tablet (batch no. 1790398) for Venous thromboembolism. CO-SUSPECT PRODUCTS included Covid-19 Vaccine for an unknown indication. The patient's past medical history included Large intestine infection, Hypercoagulability and Constipation. Concurrent medical conditions included Gout. In February 2021, the patient started Eliquis (batch no. 1790398) (Oral) at an unspecified dose twice a day. On an unknown date, the patient started Covid-19 Vaccine (unknown route). On 27-Mar-2021, the patient experienced FATIGUE (felt lousy). On 29-Mar-2021, the patient experienced GOUT (swollen index finger and swollen toe/determined to be gout). On an unknown date, the patient experienced CONTUSION (bruises are darker than normal since he has started Eliquis) and CONSTIPATION. The action taken with Eliquis(Oral) was unknown. At the time of the report, GOUT, CONTUSION and CONSTIPATION outcome was unknown and FATIGUE resolved. For Eliquis(Oral), the reporter did not provide any causality assessments. The reporter stated that he was put on Eliquis for ninety days and has used it for thirty days so far. He has had some issues that require an enema. Concomitant medications included: dark Cherry Extract - started on or after 29-Mar-2021. The reporter stated that he had been taking Eliquis for 45 days for blood clots that stemmed from a colon infection with secondary hypercoagulability. On Saturday 27-Mar-2021, the patient had his second injection of the Pfizer Covid vaccine. After receiving the vaccine, he said he felt lousy and had common side effects for a vaccine that lasted for about 2 days. On 29-Mar-2021 he woke up with a swollen index finger and swollen toe and this was determined to be gout. The gout in his index finger he had before. The patient stated that whenever he got bruises he had noticed that the bruises were darker than

*VAERS\_ID RECVDATE STATE AGE\_YRS SEX VAX\_DATE ONSET\_DATE SYMPTOM\_TEXT*

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normal since he had started Eliquis. The patient also stated that he has had considerable constipation that started before Eliquis, but still persisted at times and he had treated with enemas. Patient was a retired physician. Follow-up (30Mar2021): This is a follow-up spontaneous report from a contactable physician, based on information received by Pfizer. Most recent follow-up information was received from a physician on 30-Mar-2021 included the following: the event adverse event nos was amended as information on adverse events were received, new events and suspect product added, patient attributes, medical history, product attributes and narrative updated.

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1215649	4/15/2021			F			<p>Patient advised she took COVID-19 Vaccine and formed blood clots in leg; This is a solicited report from a non-Pfizer sponsored program: -CW2891702, received from a contactable consumer, based on information received by Pfizer from manufacturer (manufacturer control number: BMS-2021-032881), license party for apixaban. This 86-year-old female patient was involved in a patient support program. The patient (patient ID: (ID)) received APIXABAN. The report describes a case of THROMBOSIS (Patient advised she took COVID-19 Vaccine and formed blood clots in leg). Co-suspect products included Covid-19 Vaccine for an unknown indication. On an unknown date, the patient started APIXABAN (unknown route), (unspecified dose and frequency). On an unknown date, the patient experienced THROMBOSIS (seriousness criterion medically significant). The action taken with APIXABAN (Unknown) was unknown. At the time of the report, THROMBOSIS outcome was unknown. For APIXABAN (Unknown), the reporter did not provide any causality assessments. This report was received from consumer. The patient received therapy with apixaban and COVID-19 Vaccine for unknown indication. Follow-up is unable to be performed. Medical evaluation comment: This patient had blood clots in the leg after apixaban therapy. Based on the limited information regarding medical history, event details, treatment details, it cannot be ascertained that the suspect drug contributed to the reported event. The reporter's assessment of the causal relationship of the event Thrombosis leg with the suspect products was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment. Amgen's assessment: the event, Thrombosis leg, was assessed as unrelated to apixaban. No follow-up attempts are possible; information about batch number cannot be obtained.; Sender's Comments: As there is limited information in the case provided, the causal association between the event of thrombosis and the suspect vaccine BNT162B2 cannot be excluded. Based on known mechanism of action of the drug, the event of thrombosis is assessed as not related to Apixaban. The case will be reassessed once new information is available. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety</p>

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							evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
1215840	4/15/2021	AK	67	M	4/8/2021	4/15/2021	large MCA stroke, thrombolytics and interventional clot extraction
1215397	4/15/2021	AL	25	F	4/1/2021	4/12/2021	4/1/2021 patient received JNJ Vaccine 4/12/2021 Miscarriage was confirmed on Ultrasound done by and also Right Pelvic vein thrombosis seen. 4/13/2021 Patient placed on Anticoagulation.
1215952	4/15/2021	LA	72	F	2/24/2021	2/26/2021	Began with a severe cough 02/27/21 lasting for days.....possibly causing blood clots in the lungs.
1216371	4/15/2021	GA	38	F	4/13/2021	4/15/2021	I have very regular and reliable menstruation patterns and had finished my menstruation bleeding 8 days before this injection and was beginning to shed the mucous lining that traditionally follows all blood products. Today, April 15, I have begun spotting again and passing small clots. I feel fine otherwise with the exception of standard injection site discomfort.
1216052	4/15/2021	NY	34	F	3/31/2021	3/31/2021	Approximately 5 hours after the vaccine I developed a very bad headache followed by chills, sweats, congestion, chest pain, body pain, muscle pain, fatigue and fever. The muscle pain and weakness was so bad I would loose balance when walking. I then started to menstruate clots, not my normal cycle timing, which lasted about 2 days. The clots subsided but I am still bleeding today. I was in bed for 4 days with severe immune response symptoms. After those symptoms subsided the fatigue was so extreme it was hard to function.
1216090	4/15/2021	NY	78	F	4/2/2021	4/4/2021	The patient received her Moderna Covid vaccine and a couple of days later she had shortness of breath and was brought to the hospital a couple of days later. They found multiple blood clots in her lungs. The hospital discharged her too early and she had to go back, They told her to get her second dose on her regular scheduled date.

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1216137	4/15/2021	SC	67	M	3/28/2021	4/10/2021	The patient called to make us aware that he was diagnosed with a blood clot on Saturday and he wasn't sure if there was a connection or not but wanted us to report it.
1216189	4/15/2021	CA	78	F	4/1/2021	4/2/2021	78 year old woman admitted with severe back pain, inability to ambulate and leukocytosis on 3/31/21. History of hypertension, CHF, obesity, chronic kidney disease, and back pain. Work up included multiple consults. The patient was placed on SQ heparin for VTE prophylaxis. Acute L5 fracture was found along with emphysematous changes. Neurosurgical evaluation- no surgery was necessary. During the first 24 hours (before receiving the vaccine), the patient's Hg dropped 9.3 to 6.8 and platelets dropped 130K to 61 K with no apparent bleeding source. PRBC transfusion was given. GI consult was obtained the patient was scheduled to have EGD the following morning (day 3). Cardiology was obtained for elevated troponin and hypoxia. An echo obtained on day 2 showed moderate elevated pulmonary artery pressure, mild to moderate tricuspid regurgitation, and normal sized right atrium and ventricle. The patient received the Janssen vaccine upon request the morning of hospital day 2 (4.1.21 at 11:02). At 11:37PM on 4/1/21 the patient received 5mg IV metoprolol for elevated HR of 132 (BP 129/67). At 0128 on 4/2/21 the patient's heart rate dropped into the 60's and then declined further requiring cardiac resuscitation. The attempt was unsuccessful and the patient expired at 01:43 on 4/2/21. An autopsy was conducted (results available on 4/13/21) showed a 4 cm clot in the patient's right atrium and a mural thrombus in her femoral artery.
1216288	4/15/2021	CO	65	M	3/20/2021	3/23/2021	Patient received first Moderna mRNA vaccine 2/20/2021, second Moderna vaccine 3/20/21. Severe flulike symptoms after Moderna vaccine intermittently over 1 day. 3/23/2021 chest pain hospitalized severe pericarditis 750 mL. Also cardiac Cath Lab one of his blood vessels 80% occluded (I do not currently have hospital report) coronary artery stented. Failed Plavix of in-stent thrombosis and myocardial infarction recatheterization fixed thrombotic stent. Following couple weeks has had recurrent pericarditis requiring several hospitalization recurrent chest pain including recently requiring pericardial window.

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1216324	4/15/2021	WI	40	F	4/8/2021	4/15/2021	Exactly 1 week from vaccination, menstruation began approximately 2 weeks before schedule and roughly 10-12 days after date of start of previous cycle. Heavy with many clots, extreme fatigue, headache, and heavier than usual cramping. Completely unexpected and NOT accompanying any usual, predictable signs of PMS or anticipated cycle. Women need to know this is happening.
1216365	4/15/2021	NY	65	F	3/25/2021	4/13/2021	Pt was admitted to the hospital on 4/13/2021 after being found to be covid 19 positive. She reported fever, cough and chills. she was febrile 101.2 and tachycardic. She was discharged home on 4/15/2021 on xarelto 10mg for 30 day and decadron 6mg for 3 more days. She was given regeneron during her hospital stay. It was also noted that she had a superficial venous thrombosis of the right greater saphenous vein extending into the upper thigh to the upper calf.
1216439	4/15/2021	TX	50	F	4/4/2021	4/12/2021	Severe headache 2 days in duration with associated nausea and vomiting, admitted with hypertensive urgency, Cerebral Venous Sinus Thrombosis diagnosed via MRV and CTA
1216452	4/15/2021		75	F	3/10/2021	3/20/2021	within 10 days I had severe breathing problems that lasted about 4 days, had test that revealed blood clots in my lungs about a week after

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1215648	4/15/2021	CA		M	2/1/2021	3/27/2021	bruises are darker than normal since he has started Eliquis; Constipation; swollen index finger and swollen toe/determined to be gout; felt lousy; This is a spontaneous report from a contactable consumer, based on information received by Pfizer. This spontaneous case was reported by a physician and describes the occurrence of GOUT (swollen index finger and swollen toe/determined to be gout), FATIGUE (felt lousy), CONTUSION (bruises are darker than normal since he has started Eliquis) and CONSTIPATION in 92-year-old male patient who received apixaban (Eliquis) tablet (batch no. 1790398) for Venous thromboembolism. CO-SUSPECT PRODUCTS included Covid-19 Vaccine for an unknown indication. The patient's past medical history included Large intestine infection, Hypercoagulability and Constipation. Concurrent medical conditions included Gout. In February 2021, the patient started Eliquis (batch no. 1790398) (Oral) at an unspecified dose twice a day. On an unknown date, the patient started Covid-19 Vaccine (unknown route). On 27-Mar-2021, the patient experienced FATIGUE (felt lousy). On 29-Mar-2021, the patient experienced GOUT (swollen index finger and swollen toe/determined to be gout). On an unknown date, the patient experienced CONTUSION (bruises are darker than normal since he has started Eliquis) and CONSTIPATION. The action taken with Eliquis(Oral) was unknown. At the time of the report, GOUT, CONTUSION and CONSTIPATION outcome was unknown and FATIGUE resolved. For Eliquis(Oral), the reporter did not provide any causality assessments. The reporter stated that he was put on Eliquis for ninety days and has used it for thirty days so far. He has had some issues that require an enema. Concomitant medications included: dark Cherry Extract - started on or after 29-Mar-2021. The reporter stated that he had been taking Eliquis for 45 days for blood clots that stemmed from a colon infection with secondary hypercoagulability. On Saturday 27-Mar-2021, the patient had his second injection of the Pfizer Covid vaccine. After receiving the vaccine, he said he felt lousy and had common side effects for a vaccine that lasted for about 2 days. On 29-Mar-2021 he woke up with a swollen index finger and swollen toe and this was determined to be gout. The gout in his index finger he had before. The patient stated that whenever he got bruises he had noticed that the bruises were darker than



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							normal since he had started Eliquis. The patient also stated that he has had considerable constipation that started before Eliquis, but still persisted at times and he had treated with enemas. Patient was a retired physician. Follow-up (30Mar2021): This is a follow-up spontaneous report from a contactable physician, based on information received by Pfizer. Most recent follow-up information was received from a physician on 30-Mar-2021 included the following: the event adverse event nos was amended as information on adverse events were received, new events and suspect product added, patient attributes, medical history, product attributes and narrative updated.
1213360	4/15/2021	UT	71	F	3/1/2021	3/16/2021	First Pfizer vaccine on 02/04/2021, Second Pfizer on 03/01/2021. No reaction until 1:00 on Mar 16, 2021, while drinking a smoothie I experienced a severe (level 8-9) pain in my right lower quadrant of my stomach. The pain never let up, thinking it was the Greek Yogurt not agreeing with me, I took 2 Tums followed by Daily Ease and laying down with a heating pad. After 6 hours of the pain we went to the ER. Given Dilaudid through I.V., took pain away. Had CT scan which showed a grapefruit mass in the Cecum area, an ultrasound confirmed this. Mar 17, 2021 had a colonoscopy and was told by the G.I. doctor it was a cancerous tumor and would need surgery the following week. The surgeon later suggested it could be a lymphoma in the colon, still requiring surgery. A CT scan on 03/18/2021 of my lungs showed all clear. I was discharged on 03/18/2021. The pathology report showed only dead tissue and would require another colonoscopy, done on 03/26/2021. The conclusion was a BLOOD CLOT.
1215851	4/15/2021	CO	87	F	3/4/2021	4/5/2021	deep vein thrombosis pulmonary embolism

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1214484	4/15/2021	SC	35	F	3/7/2021	3/31/2021	35yo G2P2 s/p term spontaneous vaginal delivery @ 38 wks gestation. On postpartum day #2, complained of pain and palpable varicosity behind lateral left knee. Doppler studies revealed superficial venous thrombosis, no DVT. Patient discharged on postpartum day #2 on prophylactic Lovenox daily. Patient Rh-negative - received Rhogam 1/22/21 during pregnancy and again after delivery. Otherwise, had no maternal complications this pregnancy. After the fact, pt notes that she has a sister with a history of unprovoked DVT in the past.
1216440	4/15/2021	VA	28	F	4/12/2021	4/12/2021	The evening after the first COVID vaccine dose, my sister noticed dark stained vaginal discharge, resembling beginning or late stages of the menstrual cycle. This continued for 2-3 days; with dark clots, with every wiping, and on underwear. Her menstrual cycle had finished for 8-9 days.
1215349	4/15/2021	MD	67	M	3/10/2021	3/11/2021	Stroke resulting from Blood Clot . Hospitalized at Hospital for three days.
1214423	4/15/2021	IN	55	F	3/20/2021	3/31/2021	Charlie horse began 10 days after vaccine, leg felt full with cramping not allowing motion, went to ER diagnosed with blood clot in left calf
1214428	4/15/2021	TX	68	M	3/12/2021	3/24/2021	Patient has blood clot
1214468	4/15/2021	CA	77	M	1/24/2021	1/28/2021	Deep venous thrombosis. Weight loss, severe fatigue
1214571	4/15/2021	LA	62	F	3/30/2021	4/1/2021	Started on April 1 I was hurting in m y grove area, Friday April 2 I went to the clinic I had my shot at. They did a chest extra to make sure I didn?t, have a blood clot. When home on Saturday I could hardly walk and get up on my own. It would rotate to both hands and wrist couldn?t bend my fingers. Went to Dr took labs if need contact physian. Went to ER twice and gave me a steroid shot. Gave me pain medicine and medpack
1214577	4/15/2021	VA	49	F	4/8/2021	4/14/2021	RLE thrombosis of greater saphenous vein

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1214597	4/15/2021	CO	56	M	2/3/2021	2/23/2021	2nd dose Moderna administered on Feb 3rd, fatigue/ shortness of breath week of Feb 23rd, admitted to Hospital on March 1st, spent 18 days in ICU, developed Blood CLOTS which one attached to lung, blood clots In left leg as well, no family history of blood clots and no injuries to cause blood clots.
1214605	4/15/2021	OH	43	M	3/17/2021	4/12/2021	Bilateral pulmonary embolism which was diagnosed on 4/14/21 after 2 days of severe shortness of breath. Associated with hypoxia requiring supplemental oxygen. Patient is morbidly obese which is only other risk factor for pulmonary embolism. He denies history of increased sedentary activity, denies recent travel, denies known history of a hypercoagulable disorder or family history of blood clots. No other causative factors for the pulmonary emboli have been identified.
1214606	4/15/2021	DE	55	F	3/27/2021	3/27/2021	4 hrs after onset of severe headache and body pain in lymph nodes under arm pit breast, on top of kidneys and in stomach fatigue low fever. After 4 days of that I got a really super heavy period with cramping and blood clots in my menstrual flow. It was a horrible period, while the one after the surgery in Feb was very light. Dizzy and fatigue 10 days after shot on the April 8 I took a fall from a chair outside, and from Thursday to the Saturday 10th I ended up in the Emergency room with a concussion and head symptoms including dizziness and nose bleeds. This was from a simple fall, and i suspect the covid shot might have caused complications after the fall with additional swelling and bruising.
1214679	4/15/2021	NC	29	F	3/8/2021	3/24/2021	cerebral venous sinus thrombosis
1214697	4/15/2021	TX	82	F	3/15/2021	4/12/2021	Janssen COVID-19 Vaccine EUA Patient received J&J COVID Vaccine on 3/15/2021 per vaccine card. Patient had an ED Visit on 3/17/2021 for a chief complaint of lightheadedness and was diagnosed with Pneumonia with Chest X-ray showing small bilateral pleural effusions with underlying atelectasis or consolidation. On 4/12/2021, Patient presented to ED as instructed by outside physician for finding of blood clot on CT the morning of 4/12/2021 (Pulmonary emboli at the left upper lobe). The patient had CT scheduled during an office appointment on 4/5/2021. Patient admitted for treatment of pulmonary embolism.

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1214710	4/15/2021	VA	64	F	3/13/2021	4/15/2021	Headache. Severe , burning, nerve pain in neck shoulders and both arms . Right arm swollen from elbow to wrists. Went to Dr. on 3-19-21 . Told to return in 3 days if not better. They said pulse was ok so prob not a clot. I had pain for two weeks but did not return. At end of two weeks swelling gone . Still some residual pain in right arm, but not constant.
1215016	4/15/2021	IL	62	M	3/13/2021	3/22/2021	I received the Janssen vaccine on March 13. By the next weekend, I had what I thought was a spider bite on the inside of my left thigh. That "bite" got worse--bigger, hot to the touch, and then red. On the weekend of the 27-28 of March, it was red, raised and very painful even when not touched. I called my family doctor on Monday morning, the 29th of March, and I was sent to the Emergency Room, where I was diagnosed with a 7cm thrombosis in my left greater saphenous vein, which is treated the same as a DVT. I was treated first with Lovenox injections, then Eliquis 10 mg 2x daily, now 5 mg 2x daily. The blood clot is still painful to the touch.
1215073	4/15/2021	MD	65	F	3/10/2021	4/10/2021	On 4/10/21 to Urgent Care. Found blood clots in my lungs and Pneumonia, Clots removed at Hospital on 4/11/21. Hospitalized until 4/13/21. Treatment - blood thinners (enoxaparin, heprin and steroids), azithromycin, Advair disk, albuterol, Spiriva, Symbicort Outcome: Still trouble breathing, slow moving and sore from the incision.
1214739	4/15/2021	OR	43	F	4/9/2021	4/12/2021	I had the the vaccine on Friday then Monday i had a stroke from a blood clot
1215158	4/15/2021	OK	53	M	4/7/2021	4/10/2021	Patient developed a blood clot
1215019	4/15/2021	AZ	65	M	4/2/2021	4/13/2021	Patient right leg became very swollen from knee down and was very painful to walk. Patient went to Urgent Care and was told that he would need to have ultrasound done to see what was going on. Patient went to Imaging and was told that he had several blood clots through out his right leg. They advised him to go to emergency room evaluation. Patient went to Medical Center and it was confirmed that patient had blood clots and was put on Xarelto for treatment.

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1215014	4/15/2021	MI	50	F	4/9/2021	4/12/2021	Monday started having swelling behind my neck between my two shoulders and then a headache began. Went to Healthcare expressed by the doctor did not think it was blood clot, but probably related to the vaccine. Gave me a steroid and muscle relaxer sent me home to call provider next day. Had Televisit with primary?s Wednesday April 14, 2021, by then news had broke about the new type of blood clot CVST and the low platelet count, I explained still had headache and swelling, sour stomach over night(have had this before) and felt weak for a brief few minutes on right side but quickly went away, also was walking for a brief few minutes like I was drunk, again went away after a few minutes. Discussed with primary my anxiety could be contributing to some of the extra feelings I was having, agreed to do bloodwork to check platelet levels. She did not think it was blood clots discussed with me about what I needed to look for and to go to ER immediately if I experienced any of them. Blood work did today, Thursday April 15, 2021. still headache and some swelling in back of neck between shoulders, dizzy off and on. All pain moderate to mild. Awaiting blood work for next step.

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1214990	4/15/2021	RI	74	F	4/6/2021	4/11/2021	5 pm on Sunday, I started getting pains on my lower leg. Not like an ache. All up and down the inside of the leg (the pain was). There was a pressure point where I found a point where if I pressed it, it was really painful. My skin - the inner leg towards the back - it was really really sensitive. If you touched it lightly it felt painful - not a searing pain. If I massaged it, it would go away but in a few minutes it would come back. I took an aspirin in case of a clot. At this time, I was thinking of deep vein thrombosis. Gradually, it went away. It lasted quite awhile - it lasted between 2 or three hours like this. Even now, the skin isn't sensitive, but I can still press that one point and it hurts. (That pressure point.) I went to the Doctor on the 13th, he sent me to an Ultrasound there wasn't a clot in the leg. That came out fine. When I had the IBS for four months (with a lot of diarrhea). I just found out yesterday that my magnesium was low and they gave me a drip for that. My potassium was a little low also. I had the magnesium drip last night - it was an Hospital ER visit - but it was for bloodwork that had been done yesterday to check me after IBS symptoms.
1214815	4/15/2021	OH	44	F	3/11/2021	3/24/2021	Patient started not feeling well on 3/24. She was experiencing dizziness, headache, chills and fever. She contacted her doctor on 3/25 and he thought maybe she had an inner ear infection. Symptoms continued to worsen and eventually an ambulance was called on 3/27 because patient stated she was having severe SOB and headache along with dizziness and fever. Patient was transported to Hospital where they tested her for covid and pneumonia. Both came back negative. After several tests it was confirmed she had a blood clot in her lung and was also told she had clots in her leg and heart as well. She was in the hospital for 3 days where she was given heparin and several medications for the headache. Patient was discharged on lovenox and coumadin and eventually switched to xarelto by pcp who is managing her anticoagulation. She still has follow up appointments with a cardiologist and neurologist. She said she is still experiencing some dizziness and SOB but overall doing better

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1214759	4/15/2021	GA	54	M	3/15/2021	3/26/2021	Pain, swelling left knee found to be a blood clot when he went to the Emergency Room at hospital. Visit was on 3/31/2021 Treatment with rivaroxaban and bed rest. Pain and muscle spasms persist as of 4/15/2021
1214942	4/15/2021	PA	44	F	3/15/2021	3/15/2021	Ongoing throbbing headache since 20 minutes after vaccine was administered. No previous history of headaches like this. Went to ER and ruled out clot via MRI/MRV and was given cocktail injection with Benadryl, Gadoteridol, Ketorolac, with improvement of headache for 5 hours.
1214894	4/15/2021	OH	51	M	3/27/2021	4/5/2021	Transient Ischemic Attack acute CVA Stroke caused from blood clot to bottom left of the cerebellum.
1214852	4/15/2021	KY	72	F	2/21/2021	2/22/2021	2/25--4 days after second COVID vaccine patient visited ED for c/o SOA and dyspnea. Chest CT shows "small sized pulmonary emboli in the right middle lobe branches", Venous doppler shows "venous thrombosis involving the right posterior tibial venous segment". Hospitalized for 2 days--discharged home.
1214952	4/15/2021	MN	50	M	3/5/2021	3/15/2021	10 days after 1st shot. Blood clot traveled to right lung. Placed on blood thinners, and pain meds, follow up treatment scheduled for mid May. Unknown reason for blood clot. No prior injuries or surgery.
1207994	4/14/2021	CA	71	M	3/26/2021	3/28/2021	Blood Clot on back of leg
1208026	4/14/2021	IA	31	M	3/26/2021	4/7/2021	Patient received vaccine through pharmacy at employer vaccination event. Presented to clinic on 04/13/2021 and noted to have imaging confirmed "There is occlusive superficial clot starting the upper lateral right thigh and extending distally through the mid to distal lateral calf. This appears to be within a superficial varicosity. Findings are consistent with extensive superficial thrombophlebitis of a varicose vein of the right lower extremity.~~
1208046	4/14/2021	GA	52	F	3/21/2021	3/31/2021	Severe r sided abdominal pain and headache. Was seen in ER, labs and spiral, renal protocol, CT negative. No evaluation for clots was done.

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1208082	4/14/2021	MA	92	M	3/8/2021	3/23/2021	Pt had AFIB and was on ELIQUIS 2.5 mg BID. He began to bleed, a lot. We stopped DOAC, discussed possibility pt might die from blood clot without the DOAC. He had vaccine after stopping DOAC (stopped DOAC 2/24/21). On 3/8 he had the Janssen Vaccine. On 3/15 he awoke w weakness, inability to speak. Transferred to hospital where he was diagnosed w having major stroke, admitted to hospital. They decided NOT to use anticoagulant because he had too great a risk of bleeding.
1208107	4/14/2021	PA	74	M	3/7/2021	3/7/2021	Patient noticed blotches on both legs approximately 6 to 7 days after vaccine was administered. On 03/30/2021, patient fell to ground, unable to get up. Patient was taken by ambulance to Hospital emergency room. Scans revealed patient had multiple blood clots and was operated on. Later in the stay, patient developed widespread hematomas in groin, stomach, rear, and both legs. Patient was released from hospital on 4/8/2021.
1208225	4/14/2021	CA	69	F	2/6/2021	2/23/2021	Weakness in left leg, blod clots in lungs, severe headaches continuing I went to emergency on February 23, 2021 where I treated for weakness in left leg and was admitted to hospital where I received treatments for a double pulmonary embolism on March 1.
1208174	4/14/2021	AL	28	F	4/7/2021	4/7/2021	Vomiting for 48 hours, nausea, headache, chills, fever 102 for two days; period started and bleeding increases daily. Vaginal bleeding still heavy with dime size clots.
1207821	4/14/2021	SC	39	F	4/8/2021	4/8/2021	Vaccine 4/8 @ 3:15 pm Local injection site pain 4/8 @ 6:30 pm 4/9: upon waking (6 am) pain and local heat at injection site; all over muscle pain; all joints in pain; temporary fever over 99 F briefly 12 pm - 12:30 pm 4/10: upon waking (7:30 am) all pain gone other than knee discomfort. knees appeared normal, but had fluid buildup preventing full range of motion. Knee fluid and inability to kneel due to pressure and pain persisted through 4/13. Began taking ibuprofen 400 mg 4/13 morning at 4 hours intervals. Noted reduction in swelling of right knee after 5 hours. No change in left knee. 4/14: noted minor reduction in knee swelling of left knee upon waking at 6 am. Consulted NP 4/14 @ 9:30 am. She suggested increasing dose to 800 mg every 8 hours for up to 5 days, wrapping knees for compression and ordered an ultrasound for blood clots



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1208253	4/14/2021	TX	82	M	1/7/2021	1/19/2021	He suddenly suffered a severe stroke/blood clot in brain on January 19, 2021 which was 12 days after he received his first dose of the Moderna vaccine. He went via ambulance to hospital and was inpatient there at Hospital for 2 nights.
1208261	4/14/2021	NH	32	F	1/16/2021	2/5/2021	Acute bilateral deep vein thrombosis and bilateral pulmonary emboli
1208115	4/14/2021	CO	60	F	3/18/2021	4/1/2021	on 03/22/2021 I had a red inflamed area on left Achilles tendon area, off work for two days, negative US for DVT I had twisted my knee on 03/29/2021, negative DVT MRI meniscus tear I got a blood clot behind my left knee on 04/04/2021 left calf started hurting on 04/01/2021, got intense on 04/04/2021 went to UC US was positive for DVT I have never had one, no health issues, was advised to report blood clot
1207984	4/14/2021	NY	67	F	2/14/2021	2/15/2021	I did not feel well starting the day after my second Moderna shot, 2/15/2021, arm swollen, hard and red throughout week. Started having difficulty breathing within a couple of days, brushed it off and tried to function as normal but by 2/21/2021 I could no longer function and had difficulty breathing if I tried to do anything and went to emergency room. Diagnosed with multiple blood clots in both lungs.
1207898	4/14/2021	IL	56	F	4/7/2021	4/7/2021	Left arm and left neck/face tingling, decreased sensation with subsequent Bell's palsy like facial asymmetry on the left side, brain fog, dizziness with position changes, pressure in head when bending over behind the left eye, aching pain in left arm, fullness in the anterior lower right neck, episode of visual stars, food and drink dripping/falling out of left side of mouth, Pain in left rib cage/chest into the left back causing her to breath shallower. ER evaluation confirmed CT finding of right superficial vein thrombosis just above the sternoclavicular joint - see imaging report info.

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1207891	4/14/2021	MS	60	F	2/1/2021	2/1/2021	Took the moderna 1st test and within two hours of the vaccine, between the forefinger of my left hand and the thumb began to swell, tighten. I observed it, it appeared to be a large clot, it stiffened almost paralyzing the area between these two fingers, it hurt, and then as suddenly as it came it left. No further on the first vaccine. On the second vaccine in the same hand, a day after the shot, my left hand swelled from the wrist to the fingers but especially in the area of the back of the hand. it nearly paralyzed moment in the hand, for at least two days. it hurt extremely when I would attempt to move the hand back at the wrist, to move the hand in any way. I took two motrins on the second day and it went away as suddenly as it began. I have not had any other problem to date
1207773	4/14/2021	IN	71	M	2/26/2021	3/15/2021	2nd moderna vaccine was given to my dad on 02/26/2021 and on 03/15/2021 my dad was visiting me all day and he acted fine and normal. At the end of our visit between 8 & 9 pm we went to the store where he started to gasp for breath. He had to keep stopping and said he couldn't breath. I had him sit several times because I didn't know how bad it was. By the time we reached the doors to leave after a short trip he almost fell over and he became confused and said he couldn't breath. I had another customer get my dad a wheel chair close by while I called 911. The ambulance came quickly but at the hospital my dad went into cardiac arrest and his heart stopped 2 or 3 times and it had to be restarted. When I was able to get to the hospital my dad was on a ventilator and sedated. They had put him on medicine to blast the blood clots they had found. They said he had 2 very large blood clots with one on each lung. Later his kidneys started failing him and they said he would need to go on dialysis as soon as the next day. Later that night they told me my dads heart was shutting down and he had developed pneumonia. My dad died that night and I had to watch him take his last breath. If you want further information please contact Medical center would be the ones to contact for all information and my dad was in the critical care unit.

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1207844	4/14/2021	NY	77	M	2/26/2021	2/28/2021	He got the vaccine, and didn't have any real reaction, anything unpleasant, he had a numb lip and 2 fingers were numb. He called his doctor and she told him to go to the ER, which he did at Hospital. They did a CAT scan of his brain. They tried to do an MRI and they pushed his head against the machine as his back is curved and he stopped breathing. They had given him 2 narcotics for anxiety before the scan. He was then transferred to Hospital in . He saw Cardiophysilogist/IM and he found that he had a blood clot (? where), and they inserted a pacemaker through his groin as his pulse dropped to 40 BPM. He was hospitalized for 7 days, and discharged him with instructions on what he is able to do. They started him on new blood pressure medicines for his kidney's. On 3/26/21, lot# 028A21A. He subsequently had the 2nd vaccine, and all liquids emptied from his body (vomiting and diarrhea), at the same time, and then he was fine once everything settled down which lasted for about 3-4 minutes and then he was fine.
1207793	4/14/2021	TN	49	F	3/16/2021	3/21/2021	About a month after the shot, I developed a blood clot in my lung. The clot was found by a CT scan. I am currently taking Eloquis to hopefully dissolve the clot. I have been overly tired with little energy and some muscle/body aches.
1207778	4/14/2021	TN	33	F	4/9/2021	4/9/2021	PATIENT RECEIVED JANSSEN VACCINE ON 4/9/21. 10 HOURS POST-DOSE PATIENT REPORTS FLU LIKE SYMPTOMS AND 4 EPISODES OF SYNCOPE. SHE THEN REPORTS PAIN IN LEGS AND ABDOMEN. ULTRASOUND OF LEGS WERE NEGATIVE FOR BLOOD CLOTS. TODAY 4/14/21 SHORTNESS OF BREATH HAS NOT IMPROVED AND PAIN IN LEGS IN ABDOMEN HAS NOT IMPROVED. PATIENT IS GOING TO ER FOR EVALUATION.
1208285	4/14/2021	WI	72	M	2/17/2021	3/5/2021	Blood clot in brain caused stroke
1208555	4/14/2021		18	F	4/9/2021	4/12/2021	multiple large blood clots from her nares on Monday 4/12

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1207738	4/14/2021	TX	65	M	4/12/2021	4/14/2021	Pt states that he had some stomach pain as well as slight leg pain. I instructed him to call his doctor and let them know because it might be signs of a clot and out of caution the doctor might want to see him.
1207850	4/14/2021	CA	29	F	3/18/2021	3/19/2021	Severe menstrual pain although I was not actively on my menstrual cycle. Ended period on 03/11/2021 and started heavy brown clot like bleeding one day after second dose on 03/19/2021. After second cycle one month later in April, have severe severe cramping and menstrual pain.
1208468	4/14/2021	NY	45	F	4/9/2021	4/9/2021	DAY 1- two hours after vaccine my right arm and right leg felt restricted, numb and had some tingling in my hand, dull headache, muscle pain and dizziness. Day 2- mild pain at injection sight, muscle pain and general tirednes, dull headache,dizzy, right arm& left arm felt restricted and numbness in right pointer finger. Right leg felt restricted and pain behind the knee. Day 3- dizzy, dull headache, faint, high blood pressure, right arm & leg and left arm felt restricted and numbness/tingling in right hand. Pain behind right knee persisted. Went to ER Sunday early afternoon. Diagnosis is a cerebral venous thrombosis in sinus cavity. Still experiencing general weakness/tired, dizzy/unbalanced.
1207088	4/14/2021	FL	54	F	3/22/2021	4/5/2021	The week of April 5, I believe it was April 5 & 6, I thought that I was coming down with a sinus infection. I was having some blood when blowing my nose and remember seeing some small, hard balls which I now realize were clots. I did not go to the doctor because my back was very bad and I was in a lot of pain and I had an upcoming appointment with my doctor. I believe that the symptoms resolved after 2 or 3 days and I did not even mention it to my doctor when I saw him. I felt a lot of pain in my leg, but this is probably due to my ongoing sciatica/radiculopathy /bursitis problems that I experience.

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1207707	4/14/2021	OH	46	F	3/25/2021	3/31/2021	I was sick the day after both vaccination, just flu like symptoms the following day. Approx 5 days later I woke up and my right leg was sore, all the way down my inside vein. I had varicose veins in this leg for years, but this was different. It was painful, swollen, red, warm and the vein is hard. I was scared a DVT may be developing and went to the ER. An ultrasound showed there was no DVT and was told to take ibuprofen for the pain and heat to the leg and a diagnosis of Thrombophlebitis. I followed up with a vein doctor. He performed an extensive ultrasound, showing a watch spot for a possible clot turning into a DVT and placed me on blood thinners for 6 weeks, and to wear compression hose. I know I had previous varicose vein problem in this leg and the vaccination did not cause this, but I do think it caused the Thrombophlebitis. I am reporting this because this should be looked into, there are others with vein issues that maybe should be aware of this possible side effect.,
1208759	4/14/2021	LA	56	F	2/22/2021	2/27/2021	Blood Clots in both little toes. Eliquis 5 mg, Gabapentin 300 mg, Tramadol 50 mg.
1208750	4/14/2021	OR	77	F	3/10/2021	3/24/2021	Fell two weeks after immunization. Developed blood clot after procedure. Husband concerned immunization is cause of clot and not the surgery or down-time after the procedure. Transferred to new hospital from previous hospital and had significant stroke due to clot
1208715	4/14/2021	TN	68	M	1/20/2021	1/24/2021	Swollen right leg in AM four days after vaccine. Diagnosis of DVT next day, five days after vaccine. Have been on eliquis for about 4 months. Leg is still swollen. Not surprising since the covid spike protein causes blood clots.
1208701	4/14/2021	CA	65	F	3/1/2021	3/22/2021	Migraines, lung infection, blood clots, pain in lungs, shortness of breath.

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1208676	4/14/2021	TX	55	M	4/3/2021	4/3/2021	Approximately eight hours after receiving the shot, I started getting a headache, body aches, and chills (April 3rd, 8 p.m.). I went to bed and had severe chills and body sweats for the entire night. The primary symptom to report is that my heart raced all night. It felt like it was beating at about 140 to 150 Hz or higher. When I woke up in the morning, it felt like my chest had been pounded on all night. The pain was in my sternum area. The headache and body aches took a little over a day to go away. The chest pain took a couple of days to die down. On April 12th, I walked my dogs in the morning and felt out of breath, which isn't normal for me. In the afternoon, while working at my desk at home, I started getting more and more severe chest pain and then started getting dizzy and felt weak. I drove myself to the local ER and they tested me for a heart attack. All tests came back negative. They suggested going to another facility to get checked for clots or to make an appointment with a cardiologist. The next day, after talking to a doctor friend, he suggested going to the ER facility to get imaged for clots and to get fully checked out. No cardiologist appointments were available till the next week. I went to the ER facility and was there for seven hours getting tested. They came back and said all test results were negative and that my heart looked fine. They did not have any suggestions for what might be causing the pain in my chest.
1208654	4/14/2021	WI	87	F	3/12/2021	3/15/2021	Patient presented 3 days after her second DuoNeb vaccine with weakness dizziness chest pain or shortness of breath and was initially diagnosed with a pneumonia by chest x-ray obtained with antibiotics without improvement. Subsequently she was hospitalized and CT of the chest showed left lower lobe segmental pulmonary embolism. The patient never had history of venous thromboembolism in the past. She had weakly positive anticardiolipin antibody of IgG type of unknown significance. She was treated initially with antibiotics but after diagnosis of the blood clot she was started on anticoagulation with apixaban with improvement

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1208579	4/14/2021	NY	79	F	1/31/2021	2/3/2021	Developed blood clot in heart -- > went into Atrial Fibrillation with no prior history of A Fib -- > Large clot was thrown from the heart into the brain splitting into two clots, one blocking brain stem and one blocking right hemisphere -- > Death on 2/10/21
1208490	4/14/2021	AZ	28	F	4/5/2021	4/9/2021	The day I received the shot, I started to feel severe fatigue, headache, light-headed, and started running a fever about 6 hours after the shot was administered. The next day (4/6) was worse. Severe fatigue, muscle aches, headache, loss of appetite, fever (101.5 was the highest I notice but seemed to be around 101.1-101.3 all day), and general flu like symptoms. However, I also started experiencing abnormal menstrual bleeding. I am on the Depo shot and have been for some time. Due to this, I do not usually experience any menstrual bleeding so I found this to be a little odd. It was not heavy but it was noticeable and contained quite a few clots. Day 3 (4/7) was about the same except my fever came down and ranged from 99.8-101.1. Abnormal menstrual bleeding continued. New side effect this day included diarrhea. Day 4 (4/8) I started to see improvement. No fever (that I could tell). Remaining side effects included mild headache, fatigue, diarrhea, and abnormal menstrual bleeding. Day 5 (4/9), I had one of the worst nose bleeds I've ever had in my life. I apologize for the graphic description but it lasted about 20 minutes and my bathroom looked like a crime scene after. Blood was pouring out of my left nostril and I threw two large clots that were about the size of slug (or slightly larger than a fun size snickers... I wish I had a better way to describe it). I've had some bad nose bleeds, particularly when I was on Accutane, and this was worse! The rest of the day I felt like I was improving. Energy levels were better. No fever. Menstrual bleeding stopped. Only lingering side effect was mild headache and mild diarrhea. Since then I've continued to feel better and the diarrhea seems like it's improving. Mild headache persists. Only new item is an annoying twitch in my left eye that started on Monday (4/12).

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1208484	4/14/2021	WA	87	F	3/24/2021	3/24/2021	3hrs after the patient's vaccination, she fell to the floor and was unable to get up, noted to have R sided facial droop, inability to speak, R sided weakness. Found to have a large stroke with left sided M2 MCA clot noted on CT angiogram.
1208289	4/14/2021	FL	32	F	4/2/2021	4/6/2021	Approximately one week after receiving the second dose of the vaccine my wife felt a pain in her left leg. The pain did not feel like a muscle pain and continued for a few days. She went to an urgent care and an MRI of her leg was conducted. She was diagnosed with a blood clot and has begun treatment. My wife is healthy, young and has no family history of blood clots prior to this incident.
1208463	4/14/2021	PA	45	F	3/13/2021	3/29/2021	I had horrible pain in my left calf that travelled to my thigh. I went to the hospital 2 weeks later and found that I have a blood clot in my lower leg (front ankle area). I am on blood thinners and will be seeing a Hematologist.
1208432	4/14/2021	CA	84	F	3/1/2021	3/4/2021	Pt presented with acute onset of right vision loss. She was seen by ophthalmology and diagnosed with central retinal artery occlusion. She had to be changed to warfarin as this clot developed while she was already on eliquis. She still has some vision loss.
1208402	4/14/2021	CO	82	F	1/30/2021	3/25/2021	Patient presented to ED ~2months after 2nd Moderna vaccine with multiple subsegmental PEs as well as small popliteal and calf vein thrombosis. Admitted for 2 days for anticoagulation then sent home on oral anticoagulation in stable condition. No history of thrombosis.
1208368	4/14/2021	UT	33	F	4/5/2021	4/12/2021	Upper abdominal pain started on 4/11/21 and on about night of 4/12/21 left calf pain woke patient up. Patient notified this PCP's office with these symptoms on 4/13/21 at 10:28 at which time patient was referred to the hospital ER due to 6 known cases of women who had received Johnson & Johnson vaccine and developed rare type of blood clots and patient's above symptoms to rule out deep vein thrombus. At the hospital ER provider did physical exam and ordered lab which confirmed patient had no deep vein thrombus. Patient was discharged home with diagnoses of left calf pain and dyspepsia. Patient continues to have abdominal intermittently but left calf pain has been resolved.



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1208347	4/14/2021	NY	62	F	3/5/2021	3/12/2021	4/14/21 Per Patient, received Janssen vaccine on 3/5/2021, began experiencing headaches on side of face and intermittent sharp left leg pain 3/12/2021, does not usually get headaches and thought related to dental work, 4 tooth implants, evaluated by dentist who said headaches not related to dental work, had been more active, walking with nice weather and thought leg pain might be caused by tick bite, left knee "gave out", husband looked at back of leg and did not see any evidence of tick bite, noticed varicose veins had worsened (more prominent, not red or swollen) and thought should be checked, appointment at center 4/8/21 and is under the care of Dr, has follow up appointment 4/21/2021. Placed on blood thinner Xarelto 15 mg tablets, 2 tablets daily x 21 days, then reduced to 1 tablet daily x 22 days for blood clots. Headaches and leg pain improved after starting medication. Signed up for program 4/13/21 after suggested by daughter.
1208319	4/14/2021	NY	50	F	3/21/2021	3/24/2021	The patient is a 50 year old female with no medical problems who developed sudden severe headache on 3/24 accompanied by nausea and vomiting. She presented to urgent care on 3/25 and was considered to be dehydrated and given IV fluids. On 3/27 she developed left hand weakness. On 3/29 she revisited urgent care with residual symptoms plus hand weakness and was sent to hospital where she was admitted and MRV demonstrated Cerebral Venous Sinus Thrombosis of the sagittal sinus, right transverse sinus, and right sigmoid sinus. The left transverse sinus may also be occluded or congenitally absent. There was no evidence of hemorrhage or stroke. The patient was admitted and started on heparin then transitioned to Eliquis and discharged. On 4/3, she had worsening of symptoms consisting of dysarthria, left facial, and worse left arm and hand weakness. She was readmitted to hospital then transferred to hospital for further management.
1208315	4/14/2021	OH	58	M	3/12/2021	3/26/2021	Patients power of attorney called to let us know patient had received Janssen vaccine on 3/12/21 and on 3/26/21 was hospitalized due to a clot and stroke. Patient had history of strokes in past.

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1208308	4/14/2021	TX	63	M	3/5/2021	3/14/2021	Extreme pain in lower R leg, which had had a femoral bypass in May 2020. After a couple days I called my vascular team and they took me into surgery immediately. They did some kind of pharm treatment to break up the clot. Had procedure everyday for 3 days where they ultimately used some balloon device to open up the artery again. Still monitoring, am scheduled for another follow-up next week. I'm still vertical, but they had said the leg itself might be in jeopardy. Not happy with Pfizer, that's for sure.

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1208296	4/14/2021	IN	78	M	4/9/2021	4/13/2021	<p>Patient states on Friday, 4/9, he went to the pharmacy to receive his J&amp;J Covid-19 vaccine. He states on Saturday morning, his R nostril began to bleed, and continued to bleed until Monday. He states on Wednesday, 4/7, he noticed oral sores that at first were not painful, but large. He was worried about it interfering with his shot, but because he had waited so long to get it, he decided to proceed anyway. He denies any fever or chills, no frank diarrhea, but occasional loose stools, without blood seen. He denies HA, vision changes, or focal neuro deficits. On Sunday, 4/11, the patient ended up going to ED to evaluate his epistaxis, the MD attributed it to his elevated BP, the patient reports it being 160s/90s. They gave him new BP medications, which he took, but when he saw the Dr., he instructed the patient not to keep taking his BP meds. When asking the patient if anything correlates with foods he eats, the only thing he can pinpoint it to, would be pico de gallo. He states it has irritated his mouth before. He also reports recently taking his wife's supplement (unknown name) but thinks it is for cholesterol. He took that approximately 1 week ago. No new changes in food habits, mouthwash, or toothpaste. He states once his sores began to get a little painful, he went to buy a special mouthwash for oral sores (unsure name). His only reported allergy is to Lisinopril, which his reaction was a whole body rash. He states they did not pack his nose or do anything for his epistaxis at the ER, but eventually he let the nostril clot with blood. Now he feels fullness in the nare, but does not want to disturb the clot in fear that it will re-bleed. His wife also noticed a petechial rash that began on his BLE, he is unsure when that started. He presented to ED on 4/13, due to his PCP instructing him to be evaluated when he had outpatient labs done and revealed a PLT count of 4,000. In the ED, the patient had normal vital signs. He was transfused one unit of PLTs. He also had a negative head CT. He was also started on decadron 40mg PO daily by heme/onc. Patient tells me today his sores are less painful and feel smaller than usual. Heme/onc also ordered 2 IVIG 1,000 mg/kg/day x2 doses.</p>

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1208528	4/14/2021	TX	33	F	3/18/2021	3/20/2021	3/18?got shot I was terribly sick for 24 hours?throwing up, body aches, hot flashes. I was in bed. 3/20?got period 3/21?I was gushing blood like never before in my entire life. I went through a menstrual cup in 1.5 hours. This excessive cycle lasted for days. My period is normally 3/4 days and this one was 6/7 days. I also passed 3 golf ball sized blood clots. I have never in my life passed a clot, let alone three that size. The next cycle I had a tiny bit of break through bleeding the day I ovulated?that never happens. Then this cycled I have felt crampy and bloated. Like I am going to start my period at any minute but do not. I am expecting my next period in less than a week. But this cycle has been completely abnormal and nothing changed but getting the shot two days prior to it starting.
1206421	4/14/2021	CA	17	M	3/11/2021	3/14/2021	Blood clot in right calf. Noticed pain and knot in calf on Sunday 3/14/2021. It worsened over the next few days. Went to Urgent care on 3/18 and they sent us straight to ER for Ultrasound. In hospital they found it was a clot identified as deep vein thrombosis, and started a treatment of blood thinner and pain medication.
1207166	4/14/2021	MD	42	F	3/29/2021	4/2/2021	I had a sudden, large, spontaneous bruise on the index finger of my left hand with no precipitating incident or injury. It filled the space between my first and second knuckle completely and extended into the finger tip and below the second knuckle. It is only in hindsight that I thought it could be a blood clot, although I am not sure. It resolved on its own with a few days, although I unfortunately don't know exactly when.

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1208808	4/14/2021	IL	33	F	2/19/2021	3/8/2021	January 13th 1st Pfizer - no side effects Feb 19th 2nd Pfizer - fatigue, body aches x3 days, after that tired Week of March, noticed bruising easily all over and bleeding a lot after Botox treatment on 3/18, no aspirin use or OTC supplements Week of March 22, noticed bruising without reason and petechiae, sent message to PCP on 3/31/2021, he gave lab order for CBC and prothrombin April 2nd, got CBC and prothrombin, results showed low platelets at 25,000 and high MPV at 14.5, everything else was normal April 3rd, PCP sent me to ER to verify due to low level, labs there verified low platelets at 23,000, put me on prednisone 40mg QD, advised I see hematology Saw Hematology April 5th, platelets went up to 33,000. All other labs WNL except 11 for white count. NEG hep, hiv, ana, no known cause. Increased prednisone to 60mg.. but could only handle that for 3 days, and went back down to 40mg Saw Hematology on April 12th, platelets up to 120,000 (almost to normal range), white count high (13), neutrophils high, fever 99.5, rib pain upon pressure April 13th, CT Scan of chest WNL April 14th, FULL BODY RASH Ultrasound of abdomen scheduled for 4/21
1207099	4/14/2021	GA	27	F	2/28/2021	4/10/2021	My menstrual cycle came on 5 days early but when it came on I had large blood clots. I've never had my cycle come on early. I take birth control tablets the correct way and the Saturday when I started bleed, I had taken my tablet at my regular time that day. I also usually don't have heavy periods at all so the amount of blood so early was unusual for me.
1208205	4/14/2021	GA	70	F	3/27/2021	4/12/2021	deep vein thrombosis, swelling, pain in both legs and lower abdomen. warm and red skin. red swollen veins.

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1206989	4/14/2021	OH	56	F	3/31/2021	4/3/2021	I HAD THE PFIZER VACCINE ADMINITERED AT FACILITY ON 3/31/21. THIS WAS THE FIRST DOSAGE. ON DAY 5 I HAD PAIN IN MY LEFT LEG FROM GROIN TO CALF. BY DAY 5, I BEGIN TO LIMP, MY LEG WAS BURNING, INCREASED PAIN AND I COULD FEEL WHAT I BELIEVE TO BE BLOOD CLOTS AND MY LYMP NODE IN MY LEFT GROIN FELT SWOLLEN. OVER THE COURSE OF 2 DAYS, THE PAIN BECAME WORSE. I CONTACTED MY DOCTOR AT FACILITY FOR A TELEPHONE INTERVIEW IN REGARDS TO WHAT I STATED ABOUT THE PAIN. CLOTS, SWOLLEN LYMP NODES ETC.. AND EXPLAINED THAT THIS OCCURED AFTER OBTAINING THE COVID-19 VACCINE. I WAS ADVISED TO HAVE A DOPPLER PERFORMED AT THE ER. I WENT TO THE ER LATER THAT EVENING AND WAS TOLD THAT DOPPLERS WERE NOT COMPLETED AFTER 4 P.M. BLOOD WORK WAS PERFORMED BY HOSPITAL. MY LAB WORK WAS NORMAL AND I WAS ADVISED THAT I WOULD BE CONTACTED THE NEXT MORNING FOR AN APPOINTMENT FOR THE DOPPLER. ON 4/8@1:00 PM, I HAD THE DOPPLER PERFORMED AT HOSPITAL. I WAS TAKEN BACK TO THE ER AND WAS INFORMED THAT I HAVE DVT AND THIS WAS POSSIBLY LIFE THREATING. I HAD NO PRIOR HISTORY OF CLOTS. I'M CURRENTLY TAKING ELIQUIS FOR THE BLOOD CLOTS, WEARING A COMPRESSION GARMENT AND TYLENOL FOR PAIN. I WAS ADVISED TO HAVE ANOTHER DOPPLER COMPLETED IN 6 MONTHS

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1206927	4/14/2021	MA	63	F	3/12/2021	4/4/2021	burning sensation in the lung; had labored breathing,they found several clots in right leg and lungs; It was shiny and hard and calf blewup twice the size,they found several clots in right leg; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (had labored breathing,they found several clots in right leg and lungs) and THROMBOSIS (It was shiny and hard and calf blewup twice the size,they found several clots in right leg) in a 63-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 002B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Family history included Clot blood (Family history of clots; her father and his sister had clots after surgery). Concurrent medical conditions included Burning sensation. On 12-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Apr-2021, the patient experienced PULMONARY EMBOLISM (had labored breathing,they found several clots in right leg and lungs) (seriousness criterion medically significant) and THROMBOSIS (It was shiny and hard and calf blewup twice the size,they found several clots in right leg) (seriousness criterion medically significant). On an unknown date, the patient experienced BURNING SENSATION (burning sensation in the lung). At the time of the report, PULMONARY EMBOLISM (had labored breathing,they found several clots in right leg and lungs), THROMBOSIS (It was shiny and hard and calf blewup twice the size,they found several clots in right leg) and BURNING SENSATION (burning sensation in the lung) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Ultrasound Doppler: several clots in right leg and lungs (abnormal) several clots in right leg and lungs. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant products were reported. Patient was taken to the ER (emergency room). The physician suspected blood clots and treatment included was blood thinner. Patient reported that "patient got ultrasound done on Monday, and they found several clots in right leg and lungs".; Sender's Comments: Based on the current available

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1206902	4/14/2021	LA	65	F	3/3/2021		<p>information which includes a strong temporal association between the use of the product and onset of the reported events, and excluding other etiologies, a causal relationship cannot be excluded</p> <p>her left leg was swollen; two red clots on left leg; right feet was hurting; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (two red clots on left leg) in a 65-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. Unknown) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced PERIPHERAL SWELLING (her left leg was swollen), THROMBOSIS (two red clots on left leg) (seriousness criterion medically significant) and PAIN IN EXTREMITY (right feet was hurting). At the time of the report, PERIPHERAL SWELLING (her left leg was swollen), THROMBOSIS (two red clots on left leg) and PAIN IN EXTREMITY (right feet was hurting) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.</p>



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1206894	4/14/2021	TX	54	F	3/26/2021	3/26/2021	Massive stroke; After second vaccination, immediately felt terrible; This spontaneous case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (Massive stroke) in a 54-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (Medical history not provided.). Concomitant products included DIAZEPAM (VALIUM), ONDANSETRON (ZOFRAN [ONDANSETRON]), ATORVASTATIN CALCIUM (LIPITOR) and LISINOPRIL for an unknown indication. On 26-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Mar-2021, the patient experienced VACCINATION COMPLICATION (After second vaccination, immediately felt terrible). On 28-Mar-2021, the patient experienced CEREBROVASCULAR ACCIDENT (Massive stroke) (seriousness criteria hospitalization and disability). At the time of the report, CEREBROVASCULAR ACCIDENT (Massive stroke) and VACCINATION COMPLICATION (After second vaccination, immediately felt terrible) outcome was unknown. Treatment included t pack clot bursting stroke medication. Stroke has affected the patient's vestibular system and balance and has caused vertigo, she is now crippled. These symptoms are ongoing and similar to what the reporter experienced Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
1207158	4/14/2021	MN	67	F	3/12/2021	3/26/2021	Superficial thrombosis in left calf muscle Eliquis prescribed Follow up with vascular MD Compression stockings prescribed.

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1206843	4/14/2021	OH		F		4/8/2021	FELT HARDER TO BREATHE WITH MASK; JOINT PAIN ALL OVER; CHILLS; FEVER; MASSIVE HEADACHE; SWEATING; This spontaneous report received from a patient concerned a 42 year old female. The patient's height, and weight were not reported. The patient's past medical history included bypass surgery, and blood clots, and concurrent conditions included non smoker. The patient experienced itching and rash when treated with heparin. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808978, expiry: not reported) dose was not reported, administered on 07-APR-2021 15:00 to Left Arm for prophylactic vaccination. Concomitant medications included acetylsalicylic acid for drug used for unknown indication. On 08-APR-2021, the subject experienced sweating. On 08-APR-2021, the subject experienced joint pain all over. On 08-APR-2021, the subject experienced chills. On 08-APR-2021, the subject experienced fever. On 08-APR-2021, the subject experienced massive headache. On 09-APR-2021, the subject experienced felt harder to breathe with mask. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from sweating, joint pain all over, chills, fever, and massive headache on 08-APR-2021, and the outcome of felt harder to breathe with mask was not reported. This report was non-serious.
1207256	4/14/2021	AL	26	M	4/8/2021	4/8/2021	Severe convulsions, harsh chills, 102 fever, sweating, and migraine headache around 9 hours after vaccination. I have had a strange and non-stop headache ever since that day, and my entire body feels like I had went to the gym and did hardcore aerobics. Those are the main two symptoms I still have as of now. I am afraid my body is being set up for a blood clot.

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1206416	4/14/2021	CA	67	M	2/27/2021	3/20/2021	24 hours after 2nd vaccine, usual injection discomfort, low back ache, felt not well, minor, resolved quickly. 3 weeks after 2nd vaccine, onset of new bilateral lower extremity 3+ pitting edema. No previous episodes. Very active, healthy exercising/running life style. some relief with self administered HCTZ and leg elevation. Very unusual, not expected, no obvious explanation. Waxed and waned. No fever, SOB. No risk factors for DVT. Painful due to new acute stretching of skin around ankle up to mid calf. consulted ab PMD 4/11/21, suspecting side effect of amlodipine or lisinopril, however, I've taking these meds for years. This is very unusual. Lab. tests are ordered. My concern is clot.
1206389	4/14/2021	VA	44	F	3/24/2021	3/26/2021	Within 48 hours after I received my vaccination, I started to experience severe back pain. I then noticed that I had two bruises on my back. I put a ThermaCare patch on each of the bruises to help with the pain. Within two days, the pain started to go away and the bruises started to fade. The next day, I started to experience severe back pain again and I noticed that I now had three different bruises on my back. I put a ThermaCare patch on each of the bruises and started to take some Tylenol for the pain. I also called my Primary Care Physician. I went in to see PCP on April 1, 2021. During this visit, doctor indicated that I seemed to have burst blood clots in my back. I currently have a little back pain but, I still have the three bruises. They are starting to fade but, they are still very noticeable.

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1206380	4/14/2021	TX	19	F	4/8/2021	4/10/2021	On 4/8/2021 I developed a headache after receiving the Johnson and Johnson vaccine. I took the next few days easy, and laid in bed for the majority of the weekend. On 4/10/2021 I left my residence to get dinner and noticed I was short of breath just walking from the building to my car. The shortness of breath worsened over the next few days. On 4/13/2021 I called a clinic and told them I had been short of breath and they directed me to the ER. I arrived to the ER around 2:30 in the afternoon. They ordered a chest x-ray and ran a test to determine if I could have a blood clot. The test came back with results indicating I could have a blood clot, so they did a chest CT and an MRI. The chest CT showed a blood clot in my left pulmonary artery. They prescribed a blood thinner, told me to stop taking oral birth control, and discharged me.
1206362	4/14/2021	TX	39	M	2/4/2021	2/8/2021	05JAN21 shot #1, 08JAN21, Migraines start 08FEB21, Onset of severe abdominal pain 15FEB21, ER Visit admitted due to CT scan finding hepatic portal vein thrombosis 16-18FEB21, treated with heparin, while doing dozens of blood tests 18FEB21, discharged with Eliquis 5mg twice daily for 90 days 05MAR21, persistent migraines end Currently awaiting follow-up with heptologist and hematologist
1206334	4/14/2021	OR	56	F	3/12/2021	4/5/2021	Redness at site. On April 5, I had severe stomach pains and then a head ache started. They did a CT Scan and found a Portal Deep Vein Thrombosis. I had to be rushed by ambulance to a bigger hospital and was in the hospital for 2 days.
1206312	4/14/2021	CO	81	M	1/31/2021	3/4/2021	Lung blood clot found after emergency room visit experiencing shortness of breath 03/04. Tennis ball size neck lymph node swelling starting 02/25. Joint pain and swelling starting 2/22
1206307	4/14/2021	KY	42	F	2/4/2021	2/24/2021	I was admitted to ER with stroke and right arm weakness. While I was in the ER, I also developed unconsciously seizure. The diagnosis are Cerebral Venous Thrombosis (CVT, multiple clots) and Cerebral Venous Sinus Thrombosis (CVST), Focal motor seizure and Cerebral Edema.

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1206305	4/14/2021	WA	45	F	2/24/2021	2/25/2021	Severe headaches and ear pain on right side of ear. She thought she was getting migraines (but hadn't suffered from migraines in over 20 years). Went to doctor on 3/3 due to severe pain. No thoughts of what it could be. Continued headaches with no relief. Received migraine shots in hip on night of 3/11. Severe stroke on 3/13. Should not be at risk for a stroke and does not have any typical factors for being at risk. Has been in hospital and in-patient rehab since. Has a fully occluded clot in her right ICA.
1206275	4/14/2021	FL	35	F	4/7/2021	4/10/2021	I had my period two weeks ago and fell on it again. It's really heavy and contains lots of clots. Menstrual cramps.
1206889	4/14/2021			F	3/26/2021		spit out blood and blood clots; This spontaneous case was reported by a consumer and describes the occurrence of HAEMATEMESIS (spit out blood and blood clots) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event (No reported medical history. ). On 26-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced HAEMATEMESIS (spit out blood and blood clots) (seriousness criterion medically significant). At the time of the report, HAEMATEMESIS (spit out blood and blood clots) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were not provided, no treatment information were provided. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
1207498	4/14/2021	NJ	46	F	4/1/2021	4/10/2021	blood clots in the both lungs

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1207683	4/14/2021	WA	60	M	3/8/2021	3/17/2021	Blood clot in left leg; first noticed on March 17; swelling and pain bad by March 19, called advice nurse who told me it sounded like a blood clot and told me to go to emergency room.
1207681	4/14/2021	CA	40	F	3/22/2021	4/9/2021	3/22/21- Raging headache, extreme chills. 4/9/21- Left foot swelled up like a grapefruit, was worried about blood clot when I saw them on 4/10/21.
1207638	4/14/2021	NV	50	F	3/24/2021	3/25/2021	Pulmonary Embolism (blood clot)
1207618	4/14/2021	MI	50	F	12/23/2020	3/8/2021	Blood clot left calf
1207615	4/14/2021	OH	51	F	3/3/2021	3/7/2021	Presented to UCC on 3/7/2021 with complaints of left leg pain/swelling, had cervical block 03/02. when she got home she noted some groin pain,. and this morning left leg was so swollen. she is also complaining of mild shortness of breath. denies chest pains, was tachy at triage. She was then transferred to Emergency Department. Per their report: The patient presents with a swollen discolored left lower leg. She does have discoloration and I am concerned for massive DVT and cerulea dolens. She does have really minimal pain to the leg except to the groin, she has intact pulses, I have low suspicion for acute ischemia/arterial clot. She does complain of some mild dyspnea with exertion above baseline so I do have concerns for possible PE. She is hemodynamically stable, appears in no distress. She is on oral contraceptives, mild obesity, no other significant VTE risk factors. I am going to empirically start her on heparin, I have also ordered a CT PE and a CT abdomen pelvis to check for proximal propagation of the DVT along with a left lower extremity duplex Doppler ultrasound. Duplex ultrasound also showed extensive left lower extremity DVT up to the common femoral, she does have bilateral PEs without evidence of significant clot burden or heart strain, she is hemodynamically stable with normal pulse oximetry. The patient also has clots proximal up to her IVC. I discussed this with Dr. of vascular surgery for possible thrombolysis therapy of the left lower extremity. She was discussed with SOUND for admission.

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1207571	4/14/2021	NC	72	F	2/12/2021	3/3/2021	er visit turned into a hospital stay in ICU....due to blood clots that were in the lungs that were so pervasive a heart attack ensued due to the pressure from the lungs
1207568	4/14/2021	OH	63	M	3/9/2021	3/16/2021	Between 3/9 and 3/22 patient experienced unilateral ankle swelling. Dr prescribed furosemide with no effect. Patient did doppler US and other screening for blood clot and did not find a DVT/peripheral clot. Swelling has since decreased. Patient was taking meloxicam for shoulder pain x 1 week around the time of the vaccination.
1207539	4/14/2021	PA	40	F	3/26/2021	4/3/2021	Chills/shaking began approximately 8 hours after injection. Other symptoms of an achy upper body, temperature of 103.1, and nausea came shortly after initial symptoms (within 1 hr.). In the middle of the night, I began heavily sweating (something I have never experienced). I was drenched with sweat and needed to change in the middle of the night. Absolutely no energy and a horrible headache. 24 hrs. after the injection I no longer had a high fever. However, consistently for a week, every day, I had at least one symptom (headache, nausea, chills, or lack of energy) at some point throughout the day. When I received the injection, I was on day 2 of my period. It ended one day later than normal. However, what was not normal was that on 4/3/21, I began to bleed again. I passed 2 clots and had spotting for an additional 5 days. This is in no way normal to my cycle.
1207534	4/14/2021	TN	30	F	4/5/2021	4/5/2021	Headache blood clots dizziness on and off and reduce of appetite
1207173	4/14/2021	FL	77	M	2/25/2021	2/26/2021	The night after receiving the vaccine he developed hematuria. This continued until his second dose of vaccine. After the second dose of vaccine, the hematuria worsened so much so that he was just leaking blood from the urethra even without urination. With urination he was passing frank blood and clots. He stopped clopidogrel and aspirin and it totally resolved. He underwent cystoscopy and there were no lesions identified. He resumed clopidogrel and aspirin and has not had any more bleeding.

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1207508	4/14/2021	MI	83	M	3/5/2021	3/7/2021	3/5/ 21 Received J & J at facility. 3/7/21 Client had troubles walking and went to Urgent Care. then he went home. He did not have good control (wife described that his legs did not have strength but was able to walk. Symptoms started getting better later that day. 3/15 He got up and he said he was not feeling to good. Chest hurt and shoulder hurt. Wife took him to the ER at Hospital. He was transported to Hospital. 3/16/21 Hospital did a Heart catherization. He had a complete blockage in the widow maker and 2 stents were put in. He had 2 blood clots in the Widow Maker. 3/18/21 He was discharged from the hospital. He is doing ok but he has no energy.
1207201	4/14/2021		59	F	4/5/2021	4/7/2021	CRVO per ophthalmology note: States that she developed a headache on the right temple and right eye approximately 1 week ago. This resolved. This last Sunday 4/11/21 and later that day her vision in the left eye became suddenly dark and is what prompted her to be seen by an ophthalmologist. She was seen by Dr yesterday and was referred to Dr for further evaluation. Patient states that her right eye vision has been seeing "diamond" shapes that she noticed yesterday. She currently has an intense headache that is all over her head and eyes. She reports nausea since 4/11/21. States that she had floaters and flashes of light in the left eye on Sunday 4/11/21. She is worried about the vein in the back of her right eye as well, Dr told her it looked constricted. She felt that her jaw was strained and tight yesterday. States that she received her COVID Vaccine last week and she wonders if this caused her blood clot.
1207493	4/14/2021	MA	55	F	4/12/2021	4/14/2021	moderate pain in arm; moderate headache then sudden bloody nose 2 days later from right nostril with two large blood clots. Headache remains.
1207473	4/14/2021	IA	44	M	3/9/2021	3/19/2021	Got the J&J on March 9th. Had severe cramp/knot in my left leg starting the 19th. Lasted through the 29th and right leg got it the 24th through 30th. I attributed it to pushing too hard at the gym. When they didn't go away after heat/cold/rolling/hot tub I did worry about clots, but not due to vaccine. Was going to call Dr but they went away.



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1207440	4/14/2021		74	M	3/6/2021	3/12/2021	Massive heart attack due to blood clot. Heart Cath putting in a stint with over night stay in hospital
1207401	4/14/2021	FL	64	F	3/30/2021	4/10/2021	SUDDEN DEATH - PULMONARY EMBOLUS DUE TO DEEP VEIN THROMBOSIS RIGHT POPLITEAL VEIN
1207377	4/14/2021	OK	78	F	3/15/2021	3/15/2021	Patient had vaccine on 03/15/2021. Started complaining of extreme pain in RLE by that evening. Patient contacted health agency and portable x-rays came out to view RLE. No fractures were seen. Pain continued and was unmanageable by 03/20/2021 and patient was transported to the ER. Patient was found to have blood clot in RLE and admitted to ICU. Patient further declined while admitted having multiple system failure and passed away on 03/25/2021.
1207366	4/14/2021	NJ	66	M	3/23/2021	4/3/2021	numbness in right foot, pain and numbness in right leg below the knee. Immediately had ultrasound of leg to confirm no blood clots. Then saw neurologist and orthopedic doctors. They suspect common neuropathy. Started taking 30 days of 15mg Miloxacin and started PT. MRIs of back and leg to be done 4/15. Nerve function test to be done on May 20. No change after 4-5 days.
1207344	4/14/2021	MI	36	F	4/10/2021	4/11/2021	Large blood clots- that are not normal for my period. Large clots, 1/2 dollar size 4-5 times a day. Which is not normal, my period should be winding down, and it is ramping up and at like Period Day 6, bleeding through a pad an hour or 2 hours and large clots. Clots started and higher bleeding after the vaccine.

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1207337	4/14/2021	NH	44	M	3/19/2021	3/22/2021	<p>FINAL DIAGNOSIS: o Acute pulmonary embolism and DVT SECONDARY DIAGNOSIS: Principal Problem: Pulmonary embolism and infarction (CMS/HCC) POA: Yes Active Problems: Tobacco abuse POA: Yes Opioid dependence (CMS/HCC) POA: Yes Pulmonary embolism (CMS/HCC) POA: Unknown DVT (deep venous thrombosis) (CMS/HCC) POA: Unknown Chest pain POA: Unknown Hemoptysis POA: Unknown Resolved Problems: * No resolved hospital problems. * PDMP Query Date: 03/24/21 PDMP Comments: 03/22/21 suboxone 8mg/2mg #14/14 days multiple fills -----</p> <p>----- BRIEF HOSPITAL COURSE: a 44 year old male with h/o of anxiety, depression, substance use on Suboxone, history of alcohol abuse, admitted 3/24/2021 with pleuritic chest pain and shortness of breath. Evaluation was positive for bilateral DVT and pulmonary embolism Bilateral PE, infarction, bilateral DVTs -No obvious precipitating factors -patient underwent first COVID 19 vaccine injection, is actually due for second shot. Unclear if this is contributed, recommended to hold on getting second dose and discuss this with PCP. -Also follow-up with PCP for appropriate cancer screening -patient was treated with therapeutic subcutaneous Lovenox, remained hemodynamically stable and is feeling better today. Upon discharge we'll prescribe Elocon is 10 mg b.i.d. for another 5 days followed by 5 mg b.i.d. maintenance dose. He will be provided with coupon for 1 month supply, he was recommended to follow-up with PCP for further recommendations. He will probably need anticoagulation for at least 6 months or longer depending on further course. -Echocardiogram showed ejection fraction 50-55%, Mild mitral valve prolapse no evidence of RV strain. Hemoptysis -Most likely was related to PE and infarction -resolved. Pleuritic chest pain, h/o Afib -Most likely pain was secondary to PE, improved - Continue Cardizem as prior to admission -Stop aspirin since patient will be on anticoagulation therapy History of opioid dependence, alcohol abuse Continue suboxone Ongoing smoking smoking cessation was advised Disposition: Routine Discharge Home CONSULTS: Consults Ordered during this Encounter Procedures ? Ancillary Service Request - IV Team New</p>

VAERS\_ID RECVD STATE      AGE\_YRS SEX      VAX\_DATE ONSET\_DATE SYMPTOM\_TEXT

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IV Start (multiple sticks for labs) ? Ancillary Service Request - Social Services    PROCEDURES: Procedures Ordered during this Encounter Procedures ? Patient is currently on therapeutic anticoagulation (warfarin, Pradaxa, IV heparin, Rivaroxaban) - no reassessment    RADIOLOGY TESTS: CT CTA Chest Final Result    1. Segmental and subsegmental pulmonary emboli throughout the right lung, most prominent in the right lower lobe. Segmental and subsegmental pulmonary artery the left pleural effusion. 2. Wedge-shaped opacities at both lung bases concerning for small pulmonary infarcts.    3. No findings of right heart strain or pulmonary hypertension.    Impression discussed with Dr of the ER at 20:44 on 03/24/2021 by phone. Electronically signed by: MD 3/24/2021 8:46 PM    US Legs Bil Venous DVT Final Result    Bilateral posterior tibial vein thrombosis.    This critical result was called to the clinical team, including by telephone, at 6:00 PM by the sonographer, according to internal Department documentation.    Electronically signed by: MD 3/24/2021 6:16 PM    XR Chest PA and Lateral Final Result Small bilateral pleural effusions. Streaky left basilar opacity may reflect atelectasis or infiltrate. Small right basilar opacity of uncertain significance. All opacities are new since 2016. No pneumothorax.    4 week follow-up is recommended. If the abnormalities have not resolved by then, chest CT is recommended.    Electronically signed by: MD 3/24/2021 5:36 PM

----- PROPOSED MANAGEMENT  
 PLAN: Risk for readmission within 30 days: o Low  
 Pending results: Unresulted Labs    . . .  
 Comprehensive Metabolic Panel [124639904]  
 Collected: 03/24/21 1818    Updated: 03/24/21 1823  
 Specimen Source: Blood, Venous    Morphology [124639439]    Collected: 03/24/21 1700    Updated: 03/24/21 1715    Specimen Source: Blood, Venous  
 Comprehensive Metabolic Panel [124637329]  
 Collected: 03/24/21 1700    Updated: 03/24/21 1705  
 Specimen Source: Blood, Venous    Troponin, HS [124637342]    Collected: 03/24/21 1700    Updated: 03/24/21 1705    Specimen Source: Blood, Venous  
 Recommended Testing: o Refer to Hospital Course  
 DISCHARGE MEDICATIONS: Medication List    STOP

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							taking these medications aspirin 81 MG Chew TAKE these medications Dose Ordering Provider Morning Afternoon Evening Bedtime apixaban 5 MG Tabs Commonly known as: ELIQUIS Instructions: Take 2 Tabs (10 mg total) by mouth TWICE A DAY for 5 days, THEN 1 Tab (5 mg total) TWICE A DAY. Start taking on: March 26, 2021 Signed by: MD buprenorphine-naloxone 8-2 MG Film Commonly known as: SUBOXONE Instructions: Dissolve 1 Film under the tongue DAILY for 14 days. Instructions: NADEAN: xe2109242 Dose: 1 Film Signed by: MD diltiazem CR 240 MG Cp24 Commonly known as: DILACOR XR Instructions: Take 240 mg by mouth DAILY. Dose: 240 mg Where to Get Your Medication apixaban 5 MG Tabs High-risk Medication Changes: o Refer to Hospital Course PTA Medication Changes: o Refer to Hospital Course
1207693	4/14/2021	CA	55	F	4/2/2021	4/3/2021	The day after my vaccination, my lymphdema was acute. I have had lymphedema since 2018 when I had a lymph node removed due to melanoma. Ever since my right leg and foot often swell up by the end of the day. Following the shot, the next day my leg and foot were swollen at the beginning of the day and all day and much more painful than usual. I did some exercises to relieve the pain and by Sunday felt better. I didn't think much of this but in light of the blood clot side effect that some have experienced I thought it might be helpful to mention this side effect I experienced.
1207527	4/14/2021	MD	27	F	4/8/2021	4/13/2021	I had a fever of 103.8 8-12 hours after the vaccine. After the first 24 hours all normal side effects went away. Yesterday (day 5), I started having leg discomfort and it continues today. Could easily be a pulled muscle but I'm also concerned about blood clots so I'm watching my symptoms and if anything worsens, I will get seen by patient first.
1210395	4/14/2021	NJ	48	M	2/17/2021	3/5/2021	I got my second Pfizer covid shot on 2/17/21. Since then I have ahad 2 large blood clots form in my lower right leg. I had one in the same place 24 years ago.

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1210605	4/14/2021	UT	36	M	3/10/2021	3/13/2021	I had the 1st shot on Wednesday March 10th. On Sunday the 14th, just before going to bed at about 11pm, I went to pee. The urine was very dark brown. Didn't appear to have any red for blood. The next day I felt like water was being retained and it felt that I couldn't empty the bladder and pee was coming out slower than usual. Late Monday the 15th before bed I peed another dark brown urine and a red blood clot came out. At that point I became very concerned and sent to see the doctor on the 16th. Referred to a kidney specialist for March 31st. Between March 14th to March 29th , somedays I felt like I was retaining water, most days felt like I couldn't empty my bladder with slow flow. With the recent news of the concerns of blood clots with vaccines, I felt that I should report this.
1210554	4/14/2021	IL	65	F	3/16/2021	4/13/2021	Bilateral pulmonary embolisms requiring ICU admission. Patient presented to Emergency Room on 4/13/21 with presented to the ED with shortness of breath and chest pain. The patient notes that she developed shortness of breath, particularly with exertion, about 1 week prior to presentation. 2-3 days prior to presentation, she developed pleuritic chest pain on the right anterior chest. She denies any recent fevers, chills, weight changes, palpitations, cough, sputum production, abdominal pain, nausea, vomiting, diarrhea, constipation, lower extremity edema. She does note that she received her first dose of the COVID-19 vaccine on 3/16/2021 and was due for dose#2 on the day of admission. She denies a personal history of blood clots and denies current smoking, estrogen use, or recent surgery. She does note a history of blood clots in her sister, but she is unsure whether they were provoked or unprovoked. Patient required BiPAP on admission and was initiated on a heparin drip. Initial CT w/ some concern for R heart strain, however, echocardiogram showed no signs of R heart strain and she was hemodynamically stable. She was weaned from the BiPAP to Non-rebreather, and eventually nasal cannula. The heparin drip was transitioned to lovenox with plans to go home on a DOAC. Still hospitalized at time of event report.

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1210553	4/14/2021	CO	54	M	3/25/2021	4/6/2021	4/6/21 - got bloody nose at 10:00 A.M, which would not stop. Nose still bleeding 2 hours later, got dizzy, so lied down. Vomited blood and could not stop the bleeding. Went to the ER at 2:00 PM, to have them stop the bleeding 4/6/21- E.R. - Fainted n the lobby while waiting. Taken back to room and given IV and gave multiple tests. E.R. doctor put packing in nose to slow bleeding. Still The Diagnosis was Epistaxis and Vasovagal syncope, and advised to follow up with my doctor and otalaryngologist. 4/8/21- Nose bleeding finally cam to stop in the evening, but had fatigue, weakness, irregular heartbeat, and shortness of breath 4/9/21- ENT and Allergy removed packing, completed nasal scope. Nose still felt like it was stuffed with blood clots until 4/13/21
1210548	4/14/2021	VA	23	M	4/8/2021	4/10/2021	Swollen leg possible blood clot, couldn't walk for days. got antibiotics and its coming along still swollen but able to walk again somehow
1210545	4/14/2021	CA	56	F	4/10/2021	4/10/2021	First night:excruciating headaches,pain in the neck,eyes hurt,stomach pain slight fever and chill so i took ibuprofen and that helped headaches and early sunday morning took aspirin also helped Second day: all day muscle aches over body and very tired. Third day : my left arm that had vaccine hand and arm went numb for half hour an went away. Forth day:more than half day my vaccine arm and hand numb and try to shook it up but no luck and heard bad news about Janssen. I am very scared and worry about this vaccine about blood clot. they said it happened 6-13 days after vaccine shot. it's been only 5 days for me and i am very scared.
1210530	4/14/2021	NE	64	F	4/9/2021	4/9/2021	Blew my nose on 4/14/21 at 7:30 p.m. only to have my left nostril start bleeding like a faucet. It continued for approximately 10 minutes until I hacked out what looked like a clot from my throat about the size of a 50 cent piece. My nose then stopped bleeding and after clearing my throat several times for about 20 minutes, everything is clear. I placed a cold pack on my face for about 20 minutes. This is definitely an odd thing for me. I do not smoke and never have. I felt fine before the nosebleed and feel absolutely fine now, an hour after the event started. I didn't feel bad during the nosebleed, only scared.

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1210520	4/14/2021	FL	64	F	3/16/2021	3/25/2021	Cranial and spinal SAH hematoma at roughly same time as heart attack. Cause of hematoma was unknown. Potentially a side effect of elliquis; but her cardiologist does not believe ellipsis was the cause. Heart attack at similar time due to blood clot and blocked artery and possibly reaction of body to hematoma. We do not have any hard data that either are related to the vaccine; but are reporting them under the advice of a doctor to give information for science.
1210103	4/14/2021	UT	45	M	4/7/2021	4/14/2021	nausea, vomiting, diaphoresis, dizziness, headaches, bilateral transverse sinus thrombosis
1210412	4/14/2021	NY	49	F	3/3/2021	3/3/2021	I had my second shot and the same night developed a clot in my arm. I had blood coagulation labs drawn and my C protein and cardiolipin have altered and show I may get clots now. I had labs previous to this because of my gallbladder surgery and all my blood was normal.
1210718	4/14/2021	MO	39	F	3/14/2021	3/14/2021	After receiving my vaccine on March 14th, I started experiencing pressure in the left side of my head and severe headache. As the days progressed, I was continuing to have severe headaches for the next couple of weeks. I was taking exedrin Migrane medicine to try and calm it down. When I would try an work out it was worse, it was like the pressure on the left side of my brain was expanding and it would be worse. My legs and body did feel weak. It has slowly gone down with less and less of these headaches over the last couple of weeks. They were definitely different than what a normal migraine feels like and very specific type of feeling. I don't know if I have had any clots or not, but I am currently trying to get into a neurologist to get looked at to make sure there is not something else going on. I am going to try and contact Johnson and Johnson to see if they can help refer to a neurologist because I currently do not have health insurance.
1210365	4/14/2021	MD	65	F	3/8/2021	3/11/2021	left knee swollen: x-ray done on 3/15/21, showing nothing wrong, doppler test done on 3/19/21- no blood clots, MRI done on 4/14/21, waiting on results: shortness of breath started on 3/12/21 and lasted about 3 weeks.

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1210361	4/14/2021	NM	72	M	3/10/2021	4/9/2021	Pt developed edema and pain to LLE from knee down to ankle on 4/9/21. Describes skin tightness and redness.. No fever, but with chills. Given crutches to avoid weightbearing on left leg. Pt is being worked up for potential blood clot, US Left venous duplex. Pending results for exams, Sent to emergency room on 4/13/21 by reporting nurse.
1210346	4/14/2021	VA	44	F	4/9/2021	4/13/2021	Hemorrhage like bleeding, soaked up 4 maxi pads within a 30 minute span. Expelled Blood clots the size of apples. Went to ER. Blood loss and clots resembled the look of a miscarriage, but pregnancy test, can back negative. Multiply tests were ran. This carried on from 1:30 to 8pm, when fentaNYL and ompaque was given for pain. Blood Pressure was also high 154/119 and temp 99.
1210261	4/14/2021	IN	52	F	3/29/2021	4/8/2021	patient admitted to hospital with blood clot on 4.8.21
1210248	4/14/2021	IA	46	F	3/24/2021	3/27/2021	Patient states that 3 days after she received the Pfizer vaccine she started a menstrual cycle. When she came back to the pharmacy three weeks later she stated she was still having her menstrual cycle, and the bleeding was very irregular, sometimes clotty. She said she had just finished her menstrual cycle before receiving the first dose so shouldn't have had a cycle, and that also she was always very regular with her cycles prior to this.
1210139	4/14/2021	CA	55	M	3/25/2021	4/1/2021	Deep Vein Thrombosis of Right Leg
1210136	4/14/2021	IA	52	F	3/6/2021	3/10/2021	was found to have a blood clot in my left leg .
1210436	4/14/2021	MD	32	F	3/26/2021	3/28/2021	Menstrual cycle started over a week early and was very heavy with visible clots, swollen lymph node on left side underarm
1210894	4/14/2021	TX	45	F	3/5/2021	3/26/2021	Blood clot in lower right leg (calf), resulting in pulmonary embolisms and use of blood thinners. Due to fibroids, this caused excessive bleeding leading to anemic condition and the need for several blood and iron transfusions. Solution was to perform hysterectomy to eliminate fibroids and bleeding to be able to continue use of blood thinners for blood clot condition.



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1208162	4/14/2021	IL	55	F	3/11/2021	3/25/2021	Blood Clot in right calf. deep arterial thrombosis
1208872	4/14/2021	PA	41	M	3/20/2021	3/21/2021	On March 20th I received the J&J covid-19 vaccine shot. Starting on March 21st I begin to experience symptom such as fever, chills and body aches. That lasted for about 2 weeks. The week of April 5th- I been to experience struggling the ability to breathe. I was having serious pain in my left side of my chest and in the lower left side in my back. It was so severe, I went to the hospital on April 8th and at the hospital the Doctors discovered I had blood clots in my lung. I was in the hospital for 2 days. Iam currently on blood thinners inhaler and and oxygen.
1211350	4/14/2021	NC	87	F	4/1/2021	4/4/2021	Early on Sunday morning, April 4th, patient woke up with swollen right hand with immense pain. On Monday, April 5th an ultrasound confirmed a blood clot in her right forearm.
1211308	4/14/2021	FL	61	M	4/9/2021	4/10/2021	Passed 2 blood clots via urine. No pain and none since.
1211304	4/14/2021	ME	36	M	4/8/2021	4/8/2021	On the evening of 4/8/2021 at around 8 pm I began experiencing an upset stomach (felt like I might throw up) and then shaking in my stomach started and I got a lot of chills and a headache. Then I spiked a very high fever and sweat like crazy. I was shaking like crazy and had to call a doctor on call twice. I had full body pain and was very sleepy. The fever and chills lasted a bit over 2 days but unfortunately the pain in my body had not gone away. Currently (4/14/2021) I have pain in all my joints and my neck and back and I noticed a rash around my right knee. I have felt very tired. I have felt some mild shortness of breath, which may be seasonal allergies (discussed with a nurse earlier, my oxygen levels are 98 percent today, so I am breathing fine, but there is a sensation of shortness of breath) . I have consulted my primary care office about the above and they are speaking to the doctor. I am trying to limit my exposure to any hospital setting until the 14 days (2 weeks) is up from the vaccine. Hopefully these symptoms will go away soon and hopefully none are related to a blood clot issue. We'll see if my doctor or you guys may recommend a future platelet test?

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1211294	4/14/2021	FL	41	M	1/27/2021	3/16/2021	I suffered a stroke on March 19, 2021 that effected my Occipital and Temporal Lobes on the right side of my brain. The primary symptom was almost total and complete blindness. Taken to emergency room, made a stroke alert, tPA cleared clot, spent 5 days at the hospital.
1211121	4/14/2021	MN	61	F	3/7/2021	3/8/2021	Whether the adverse events were caused by the vaccine is to be determined. We are available to discuss more details if this information can be used to help others from experiencing these reactions. The morning after getting the vaccine, patient discovered that she could not swallow. As her condition worsened, she was taken to the emergency room. Over the past month, patient went to the emergency room 4 times. The last time resulted in extended hospitalization that continues to this day. In addition to the swallowing problem, two other major adverse events need to highlighted. First, on 27 March, while in the hospital, vaginal bleeding started. On 29 March, her doctor, performed a hysteroscopy/DNC finding "an unexplained blood clot (hematoma)." The second major event was when patient demonstrated significant confusion and lack of memory. On 7 April, she was diagnosed with Metabolic Encephalopathy. Neurologists at the hospital suspected that her MS was reacting to her UTI and once the infection is eliminated her memory should come back. But as of 10 April, she was still having issues including hallucinations. Although she is eating some as of 13 April, she is still very weak and will likely be moved from the Hospital to a rehab facility. She still does not remember much of the last 37 days.
1210615	4/14/2021	NJ	63	F	3/8/2021	3/9/2021	On March 8th received the J&J shots, March 9, 10th & 11th was extremely nauseous in the morning. On the 12th had severe chest pains which I chalked up to a very bad case of heart burn. On March 24th, while driving I had two major (what I thought at the time) was panic attacks...body started shaking, heart was beating like crazy, couldn't catch my breath, felt like I was going to pass out or die. Had to pull over twice to calm myself down. (From what I read this could be a sign of a blood clot but I am not a doctor.) Had minor heart burn until April 5th....which ironically was the end of my 28 days until the vaccine fully kicked in. Just reporting what happen. I feel fine now.

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1210915	4/14/2021	CA	57	M	4/11/2021	4/14/2021	Patient seen in ED with CC of unilateral leg pain x3 days. Pt attributes the leg pain developed shortly after receiving the J&J COVID Vaccine. Ultrasound demonstrates superficial thrombosis of greater saphenous vein. Hemodynamically stable. Pt prescribed Eliquis 10mg bid x7 days followed by 5mg po bid. Cannot confirm pt has been administered J&J vaccine -not documented in medical chart, pt only self-reports. Also with sedentary lifestyle/bed-bound.
1210630	4/14/2021	OH	59	M	3/4/2021	3/6/2021	Mother called health department today, 4/14/21, to report reactions son experienced after receiving vaccine 3/4/21. She stated that on 3/6/21 he started having headaches, weakness and leg cramps. He went to the hospital two times with complaints. On 3/15/21 he was unable to walk/drive because headaches were severe. On 3/30/21 he passed out, squad was called. He was not responsive and was put on a vent at the hospital. A "scan" showed blood clots in brain and heart. This individual passed away on 4/4/21.
1210820	4/14/2021	WI	37	F	3/30/2021	4/8/2021	I had no side effects until the first day of my menstrual cycle. I felt extreme fatigue, vomiting, and severe diarrhea for my entire cycle (5 days). I also bled heavier than normal and had an uptick in noticeable, large blood clots. Symptoms lessened on the 5th day and completely stopped when my cycle finished.
1210811	4/14/2021	WV	28	F	2/8/2021	2/23/2021	Deep vein thrombosis in right arm pit
1210805	4/14/2021	FL	30	M	3/25/2021	4/6/2021	Deep vein thrombosis (DVT) of axillary vein of upper right extremity, sub clavain vein and pulmonary embolism of right and left lung. Treated with injected Lovenox.
1210794	4/14/2021	FL	43	M	4/7/2021	4/8/2021	Cold sweats starting Thursday evening, Friday sweating at night, and Saturday morning ~6:00 am with chest pain and sweats. Pain intensified and brought to Urgent Care at 8 am where an EKG was completed and showed signs of a heart attack. Was rushed to Hospital Emergency room. Admitted and examined. Completed an angiogram and noted that there was a blood clot that appeared to dissolve. Troponin levels were high showing damage to the left artery. Spent the night in the hospital. Prescribed medication for cholesterol, blood thinners, and seeing a cardiologist.

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1210787	4/14/2021	MD	57	M	3/27/2021	3/29/2021	Pt developed abdominal pain and anorexia beginning two days after receiving vaccine dose. Presented to ED and found to have portal vein, SMV and splenic vein thrombosis. Underwent TIPS c/b recurrent thrombosis x 2 and cecal pneumatosis s/p exploratory laparotomy, open abdomen, delayed closure. He was mechanically ventilated and briefly requiring vasopressor support, now extubated and off pressors. Remains inpatient on anticoagulation and TPN. Hematology work-up while inpatient was negative.
1210766	4/14/2021	FL	61	F	3/19/2021	3/29/2021	3/29/21 6 pm - Severe pain lower right leg, ankle, and foot, unable to weight bear on right leg About an hour later I was able to walk a little. Stayed off my feet. Right foot became very cold. 3/30/21 Saw my primary care physician at med center. She sent me for an ultrasound at medical arts. From there I was sent to the emergency room at hospital. I asked the attending physician assistant about a correlation between the blood clot and the Covid vaccine because I had read about it being a concern in other countries. He stated that was a bunch of baloney. Was told to have a repeat ultrasound in a few days and was prescribed a 30 day starter pack of Xarelto and released. 3/30 repeat penis ultrasound of right leg showed the same results. 4/1 appointment with hematologist. Prescribe Xarelto for three months and ordered a repeat ultrasound in three months and bloodwork at that time.
1210737	4/14/2021	MA	33	F	3/7/2021	3/8/2021	Approximately five hours after receiving the shot, I developed a headache. Within 12 hours, I had chills, sweats, and fever for approximately 12 hours. The morning after receiving the shot, I developed neck and shoulder pain which became more sever on the next 2-3 days. The neck and shoulder pain has been ongoing for 5 weeks since receiving the shot on the injection side. I have seen my primary care physician twice, most recently to rule out a blood clot (yesterday 4/13). I have also received physical therapy. There was no neck injury or pain prior to the vaccine.

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1210829	4/14/2021	TN	24	F	3/29/2021	4/5/2021	One week after receiving my 2nd dose, I developed small, red, dry patches of skin on my torso and chest area. They have been spreading and increasing daily. I received a steroid shot just today and Clotrimazole-Betamethasone cream to apply. Am awaiting results of this treatment.
1211070	4/14/2021	IA	59	F	4/10/2021	4/10/2021	Left thigh numbness, patient said relieved with chiropractor adjustment. I suggested rule out blood clot.
1209082	4/14/2021	LA	35	M	4/9/2021	4/10/2021	Running nose bleeding blood clot coughing tied arm hurting
1209297	4/14/2021	TN	63	F	2/24/2021	2/28/2021	2/28/21 Four days after 1st Pfizer vaccine 2/24/21 Severe cramping and swelling in my right leg and ankle. 3/9/21 Work clinic advised to seek medical attention 3/9/21 Hospital Emergency Room Diagnosis: Deep Vein Thrombosis (DVT)- Blood Clot 3/10/21 Thrombectomy Surgery & Released 3/11/21 Swelling in right leg and ankle Returned 3/12-16/21 Readmitted - Blood Clot returned Currently under several doctors care.
1209277	4/14/2021	NC	83	M	3/10/2021	3/31/2021	Received Janssen Vaccine on 03/10/2021 IM Left Deltoid. Reported started having "dizzy spells a couple weeks after" receiving his vaccination. Reports then started having "leg heaviness". Was hospitalized with hospital on 04/11/2021 with a blood clot "behind right knee".
1209247	4/14/2021	TX	24	F	3/3/2021	3/12/2021	Severe Vascular Thrombosis (vomit, loss of balance, numbness in arms and legs, lost of speech, impaired vision) had to be hospitalized for 4 days, and had some brain damage from the thrombosis.

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1209217	4/14/2021	CA	61	F	4/9/2021	4/9/2021	4/9/21-30 minutes to 1 hour after receiving 2nd dose of vaccine patient had bloody nose, clots, with bleeding sores on tongue and side of mouth. Began to have bruises on arms, feet and legs. Blood in urine and bruises on back. Presented to emergency department on 4/11/21. CT brain revealed a right sided posterior temporal hemorrhage. Patient was emergently treated with platelets, DDAVP, factor VII, Decadron, IVIG. 4/12/21, patient denies headache, changes in vision, double vision, change in sensation, including burning, pinprick, numbness, no focal or motor weakness. No change in bowel or bladder control. No sensory changes. Patient states she is now back to her normal state of health, save for the bruising described.
1209216	4/14/2021	MD	57	M	4/8/2021	4/12/2021	Blood Clot-Bad swelling in right arm. Arm tingling, numbness and discolored. Arm is swollen from top of arm to fingers. Notice first sign on Monday morning (04/12/2021) when i awoke from bed around 7:00am.
1209183	4/14/2021	SC	99	F	4/12/2021	4/13/2021	Patient was vaccinated at 2PM (4/12/21) and caregiver said that at 4AM during the night(4/13/21) patient woke up very nauseated. She immediately vomiting and it contained blood. As she vomited more, numerous clots came out which resulted in caregiver calling 911. Patient was admitted immediately to hospital where she remains today (4/14/21). Doctors have performed an endoscopy and other tests to determine the source of the blood clots and treatment options. Caregiver is available if more details are needed.
1209140	4/14/2021	KY	33	F	2/18/2021	3/2/2021	Pain in calf, swelling in lower leg (left leg), weakness/numbing in that leg- led to blood clot diagnosis.

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1209308	4/14/2021	SD	54	M	1/6/2021	1/7/2021	Muscle tightness - soreness - at the arm with the injection and it was for about three and five days. Maybe about 2 weeks from vaccine - I had some congestion (nasal congestion and sneezing) - it was odd (not allergies) and it lasted a solid with heavy heavy drainage and that lasted about two days. I had to use the Mucinex D for it. Then I had the nose bleed - it wouldn't stop bleeding in right nostril. I went to ER - Sunday, the 28th - started at 10:30 pm and after midnight on the 29th it was after 4 hours of bleeding when I went to ED in town. The doctor said my nasal passages were really dry because of the weather. I was using a travel CPAP that doesn't have a humidifier. They cleared a giant clot in the back of my throat - it was the size of a hamburger - it was huge. They used a nasal vasodilator - it looked like nasal spray and they did it and stopped. Vitals were stable and they sent me home. I might have one bloody nose after - a week after and they had given me the nasal vasodilator and that stopped it. They also prescribed a nasal saline spray and I only use the CPAP with the humidifier now.
1209104	4/14/2021	MI	73	F	3/8/2021	4/5/2021	3 weeks post vaccination patient developed chest pain and shortness of breath. Was able to tolerate symptoms, then had radiation treatment and developed more shortness of breath. Was transported via EMS to hospital where an xray and MRI were completed and showed multiple blood clots in her lungs. Venous Doppler was also completed and blood clots were found in her legs. She was subsequently admitted to hospital.
1209054	4/14/2021	TN	59	F	2/11/2021	2/15/2021	received 2nd dose on 2/11/2021. Woke around 4AM on 2/15/2021. Noted blurry vision in left eye. By 8am had progressed to blackness starting at inner visual field and spread to total blindness by 9:30am. Went to urgent visit with optometrist. Appt was made for urgent work in with a Retinal Specialists on 4/16/2021. Diagnosed with left retinal vein thrombosis. Ordered further testing. MRI of brain and orbits, TEE, carotid ultrasound and sent to hematology/oncology for evaluation. Only finding on bloodwork was elevated homocysteine. Being treated for HTN now with Metoprolol, Amlodipine, Losarten/HCTZ, Crestor and BASA, MVI. Vision is unchanged. Blindness remains in left eye. Right eye at this point is unaffected.

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1209042	4/14/2021	MA	79	M	4/14/2021	4/14/2021	large clot in his great saphenous vein identified today when he saw Dr. on ultrasound
1208910	4/14/2021	CA	69	F	2/17/2021	3/8/2021	Blood clots developed in lungs. Felt restricted breathing beginning approx. 2 1/2 weeks after 2nd shot. She had an online dr visit and was diagnosed with pneumonia, which appeared to be an error. She took a ZPac for 5 days, but the pain persisted. She then went to the ER April 9th to learn of blood clots and then found cancer. It is uncertain if the vaccine played a role, but we are reporting due to the timing.
1208897	4/14/2021	ND	44	F	3/4/2021	4/1/2021	Within 8 min my left hand swelled and lasted for close to a week even after taking benadryl within the hour. 2 days following second shot my injection site swelled approx baseball size and lasted a week. Today i was seen for swelling on my left shin, no blood clot.
1208891	4/14/2021	NJ	54	F	4/3/2021	4/8/2021	Hemmoriged and passed many clots from my reared. Lost a lot of blood. Fainted and threw up. Was in ICU for 2 nights. Had 2 blood transfusions. They clamped area where polyp was removed on March 30th.



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1209997	4/14/2021	IN	51	F	3/27/2021	3/27/2021	I submitted a report after my first dose of the vaccine , and now this is the report after my 2nd dose of the Pfizer vaccine: I got the 2nd dose at 4:10pm. I did not feel the shot at all this time, but my arm was a bit achy soon after. One hour after the shot my leg muscles hurt and I felt fatigued. Two hours after the shot I felt really tired and really silly, kind of loopy. Three hours after the shot my L arm was hurting more and it hurt to take the band aid off. Then my stomach started feeling upset. I went to bed at 10:30pm and had a very rough sick night. I was awake most of the night, only dozing a few times. I had a fever (101) and chills; nausea and belching; dry mouth; aching and strange pains coming and going; a slight headache; and my L arm was hurting. By 7am I started crying, and I had more physical pain. I got up at 8am feeling so sick with extreme fatigue, headache, and in a lot of pain in body. My Mom had to make my breakfast for me and I took small bites of that oatmeal throughout the day. I couldn't eat very much because my stomach was so upset. I felt hot and cold and got chills often during the day. By 6:45pm the fever returned (100.3) and I felt sicker again with head and tummy hurting; body aching; and nausea. Finally at 8pm I took 2 Tylenol which helped a lot, but then I worried what if that reduced the effectiveness of the vaccine. I went to bed at 9:15pm and fell asleep right away, but woke up many times soaking wet with sweat. The next day I still had trouble with temperature regulation and I felt very tired and headachy and my L arm still hurt. A few days later I got my menstrual cycle about one week early, and it was the strangest period I've ever had. It was a very light flow, I had lots of clots, and along with the small amount of blood, there was lots of clear stretchy mucous like I get at ovulation. After my first vaccine dose I got my period a few days later also, but that time I only had brown spotting for 4 days and no regular blood flow at all, so this time it was slightly more of a period, but it was really not my usual kind of period. Overall, I felt completely whacked and wrecked by the 2nd dose. It was a terrible experience.
1210908	4/14/2021	FL	59	M	3/17/2021	3/27/2021	blood clot
1208879	4/14/2021	NY	64	F	4/6/2021	4/13/2021	Left saphenous superficial vein thrombosis

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1208878	4/14/2021	TN	76	F	2/26/2021	3/1/2021	Two blood clots in right lung two days after second vaccine. I was hospitalized and I am now on oxygen 24/7 and I'm taking blood thinner Eliquis.
1209129	4/14/2021	NY	68	F	3/1/2021	3/16/2021	Bad chest pains, palpitations and high blood pressure. Ct scan found two small clots (pulmonary embolism)
1209916	4/14/2021	IA	55	F	3/25/2021	3/25/2021	stated that while she was getting her 2nd shot, that she called the HD to report swelling of her right hand and development of blisters. States that the employee told her that was not a side effect and told her to move her arm about to increase absorption. She mentioned that blisters formation and later popped with redness and pus draining from her left hand. MD was consulted who was concerned about a blood clot but doppler was negative. Today, remnants of that swelling persists but the redness has gone away. blister is dried and healing with no s/s of redness, drainage, however, top part of hand is swollen. Encouraged to elevate left arm to promote return to normal size of arm. Notified to call HD a
1209859	4/14/2021	PA	62	F	4/1/2021	4/2/2021	Slight headache that day (4/1). The next day (4/2), weakness in left leg and arm. On 4/3 went to ER, admitted to NeuroScience ICU. Diagnosed with small blood clot and small bleed in brain--- dural venous sinus thrombosis. The neurology team said this was very unusual and very rare in this part of brain--where the blood flows back to the heart from the brain. They did alot of tests on every part of my body looking for the cause and found nothing. They think it was vaccine induced and repoted it to the CDC. Left leg and arm weakness remains with no changes yet. Now taking blood thinner and doing physical therapy
1209032	4/14/2021	GA	62	F	4/6/2021	4/7/2021	Persistent rectal bleeding and passing blood and blood clots for 7 days since vaccination. Bleeding occurs with stool and throughout the day, requiring the use of pads.

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1209395	4/14/2021	MD	68	M	4/6/2021	4/13/2021	Developed chest pains, Rehabilitation Center moved to hospital on 4/13/2021. Took a turn for the worse in the evening of 4/13/2021. Hospital found fluid on lung x ray. He was placed on ventilator overnight preformed CT Scan the afternoon of 4/14 and discovered several bloods clots In right lung. Patient still in hospital under sedation and on ventilator. Hospital has started him on Heparin.
1209889	4/14/2021	FL	20	F	3/23/2021	3/24/2021	About 10 hours after receiving my vaccine- I became extremely ill. I had migraines, fever of 101, chills, nausea, tightness of chest, abdominal pain, difficulty with my stool / bowl movements, and body aches. I could not move, and most effects subsided after laying in bed for two/three days straight. However, continuing up to today (three weeks later) I have still had tightness of chest/throat, bowl difficulties, and abdominal pain. I also noticed that for the past 2/3 weeks I have also had blood spotting with clots alongside my abdominal pain. It has not yet subsided.
1209826	4/14/2021	MN	42	M	3/9/2021	3/31/2021	He developed Superficial Phlebitis in the left lower leg on 3/31/21, and was seen in the ER. He reports concern to me on 4/14/21 that due to reports of blood clots with the Janssen vaccine, that he is concerned that his vaccine on 3/9/21 may have provoked the blood clot. He still has some phlebitis in the lower left calf. Note, he is on self given testosterone, which may also contribute.

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1209886	4/14/2021	TX	35	F	3/31/2021	4/4/2021	Initially pain all over and muscle and joint pain that started passing over first 3 days, on 4th day symptoms subsided but noticed charley horse in right leg, persisted for 4 days and started treating as if blood clot by drinking water, raising leg, taking Aleve, and hot pad so symptoms subsided. Began having difficulty breathing even though symptoms passing so still concerned by the 10th day sought medical treatment and testing for clot. Diagnosis was dehydration likely caused by menstruating at same time as vaccination. Prescribed nsaid and muscle relaxer to reduce symptoms and action plan for increasing water and natural iron intake prior to next dose to prevent more dangerous complications. Had hospitalization for SARS in 2009 and also treated for dehydration, did not consider the vaccine might have a similar effect to the prior infection since I was coughing so hard I was vomiting up all water for 3 days, but my vaccine symptoms were VERY similar to the 2009 illness in slow mo without the coughing including the pain and nausea (hospital could only confirm it was an unknown coronavirus at the time my roommate brought from another county, he was a another race native and very ill but was not hospitalized and didn't disclose he was sick so he wouldn't miss the start of the semester in quarantine, flew anyway and didn't tell us until I was hospitalized). Still dehydrated at 2 weeks after vaccine (today) but functionally symptom free at this time. Menstruation was normal, lighter flow than usual, and lasted 7 days which is normal for me post-IUD. Symptoms persisted after period stopped but progressively improved thereafter, unclear if because of home care for potential clot or because no longer menstruating so better able to retain water.
1209797	4/14/2021	CA	86	F	3/18/2021	3/27/2021	vomiting, shortness of breath, hospitalized, chart shows she suffered from blood clot, hospital has extensive records from tests

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1209796	4/14/2021	AK	45	F	3/17/2021	3/20/2021	<p>I received the vaccine at approx 930 am, Wed, March 17 (Johnson and Johnson Lot 1805020) at the Facility by Fireman(Emergency Responders). Vaccine was from Health Care. At first, after about 15 minutes I was feeling a little flush, there were light red splotches on my skin (only a couple, very light red - like when i get really nervous and get red splotches on my neck.) I felt a little nauseous and dizzy off an on for about an hour (but i had not had anything to eat or drink yet that day either). The site of the shot was a little sore and warm about an inch or two away from the needle injection site, but not a big deal. That night my right arm (which is where i received the shot) ached terribly, all the way from my shoulder to my fingers. The next day (Thursday, March 18) was the same. Sometimes my left arm tingled like it was starting to fall asleep. This went on the whole next day. Injection site still sore too, and warm. The day after that (Friday, March 19) the injection site was sore (like a sore muscle) and that was it. Saturday, March 20, the same until about midnight. Around midnight my son, and I came upstairs from watching tv and my arm (at my wrist) was aching intensely! I looked down and there was a small lump where one if the veins are. I can see my veins easily here and I am very light-skinned. Son could also see the lump. My arm kept aching so badly! I was messaging the lump over and over. After about 5-10 minutes it went down a little bit, ached a little less, and i left it alone. The next day it looked like i had a bruise on my wrist and hand (where the meaty part of your hand is going to the thumb. The next day, Sunday, March 20th, a neighbor said it could be a blood clot and i took an aspirin. Today, Wednesday, April 14, 2021. Approx 1130am, after getting out of bed, getting some coffee. I was sitting at my desk in my home office, took my medication and took my first sip of coffee. All of a sudden, my chest starting hurting. I cant say where the pain originated, it was in the chest/upper stomach area. It ached a lot, I felt very flush, I honestly cant remember if it were hard to breath, all i could think is "what is this?". I didn't know if i would throw up, burp, pass out. the aches starting migrating, still saying in the chest, but expanding to my lower back. I got out of my chair and tried to move around...it took a good 3-5 minutes before it started to dissipate and I took another aspirin.</p>

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1209778	4/14/2021	NY	87	F	3/12/2021	3/26/2021	Patient was admitted to the hospital 12 days (3/24/21) after vaccine dose administration (3/12/21) sent in for refractory abdominal pain, nausea and vomiting. On admission, a CT Abdomen/Pelvis with contrast was largely unremarkable including reported demonstration of patent portal vein. During the course of the hospitalization the patient developed a portal vein thrombosis visualized on 3/26 by ultrasound. She also received Heparin SQ from 3/27/21 through 4/2/21 but not sent home on anticoagulation. Her course was also complicated by a seizure and Bacteroides bacteremia. MR Brain did not demonstrate thrombosis
1209527	4/14/2021	TX	25	F	3/24/2021	4/7/2021	Blood clot in left leg
1209427	4/14/2021	ME	70	F	3/3/2021	4/13/2021	Patient experienced some extreme "charlie horse" cramps in her legs occasionally in the weeks following vaccination. She did not report them to the pharmacy until 4/13/21 when she saw the news regarding the blood clot adverse events and thought it may be relevant. She had charlie horses in the past but had not had them in recent history until after her vaccine. It happened 3 times, all in the middle of the night, mostly in her right leg. She did not need to see medical attention for any of them.
1209596	4/14/2021	OR	64	M	3/25/2021	4/14/2021	4-1-21-headache, indigestion, 4-2-21 ER visit, with admission, R/O MI. 4-3-21 transferred via ambulance for pulmonary embolism almost occluding pulmonary artery with peripheral and additional pulmonary clots. Performed thrombectomy immediately on arrival to hospital. Then 48 hours heparin therapy, home on Eliquis
1209582	4/14/2021	MI	48	F	3/4/2021	3/4/2021	Tightness in chest. Pain and soreness in arm. Swelling started evening of the injection and continued throughout the weekend when I went to the hospital. In 48 hours the injection site was painful, red, hot to the touch and very swollen. Two trips to ER on 4/7 being treated for allergic reaction. On 4/8 went to doctor and was ad used to go to ER for testing. Was admitted for cellulitis and severe infection and hospitalization until 3/10. Subsequent return to ER 3 days later for follow up because of swelling and elevated white blood cell count, elevated blood work suggesting blood clots.

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1209534	4/14/2021	TX	70	F	3/15/2021	4/2/2021	J&J vaccine 3/15 and on 4/2/2021 I thought I pulled a muscle and my leg started swelling, but my right leg only. I thought it would go down and my leg and foot started swelling up and my foot got really cold. I went to the hospital on 4/11 and they said it was a DVT and they checked my lungs and said I had small blood clots in my lungs as well. They put me on Eliquis to keep my blood thinned out.
1209444	4/14/2021	CO	44	M	3/10/2021	3/13/2021	Blood clots in my lungs
1209473	4/14/2021	AZ	50	F	1/29/2021	2/17/2021	I did not know this could possibly be a side effect of the vaccine until my school nurse alerted me to the possibility and advised me to report my reaction. I developed sinus congestion that I did not think was serious in the weeks after the vaccine. I had headaches and nasal congestion. many weeks after the vaccine, I sniffled and a large mass went down my throat, again I thought nothing of it. Last weekend, I got a very painful headache behind my other eye. I massaged my brown-bone and a large walnut sized and shaped mass, brown and red in color, shaped exactly like a shelled walnut with lobes came out of my nose. My school nurse told me this sounds like it was a sinus blood clot and to alert the clinic. The clinic in town where I got my vaccine said because I am not ethnicity, I had to report it myself on VAERS.
1209811	4/14/2021	MI	62	F	3/31/2021	4/4/2021	received Jansen vaccine on 3/31/21 and the following day I had a headache,, achy and tired. I expected this, but a few days later I was still having what I describe as migraine type headaches and at one point I was sweating profusely, dizzy massive headache with not only nausea, but dry heaving so bad I could barely get to my medication and seriously thought it would never subside. I continued with headaches up until today April 14. This is the first day I have not had a headache. I contacted my vascular doctor as I had a blood clot several years ago and he has prescribed Eliquis twice a day for the next 2 weeks. Today marks 2 weeks and like I said, it's the first day I have not had a headache

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1202169	4/13/2021	VA	41	F	3/23/2021	4/7/2021	on 4/7/2021 pt noted a soreness in her left leg she notified our office on 4/9/2021 and a doppler L leg was coordinated with showed L superficial vein clot but no DVT pt was instructed to hold her OCP; take advil TID and apply warm compresses
1202184	4/13/2021	UT	64	M	3/17/2021	3/22/2021	Blood clots in both lungs. Admitted to the hospital with severe pain in chest, trouble breathing, within 5 days of vaccination. Put on blood thinners to help get rid of the clots. Extreme fatigue before admittance to the hospital as well as ongoing extreme fatigue.
1202185	4/13/2021	ND	54	F	3/11/2021	3/14/2021	Blood clots running down the back of throat. Resolved by the following day.
1202196	4/13/2021	DE	87	M	3/26/2021	3/1/2021	LOWER LIMB EMBOLISM-BLOOD CLOT, TIGHTNESS, HEAT AND PAIN WHEN WALKING, TREATING PHYSICIAN COULD NOT CONTRIBUTE TO ANY OTHER HEALTH CONDITIONS OR REASONS
1202241	4/13/2021	GA	95	F	2/25/2021	4/10/2021	nonocclusive deep vein thrombosis (extending from upper femoral vein to Popliteal vein in left leg,, ) pulmonary embolism affected left pulmonary lobe) - no heart damage or pulmonary infarct; Was hospitalized at Hospital on Saturday 4/10 and discharge is scheduled for 4/13.
1202339	4/13/2021		39	F	3/13/2021	3/24/2021	Vaginal Bleeding: Menstruation began 1 day after the vaccine, which was normal and expected based on cycle tracking. 9 days after the vaccine I experienced spotting that was random for about 1 week. 21 days after the vaccine I had heavier bleeding (what I consider medium flow) and large blood clots were passed on days 26 and 27 after the vaccine. The blood clots were usually the size of a grape but two of them were golf ball sized, which is unusual for my body. I have bled for a total of 16 out of the 31 days since I had the vaccine. The frequency, amount, and consistency is not normal for my body.
1202477	4/13/2021	GA	44	F	3/26/2021	3/28/2021	Skin discoloration/possible blood clot on right calf. Occasional tingling in legs and arms.



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1202363	4/13/2021	MI	65	M	4/9/2021	4/10/2021	Severe Bloody nose, with quarter size blood clots that took more than 45 minutes to stop. Never had a bloody nose in his life. They told us it was from our dry house, but we had not not had the heat on. It stopped bleeding and we went home. Had bad headache for two days following.
1201995	4/13/2021	OH	45	F	4/8/2021	4/8/2021	Fever at 100, massive headache, crucial body aches, fatigue for 5 days and still not able to go to work. Dizziness and nausea.. the appearance of a clot between my neck and shoulder..
1202482	4/13/2021	TX	48	F	4/6/2021	4/12/2021	blood clots
1202374	4/13/2021	WI	74	F	3/5/2021	4/3/2021	Acute pulmonary embolus with mild right heart strain. Woke at 3am on 4-3-21 with severe pain and difficulty breathing, went to emergency room and was given a CT scan, diagnosed and treated with Heparin IV. drip and admitted to the hospital. Later an ultrasound test showed another clot in my left leg so I was started on Apixaban (Eliquis) 5 milligram . Released and sent home on 4-5-21
1202428	4/13/2021	PA	25	F	3/7/2021	3/22/2021	From Monday (3/22/21) to Friday, I could hardly breathe. My resting heart rate was around 110-120bpm. On Wednesday I went to the Hospital and for chest pain (when I would breathe in), shortness of breath, rapid heart rate, and a fever (on Monday). They ran many tests with chest scans and found all to be clear except I had a ?extremely elevated? white blood cell count. They said they ran blood tests and did not think I had blood clots and they did an MRI and chest x-ray and could not find anything. They sent me home to rest. The rest of the week I had trouble breathing and it slowly started getting better on Friday.
1202434	4/13/2021	OH	45	F	4/8/2021	4/10/2021	Started my menstrual cycle 6 days early, heavier than normal and increased cramping. Also, many small clots being expelled

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1202298	4/13/2021	PA	55	M	3/19/2021	3/25/2021	Starting slurring speech, right arm went numb and right side of face was not responding. Went to ER and they confirmed he was having a stroke. Continued to have multiple strokes at ER from 8:40pm last one was 1:30am (4 hours after clot buster given). Cause of stroke is still undetermined no clots found, no high blood pressure and no high chlorestrol.
1201961	4/13/2021	MN	31	M	3/10/2021	3/20/2021	10 after I received the Janssen Covid-19 vaccine, I admitted myself to the emergency room with severe chest pain and very difficult time breathing. They ran CT scans and found multiple blood clots in both lungs, pulmonary embolism. They put me on blood thinners and transferred me to another hospital. There they monitored me for a couple days and released me with a prescription for blood thinners.
1201899	4/13/2021	KY	64	F	3/26/2021	4/1/2021	Had systems of fatigue and chest pain. Went to hospital of 4/12/2021 . Learned that had blood clots in lungs that I previously did not
1201910	4/13/2021	UT	48	F	3/11/2021	3/18/2021	Exactly one week after my shot, I have been experiencing the longest and worst period I have ever had. I did not connect the two at the time. But I now feel this was a reaction to the vaccination. I am passing blood clots, undergoing blood tests and having a ultrasound on my uterus because it is so out of the ordinary.
1201947	4/13/2021	TX		U			On March 18 sore on the right arm, 3/19 chills,fever, cough, taste was off by salty every tasted like pure salt even a piece of candy. Back pain on lower back and stomach pains and inflammation of the stomach. Started with very painful back pain went to the doctor and gave him antibiotics and pain medicines and since he was not recovering with the medication they admitted him to the hospital on 4/9 with a blood clot in the portal vain causing no draining from liquids to the intestines and was placen on blood thinners

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1201883	4/13/2021	ID	58	F	2/19/2021	3/29/2021	Patient had a CVA (ischemic stroke) on 3/29/21 and was hospitalized for two days. Her signs/symptoms included sudden inability to form words, slow speaking, inability to write, inability to text/use cell phone, elevated blood pressure. She arrived to the hospital within 30 minutes of the start of symptoms and had a CT done that show no blood clot but an MRI about 12 hours later showed an ischemic area approximately the size of a quarter in her basal ganglia. After discharge from the hospital, she is following up with speech therapy, occupation therapy, and physical therapy. She was started on lisinopril, atorvastatin, plavix, and aspirin in the hospital and will continue those indefinitely.

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1203128	4/13/2021	FL		M			<p>DVT; PULMONARY EMBOLISM; KIDNEY BLEEDING; This spontaneous report was received from a physician, and concerned an adult male patient (greater than 50 years old). Initial report was processed along with additional information received on 12-APR-2021. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine AD26.Cov2.S (suspension for injection, intramuscular, batch number was not reported) dose and site of vaccination were not reported, administered on 20-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On an unspecified date in 2021, the patient experienced deep vein thrombosis (DVT), pulmonary embolism (PE), and kidney bleeding. The patient was admitted to the hospital and was treated with heparin as well as an inferior vena cava (IVC) filter (put in after he experienced bleeding from his kidney). Laboratory data included: a negative COVID-19 virus test, and throughout hospitalization his platelet count (NR: not provided) was normal: 191,000 and 264,000 (units not provided). The patient's test came back positive for one copy of the Factor V Leiden mutation which predisposed him to blood clots. On 12-APR-2021, the patient was to start a trial to Lovenox (enoxaparin sodium); they will assure there is no bleeding, prior to discharge. At the time of this report, the patient was still hospitalized but doing well. Action taken with Covid-19 vaccine AD26.Cov2.S was not applicable. The patient was recovering from DVT, pulmonary embolism, and kidney bleeding. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: v0 An adult (greater than 50 years old) male patient with a past medical history remarkable for the Factor V Leiden mutation experienced deep vein thrombosis, pulmonary embolism, and kidney bleeding on an unspecified date after receiving Janssen COVID-19 Vaccine Ad26.COV2.S. The patient was admitted to the hospital and was treated with heparin as well as an inferior vena cava (IVC) filter (put in after he experienced bleeding from his kidney). The patient had a negative COVID-19 virus test, and throughout hospitalization his platelet count was normal: 191,000 and 264,000 (units not provided). The Factor V Leiden mutation is known to predispose patients to venous thrombosis, therefore the causality for deep vein</p>

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							thrombosis, pulmonary embolism as well a consequent kidney bleeding most likely due to heparin treatment is assessed not related to the vaccination.
1202513	4/13/2021	CA	48	F	1/12/2021	1/14/2021	The first night vaccine developed telengectasias on my face. A couple of days later petechaie and extreme left arm soreness. A few days after that I had small splinter hemorrhages in multiple fingernails. A week later I developed Raynauds syndrome which then evolved to vasculitis in my fingertips. I had to go to urgent care when first started and multiple trips to Rheumatologist and have been on and off steroids and vasodilators due to vasculitis in my fingertips. I have splinter hemorrhages and small clots in my capillaries in my fingertips that are cutting off blood supply even without cold vasospasm.
1202025	4/13/2021	KY	58	F	3/16/2021	4/7/2021	Went to the doctor 4-7-2021 for a possible blood clot in my left lower leg and I was sent straight to the hospital for a test to check for a blood clot. It came back negative but my leg was streaky red and hot to the touch. It went away later that day
1201955	4/13/2021	CA	64	F	2/4/2021	2/16/2021	Shortness of breath , extreme pain 3 hospital visits until blood clot was detected,now on blood thinner Eliquis
1202135	4/13/2021	OR	86	F	3/10/2021	3/17/2021	Reporting for a friend she is in the hospital, all events may not be filled in, but I thought it was important to report sooner than later due to the news on other vaccines. Patient had her second shot around 3/7/2021 u sure as she is in a rehab facility time of day was 1630. On the 17 th of March she started having back pain then wasn?t able to get herself to the hospital called 911 and was transported to the hospital and that night had emergency surgery for a blood clot in her neck. She was in rehab and got rushed back to the hospital and had a pacemaker placed. She is still in a rehab facility.

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1201967	4/13/2021	TX	36	F	3/25/2021	4/9/2021	36 y.o. female referred for the above chief complaint. She has no significant medical history and presented with a headache that became severe 3 days ago. She received the Johnson and Johnson COVID vaccine on March 25th and had a mild headache following that which she attributed to the vaccine. 3 days ago the pain became excruciating and was associated with vomiting. This prompted presentation to the ED where she was treated with Dilaudid. She was discharged home and has been using her mom's headache cocktail with some transient relief. She presented back to the ED today with continued symptoms. MRV revealed a venous sinus thrombosis and neurology was therefore consulted. She has no history of clots personally or in the family. Her dad did have a stroke in his 50s. Patient otherwise denies any other associated speech change, vision change, extremity numbness, extremity weakness, coordination difficulty, or dizziness. Patient admitted to the neurology ICU and started on anticoagulation.
1202010	4/13/2021	VA	43	F	4/1/2021	4/1/2021	Fever Severe Cold/Chills Fatigue Headache Nausea Body Aches Chest pressure Knot (perhaps a clot in left leg behind the knee)-(still as of 4/13) Severe on-going Dizziness (still as of 4/13)
1202048	4/13/2021	MS	53	F	4/2/2021	4/11/2021	Woke up Sunday morning with a blinding headache, couldn't get relief with Tylenol. Tried warm towels, cold towels, shower, etc. Felt like sinus pressure. Lasted most of the day. Woke up Monday morning with clots of dark black blood in my nose. But no more headache.
1202064	4/13/2021	KY	40	F	4/6/2021	4/7/2021	Pt says she has a knot at the injection site that developed day after the injection and hasn't gone away even though it's been a week. According to the patient, she has a family history of blood clots and pulmonary embolisms. She was advised to contact her primary care provider and get the proper diagnostic tests.

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1202072	4/13/2021	CA	86	F	4/9/2021	4/11/2021	PATIENT WOKE UP AT 12 AM THROWING UP BLOOD AND FEELINGS OF PASSING OUT, 911 WAS CALLED AND AMBULANCE TOOK HER TO HOSPITAL, WHERE THEY DETERMINED IT WAS A STROKE AND MOVED HER TO ANOTHER HOSPITAL, WHERE CURRENTLY BEING TREATED DETERMINED BLOOD CLOT IN BRAIN. MOST LIKELEY DUE TO VACCINE SHOT.
1202133	4/13/2021	NJ	61	F	4/5/2021	4/10/2021	Around noon on 4/10, 5 days after shot, I started feeling a buzzing sensation in my right arm, as if my cell phone was vibrating. This persisted around 48 hours, stopping sometime around noon 4/12. A web search led me to issues with nerve damage and the further down the rabbit hole I went, possibly Parkinson's disease. This is a degenerative brain disorder. I scheduled appointment with my internist ASAP for May, the soonest I could get in. I also cold called a Neurologist office and they advised me to first see the internist. When I got up today and saw the issues with the J and J vax, and the rare instance blood clots in the brain, I thought my experience of 48 hours of some kind of nerve damage(?) or stimulation could be relevant or at least reported to someone.
1201948	4/13/2021	LA	43	F	2/25/2021	3/6/2021	X4 BLOOD CLOTS WITH 1 MONTH
1202715	4/13/2021	WI	41	F	2/4/2021	4/13/2021	I developed a sudden, sharp stabbing pain in the left side of my head while at work. I had not fallen nor had any injuries/illness. I went to ER; CT scan was concerning for clot in sinus so I was sent via ambulance to inpatient neurology where further MRI/MRV scans determined it was not in fact a clot, but a small bleed of unknown origin. Again, I had no injuries. I was hospitalized while multiple scans were completed along with lab work. Home now following up with neurology, still have head pain, unable to fully work, etc. Hematoma is still there but not growing.

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1203350	4/13/2021	CA	30	F	2/10/2021	3/19/2021	Severe headaches began 3/19/21; Urgent Care treated with meds and did CT Scan; sent to ER on 3/25/21. Admitted to hospital. MRI and CT scans done; Lumbar Puncture done--no bacteria; diagnosed as Cerebral Vascular Sinus Thrombosis; treated with Lovonox for 5 days then switched to Pradaxa when released from hospital; given oxycodon, dilaudid, and tylenol for pain. Starting 4/1/21, numbness in right arm down to fingers. Sent to ER again on 4/8/21 as headaches and numbness worsened. MRI and CT done. Clot dissolving but pain continued at 10/10 level. Released and continues on Oxycodon, Tylenol, Elavil, without relief as of today, 4/13/21. Still incapacitated by pain and unable to walk at length, work, or any normal activities.
1203359	4/13/2021	MT	40	F	1/12/2021	1/27/2021	Arterial blood clot to the superior mesenteric artery resulting in ischemic necrosis of the small bowel.
1201055	4/13/2021	NJ	83	F	3/19/2021	4/7/2021	Shortness of breath and rushed to ER - they found massive blood clot in both lobes of my lungs. No sign of Deep Vein Thrombosis - seems a mystery. Almost fatal if not gotten to ER so quickly they said. I was in the ICU from 4/7 - 4/10
1201882	4/13/2021	AZ	34	M	4/9/2021	4/10/2021	Janssen COVID-19 Vaccine EUA I got swelling and considerable pain at the injection site. The swelling started growing and started giving itching sensation. Right now, I have 2inch by 1 inch size clot with reddish skin and swollen. And I feel numbness or soaring feel in the left arm. I am heading to an in person doctor visit to understand more on this problem.
1203334	4/13/2021	IL	70	F	2/23/2021	3/10/2021	Dose 1 was administered;10 days prior to dose 2 patient began to have shortness of breath. Dose 2 was administered 3-23-21, Moderna Lot 006B21A. Severe sob and left sided pain 3-23-21 @ 5:30pm/difficulty moving around. Sought treatment at Hospital on 3-25-21 as symptoms were increasing in severity/chest xray and CT revealed pulmonary embolisms in both lungs; Heparin was started/transported by ambulance to another hospital for clot removal. Decided not to do procedure and was kept on Heparin for 24 hours. Began Eliquis that Friday/symptoms began to resolve and was dc'd on Saturday.



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1203313	4/13/2021	TX	44	M	3/13/2021	4/12/2021	PT EXP SHORTNESS OF BREATH AND CHEST PAIN; SELF REFERRED TO ER. D-DIMER ELEVATED. CHEST CTA SHOWS SOLITARY RIGHT UPPER LOBE PULMONARY ARTERY PULMONARY EMBOLISM. BILATERAL LOWER EXTREMITY ULTRA SOUND SHOWS THROMBOSIS FEMURAL ARTERY NO PERSONAL OR FAMILY HISTORY OF BLOOD CLOTS AND NO HISTORY OF BLEEDING EPISODES OR LONG TRAVEL OR SEDENTARYNESS.
1203308	4/13/2021	NJ	76	M	3/12/2021	3/30/2021	Acute metabolic encephalopathy, BPH with urinary obstruction due to blood clot. Patient was vaccinated at a pharmacy with Janssen covid-19 vaccine and experienced headaches and dizziness. Then began to have urinary retention which was believed to be due to a large blood clot requiring 12x 100mL flushes. Patient went to ED at medical center on 3/30/21 and was admitted. He was discharged to nursing home on 4/11/21.
1203288	4/13/2021	AZ	79	M	3/17/2021	4/13/2021	pt developed a blood clot in his ear and sought treatment 9 d after vaccination
1203273	4/13/2021	TX	63	M	4/7/2021	4/8/2021	Patient reports that several hours after receiving the vaccine that he became short of breath, he was taken to the hospital via ems, Diagnosed with blood clots at hospital. Reports he is now on blood thinners. I spoke with the patient and told him I would be reporting this information and that he may be contacted.
1203268	4/13/2021	CA	57	F	4/7/2021	4/8/2021	3 blood clots along the left arm where the vaccine was administered.

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1203266	4/13/2021	MA	31	F	4/3/2021	4/4/2021	All regular side effects on day 1 + day 2. (Fever, chills, bone and muscle aches, headache). Shortness of breath started the next day on Sunday , extreme, far beyond normal asthma or any asthma attack. Went to urgent care on Tuesday- they said it was likely a side effect of j & J and tested me for COVID, kidney disease other things, all came back negtative. Apparently I wasn?t the first person they had seen with shortness of breath. Blood in cough and spit on Wednesday after 2.5 days of shortness of breath. Dizziness (extreme) throughout and chest pain, sternum hurt, chest tightness. Went to Er. They ran a lot of tests and they too said they had seen others with shortness of breath from j and j. They ruled out many things like pneumonia, a birth control blood clot, any lung diseases with X-rays and blood tests. I was given torkeril to ease the chest pain and tightness which it did. Blood stopped coming up in tissues. Doctor said likely inflammatory reaction to the vaccine in lungs, (I have a piece of paper proving that) and cartilage and sternum., which hurt extremely when he touched it. Blood was likely from burst capillaries from overcompensation from trying to breathe. Recommended I return if more blood came up, which it hasn?t. Shortness of breath has not subsided. I can?t even hold a phone app without being winded. So email back, don?t call.

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1203245	4/13/2021		71	M	2/6/2021	3/25/2021	similar to a stroke/blood clot in brain; reduced mobility; massive weakness; Twitching; blood pressure high; This spontaneous case was reported by a patient (subsequently medically confirmed) and describes the occurrence of CEREBROVASCULAR ACCIDENT (similar to a stroke/blood clot in brain), MOBILITY DECREASED (reduced mobility), ASTHENIA (massive weakness), MUSCLE TWITCHING (Twitching) and BLOOD PRESSURE SYSTOLIC INCREASED (blood pressure high) in a 71-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 039k21A and 036A20A) for COVID-19 vaccination. The patient's past medical history included No adverse event. Concomitant products included METOPROLOL and PROSTATE CONTROL for an unknown indication. On 06-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 25-Mar-2021, the patient experienced CEREBROVASCULAR ACCIDENT (similar to a stroke/blood clot in brain) (seriousness criterion hospitalization), MOBILITY DECREASED (reduced mobility) (seriousness criterion hospitalization), ASTHENIA (massive weakness) (seriousness criterion hospitalization), MUSCLE TWITCHING (Twitching) (seriousness criterion hospitalization) and BLOOD PRESSURE SYSTOLIC INCREASED (blood pressure high) (seriousness criterion hospitalization). The patient was hospitalized from 25-Mar-2021 to 26-Mar-2021 due to ASTHENIA, BLOOD PRESSURE SYSTOLIC INCREASED, CEREBROVASCULAR ACCIDENT, MOBILITY DECREASED and MUSCLE TWITCHING. The patient was treated with ATORVASTATIN CALCIUM (LIPITOR) ongoing since an unknown date at a dose of 40 mg at bedtime. At the time of the report, CEREBROVASCULAR ACCIDENT (similar to a stroke/blood clot in brain), MOBILITY DECREASED (reduced mobility), ASTHENIA (massive weakness), MUSCLE TWITCHING (Twitching) and BLOOD PRESSURE SYSTOLIC INCREASED (blood pressure high) outcome was unknown. Not Provided; Sender's Comments: Based on the current available information and temporal association between the use of the product

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							and the start date of the events, a causal relationship cannot be excluded.
1203182	4/13/2021	WA	80	F	3/10/2021	3/11/2021	Morning on 3/11 awoke with fever and body aches, breathing became difficult over the next several days, along with light headedness. ED visit on 3/14 diagnosed with COPD flare advised to follow up with PCP. 3/22 follow up with PCP, discovered blood in stool sent to ED. Admitted on 3/22 with low hemoglobin and blood in stool. Endoscopy on 3/23 and coloscopy on 3/24. Source of bleed undetermined. Released on 3/23. 4/1 returned to ED as symptoms continued. D-dime blood test and CAT found blood clots in lower right lung. Prescribed Eloquis and released. Returned to ED on 4/5 admitted with low hemoglobin (7.1) bleeding, breathing difficulty. Endoscopy repeated on 4/6 not bleeding found. Released on 4/9.
1202729	4/13/2021	CA	88	M	2/14/2021	2/16/2021	On Sunday afternoon, March 14, I received the first dose of the Pfizer vaccination. On the morning of March 16 I had a sudden hit of fatigued and my left leg started going numb while doing some menial work in the yard, The numbness cleared when I went inside and laid down but some form of the fatigue persisted for several days. Then, on March 28, two weeks after the vaccine, I woke up to a leg severely swollen from toe to hip. I waited two days to see if it went down but it only got worse, swelling to double the size by volume. I went to the doctor and they sent me to the hospital for ultrasound, suspecting a blood clot. No blood clot was evident but there were multi swollen limp nodes in the upper leg area. The problem worsened and two days later I was sent in for a CTscan which now showed multi blood clots near the swollen limp nodes. I was barely able to walk as major pain persisted with no signs of decline. I am now on blood thinner. It has been 2 months since the vacination and my leg is still swollen the same amount (2X by volume).
1202613	4/13/2021	MI	71	F	3/24/2021	3/31/2021	Seven days after Moderna vaccine I got up and started feeling a warmth in my leg that started in foot and went up and it started hurting really bad, called an ambulance and went to hospital and because of blood clots, I had to have emergency surgery, it was very huge arterial clot, and developed shingles as well.

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1202539	4/13/2021	PA	45	M	3/26/2021	3/27/2021	Symptoms: Headache, tiredness, upper abdomen pain, vomiting, lower abdomen pain Outcome: Mesenteric Thrombosis, found via CT scan w/dye Treatment: Heprin in hospital, xarelto at home
1202540	4/13/2021	MD	66	M	3/8/2021	3/12/2021	Blood clot in right leg, with pain and swelling. Treatment with warfarin therapy
1202568	4/13/2021	MT	39	F	3/26/2021	4/5/2021	Possible blood clot in L knee, appears to be superficial. I get these frequently (about once a year).
1202578	4/13/2021		36	M	4/6/2021	4/11/2021	Swollen and painful spot on my right leg. No bruise. Thought it was workout related but didn't bump it on anything. It seems to match description of a blood clot.
1202588	4/13/2021	TN	57	M	3/11/2021	3/13/2021	Adverse event #1: Flu-like symptoms, severe headache, vision blurriness, lasting roughly 10 days. Adverse event #2: Deep Vein Thrombosis in the left Popliteal vein with moderate associated edema and pain. Required Emergency Room visit, diagnosis, and treatment with Eliquis. This event prevented normal daily work activities for 5 days, after which edema and pain has mostly subsided.
1203153	4/13/2021	MI	71	M	3/30/2021	4/2/2021	pt says he had chills, fever, headache, body aches and pain. Lymph nodes were swollen under his left arm. A couple days after taking the vax he was passing blood clots when using the bathroom. Pt states this lasted about 4 days. By 4/3/2021 all symptoms had subsided.
1202608	4/13/2021	TX	63	M	3/18/2021	3/1/2021	started coughing on 03/27/2021 and was taking to hospital on 03/30/2021. There he was treated for blood clots with anticoagulants and a filter placed in the vena cava.
1202749	4/13/2021	FL	84	F	3/8/2021	3/18/2021	Pt was seen by me for full arm thrombosis and CNS thrombosis which occurred approximately 1 week following second vaccine

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1202622	4/13/2021	CO	62	F	3/5/2021	3/13/2021	Severe pain in right side radiating up to shoulder. Diagnosed as a Pulmonary Embolism. On April 7, 10 days after second Pfizer Covid vaccination shot, (administered on March 26), patient developed severe pain in her left leg. Numerous tests for blood clots proved negative and on April 10 she developed a rash and blisters which is believed to be Shingles.
1202639	4/13/2021	NY	50	F	4/1/2021	4/9/2021	Develop a blood clot lost vision in left eye due to stroke. I'm still in the hospital. I am 50 and had a stroke a week at getting that vaccine TPA shot. Given. Clot buster
1202649	4/13/2021	WA	74	F	3/1/2021	3/31/2021	Blood clots then death
1202689	4/13/2021	WV	41	M	3/20/2021	4/10/2021	PATIENT REPORTS COUGHING UP BLOOD CLOTS FOR THE PAST 3 DAYS AND SENT PICTURE OF 1 THAT WAS COUGHED UP
1202713	4/13/2021	PA	48	F	3/22/2021	3/23/2021	Slight fever 12 hours later. Headache the next day. Severe headache with nausea two weeks later that lasted more than a day. Notice a small clot in left forearm. No pain, though.
1202529	4/13/2021	FL	28	F	12/24/2020	1/4/2021	Blood clot in left Iliac vein
1202602	4/13/2021	NE	86	M	3/9/2021	3/19/2021	Bilateral pulmonary emboli and bilateral deep venous thrombosis
1200326	4/13/2021	SC	45	F	2/4/2021	2/7/2021	A couple of days after the receiving the vaccine I started having severe heart palpitations. I noticed that a hemangioma on my lip was extremely swollen and black and blue looking while experiencing the palpitations. I was also dizzy. I sent pictures of mu lip to my doctor at college and he encouraged me to see my primary care doctor. Both doctors agree that they suspect I had a blood clot. I also haven't had a regular period since the vaccine. I had one brief period shortly after the vaccine, and it was unlike my periods before the vaccine. I haven't had a period in two months and I don't believe that is coincidental as I was 28 days regular before the vaccine.

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1201064	4/13/2021	FL	51	F	3/25/2021	4/2/2021	pain in left leg bulging veins just above the knee were enlarged (I usually have varicose veins) pain was intense and so I wore my compression sock for Friday and Saturday (I have had one prior superficial clot after a flight 6 years ago)
1201181	4/13/2021	NJ	76	F	3/21/2021	3/23/2021	Leg blood clot that traveled to my lungs leading to A Pulmonary Embolism
1201139	4/13/2021	PA	64	M	4/10/2021	4/11/2021	pt says he had headache, fever, chills, leg pain and SOB. Pt is feeling some better but still has a headache. Pt wants to know if it is safe to take aspirin in case of chance of getting blood clots. Pt will contact his PCP for medical advice.
1201126	4/13/2021	MI	50	F	3/15/2021	3/28/2021	Blood clot, stroke, severe headaches, dizziness, vomiting
1201117	4/13/2021	MI	22	F	3/30/2021	4/1/2021	Janssen COVID-19 Vaccine EUA. Vaccine burned while being injected and for about 4 hours afterwards. Arm hurt for a good week after as well. Had a small red raised bump at injection site for about 6 days. Have not had a period for 4 years due to my birth control, got my vaccine on 03/30/2021 and then started a brown and clotty period on 04/01/2021. Period last about 9 days and seems to be gone now besides an odor. Had undescrivable cramping in abdomen. Had some type of stomach bug (fever, vomiting, diarrhea) on 03/27/2021 that lasted about 72 hours. Then had another episode of diarrhea on 04/04/2021. Currently having bad headaches and right thigh cramps. Blood pressure and temperature seems to be running higher than my normal still.
1201057	4/13/2021	MD	39	F	3/15/2021	3/29/2021	1st night very out of breath. O2 at 93 on sensor at home. Felt better next day. 3/29/21 - went to ER for blood clot in left leg.

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1201033	4/13/2021	NC	51	F	4/7/2021	4/7/2021	at 11:30 pm on 4/7/21 I had extreme, spontaneous, stomach cramps so bad I thought I was going to pass out, that lasted for one hour, then diarrhea. A few hours later I started blood red rectal bleeding. At the hospital I was diagnosed with Ischemic colitis (from colonoscopy) and a blood clot was also found, portal vein thrombosis. I am 100% certain the extreme stomach cramps were brought on by the vaccine and that in turn caused the ischemic colitis, the blood clot may or may not have already been there. Note: The Dr.'s were not interested to tie any relation to this episode with the vaccine which was quite frustrating as it was quite obvious
1201016	4/13/2021		32	F	3/23/2021	3/23/2021	Around 6 hours after the shot, patient started feeling headaches. Later that evening came muscle pain, chills, high fever, nausea, vomiting, and migraines. The next day, most side effects went away except for the looming headache. Since the vaccine, patient has been experiencing episodes of dizziness and lightheadedness. There was an article that came out today as it relates to blood clots being a possible side effect of the vaccine and to report any feeling of headaches or possible symptoms that may be related to that.
1199631	4/13/2021	CO	44	F	2/23/2021	2/26/2021	Blood clot. Right leg. Treatment Lovenox injections and Pradaxa blood thinner medication. Time on Pradaxa to be determined on resolution of blood clot.
1200992	4/13/2021	DC	39	M	3/13/2021	3/29/2021	I developed leg pain in my right leg 2 weeks after vaccination. A week later, I went to the hospital and they confirmed "Acute deep vein thrombosis) DVT of calf muscle vein of right lower extremity" and at least one additional superficial clot. I was prescribed blood thinners apixaban (Eliquis) and was discharged. I'd previously had a clot in the same leg in 2009.



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1199637	4/13/2021	VA	36	F	4/7/2021	4/9/2021	Extended menstrual bleeding and spotting after receiving COVID vaccine. Received second Pfizer vaccine on day three of monthly period and heaviest day had passed. Typically have heavy bleeding/cramps on day #2 ONLY. After receiving vaccine, menstrual bleeding continued for longer/heavier than occurred during Pfizer vaccine #1. Seeing spots of bleeding and clots on day 8 which has never occurred during my cycles, even during periods of extreme stress. Menstrual bleeding is typically noticeable for me for 5-6 days and have never seen clots this far into my cycle. Only other physical side effects were feel of malaise day after receiving injection + headache + soreness in left arm injection site + pain on outside of left breast under arm and next to rib cage (no extreme tenderness to right breast).
1200987	4/13/2021	IL	48	M	4/12/2021	4/12/2021	The fire department came to his house as he is a paraplegic to give him the vaccine, and he can't move, is fatigued, has tightness in his joints, and has stomach issues, and takes Oxybutynin to control his urine and doesn't know what he's supposed to do. Off and on he has had a headache. Doesn't understand why they would give him a shot if it gives people a blood clot and he's a paraplegic. He already has an IVC filter in his veins to prevent him from getting blood clots.
1200861	4/13/2021	NV	63	M	3/11/2021	3/23/2021	He had his vaccine in different state while visiting his daughter. Returned home and was found to have a blood clot behind his left knee. Also, he called the doctor last week and told him that he believes he has another one above the left ankle. He has an appointment on Thursday to see him again. He had two venous ablation procedure in both legs in late November/December of 2020. He was taken off of the baby aspirin and then put on Xarelto. The 2nd possible blood clot appeared about 10 days ago above the left ankle.

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1201212	4/13/2021	WA	52	F	3/14/2021	3/24/2021	on 3/24 I had a TIA with an intense heat pressure behind the right temple which resulted in complete numbness, heaviness, and tingling on my entire right side of the my body. I was transported by ambulance to the hospital. A CT and MRI was done, no signs of blood clots or stroke. I am still experiencing numbness and tingling in the right arm. Follow up appointments with the eye doctor indicate additional vision loss in the right eye with pressure behind the eye. I have a follow up appointment today with the neurologist for a brain scan and tomorrow for an eeg. My PCP, eye doctor, and neurologist believe it may be a blood flow issue. I have not had this type of event before.
1200652	4/13/2021	MA	58	F	4/7/2021	4/9/2021	Janssen COVID-19 Vaccine EUA Approx 20 hours later the headache and some body aches and feeling tired Approximately 26 - 30 hours later noticed my hands really swollen and took rings off * Approximately 48 - 52 hours later very heavy dark slightly clotty nosebleed while eating dinner (no previous issues in years of having a nosebleed)
1206232	4/13/2021	CA	50	M	4/2/2021	4/9/2021	Leg pain in left calf for a number of days starting almost a week after getting vaccinated. I thought it might be a blood clot (this was e any news of blood clots was known). I had an ultrasound and it showed nothing. But I thought I'd report it anyway.
1203360	4/13/2021	TX	59	M	3/19/2021	3/21/2021	PATIENT CALLED Hospital 04-13-21 AND REPORTED HE HAD A STROKE 2 DAYS AFTER VACCINATION AND WENT TO another HOSPITAL. HE VERBALLY STATES IS HAVING PHYSICAL THERAPY FOR THIS STROKE. ENCOURGAED PATIENT TO SELF REPORT THIS EVENT. PATIETN WAS CALLING Due to THE TV NEWS NOTIFICATION OF THE J&J VACCINE PLACED ON HOLD DUE to IT CAUSING STROKES AND BLOOD CLOTS. PATIENT NOR DID HOSPITAL NOTIFY original HOSPITAL ON THIS PATIENT STROKE EVENT.

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1200839	4/13/2021	VA	37	F	1/7/2021	2/7/2021	On 12/17/2020 I received the 1st Covid vaccine at a Medical Center. I received the 2nd dose on 1/7/2021. Then on 2/7/2021 I began feeling a pain in my right side. I initially brushed it off but the next morning I could barely move. Thinking it was appendicitis I went to the Emergency Department where I was diagnosed with a right-sided Ovarian Vein Thrombosis. This is a very rare blood clot of which I have no risk factors. I was referred to a Hematologist/Oncologist at a Medical Center. I am currently on Eliquis until May 14th at which time I will be reevaluated by Dr.
1200818	4/13/2021	UT	60	M	3/31/2021	4/8/2021	Symptoms of Mini Stroke (TIA) 8 days following 2nd vaccine. No previous history of blood clots.
1200719	4/13/2021	NY	86	F	2/21/2021	2/21/2021	She had a stroke caused by blood clot in brain. Suffered a second stroke 4 weeks later. Has weakness left leg. Is now in Rehab Center
1199724	4/13/2021	MD	32	M	4/11/2021	4/11/2021	General muscle ache Dizziness Chills Very severe headache blew out my nostrils this morning and clotted blood came out
1200666	4/13/2021	MO	62	F	12/30/2020	1/11/2021	4 small ischemic clots in the brain causing stroke
1199989	4/13/2021	TX	50	F	3/18/2021	3/20/2021	IRREGULAR AND HEAVY PERIOD!!!. Vaccine received on last day of menstrual cycle. Two days later started spotting on daily basis and with clots which continued until I started on progesterone on April 8, 2021 (prescribed for 10 days). Even with the pill, I continue to spot lightly. I am unsure about getting the second dose of the Moderna Covid vaccine on 03/15/2021. Even with a history of previous fibroid removed around 2014. My period seem has never behave "non-stop" like this.
1200604	4/13/2021	VA	66	M	3/3/2021	3/14/2021	Deep Vein Thrombosis in left calf. Pain in leg. Treating with Eliquis for three months. Still in treatment but no more pain.

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1200509	4/13/2021	KY	59	F	3/18/2021	3/23/2021	Pain started on inside of right calf on 3/23/2021, but continued to spread up and down from just above ankle to groin area. Three areas were extremely painful to touch. Diagnosed as blood clots in the saphenous vein. Put on ibuprofen, keflex and famotidine on 3/29 and advised to elevate and use moist heat to help clots resolve. Pain started subsiding on 4/3 but is still there, just not as bad. Referred to vascular surgeon, on 4/6/2021. He recommended following advice from since they seem to be resolving and are not in the deep femoral vein. As of today, 4/13/2021, pain is still there although somewhat improved.
1200482	4/13/2021	CT	55	F	3/8/2021	3/13/2021	I woke up on Saturday 3/13 and noticed that my vision on my left eye was very fuzzy and stayed that way for a few days. I made an appointment to see my optometrist on Wednesday 3/18 and he referred me to a retina specialist Dr. I saw Dr on Friday 3/19. He ran tests and diagnosed me with branch retinal vein occlusion in my left eye. This is typically caused by a blood clot in the eye. The occlusion caused swelling in my retina and macula which caused my vision loss. I was treated with an injection of Eylea (anti-VEGF) to reduce the swelling on my retina/macula. I will need to have these injections every 4 weeks to maintain my sight.
1200466	4/13/2021	NJ	55	F	4/7/2021	4/13/2021	Severe sub cutaneous clots observed at site of vaccine Injection .
1200335	4/13/2021	NJ	41	M	2/23/2021	3/20/2021	Blood clot in right hand. Could not feel right thumb pointer and middle fingers and they turned purple. Went to hospital and treated with Heprin. Outcome - still have the blood clot. Put on Eliquis. Also developed high blood pressure from event and put on valsartan
1201222	4/13/2021	MI	29	F	3/22/2021	4/8/2021	small blood clot when tried to donate blood 2.5 weeks after shot, preventing me from finishing donation
1200702	4/13/2021	OH	39	F	4/11/2021	4/12/2021	Had a huge blood clot come out of my nose after a nose bleed. I do not get nose bleeds so this was very strange. Took me 15 minutes to get it to stop bleeding.

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1201478	4/13/2021	AZ	29	F	3/27/2021	4/3/2021	I was having intense chest pain, weakness/faintness feeling a few days after second dose of Moderna vaccine. I went into the ER after 4th day of pain. ER did a CT scan and found a couple blood clots in my right lung (pulmonary embolisms) along with tissue on lung. An ultrasound of my heart and legs were done to find the source of these blood clots and neither tests found blood clots or indicators that this is where they originated. I am currently in blood thinners in order to reduce the clots.
1201811	4/13/2021	NY	73	F	2/28/2021	3/3/2021	Painful swelling of the entire left leg and foot. MD ordered x-rays, ultrasound and MRI to rule out blood clot, cysts or tears. MRI did show two meniscus tears, however they were not new and had not been bothersome prior to the swelling. Referred to an orthopedic knee doctor who injected Cortisone into my left knee to reduce the inflammation. Which it did. The leg continues to have intermittent pain but the swelling is gone. The swelling lasted four(4) weeks.
1201774	4/13/2021	MI	64	M	4/10/2021	4/12/2021	Pain lower left back. Started to pee blood and blood clots

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1201764	4/13/2021	HI	69	M	4/10/2021	4/10/2021	- The following message was transmitted to my PCP on Sunday, 04/11/2021, about 11 PM. - Hello, yesterday, Saturday, April 10th, 2021, I received the Janssen (O42A21A) single-dose vaccine around 10 AM. About an hour after arriving home, i started having some of the most common symptoms reported, as in the following: Low-grade fever 99.3', Marked fatigue, mild muscle aches, some dizziness and generalized weakness. Took one 800mg Ibuprofen and rested. Last night, at around 10 PM, I had one episode of hematuria with some visible small-to-medium sized red clots, with no pain or discomfort on urination. Today, in the AM, I took another 800m Additional information for Item 18: 800mg Ibuprofen tablet, and by 12 noon, there was less fatigue and weakness, as I moved on in the day, the other symptoms improved or sub-sided, Except, for some, small clots, in a otherwise normal-appearing colored urine, around 1 PM. My B/P was 148/78, pulse 70, which is normal range for me. Additional information for Item 18: On Monday, 04/12/2021, during the day-time, I again experienced severe-to-moderate fatigue, and some dizziness, and then, last night, at around 7 PM, and 10 PM, I had two separate episode's of hematuria with some visible small-to-medium sized, Dark red clots this time, with no pain or discomfort on urination.
1201747	4/13/2021	AZ	92	M	1/15/2021	2/23/2021	Father started complaining about his right leg after first dose of Vaccine. After second dose on Feb 12, 2021, Father started complaining much more about his leg. On Feb 23, 2021 it was diagnosed Father had a Blood Clot in his leg.
1201742	4/13/2021	TX	76	M	4/8/2021	4/8/2021	Patient reported thinking he had a blood clot in both legs. Patient stated Saturday night he experienced severe leg pain in both of his legs lasting 30 minutes later. Patient stated that he felt as if he had pain in every muscle in both of his legs; patient stated that he could not stand for quite some time once pain began. Patient stated that pain caused him to wake up. Patient stated that he did not have any other problems afterwards.

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1201729	4/13/2021	IL	60	F	3/25/2021	4/11/2021	Called 911, hospital dianosed with Vertigo. woke up in bed during night turned to right side and got dissy and nausus, happened twice called 911, hispital dianosed with vertigo , ct scan showed no clots in neck or brain, said could be iner ear, follow up with family doctor. was givenMeclizine 25 mg tablets, Ondansetron ODT 4mg tablets
1201709	4/13/2021	IL	47	F	3/17/2021	4/2/2021	I started having left abdominal pain under my ribs (spleen and liver) on the afternoon of Friday, April 2 that lasted though Sunday, April 11. I went to the ER at 1am on Sunday, April 4 because the pain would not improve and kept me awake. I was admitted to the hospital for two days with a host of CT scans, blood work, Xray and ultrasounds for a diagnosis of splenic infarction and inflammation of the liver which I have never had before. No other clots were found, just evidence of spleenic infarction and inflammation of the spleen. Labor shows evidence of the diagnosis and I have now been put on low dose aspirin 81 for blood clot concerns and preventative by the advise of Hemotologist.
1201649	4/13/2021	FL	61	F	4/6/2021	4/7/2021	Beginning approximately 10 PM (about 8 hours post-injection), I started to have chills (feet were freezing) and was exhausted. Went to bed, and slept most of the night, only waking once to urinate and to drink a small amount (approx 2 oz) of Coca Cola -- I was very nauseous and thought it would help settle my stomach. During the night I sweated profusely. At 8 AM, I woke again and went to urinate. At that time I felt very nauseous, dizzy, and light headed. When I walked about 2 -3 feet to my bedroom, I collapsed on the floor - unconscious. My partner called EMS, they arrived minutes later. By then I was conscious. They transported me to Medical Center Emergency Room, where I remained for several hours. They indicated that my SYNCOPE was a result of dehydration. TODAY, 4/13, news of BLOOD CLOTS has compelled me to report my adverse reaction.

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1201641	4/13/2021	GA	60	F	3/9/2021	3/16/2021	Within 7 days of vaccine, I began experiencing aching of right posterior leg just below knee. Applied heat, elevated and just continued to ache intermittently, daily. Waited and disregarded as anything to worry about. After 2 wks of continued symptoms despite no redness, swelling or positive homans sign, being a health care professional (RN), I decided to seek evaluation at local ER to rule out DVT. On April 1st, I presented to ER, Address and number provided.completed and diagnosed with posterior tibial venous thrombosis on
1201612	4/13/2021	NV	58	F	3/23/2021	3/23/2021	On 23 March 2021 I received the Janssen Covid-19 Vaccine LOT #1805025. I contacted Johnson & Johnson via phone to report that I was experiencing an intense, deep pain in my upper left thigh and a headache about two hours after receiving the Janssen vaccine. Case #ICSR Information : 20210346108 JANSSEN COVID-19 VACCINE SECURE! The pain in my thigh worsened whenever I stood or sat still. I inquired if thrombosis is a side effect or something that I need to be concerned about. The woman on the phone said she looked up thrombosis, but did not see it listed. I asked if I should start taking aspirin. The woman on the phone said that she could not give me medical advice. I was so concerned that I took a full aspirin about every four hours for twelve hours on that day and a full aspirin for about three days thereafter and two baby aspirin ever since. The pain in my thigh diminished by 26 March 2021, but ended a few days later. The headache occurred intermittently. I have had some chest discomfort since then, but it hasn't risen to the level of angina. I am still concerned about thrombosis because of the intensity of the pain.



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1201593	4/13/2021	CA	46	F	4/1/2021	4/12/2021	I had the J&J vaccine on 4/1/21. I have a history of blood clots. I have tested positive twice. Once back in 2001 when I was pregnant and later on around 2008. I have had these symptoms before, but since I have a rare bone disease and have medical issues I really don't like to complain and just deal with this stuff with the pain pills I have a prescription for. Anyway, yesterday I was feeling a little off. My hands, feet and limbs in general tingling. I had a headache which is rare for me and tried to drink extra water, but by 5pmish came I took a handful of tylenol since I had an after work walk to go on with a girlfriend. After the walk I came home and had a desire to lay down and go to sleep. my leg was starting to go from tingle to burn. i decided that i needed to eat some dinner. after dinner i was struggling with breathing while sitting in the recliner chair watching TV, so I told my other half I needed to lay down, this was around 7pm. Then it was just a crazy leg burn from the back of my knee into my foot. I was describing it as if I someone pour gasoline on me and lite the match and I was burning alive. I took a muscle relaxer and forced myself to sleep. The day after the J&J shot. i had chills and was so cold that mid day when I had breaks during my work from home, i climbed in bed with a heating pad to warm up. the shot also left a scare on my arm, which i found odd since i give myself six injections a week for my bone disease. I tested positive with Covid December 20th, 2020 and it was a rough first week, but after about 10 days I was pretty much back to walking around and feeling better. You're more than welcome to have all of my medical record information, just let me know what you need. My doctor switched over to a different portal that I don't have access to and I haven't talked to her or her office since I had covid back in December and it's still a few hours before her office opens to report this, but I saw this on the news. My leg is still tingling and stiff. Again this is not my first time going through this, so I usually just push through it, but since I saw the news I am reporting it.
1201518	4/13/2021	NC	43	F	4/6/2021	4/11/2021	Blood in stool with some clots

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1201500	4/13/2021	KY	63	F	3/29/2021	3/30/2021	Blood clot in leg. Began as pain and skin discoloration in leg, eventually went to emergency room on 07Apr2021 and diagnosed with ultrasound. Treated with Xarelto, ongoing. Acute right lower extremity superficial thrombophlebitis noted in the greater saphenous (above knee). This superficial thrombophlebitis extends more than 10 cm in length. It does not extend into the deep system but is about 1.3 cm from the origin of the common femoral vein.
1201200	4/13/2021	TX	47	F	3/11/2021	4/3/2021	Dermatitis on torso, hands and feet, skin peeling on left foot A few nosebleeds with small clots
1201378	4/13/2021	CA	46	F	4/8/2021	4/11/2021	Approximately three days after vaccine, I experienced a blood clot. This caused an acute ischemic stroke in my left frontal lobe, resulting in muscle weakness and partial loss of use in my right leg.
1201270	4/13/2021	MA	66	F	3/19/2021	3/24/2021	Blood clot on middle joint of right hand pinky finger. Pressure bandage, heat, Advil. Decreasing in size after 18 days.
1201299	4/13/2021	NY	44	M	4/7/2021	4/9/2021	I had difficulty to think all friday afternoon(2 days after injection). After going to bed around 9:30 PM and therefore lying down I suddenly started to cough. It last for about 10 minutes, I could not stop. I also started to sweat. At this time I believed I got COVID-19 at the vaccination site and moved to another room to avoid to expose furthermore my wife. I did not cough anymore since then. Today after reading the news and symptoms of blood clot in the lung, I prefer to report this incident.

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1201310	4/13/2021	IL	49	F	3/20/2021	3/26/2021	I have a history of untreated fibroids that were diagnosed in December 2019. Because the coronavirus pandemic began in February 2020, elective surgeries were not allowed in my state. My bleeding and blood clots were caused by the fibroids during menstruation. On March 20, 2021, I received the Johnson & Johnson 1-shot COVID vaccine. By March 26th, the blood clots that were coming out of my body were enormous. They had NEVER been that large. Being concerned, I immediately saw my doctor as soon as my period ended. Today, I learned the J&J vaccine has been paused due to blood clots. I believe that my blood clots became so large because I was given this particular vaccine. WOMEN SHOULD BE ADVISED THAT IF THEY HAVE BLOOD CLOT CAUSING FIBROIDS, DO NOT TAKE THE JOHNSON & JOHNSON COVID-19 VACCINE.

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1201333	4/13/2021	MT	29	F	4/8/2021	4/9/2021	Headache (turned into a migraine), extremely drained of energy, lack of appetite, and felt off all day (4/9/21). The next morning (4/10/21) felt the same as the day before, however, had several episodes where I would get really light headed, dizzy, and nauseous. Went to Home Depot at 2:15pm (4/10) and while there my vision blurred and started to fade, I had ringing in my ears and couldn't hear out of the right and barely was able to hear out of the left. I got very nauseous and I couldn't breathe. I managed to sit on something and put my head between my legs that helped. Fortunately my step- dad was with me and helped me outside while I could barely see and hear and he stated I was very pale. I was having a hard time talking or being coherent. Once outside the symptoms slowly cleared over about the next 6-7 hours. At 4:45pm my mom decided to take me to the doctor but the walk in had just closed and I went to the ER. They stated I had elevated d-dimer and did a chest CT scan to check for blood clots around 7:30pm (I believe not sure exact time) doctor stated they came back clear but when asked if he suspected that the episode and symptoms were due to a dissipated blood clot he would not directly answer it. I overheard him dictating his notes and he stated he believed as such. I have never experienced anything like this before. I still felt drained, headache (migraine), occasionally dizzy, and lack of appetite (4/11/21, 4/12/21) and still currently feel the same drained, migraine, lack of appetite, and occasionally dizzy.
1201372	4/13/2021	KY	92	F	4/1/2021	4/7/2021	Resident c/o L arm pain on 4/7/2021 approx 2300. Resident transferred to ED for evaluation, CT abnormalities, transfer to higher level of care, clot manually removed on 4/8/2021, resident returned to nursing facility on 4/12/2021 without complications
1201494	4/13/2021	OH	82	F	3/6/2021	3/12/2021	Suprafacial blood clot in lower left leg. Pt contacted PCP, told to take 2 X 81mg aspirin for two weeks. Symptoms have resolved as of 4/13/21 when first reported to pharmacy.
1201376	4/13/2021	CA	55	M	3/19/2021	3/22/2021	blood clot formed in left leg in surface vein, at intersection with deep vein.

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1201482	4/13/2021	KY	52	F	3/5/2021	4/4/2021	Patient had the vaccine on 3/5/21. She then had major abdominal surgery which included abdominal reconstruction, hernia repair and excess skin removal on 3/19/21. She was released from the hospital on 3/22/21. She was readmitted on 4/4/21 for blood clots.
1201386	4/13/2021	PR	50	M	3/17/2021	4/7/2021	developed a rare disorder involving blood clots within about two weeks of vaccination.
1201389	4/13/2021	CO	27	F	4/12/2021	4/13/2021	Believe I may have passed a blood clot through urine or vagina early this morning. It appeared to be quarter sized. Non painful, one time event. Also have intense back pain and leg aching. Still feverish and have mild headache as well.
1201418	4/13/2021	SD	47	F	4/2/2021	4/6/2021	Patient reports blood clots and longer bleeding time than usual with flossing.
1201442	4/13/2021	KY	42	U		4/3/2021	Blood clot in eye 4/3, did not seek medical attention for this.
1201471	4/13/2021	KS	54	F	4/1/2021	4/2/2021	Blood clot on 4/2 in left calf
1201835	4/13/2021	PA	59	F	3/12/2021	3/19/2021	Low grade fever, aches & chills on 3/13/21 & 3/14/21. Felt better 3/15/21 through 3/18/21. Side effects ( fever, aches, chills ) returned on 3/19/21 & 3/20/21. Suffered stroke on 3/21/21 at 3:30 AM due to blood clots. Passed away on 3/22/21.

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1201374	4/13/2021	GA	53	F	3/16/2021	4/3/2021	On 4/3/21 the patient presented with a 1 week history of slowly progressive shortness of breath and 3 day history of left upper quadrant pain. CT revealed bilateral segmental and subsegmental pulmonary emboli, moderate splenic enlargement, and small volume perisplenic hemorrhage. Continuous infusion heparin was started for the bilateral PE. On 4/4 an inferior vena cava filter was placed and patient was vaccinated with Acthib, Bexsero, and Prevnar vaccines in anticipation of splenectomy. On 4/7 a laparoscopic splenectomy was performed. The spleen was evaluated by pathology which reported "Organizing blood clot on surface, consistent with rupture. No evidence of malignancy." The patient remains inpatient while recovering from surgery. On 4/12 she was transitioned to rivaroxaban for therapeutic anticoagulation. Please note as of 4/13 the patient remains hospitalized.

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1205233	4/13/2021	PA	68	F	3/17/2021	3/19/2021	had swelling and pain in her wrist; had swelling and pain in her wrist; her fingers turned a deep blue; caller was given some medication to dilate her blood vessels; This is a spontaneous report from a contactable consumer. A 68-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered on right arm on 17Mar2021 17:00 (Batch/Lot Number: EN6206) at single dose (at the age of 68 years old) for COVID-19 immunisation. The patient had no medical history. Concomitant medications included levothyroxine sodium (SYNTHROID) taken for an unspecified indication, start and stop date were not reported. On 19Mar2021, the patient had swelling and pain in her left wrist, the following day her fingers turned a deep blue. The patient was sent to the hospital to rule out a blood clot, they couldn't find a clot and couldn't tell the patient if this was related to the vaccine. The patient was given some medication to dilate her blood vessels to take when the patient gets the second if she needs it. This happened in the opposite arm that the caller received the vaccine. The patient had an angiogram of the wrist on 21Mar2021, they injected dye into the patient's wrist then she went through the CT scan on 20Mar2021 and the results were negative. The patient was hospitalized on 20Mar2021 to 22Mar2021. The outcome of her fingers turned a deep blue recovered on 22Mar2021 and other events was recovered on Mar2021.
1205023	4/13/2021	MD	18	F	4/3/2021	4/13/2021	Severe headache this morning and all today. We went to the pediatrician and they performed neurological tests because of the blood clots that were reported. She was sent home and alerted to go to ER if any other symptoms develop

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1205545	4/13/2021	AL	81	M	2/17/2021	3/11/2021	Patient experienced shortness of breath a few days leading up to the adverse event. On the evening of March 11, 2021, he collapsed. An ambulance was called and he was taken to Emergency Room. He stayed there until the morning of March 12, 2021 when it was discovered that he had multiple blood clots in his lungs. At that time, he was air lifted to Hospital Intensive Care where he stayed until March 17, 2021. At that time, he was moved to Health Rehabilitation Hospital of where he stayed until March 27, 2021. First vaccination was on 01/22/2021; Second was on 02/17/2021.
1205477	4/13/2021	NE	67	F	4/12/2021	4/13/2021	PATIENT WENT TO THE HOSPITAL AFRAID THAT SHE HAS A BLOOD CLOT.
1205474	4/13/2021	NY	69	F	3/9/2021	3/1/2021	She fell twice. The second time was due to a blood clot on the brain that led to multiple bleeds under dura and the brain. She needed an emergency craniotomy and is now undergoing acute rehab for speech, PT and OT.
1205446	4/13/2021	WA	76	M	3/15/2021	4/1/2021	Pt states that about 3 weeks after the vaccine, pt experienced pain in his right calf where he did not feel like he can put any weight on it. Pt states going to the doctor to check on the leg, ran tests, and also did an xray. Pt states the Dr did not find a clot and mentioned that perhaps it was a sprain/strain. The pt did not agree that it was a sprain and wanted the pharmacy to report this adverse event. No other side effects were reported. Recommended that pt goes back to doctor to get leg checked out some more.



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1205445	4/13/2021	MN	33	F	4/9/2021	4/9/2021	Tachycardia. I had the expected side effects of headache, chills, body aches, fatigue and fever (102.6 F) but began to experience symptoms of pounding/racing heart that worsened through the evening. By 10:00 pm my heart rate was bouncing around between 130 bpm and 155 bpm, and I was beginning to have pain in my lower legs/ankles. Was told by a on call nurse for my clinic to go to the ER. I was in the ER for about 5 hours, roomed the whole time as they worked to get my heart rate down and checked to make sure I didn't have a blood clot. They performed an EKG and CT Scan of my chest, both were fine. I was eventually allowed to leave after 4 am on 4/10/21 after my heart rate got into the high 90's with only small spikes into the 110's with slight movement and once my fever had broken.
1205440	4/13/2021	IL	35	F	4/1/2021	4/2/2021	Prior to vaccination bowel movements were every 2 or 3 days with mild constipation. Mild diarrhea like symptoms began the morning after the vaccination. Bowel movements were at least 4 to 5 times a day for the first 3 or 4 days and then to 3 to 4 times a day. Bowel movements included sticky/slime looking substance what may have looked like blood clots. Symptoms lasted from 4/2/2021 to approximately 4/11/2021. Bowel movements are now 2 to 3 times a day but normal, with no other substance.
1205425	4/13/2021	DE	44	M	4/9/2021	4/10/2021	itchiness, extreme thirst, pain in leg reminiscent of blood clots I have had in the past
1205424	4/13/2021	MT	61	F	4/1/2021	4/4/2021	Left chest pain no MI, PE....acute crisis with clot ruled out CBC showed giant platelets and variant leukocytes which have not been present before
1205392	4/13/2021	ID	63	F	2/16/2021	2/16/2021	blood clots in left leg and both lungs diagnosed on 2/22, died 2/24
1205385	4/13/2021	MA	45	F	3/8/2021	3/14/2021	Long period with heavy bleeding with blood clots. This has never happened before in my entire life.
1205585	4/13/2021	FL	66	M	2/11/2021	4/3/2021	Blood clot in the middle cerebral artery leading to ischemic stroke
1206172	4/13/2021	FL	51	F	2/14/1970	3/27/2021	Severe blood clots,surgery sbc filter

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1205684	4/13/2021	NM	58	F	3/24/2021	4/3/2021	Blood Clot blocked oxygen to the brain. Suffered a severe stroke. Was hospitalized. Suffered brain swelling. Lost brain function. Died.
1203375	4/13/2021	VA	63	M	3/6/2021	3/14/2021	Beginning March 14 pain in right thigh and right calf. Went to family doctor March 19th said could be dry skin used skin cream no change. Went to hematologist on 26th blood test for blood clots came back normal. On March 29 had ultrasound on right leg for blood clots came back normal. On April 5 went back to famil doctor with pain still in right leg and thigh awaiting blood test results.
1205201	4/13/2021	MO	42	F	3/15/2021	3/18/2021	Three days after receiving the vaccine, I developed a blood clot in the lining of my stomach.; This is a spontaneous report from a contactable consumer. A 42-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; Batch/Lot Number: EN6201), dose 1 via an unspecified route of administration, administered in Arm Left on 15Mar2021 11:30 as SINGLE DOSE for covid-19 immunization. The patient medical history was not reported. Concomitant medication(s) included ethinylestradiol, norgestimate (SPRINTEC) taken for an unspecified indication, on an unspecified date. On 18Mar2021 05:30 the patient experienced three days after receiving the vaccine, developed a blood clot in the lining of her stomach (thrombosis). The patient was hospitalized for three days after receiving the vaccine, developed a blood clot in the lining of her stomach for 3 days. Therapeutic measures with blood thinners were taken as a result of three days after receiving the vaccine, developed a blood clot in the lining of her stomach. The outcome of the event was recovered. Information on Lot/Batch number was available. Additional information has been requested.

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1205190	4/13/2021			U	3/9/2021		<p>her veins were swollen and she had blood clot.; her veins were swollen and she had blood clot.; severe earache; severe headache; her mouth and throat were on fire.; her mouth and throat were on fire.; This is a spontaneous report from a non-contactable consumer (other HCP) via medical information team. A patient of unknown age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiration date were not reported) via unknown route of administration on 09Mar2021 as single dose for covid-19 immunisation. Reportedly, patient got the first dose of the Pfizer COVID-19 vaccine on 09Mar2021. After that, she had developed severe earache, severe headache, her mouth and throat were on fire. Few days later, her veins were swollen and she had blood clot. She was also afraid to take her medication, Eliquis, since there may be more adverse events from that medication. Patient was scheduled for her second shot of the Pfizer COVID-19 vaccine today, 20Mar2021. She was told that the adverse events after the second dose of the vaccine are worse than the first dose. She has also read that people die from the vaccine. She wants to cancel her appointment today. She wanted to know if the vaccine would be 80-85% effective after a single dose. She wanted to know if she would be ok with just one dose of the vaccine. No PQC was present. The outcome for the events was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the information currently available, a possible contributory role of the suspect vaccine BNT162B2 in triggering the onset of thrombosis and other events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>

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1205143	4/13/2021	CA		U	2/25/2021	3/24/2021	DVT; blood in urine; This is a spontaneous report from a contactable consumer (patient) via the Pfizer-sponsored program. A patient of unspecified age and gender received the second dose of bnt162b2 (BNT162B2, Solution for injection lot number and expiry date were not reported), via an unspecified route of administration on 25Feb2021 as single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient previously received the first dose of bnt162b2 (BNT162B2, Solution for injection lot number and expiry date were not reported), on 03Feb2021 for COVID-19 immunization. On 24Mar2021, the patient had blood in urine. After visiting ER (emergency room) 2 times, the patient got DVT (Deep Vein Thrombosis). The doctors were also not sure if that's because of the shot or not. Outcome of the events was unknown. Information on the lot/batch number has been requested.
1205100	4/13/2021	MO	58	F	3/23/2021	4/2/2021	About two weeks after getting the first vaccine, experienced swollen sinuses and was blowing blood clots out of my nose (in the sinuses). Given Prednisone 20mg twice a day for 4 days, and Azithromycin 250 mg, for five days, for sinus and upper respiratory infection
1205086	4/13/2021	VA	62	F	4/7/2021	4/12/2021	Patient's husband called to report that his wife was in the hospital due to a blood clot that formed in her leg. He stated that she was having organ failure. Patient is currently being treated at a local hospital for blood clots that were moving and affecting her organs.
1205079	4/13/2021	FL	76	F	3/16/2021	4/1/2021	Pt stated that approximately two weeks after vaccination she went to her physician office for an issue with her eye. Her eye was severely red. At the physician's office, the physician told the patient that there was a small blood clot in her eye. The patient stated she didn't think anything of it at the time, but now that the CDC came out with the statement about the Janssen vaccination, she decided to report to the pharmacy.

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1205072	4/13/2021	MA	60	F	3/4/2021	3/17/2021	Two weeks after 1st Pfizer shot I began to have very heavy breathing while on a daily walk that continued with any exertion. It continued for several days. I called PCP and was seen. Chest Xray & bloodwork was done. Was called to go to E.R. for CT scan of lungs. Pulmonary Embolisms were seen and a blood thinner was given. Heart monitored for previous Afib (ablation performed 5 yrs ago). CT scan w/dye was done of abdomen, Right leg ultrasound with compare L, MRI w/contrast done of abdomen/pelvis. No reason has been found for cause of several blood clots in both lungs - sub arteries. Am being followed up by Vascular Doctors in 2 weeks.
1205071	4/13/2021	OH	85	U	2/11/2021	2/18/2021	On February 18, 2021 between hours 18:20-18:40 and a week after taking the second shot, patient lost balance (fainting) at home, fell, bruised a rib and fractured skull, causing subdural hematoma (bleeding outside of the brain). Bleeding stopped and several CT scans were performed. Under medical supervision, an anticoagulant medication was stopped to allow for healing. On February 20, 2021, moved from ICU to regular hospital room and on February 23 moved to another hospital for intense rehabilitation. Within days a thrombus developed causing a minor Cerebrovascular Accident, which was immediately identified by a medical doctor and nursing staff. On March 2, 2021 at 10:30 am moved to a Medical Center for further treatment. An endovascular thrombectomy for the removal of a thrombus was performed by a doctor. After recovery in the Neurosciences Critical Care ICU, under amazing care by the doctors, further thrombi developed on patient's lungs and around the bowel. Patient expired at 8:01 on March 4, 2021 due to Ischemic Complications of Thrombi/Thromboemboli.
1205067	4/13/2021	LA	18	F	4/6/2021	4/6/2021	Evening after shot had fever of 102.3, chills, body aches bad enough to make it hard to walk. Those ended by next day. Developed very sore left hip/buttocks. Pain up to level 8. Now about 3-4. Saw pediatrician today to see if there was concern for blood clot. Was told to watch for sudden changes and sharp pain.

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1205036	4/13/2021	PA	65	M	3/19/2021	3/30/2021	On March 30th started with headaches then progressed to shortness of breath while moving. Then on April 4th transport to hospital via EMT was tested for Covid 19 results was negative. It was determined that blood clots were found in Right leg & Left leg and both lungs and now blood clot was found in heart. PT has low platelets, low blood pressure. While in the hospital pt was given herapin . Patient has remained in ICU since the 4th to present time.

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1205263	4/13/2021	MN	56	F	3/24/2021	3/1/2021	allergic reaction/Allergic anaphylactic reaction; lungs were filling up with fluid; throat was closing; Main trouble is breathing and is out of breath; legs sore; Throat sore; Cough; hard for her to walk; tired; trying to swallow a tablet and digest it and it gets stuck; trying to swallow a tablet and digest it and it gets stuck; breathing was heavy; choking; trying to swallow a tablet and digest it and it gets stuck; This is a spontaneous report from a contactable consumer. A 56-year-old female patient received bnt162b2 (BNT162B2 reported as PFIZER COVID 19 VACCINE), dose 1 via an unspecified route of administration in the right arm on 24Mar2021 (Lot Number: ER2613) as a single dose for to prevent COVID (covid-19 immunisation). Medical history included having blood clot from 2019 to Mar2021 which the patient stated a couple of weeks ago (Mar2021), she had an ultrascan in her leg and the blood clot was not there, but she is on medication. The patient has recovered completely from blood clot (not ongoing). Concomitant medication included warfarin (WARFARIN) to prevent from having blood clot ongoing since Jun2019. The patient previously took gabapentin for pain but had throat started closing, allergic reaction, coughing and was intubated until she was released from hospital; and albuterol [salbutamol] for dyspnoea but had nebulizer to open up her airways and prevent closing and did not work (drug ineffective). The reporter mentioned that the patient ended up in the ICU because of the COVID vaccine. As soon as the vaccine was administered within seconds, the patient experienced a reaction and was given an epi pen, another epi pen even an epinephrine drip and was sedated and intubated. The reporter mentioned that they gave the patient the first shot of epi pen and it did not work, and she was given a second one and a third one plus steroids. By the time the ambulance people arrived, they hooked the patient up to an IV and gave her additional epinephrine and administered another epinephrine. The ambulance guy told her; she does not need to keep up with them because they needed to go to the hospital ASAP because the patient is not getting better but getting worse. Once the patient got to hospital, she was intubated because her throat was closing. The reporter stated that the patient has allergies to begin with and this was worse than the first time she had to be intubated. The epi pens did not work, the patient was

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intubated and then had to be sedated. The patient was on Propofol in order to sedate her and later on in the evening was given Fentanyl to relax her then the epinephrine drip was removed at 6 pm on 24Mar2021. The epinephrine drip was started in the emergency room and the patient could not be moved to the intensive care unit until she was somewhat stable. The patient was moved to the intensive care unit and was there overnight and by the time next morning she was able to be extubated where they removed the tube from her around 9:30 to 10:00 25Mar2021. Of course, the patient was taken off Propofol, but she went through a lot and her legs are sore, throat is sore, and is coughing on 25Mar2021 because of the side effects from being intubated and that she went through a lot. The intensive care unit doctor said that the patient can no longer have the vaccine and she would only be 70% protected till whenever they are not sure how long the vaccine will last. The adverse events almost took the patient's life which made the reporter angry at that. The reporter is not sure what the contents in the vaccine that it in the other drugs and vaccines since there is something that is contained in all of them and the patient was not allowed to have any whether it is the Pfizer or Moderna and it is even up for discussion for even the flu shot because of the reaction and there does not want to be any chances and that everything should be proceeded with caution. The reporter wanted to know what is in the COVID 19 vaccine to see about what could have caused the allergic anaphylactic reaction. The reporter stated and the fact that the epi pen did not work, she was taken aback. The reporter added that the doctor had a hard time intubating because of her throat but they were able to intubate from the second time. The reporter stated that it is taking a while but her wife is recovering and feeling it is taking a while taking a little bit longer. The reporter also stated that they kept the patient in the intensive care unit overnight and after the tube was removed in the morning, by the late afternoon she was moved to a different floor to continue to be observed and the intensive care doctor said 2 days out her wife would be safe to go. The patient stood up but it was hard for her to walk on 25Mar2021 because it could have been from the epi pen, but she is not sure. The patient stated the side effect came out of the allergic reaction and it was on Thursday 25Mar2021.



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Patient stated the main trouble is her breathing, she is out of breath still and really sore throat on 25Mar2021. The patient stated that the leg sore is still ongoing and is about the same. It was mentioned that the throat sore was still ongoing but some days are worse and some days are better. The patient stated that when she has a problem trying to swallow a tablet and digest it and it gets stuck on Mar2021. It was stated that the cough was not going away. The cough comes and goes away. She will cough for five minutes constantly and then it disappears then she will fall asleep and wake up coughing. It's as if she is choking (Mar2021). When she is talking, she coughs more. With regards to the allergic anaphylactic reaction, the patient stated she is experiencing the aftereffects of the allergic reaction and being intubated like being out of breath. The patient stated that will come in time and that's what happens when she gets intubated. Her breathing was heavy and comes back fully with rest on Mar2021. This has taken a lot out of her. She was feeling tired which was still ongoing it is about the same but comes and goes on 25Mar2021. The patient is experiencing lingering side effects and the patient does not feel as if she has recovered completely. It was also mentioned that the patient was intubated on 24Mar2021 to 25Mar2021. It was reported that treatment of the patient included Epi Pen, Epinephrine Autoinjector USP 0.3 mg (Epinephrine injection manufacturer was Mylan) which the patient was given at least three injections (two in the right leg and 1 on the left) then received another in the ambulance (unknown site). Patient received an Epinephrine drip and it was like 0.1 mg all the way up until 6 pm (only on 24Mar2021). The epinephrine drip was started when patient was intubated at the hospital. It was given for patient's allergic reaction through IV. The patient's lungs were filling up with fluid so her airway was restricting her from breathing and to prevent damage of the lungs that is when the intubation came in. The patient also received Prednisone which the reporter does not recall when this medication was started it may have been after the epinephrine drip was removed but she is not sure if they started the prednisone after or if it was the same evening which the reporter kind of thinks it was. The reporter stated that the patient took Propofol 24Mar2021 to 25Mar2021 which was given through the patient's IV and was given to help her airways being

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							intubated, they sedate their patients. The patient also received fentanyl which must have been added either right before Epinephrine drip was removed or after but reporter does not recall. Patient was given Fentanyl 24Mar2021 to 25Mar2021 through her IV. Patient received this medication to relax because sometimes it is like some patients tend to want to sit up and kind of hear you, hear what people are saying and to relax patient sometimes because they can get scared and not exactly sure what is going on. The events anaphylactic reaction, pulmonary oedema, throat constriction and breathing difficult. The patient underwent lab tests and procedures which included lung was checked from a CT scan was unknown results on 12Jun2019, D dimer test was elevated on an unspecified date, ultrascan in her leg (ultrasound scan) blood clot was not there on Mar2021 and weight was probably weighs 180 or her weight may be a little less like 175 on an unspecified date. The outcome of the events anaphylactic reaction and throat constriction were recovering, as for the events leg pain, throat sore, cough and tiredness were not recovered while the outcome of the other events was unknown.
1205934	4/13/2021	AR	30	F	3/10/2021	3/23/2021	Venous blood clot in leg, and lunnv
1206257	4/13/2021	TX	42	M	4/1/2021	4/7/2021	Severe leg pain first, then trouble breather. Shortness of breath and tightness in chest. Thought it was severe congestion... delayed going to the ER. Finally went in due to vomiting trying to get breath. Had LAD 90% blocked and blockage in the right leg still in hospital receiving treatment. Will Catheter scope the right leg to very clots and severity.
1206245	4/13/2021	AR	69	M	1/4/2021	2/23/2021	Headache started 2-23, on 3-5 had MRI brain that showed central venus sinus thrombosis from transverse sinus to sigmoid sinus and jugular vein. Treated with SQ Lovenox followed by oral Coumadin. Headache has resolved and I am still alive. I have not yet had repeat MRI to recheck thrombosis.
1206218	4/13/2021	CA	52	M	3/13/2021	3/24/2021	Left Distal Deep Vein Thrombosis Prescribed Eliquis for 3-6 mo.

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1206156	4/13/2021	IL	64	F	3/10/2021	3/19/2021	Nine days after vaccination developed pain and swelling in lower right leg, ankle and foot. Red discoloration of lower leg and purple and blue discoloration on ankle/foot. Went to ER suspected blood clot. Ultrasound and blood work were done. NO blood clot was found.
1206065	4/13/2021	MO	46	F	3/19/2021	4/13/2021	First day of menstrual cycle has produced large clots and severe cramping. Normally my periods are light with zero cramps. I was in so pain today I was unable to work even after taking 1200mg of ibuprofen
1206037	4/13/2021	NH	39	F	3/31/2021	3/31/2021	Within half hour, experienced sharp nerve pain and numbness on right side of face, opposite side of injection. Later that evening ~8pm experienced sharp nerve pain at right fingertips and groin, and nausea. Had soreness on left arm (injection site) and nausea that lasted for 3 days. 6 days later, had soreness under left armpit that lasted for 3 days. No noticeable swelling. Next day had severe migraine that caused blurred vision and nausea. Migraines lasted for 3 days, took Ibuprofen (2 - 200mg tabs 2x daily). Next day, had subconjunctival hemorrhages of right eye, 2x . Only other medication I take is birth control pill, Tri-Previfem. Pt is in good health. No history of high blood pressure, blood clots, diabetes, or other known health conditions Pt has routine annual health exams, in good health.
1206024	4/13/2021	PA	60	F	3/15/2021	4/8/2021	stroke caused by 2 cerebral blood clots
1206018	4/13/2021	IL	52	F	3/11/2021	4/9/2021	I had a blood clot in my left lung. went to ER , spent three days in the hospital was given medications (Xarelto ) required to taking medication now for a least a year.
1205996	4/13/2021	NV	49	F	4/6/2021	4/9/2021	Nearly a week after injection, injection site is still visibly swollen, slightly warm to touch. Blood clot passed vaginally (outside of normal menstruation schedule).
1205989	4/13/2021	OH	85	F	2/11/2021	2/28/2021	Blood clots in leg and both lungs; shortness of breath. Shortness of breath for 1 week before seeking medical attention on March 7th. Admitted to hospital through emergency room on March 8th. Hospitalized from March 8-14. Put on Coumadin. Sent home with supplemental oxygen.

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1205972	4/13/2021	NM	37	F	2/5/2021	2/10/2021	Been severely ill have cold sweats, swollen lymph nodes, leg pain that feels like blood clots or swollen vessels dizziness temple swelling abdominal pain went to several doctors and they say nothing wrong but I feel horrible like I was going to die heart beating fast cold feet and hands
1205576	4/13/2021	OH	49	F	3/3/2021	3/4/2021	I was diagnosed with a blood clot in my right leg.
1205939	4/13/2021	CA	55	F	4/3/2021	4/11/2021	All was fine till day 9 evening when my right eye kept watering, and I brushed my teeth water shot out right side. Next day same thing with blurred speech. I went to hospital, had CT and MRI. No blood clot determined its bells palsy. I have been healthy except for mild seasonal allergies
1205227	4/13/2021	CA		U	2/25/2021	3/24/2021	I got DVT-Deep Vein Thrombosis; blood in my urine; This is a spontaneous report from a contactable consumer (patient) via the Pfizer sponsored program. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration on 25Feb2021 (Batch/Lot number was not reported) as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Historical vaccine included PFIZER BIONTECH COVID 19 VACCINE first dose on 03Feb2021 for COVID-19 immunisation. The patient got dvt-deep vein thrombosis on an unspecified date with outcome of unknown and blood in urine on 24Mar2021 with outcome of unknown. It was mentioned that the patient got first shot on 03Feb21, and second shot on 25Feb21. But on 24Mar21, blood in his/her urine. After visit ER 2 times, the patient got DVT (Deep Vein Thrombosis). Also doctors were not sure that's because of the shot or not. Information on the lot/batch number has been requested.

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1205919	4/13/2021		23	M	1/4/2021	1/12/2021	Approximately 7-10 days or so after receiving the first dose of the pfizer Covid vaccine I started to develop this red, nodule-like, painful "rash" on both of my forearms. Not only the left arm where the vaccine was administered. This did not go away after a couple of days, and I was instructed by a physician to being taking Benadryl. This appeared to alleviate the symptoms (no visible red nodules anymore) 4-5 days prior to my second dose, so I stopped the medication and presumed it was done. Then, within 4-5 hours of receiving my second Pfizer covid vaccine, I broke out into the same red, painful, nodule-like "rash" along both of my forearms. This time was worse than the previous reaction. I was instructed to take Allegra at the time by a physician, which I did for approximately 4 weeks. This seemed to get rid of the symptoms I was experiencing, and I could not visualize the nodules on my forearms anymore. However, after approximately 2 weeks, I noticed a painful and swollen vein in my right forearm, opposite arm to the one I received the vaccine in. I did not think much of it at the time, since I had no other associated symptoms. Then, over the next couple of weeks, it appeared to become more swollen and painful. Also, I saw another swollen vein near my knee. On April 6, I had labs drawn and CBC, CMP, TSH, and ESR came back normal, but the CRP was elevated. Thus, I was instructed to begin aspirin 325mg, which I took for 4 days beginning April 8th and ending April 12th. On April 13th, an official ultrasound confirmed a DVT in my right popliteal vein, a superficial thrombus in my proximal great saphenous vein, and a superficial thrombus in my right forearm where the pain originated from weeks prior. The initial presumption at this time is that the clots are vaccine-related, but could be linked to an underlying blood disorder that was triggered by the vaccine. Blood hyper coagulation labs have not yet come back. I was initiated on Eliquis starting April 12th for the DVT.
1205904	4/13/2021	MD	27	F	4/5/2021	4/7/2021	Two days after vaccine - severe bloody nose. Clots of blood came out.
1205903	4/13/2021	CA	70	F	3/12/2021	3/14/2021	What appeared to be blood clots on both forearms.

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1205882	4/13/2021	OR	67	F	4/2/2021	4/3/2021	On 2nd day: Very bad headache, almost fainted, took Tylenol (6/day of 500mg), drank fluids, blood pressure low. Better on day3, only slight headache. On 9th day: felt soreness in right calf muscle, no swelling or redness. Thought it was due to low physical activity. No stamina. Tire very easily and get sweaty upon little exertion On 10th day: felt sharp jabbing pain in chest when taking deep breath or yawning. No actual shortness of breath. On 11th day (today): decided to start taking full strength aspirin in case it is a blood clot. Took 1 in a.m. 1 in p.m.
1205860	4/13/2021		88	F	2/19/2021	2/21/2021	Fatigue, dizziness, weakness. Issues with breathing caused hospitalization 3 days after shot. Blood clot located in lung and 2 in right leg. Hospital stay 11 days, step down facility roughly 2 weeks, PT/OT upon arrival home.
1205849	4/13/2021	NV	66	M	3/10/2021	3/13/2021	3/13/2021: Red rash/hives on arms, neck, scalp, chest, back / was treated at ER with benedryl, given albuterol inhaler to take 2 puffs, 4X day for 7 days; prednisone, 40mg daily for 5 days 3/16/21: had mini stroke at home, called ambulance, they administered a series of tests and determined that all his vital signs were normal and asked if he wanted to go to hosp for add'l testing and pt refused. 3/17/21: had 2nd mini stroke in vehicle, went straight to Hosp ER and was admitted. CT scan and MRI determined that I had suffered 2 strokes due to blood clots in the rt side of brain. Was told to take 325 mg of aspirin a day and released on 3/19/21 with instructions to f/u with PCP and Neurologist. PCP recommends that I should NOT take the 2nd dose of the Moderna vaccine.
1205821	4/13/2021	NJ	59	F	3/31/2012	4/1/2021	1st Vax: 03/01/2021 Allergic reactions, Angioedema , Facial swelling, arm and leg swelling, Covid Arm, Injection Site Swelling, fever, chills, crusty lesion behind left knee, 2 types of rashes on legs- pinpoint red and a bumpy, itchy contact dermatitis. 2nd Vax: 03/31/2021 Same as above plus severe non- migraine headache, low fever, throwing blood clots and greenish brown mucus from sinuses and sputum, a Wheezing, given albuterol at ER, stomach and back/leg pain worse than usual.

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1205819	4/13/2021	PA	44	F	3/10/2021	3/25/2021	Had chest pain on and off for 5 days (started Thursday 3/25), which I thought was related to acid reflux. On Tuesday 3/30 when it became worse and was no longer managed with ibuprofen I went to patient 1st. I was given an ekg which was abnormal and then sent to ER. There it was determined that I had a blood clot and 100% blockage in my right coronary artery. That night I had surgery and they placed a stent.
1205766	4/13/2021	IN	50	F	3/8/2021	3/20/2021	I had rear end pain started March 20 in the morning, it gets worse and worse till 3/23 that I can not tolerate and had to call clinic to make appointment. They got me in on March 25 (Thursday). Dr inspected and told me it's thrombus that caused huge pain. They did the surgery right away, removed thrombus. I never had blood clots problem and I was healthy, which my blood test result can prove. Thrombus generated 12 days after my J&J vaccine shot, I am reporting this side effect. You may find all my medical record from Doctor's office.
1205729	4/13/2021	GA	73	M	3/12/2021	3/18/2021	My husband is still in hospital trying to recover. He had bad headaches that then led to seizures and confusion ,blood clots, and has been hospitalized since. He's literally fighting for his life and tomorrow Wednesday April 14 th he will be transferred to a rehabilitation center.
1205725	4/13/2021	GA	65	F	4/12/2021	4/12/2021	IN THE 15 MINUTE WINDOW AFTER VACCINATION PATIENT DEVELOPED SWELLING AND REDNESS ON HER RIGHT LEG, THAT WAS WARM TO THE TOUCH. PATIENT HAD AN INCREASED BREATHING RATE, AND REPORTED FEELING STRANGE. PATIENT WENT TO ER, ER CONFIRMED SWELLING IN LEG WAS NOT DUE TO A CLOT. PATIENT TOOK BENADRYL.
1205971	4/13/2021	OR	65	F	3/11/2021	4/1/2021	Experienced very sore calf within 2 weeks of vaccine but thought it was from snowshoeing. Then on April 8 I developed vein inflammation in two areas. An ultrasound on April 13 showed two blood clots. One superficial and one dt
1203817	4/13/2021	NY	59	M	2/10/2021	2/23/2021	Blood Clot detected liver vein. Dr. placed me on Xarelto

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1204211	4/13/2021	TN	64	F	3/17/2021	3/24/2021	extreme shortness of breath after one week and admitted to hospital with blood clots in both lungs and a collapsed lobe in right lung within two weeks
1204203	4/13/2021		24	F	3/31/2021	4/4/2021	THREE DAYS AFTER VACCINATION, MY DAUGHTER STARTED BLEEDING INTENSIVELY THRU HER NOSE. PRESSURE WAS APPLIED BUT HEMORRAGE LASTED FOR 15 MINUTES. AT THE END, A BLOOD CLOT WAS EXPELLED NASALLY.
1204189	4/13/2021	FL	63	F	3/23/2021	3/23/2021	I ended up with DVT blood clot. Injection was very painful and pain lasted 2 days, expected that. Day 3 woke with bright red rash, itchy, swollen and lumpy on inside upper arm. Could not get answers, lived on Benydril for 3 days. Day 4 called CDC, FDA, Health Dept & Moderna. Moderna was only person that I was able to talk to someone, had no clue. Had to google to find out I had Covid Arm since no one knew anything. Day 5 ..The lump moved or maybe different one to inside my inner elbow and was painful. Did not read pain as a symptom of Covid Arm and went to ER



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1204138	4/13/2021	RI	59	F	4/10/2021	4/11/2021	As described above, about 13 hours after the vaccine I woke up at 3 am with a severe pounding and constant headache. I was also extremely fatigued so much so that I did not get out of bed or do anything all day 4/11 and didn't start feeling better until the following Monday. Then I hear in the news about the 6 adverse reactions and the J&J vaccine shutdown, possibility for blood clots etc. and to keep an eye out for various symptoms over next 2-3 weeks! It was stressful enough registering and not being able to secure the Moderna or Pfizer so I just said ok and got the J&J. Now I have something else to worry about. Heart and blood clot issues are in my family. I do not take any blood thinners and don't plan to. But now am questioning whether I should have gotten the vaccine at all. I have had enough chronic illness in my life. In fact, December 2019 I was in another town taking care of my mother and her subsequent death when I caught someone's cough. Urgent care diagnosed me with pneumonia, fluid in the lungs, put me on course of antibiotics. I couldn't breathe, needed a nebulizer etc. They called me and said it was not pneumonia or flu a or b (I get the shot every year) and to go to the ER if it got worse. I couldn't eat or move much for three weeks and breathing was extremely difficult. I had to get a nebulizer. Eventually went away. Then in March Covid 19 became official. When I tested for Covid 19 here at a state site in 2021, I tested negative.
1204135	4/13/2021	KY	29	M	4/9/2021	4/9/2021	PATIENT STATES HE HAD COVID TWICE LAST YEAR AND THE VACCINE HAS BEEN WORSE. STARTING 2 HOURS AFTER VACCINATION HE HAD CHILLS, INTOLERABLE BODY ACHES, NAUSEA, VOMITING, FEVER. THEY LASTED 48 HOURS. BODY ACHES ARE STILL OCCURING 96 HOURS LATER. FEVER BROKE WITH TYLENOL. PATIENTS POA (HIS AUNT) CONCERNED ABOUT BLOOD CLOT.
1204121	4/13/2021	MN	70	F	3/5/2021	3/17/2021	Noticed shortness of breath, extreme trouble breathing that worsened over 3 days. Cat scan was performed at hospital finding blood clots on lungs. Surgery was performed to eliminate the blood clots.

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1204098	4/13/2021	TN	48	F	3/20/2021	4/8/2021	On April 8, 2021, 19 days after the vaccine, I started experiencing COVID symptoms including a stuffy nose, headache, body aches, fatigue. On April 12, 2021 I tested positive for COVID. On April 13, 2021 I had a severe headache and doctor advised me to take a baby aspirin daily to avoid possible blood clots.
1204092	4/13/2021	TX	26	M	3/12/2021	4/5/2021	Pfizer COVID-19 Vaccine EUA Patient received Pfizer COVID vaccine on 3/12/2021. Patient presented to outpatient clinic on 4/8/2021 for complaints of leg pain since Monday 4/5/2021. Patient states that Monday he woke up with point tenderness in his left calf which went away after about 2 hours. Tuesday, he woke up the same pain, which is persistent to this point. Patient denies exacerbating or relieving features. Patient denies trauma, no precipitating event and denies history of similar symptoms. Patient has not presented for medical attention for this prior today. Patient had a venous doppler ultrasound which showed a clot in the posterior tibial vein. Patient started on apixaban
1204058	4/13/2021	VA	84	M	3/12/2021	3/26/2021	Patient started having abdominal pain on March 26, 14 days after vaccination. Went to ER on March 29 and was admitted. Diagnosed with blood clot in spleen. Discharged from hospital on March 31.
1204047	4/13/2021	IL	38	F	3/21/2021	4/13/2021	Same day:Tingly arm. Metal taste in mouth. That night: very sore arm. Nausea started and dizzy spell at night. Nausea lasted 2 days 3 weeks after shot: spotting about 6 days before period. Heavy period with clots that came a few days early.
1205012	4/13/2021	IL	35	M	3/23/2021	3/29/2021	Lower leg pain, confirmed clot about 4 inches long via an ultrasound on 4/9
1204222	4/13/2021		24	F	3/31/2021	4/4/2021	THREE DAYS AFTER VACCINATION, MY DAUGHTER STARTED BLEEDING INTENSIVELY THRU HER NOSE. PRESSURE WAS APPLIED BUT HEMORRAGE LASTED FOR 15 MINUTES. AT THE END, A BLOOD CLOT WAS EXPELLED NASALLY.

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1205261	4/13/2021	MN	86	F	3/24/2021	3/1/2021	Diarrhea; Vomiting; Weak; Found Slumped Against the Wall; Low Potassium; MRI Found Multiple Small Emboli in Brain; thrown more clots; Aphasia; Difficulty Walking; potassium dropped and she went into A-Fib and threw clots; potassium dropped and she went into A-Fib and threw clots; has problems with recent memories; confusion; food sensitivities; This is a spontaneous report from a contactable physician (patient's daughter). An 86-year-old female patient received her second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not provided) at the age of 86-years-old, via an unspecified route of administration on 24Mar2021 at 14:00 at single dose for COVID-19 immunization. Medical history included high blood pressure diagnosed in 1971 (reported as 50 years ago) and ongoing; type 2 diabetes in 2011 (reported as 10 years ago) which resolved in 2019 (about 2 years ago) after the patient lost some weight; she had an episode of A-Fib in 2019 when her potassium was low (lower than the current hospitalization), once the potassium was corrected, her A-Fib resolved. The physician stated that patient has shrunk and was now about 5 foot 2 inches. Clarified that this has not recently occurred since the vaccine; stated it was happening just with age. The patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's concomitant medications were not reported. The patient did not have any issues with the first dose of the vaccine. She received her second vaccine dose on 24Mar2021. The physician spoke with the patient on Friday, 26Mar2021, and the patient was fine. On Saturday, 27Mar2021, the patient had an episode of diarrhea, vomiting and was weak. The lady cleaning the patient's house found her slumped against the wall. The physician met them at the hospital and said the patient seemed okay. They thought it was just an issue from her potassium being low on Mar2021, so they gave her that. The hospital did a CT scan that showed nothing on Mar2021. The hospital did an MRI of the head that showed multiple small emboli in the brain on Mar2021. The physician believed that the patient must have thrown more clots because she became aphasic on Mar2021

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and could not name things. The patient also had difficulty walking on Mar2021. The physician felt it was important to call and report this since she has heard of people throwing clots with vaccines. The physician did not know if the events were related to the vaccine. The patient was in the hospital for 7 days (as reported). She was now able to walk with some assistance. The patient's son thought that the patient was okay when he went to see her. Since the reporter was a physician, she knew which questions to ask the patient and saw that she still had some problems. The patient could remember some things but has problems with recent memories on an unspecified date in 2021. She also has some confusion on an unspecified date in 2021, such as she thought she was in a boat hospital. The physician was uncertain if the vomiting and diarrhea was somewhat better. They were wondering if the patient has some food sensitivities (2021). The patient also had carotid studies done in the hospital on Mar2021 and they were fine. They believed that patient's potassium dropped, and she went into A-Fib and threw clots on Mar2021. The clots must have come from the heart valves since the carotid studies were fine and if the clots had been in her legs, they would've gone to her lungs not to her brain. The patient underwent lab tests and procedures which included CT scan: negative, potassium: low, carotid studies: fine, MRI of the head: multiple small emboli in brain, all on Mar2021; and potassium: low, height: 5 foot 2 inches (shrunk), and weight: lost, all on an unspecified date. The events diarrhea, vomiting, weakness and fall required emergency room visit. The outcome of the event difficult walking was recovering and unknown for all other events. The events diarrhea, vomiting, weakness, fall, potassium low, cerebral embolism, thrombosis, and "potassium dropped and she went into A-Fib and threw clots" were assessed as serious due to hospitalization and being life threatening; and the events aphasia and gait disturbance were assessed as serious due to hospitalization. All other events were non-serious. The patient was hospitalized from 27Mar2021 until 02Apr2021. Information about the lot/batch number has been requested.

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1203969	4/13/2021	NC	22	F	4/8/2021	4/8/2021	- 22 year-old female - Tested positive for COVID-19 on January 31, 2021. My symptoms lasted 21 days and started with major gastrointestinal issues, headache, and cough. - Had a negative COVID-19 PCR test on February 25, 2021 - this negative PCR was needed to travel back. - Landed on February 28, 2021 and completed my quarantine at my parents house. - I returned to work on the 15th of March, 2021. - Over the weekend I traveled and flew back on April 5, 2021. Because I had flown, I was doing a courtesy and went to the local store to get a rapid antigen test. APRIL 8, 2021 - left work at 12:30 and went to the store to get the rapid antigen test which came back positive. I was told by the nurses that it only came back positive because it has been less than 90 days since I initially tested positive. I was told I did not need to self-isolate and could go about as normal. I had my second dose of the Moderna vaccine on this day at 2:00 p.m. I went to get my second jab. Just to be safe, after my jab I went to the local urgent care where they took a nasal swab for a PCR test. The results of the PCR test came back Saturday, April 10 about 7:30 that evening and the result was "NOT DETECTED". SYMPTOMS: Thursday, April 8th about 8:00 pm I started to have difficulty breathing and taking a deep breath was difficult. I put it down to anxiety about the initial positive test. Saturday, the difficulty breathing continued, along with new pressure in my chest. I was unable to sleep Saturday night - as soon as I was nearly sleep, I would wake up gasping for a breath. Sunday, the pressure in my chest continued and so did the difficulty breathing. I went to the Emergency Room on Sunday, April 11 about 4:15 pm - they took a chest x-ray, ran blood tests, and did an EKG which all came back completely normal - no pneumonia, heart attack, or blood clots. The doctor gave me a 1 mg dose of an anti-anxiety medicine because he could tell I was very stressed. He later prescribed me Prednisone (3 tablets a day for 4 days). As of today, I am still having a very hard time taking a full, deep breath and continue to have pressure in my chest.

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1203725	4/13/2021	IN		U			10 days after receiving my first Pfizer shot I suffered a stroke that was caused by a blood clot. I was unable to speak for a short time the morning of 4/1/2021 and went to emergency room at. My speech had already returned and I was no longer having symptoms. There were numbers tests and scans run and it was confirmed that I had a stroke that was caused by a blood clot. There were no obvious issue present to why I would have had this happen.
1203666	4/13/2021	CO	52	F	4/4/2021	4/5/2021	Patient developed a severe headache, nausea, and vomiting on 4/5 PM. She continued to have severe headache, improving to a 5 and then worsening to a 10 for several days. She had some chills develop the AM of 4/6, but no fevers, myalgias, rash, or other side effects. She went to ED on 4/9 and was transferred to our facility. Found to have subarachnoid hemorrhage. CT angio without evidence of clot. No clear etiology for bleed per neurosurgery
1203538	4/13/2021	TX	63	F	3/9/2021	3/17/2021	I had a discoloration on my left breast and slight pain underneath my left arm. I had NO redness, NO swelling and NO heat underneath my arm. I had a mammogram and the radiologist asked for an ultrasound. The ultrasound revealed a deep vein thrombosis underneath my left arm.
1203501	4/13/2021	OK	54	M	3/12/2021	4/11/2021	Blood clots in kidney. Currently hospitalized.
1203471	4/13/2021	MA	47	F	2/11/2021	3/20/2021	I had a blood clot in my right leg . It started to bother me on 3/19/21. I called my doctor on 3/22/21 and she advised that I be seen in the ER. The ER doctor confirmed that I had a blood clot in my leg and I was treated with Lovenex. In addition to the clot in my leg, I have multiple bruises on my arms and legs where blood vessels broke in the couple days before and after the ER visit. I also felt very out of shape, with trouble getting enough breath. Within 2 days of getting the Lovenex, I felt like I could breath normally and my symptoms improved. Not sure if it is connected to the vaccine but thought it was important to report. I am an active, otherwise healthy person who walk at least 5 miles daily. The blood clot was very unexpected.

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1203462	4/13/2021	CO	66	F	3/21/2021	3/24/2021	On 3/24/21, just three days after receiving my second Pfizer vaccine, I started noticing excruciating pain in my left calf. I managed the pain with Tylenol, but as it continued to get worse and debilitating, I saw my doctor on 3/30/21 who immediately scheduled an ultra sound. On 3/31/21 at 9:00 am, I had the ultra sound and the results were DVT (BLOOD CLOT). SEE DETAILED RESULTS IN ITEM 19.
1203460	4/13/2021	OH	40	M	3/10/2021	3/15/2021	Pt had Covid in November 2020. He was in the hospital and had blood clots in the left leg.
1203447	4/13/2021	OH	23	F	4/8/2021	4/9/2021	Around 2:30pm on 4/9/21 (one day after vaccination) I got a Charlie horse in my right calf. I didn't think much of it. About 20 minutes later when trying to get out of bed I got another Charlie horse in my left calf this time. This one was much more painful and intense. After it let up I laid there for a little longer and tried to get up when my leg calf, again, got another Charlie horse in the same place. This happened a total of 4 times, back to back to back to back. Each Charlie horse I had in my left calf was especially intense and painful, worse than any Charlie horse I'd ever had before. I don't get Charlie horses often, but I have been a lifetime athlete so I'm familiar with the feeling. I had not previously worked out in the days leading up to my vaccine. I'm not even sure this is an adverse effect of the vaccine, I just didn't know if anyone had had a similar reaction and have been made aware that blood clots have also been a concern with the J&J vaccine. I'm also unsure if my Zolof, which has a warning that it may cause dizziness, may have reacted with the vaccine to make me incredibly dizzy. But around 04:00am on 4/9/21 (I work night shift) I became increasingly dizzy making it difficult to perform the tasks at hand. Enough so that I had to sit down and even reading words off a computer screen made me dizzy. I couldn't drive home from work at 07:30am that morning because I was concerned with my dizziness. It had subsided by the time I woke up at 02:00pm later that day.

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1203443	4/13/2021	NY	30	F	4/3/2021	4/4/2021	The adverse symptoms I experienced were abnormally severe/heavy menstrual bleeding and abdominal pain. I was on Day 4 of my menstrual cycle on the day of my injection (April 3, 2021). My menstrual cycle usually starts to go away on Day 4 and concludes by Day 7. But the day after my injection, in addition to experiencing the common side effects of fever, chills, aches, and headaches, I also experienced an uptick in bleeding, which included severe/heavy menstrual bleeding with very frequent and large blood clots. That same day (April 4), I started my new birth control cycle as prescribed. By Day 8 (April 7, 2021), my menstrual bleeding continued to be so severe/heavy that I went to my OB-GYN for testing. The OB-GYN ruled out everything but the vaccine as an environmental factor. It was suggested that I take 600mg of Motrin every 6-hours for 48 hours. My menstrual bleeding continued for several more days until concluding on Day 12 (April 11, 2021) but I am still experiencing abdominal pain.
1203430	4/13/2021	CA	52	F	4/2/2021	4/3/2021	Almost immediately (remember noticing the next day after my vaccine shot), a very hard big lump started forming about an inch lower than where the injection needle went in (it was definitely about an inch down from where my band-aid was). The lump got bigger and harder over the last week and seemed to spread out into like a sideways egg shape. My skin there almost looked like a light purple bruise in the shape of a sideways egg. It has gone down now in the last couple of days, but there is still a hard nugget of lump there. It has me concerned like it could be a blood clot or something.
1203392	4/13/2021	ID	48	M	4/6/2021	4/11/2021	Sunday morning, 4/11/21, had severe itching in hands/feet that was improved by deep massage and hot water. Also had hives on flanks that moved up sides. Initially took Benadryl 1 tab twice and then in evening took 2 tabs d/t worsening symptoms. Next day had similar symptoms but hives also on trunk that traveled up to neck and jawline. Denies airway involvement or s/sx of blood clots.
1203902	4/13/2021	VA	77	F	3/13/2021	4/7/2021	Blood Clot which led to Pulmonary Embolism, Pneumonia, and death.
1204868	4/13/2021	OK	55	M	3/3/2021	3/3/2021	I peed a blood clot and had to go to the ER on 03/30/21



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1203844	4/13/2021	OH	53	M	3/24/2021	3/30/2021	4/1/2021: SEVERE LEG PAIN, PRESENTED TO HOSPITAL ER AND WAS FOUND TO HAVE ACUTE DEEP VENOUS THROMBOSIS LEFT LOWER EXTREMITY. 4/4/2021: SEVERE SHORTNESS OF BREATH, SQUEAD WAS CALLED AND HE WAS TAKEN TO HOSPITAL ER WHERE HE WAS FOUND TO HAVE BILATERAL PULMONARY EMBOLISM
1204971	4/13/2021	TN	73	F	3/1/2021	3/1/2021	Blood clot in large intestines which caused loss of blood supply and oxygen so it rotted which in turn rotted her small intestine and bowels which all had to be removed shut down her kidneys and liver
1204231	4/13/2021	NM	93	M	3/15/2021	4/3/2021	Suffered from a stroke on 4/3/21 from a blood clot in his brain stem. Prior to vaccine he was healthy and 100% independent, still drove, did grocery shopping, yard work, etc. Now he cannot move his left side and was placed on hospice as he has lost his will to eat, drink, or live.
1204833	4/13/2021	PA	39	F	4/5/2021	4/6/2021	Blood clot at injection site in left arm. Place where I was injected still hurts and feels like there is a bullet lodged under my skin when I touch my arm. The pain isn't as severe as it was last week but the blood clot is still there under my skin.
1204803	4/13/2021	CA	46	M	3/16/2021	3/18/2021	Heart attack after J&J vaccine - My husband, complained of on and off chest/lung discomfort after two days getting the vaccine. This continued for about 3-3.5 weeks. On the night of Apr 16, he went to bed early not feeling well. Next morning he complained of heaviness in the chest area. We immediately consulted Dr., and mentioned that he got the vaccine. Dr. advised us to immediately go to an Emergency Room. Patient was found to be having a heart attack. His right artery was 100% blocked. The 3 left arteries had no blockage at all. Angioplasty was done and he had a stent placed in right artery. The clot was removed as part of angioplasty. He now needs to be on blood thinners for life.

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1204788	4/13/2021	WI	84	F	2/1/2021		<p>Diverticulitis arteries; I had a blood clot after ultra sound; sore arm/Feel sore arms after the first dose; spinal nerve damage/Spinal nerve pain; Legs are burning hot now; Pain felt in calf and thigh; Bone density test/Ultra sound bad; This is a spontaneous report from a contactable consumer(patient). An 84-years-old female patient received BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 1 intramuscular, administered in Arm Left on 01Feb2021 11:30 (Batch/Lot Number: EN5318) as SINGLE DOSE, dose 2 via an unspecified route of administration, administered in Arm Left on 22Feb2021 11:30 (Batch/Lot Number: EN6200) as SINGLE DOSE for covid-19 immunization. Medical history included angina from 2002 and ongoing, She says she has angina, and if she would have beating problems can she take a Nitro, cholesterol, depression from 2008 to an unknown date, blood pressure, anxiety from 2018 to an unknown date, arthritis from 1998 and ongoing Illness/AE: Arthritis Onset Date: 1998-2002 Stop Date: Ongoing , hypertension from 2002 and ongoing, blood cholesterol increased from 2002 and ongoing, ongoing urinary tract infection On and off, coronary artery disease from 2005 to an unknown date On and off, Family medical history included Mother coronary artery disease Died on 18Oct1967 and Father 1936 other. Concomitant medications included amlodipine taken for blood pressure abnormal from 2017 to an unspecified stop date; atorvastatin taken for blood cholesterol abnormal from 2002 to an unspecified stop date; bupropion taken for depression from 2008 to an unspecified stop date; buspirone taken for anxiety from 2008 to an unspecified stop date; carvedilol taken for blood pressure abnormal from 2002 to an unspecified stop date, 2x a day carvedilol 12.5. On an unspecified date, the patient experienced diverticulitis arteries, had a blood clot after ultrasound, sore arm/feel sore arms after the first dose, spinal nerve damage/spinal nerve pain, legs are burning hot now, pain felt in calf and thigh, bone density test/ultrasound bad. The patient underwent lab tests and procedures which included blood test: unknown results, computerized tomogram: diverticulitis arteries-On and off, investigation: unknown results. Comments: Going to pain clinic. On always, ultrasound scan: bad on Comments: Ultrasound bad, urine analysis: unknown results on comments: on and off. Treatment received for</p>

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1204782	4/13/2021	MA	62	F			<p>the events sore arm/feel sore arms after the first dose and spinal nerve damage/spinal nerve pain. Outcome of all events was unknown. Follow-up (29Mar2021): This is a follow-up report combining information from duplicate reports 2021138557 and 2021162095. The current and all subsequent information will be reported under manufacturer report number 2021162095.</p> <p>Blood clot; COVID-19; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clot) in a 62-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history reported.). Concomitant products included PARACETAMOL (TYLENOL) for an unknown indication. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clot) (seriousness criterion medically significant) and COVID-19 (COVID-19). At the time of the report, THROMBOSIS (Blood clot) and COVID-19 (COVID-19) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, SARS-CoV-2 test: positive (Positive) positive. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Products known to have been used by the patient, within two weeks prior to the event, included blood thinner medication. Treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1204779	4/13/2021	VA	80	M	1/20/2021	3/31/2021	Clot blood; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Clot blood) in an 80-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031M20A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No medically reported history). On 20-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 17-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 31-Mar-2021, the patient experienced THROMBOSIS (Clot blood) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Clot blood) outcome was unknown. The patient was diagnosed with blood clots in legs and lung. Very limited information regarding this event has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.
1204744	4/13/2021	FL	42	F	4/8/2021	4/9/2021	Woke with: Blood Clots in my left arm at injection pt and lower arm, wrist, hand. Blood Clots in my left leg, mainly calf, lower leg, ankle, some in thigh. Larger, more numerically present than in past from antihistamines. None present before Vax, allergen-free diet prevents usually.
1204726	4/13/2021	NY	64	M	3/7/2021	4/6/2021	Patient vaccinated on 3/7/21, on 4/2 presented pain in left leg and some redness, on 4/3 some dizziness, lightheadedness, difficulty with vision in right eye, some slurred speech; on 4/5 his health aggravated and EMS was called and taken to hospital; spouse informed that patient had a blood clot in stem of brain; on 4/6 patient died. No autopsy performed
1204715	4/13/2021	FL	73	F	2/11/2021	2/21/2021	Blood clot in left leg
1204702	4/13/2021	OR	75	M	3/10/2021	3/24/2021	Patient seen in clinic on 04/07/21 reporting 2 weeks of right leg swelling and calf pain. Vascular ultrasound on 04/07/21 showed blood clots in legs. Lovenox injections started 04/07/21. Warfarin started 04/08/21.

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1204693	4/13/2021	OR	49	F	3/12/2021	4/8/2021	<p>presents with progressively worsening dyspnea on exertion for the last few weeks, much worse over the last one day. Patient reports feeling fatigued, having cough, and feeling more short of breath for the last day, and has developed central chest pain which is pleuritic in the emergency department. She reports that the chest pain is 4/10 in severity and does not radiate. Her caregiver at bedside reports that the patient has had worsening dyspnea on exertion for the last 3 or so weeks. Of note, she becomes dyspneic with limited exertion, such as going up a flight of stairs, at baseline. She had a fever of 101.4 °F at home earlier today, but denies chills or diaphoresis. He had 1 episode of nonbloody vomiting earlier today. Denies nausea at this time. She received her second dose of the Moderna COVID vaccine yesterday, 4 weeks after the first. They note that approximately 5 years ago, she had a prolonged admission for which she was transferred to OHSU and was on ECMO for a time before making a nearly full recovery. She has had the baseline dyspnea on exertion since that time. Review of Systems Constitutional: Positive for fever and malaise/fatigue. Negative for chills. HENT: Negative for sore throat. Eyes: Negative for blurred vision. Respiratory: Positive for cough and shortness of breath. Negative for hemoptysis, sputum production and wheezing. Cardiovascular: Positive for chest pain. Gastrointestinal: Negative for abdominal pain, diarrhea and vomiting. Genitourinary: Negative for dysuria and frequency. Musculoskeletal: Negative for back pain. Skin: Negative for rash. Neurological: Positive for weakness. Negative for tingling, sensory change and focal weakness. Endo/Heme/Allergies: Does not bruise/bleed easily. Psychiatric/Behavioral: The patient is nervous/anxious. Past Medical History: Past Medical History: Diagnosis Date ? Developmental delay, moderate since birth Functional equivalent to 10-12 year old, no formal testing done otherwise. ? DVT (deep venous thrombosis) (HCC) 1/2016 while on ECMO ? Personal history of ECMO 1/2016 - ARDS after unknown viral illness Past Surgical History: Procedure Laterality Date ? LUNG BIOPSY Left 1995 Mass noted following an MVA, was benign ? MASS EXCISION Right 2006 Growth removed from right knee ? PROCEDURE N/A 1/20/2021 Procedure: LAPAROSCOPIC CHOLECYSTECTOMY;</p>

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CHOLANGIOGRAMS; Service: Procedures; Laterality: N/A; POSSIBLE COMMON BILE DUCT ? PROCEDURE N/A 1/20/2021 Procedure: RIGID ESOPHAGOGASTRODUODENOSCOPY; Service: Procedures; Laterality: N/A; Medications administered in the ED: Medications doxycycline (VIBRAMYCIN) 100 mg in sodium chloride 0.9 % (NS) 100 mL IVPB (100 mg Intravenous New Bag 4/9/21 2235) ceftriaxone (ROCEPHIN) 1 g in 50 mL SNAP IVPB (0 g Intravenous Stopped 4/9/21 2234) Physical Examination: GEN: Very pleasant female sitting up in bed in NAD. Slightly anxious appearing. HENT: Moist mucous membranes. No posterior oropharyngeal erythema or exudates. NECK: Supple. No cervical or supraclavicular lymphadenopathy. CARDIOVASCULAR: Tachycardic rate and regular rhythm. No murmurs, rubs, or gallops. No pain with palpation of chest wall. PULM: Normal effort. No use of accessory muscles. Clear to auscultation bilaterally. No wheezes or crackles. ABD: Soft. Non tender. Non distended. EXT: No lower extremity edema. SKIN: No suspicious lesions noted on the exposed skin. EKG: 04/09/21 Rhythm: Sinus tachycardia Rate: 111 Axis: normal Intervals: normal Concern for possible inferior infarct noted, but felt less consistent with true ST depression Recent Imaging: Chest x-ray, 04/09/21: FINDINGS: LUNGS: Slightly low lung volumes. There is hazy reticulonodular interstitial opacity seen within the left mid and both lower lung zones suspicious for interstitial pulmonary edema. CARDIAC: Slightly worsened mild cardiomegaly. MEDIASTINUM: Normal. PLEURA: No pleural effusion or pneumothorax. LINES/TUBES: None. BONES: There is mild rightward convexity curvature of the thoracic spine along with minimal multilevel degenerative change. OTHER: Surgical clips overlie the left lung apex medially and the right upper abdominal quadrant. IMPRESSION: 1. See above. CT angiogram pulmonary: FINDINGS: Motion degrades image quality slightly. No pulmonary arterial filling defects are identified. Mild lower lobe predominant atelectasis and/or scarring. A single small bulla is present in the left lower lobe of the lung. Lungs are otherwise clear. Large airways are patent. Small bilateral dependent pleural effusions which are new relative to the comparison examination. No pneumothorax. Heart is normal in size. Relatively low

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attenuation pericardial effusion is present which is new relative to the comparison examination. Pericardial fluid measures up to 1.7 cm in thickness. No thoracic aortic aneurysm or dissection. No mediastinal mass or lymphadenopathy. Two small enhancing foci are present in the liver, larger 1.8 in length which are similar to the comparison examination. Interval cholecystectomy. Visualized upper abdominal contents are otherwise without significant abnormality. There has been partial resection of the left 5th rib. Osseous structures are otherwise intact. IMPRESSION: 1. No evidence of pulmonary embolism. 2. Pericardial effusion and small bilateral pleural effusions which are new relative to comparison examination. 3. Two small enhancing liver lesions which are not further characterized by this examination but are similar to comparison examination. These could potentially represent hemangiomas. Assessment / Plan a 49 y.o. female with history of hypertension, developmental delay, DVT x1 not currently on anticoagulation, GERD, and anxiety who is being admitted for acute hypoxic respiratory failure, felt likely secondary to fluid overload from cardiomyopathy from pericarditis with associated pericardial effusion. #Acute hypoxic respiratory failure #Elevated Pro BNP #Cardiomegaly #Dyspnea on exertion #Pleuritic chest pain #Elevated D-Dimer Acute. Hemodynamically stable. On room air at home, and requiring 3 L via NC here. Considerations include new onset CHF, PE, PNA, PTX, pericarditis, pericardial effusion. Presentation most concerning for new onset CHF/cardiomyopathy from pericarditis with associated pericardial effusion, as demonstrated on CT angiogram. She has significantly elevated CRP which further supports pericarditis, and onset of symptoms approximately 7 to 10 days after receiving her first COVID-19 vaccine dose 4 weeks ago, which may be associated. Also possible viral or idiopathic. Mildly elevated BNP and pleural effusions suggesting cardiomyopathy. Patient had a fever to 101.4 °F earlier today, per caregiver at bedside, and has had shortness of breath and cough, and thus pulmonary infectious process strongly considered, though clinically I feel infection less likely. She has a chronic leukocytosis and WBC is 21 today. She received ceftriaxone and doxycycline for pneumonia today in the ED, and may

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							consider continuing these tomorrow. No evidence to suggest tamponade on bedside POCUS. - Admit to PCU with tele - Echo in AM - Ibuprofen 800 mg 3 times daily and colchicine 0.6 mg daily for treatment of pericarditis - Diuresis: 40 mg IV Lasix given at 0037 - Respiratory support as needed, wean as tolerated - RTDP - Incentive spirometry - Consider continuing antibiotics pending clinical status in AM #Leukocytosis Acute. WBC 21.5 on admit, increased from 15.1 two and a half months ago, but that was at end of admission for cholecystitis. Potentially due to inflammation, possibly infectious process. See discussion above. - Trend with CBC #Hypertension Chronic, presumed well controlled. - Continue home hydrochlorothiazide and losartan #Thrombocytosis Acute. Suspect reactive thrombocytosis due to inflammation from pericarditis. - Daily CBC while inpatient #Elevated AST and ALT Acute, mild. Most likely secondary to congestive hepatopathy. Will trend. - AM CMP #Hypoosmolar hyponatremia Acute, mild. Considerations include beer potomania, hypothyroidism, SIADH, low solute diet ("tea and toast"), increased free water intake, medication induced (SSRIs, thiazides). Suspect low solute diet. SIADH from pulmonary pathology is also possible. - Repeat BMP #Anxiety Chronic, presumed stable. - Continue home sertraline Ppx: Lovenox Central Lines/IVs/Tubes/Drains: PIV CODE: Full Dispo: PCU with tele Active Hospital Problems Diagnosis SNOMED CT(R) Date Noted ? Elevated brain natriuretic peptide (BNP) level HORMONE LEVEL - FINDING 04/09/2021 ? Cardiomegaly CARDIOMEGALY 04/09/2021 ? Leukocytosis LEUKOCYTOSIS 04/09/2021 ? Acute respiratory failure with hypoxia (HCC) ACUTE RESPIRATORY FAILURE 04/09/2021 ? Dyspnea on exertion DYSPNEA ON EXERTION 12/21/2015
1204249	4/13/2021	WA	63	M	3/27/2021	4/5/2021	Deep vein thrombosis, left leg
1204650	4/13/2021	TX	65	M	3/11/2021	3/16/2021	On Tuesday March 16 started having difficulty breathing went to ER. Blood Clots in both lungs. Was admitted and was treated in hospital until Friday March 19.
1204240	4/13/2021	VA	62	M	4/11/2021	4/13/2021	Left Leg Superficial Thrombosis.



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1204289	4/13/2021	IN	40	F	3/23/2021	4/5/2021	Woke with nausea, vomiting, climbing fever upto 103, body aches, chills on 4/5/21. Symptoms resolved but felt tired on 4/6/21. Morning of 4/7/21, woke with shortness of breath and chest pain. Negative COVID-19 test. Went to hospital and did a cardiac workup and blood work, CT scan followed that showed several blood clots in lungs. Was given heparin bolus, and continued for an additional day, then switched to Eliquis. Hospitalization duration was 2.5 days.
1204331	4/13/2021	CA	20	M	4/12/2021	4/12/2021	It is now the next day, and I feel significantly better. I have pain at the injection site, some muscle fatigue, a little bit of a depleted appetite, tiredness in my eyes and head (likely due to lack of quality sleep), and a bit of sweating, but my pain has reduced to maybe a 2/10 or 1/10 (i.e., not even uncomfortable). I did end up getting decent sleep between 2 AM and 12 PM with only a few interruptions of family members checking on me. The only notable pain that is worrying me is abnormal soreness in my right wrist that is not the result of overuse, overextension, etc., although I was able to take care of that pain with another 3 Advil pills. I am considering scheduling a doctor's appointment, as I know the J&J vaccine got recalled today for blood clots. My assumption is that because I am a healthy 20-year-old, my immune system overreacted to the vaccine, but I want to check to make sure that it doesn't cause any additional health problems.
1204386	4/13/2021	CO	63	F	3/29/2021	4/4/2021	4/4/21 Swelling below waist, including buttocks, hips, thighs, and knees. Severe itching and pain. 4/7/21 Swelling spread to calves and ankles. Severe pain and itching. PCP prescribed 50 mg Benadryl every 6 hours and was told to go to Urgent Care if symptoms persist. 4/9/21 Went to Urgent Care Clinic due to excruciating pain in legs. Admitted to accompanying ER. Received IV and had blood drawn, showing extremely low platelet levels (37k). Discharged with prescription for antihistamine, steroid, and hydroxyzine HCL. Ultrasound taken but did not show blood clots. 4/11/21 Pain and itching spread to both arms. Extreme pain when standing and walking. 4/13/21 Went to ER. Ultrasound confirmed multiple blood clots. Discharged with prescription for Xarelto.

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1204408	4/13/2021	MN	49	F	3/30/2021	4/2/2021	I peed some blood clots for 2 days, it was sporadic, not every time I went to the restroom. My urine turned orange.
1204630	4/13/2021	MN	67	M	3/17/2021	4/5/2021	rt superficial lower extremity thrombosis- redness, tenderness, swelling rt lower extremity.
1204448	4/13/2021	TX	59	F	3/5/2021	3/7/2021	To summarize our conversation, you stated that you received the second Pfizer vaccine on 3/4/21. Three days later, on 3/7/21, you began to have fatigue, shortness of breath, dizziness and chest pressure. Because all symptoms continued for 24 hours, on the evening of 3/8/21, you took yourself to the Emergency Department. Your ER work-up included a CXR (negative), an EKG (showing a left bundle branch block), serum bloodwork (negative for MI), however, the D-dimer and spiral CT were both positive for a pulmonary emboli (i.e. a blood clot in your lungs). You were admitted to the hospital and started on the blood thinner, Eliquis. During your 3-day hospital stay, your work-up also included a bilateral lower extremity Doppler study (negative) and an echocardiogram (showing left ventricular hypertrophy). You were discharged on all of your previously prescribed medications (see list below), except for the fish oil. You were also started on Eliquis. Since discharge, you have followed up with your PCP and have been referred to a cardiologist and pulmonologist. To date, you have had no further symptoms. PAST MEDICAL HISTORY: hypertension, hypercholesterolemia, pre-diabetes. PRE-VACCINE MEDICATIONS: losartan, HCTZ, amlodipine, Welchol, fenofibrate, fish oil. POST-ER VISIT MEDICATIONS: losartan, HCTZ, amlodipine, Welchol, fenofibrate, Eliquis.
1204459	4/13/2021	AZ	79	M	3/17/2021	3/25/2021	blood clot in left ear
1204523	4/13/2021	CA	41	F	1/21/2021	1/22/2021	Heavy vaginal bleeding with heaving clots since the first does was administered. Vaginal bleeding continues as of today, April 13,2021 at 2:36pm 2nd side effect was herpes outbreak on right eyelid, my primary care provider was notified.

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1204579	4/13/2021	MI	81	F	1/13/2021	1/30/2021	Jan 13 first dose received...Jan 30th collapsed at night by herself. Was able to get up and go back to bed. Next day was taken to urgent care and sent by emergency to hospital. Suffered large blood clot in the leg that broke off and traveled to the lungs. Acute saddle pulmonary embolism with acute cor pulmonale. Was put on blood thinners and released from hospital on 2/2. As soon as we got home from the hospital she suffered from a massive gastrointestinal intestinal bleed and had to be rushed back to the hospital. Two days later while still in the hospital she suffered a mild heart attack and had a stent inserted.
1204419	4/13/2021	AR	65	M	4/2/2021	4/6/2021	Swelling in lower right leg, ankle, foot; Venous Doppler ordered; blood clot detected; doctor examination; Eliquis prescribed.
1198162	4/12/2021	MO	45	F	3/13/2021	3/20/2021	My sister received the Janssen vaccine on March 13, 2021. One week later, March 20, 2021, she started complaining of severe headaches, dizziness and vomiting. This continued so she visited the ER on Wednesday, March 24, 2021, where she suffered a cerebral venous sinus thrombosis. She was pronounced brain dead on March 27, 2021, which is also the same day she was pronounced dead.
1198613	4/12/2021	NV	69	F	1/19/2021	1/26/2021	Eight days following the first vaccine I was admitted with massive blood clots to my legs and lungs. I was hospitalized for 8 days. Four days were in ICU.
1197638	4/12/2021	CO	38	F	3/13/2021	3/19/2021	Patient presented with acute abdominal pain, DIC , thrombocytopenia and found have small bowel gangrene due to SMA thrombosis. Underwent Laparotomy with small bowel resection. Was in the ICU and currently on TPN and IV antibiotics.
1197857	4/12/2021			U			PATIENT BEGAN SLURRED SPEECH AND WEAKNESS IN LEFT SIDE ONE WEEK AFTER VACCINATION. DAUGHTER, WHO IS A NURSE, NOTICED AND MADE PATIENT GO TO ER. THERE, PATIENT HAD A SCAN DONE THAT REVEALED TWO BLOOD CLOTS, WHICH HAD CAUSED A STROKE, IN THE BACK OF THE BRAIN. PATIENT WAS KEPT FOR OBSERVATION OVER NIGHT IN THE HOSPITAL AND THEN RELEASED.

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1197881	4/12/2021	FL	67	F	3/29/2021	4/1/2021	During the middle of the night on Thursday April 1, 2021 when I was sleeping I woke up with terrible cramping in both calves of my legs and in left foot after receiving my first dose of Pfizer Covid-19 vaccine on Mar. 29 at a pharmacy at 1:53 P.M. I have had cramping in my legs/feet/toes before so this could be totally unrelated. I have Theraworx in my nightstand and put some of it on which helped and they went away. I heard about blood clots possibly associated with other Covid-19 vaccine from another mfg. so just wanted to report this and make sure it is safe for me to get my 2nd dose of Pfizer vaccine on April 19th.
1197898	4/12/2021	OH	45	F	4/8/2021	4/9/2021	Chest heaviness/pain accompanied by fatigue, dizziness, shortness of breath, and nausea. Given the combination of symptoms, I presented to a local emergency room to be evaluated for a heart condition. ER doctor evaluated to rule out heart attack, stroke, and/or blot clot. All tests appeared normal. Symptoms attributed to side effects from vaccination.
1198435	4/12/2021	MI	63	F	4/5/2021	4/6/2021	12 hours after receiving 2nd vaccine (4-5-21) I started throwing up through Tuesday 4-6-21. Then on 4-7-21, my left leg calf was very sore and hard for me to walk, Got worse, so on 4-9-21 went into Urgent care and through a vascular ultra sound determined I had a very Large blood clot in my calf. (ACUTE THROMBOSIS OF THE LEFT PROXIMAL PERONEAL VEIN)
1198041	4/12/2021	PA	50	F	3/25/2021	4/1/2021	Menstrual period began two days after 1st Moderna vaccine with spotting on 3/27/21. One week after vaccine, heavy period began with several fist-size clots the evening of 4/1/21. Today is 4/12/21 and I am still having my period. It has lightened up but not stopped after more than two weeks. My age is 50 and I am in peri-menopause.
1195691	4/12/2021	FL	28	F	2/17/2021	3/1/2021	One month after having my second covid vaccine, I had the worse menstrual cycle of my life. I had heavy bleeding for 4 days and horrible menstrual cramps. So bad that motrin/tylenol did not take away the pain. Also passed a lot of clots. Also after my period, I've had continual bleeding/spotting. I've even gone to the OBGYN to get checked. I'm still bleeding...

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1197333	4/12/2021	KY	57	F	2/27/2021	2/27/2021	PATIENT WAS IN GOOD HEALTH WHEN VACCINATED ON 2-27-21. BY 3-3-21, PATIENT REPORTED TO ER WITH SHORTNESS OF BREATH AND SEVERE FATIGUE. PATIENT WAS ADMITTED TO HOSPITAL WITH DEHYDRATION AND POSSIBLE PNEUMONIA. ONCE ADMITTED, SEVERAL BLOOD CLOTS WERE FOUND IN PATIENT'S LUNG. PATIENT SPENT 4 DAYS IN HOSPITAL AND WAS THEN DISCHARGED. SHE IS SINCE IN GOOD HEALTH.
1196279	4/12/2021	IL	37	F	4/8/2021	4/9/2021	Received shot on day 4 of period cycle when it was winding down. About 24 hours after receiving, flow began to increase dramatically and continue for 48 hours, with many clots and cramping. Never experienced something like this before.
1195850	4/12/2021	MN	84	M	3/1/2021	3/7/2021	Death by clot
1197276	4/12/2021	CT	29	F	4/11/2021	4/12/2021	Having pain and tightness below my left knee in inner calf wondering if a blood clott - not typical nor have I ever experienced this before.
1197104	4/12/2021	NY	32	F	4/3/2021	4/3/2021	I had diarrhea about 20-40 minutes after receiving my first dose. I then got my period a few hours later. It was on time, however, it was extremely heavy. On the 3rd day, I began to have very large blood clots. I spoke to my gynecologist and she started me on birth control that sane day in order to stop the bleeding.
1196867	4/12/2021	AZ	65	F	4/1/2021	4/9/2021	12 hrs later bleeding for nose, coughed up a blood clott, about 8 hrs after that went to the bathroom and had a little blood in toilet. During the next few days sore muscles and pressure in my sinus eye area, and little ache on top of my head.

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1196748	4/12/2021	CO	61	M	4/6/2021	4/6/2021	Pfizer-BioNTech COVID-19 Vaccine EUA: patient presents to clinic three days after vaccination reporting pain and swelling in left lower leg starting shortly after receiving vaccine. Vital signs all within normal ranges. Physical exam shows asymmetrical left lower leg edema with pitting edema 2+ to the level of knee. Both knees have decreased range of motion and effusion (during visit underwent bilateral knee arthrocentesis). Normal pulmonary effort and no respiratory distress. Patient diagnosed with deep vein thrombosis (DVT) and started on anticoagulation.
1196712	4/12/2021	MI	51	F	3/12/2021	3/22/2021	Couple days after they release patient from the hospital she start with Pain, we take her to the emergency room and they made a CAT scan finding a Blood Clot on the Porta vein, she start with Blood thinners and she still on treatment because that.
1196028	4/12/2021	MD	49	F	2/10/2021	2/11/2021	Abnormal uterine bleeding. Started morning after an evening 2nd dose. Normally 28 day cycle very routine. Started a week early and has not stopped since, 8 and a half weeks so far. Large clots at times. Is a change from baseline, not blamed on stress please. As still ongoing and labs pending, uncertain outcome at this time.

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1196323	4/12/2021	CO	32	M	3/22/2021	3/28/2021	Patient symptoms of chills, headache, and body aches began on Sunday 3/28, 6 days after vaccination. One day later, on 3/29, patient started experiencing pain in the right armpit, the same shoulder where the vaccine was received. That pain built up until Wednesday 3/31, when the arm was very swollen, purple, and rapidly losing sensation. The patient went to the ER. In the ER, via ultrasound, the patient was diagnosed with deep vein thrombosis of the right subclavian and axillary veins. From 4/1 to 4/2 the patient underwent an interventional radiology procedure, thrombolysis, using tPA directed by catheter to the site of the 12 cm long clot. On 4/2, it was determined that the flow was not restored to the vein, and the radiologist informed the patient that right first rib removal would be necessary. On 4/9, right first rib resection surgery was performed to alleviate pressure on the subclavian vein. Patient is currently recovering on the blood thinner Eliquis. Additional procedures for thromboectomy and angioplasty will follow in approximately two weeks to clear the subclavian and axillary veins.
1196269	4/12/2021	IL	65	M	2/16/2021	3/2/2021	Patient received Pfizer COVID vaccines 1/26/21 and 2/16/21. Developed dyspnea and fatigue 2/2021. Admitted to hospital on 3/2/21 with extensive bilateral acute PE (5 lobes). Right acute occlusive DVT in femoral/popliteal veins and partial thrombosis in the left (age indeterminate) of the femoral and popliteal veins. TTE ok. Started on heparin and transitioned to Eliquis (10 BID x7 days then 5 BID). Normal PSA (0.34)
1196263	4/12/2021	MD	69	M	4/9/2021	4/10/2021	passed blood clot in urine
1196171	4/12/2021	WI	34	M	3/31/2021	4/5/2021	Blood clots (DVT in right leg and three pulmonary embolisms in right lung), symptoms appeared around 4/5/2021 and diagnosed on 4/9 and 4/10. Also started experiencing diarrhea during the same time period. Being treated with Xarelto and Azithromycin.

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1196101	4/12/2021	FL	57	M	3/23/2021	4/9/2021	Blood Clot On Friday, April 9th I started with a pain in my ankle around 4PM. It was getting worst and worst. It got red, swollen and I was unable to walk normal, I started limping. Around 2PM on Saturday, April 10th, I went to the ER and I had my ultrasound done. I have a blood clot. They prescribe me Eliquis; 10 mg twice a day for one week and 5 mg twice a day for two to six months...



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1196521	4/12/2021	NY	47	F	4/5/2021	4/5/2021	<p>5 April 2021, at 14:15: Approximately 45 minutes after my initial Moderna vaccine the left side of my face became freezing cold and numb. The progression was instantaneous yet started deep in my inner left ear and around the outside corner of my left eye and instantly moved up to my forehead (crossing the midline), then down the midline of my face encompassing my left eye, the left side of my nose, lips, roof of my mouth, gums, tongue, back over to my left cheek area all the way to my left ear. Simultaneously, I had a surge of metallic-tasting saliva, and I had a tingling vibration (tingling without the pins-and-needles) in both of my hands and on my left shin, just above my ankle to just below my knee. It all happened so fast that I could not talk and verbalize what was happening, I could only hold up my hand in a STOP position. My airway was open and I did not have any respiratory issues. The numbness in my face was about a 9 out of 10. Very numb, very frozen. We went back to the vaccination site and I was put under observation for an additional 15-20 minutes. The observation was 100% hands-off?no BP, no pulse ox, no temperature. I was released with the advice that if I developed any breathing difficulties that I was ?to go to the local emergency room.? 5 April 2021, at 19:00. The numbness receded to about a 5 out of 10. I did not have any respiratory issues, but was able to start noticing other parts of my body that were numb: the entire roof of my mouth; my teeth/gums from the midline-left; when I swallowed I noticed that my throat had no sensation on the left side and felt ?smooth?; both deep, inner ears ached without the any sharp pain. I had a massive headache and took 400mg of ibuprofen and went to bed. 6 April 2021, 09:00. After waking I got out of bed and noticed that my left leg was weak. I thought it was the position that I had been sleeping in, yet it did not?and still has not?gone away. The numbness in my face was still present and that it had extended down onto my lower lips and chin. Most of the left side of my face felt like heavy Silly Puddy, it felt swollen and stiff. The outside corner of my left eye, the left side of my nose, forehead creases and ear were stationary and not moving. My blinking felt off, but didn?t look off. I could now tell that the entire left side of my body was markedly weaker than my right side, my balance was off. I could not feel sensation in my chest/lung cavity as I inhaled and exhaled like I could on</p>

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							<p>my right side. I did not have any airway or breathing difficulties. I rested and hydrated. 6 April 2021, 20:00. A rash of itching, burning hives erupted onto my lower left jaw from just outside my lip line and spread along the curve of my lower jaw bone to my hairline. By 22:00 the itch and burning had subsided, but I could feel that it was still there. 7 April 2021, 02:30. I woke up with excruciating, stabbing ear pain in my right inner ear. I took ibuprofen and tried to fall back to sleep. 7 April 2021, 09:00. My face felt increasingly swollen and stiff and the numb/tingling/vibration sensation in my lower left leg began to spread to my inner leg, around to my calf, up and over my knee to my upper thigh; my leg became so weak that it buckled. We spoke to a nurse advice line and she recommended going to the emergency room. 7 April 2021, 15:00. Dr. saw me. I was given to CT Scan to rule out stroke and an ultrasound to rule out blood clot. I was given the diagnosis of Bell's Palsy and was put on antiviral medication; I declined the steroids because they increase my allergic response reactions. 11 April 2021, 18:00. My face started to swell up over my left eye, left cheek, left ear and over to my right cheek. It did not restrict my airway. I went to bed. 12 April 2021, 17:30. My face?midline to left?is still numb; the left side of my body?especially my left leg?is still markedly weaker than my right; I get winded easily; I tire easily; my mouth still tastes metallic; I still have inner earaches on both sides; my eyes are extremely dry. I am also a yoga instructor. I know my body. I was perfectly able-bodied and healthy at 13:20 on 5 April 2021, 45 minutes later my world unraveled and no one knows how long it will last.</p>
1199422	4/12/2021	OH	98	F	1/28/2021	2/25/2021	Patient passed away from blood clot, did not feel well after 2nd shot
1198032	4/12/2021	WY	69	M	1/27/2021	1/28/2021	Patient has had L leg blood clot and multiple mental co-morbidity-Anemia, hypertension, heart disease, hypokalemia, liver enzyme off per MD, poor nutrition, tremors, hypothyroidism, COPD, small vessel disease of the brain

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1199475	4/12/2021	WA	33	F	4/2/2021	4/6/2021	I'm not a medical professional, I'm reporting this due to the proximity in which the events occurred. I am a 33 year female with no history or family history of blood clots. I received the 2nd dose of my Pfizer vaccine on Apr 2 and on Apr 5 I began experiencing pain in my right leg. I had not injured it, and by Apr 14 I felt compelled due to the increased pain to contact a medical professional. They ran a d-dimer and mine came back high at 0.89. I was instructed by my PAC to go to the ER and tell them about the elevated d-dimer results. At the ER they performed an ultrasound and confirmed "Acute occlusive deep venous thrombosis in the right calf involving the entire length of 1 peroneal vein.". They also performed a CT scan on my chest and discovered "Right lower lobe distal segmental and subsegmental pulmonary artery emboli". They also performed a series of blood tests, all of those came back fine. I am being treated with 15mg of rivaroxaban (Xeralto).
1198615	4/12/2021	WI	28	F	3/26/2021	4/1/2021	Received Moderna COVID vaccine on 2/26/2021 and 3/26/2021. After initial dose she was fatigued. had also taken Plan B 3/1/2021. Fatigue lasted 1 month. 5-6 days after second dose she developed shortness of breath and chest pain. and 9-10 days later noticed a prominent vein in the leg. Called physician office 4/8/2021 and sent to urgent care then ER, found to have superficial thrombosis in leg and multiple bilateral segmental and subsegmental pulmonary emboli.

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1199238	4/12/2021	NC	52	M	3/5/2021	3/29/2021	Approximately three weeks after receiving Johnson & Johnson vaccine, I began to get pains in legs. Calves were aching and throbbing. Didn't think anything of it at first....just thought achy muscles and such. The day before Easter (April 3rd 2021) decided since the pain was continuing and the internet will scare you to death - I went to a local Emergency Room in advance, I had an ultrasound on my left leg and it was noted I had DVT. (blood clot in left calf) To briefly explain: I had an achilles issue back in Nov. 2020 (slight micro tear - achilles tendonitis) I thought maybe this was related to that, as I had not been to the doctor to get it checked until early March 2021. and it bothered me off and on for a few months. I thought the calf pain may have been related to that? I explained to the emergency room doctor about my achilles and thought it was an issue related to that. They decided to perform an ultrasound on my left leg. Which noted the DVT/Blood Clot. They put me on a starter pack of Xarelto and I am to follow up with my normal doctor on April 22, 2021.
1199137	4/12/2021	WI	41	F	4/8/2021	4/9/2021	At the time of the shot I felt the stuff going into my system and all the way down my whole right side all the way down to my right leg. It wasn't painful or anything I was just aware that something was just injected into my body. About an hour after my injection I had a pain go into my hand a few times and I had to keep moving it around to make it go away which it did. That night had neck pain. That night I woke up to a pain in my right calf muscle and I thought I was going to get a Charlie horse so I got up and walked it off. It never got as bad as a Charlie horse. So I went to sleep and not much longer I woke up to the same thing in my left calf muscle. So I got up and walked around. Next morning Same thing happened. So I called the place I got the shot and they suggested taking magnesium pills and electrolytes as well as did my Dr Office. So I did that. Two days later I was feeling a pain in my left back shoulder blade. It eventually went away. I was worried about blood clots, but idk what caused this? Had diarrhea for a few days. And sweats the next morning. I?m day 5 into the first shot of Pfizer right now. I?m worried if I should get the second shot because of the leg cramping.

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1199088	4/12/2021	IN	45	F	2/13/2021	2/18/2021	My last period prior to my first vaccine shot had been in June 2020. All signs, including blood work, pointed to me having entered menopause. My mom also went through menopause at age 45 when her periods suddenly stopped, so I figured I was following in her footsteps. On Saturday, February 13, 2021, I received my first dose of the Moderna vaccine, and by Thursday morning, I was spotting. This was very surprising since I had not had a period in several months. Over the course of a couple of days, it turned into a full-blown period with the most severe cramping I've ever had in my life. By Saturday, they felt like labor contractions, and I was releasing sizable blood clots. I made an appointment at our health clinic, and all bloodwork again pointed to menopause. After my 2nd Moderna vaccine, I again experienced just a tiny bit of brown spotting a few days after the vaccine. However, it did not progress into a full-blown period that time.
1198895	4/12/2021	CO	58	F	3/6/2021	3/18/2021	I was given my first Covid vaccine on 3/6/21. About 12 days later I started having some difficulty breathing, pounding heart and some dizziness. My symptoms got worse one the next week and a half. I went to an emergency room on 3/28/21 and was admitted to an ICU with a Saddle Embolus of Pulmonary Artery with Acute Cor Pulmonale. Many blood clots in my lungs and one very large one in the artery between my heart and lungs. I am now on Blood Thinners.
1198759	4/12/2021	CA	38	F	3/26/2021	3/31/2021	Sever headache and nausea 24 hours after shot. Then 5 days after shot sever abdominal pains on the right side. Was hospitalized and they found a blood clot in a vein leading from my ovary on the ride side. Treatment was Eliquis and further testing.
1198698	4/12/2021	IA	66	M	3/20/2021	3/28/2021	Patient received his first Pfizer shot on March 20th. He began to have pain in the back of his right knee which sent him to the ED. Upon further investigation, he was found to have a blood clot and was given Eliquis as a blood thinner. His physician requested that he make a report as he received his first COVID shot 8 days prior to the blood clot. He denies any diabetes, chemotherapy that may have irritated his vessels. Gabapentin,

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1199137	4/12/2021	WI	41	F	4/8/2021	4/9/2021	At the time of the shot I felt the stuff going into my system and all the way down my whole right side all the way down to my right leg. It wasn't painful or anything I was just aware that something was just injected into my body. About an hour after my injection I had a pain go into my hand a few times and I had to keep moving it around to make it go away which it did. That night had neck pain. That night I woke up to a pain in my right calf muscle and I thought I was going to get a Charlie horse so I got up and walked it off. It never got as bad as a Charlie horse. So I went to sleep and not much longer I woke up to the same thing in my left calf muscle. So I got up and walked around. Next morning Same thing happened. So I called the place I got the shot and they suggested taking magnesium pills and electrolytes as well as did my Dr Office. So I did that. Two days later I was feeling a pain in my left back shoulder blade. It eventually went away. I was worried about blood clots, but idk what caused this? Had diarrhea for a few days. And sweats the next morning. I?m day 5 into the first shot of Pfizer right now. I?m worried if I should get the second shot because of the leg cramping.

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1194141	4/11/2021	GA	49	M	4/1/2021	4/1/2021	very much like a blood clot; R leg swelling; very hematoma; big red patch; warm sensation in the the leg; pain that he never had; normal pain in the injection site; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (very much like a blood clot) in a 49-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 01-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Apr-2021, the patient experienced VACCINATION SITE PAIN (normal pain in the injection site). On 04-Apr-2021, the patient experienced THROMBOSIS (very much like a blood clot) (seriousness criterion medically significant), PERIPHERAL SWELLING (R leg swelling), HAEMATOMA (very hematoma), ERYTHEMA (big red patch), FEELING HOT (warm sensation in the the leg) and PAIN IN EXTREMITY (pain that he never had). At the time of the report, THROMBOSIS (very much like a blood clot), PERIPHERAL SWELLING (R leg swelling), HAEMATOMA (very hematoma), ERYTHEMA (big red patch), FEELING HOT (warm sensation in the the leg), PAIN IN EXTREMITY (pain that he never had) and VACCINATION SITE PAIN (normal pain in the injection site) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route) was unknown.; Sender's Comments: Very limited information regarding these events has been provided at this time. The events are probably related to the patient's comorbidities
1194975	4/11/2021	CA	33	M	4/10/2021	4/10/2021	Severe shaking. Admitted to ED for 180/90 blood pressure and rapid heartbeat (>120). Screened for potential pulmonary embolism and blood clots

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1194958	4/11/2021	CA	62	F	1/27/2021	1/29/2021	2 days after i received the vaccine had difficulty breathing shortness of breath and on 5 and 6 days also then had chills hand tremors loss of appetite nausea this continued for 2 more months. I went to Urgent care and on March 26 then found a clot in my right lung. I am on warfin now and none of these symptoms did I have prior to the vaccine. I had 5 covid tests to see if I had COVID but all the tests were negative.
1194716	4/11/2021	NM	47	F	3/25/2021	4/9/2021	Abnormal menses. Huge clots. Velocity and volume of blood extreme. (Different from previous experiences of menorrhagia). The only other time I experienced this type of dramatic and concerning bleeding was after I took the Hepatitis vaccine (first shot) about 2 years ago. I think that's the only other vaccine I've had as an adult. There is mention of heavy bleeding as a rare side effect for Hepatitis vaccine, and I surely hope you will study this effect from Covid vaccine as it took nearly a year to regulate my cycle after the Hepatitis vaccine reaction. I've seen some reports suggesting that the excessive bleeding that women are experiencing after the Covid vaccine is due to stress and that is just plain insulting. Stress does affect the menstrual cycle; that is well-known, but this is something entirely different. I have also had small clots in the nose during the past several days, which again, is highly abnormal for me. Thank you for looking into the bleeding side effects that hundreds (if not more) women are struggling with at this time.
1194661	4/11/2021	WA	27	F	3/21/2021	3/21/2021	had headache rest of the day, mild and tolerable, most of thursday had headache and body aches was able to work. Friday I felt better friday night I started to get a headache again this time only on my right side, with lots of pressure. Saturday I had pressure and dull headache all day, I took Tylenol and Ibuprofen with no relief. Sunday I went to urgent care the headache was much worse now on the left side of my head, urgent care misdiagnosed me as having a sinus infection. Early monday morning I work up to a hard pulsing pain in my head, went to the ER where they found I had two blood clots in my brain (acute cerebral sinus thrombosis), one significant one obstructing blood flow and one much smaller one.



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1194371	4/11/2021	IN	43	M	2/17/2021	2/22/2021	Blood clots both times in left leg after each dose. Emergency room visit required
1194136	4/11/2021			M	3/26/2021	3/31/2021	was hospitalized with multiple blood clots; This spontaneous case was reported by a physician and describes the occurrence of THROMBOSIS (was hospitalized with multiple blood clots) in a 61-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 017B21A) for COVID-19 vaccination. The patient's past medical history included Surgery (on his shoulder.) on 12-Mar-2021. On 26-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 31-Mar-2021, the patient experienced THROMBOSIS (was hospitalized with multiple blood clots) (seriousness criterion hospitalization). At the time of the report, THROMBOSIS (was hospitalized with multiple blood clots) had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant drugs were not reported. Treatment information was not provided.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported event of thrombosis, a causal relationship cannot be excluded.

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1194118	4/11/2021			U			<p>Blood clots; Felt extremely ill; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clots) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Cancer and Autoimmune disorder. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clots) (seriousness criterion medically significant) and MALAISE (Felt extremely ill). At the time of the report, THROMBOSIS (Blood clots) and MALAISE (Felt extremely ill) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1194117	4/11/2021	MI	84	F	1/28/2021	2/20/2021	Blood clot in lung; fever; Difficult breathing; This spontaneous case was reported by a consumer and describes the occurrence of PULMONARY EMBOLISM (Blood clot in lung) and DYSPNOEA (Difficult breathing) in an 84-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 010A21A and 007M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). Concurrent medical conditions included Hypertension. On 28-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 20-Feb-2021, the patient experienced DYSPNOEA (Difficult breathing) (seriousness criterion medically significant). On 27-Feb-2021, the patient experienced PULMONARY EMBOLISM (Blood clot in lung) (seriousness criteria hospitalization and medically significant) and PYREXIA (fever). At the time of the report, PULMONARY EMBOLISM (Blood clot in lung), DYSPNOEA (Difficult breathing) and PYREXIA (fever) outcome was unknown. Treatment details included Heparin, Xarelto. Based on the current available information a temporal association between the use of the product and the onset date of the events, and with reoccurrence of blood clot with second vaccine use, causal relationship with the events cannot be excluded. Fever is consistent with the known safety profile of the vaccine.; Sender's Comments: Based on the current available information a temporal association between the use of the product and the onset date of the events, and with reoccurrence of blood clot with second vaccine use, causal relationship with the events cannot be excluded. Fever is consistent with the known safety profile of the vaccine
1195233	4/11/2021	IL	40	M	3/30/2021	4/3/2021	Pain underneath right rib cage and difficulty breathing. It got worse over two days and then I was hospitalized. Coughed up blood. Tested with Heparin drip and now I'm on Xarelto. No previous history of blood clots. This happened three days after second vaccine

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1192803	4/11/2021	IL	61	F	3/24/2021	3/29/2021	I experienced a slight headache sore arm and elevated blood pressure after the shot. My blood pressure is usually very well controlled. On Monday the 29th, at about 3:30 pm, I started to slur my words. At first we blamed it on the Novocaine earlier in the day, but I had been talking fine after it and had had it many, many times before and it was worn off. We called my doctor's office after my right arm and leg became very heavy and awkward. They told me to go to the nearest hospital. When I got there, I presented as a full stroke. I was very hard to understand and my mouth drooped and I had very little use of my right arm and leg. They ran tests, but could not give me the medication because I was already on Eliquis. They thought they saw a small clot very high up. I was hospitalized over the next four days and improved my speech dramatically after a bad headache on March 30. The doctors go back and forth to whether it was a Acute Ischemic Stroke, which is what my paperwork says and a complex migraine. I do not experience migraines or anything like this ever before. I did not have a real headache on the 29th. Since my symptoms, right arm and leg difficulties are still here, my Doctor believes it was a stroke. I have an appointment with a Neurologist and I have to have another MRI. I am going to Physical Therapy. My Doctor told me to fill this out, she thinks it may be from the vaccine.
1195446	4/11/2021	LA	62	M	3/11/2021	3/18/2021	Blood Clots in legs and lungs
1192802	4/11/2021	NJ	62	F	2/26/2021	3/5/2021	Blood Clots, Stroke

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1193466	4/11/2021	SC	32	F	4/7/2021	4/8/2021	On 4/8 the expected flu like symptoms began. On 4/9 around 10am my back and chest hurt. Around 12pm on 4/8 I had severe nerve like pain in my neck, back, chest that was radiating throughout my arms and body. I went to the ER they did an EKG, X-ray, blood test, contrasted CT scan to rule out blood clots. My blood pressure and pulse and respiratory were all high. I was given morphine, toradol and a steroid through IV to control the pain. The pain caused me to feel immobile due to the more I moved the more it hurt. I was discharged after no life threatening issues were found even still with an elevated bp and pulse. The doctor did say he was concerned of the pain radiating but was unable to state from what. I was sent home with morphine pills (which I have no taken any as we are in a large opioid pandemic as well and I am a clinical therapist). I could not sleep when I returned home. I had to sit straight up. I took Tylenol and it relieved the pain slightly. On 4/10 I attempted a car ride to get out of the house. Shortly after leaving my house my face became bright red, I couldn't breathe well, I felt extremely hot and the pain was no radiating down my legs. I went to the pharmacy that gave me the shot as they have a clinic. My bp was 147/97 with a pulse of 116 and a fever now of 101.4 ( I havent had the fever until this point). They advised me to go back to the ER. Upon arriving to the ER for the second time in two days. Same test were given besides the CT. I was given toradol by IV and saline again. The pain continues to radiate though my body. I can barely move. Again it is not muscle pain but nerve pain! I can barely move my neck or legs. The hospital discharged me again as administer a Covid test. The rapid was negative. These are symptoms from the shot there is no coincidence. My wbc was 7.2 on 4/9 but 17.1 on 4/10
1195472	4/11/2021	TN	67	F	3/4/2021	4/6/2021	Rectal bleeding 2 days after receiving 2nd shot in arm on 1 April 2021. . Rectal bleeding only occurred after bowel movements that were loose. Experienced some diarrhea 2-3 days and rectal bleeding continued until 9 April before slacking up. Blood in stools, watery and dark red. Upon tissue wiping, observed stringy, dark red blood, clot like discharge. Some stomach cramping 2-3 days after 1 April. Felt some slight fatigue and sleepy.

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1195044	4/11/2021	NY	45	F	4/5/2021	4/7/2021	PT STATES 4/7 AT 3PM SHE NOTICED SWELLING IN LEG AND WENT TO ER. DIAGNOSED AS SUPERFICIAL BLOOD CLOT IN LEFT LEG. SHE WAS TOLD TO COLD COMPRESS, WALK AND ELEVATE TO REDUCE SWELLING. TODAY SHE FELT DIZZY AND THOUGHT SHE MIGHT HAVE MORE BLOOD CLOTS, SHE WAS REFERRED TO ER AGAIN WHERE THEY GAVE HER ASPIRIN 81MG AND THERE WERE NO ADDITIONAL CLOTS, HER FIRST VISIT CLOT WAS HEALING.

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1188842	4/10/2021	CA	74	F	1/28/2021		<p>Blood clot; Fatigue extreme; muscle soreness; loss of appetite; Unable to get out of bed for four days so then they took her to the ER; Lack of circulation on legs due to blood clot produced a wound to develop in her leg; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clot) and FATIGUE (Fatigue extreme) in a 74-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 025A21A and 007M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 28-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clot) (seriousness criteria hospitalization and medically significant), FATIGUE (Fatigue extreme) (seriousness criterion hospitalization), MYALGIA (muscle soreness), DECREASED APPETITE (loss of appetite), MOBILITY DECREASED (Unable to get out of bed for four days so then they took her to the ER) and LIMB INJURY (Lack of circulation on legs due to blood clot produced a wound to develop in her leg). The patient was hospitalized on 22-Mar-2021 due to FATIGUE and THROMBOSIS. At the time of the report, THROMBOSIS (Blood clot), FATIGUE (Fatigue extreme), MYALGIA (muscle soreness), DECREASED APPETITE (loss of appetite), MOBILITY DECREASED (Unable to get out of bed for four days so then they took her to the ER) and LIMB INJURY (Lack of circulation on legs due to blood clot produced a wound to develop in her leg) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route), the reporter did not provide any causality assessments.</p>

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1191824	4/10/2021	MI	78	F	3/11/2021	3/12/2021	<p>it began working up her arm with arm pain and chest pain which persisted and she went to the hospital and was admitted for 23 hours; it began working up her arm with arm pain and chest pain which persisted and she went to the hospital and was admitted for 23 hours; blood pressure went up to 198/203; still has tiredness; difficulty swallowing like her throat is still tight; difficulty swallowing like her throat is still tight; short of breath; This is a spontaneous report received from a contactable consumer (patient). A 78-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: EN6205), first dose via an unspecified route of administration, administered in Arm Right on 11Mar2021 11:00, single dose for covid-19 immunisation. Medical history included silent heart attack, ongoing Barrett's oesophagus from 2008, fall she had over two months (2021), eye surgery on an unknown date. She does not get any shots and can't have shots even for the flu shot because she had problems with two flu shots she had; states she had a problem with each one of the flu shots and does not know the names of the flu shots and has no lot numbers to provide for them; states she had the flu shots in the early 1990's and worked in healthcare and had to have them and they told her back then if she wanted to work she had to have the flu shots and then she got sick with both of the flu shots and they said they guessed they would not force her to have the flu shots. The patient's concomitant medications were not reported. Patient had the first dose administered and then about 14 hours after (12Mar2021) that she had no problems until it began working up her arm with arm pain and chest pain which persisted and she went to the hospital and was admitted for 23 hours. She does not know what to do about getting the 2nd dose of the vaccine and was at her cardiologist's this week and he said he is not familiar with the Pfizer vaccine causing chest pain; caller states she has a history of silent heart attacks. She still has tiredness and difficulty swallowing like her throat is still tight and they told her to mention if she does go for the second dose of the vaccine to mention that she had this situation. The chest pain and arm pain began 12Mar2021 and the arm pain is in her right arm where the vaccine was administered and the arm pain and chest pain have resolved; states the arm pain and chest pain stopped and she thinks that lasted</p>



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about an hour and a half and she called a family member to take her to the hospital; states about 2:30am that same day she was admitted the morning of 12Mar2021 and was discharged on 13Mar2021. They ran every test known to the patient and for a while her blood pressure went up to 198/203 in the emergency room (12Mar2021) and she is not on any medication; caller states she does have Crestor but has not started on it and has not taken it yet. The tiredness and difficulty swallowing like her throat is still tight began the same time she was having the chest pain and she is not having any chest pain or anything like that right now but the tiredness and difficulty swallowing like her throat is still tight is still ongoing; states she did go get cardiac clearance to make sure which was this past week and she does not feel well and like for her the tiredness is bugging her. The tiredness and difficulty swallowing are better but she knows they are there and she tries to swallow something and is like boy her throat is still tight. They did an ultrasound in her left leg because she was limping from a fall she had over two months ago but still has a sore ankle from that and they sent her down for the ultrasound and a CT looking for blood clots in her lungs because she was short of breath (12Mar2021); caller states she thinks they were running everything they could to rule out things; states everything was negative for the CT and ultrasound and she believes the CT and ultrasound were done on 12Mar2021. She has no idea when she was diagnosed with silent heart attacks but they kept asking her about this when she went in for eye surgery and asked her when she had a heart attack and she said she had never had one and they said yes she had and she never knew. She just set up a HCP appointment after the reported events with a gastroenterologist because she has Barrett's and because of the esophagus she did not know if it flared up by the Pfizer vaccine and that caused the pain because the two pains of the heart and esophagus mimic each other with pain going up into the jaw so they were ruling out which one it was; states she went out as an atypical chest pain and called the cardiologist and went in and went over her records from the hospital with the cardiologist. She does not know what caused what in terms of the pain. The outcome of the event blood pressure increased was unknown, chest pain and pain in arm was recovered, other events was recovering.

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1191810	4/10/2021	MI	55	M	3/18/2021	3/19/2021	they had a ultrasound done and found out I had a number of clots in that position; a sore Leg, Upper part of the left calf 2 inches below the knee on the backside; This is a spontaneous report from a contactable consumer. A 55-years-old male patient received bnt162b2 (PFIZER-BIONTECH mRNA COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 18Mar2021 15:00 (Batch/Lot Number: En6207) as SINGLE DOSE for covid-19 immunisation. Medical history included Treatable Acid reflex, anxiety and mild depression. Concomitant medications included omeprazole, buspirone and alprazolam for unspecified indication. Patient had the Covid shot on 18Mar2021 at about 3 PM the next morning (on 19Mar2021 06:00) patient woke up with a sore Leg, Upper part of the left calf 2 inches below the knee on the backside. After it did not go away, he went to the doctor then they had a ultrasound done and found out he had a number of clots in that position. Treatment received for the adverse event includes they put patient on a blood thinner. Prior to vaccination, was the patient did not diagnose with COVID-19. Since the vaccination, the patient has been tested for COVID-19. patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 24Mar2021. Covid test post vaccination done via nasal Swab, They had the results in 15 minutes, covid test result Negative, ultrasound scan: clots in that position on 19Mar2021 found out, had a number of clots in that position. Outcome of the events was recovering.

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1191776	4/10/2021	FL	84	F	2/19/2021	2/19/2021	ringing in her ears; Blood pressure went up; This is a spontaneous report from a contactable consumer (patient). An 84-year-old female patient received her second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were unknown) at the age of 84-years-old, via an unspecified route of administration on 19Feb2021 at 11:30 at single dose for COVID-19 immunization. Medical history included high blood pressure diagnosed 3-5 years ago and ongoing and blood clots (reported as blood thinner) from an unspecified date and ongoing. Concomitant medications included rivaroxaban (XARELTO) from 2020 and ongoing as blood thinner, metoprolol from 2018 and ongoing for high blood pressure, amiodarone from 2020 and ongoing for high blood pressure, and ongoing normal supplement. The patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9263) at the age of 84-years-old, via an unspecified route of administration in left arm on 22Jan2021 at single dose for COVID-19 immunization. On 19Feb2021 at 15:30, four hours after the second dose of the COVID vaccine, the patient started having ringing in her ears and it has not gone away. It was like a truck in her head, she felt like she was losing her mind, it was driving her insane. She could not live like this; it was the worst thing in the world. Her blood pressure went up. She went to the ER for the ringing in ears and had to stay for 2 days at the hospital because they saw a blip on her EKG and it turned out to be nothing. She was hospitalized from 19Feb2021 to 21Feb2021. She has seen 3 doctors. One of them recommend a stress test which was done on 2021 and it was ok. She went to the doctor's office and they thought she had fluid, but it was not there; the neurologist said there was nothing they could do. With regards to treatment for ringing in hears, first, she stated nothing, she did not know what to do. She has gone to 3 doctors and one of them prescribed prednisone but that did not help. She had to take an MRI yesterday (25Mar2021) because they wanted to make sure her brain was okay, and it was all normal. The outcome of the event ear ringing was not recovered and unknown for all other events. Information on the lot/batch number has been requested.

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1191609	4/10/2021	OH	42	M	2/6/2021	3/7/2021	Approximately one week after my second dose my right leg began swelling. For three weeks after the swelling began it would get better than get worse. On Tuesday, March 30, 2021 my entire leg swelled to twice its normal size at which time I went to the emergency room and a blood clot was diagnosed in my right leg. I completed a multitude of tests and bloodwork with a hematologist and there are no factors or reasons they can identify as to why I developed a blood clot.
1191351	4/10/2021	IN	45	F	4/5/2021	4/9/2021	I reported previously that the day of the shot (that evening at close to midnight) I fainted. I woke up on my bathroom floor. I walked down my hall and saw black dots and felt dizzy with nausea. The next thing I knew I was on the bathroom floor and didn't remember how I had gotten there. It is Friday and I now am experiencing shooting pains in the side of my head. I also have been experiencing pains in my calf muscles and some chest pains. I am still extremely tired and having abdominal pain. I have contacted my doctor's office about the fainting but I am going to call Monday to get an appointment to get checked out. I am concerned about possible blood clots.
1191213	4/10/2021	PA	49	M	4/8/2021	4/8/2021	systemic reaction followed by deep vein thrombosis
1191129	4/10/2021	TN	60	M	3/18/2021	3/30/2021	The night after my first vaccine, I awoke at about 3:45AM with extreme aches and pains all over my body for about 4 hours, then I was okay. Twelve days later, I tried to go for a short walk with my wife and the pain in my left leg was horrible at times. The calf muscle was swollen and pink and very warm to the touch. Also my toes were kind of purple and my ankles were badly swollen. I thought the toes and ankles might be related to my Bradycardia, but the calf muscle sent us to the ER to be checked for a blood clot. They did check the major arteries, as those are the dangerous ones, but did not check the calf as they said if one was there it wouldn't throw to the lungs or heart. I was discharged. The swelling went down in the calf. Still some aches in the back of both legs now when I walk very far - but really not bad. Having the purple toes and a possible blood clot... my daughter who is a nurse encouraged me to submit this information. Thank you.

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1190993	4/10/2021	AL		M	2/6/2021	2/1/2021	blood clots in his lungs; Lot of pain in his left side; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 2 via an unspecified route of administration on 06Feb2021 as single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient previously took bnt162b2 for COVID-19 immunisation and had lot of pain in his left side (1 st dose-During period (first part of Jan and part of Feb) he was bedridden). It was reported that caller received the first dose of the Pfizer-BioNtech Covid-19 vaccine on 16Jan2021, in the hospital. On 06Feb2021 he received the second dose of the vaccine. Twelve days later he was diagnosed with multiple blood clots in his lungs, from Feb2021 he was hospitalized, he was prescribed to take Eliquis (Apixaban; blood thinner) 5mg tablets for 6 months. During that period (first part of Jan and part of Feb) he was bedridden because he had a lot of pain in his left side and it would not let him get out of bed, so he was on bed for a while. His primary care doctor told him that the clots might have appeared in his leg and went to his lung. Caller would like to know if any participant developed blood clots during the clinical trials of the vaccine. Therapeutic measures were taken as a result of blood clots in his lungs. The outcome of events was unknown. Information on the lot/batch number has been requested.

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1190983	4/10/2021	MI	31	F	3/3/2021	3/3/2021	My period had ended four days before the vaccine. I always have very regular periods. The night of the vaccine, I started bleeding heavily with large blood clots and continue to do so.; This is a spontaneous report from a contactable consumer (patient). A 31-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EN6206), via an unspecified route of administration administered in left arm on 03Mar2021 as SINGLE DOSE for COVID-19 immunisation. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested for COVID-19 since the vaccination. Medical history included long QT syndrome. The patient had no known allergies to medications, food, or other products. Concomitant medication included nadolol. On 03Mar2021 the patient experienced "My period had ended four days before the vaccine. I always have very regular periods. The night of the vaccine, I started bleeding heavily with large blood clots and continue to do so." The reporter considered the event as non-serious. There was no treatment received for the event. The patient was recovering from the event. The patient received the second dose of bnt162b2 (lot number: ER2613) on 24Mar2021 in the left arm. No follow-up attempts are needed. No further information is expected.

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1190964	4/10/2021	TX	72	F	3/9/2021	3/13/2021	the problem was a bloodclot; slight swelling of right foot; This is a spontaneous report from a contactable consumer, the patient. A 72-years-old non-pregnant female patient received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration in the left arm on 09Mar2021 13:30 (Batch/Lot number was not reported) as single dose for COVID-19 immunisation. Medical history included diabetes, high blood pressure and allergy to tape. Concomitant medications included levothyroxine; olmesartan; metformin; all were taken for an unspecified indication, start and stop date were not reported. The patient did not receive any other vaccine within four weeks prior to BNT162b2. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 13Mar2021 15:00, the patient noticed slight swelling of right foot and on 14Mar2021, the swelling increased so the patient texted the nurse who arranged appointment. The nurse said to contact the doctor and the patient spoke with registered nurse (RN) on duty who told the patient to go to the emergency room (ER) because the symptoms indicated the problem was a blood clot. The ER doctor examined and ordered an ultrasound and the results confirmed blood clot. The patient was given a prescription for blood thinner to take for 21 days (times/day, 15mg) and was told to make an appointment with the primary doctor. The patient's doctor was on spring break and she was walked in to see another doctor who said swelling looked improved and showed her where the clots were located. The patient saw her primary doctor today and she ordered a visit with a hematologist as soon as possible (ASAP) because of concerns about possible underlying issues. The outcome of events, slight swelling of right foot and the problem was a blood clot was recovering. The lot number for the vaccine, BNT162b2, was not provided and will be requested during follow up.

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1190955	4/10/2021		69	F	2/16/2021	2/16/2021	<p>blood clot in the lung; my left leg from the knee down started to swell; my left leg from the knee down started to swell, get really hard and became very painful/I could hardly walk and after and pain was so intense; my left leg from the knee down started to swell, get really hard and became very painful/I could hardly walk and after and pain was so intense; blood clot in the leg; This is a spontaneous report from a contactable consumer (patient). A 69-year-old female patient (patient was not pregnant at the time of vaccination) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot number: EN3248, Expiry date: unknown) via an unspecified route of administration, administered in left arm on 16Feb2021, 15:30 PM at a single dose for covid-19 immunisation (age at vaccination was 69 years). Medical history included blood pressure and thyroid. Concomitant medication patient received within 2 weeks of vaccination included levothyroxine, valsartan, furosemide, acetaminophen. No other vaccine was received within 4 weeks prior to the COVID vaccine. On 16Feb2021, 3 hours after the patient received the vaccination at 18:30 the patient's left leg from the knee down started to swell, got really hard and became very painful. She could hardly walk and afterwards the pain was so intense that she went to the doctor. Doctor took X-rays of her left leg on 16Feb2021, then he diagnosed her with blood clots. He gave the patient 2 heparin shots and immediately sent her to the hospital for a deep vein ultrasound on 16Feb2021. The results showed blood clot in the leg. The patient was prescribed medication and sent home. Her leg continued to be rock hard and painful. On 02Mar2021, the patient was sent for a blood panel work up. There was no improvement. On 08Mar2021, the doctor sent her for a lung CT scan. On the same evening, the patient was called to the doctor's office and was sent to ER immediately as the results showed blood clot in the lung. The patient's dose of Eliquis was doubled. This has now been going for 5 weeks, the patient had not been without pain during this time. Her left leg hardness had gone down a little but was still twice the size of her right leg, knee was huge. The swelling never goes down, not even at night. No covid prior vaccination and no covid tested post vaccination was reported. This case was reported as serious. The outcome of all the events was not recovered. No follow-</p>



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1190936	4/10/2021	WA	67	M	3/16/2021	3/1/2021	up attempts are possible. No further information is expected.  Hypertensive crisis at 180/95; Vascular thrombosis; Head is spinning; This is a spontaneous report from a contactable consumer (patient). A 67-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EN6198), via an unspecified route of administration in left arm, on 16Mar2021, at a single dose, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had no known allergies to medications, food, or other products. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The most recent COVID-19 vaccine was administered in a hospital facility. In Mar2021, the patient's head was spinning, there was a hypertensive crisis at 180/95 for 2 times, and there may be a vascular thrombosis. It was unknown if treatment was received for the adverse events. The events were considered non-serious by the patient. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was unknown.

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1188818	4/10/2021	TX	66	M	3/2/2021	3/1/2021	weakness; inability to rise; frequent urination; lack of taste for food/loss of sense of taste; inability to produce a bowel movement; inability to walk/inability to reach bathroom; blood sugar higher than normal; blood pressure higher than normal; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of GAIT DISTURBANCE (inability to walk/inability to reach bathroom), ASTHENIA (weakness), DYSSTASIA (inability to rise), POLLAKIURIA (frequent urination), AGEUSIA (lack of taste for food/loss of sense of taste) and CONSTIPATION (inability to produce a bowel movement) in a 66-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 012A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 (10 day hospitalization and administration of oxygen therapy) on 01-Nov-2020. Concurrent medical conditions included Hypertension and Diabetes mellitus. On 02-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Mar-2021, the patient experienced GAIT DISTURBANCE (inability to walk/inability to reach bathroom) (seriousness criterion hospitalization), ASTHENIA (weakness) (seriousness criterion hospitalization), DYSSTASIA (inability to rise) (seriousness criterion hospitalization), POLLAKIURIA (frequent urination) (seriousness criterion hospitalization), AGEUSIA (lack of taste for food/loss of sense of taste) (seriousness criterion hospitalization) and CONSTIPATION (inability to produce a bowel movement) (seriousness criterion hospitalization). In March 2021, the patient experienced BLOOD GLUCOSE INCREASED (blood sugar higher than normal) and HYPERTENSION (blood pressure higher than normal). The patient was hospitalized from 03-Mar-2021 to 06-Mar-2021 due to AGEUSIA, CONSTIPATION, DYSSTASIA, GAIT DISTURBANCE and POLLAKIURIA, and then from 03-Mar-2021 to 06-Mar-2021 due to ASTHENIA. On 06-Mar-2021, GAIT DISTURBANCE (inability to walk/inability to reach bathroom) and CONSTIPATION (inability to produce a bowel movement) had resolved. On 24-Mar-2021, ASTHENIA (weakness), DYSSTASIA (inability to rise) and AGEUSIA (lack of taste for food/loss of sense of

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taste) had resolved. At the time of the report, POLLAKIURIA (frequent urination), BLOOD GLUCOSE INCREASED (blood sugar higher than normal) and HYPERTENSION (blood pressure higher than normal) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medications were not provided by the reporter. Treatment History includes ER visit, hospitalization, IV fluids, IV medications, "injections for blood sugar", EKG, scope to check for blood clots, physical therapy. Based on the current available information, a strong temporal association between the use of the product and the start date of the events, a causal relationship with the events cannot be excluded. Causality for hypertension and blood glucose elevated is confounded the concurrent history of hypertension and diabetes mellitus; Sender's Comments: Based on the current available information, a strong temporal association between the use of the product and the start date of the events, a causal relationship with the events cannot be excluded. Causality for hypertension and blood glucose elevated is confounded the concurrent history of hypertension and diabetes mellitus

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1188857	4/10/2021	NJ	55	M	3/16/2021	3/23/2021	experienced blood clot; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (experienced blood clot) in a 55-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 038A21A) for COVID-19 vaccination. Concurrent medical conditions included Factor V Leiden mutation. Concomitant products included RIVAROXABAN (XARELTO) for Factor V Leiden mutation. On 16-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, the patient experienced THROMBOSIS (experienced blood clot) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (experienced blood clot) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The patient was treated with blood thinner Xarelto (rivaroxaban) on a daily basis for factor V mutation and was treated with the same for blood clot.; Sender's Comments: Limited information regarding the event has been provided at this time and a causal relationship cannot be excluded

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1189387	4/10/2021	TX		F		3/13/2021	<p>FLU LIKE SYMPTOMS; TINGLING IN LIPS; TONGUE FELT THICK/HEAVY; ELEVATED HEART RATE; HEART BEGAN RACING (CONSISTENT95-100 BPM); This spontaneous report received from a patient concerned a 24 year old female. The patient's height, and weight were not reported. The patient's past medical history included covid, breast cancer, skin cancer, and clot, and concurrent conditions included seafood allergy, erythromycin allergy, sulfa allergy, high cholesterol, thyroid, glucose intolerance, non-smoker, and non-alcoholic, and other pre-existing medical conditions included the patient has no history of drug abuse. patient height was 5'7 and weight was 220. patient did not have illness at the time of vaccination, has past history of similar events, did not have any adverse event after any previous vaccination, did not have any pre-existing acute illness 30 days prior to vaccination, no history of hospitalization in last 30 days with cause, no any family disease history, patient was not pregnant at the time of vaccination, and not breastfeeding at the time of reporting. The patient was previously treated with semaglutide for clot, and levothyroxine sodium. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose was not reported, administered on 13-MAR-2021 for prophylactic vaccination. Concomitant medications included paracetamol for cholesterol, atorvastatin for glucose intolerance, levothyroxine for thyroid disorder, and rivaroxaban for thyroid disorder. On 13-MAR-2021, the subject experienced tingling in lips. On 13-MAR-2021, the subject experienced tongue felt thick/heavy. On 13-MAR-2021, the subject experienced elevated heart rate. On 13-MAR-2021, the subject experienced heart began racing (consistent95-100 bpm). Laboratory data included: Heart rate (NR: not provided) 95-100 BPM. On 14-MAR-2021, the subject experienced flu like symptoms. Laboratory data included: Body temperature (NR: not provided) 100.1 F. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from tingling in lips, tongue felt thick/heavy, elevated heart rate, and heart began racing (consistent95-100 bpm) on 14-MAR-2021, and flu like symptoms on MAR-2021. This report was non-serious.</p>

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1189595	4/10/2021	FL	42	F	3/27/2021	3/27/2021	Vaginal bleeding and cramping similar to menstruation the same night as second dose was administered. Last menstrual cycle was on 11/06/2020. No period since then (due to birth control). On 03/27/2021 I started bleeding and thought how weird after all this time of not having it. The flow is light throughout the day but when go urinate there are little blood clots almost every time. The cramps are sporadic and the bleeding is going on 2nd full week without no break in between as of this date.

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1189625	4/10/2021		73	M	2/1/2020	1/1/2021	<p>Deep vein thrombosis; This spontaneous case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (Deep vein thrombosis) in a 73-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Co-suspect product included non-company product IBRUTINIB (IMBRUVICA) tablet for CLL. The patient's past medical history included Blood immunoglobulin G (low levels from past 20 years). Concurrent medical conditions included Chronic lymphocytic leukemia, Depression, Drug allergy (allergic reaction to Rituxan.) and Glaucoma. Concomitant products included FLUOXETINE HYDROCHLORIDE (PROZAC) for an unknown indication. In February 2020, the patient started IBRUTINIB (IMBRUVICA) (unknown route) 420 milligram once a day. On 20-Dec-2020, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Jan-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. In January 2021, the patient experienced DEEP VEIN THROMBOSIS (Deep vein thrombosis) (seriousness criterion medically significant). At the time of the report, DEEP VEIN THROMBOSIS (Deep vein thrombosis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In January 2021, SARS-CoV-2 antibody test (610-1600): 347 (Negative) 347. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Other history included: no alcohol use, no drug abuse, non smoker Treatment information were not provided. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, the patient's past medical history of CLL and drug IBRUTINIB can contribute to this event. further information has been requested Reporter did not allow further contact; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, the patient's past medical history of CLL and drug IBRUTINIB can contribute to this event. further</p>

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1189629	4/10/2021	NY		F	3/1/2021		<p>information has been requested</p> <p>Blood clot on her eye after vaccination; Her HCP told her that she could wait even 3 months to get the 2nd dose; This spontaneous case was reported by a patient (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Blood clot on her eye after vaccination) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Enucleation of eyeball. In March 2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clot on her eye after vaccination) (seriousness criterion hospitalization) and OFF LABEL USE (Her HCP told her that she could wait even 3 months to get the 2nd dose). At the time of the report, THROMBOSIS (Blood clot on her eye after vaccination) and OFF LABEL USE (Her HCP told her that she could wait even 3 months to get the 2nd dose) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was unknown. Treatment information not provided. Her HCP told her that she could wait even 3 months to get the 2nd dose Patient decided not to give more information as she believed it wouldn't help her. Reporter did not allow further contact; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>



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1189636	4/10/2021	NC	81	M	1/2/2021	1/16/2021	Blood clot in leg; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Blood clot in leg) in an 81-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 039KZ014) for COVID-19 vaccination. The patient's past medical history included No adverse reaction (No reported medical history.). On 02-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Jan-2021, the patient experienced THROMBOSIS (Blood clot in leg) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood clot in leg) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment information was not provided. Company Comment Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
1189666	4/10/2021	MA	44	F	3/15/2021	3/30/2021	Pulmonary Embolism. Emergency open heart surgery. Coded for 4 minutes. In ICU and Hospital. Kidney failure.....Total blockage of left lung. 9 inch clot in right ventricle.
1189855	4/10/2021	VT	69	F	3/31/2021	4/5/2021	nosebleeds 5, 7 and 9 and 10 days after -vaccine. heavy bleeding for one hour coughing up blood clots. Finally stopped with pressure and cold compresses. Was on the verge of going to ER two times. Three additional lighter nosebleeds in the morning prior to three of them . Have not had nosebleeds for several years. very tired. Last one this a.m. Fear more.
1190415	4/10/2021	AZ	67	M	3/2/2021	3/12/2021	Blood clot in brain causing a small stroke affecting right arm, wrist and hand

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1191825	4/10/2021	NH	76	M	3/9/2021	3/12/2021	DVT L leg, possible PE; DVT L leg, possible PE; This is a spontaneous report from a contactable physician. A 76-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date were not reported), via an unspecified route of administration on 09Mar2021 (at the age of 76 years old) at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously took NSAIDS. The patient experienced DVT L leg, possible PE on 12Mar2021. Treatment given included Eliquis. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19. The outcome of the events was recovering. Information on the batch/lot number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events deep vein thrombosis and possible pulmonary embolism occurred in a plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1190879	4/10/2021	KY	50	F	3/14/2021	3/15/2021	Superficial blood clot in right upper thigh; This is a spontaneous report from a contactable consumer (patient). A 50-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration administered on arm left on 14Mar2021 12:00 (Batch/Lot number was not reported) as SINGLE DOSE for COVID-19 immunization at the Pharmacy or Drug Store. Medical history included ongoing birth control. Concomitant medications included unspecified birth control pills and vitamins. The patient was not pregnant (including the time of vaccination). On 15Mar2021 12:00, the patient experienced superficial blood clot in right upper thigh. The patient had no COVID-19 prior vaccination and not tested for COVID-19 post vaccination. The patient was treated with apixaban (ELIQUIS) 10 mg. The patient was recovering from the event. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

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1191817	4/10/2021		59	M	3/24/2021	3/25/2021	<p>Developed Left lower extremity DVT 24 hours after vaccine; This is a spontaneous report from a non-contactable Physician. A 59-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot number not provided), via an unknown route, on 24Mar2021 (at the age of 59-year-old) at a single dose for COVID-19 immunisation. Relevant medical history included hypertension (HTN), diabetes mellitus (DM) and hyperlipidemia (HLD). The patient did not have history of deep vein thrombosis (DVT) and no other risk factors. The patient was not diagnosed with COVID-19 before vaccination. No relevant concomitant medications were provided. She developed left lower extremity DVT 24 hours after vaccine, on 25Mar2021. The event required emergency room visit. The patient was treated with an anticoagulation therapy. Post vaccination COVID-19 test was not done. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on the information currently available, the event deep vein thrombosis was most likely due to the patient's underlying hypertension, diabetes mellitus and hyperlipidemia. However a possible contributory role of vaccine BNT162B2 to the event can not be totally excluded. Case will be re-assessed upon the additional information provided. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.</p>

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1188528	4/10/2021	IL	40	F	4/6/2021	4/6/2021	Noticeable increase in menstrual cycle- bleeding increased 6-7 hours post injection, and was accompanied by very large clots. (Not normal ) This lasted two days. Intense chills/shivering. Night sweats, nausea. This was the night of the injection. Headache. Everyday since injection. Throbbing in left temple. Muscular pain, left deltoid. This has increased since day of injection. Redness, swelling, pain at injection site that has intensified since injection. (No other indicators of it being an infection. Not warm to touch, no oozing or bleeding or any type of fluid.) Left forearm muscle pain, left wrist pain- almost like a dull ache going down arm.

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1192114	4/10/2021	IA	52	F	3/31/2021	3/31/2021	got extremely weak, very weak in the shower and didn't know if she will be able to keep standing up; chest pain in my right side; my left leg started aching; my toes tingle like they have fallen asleep on that left side; heart was beating faster than what it should have been, they said she was tachycardic and her heart was racing; heart was beating faster than what it should have been, they said she was tachycardic and her heart was racing; Redness; back was all red, really red; The initial case was missing the following minimum criteria: unspecified product. Upon receipt of follow-up information on 01Apr2021, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable consumer reporting for herself. This 52 years old female patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EP7533) on 31Mar2021 at 09:30, for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient received the vaccine on 31Mar2021 at 9:30 and was fine all day until 7 o'clock at night. She went to take her shower and got extremely weak, very weak in the shower and didn't know if she will be able to keep standing up, so she got out of the shower, went upstairs; the weakness persisted and then she started feeling chest pain in her right side, her left leg started aching and her toes tingled like they had fallen asleep on that left side so she got scared and went to the emergency room where they kept her overnight. Her heart was beating faster than what it should have been, they said she was tachycardic and her heart was racing and that was why they kept her at the hospital. She also had redness, her back was all red, really red. They did lots of lab work and blood work, a stress test, an ultrasound on her left leg for blood clot and a CAT scan on her heart, all with unknown results. When probed about hospitalization, she stated to stay overnight. She was hospitalized on 31May2021 at about 19:30 and did not get out until 13:30 on 01Apr2021. Events outcome was unknown.

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1191842	4/10/2021	MA	69	F	2/9/2021		Thrombosis pulmonary; This is a spontaneous report from a contactable consumer. A 69-year-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration on 09Feb2021 as SINGLE DOSE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient experienced thrombosis pulmonary. Outcome of the event was unknown. Information on the lot/batch number has been requested.
1192464	4/10/2021	AL	82	F	2/23/2021	4/6/2021	Fatigue, achy all over, pain under right rib cage that hurt threw to my back. Went to med center and was seen by Dr. He was concerned so that he insisted that I go to the hospital to be admitted on Tuesday 4/6/21. Was admitted and blood work was done and ct abdomen and car which was negative. More lab work was done on 4/7/21 which showed a elevated d-dimer. At that time a ultrasound of legs done which showed a clot in my right leg. Then a ct chest was scheduled and done 4/8/21 which showed a clot in my right lung.
1192294	4/10/2021	MN	39	F	4/1/2021	4/2/2021	Fever 100 degrees for 36 hrs Fatigue for 48 hrs Headache for 1 week post Menstrual cycle started 6 days early Menstrual cycle was heavier and many clots noted
1192235	4/10/2021	MA	43	F	3/26/2021	4/5/2021	New onset DVT/PE blood clots. Diagnosed after patient had new onset right calf pain and cramping about 9 days after receiving second Moderna COVID vaccine, came to hospital had an ultrasound which showed clot, then had CTA chest which confirmed pulmonary embolism (both done on 4/7/2021). She has no other known risk factors for thromboembolism, however a hypercoagulability work-up is also underway and will not be completed for several months.
1191982	4/10/2021	CO	67	M	3/12/2021	3/31/2021	Swelling in lower right leg caused by blood clot in thigh

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1191960	4/10/2021	FL	49	F	3/20/2021		Blood clot in LAD which caused a STEMI; Blood clot in LAD which caused a STEMI; This is a spontaneous report received from a contactable consumer (female). A 49-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: EN6208), first dose via an unspecified route of administration, administered in Arm Left on 20Mar2021 08:15 (at the age of 49 years old), single dose for covid-19 immunisation. Medical history included hypothyroidism, Penicillin allergy, both from an unknown date. The patient was taking unspecified concomitant medications within 2 weeks of vaccination. The patient experienced blood clot in lad which caused a STEMI on an unspecified date (reported as 03Mar2021 15:15, for clarification since before vaccination date). The outcome of the events was unknown. The events was assessed as serious, causing hospitalization, disability and was life-threatening. Treatment for the events were Balloon in LAD / clot buster. The patient underwent lab tests and procedures which included COVID-19: negative on 03Mar2021. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Information on Lot/Batch number was available. Additional information has been requested.



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1191881	4/10/2021	GA	73	M	3/1/2021	3/22/2021	Hospitalized with blood clots in his lungs and a-fib; Hospitalized with blood clots in his lungs and a-fib; This is a spontaneous report from a contactable consumer. A 74-year-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 01Mar2021 (Batch/Lot number was not reported) as single dose for COVID-19 immunization. Medical history included covid-19 prior vaccination: Yes. The patient had no known allergies. The patient's concomitant medications were not reported. The patient previously took bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) for COVID-19 immunization. On 22Mar2021 at 10:00 (reported as 3 weeks after the his second shot), the patient was hospitalized with blood clots in his lungs and a-fib. The patient was currently in the hospital. The patient was treated with oxygen and anticoagulant. The outcome of the events was not recovered. Follow-up attempts are completed. No further information is expected.

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1191916	4/10/2021			F			<p>she had developed what she believes is a blood clot in her leg; This is a spontaneous report from a contactable other healthcare professional (nurse) via medical information team. The contactable consumer reported for her mother that a 77-year-old female patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, formulation: solution for injection) intramuscularly on an unspecified date as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient previously took her first dose of bnt162b2, on an unspecified date for covid-19 immunisation. The patient's mother received the second dose of the covid vaccine yesterday morning. When the caller saw her mother last night, she had developed what she believes is a blood clot in her leg on an unknown date. The reporter would like to know whether a blood clot is a possible side effect from the covid vaccine. The patient did not receive any type of treatment for the adverse event. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported event of Thrombosis leg due to temporal relationship. However, the reported event may possibly represent intercurrent medical condition in this elderly patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including venous doppler of lower extremities and coagulation panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>

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1191906	4/10/2021			U	2/3/2021		<p>after the 2nd shot, my platelets were lower to 369 which was normal for me; This is a spontaneous report received from a contactable (reporting for self). A patient of unspecified age and gender received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VAC-CINE, Formulation: Solution for injection, lot number and Expiration date was not reported) via an unspecified route of administration on 03Feb2021 as single dose for COVID-19 immunization. Medical history included polycythaemia vera, essential thrombocythaemia. The historical vaccine included first dose of BNT162B2 received on Jan2021 for COVID-19 immunization. The patient's concomitant medications were not reported. The patient previously took jakafi for polycythaemia vera and experienced skin lesion. It was reported that patient received her/his two BNT162B2 Covid 19 vaccine back in Jan2021 and 03Feb2021. After her/his 2nd shot of BNT162B2, her/his platelet dropped down around 400. Patient was using medication Jakafi up until Dec2020. But patient had skin lesions and he/she dropped it. So, at the time patient received the vaccines, he/she was not on any medication. Patient was asking that can you look into if BNT162B2 or similar medication can possibly be produced to drop down the platelet level and hemoglobin for the patients who have Polycythemia Vera and Essential Thrombocythemia. Patient wrote to Pfizer because the BNT162B2 could be a way to find a medication for Polycythemia Vera and Essential Thrombosis. Because right after the 2nd shot, "my platelets were lower to 369 which was normal for me". Patients platelets were over 1000 when he/she started the Jakafi medication. It did drop to 500-600 but not lower than that. Patient not sure if it was the vaccine that helped to lower platelet but, patient was trying to see if it can be studied to find a medication for the referenced diseases. The outcome of the event was unknown. No follow-up attempts are needed. No further information is expected.</p>

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1191777	4/10/2021	NY	69	F	3/26/2021	3/26/2021	Weight: Gained 25lbs; Arm is slightly tender; arm might get a little stiff; excruciating leg cramping going from her buttock down behind her knee and rolling to the inside of her thigh/the same pain occurred on the opposite leg around noon and lasted for 15 minutes; excruciating leg cramping going from her buttock down behind her knee and rolling to the inside of her thigh/the same pain occurred on the opposite leg around noon and lasted for 15 minutes; the inside of her thighs were a little red on the side, both legs from her thighs to her knees; the shot is already fogging her mind; This is a spontaneous report from a contactable consumer (patient). A 69-year-old female patient received the first dose of NT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration, administered in left arm on 26Mar2021 08:30 (Lot Number: ER8727; Expiration Date: 31Jul2021, at age of 69 years old) at a single dose for covid-19 immunization. Medical history included allergies: Penicillin, Ampicillin, hair color product. The patient's concomitant medications were not reported. She was allergic to Penicillin, and Ampicillin. As a child, always reacted strongly to any vaccination she was given with a fever and flu like symptoms for a couple of days. With Ampicillin, she thought she was having a heart attack. Was told to stop Ampicillin immediately because she could get a heart attack. This was when she was 25 years old and she never went to the ER. She was allergic to a hair color product in the 1990s and it made her scalp itch really badly. Was given a cortisone shot, which she reacted immediately breaking out head to toe in hives. Has no NDC/LOT/EXP for the vaccinations she reacted strongly to as a child. Stated this was in the 1950s or early 1960s. Clarified she did not have a heart attack with Ampicillin, but it felt like she was having one. Has had cardiograms per her request and her heart and heart walls are perfect. The patient received the first dose of the Covid vaccine at 8:30 a.m. this morning on 26Mar2021. Caller reports around 11 a.m., she experienced excruciating leg cramping going from her buttock down behind her knee and rolling to the inside of her thigh, states that the pain lasted 15 minutes. The patient reports the same pain occurred on the opposite leg around noon and lasted for 15 minutes, states that "the pain was so excruciating that she could barely stand up and it was so agonizing it was

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unbelievable." The patient noticed that the inside of her thighs were a little red on the side, both legs from her thighs to her knees. The patient states that she has not been in the sun, and didn't think it was anything alarming, but this is abnormal for her, states that she received the vaccine in the right arm and her upper torso is fine and her head is clear, asked if anyone else had reported this reaction. She was planned to received the second dose on 16thApr in the early afternoon. The patient stated the COVID shot was already fogging her mind. The patient felt pretty good after first shot. Felt nothing. Fifteen minutes before leaving the diner she got a leg cramp. Was sitting in a booth and didn't think much of it. Attributed it to the way she was sitting. Around 11AM when she got back to her garage, she was in agony. It hurt from the top of her rear all the way down the side to the back of her knee and rolled to the inside of her thigh. She was in such agony and didn't know if she could get out of her chair and walk. By the time she reached her apartment it has subsided. An hour later, same thing happened in the left leg. She was laying in bed and texting because she didn't know if she would get any other reaction. This leg cramp was even worse. She was in tears. Got off bed to try and walk it off. Initial leg cramp happened in right leg. Was excruciating. Both times it lasted for 15 minutes. Both cramps were from her buttocks, all down to her knees, and rolled over into her thigh. Didn't know if that was a reaction. It is not typical of anything written on Pfizer's information or that she had heard. She was concerned. Heard about blood clots, but not with this particular product. Stated second leg cramp subsided. If it hadn't, she wouldn't have gone to the ER. Leg cramps was so excruciating. Originally thought it was coincidental and stated she will be 70 on (Date withheld). To say she has never had leg cramps before would be a lie. The way the leg cramps were timed was kind of weird. It was absolutely the same kind of cramp and location just on the a different leg. Weight: Gained 25lbs. Doesn't have COVID or any symptoms. Tested three to four months ago and was negative. Received first dose COVID-19 Vaccine today, 26Mar2021, at 08:30AM. First leg cramp began 11:00AM in right leg. Second leg cramp began Noon in left leg. Each time lasted 15 minutes. Not having leg cramps right now. Could barely talk when having leg cramps. Was worried about getting clots in

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1191897	4/10/2021	PA		F			<p>legs. Otherwise she would think it was because she was getting older. She doesn't get leg cramps very often. Doesn't know when the last time she had leg cramps prior to today. Nurse technician at vaccine faculty stated caller's allergy history wouldn't be a problem and she only had to sit for 15 minutes. Received the COVID-19 Vaccine and hardly felt it. Waited for 15 minutes. She was fine until 11AM. She was fine now, but her arm might get a little stiff tomorrow. Arm was slightly tender. Surprised she felt something in her legs. Doesn't know whether to associate it with COVID-19 Vaccine or not. Has nothing to complain about in the upper torso or from the waist up. Wants to know if this is a reaction or coincidence. Stated she expected to have a stiff arm. The outcome of the event "Cramps in legs" and "pain" was recovered on 26Mar2021. The outcome of other events was unknown.</p> <p>blood clot on the lungs; This is a spontaneous report from a Pfizer sponsored program. Received from a contactable consumer. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient already got the 1st dose of the vaccine and have a 2nd dose schedule tomorrow. They wanted to reschedule the 2nd dose because the patient was in the hospital and might have a blood clot on the lungs. Treatment was received. The outcome of the event was unknown. Information on the batch/lot number has been requested.</p>

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1191928	4/10/2021			M	2/6/2021	3/10/2021	was diagnosed with multiple bilateral pulmonary blood clots; This is a spontaneous report from a contactable Nurse (patient's wife). A 73-year-old male patient (Husband) received BNT162B2 (PFIZER-BIONTEC COVID-19 mRNA VACCINE, Solution for injection, lot number and expiry dates were not provided), via an unspecified route of administration, on 06Feb2021, as a single dose for COVID-19 immunisation. Patient's medical history and concomitant medications were not reported. It was reported that patient received his first COVID vaccine dose on 06Feb2021. On 10Mar2021 he was admitted to the hospital for trouble breathing and was diagnosed with multiple bilateral pulmonary blood clots. He was hospitalized from 10Mar2021 to 13Mar2021. Seriousness of the events was reported as hospitalization. Outcome of the events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: Based on temporal association, a contributory role of multiple bilateral pulmonary blood clots cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified.
1192257	4/10/2021	FL	74	M	3/30/2021	3/31/2021	3/31/2021 - Nausea 4/01/2021 - Fatigue, stood up after nap and fell with injuries 4/03/2021 - Lymph Node Left Arm enlarged to size of Golf Ball 4/04/2021 - Left Arm very noticeably swollen with rash on both fore-arms 4/05/2021 - Loss of Appetite (not loss of taste or smell) 4/06/2021 - Lymph Node swelling now size of lemon+ 4/09/2021 - Dr visit: Stat Ultrasound: no blood clots. Started on Antibiotic CEFDINIR 300mg 4/10/2021 - Still reduced appetite, arm swelling the same
1185426	4/9/2021		50	F	4/4/2021	4/4/2021	lymph node swelling with pain; blot clot, blue bruise like

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1185441	4/9/2021	CA	79	F	2/20/2021	3/5/2021	13 days after receiving the second dose I was walking my trash can to the street and I could not breath very well. I went to the Urgent Care and was told I had blood clots in my lungs. I was hospitalized and given treatment for the blood clots.
1185467	4/9/2021	TX	63	F	3/17/2021	3/27/2021	Developed blood clots in my lungs. Had a pulmonary embolism performed to dissolve the clots.
1186057	4/9/2021	KY	48	F	4/6/2021	4/8/2021	swelling, redness, and warmth in shoulder of right arm starting about 7-8pm on 04/08, patient went to emergency room on 04/09 where they did an ultrasound and diagnosed her with a superficial blood clot. they told her to take aspirin every day for one month and then return to doctor for a re-evaluation.
1186160	4/9/2021	CA	25	F	3/11/2021	3/15/2021	I had an odd menstrual cycle - the byproduct was a lot more clumpy and clotty than usual. I have typically been having regular cycles for the last few years (28 days), but this one occurred 14 days after the last ended (March 1), and 15 days before the next started (April 5). It lasted a typical amount of time (3 days). I have been feeling more tired than usual. Could be other factors.
1186830	4/9/2021	KS	62	F	3/30/2021	3/30/2021	Patient reported to the pharmacy that she was admitted to the hospital for blood clots shortly after receiving the vaccination and was there for at least 10 days
1185321	4/9/2021	CA	35	F	3/18/2021	4/1/2021	I started to feel pain in both knees going down both legs around 4/1/21. An ultrasound was performed and a blood clot was found in my left lower leg.
1184334	4/9/2021	VT	72	F	3/31/2021	4/2/2021	Two days after vaccine experienced shortness of breath and tachycardia. Went to ER. After testing, diagnosed with pulmonary emboli in each lung (one each). 1 blood clot also found in ankle.
1186196	4/9/2021	TX	73	M	2/11/2021	2/12/2021	fever and associate shivering day after the injection. Sever incapacitating muscle spasm in left leg two days after ijection . Three weeks later second muscle spasm but not as sever. Discomfort in leg prsisted and diagnosed through ultra sound blood clot in left leg.
1185151	4/9/2021	VA	40	F	4/6/2021	4/8/2021	Acute onset large clot and profuse first time nose bleed (posterior potentially from sinuses which hurt), petechiae



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1185007	4/9/2021	NY	56	F	4/8/2021	4/8/2021	At the evening first veins started to bulge ( on the left arm), than they moved to the Lt neck, Lt and Rt breast and by the morning i had it on Bilateral popliteal fossas ( behind both knees). I called to Moderna and they said they do not know what to do with it. It looks like vein blockage and thrombosis
1184977	4/9/2021	WI	68	M	3/8/2021	3/14/2021	3/14/2021 Tightness in chest, attributed to physical work outside, 3/15 still felt tightness, 3/16 getting winded and went to the ER around 5:30pm, they took blood and ran test EKG, X-ray and ECHO complete with TTCV, ultrasound of chest, and test showed multiple blood clots in both lungs; by this time he was having trouble breathing and was admitted because of the blood clots. He was given Heparin and Vicodin through IV, on 3/17 they ran more test to see where blood clots came from and where they came from but nothing was found in legs. he was in a lot of pain Wednesday and he was sent home on 3/19.
1184709	4/9/2021	NY	43	F	3/12/2021	4/6/2021	Blood clot greater saphenous vein. Diagnosed 4/6/21
1187427	4/9/2021	GA	51	F	3/11/2021	3/15/2021	Chest heaviness and Extremely bad leg pain; lower leg (calves) hurt the worse. I have been feeling the pain since Monday, March 15. I went to the Urgent Care on March 16; I was sent to the ER where I stayed overnight. They ruled out heart related issues and blood clots. I had a follow up appointment on March 26; he said that he had seen patients who experienced the same, and it was due to the vaccine. Unlike them, my pain remained. He thinks that the vaccine triggered something else in me. After his appointment, I saw my orthopedist who prescribed meds to help with leg pain. If pain is not better in a month, then he will order a MRI. I saw my rheumatologist Monday, April 5. She is going to work with my orthopedists to treat me. Currently, I am doing the exercises that were prescribed for me to do at home, and I am on pain meds.

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1184432	4/9/2021	MN	71	F	3/1/2021	4/8/2021	Patient had an existing popliteal cyst in the left leg with intermittent leg pain, and swelling. Chronic varicose veins present and a referral was sent to general surgery due to 2 + pitting edema . Patient had numerous MRI's, US, and CT's previously with no evidence of a blood clot. Patient had a left leg venous insufficiency ultrasound completed on April 8th, 2021, provider was immediately called due to an incidental finding of a new DVT, patient was placed on Eliquis and will follow up in clinic.
1188223	4/9/2021	MN	77	M	3/16/2021	3/19/2021	3/16/2021 Received 2nd Moderna Covid-19 vaccine 3/25/2021 Trouble breathing when exercising so stopped after 5 min and usually do 20 min; temp elevated for me normal 97.6 and was between 98.6 and 99.3, hacking up yellowish phelgm. Phelgm had been coming up for longer period of time. 3/26/2021 went to clinic and put on treatment for possible bronchitus. Z-Pak and Prednisone 5 days and asked to schedule x-ray to see if something more showed. 3/30/2021 Completed meds and x ray scheduled. No improvement in breathing 4/1/2021 was finally able to get chest x-ray 4/2/2021 x-ray showed nodule on lung & calcified grandular - told to schedule ct to check out nodule - told clinic still no change in condition 4/5/2021 called clinic again due to pain overnight in left lung. Trouble getting ct scheduled so clinic sent to me emergency room rather than schedule ct 4/5/2021 - At ER blood work, x-ray and ct scan completed. CT chest was significant for large bilateral pulomanry emboli w r ventricular strain. Also r middle lobe lung nodule and r adrenal nodule. Started on heparin drip and admitted. Hospitalized 4/5 and sent home 4/8. Sent home on Xarelto to continue at least 3 months and consult w family doctor to determine cause of submassive clots and further treatment.

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1183985	4/9/2021	NY		M	9/18/2020	9/19/2020	Fluid in his bottom right lobe of his lung where the cancer is; Inflammation in the bottom of his lung; in lower right lobe of lung; Blood pressure isn't stable; going up and down; Blood pressure issues; Exhausted; fatigue; Trying to control his blood pressure and his pulse issues, pulse incomplete; Muscle weakness was severely progressing; Bad reaction to the Covid vaccine; Blood clot on his lung; Raspy voice; the patient had been sick; Moderate headaches; Passed away; This is a spontaneous report from a contactable consumer (patient) based on the information received by Pfizer from Pharmaceuticals (Manufacturer control number 2020CAT00505). A 74-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date at single dose for COVID-19 immunisation. Co-suspect drug included amifampridine phosphate (FIRDAPSE) orally, from 18Sep2020 to an unspecified date at 10 mg thrice daily, from 02Oct2020 to an unspecified date at 20 mg thrice daily, for Lambert-Eaton myasthenic syndrome. Medical history included Lambert-Eaton myasthenic syndrome (he could not walk without FIRDAPSE), migraine ever since he was a kid, small cell lung cancer (in liver and lymph nodes; brain metastases), metastases to liver, metastases to lymph nodes, radiotherapy of his head and lung for his cancer, gait disturbance from an unknown date and unknown if ongoing, muscular weakness from an unknown date and unknown if ongoing. Concomitant medications included pantoprazole, acetylsalicylic acid (ASPIRIN (E.C.)), furosemide. The patient experienced blood clot on his lung in Jan2021 with outcome of unknown, fluid in his bottom right lobe of his lung where the cancer was on an unspecified date with outcome of not recovered, inflammation in the bottom of his lung; in lower right lobe of lung on an unspecified date with outcome of not recovered, raspy voice in 2021 with outcome of recovered, blood pressure not stable; going up and down; blood pressure issues on an unspecified date with outcome of not recovered, exhausted; fatigue on an unspecified date with outcome of not recovered, sick in 2021 with outcome of unknown, trying to control his blood pressure and his pulse issues, pulse incomplete on an unspecified date with outcome of unknown, moderate headaches from 19Sep2020 with outcome of recovered, muscle weakness severely progressing on an

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unspecified date with outcome of unknown, 10 mg 3 times a day wasn't enough (therapeutic product effect incomplete), on an unspecified date with outcome of unknown, he'd switch and do a couple doses of 15 mg and it was better but not enough (intentional product use issue) on an unspecified date with outcome of unknown, after he received the COVID vaccine, he experienced a bad reaction (unspecified) on an unspecified date with outcome of unknown. The events were reported as serious as involved hospitalization. The patient passed away on an unspecified date in Feb2021. It was not reported if an autopsy was performed. The clinical course of the events included the following information. On 21Sep2020, a spontaneous report was received from a consumer, via a company representative, regarding a 74-year-old male who was being treated with FIRDAPSE 10 MG (amifampridine). On 22Sep2020, additional information was received from a consumer. On 02Oct2020, additional information was received from a consumer and chemotherapy was added as a co-suspect. On 01Feb2021, additional information was received from a consumer via a company representative. On 09Feb2021, additional information was received from a consumer, and this case was determined to be the master case for cases 2021CAT00039 and 2021CAT00052 (both invalid, duplicate cases) and the information was merged into this case (2020CAT00505). This case was re-assessed as serious/unexpected, and COVID vaccine was added as co-suspect. On 18Feb2021, additional information was received from a consumer via a company representative. On 19Feb2021, additional information was received from a patient ambassador via a company representative. Medical history included LEMS (Lambert-Eaton myasthenic syndrome) and migraines. Concomitant products included: an unknown statin, pantoprazole, and acetylsalicylic acid (ASPIRIN) 81 mg. On 18Sep2020, the patient started treatment with FIRDAPSE 10 mg at 10 mg, 3x/day orally for LEMS. On 19Sep2020 and 20Sep2020, after starting the product, the patient experienced moderate headaches. On 21Sep2020, the patient did not experience a headache. On 22Sep2020, the patient experienced a headache that was "4/10." He had taken acetaminophen; aspirin; caffeine (EXCEDRIN) and ibuprofen as treatment and it "helped." The patient

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had not spoken to his HCP (health care provider) about the event but was going to call his HCP and ask to increase his dose of FIRDAPSE. The product was working and he was walking better, but he had heard people taking up to 80 mg a day. As of 22Sep2020, product use was ongoing and headaches were improved. On 02Oct2020, it was learned that his medical history included being prone to headaches (also reported as migraines ever since he was a kid) and "chemo" for small cell lung cancer stage 4 which was in his liver and lymph nodes. Concomitant products included furosemide. It was noted that the patient had been on the product for 4 to 5 days when he experienced his moderate headaches. He had the headaches for just a couple days, but he wasn't sure if it was due to the FIRDAPSE or it was the chemo. He took "a couple" of ibuprofen and he was "alright." On an unspecified date, the patient was in contact with his HCP and he was told to "keep an eye on it" (presumed headaches) and see if it got worse. They agreed that it could have been the chemo or a "fluke" thing. He also spoke to his HCP about his FIRDAPSE dose of 10 mg, 3x/day not being enough. He would switch and do a couple doses of 15 mg and it was better, but not enough. His HCP thought he should be taking 20 mg 3x/day, so he was working with the patient's insurance and pharmacy to get it changed. As of 02Oct2020, FIRDAPSE and chemo treatment were ongoing and moderate headaches were resolved (reported as he'd been good for a few days). On 01Feb2021 and 09Feb2021, it was learned that on 02Oct2020, the patient's FIRDAPSE dose increased to 20 mg, 3x/day. On an unspecified date, the patient received the COVID vaccine at an unreported dose, route, and frequency of administration for an unreported indication. After the patient received the COVID vaccine, he experienced a bad reaction (unspecified). Since 27Jan2021 (reported as since Wednesday, relative to 01Feb2021), the patient had been sick. On 31Jan2021, the patient went to the emergency room, and they thought he had a blood clot on his lung. Subsequently, he was admitted to the hospital. Initially, when the patient was in the hospital, they took all his medications away, including his FIRDAPSE, as the pharmacy was managing his medication. The patient wife was able to get the doctors to let the patient keep his FIRDAPSE in his room with

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him before he missed any doses because he could not walk without his FIRDAPSE. On an unspecified date in 2021, the patient had radiation of his head and lung for his cancer (previously reported medical history), and "they" (presumed his medical provider) said he could have a raspy voice and headache, which he did experience but then resolved. While in the hospital, the patient's blood pressure was not stable. It went "up and down, up and down." He had fluid in the bottom right lobe of his lung, where the cancer was, and they could not "tap it" due to the blood pressure issues. They were trying to get the fluid out every other way they could. The doctors said he had inflammation in the bottom of his lung. He was given a "good dose" of prednisone, but he was just exhausted. They were trying to control his blood pressure and his pulse. When they got one of them "up," the other went "down." The doctors said that the patient's LEMS had nothing to do with why he was in the hospital. His wife expressed her gratitude for the FIRDAPSE and how it had helped him. As of 09Feb2021, treatment with FIRDAPSE was ongoing. The patient was still in the hospital and not doing well, also reported that he was still the same, he had not improved but he had not worsened. The blood clot on his lung, blood pressure fluctuation and pulse issues, fluid in the bottom right lobe of his lung, inflammation in the bottom of his lung, and exhaustion were not resolved. The status of the bad reaction to the COVID vaccine was not reported. No additional information was provided. On 18Feb2021 and 19Feb2021, it was learned that the patient's medical history included: muscle weakness and lung cancer with brain metastases. On unspecified dates, after starting FIRDAPSE, the patient's muscle weakness began severely progressing, and he experienced fatigue. The weakness was worsening significantly, even after being on the medication (presumed FIRDAPSE). On 14Feb2021 or 15Feb2021, the patient was discharged from the hospital. On 18Feb2021, the patient took his last dose of FIRDAPSE. On 18Feb2021 or 19Feb2021 (reported as last night, relative to 19Feb2021; yet also reported as either 18Feb2021 or 19Feb2021), the patient passed away. The cause of death was unknown. A 74-year-old male, with a history of migraines and chemotherapy for metastatic small cell lung cancer, was taking an unknown statin, furosemide, pantoprazole, and

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Aspirin. He added FIRDAPSE for LEMS on 18Sep2020 and experienced headaches for a couple days, but he wasn't sure if it was due to the FIRDAPSE or chemo. After COVID vaccine, he experienced a bad reaction (unspecified). Since 27Jan2021, he was hospitalized with a blood clot on his lung. He had brain and lung radiation for cancer. While in the hospital, he had fluid and inflammation in the bottom right lobe of his lung, where the cancer was, which could not be drained due to labile blood pressure. His muscle weakness began progressing and he experienced fatigue. In Feb2021, he was discharged on FIRDAPSE. A few days post-discharge, he died. Based on the information provided, the events were assessed as unrelated. Information on the batch/lot number has been requested.; Reported Cause(s) of Death: Passed away

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1183942	4/9/2021		37	F	2/12/2021	2/1/2021	administration date 12Feb2021/administration date 26Jan2021; administration date 12Feb2021/administration date 26Jan2021; had breakthrough bleeding for the first time ever. Periods were significantly heavier with massive clots; This is a spontaneous report from a non-contactable consumer (patient). A 37-year-old female patient (not pregnant) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3249 and expiration date not provided), via an unspecified route of administration, in left arm, on 12Feb2021 10:00 (at the age of 37-year-old, not pregnant), at single dose, for COVID-19 immunization. Medical history was not reported. Patient has no known allergies to medications, food, or other products. Patient was not diagnosed with COVID-19 prior to vaccination. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No concomitant medication (reported as "patient received no medications within 2 weeks of vaccination"). The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not provided), via an unspecified route of administration, in left arm, on 26Jan2021 (at the age of 37-year-old), at single dose, for COVID-19 immunization. In Feb2021 and Mar2021 patient had breakthrough bleeding for the first time ever. Periods were significantly heavier with massive clots. Patient saw OBGYN, but no reason found except vaccine side effect. Event result in doctor or other healthcare professional office/clinic visit. No treatment received. Patient had not been tested for COVID-19 since the vaccination. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.



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1183938	4/9/2021	NJ	32	F	3/11/2021	3/13/2021	I began to bleed and pass blood clots from my vagina; I began to bleed and pass blood clots from my vagina; This is a spontaneous report from a contactable consumer (patient). A 32-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in the left arm on 11Mar2021 01:15 (at the age of 32 years) (Batch/Lot Number: EN6208) as a single dose for COVID-19 immunisation. Medical history included birth control. Concomitant medications were not reported. The patient is not pregnant. On 13Mar2021 04:00, the patient began to bleed and pass blood clots from her vagina. The event blood clots was assessed as serious (medically significant). The patient visited the doctor for the events and the events were given treatment. The outcome of the events was not recovered.
1184699	4/9/2021	UT	34	M	2/3/2021	3/19/2021	Heart attack (blood clot in major artery) approximately 6 weeks post 2nd Moderna dose. Surgery done in cath lab to address blockage. Released from hospital several days later.

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1187893	4/9/2021	GA	49	F	3/31/2021	3/31/2021	0213A21A -(The lot number is hard to read and it could be this number or the one above.) Wednesday, Thursday and Friday - I had headaches and I had extra fatigue (I already do have fatigue because I have insomnia). My arm soreness was on the other arm not on the one that I had an injection. Friday and up until yesterday, I had nausea. Saturday, I had headache and being tired. Sunday, I had chest pain (woke up with it) like a burning in my chest. My left arm, I felt a tingling down my arm to my legs - it almost felt like a blood clot was there in my arm. I had to put heat on and then ice. I couldn't extend arm because it hurt. Midnight on Monday, the burning and the chest pain was too much and I was getting worried. The only thing I have is asthma, otherwise I'm healthy. I went to ER - they gave a Cocktail of Lidocaine; Malex and something else to see if it would help with the burning in my chest. Monday, I took Tylenol. Tuesday, the chest pains were more intense. 03:00 on Wednesday am - I went back to ER. They brought me to a full chest x-ray - front, side and back and a CAT SCAN and gave me another Cocktail and also put something in my IV. This time, they sent me home with four different medicines. The meds are: Generic of Nexium; Aspirin low dose of 81 mg - bayers children - one a day; Generic version of Bentil Triacetin - I take this when I want to be still; Generic version of Valium - they gave me four of these - and I have one left that I will take tonight so I can sleep. I am taking Vit D. I haven't taken Tylenol since getting on these. I try to stay hydrated. I still have a really really funny feeling inside me. Last night, I was very restless and couldn't sleep. It makes me on borderline and dizzy and my heart starts palpitating. It's a scary feeling in my chest.
1188195	4/9/2021	MI	58	F	3/12/2021	3/12/2021	I had a number of side effects the same day...nausea, restlessness, migraine. Then the headaches & migraines continued. Previously I hadn't had a significant migraine for over a year. So far I've had 3 that required medication, & several lesser headaches. Tjis is what is unusual, & due to recent reporting regarding possible,link to brain blood clots, I'm worried.

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1188275	4/9/2021	MI	73	F	3/4/2021	3/21/2021	Pulmonary Embolism with Acute Core Pulmonale -no sign of DVT. Multiple blood clots in major arteries of both lungs. Event began with tiredness over about. 2 week period and ended in acute event with trouble breathing. Taken to hospital via ambulance. Tests also showed right heart damage due to stress from clots.
1188046	4/9/2021	PA	78	M	3/29/2021	4/1/2021	Patient came to pharmacy to say that for about 3 hours around 5 days after his 2nd dose of Moderna Covid-19 vaccine he experienced some temporary confusion/stroke like symptoms. His physician is currently trying to rule out other causes, such as an actual stroke/blood clot. At the present time, the patient feels like his normal self.
1187825	4/9/2021	NY	70	M	1/6/2021	1/20/2021	blood clot in superior mesenteric vein found with Abd CT scan placed on lovenox then xarelto with relief of sx - abd pain
1182106	4/8/2021	KS	64	M	3/15/2021	3/29/2021	Right Arm DVT and superficial venous thrombosis on ultrasound done on 3/30/2021-Pt noticed right arm soreness and discomfort then he started to have firmness which continued to get worse.
1182724	4/8/2021	WA	74	F	3/30/2021	4/6/2021	On Apr 7th at 11:30 Pm my wife went to hospital. not being able to breathe sufficiently. This started the day before on the 6th while out walking. She is in the hospital being treated for embolisms of the lungs on both sides with multiple blood clots.
1182640	4/8/2021	TX	64	F	4/1/2021	4/6/2021	Pt received vaccine on 4/1/21. On Sunday, 4/4/21, pt started to have muscle cramps in thighs and all down legs. Were so severe at times she couldn't walk. Muscle cramps subsided by 4/6/21 and pt noticed a knot on each inner thigh. Patient is concerned about the knots and if they may cause a blood clot.

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1181814	4/8/2021	GA	31	F	3/26/2021	3/27/2021	I had just had my period on 02/22/21 (first day of the cycle) and then received the first dose of the vaccine the following week (on 03/04/21). I had a slight period the day after (03/05/21) which lasted about 3 days. I thought it was just a coincidence and didn't think much of it. The same issue happened after I got the second dose on 03/26/21; I got my period again. My period is usually normal (every 27-31 days), so it was definitely strange to me that my period came so soon and both times were immediately the day after the shot. It was just a normal period with no blood clots or anything abnormal, but I do feel like it's an adverse reaction of my body to the vaccine.
1181756	4/8/2021	CA	72	F	3/10/2021	3/11/2021	blood clot in left arm causing enormous swelling
1182094	4/8/2021	CA	71	F	3/26/2021	4/2/2021	After COVID Vaccine #2, I had major brain fog, fatigue and almost constant nausea for two days. It stopped for a day, then continued from Monday afternoon and I think still continues today, April 8. However, a week later on Friday April 2, I had an extremely painful abdominal flareup with diarrhea, then blood clots throughout the night which turned out to be ischemic colitis. Hospitalized for three days, had CT scan and then a colonoscopy.
1180842	4/8/2021	OH	54	M	3/29/2021	3/31/2021	Received 2nd Moderna Covid shot on 03/29/2021 and on 03/31/2021, felt what I thought was a muscle cramp that never went away. Went to urgent care where the shot was given on unspecified date and they diagnosed what I thought was a muscle cramp area, as a blood clot.

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1182133	4/8/2021	TN	28	U	3/19/2021	3/25/2021	She received the J and J vaccine on 3/19/21 at STM. She presented to Med center with a "viral syndrome" including fevers, rigors, muscle pain and SOB. She received a Z pack. Fever persisted for 1 day after ER visit but she continued to feel badly. The following day, 3/27 she was awakened with severe R>L jaw pain, post HA with standing, pain in the cartilage on the tip of her nose and SOB. SOB resolved by 3/31. HAS persisted as did jaw pain and pain behind her eyes. ON 3/30 she noted increasing bruising and periorbital petechiae which continued through 4/5 when she sought help from Dr , her PcP. When she saw DR she was noted to have bilateral leg swelling R>>L . She had labs and a Doppler US which we are trying to locate. She had a syncopal spell on 4/6 and was brought to ER at STM where she was diagnosed with sagittal vein thrombosis, RLE DVT and thrombocytopenia.
1182180	4/8/2021	IN	66	M	1/19/2021	2/4/2021	Diagnosed on 2/4/21 with a dvt blood clot in my left leg. Currently on warfarin.

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1182480	4/8/2021	NJ	72	F	2/23/2021	3/5/2021	positive COVID-19 test with symptoms; This is a spontaneous report from a contactable consumer (patient herself). This consumer reported similar events for 2 patients (for herself and for her husband). This is the first of two reports. A 72-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), dose 1 via an unspecified route of administration, administered in top of left arm on 23Feb2021 16:10 (Batch/Lot Number: EN6200) as single dose for COVID-19 immunization (protection; felt it would help). Medical history included thinking she thinks she got COVID from her husband, ongoing headache prior to receiving the vaccine. Concomitant medication includes taking unspecified blood pressure medication and thyroid medication. Patient stated that she and her husband got the first dose of Pfizer COVID-19 vaccine and got COVID within a few days of getting the immunization. She believed they got it from the clinic. Patient stated she got COVID Vaccine 23Feb2021 at 4:10pm and she tested positive for COVID on 05Mar2021 and on that same day states she was treated with COVID antibodies/monoclonal antibodies. She thinks she got COVID from her husband. Symptoms started on 01Mar2021 with a cough, which started getting worse. Then, headache started and she felt 'all together down'. She stated that symptoms almost felt like a sinus infection. Patient stated that her doctor said that her lungs were affected. Patient stated that overall symptoms have improved, but she still experiences lack of energy and a little shortness of breath which she thought was due to the lack of energy. Patient stated that she has to sit down more due to the weakness, stating she can only walk around in her garden once before she has to sit down and take a break, which is more often than before. She stated that she did get headaches prior to receiving the vaccine, but they are normally in the back of her neck area and now they are higher in the head. Patient stated she still gets intermittent headaches, and she is not sure if they are from COVID or not. Weakness and shortness of breath started a few days later after the cough. Clarified as Wednesday, 03Mar2021 or Thursday, 04Mar2021 when these started. By the time her husband tested positive, she immediately was tested for Rapid COVID test on 05Mar2021 and they went in for antibodies. She knows that her husband had it worse, as

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							they caught hers quicker. Patient added that she always felt like she had a fever; felt flush; skin felt warm but had no fever, her highest temperature was 99.5. Patient also stated that pretty early on, her legs felt like they weighed 100 pounds, from her knee to ankle felt like they had a band around them, by the end of the week it was at it's worst. It still hurts some now, but she can get around more. Patient stated her doctor sent her to get a doppler study to make sure she didn't have any blood clots, the results were negative on Mar2021. Patient stated that her doctor told her that this could happen to people with neuropathy, which could be common for her age. Patient took a second PCR COVID test on 17Mar2021 and it was still positive. Vaccination Facility Type was urgent care not facility. The AE required a visit to Emergency Room (treated with antibodies and sent home) and Physician Office. The doctors have advised them to take the second dose three months later. Patient wanted to know if she get the second dose 3 month later and would she have to restart the series of the vaccine all over again. The outcome of the event was recovering.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021315088 same drug, similar events, different patient
1181930	4/8/2021	GA	27	F	4/6/2021	4/7/2021	Passing of blot clot in urine one day after vaccine received with no prior history of symptoms.
1181614	4/8/2021	GA	78	F	1/11/2021	3/9/2021	Moderna EUA Pt started having left leg pain, discoloration (blue-purple) and swelling on 3/9/2021. Pt went to the hospital and was later called to come back to the hospital because she had a blood clot. Pt was sent to clinic and had a procedure by to remove clots. Pt states that the clot was "2/3 size of thigh." Pt states that she is scheduled to have a second procedure in May to remove blockages from iliacs.
1181254	4/8/2021	OR	79	F	3/13/2021	3/26/2021	03-26-2021 patient developed LLE pain, progressively worsened. Admitted to hospital on 03/29 and discharged 04/01. Pt diagnosed with superficial femoral artery occlusion and popliteal artery thrombosis. Left femoral artery stent placed 03/31/2021.
1180837	4/8/2021		69	M	4/5/2021	4/7/2021	multiple deep vein thrombosis of left lower leg, started on Xarelto, hematology referral, swelling improving

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1180454	4/8/2021	MN	63	F	3/22/2021	3/23/2021	Patient received her 1st dose of Moderna on 3/22/2021, patient was observed for the appropriate amount of time and left without any reaction/concerns or questions. Patient's daughter called our facility on 03/23/2021 @ 10:00 am, she states that her mother called her and had fallen and was not able to speak appropriately. Nursing advised the patient to present to the ER, an ambulance was called and the patient went to the ER. Patient was subsequently transferred to due to space in . Patient was found to have a right internal carotid artery occlusion that required stenting and an angioplasty, she also required a right middle cerebral artery clot aspiration for a semi-occlusive clot. Patient was then transferred to for rehab for 3 days, and she was discharged home.
1180258	4/8/2021	KY	72	F	2/11/2021	2/13/2021	On day of 2nd vaccination, 2/11/21, severe momentary dizziness about an hour after then no reaction until 2/13/21. Approximately, 8P on 2/13/21, found blood in urine that lasted approximately 3 days. Towards the end of the episode, saw very small blood clots. Went to my clinic . Urine sample confirmed blood in urine, CT Scan showed no abnormalities of kidneys, and Cystoscopy with a Urologist showed bladder to be normal. Have no history of kidney stones, kidney disease or cancer. As of today's date, 4/08/21, no further episode. Lab worked showed no abnormalities.
1180000	4/8/2021	CO	33	F	3/24/2021	4/2/2021	Pain in left calf began on April 2 during a long road trip. Pain continued for several days. On April 5, I visited Urgent Care for a suspected muscle strain. They referred me to the Hospital emergency care for an ultrasound. The ultrasound detected deep vein thrombosis (DVT) (blood clot) in the popliteal vein in my left leg, above and below my knee. I am currently taking anticoagulant (Eliquis) medication to treat the DVT.
1179672	4/8/2021	GA	44	F	3/31/2021	4/2/2021	DEVELOPED BLOOD CLOT IN RIGHT BREAST - CURRENTLY BEING TREATED
1179370	4/8/2021	MA	82	M	3/11/2021	3/22/2021	blood clots in right leg and left lung



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1179308	4/8/2021	FL	53	M	3/29/2021	3/30/2021	Thrombocytopenia; Blood clots in brain; This is a spontaneous report from a contactable consumer (patient). A 53-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) solution for injection, dose 1 via an unspecified route of administration, administered in left arm on 29Mar2021 13:00 (Batch/Lot Number: EN6206) as single dose for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. On 30Mar2021, patient developed thrombocytopenia and was brought to emergency room/department or urgent care leading to admission, surgery was performed (mechanical thrombectomy) on 30Mar2021 at 10am to address blood clots in the brain. Patient was currently in ICU until he fully recovered. Patient was hospitalized in Mar2021 for 2 days. The events were reported as life-threatening and have caused disability. Outcome of the events was unknown. Information on lot/batch number has been available. Additional information has been requested.
1179009	4/8/2021	AL	70	F	3/11/2021	3/12/2021	Blood clot (brain)/ stroke
1181441	4/8/2021	NC	33	F	3/19/2021	4/1/2021	PT HOSPITALIZED WITH BLOOD CLOTS IN LUNGS. DISCHARGED FROM HOSPITAL A FEW DAYS LATER.
1183339	4/8/2021	NY	62	F	4/8/2021	4/8/2021	Heavy Nosebleed with blood clots - Nosebleed lasted 25 minutes -started in right side nose.
1182730	4/8/2021	WI	30	M	4/7/2021	4/8/2021	1:22 AM: chest pain, abdominal cramps, chills, difficulty breathing, hyperpnea, bilateral upper extremity trembling VS: pulse 112, respirations 22, temperature 37.0 Celsius, BP 156/103, O2 sat 99% on room air has history of deep vein thrombosis, pulmonary embolism 1:30 AM sent to emergency room via ambulance 4:00 AM report from emergency room: patient is stable and reported feeling better and breathing easier shortly after arriving to ER. Patient received 500cc NS bolus IV. Labs findings unremarkable. INR 2.0, PT 21.3, PTT 31. Last taken VS - BP 127/71, P109, R20, O2 93%RA. Patient will be discharging with Dx: reaction to COVID vaccine.

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1183162	4/8/2021	MA	48	F	4/6/2021	4/7/2021	Low white blood count and elevated D-dimer. Leading up to the blood work was sever chest pain, ultimately diagnosed as acute gastritis (not typical for me at all). Other symptoms were general body aches and fever. CT ruled out blood clot.
1182981	4/8/2021	NM	45	F	3/13/2021	3/23/2021	Back spasm found Blood Clots in lungs sudden on set 10 days after 2nd dose.
1182945	4/8/2021	NY	46	F	4/6/2021	4/7/2021	Massive nose bleed with a huge blood clot to follow. Went to urgent care but it had stopped by then so they sent me home and told me if it happened again to go to ER. I haven?t had a nosebleed in years so it was scary to get it the day after my vaccine. The nose bleed lasted about 10 minutes and was very strong once the clot came through it slowed down and then stopped and did not return again.

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1182773	4/8/2021	TX	58	M	2/21/2021	3/10/2021	Massive blood clot in left calf leading to pulmonary embolisms in both lungs (multiple clots in each lung); Massive blood clot in left calf leading to pulmonary embolisms in both lungs (multiple clots in each lung); This is a spontaneous report from a contactable consumer (patient). A 58-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration administered in left arm on 21Feb2021 14:00 (at the age of 58-year-old) as SINGLE DOSE for COVID-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and it was unknown if the patient has been tested for COVID-19 since the vaccination. The patient's medical history was not reported. The patient had no allergies to medications, food, or other products. The patient had no concomitant medications received within 2 weeks of vaccination. On 10Mar2021 at 11:30 AM, the patient experienced massive blood clot in left calf leading to pulmonary embolisms in both lungs (multiple clots in each lung). The patient was hospitalized for the events for 4 days. The events were also considered as life-threatening. Therapeutic measures were taken as a result of massive blood clot in left calf leading to pulmonary embolisms in both lungs (multiple clots in each lung) which included intravenous anticoagulants and injected anticoagulant. The patient was recovering from the events. Information about the lot/batch number has been requested.

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1182746	4/8/2021	NC	43	F	3/17/2021	3/18/2021	could not walk on her left foot; hot, painful patch on the inner left lower leg below the calf muscle; Left lower leg and foot bluer than right; vascular issue; pain and redness was present in the lower left calf/ a large red, hot, painful patch on the inner left lower leg below the calf muscle; pain and redness was present in the lower left calf/a large red, hot, painful patch on the inner left lower leg below the calf muscle/tenderness, pain on affected area; tightness, tenderness, pain on affected area; This is a spontaneous report from a contactable consumer (patient). A non-pregnant 43-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EN6204), via an unspecified route of administration at the age of 43 years old, administered in arm right on 17Mar2021 19:45 at single dose for covid-19 immunisation. Medical history included diabetes, Hashimoto's, PCOS (Polycystic ovarian syndrome), allergies to medications, food, or other products: contrast dye. The patient's concomitant medications were not reported, the patient had received medications within 2 weeks of vaccination, but the patient did not provide the specified drug. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Thursday morning, 18Mar2021 07:00, after vaccine, pain and redness was present in the lower left calf. This progressed to a large red, hot, painful patch on the inner left lower leg below the calf muscle. This has progressed over the past eight days and the patient had gone to Urgent Care (Sat 20Mar2021) where they were concerned about a clot and sent the patient to the ER. An ultrasound in Mar2021 confirmed there was no clot, but the Dr. did not know what the issue was. The doctor started the patient on an antibiotic. This still progressed and 25Mar2021 it spread bilaterally and could not walk on her left foot. Dr. believed it to be a vascular issue with how it presented at her office 26Mar2021 and was closely monitoring the situation. Left lower leg and foot bluer than right, redness, tightness, tenderness, pain on affected area. Subsides at various points during the day, but always returns at night. The patient was told to keep elevated, try Benadryl, and Advil and keep doctor informed to determine referral vasc Dr. The outcome of the events was not recovered. Date of start of events was reported 18Mar2021 07:00. Events resulted in Doctor or

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1182262	4/8/2021	IN	66	F	1/19/2021	4/2/2021	other healthcare professional office/clinic visit and Emergency room/department or urgent care. Case was reported as non-serious by reporter: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19.
							Diagnosed with a dvt blood clot in my left leg on 04/02/2021. On eliquis and warfarin.

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1182734	4/8/2021	NY	81	F	3/9/2021	3/9/2021	break in rash/rash in mouth and throat; sore throat; dizzy; weak; felt like sleeping all the time; pain in her arm; blood clot in right leg; couldn't walk; veins are swollen; right knee got swollen; ear ache; felt like burning/ sore in her mouth like she was burned; sore in her mouth like she was burned; nausea; headache; slight fever; This is a spontaneous report from a contactable consumer (patient). An 81-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration in right arm on 09Mar2021 (Lot Number: EL9266) at single dose for covid-19 immunization. Medical history included arthritis, respiratory issues, allergies, Eczema of the nipples and breast, arthroscopic surgeries, she lost her voice. Caller stated she exercised everyday, she did yoga. Caller reported the last 2 years she hadn't been able to climb the mountain on the stairs. Caller states she didn't catch a cold, she was fine, she was very active. She was good except arthritic conditions, she has had arthroscopic surgeries, that was a side effect of that. Caller reporting she was a first responder and had some respiratory issues. Caller stated she had some allergies, if with dust or smoke, her throat constricts, it was just small, like her throat. She cannot be around that. She got once in a while, when she got in a rush. Caller stated before the vaccine, she had eczema in her nipples, on her breast. Caller stated she never got sick, besides the rash she got once in a while. Caller states but she was very healthy otherwise, no medication, no smoking, no drinking. Caller stated she was from 9/11, this was what happened with her voice once in a while, she lost her voice. Caller stated she had had some respiratory issues and allergies and so on. Caller stated she was here for 56 years and her mother died of old age so she was not sure. There were no concomitant medications. The patient previously took advil. Caller stated she used to take Advil when she went to the gym and had problems but she hasn't taken Advil for a while. She didn't take meds. Caller stated she didn't drink or smoke because what it did was it gave you a release. Caller stated she was not taking none, she was pushing through and hoping it will heal itself. The patient experienced blood clot in right leg on 26Mar2021, break in rash on an unspecified date, headache on 09Mar2021, slight fever on 09Mar2021, veins are swollen on 12Mar2021, right

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knee got swollen on 12Mar2021, sore throat on an unspecified date, ear ache on 10Mar2021, nausea on 09Mar2021, rash in mouth and throat on an unspecified date, felt like burning/ sore in her mouth like she was burned on 10Mar2021, sore in her mouth like she was burned on 10Mar2021, dizzy on an unspecified date, weak on an unspecified date, felt like sleeping all the time on an unspecified date, couldn't walk on 12Mar2021, pain in her arm on an unspecified date. Was a first responder, sometimes break in rash once in a while. Got Pfizer 1st vaccine 09Mar, was scared to have difficulty breathing however had headache, slight fever, right knee and veins were swollen, sore throat, ear ache, nausea, rash in mouth and throat also felt like burning also was dizzy and weak and felt like sleeping all the time. Caller stated she was told by her doctor to take the shot on 09Mar2021. Caller stated she had headache, slight fever, then her head was ok the fever was gone but the headache persisted as of today. Caller stated she still had headache and ear ache and her knee got swollen, her right knee. Caller stated for a few days she couldn't walk. Caller reported she has arthritic conditions in knees, she exercises everyday and no problem, but she couldn't walk for a few days. Caller states now she is able to walk on something, but the veins in the knee were still there and she didn't know. Caller stated she was due for second next on Tuesday and she was wondering what to do. Caller stated she was honestly worried about this reaction after the first shot. Caller stated she was told the 2nd had a worse reaction, so she was really weary and worried. Caller stated she only slept 5 hours at night, but now she wanted to sleep all the time. Caller stated she had such a headache and earache. Caller stated it made her nauseous, like in a sea or something. She stated she didn't know how to explain. She didn't vomit like when you were nauseous, it wasn't that feeling. Caller stated it was just lingering like when you were in the ocean. Caller reported headache has gotten better. It has gotten worse and then gotten better. Caller stated the earache was so painful and was still there. Caller reported she got it during the day and when she lied down, but the severity had subsided. Caller stated she didn't measure fever. She wanted to say after that, her mouth was sore after fever from the heat or from the vaccination. Caller stated her mouth was still today, still sensitive. Caller reported it

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was like her throat and her mouth was so sore like a burn. Caller reported her headache was mostly on the left side, but went to the right side too. Caller reported she could feel it in her eye, it hurt and her ear hurt. Caller reported her sore throat, the upper part, was still sensitive. Caller stated she couldn't swallow, but it was clear, her mouth was clear, only the upper top she would say. Caller stated it's 99% gone, its healing. Nauseous, like in a sea, its not like she has it all day long- nauseous- maybe once a day, nothing severely like what she had for a few things. The patient had a pain in her arm and she had that symptom one night and the following day she had nothing. Her arm was cooperative. Since she had been diagnosed with a blood clot. She saw her doctor on Friday and was recommended that she took some medications. She continued to have headache which she reported, though not as bad. She also reported that she had a sore mouth and earache. She was still fighting symptoms and didn't know what to do with the blood clot. She was scared to take the blood thinner Eliquis and that she will have side effects that it will do her harm she felt Eliquis will do her harm if she received the second dose of the vaccine or takes Eliquis. She was supposed to 20mg daily which she felt will kill her given her body was not healed from receiving the first dose of the Covid-19 vaccine. There was no prior vaccinations within 4 weeks. She was prescribed Eliquis Film-coated tablet (Lot Number: ABN4449S, Expiry date: Feb2023) 20mg daily for blood clot but had not started because she felt it will kill her was scared to take the second dose of the vaccine. The patient underwent lab tests and procedures which included Sonogram: blood clot in right on 26Mar2021. Therapeutic measures were taken as a result of blood clot in right leg. There was Physician Office Visit for all events. The outcome of the event blood clot in right leg, veins are swollen, right knee got swollen, couldn't walk was not recovered, of event slight fever was recovered on 10Mar2021, pain in her arm was recovered, of event ear ache, nausea, felt like burning/ sore in her mouth like she was burned, sore in her mouth like she was burned was recovering, of other events was unknown.



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1182760	4/8/2021			M	3/10/2021	3/1/2021	they did a culture and do not know if he has a kidney infection or urinary infection.; they did a culture and do not know if he has a kidney infection or urinary infection.; He stated running a fever yesterday (100.3 degrees last night); he has a lot of blood in his urine; he had a sore arm for a couple of hours; This is a spontaneous report from a contactable consumer non health care professional via Medical Information team. A patient of 63-year male received of (BNT162B2) (solution for injection/Lot/Batch number not provided, via unspecified route of administration on 10Mar2021 at a single dose of COVID-19 immunization. The patient's relevant medical history included kidney stones, he is on blood thinners because in 2019 he had blood clots in his lungs and was diagnosed with a pulmonary embolism and thrombosis. Laboratory data included body temperature( fever) 100 degrees centigrade, Concomitant medications were not provided. It was reported that the patient had taken covid vaccine, for first shot the patient had experienced a sore arm for a couple of hours that night but no other issues. He took Tylenol after the shot that day and evening, running a fever yesterday (100.3 degrees last night), lot of blood in his urine, He started antibiotics, Macrobid. He is having some difficulty taking it so they gave another prescription, Augmentin, and he is going to call today to see if he should start taking this and stop taking the Macrobid. He is scheduled for his second dose tomorrow on 31Mar2021. He has a history of kidney stones and is not sure if that is what this is because he has a lot of blood in his urine. The only day he knows they give the vaccines is on Wednesday so if he waits he may have to wait a week. He stated he feels a little better at this moment since he has been awake since 7:00 this morning. He asked if he is still able to get his second dose tomorrow while he has a fever and patient stated some people say they have a rough time on the second shot and these are relatively young, healthy people, they did a culture and do not know if he has a kidney infection or urinary infection. For the kidney infection event was medically significant, Outcome of the events was unknown and He stated running a fever yesterday (100.3 degrees last night) was not recovered. Lot/Batch number has been requested. No further information was reported.

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1177170	4/7/2021	NC	51	F	4/1/2021	4/2/2021	6 days of heavy periods with large clots up to this morning. First time after several years of only light spotting (IUD/premenopausal). Lighter menstruation today.
1176319	4/7/2021	FL	69	M	3/24/2021	3/25/2021	Started with stomach pain that continued to increase. Went to E.R. After various test found a blood clot near stomach in vein.
1176466	4/7/2021	MN	53	M			PE; DVT; This spontaneous report received from a physician via a company representative concerned a 53 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included family history of DVT, and family history of PE. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On unspecified date in 2021, the patient experienced PE (pulmonary embolism) and DVT (deep vein thrombosis). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the PE and DVT was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210332653-Covid-19 Vaccine AD26.COV2.S-PE and DVT. This event(s) is considered not related. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY

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1176693	4/7/2021	WA	43	F	3/14/2021	3/24/2021	Adverse effect of vaccine, initial encounter (Primary). Word finding difficulty. Decreased sensation. Comments: left side of face, Neuro exam today reassuring however it would be difficult to fully "rule out" any more serious adverse reactions without intracranial imaging. Offered head CT but patient declined. Anxiety, To help mitigate anxiety when due for second vaccine. Lorazepam (ATIVAN) 1 mg tablet; Take 0.5-1 tablets by mouth every 8 hours as needed for Anxiety. Dispense: 1 tablet; Refill: 0. Patient given the following instructions and/or handouts: If your symptoms continue and you change your mind about wanting to proceed with a brain scan to rule out blood clots. Return if symptoms worsen or fail to improve. Total time spent on patient's care today including pre-visit work, face to face time, education or counseling, documentation etc. was 30 minutes.
1176884	4/7/2021	GA	69	F	2/1/2021	3/1/2021	Blood clot left arm.
1177000	4/7/2021	MI	49	F	3/12/2021	3/17/2021	Doctor determined superficial thrombophlebitis on left hand where IV 4 weeks before was taken out while at ER for kidney stone 2/18/2021. Hand was somewhat sore for weeks before vaccine. J & J vaccine on 3/12/2021. 5 days later 5/17/2021 left hand very painful and huge blood clot. Went to doctor and diagnosed blood clot and prescribed clindamycin 300 mg 3X a day for 7 days. It wasn't until the 7th day the pain was gone and swelling of the vein back to normal.
1177218	4/7/2021	TN	57	M	3/5/2021	4/6/2021	Right lower extremity deep venous thrombosis in popliteal and femoral veins, swollen discolored leg
1177158	4/7/2021	PA	67	F	3/13/2021	3/27/2021	2 weeks after initial vaccine, patient developed atypical venous thrombosis
1176103	4/7/2021	CA	25	F	12/23/2020	3/1/2021	Pelvic blood clot in right common iliac artery

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1175158	4/7/2021	TX	68	M	3/16/2021	3/1/2021	Shortness of breath; headache; Felt like at least 100 degree temp/slight fever; lack of appetite/completely lost appetite/No appetite; Body aches; Joint aches; Tiredness; Delirious; Chills; cold sweats; felt weak; flu-like symptoms; feel almost as miserable; can't taste food as well/lack of taste; diarrhea; This is a spontaneous report from a contactable consumer. A 68-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot and expiration date unknown), via an unspecified route of administration, administered in the right arm on 16Mar2021 at 10:20 as a single dose for covid-19 immunization. The patient's medical history included deep vein thrombosis (DVT) in from 2017 to 2017. Patient always had swelling on the leg where he got the blood clot. The patient's veins in his leg were damaged and the doctor takes care of his legs. He has very poor blood flow in the affected leg, that all the fluids and waters, the heart was having a hard time pumping it back up. He uses compression stockings, physical therapy, and that he raises his legs in the evening. The caller mentioned that vessels in his affected leg are damaged for good. Patient was in a treatment facility for alcoholism. Patient reported that he hasn't had a drink in 2-3 years but still has to go to treatment, caller was released from the treatment facility because he got sick with COVID. Patient had Covid-19 on 15Dec2020 to 08Jan2021 (the side effects experienced after the first dose of the Covid-19 vaccine weren't as severe, that the real virus is pretty bad). Concomitant medications included blood thinners (unspecified) and a couple of other medications. Patient reported that he skipped some doses of his regular medications while he was feeling poorly. On 16Mar2021, the patient experienced delirious, chills, tiredness, body aches, joint aches, cold sweats, felt weak and flu-like symptoms. On 17Mar2021 patient had headache, felt like at least 100 degree temp/slight fever, lack of appetite/completely lost appetite/no appetite; can't taste food as well/lack of taste and diarrhea in Mar2021; and shortness of breath on an unspecified date. It was further reported that the adverse events that he was experiencing were as bad as his experience with COVID-19 except he could breathe. Gradually over the next 24 hours and the night of 16Mar2021, he started getting chills and fevers, getting

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very tired, and experiencing flu-like symptoms. He had fatigue, cold sweats, slight fever, headache, diarrhea, and the lack of taste or appetite. He said that his adverse events started 10 hours after getting vaccinated. For the next few days, he felt weak and had to exert a big effort to get out of bed. On the second day of vaccination, he developed diarrhea and completely lost appetite. Patient also reported that he experienced body aches. He experienced body aches and joint aches. Patient had no appetite, that he still hasn't eaten much the last few days but that he has started eating today. He described his experience to be severe but not severe enough for him to be hospitalized. He said that he missed 3 days of work because of his symptoms. It was on the 6th day since he got vaccinated and everything has subsided and he was getting his energy back but he is still recovering. Patient called his physician and the nurse he spoke with stated that the first 3 days following the Covid-19 vaccine the side effects could be very severe and that the side effects could continue over next 3 days. Caller reported that he is on the 6th day now since he got vaccinated and everything has subsided as he was starting to feel better, he was coming around, but it was not 100 percent. So patient was inquiring about the second dose of the product. The patient further mentioned that the side effects following the first dose of the Covid-19 vaccine caused him to feel almost as miserable as he did when he actually had Covid. Patient also stated that he was close to calling ambulance the night of 16Mar2021 when he began experiencing AEs. The patient was delirious, he wasn't sure what was going on, that he was trying to grab his phone and text but couldn't use his phone. Patient was wandering around his room. Patient would get cold sweats at night. Caller reported on the morning of 17Mar2021, he woke up soaked in sweat. Patient called his doctor's office that he just needs guidance on whether or not to get the second dose. The headache went away gradually and was gone probably late Saturday, 20Mar2021 or Sunday, 21Mar2021. for the event tiredness, patient stated that he's still trying to regain his full strength but, 22Mar2021 was the first day that he has been able to sit up and do things and that he hasn't had to lay down all day long. Felt like at least 100 temp, patient reported that he doesn't have a thermostat. He reported that he felt feverish at least the first 3 days

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following the first dose of the Covid-19 vaccine on 16Mar2021. Body aches/joint aches, reported that the body aches and joint aches have almost completely subsided. Patient stated that he doesn't really feel them, that he is 68 and at that age you're going to feel some aches regardless if you're sick or not. Caller reported that he can barely talk, that he still doesn't feel completely right. No appetite: caller reported that when his symptoms were severe that he did not want to eat. Caller reported that he did hydrate. The decreased appetite has improved but that's still not quite what it was. Caller reported that he was trying to eat to improve his energy level. Can't taste food as well, mentioned as that everything tastes the same, whether he eats a grape or a banana. Caller reported that he noticed that he wasn't able to taste food as well the third day after his symptoms began, but states it was improving. Patient reported that the diarrhea began on 18Mar2021 or 19Mar2021 and that he can't hold it too long. He ate cereal in the morning and immediately had to use the bathroom and it's getting a little better. Patient reported that he took 1000 mg of Tylenol for 2 to 3 days in a row. He took two 500 mg tablets three times because of headache and chills. Patient stated that the only difference between the side effects he experienced following his first dose of the Covid-19 vaccine and having the Covid-19 virus was that he doesn't have any problems struggling to catch his breath. The patient recovered from the events chills on 20Mar2021, headache and felt like at least 100 degree temp/slight fever in Mar2021; recovering from tiredness, body aches, joint aches, can't taste food as well/lack of taste, lack of appetite/completely lost appetite/No appetite and diarrhea; not recovered from shortness of breath; and unknown outcome for all the other events.

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1177443	4/7/2021	OH	51	M	4/2/2021	4/6/2021	Currently, developed 3 blood clots in right arm 4 days after receiving the vaccination. First was noticed on the morning of April 6, the second in the evening of April 6, and the third was noticed on the morning of April 7. First one has appearance of cellulitis located on the forearm. Doctor issued treatment for cellulitis on April 6. Reddish/purple skin colored with grey edges in a circle. Second clot is below the skin with slight bulge closer to the elbow than the first. The third indication is in the upper arm above the elbow on inside of arm. Appearance marked by 2 curved lines similar to varicose veins just below where the clot is bulging the skin. No discoloration of the 2nd and 3rd indications of clot.
1177143	4/7/2021	RI	68	M	2/19/2021	3/31/2021	About a month after my second Pfizer inoculation I awoke one morning with almost no vision in my right eye. I was diagnosed April 1 with a blood clot in my retina that has changed my vision from 20/30 in that eye to 20/125. My left eye remains 20/20. I'm in excellent health and never had any kind of clot or eye issue. The traditional causes of Retinal Vein Occlusion don't pertain to me - no heart trouble, high blood pressure or diabetes. I'm thin and physically active, never smoked, drank or used drugs.
1175795	4/7/2021	WI	55	M	3/13/2021	3/28/2021	Patient called 4/7 to advise us of an outpatient treatment for a blood clot on 4/4/21. In hindsight, he is questioning whether there is an association between his COVID vaccine series and the clot. He received his 1st dose (reported above) on 3/13/21. Symptoms (gradually progressive redness, irritation, swelling) began approximately 3/28/21, but were not recognized as a blood clot at the time. He received his second dose on 4/3/21 (Lot EW0150) in the right deltoid muscle. He reported to the ED for treatment on 4/4/21 with continued worsening of symptoms. So far, his treatment is going well with no lasting deficits and continuing followup treatment.

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1175716	4/7/2021	MN	72	F	3/17/2021	3/19/2021	1st symptom 3/19/21 at 5:30 am - Weakness in fingers on right hand. Called nurse line, they recommended calling EMT. EMT said no stroke but could go to urgent care for further evaluation. Urgent care recommended ER. ER recommended appointment with Neurology 2nd symptom 3/21/21 slight droop on right side of mouth. Went to ER in Hospital. MRI revealed clot. Additional ultra sound of heart and carotid arteries clear. Final diagnosis: Subacute CVA-Lt Centrum Semiovale w/ right facial droop and right hand deficits. Recommendations: Nuerology evaluation, Outpatient PT/OT for right hand deficits. Hospitalization: 1 day Hospital Name: Unnamed City: Unnamed State: Unnamed
1175441	4/7/2021	TX	72	F	3/5/2021	3/17/2021	Pulmonary Embolism resulted in emergency care and 4 days in hospital with blood thinners and eventually sent home with having to give self injections and oral blood thinners. All blood tests do not show that it came from a DVT or or that it was inherited therefore, can not show where the clot came from. It is unknown or considered "Unprovoked" due to unknown cause. This causes a concern for an adverse reaction from the vaccine



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1175195	4/7/2021		20	F	1/19/2021		experiencing passing a ton of clots; I washed my face, it got extremely red; This is a spontaneous report from a contactable consumer (patient). A 20-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported) at the age of 20-year-old, via an unspecified route of administration, administered in the left arm on 19Jan2021 13:00 as single dose for COVID-19 immunisation. The patient was not pregnant at the time of vaccination. Medical history included lupus and idiopathic thrombocytopenic purpura (ITP). Concomitant medications included mycophenolate mofetil (CELLCEPT), esomeprazole magnesium (NEXIUM), medroxyprogesterone acetate (DEPOPROVERA), and propranolol; all taken for an unspecified indication, start and stop date were not reported. The patient has known allergies to rituximab and amoxicillin. As a woman, the patient was having a lot of blood clots being passed. The patient doesn't get a period because of depo, but for some reason, she was experiencing passing a ton of clots on an unspecified date. Also, after the first dose, when she washed her face, it got extremely red on an unspecified date in 2021 (She did the same in the days before and that didn't happen). The patient underwent lab tests and procedures which included Covid test: negative on an unspecified date. The outcome of the events was unknown. No treatment was received for the events. The patient received the second dose of BNT162B2 on 11Feb2021 for COVID-19 immunisation administered at the left arm. Information on the lot/batch number has been requested.
1177465	4/7/2021	SC	79	F	1/18/2021	2/8/2021	The patient started to feel swelling, redness on the interior of upper right leg. It was a swollen vein. She went to the physician on 2-15-2021. She was diagnosed with having a blood clot and had to have it removed. She is wearing compression stockings now 24/7.

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1175179	4/7/2021	NH	73	M	2/10/2021	3/11/2021	This is a spontaneous report from a contactable consumer. A 73-year-old male patient received his second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN9581), via an unspecified route of administration in left arm on 10Feb2021 (Batch/Lot Number: EN9581) as a single dose for COVID-19 immunisation. Medical history included hypertension, prolactinoma, hyper cholesterol, and allergies to penicillin. Concomitant medications received within 2 weeks of vaccination included verapamil, lisinopril, atorvastatin, and omeprazole. The patient previously received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3248) in the left arm on 20Jan2021 01:00 PM. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. He was not diagnosed with COVID-19 prior to vaccination. The patient experienced stroke due to blood clot at superior sagittal sinus of brain on 11Mar2021 13:00. The events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, and Hospitalization for 6 days. Treatment received for the adverse event included Enoxaparin injections and warfarin. Outcome of events was not recovered. The patient had not been tested for COVID-19 since the vaccination.

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1174018	4/7/2021	MD	77	F	3/8/2021	3/1/2021	<p>Couldn't breathe/shortness of breath; Back pain; blood pressure was high; was just sick; This is a spontaneous report from a contactable consumer. A 77-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in Arm Right on 08Mar2021 (at the age of 77-years-old) (Batch/Lot Number: EN6199; Expiration Date: 30Jun2021) as SINGLE DOSE for covid-19 immunisation. Medical history included ongoing blood pressure abnormal, cancer in her left lung, ongoing blood cholesterol abnormal, ongoing gastric disorder, ongoing diverticulitis Verbatim: Virticulitis. Concomitant medication included acetylsalicylic acid (ASPIRIN 81) taken for blood pressure abnormal; atorvastatin (ATORVASTATIN) taken for blood cholesterol; hydralazine taken for blood pressure abnormal; lisinopril (LISINOPRIL) taken for blood pressure abnormal from Feb2021 and ongoing; pantoprazole taken for gastric disorder from 2020 and ongoing. The patient had her first shot and after that, a week after she experienced some adverse events like back pain and sickness. After the patient started experiencing back pain, and got progressively worse, she was having problem breathing/Shortness of breath was reported. The patient was ambulated and mentioned she was brought to the hospital/stayed with her doctors overnight due to the experiences she had. She had blood work done and based on the results, they suspected a blood clot on her lung and her CT scan did show that she did not have a clot in her lung. It was also reported that they did blood test and urine test and that all that EKG because the patient had her blood pressure gone considerably high and in the blood test. She was prescribed to take Tylenol every 8 hours and a to put a back patch on the left side of her back where she is experiencing pain. Caller did not provide if she was admitted to the hospital, or if she just stayed in the ER overnight for observation. Now, she wants to know if she will still proceed with her 2nd shot on 29Mar2021. The patient underwent lab tests and procedures which included abdomen scan: normal, no indication of blood clot on 17Mar2021, angiogram: normal, no indication of blood clot on 17Mar2021, blood pressure measurement: high, blood test: a blood clot on her lung on Mar2021, computerised tomogram: normal,</p>

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							no indication of blood clot on 17Mar2021, covid-19: negative on 17Mar2021, x-ray of pelvis and hip: normal, no indication of blood clot on 17Mar2021. Therapeutic measures were taken as a result of back pain (back pain). The seriousness of the events back pain and Couldn't breathe/shortness of breath was hospitalization. The outcome of the events back pain was recovering. The outcome of the other events was unknown.
1174347	4/7/2021	AZ	66	F	3/22/2021	3/22/2021	She had a stroke on 3/28/2021 due to a blood clot in her brain; She had a stroke on 3/28/2021 due to a blood clot in her brain; Administration_date=08/03/2021 number=1/administration_date=22/03/2021 number=2; Administration_date=08/03/2021 number=1/administration_date=22/03/2021 number=2; This is a spontaneous report from a contactable consumer reporting for herself. A 66-years-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: Unknown), via an unspecified route of administration, administered in Arm Right on 22Mar2021 17:45 (vaccinated at the age of 66 years old) as single dose for covid-19 immunisation. Patient received the first dose on 08Mar2021. Medical history included diabetes; obesity; high blood pressure, iodine allergy. The patient's concomitant medications were not reported. The patient experienced she had a stroke due to a blood clot in her brain on 28Mar2021 18:30, The patient was hospitalized for she had a stroke due to a blood clot in her brain (cerebrovascular accident) for 2 days. Patient visited Emergency room/department or urgent care for events a stroke due to a blood clot in her brain and received treatment. Outcome of event a stroke due to a blood clot in her brain was not recovered. Information about lot/batch number requested.

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1174276	4/7/2021		39	M	3/24/2021	3/1/2021	fatigue/so tired, he can barely can move; silver dollar rash at the injection site; his whole calf was constricted, felt like the muscle was separating inside, compared it to the same feeling of DVT; he is limping today; feeling pain in arm; left arm hurts so bad that he can hardly move it; fever; This is a spontaneous report from a Pfizer-sponsored program, received from a contactable consumer (patient, self-reported). A 39-years-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number: ER8730; Expiration date was not reported), via an unspecified route of administration, administered in Arm Left on 24Mar2021 17:00 as SINGLE DOSE for COVID-19 immunization. Medical history included DVT (deep venous thrombosis) 3 years ago in his right calf/DVT of calf from 2019 to an unknown date (Right Calf; DVTs in his calf and had treatment with Eliquis and got off of that, had an ultrasound to check that it was gone); broke his ankle on an unspecified date in 2019; being in a tourniquet too long (DVT (deep venous thrombosis) 3 years ago in his right calf, from being in a tourniquet too long, was in an operation, was treated with ultrasound); normally when something hurts that bad, he has a softball size bruise on his arm, he has lived and had bruises like that before; Operation (DVT (deep venous thrombosis) 3 years ago in his right calf, from being in a tourniquet too long, was in an operation, was treated with ultrasound/rebreak his ankle and put rods and screws in). The patient's concomitant medications were not reported. It was reported that feeling pain in arm on 24Mar2021, fatigue on 25Mar2021, fever on an unknown date in Mar2021, silver dollar rash at the injection site on 25Mar2021. He reported that he had DVT (deep venous thrombosis) 3 years ago in his right calf, from being in a tourniquet too long, was in an operation, was treated with ultrasound. This morning (25Mar2021), his whole calf was constricted, felt like the muscle was separating inside, compared it to the same feeling of DVT that he had those years back. Patient reported that he thought he might be having allergic reaction. He was so tired, he can barely can move, he had a silver dollar size rash on his arm and his arm hurts so bad that he can hardly move it. He stated that this was weird and he has it every now and then, but it is really bad today. He states that 3 years ago he had DVTs in his

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calf and had treatment with Eliquis and got off of that, had an ultrasound to check that it was gone. He stated that his leg and it hurts so bad. It felt like has phantom clots in the same the muscles are separating again, like the muscle is trying to tear itself in half. Caller asks, the vaccine won't cause blood clots, will it?. Described about Tired, he couldn't get out of bed and he had been laying there for 3 hours this morning. Stated he ate dinner and went to bed. Stated that he works a full time job doing HVAC and goes to school full time so he could've been tired last night and not noticed it, because he is always tired, but today was different. Described about Left Arm Hurts, that it felt like when you play dead arm, that is when a person socks another kid in a certain spot, felt like he was hit with a bat in that spot. Hurt bad and he was surprised how bad it hurt. When he got the injection, he felt nothing. Now he feels like he fell down on his arm. Within a few hours he noticed it and thought it would probably go away. States that he was checking to see if he had a big ole bruise, and that when he noticed the rash. He stated that normally when something hurts that bad, he has a softball size bruise on his arm. States that he has lived an had bruises like that before. Described about Phantom DVT Pain: He stated that his leg started twitching and woke him up. he called it phan-tom DVT, it felt like DVT, like the muscles have memory and start contracting and get so tight like they are tearing each other apart again. Stated that he is limping today (25Mar2021). He stated that it was contracted for 10 minutes and his whole calf was tight. It was his right leg, the same leg as he had 3 blood clots in. He stated that he broke his ankle in 2019 and they left the tourniquet on too long and they had to rebreak his ankle and put rods and screws in and he developed DVTs in his right calf. Stated that it was treated and he had ultrasounds at 3 months, 6 months, and a year and it is all gone and he has had no symptoms since. He stated that it felt like he has 3 blood clots back hardcore with a vengeance. Stated that he had no edema in his foot, it is not full or swelling or trust him he would be running, well not running, but he would be going to the hospital. Patient was not received treatment for the events. Seriousness of the events was reported as Non-serious. Outcome of the events Fever and limping was reported as unknown and outcome of all other events was not recovered.

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1174174	4/7/2021			U	3/6/2021		<p>I broke a pimple and came liquid after taking the pimple out, it came a little thing like clear and then it came like blood; it was like a clot; broke a pimple; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration on 06Mar2021 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. Consumer stated, "I am kind of concerned because I was showering myself like 30 minutes ago, well I was cleaning my face and well you like night routine and I broke a pimple that I didn't have and came liquid after taking the pimple out, it came a little thing like clear and then it came like blood not too much for sure, then I realized that the blood that came out wasn't liquid, it was like a clot. I cleaned it with a t-shirt and I was able like to move it. So I am kind of concerned because I got my first dosage of the Pfizer vaccine on March the 6th, I am about to get my second dosage this Saturday and as you know and everyone should know right now what's going on with this (name) and (name) vaccine and then what everyone is talking about, it's impossible to not be concerned about the side effects." The event clot blood was assessed as serious (medically significant). The outcome of the events was unknown. Information on lot/batch number has been requested.</p>

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1174114	4/7/2021			F			<p>blood clot; This is a spontaneous report from a contactable consumer(patient). A female patient of an unspecified age received BNT162B,(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. prednisone (PREDNISONE), route of administration, start and stop date, batch/lot number and dose were not reported for allergies Medical history included weakened immune systems and ongoing allergies. It was reported that patient wants to know if there is any reported interactions between the use of prednisone and receiving the COVID-19 vaccine manufactured by Pfizer. She was informed that the vaccine might not work as well for patients taking prednisone. The patient has been on Prednisone for 10 years, caller heard that when the patient has been on Prednisone for that long the vaccine does not work. The patient is taking Prednisone to treat some allergies. Patient also has blood clots and wants to know if patients with a history of allergies should take the COVID-19 vaccine manufactured by Pfizer, and how could she know if she would have an allergic reaction towards the vaccine. The action taken in response to the event for Prednisone was unknown. The outcome of the event was unknown. Information on the batch/lot number has been requested.</p>



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1173987	4/7/2021	OH	69	F	3/18/2021	3/19/2021	<p>If she laid her arm on it, it was painful on the left side where she got the injection between her left breast and axilla; couldn't go back to sleep; very tired; weak; She had the lump and that was in the lymph node; painful if she put her arm down/painful on the left side/extended underneath the axilla/looked like it was connected to the breast; irregular heart beats; painful if she put her arm down/painful on the left side/extended underneath the axilla/looked like it was connected to the breast; painful if she put her arm down/painful on the left side/extended underneath the axilla/looked like it was connected to the breast; baseball sized lump. It was hard/where she got the injection; It looked like it was connected to the breast because it was so huge.; Fever blister; heart beating so out of rhythm; This is a spontaneous report from a contactable nurse (patient). A 69-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EN6207), via an unspecified route of administration, administered in arm left on 18Mar2021 at 12:20 (at the age of 69-years-old) as a single dose for COVID-19 immunisation. Medical history included ongoing coeliac disease; hypothyroidism, is diabetic and has irregular heartbeat from an unknown date and unknown if ongoing. Concomitant medications included levothyroxine taken for hypothyroidism; hydrochlorothiazide, olmesartan medoxomil (OLMESARTAN/HCTZ MYLAN) taken for blood pressure measurement; metformin, glipizide and pioglitazone hcl taken for diabetes mellitus; acetylsalicylic acid (ASPIRIN 81) taken for thrombosis; metoprolol taken for heart rate irregular, cyanocobalamin (VIT B12) taken for an unspecified indication, all from an unspecified start date and ongoing; famotidine, rosuvastatin, vitamin d2, vitamin d3 and potassium, all taken for an unspecified indication, start and stop date were not reported. The patient previously received the first dose of BNT162B2 (lot number: EN6198, NDC: 59267-1000-1, expiry: unknown) on 27Feb2021 at 1:40PM for COVID-19 immunisation. The patient got her last shot on 18Mar2021. The first day was fine. She woke up the next morning at three or four with her heart beating so out of rhythm it was crazy. It took almost the whole day. She called her cardiologist and couldn't get into them and she didn't want to go to the ER. She didn't have a way to</p>

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prove any of that. She also got a baseball sized lump. It was hard. If she laid her arm on it, it was painful on the left side where she got the injection between her left breast and axilla. It extended underneath the axilla. She wasn't able to get in with the cardiologist because she waited to late in the day. She couldn't get off the couch that day because her heart was so out of rhythm. She was very tired and wanted to just lay down. She hates going to the hospital. She doesn't want to go to the hospital. She has a history of irregular heartbeats. She should have gone in and had an EKG. She has pictures of the lump if those are needed. HCP information: Her doctor had said if she had anything like any abnormal heart beats to come in and get an EKG. She also had a fever blister on 22Mar2021 that she hasn't had in years and was asking if this influences her immune system. She had the lump and that was in the lymph node and now a fever blister on the top lip. Heart beating so out of rhythm: it lasted all that day. She took a nap after she talked to the doctor's office and slept for several hours. When she woke up it was kind of back in rhythm, but it was going in and out. It wasn't as frequent as it was prior to nap. Prior to the nap it was almost continuous. It slowed down a lot on the 19Mar2021 and was gone by 20Mar2021. Outcome of event: She has PAC's and PVC's anyway. That is why she follows up with the cardiologist. They haven't been so out of rhythm as they were after the vaccine. She couldn't go back to sleep. She still has them occasionally and that is kind of normal for her. She was weak and tired. Baseball sized lump: it has gone down. She took pictures to show her friends who were all getting the shots. It is gone now. It might have started on 20Mar2021. She woke up with the lump on Saturday. She has recovered completely. Her daughter said she needed to get it checked out. Reporter had heard of a lump on the breast was a side effect. It looked like it was connected to the breast because it was so huge. Seriousness criteria: It was irritating because it was so big. It was painful if she put her arm down. It was like her breast were engorged. Causality: Heart beating so out of rhythm: she hasn't had it that bad, so she thinks it was. She had it a long time ago, maybe once before, but it never lasted that long or took her down like that. She is not the only one that has had the complaint of irregular heartbeats. She put on social media what she

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experienced and how weak she got. Several friends said that happened to them as well. She doesn't know their history. Reporter declined to do a report on her friends. That was another reason she didn't go to the hospital. She thought it was a normal side effect. She thinks she found on her paperwork about the lump in the lymph nodes. The patient underwent lab tests and procedures which included electrocardiogram: unknown results and heart rate: irregular on an unspecified date. The outcome of the event fever blister was not recovered, while of the rest was unknown. Reporter seriousness for heart beating so out of rhythm was reported as disabling.;

Sender's Comments: Based on the information currently available and the plausible temporal relationship, a possible contributory role of suspect product BNT162B2 to the reported events 'heart beating so out of rhythm ', 'baseball sized lump (where she got the injection/It looked like it was connected to the breast because it was so huge)' cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

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1175188	4/7/2021		68	M	3/5/2021	3/5/2021	extensive proximal right lower extremity deep vein thrombosis; This is a spontaneous report received from a contactable physician. A 68-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number not reported) via an unspecified route of administration, at the age of 68-year-old, on 05Mar2021, as SINGLE DOSE for covid-19 immunisation. Medical history included hypertension and chronic kidney disease. The patient's concomitant medications were not reported. The patient experienced extensive proximal right lower extremity deep vein thrombosis (medically significant) on 05Mar2021. Therapeutic measures taken as a result of extensive proximal right lower extremity deep vein thrombosis included anticoagulation agent. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination the patient was not diagnosed with COVID-19 and has not been tested for COVID-19. Outcome was recovering at the time of the report. Information about batch/lot number has been requested.

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1178464	4/7/2021	PA	40	F	1/25/2021	1/29/2021	I have always had relatively heavy periods due to my diagnosis of VonWillebrand's disease. Four days after receiving the vaccine, my cycle came on early and I had heavier bleeding than I have ever experienced with large clots. The bleeding slowed down, but lasted for an entire month. My cycle then returned to normal. It seemed very coincidental that this happened immediately following the vaccine, and was not normal for me at all. I recently read similar stories of other women reporting this, so while at the time it was concerning, I did not report it. I am a firm believer in science and thought this was possibly just a fluke, but felt that after reading many stories of women having a similar experience, that the responsible action is to report this, to ensure that all of the data is being studied, since the vaccine is so new. That being said, I only had mild side effects from the vaccine, and I am very grateful that I was able to receive the vaccine, as I have known quite a few people that have died from COVID. This bleeding for me was not dangerous at any time, and while I was a bit faint, the bleeding during the course of the month did slow down and this all resolved. Therefore, I would still get the vaccine again. I should note that after my second vaccine, I had a few days of spotting outside of my cycle, which resolved as well. I have had no issues since.

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1173932	4/7/2021	CA	71	M	3/10/2021	3/14/2021	Right Femoral DVT; Superficial Great Saphenous Vein Symptoms; This is a spontaneous report from a contactable physician. A 71-year-old male patient received bnt162b2 (Pfizer COVID 19 vaccine), dose 2 intramuscular on 10Mar2021 (Batch/Lot number was not reported) as single dose for COVID-19 immunisation. Medical history was not reported. The patient previously received sulfasalazine and experienced allergies. Received 1st dose of bnt162b2 (Pfizer COVID 19 vaccine) intramuscular on 12Feb2021 for COVID-19 immunisation. There were no concomitant medications. The patient experienced right femoral DVT (deep vein thrombosis) and superficial great saphenous vein symptoms on 14Mar2021, 4 days after #2 vaccination, with outcome of not recovered. Therapeutic measure taken as a result of events: Xarelto. Events resulted in doctor or other healthcare professional office/clinic visit. The patient was not diagnosed of COVID prior vaccination and has not been tested for COVID post vaccination. Information on the lot/ batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
1178589	4/7/2021	GA	44	F	4/5/2021	4/5/2021	Significant swelling at base of skull with severe headache starting 11 hrs after vaccination. Superficial swelling of vein on left forearm started 46 hrs after vaccination in left upper arm. This vein had a clot that proceeded to swell and burst causing significance pooling of blood with tracking on inside of L forearm. Left arm remains warm and throbbing.

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1177623	4/7/2021	WA	48	F	3/26/2021	4/4/2021	Woke up on 4/4 with a golf ball sized, raised welt at the injection site. It was hot and very red. The next day, it was even larger, by 4/7, it had completely gone away. Everyone thinks I should also mention that I was admitted to the hospital with chest pain, high BP/Pulse on 3/31, they did a D-Dimer on me and it was elevated, suggesting a clot has formed and is in the process of breaking down. I had a CT of my chest and no PE was found, but I had thickening of my left lobar pulmonary artery wall, further supporting the suggestion of a possible blood clot. After an echo stress test, I was discharged the next day on HTN meds. I was experiencing chest discomfort prior to my vaccine, but again, EVERYONE is telling me I need to report this, so I am. :)
1178463	4/7/2021	VT	38	F	4/6/2021	4/6/2021	Had a sudden bleeding from left nostril that took 30 minutes to to stop at 3:30 pm on 4/6/2021. On 4/7/2021 at 1:05 pm sudden bleeding from left nostril again took about 25 minutes to stop bleeding had a quarter sized blood clot come out of my mouth towards end of nose bleed. Do not typically get nose bleeds. Called dr told to report incidents and to report to Ed if gets worse or happens again.

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1178288	4/7/2021	NJ		M			he has thrombosis in leg; This is a spontaneous report received from a Pfizer sponsored program. A contactable consumer (patient himself) reported that a male patient of an unspecified age received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as a single dose for COVID-19 immunisation. Medical history included metastatic cancer in the lungs (he's taking chemotherapy) and heart problems from an unknown date. The patient's concomitant medications were not reported. The patient was due the next day for the 2nd dose of the Pfizer vaccine. He was asking if he can take his pre-scheduled medication, especially he's taking chemotherapy because he has metastatic cancer in the lungs. Due also to the nature of him having heart problems, he had thrombosis in leg and he's taking blood thinner since an unspecified date. He was asking if he should stop the medication or if he can take the blood thinner before the 2nd dose. Outcome of the event was unknown. Information on the lot/batch number has been requested.
1178287	4/7/2021	MA		M	3/6/2021	3/1/2021	blood became a clot; pimple; This is a spontaneous report received from a Pfizer sponsored program received from a contactable consumer (patient). A male patient of an unspecified age received bnt162b2 (BNT162B2 reported as Pfizer Covid-19 vaccine), dose 1 via an unspecified route of administration on 06Mar2021 (Batch/Lot number was not reported) as a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported that he received Pfizer Covid-19 vaccine first dose on 06Mar2021, and second dose will be on Saturday 27Mar2021. While showering, he broke his pimple on Mar2021 then tried to remove it using the tissue and the blood became a clot. The outcome of the events was unknown. Information on the lot/batch number has been requested.



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1178277	4/7/2021	CO	73	M	2/6/2021	2/15/2021	Deep vein thrombosis in the left calf; This is a spontaneous report received from a contactable consumer (patient). A 73-year-old male patient received the second single dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration, in left arm, on 06Feb2021 (Lot Number: EM9810), at the age of 73 years old, for COVID-19 immunisation. The patient had previously received the first single dose of BNT162b2 in the left arm on 16Jan2021 (lot number: EL8482). The patient had not received any other vaccines within 4 weeks prior to the BNT162b2 administration. Prior to vaccination, the patient had never been diagnosed with COVID-19. The patient's medical history included essential thrombocythaemia and benign prostatic hyperplasia. There were no allergies to report. Concomitant medications included hydroxyurea, simvastatin, mirtazapine, and acetylsalicylic acid (ASPIRIN). The patient stated developing deep vein thrombosis in the left calf on 15Feb2021, at 06:00 (10 days after 2nd shot), requiring a visit to ER. The patient was treated with enoxaparin (LOVENOX), followed by dabigatran etexilate (PRADAXA). Since the vaccination, the patient not been tested for COVID-19. The patient was recovering from the event. Follow-up Information has been requested.

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1178260	4/7/2021	PR	37	F	1/4/2021	2/2/2021	This spontaneous case was reported by a nurse (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (Venous thrombosis in her left leg/clot was in left leg) in a 37-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 011M20A and 011J20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included LEVOTHYROXINE SODIUM (SYNTHROID) and TOPIRAMATE (TOPAMAX) for an unknown indication. On 04-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 02-Feb-2021, the patient experienced TACHYCARDIA (Severe Tachycardia/ Still very tachycardia) and FEELING ABNORMAL (Felt a little weird). On 03-Feb-2021, the patient experienced DYSPNOEA (Difficulty breathing), FATIGUE (Could not get up), ASTHMA (Asthma) and ASTHENIA (Could not get up). On 04-Feb-2021, the patient experienced CONTUSION (Bruise on her right and left leg) and VACCINATION COMPLICATION (Had a reaction to the vaccine). On 01-Mar-2021, the patient experienced DEEP VEIN THROMBOSIS (Venous thrombosis in her left leg/clot was in left leg) (seriousness criterion medically significant). On an unknown date, the patient experienced HAEMOGLOBIN DECREASED (Hemoglobin decreased) and RED BLOOD CELL COUNT DECREASED (Red blood cells are low). At the time of the report, DEEP VEIN THROMBOSIS (Venous thrombosis in her left leg/clot was in left leg), TACHYCARDIA (Severe Tachycardia/ Still very tachycardia), DYSPNOEA (Difficulty breathing), FEELING ABNORMAL (Felt a little weird), FATIGUE (Could not get up), ASTHMA (Asthma), CONTUSION (Bruise on her right and left leg), ASTHENIA (Could not get up), VACCINATION COMPLICATION (Had a reaction to the vaccine), HAEMOGLOBIN DECREASED (Hemoglobin decreased) and RED BLOOD CELL COUNT DECREASED (Red blood cells are low) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In March 2021, Haemoglobin: low gram per litre (Low) LOW. In

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1178258	4/7/2021	FL		F	3/23/2021	3/23/2021	<p>March 2021, Red blood cell count: low cells per microlitre (Low) LOW. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment informations reported were Levalbuterol tartrate and Rivaroxaba 20 mg. This case was linked to MOD-2021-059897 (Patient Link).</p> <p>Blood clot in Left Arm; itchy rash from elbow to shoulder; lump on the underside of her biceps; nauseous; couldn't lift arm up; arm sore at the injection site; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clot in Left Arm) in a 63-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history.). Concomitant products included CLONAZEPAM for Anxiety, STEROIDS for Back disorder, CITALOPRAM and MORPHINE SULFATE for an unknown indication. On 23-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, the patient experienced VACCINATION SITE PAIN (arm sore at the injection site). On 24-Mar-2021, the patient experienced MOVEMENT DISORDER (couldn't lift arm up). On 25-Mar-2021, the patient experienced RASH PRURITIC (itchy rash from elbow to shoulder), MASS (lump on the underside of her biceps) and NAUSEA (nauseous). On 27-Mar-2021, the patient experienced THROMBOSIS (Blood clot in Left Arm) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood clot in Left Arm), RASH PRURITIC (itchy rash from elbow to shoulder), MASS (lump on the underside of her biceps), MOVEMENT DISORDER (couldn't lift arm up), NAUSEA (nauseous) and VACCINATION SITE PAIN (arm sore at the injection site) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment included Benadryl for symptoms and Eliquis for blood clot.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1178023	4/7/2021	MA	37	F	3/24/2021	4/3/2021	Admitted with ischemic stroke and multiple thrombi in extremities
1177687	4/7/2021	PA	78	F	3/5/2021	3/30/2021	symptoms, signs, time course, etc.) 78 yo female patient with PMHx of paroxysmal atrial fib / COPD / smoking / anxiety-depression / obesity / arthritis and prior bil PE in 2018 after knee surgery (anticoagulated with Xarelto) who presented to FH on 03/30/2021 with SOB x2 weeks. Of note she received her 2nd COVID vaccine dose on 03/05/2021 and since she has worsening SOB. Pt reported cough w/ yellow sputum prior to her admission. At urgent care, she was hypoxic with Sat 82%, therefore she was transferred to ED for further w/u. Lab w/u showed BNP of 1,074 and trop of 32. She was found to have a negative POC COVID-19 and PCR is pending. Bil venous Dopplers show acute occlusive DVT in the R popliteal vein above and below the knee w/ slow flow in the R fem vein and no DV IN the LLE. TTE on 03/31/2021 showed EF 65-70% w/ G2DD, mod-severe RV failure and severe pulmonary HTN, mod TR, and dilated IVC. Decision was made to CT chest w/ contrast despite renal function given high suspicion for PE. CT chest w/ contrast showed large clot burden PE w/ findings c/w R heart strain, a 12x9 mm lobulated nodule in the RUL concerning for neoplasm, increasing patchy infiltrates, and increasing R pleural effusion and new trace L pleural effusion. Patient required 12L O2 via NC. IR was contacted at but felt that patient was not a candidate for CDT or for IVC filter. Patient was transferred to ICU for further care. Patient received IV heparin per the PE Protocol from, Alteplase 40mg on 4/1, and was started on treatment dose of Eliquis.
1178615	4/7/2021	AZ	57	F	3/5/2021	3/6/2021	Pain in right leg, visited doctor, had ultrasound, found blood clot, prescribed aspirin.
1172529	4/6/2021	IN	77	F	3/4/2021	4/3/2021	Blood clot that caused total vision loss in right eye. It occurred on 04/03/2021. Was treated by ophthalmologist at eye Center, and at Hospital,

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1173594	4/6/2021	NC	80	M	1/2/2021	2/1/2021	Blood clot on his left leg, from his groin to his ankle/still having the blood clot; A spontaneous report was received from a consumer concerning an 80-years-old male patient, who received Moderna's COVID-19 vaccine (mRNA -1273) and had blood clot on his left leg, from his groin to his ankle. The patient's medical history was not provided. No relevant concomitant medications were reported. On 02 Jan 2021, prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number: 039KZ014) intramuscularly for prophylaxis of COVID-19 infection. On 30 Jan 2021, approximately two weeks prior to the onset of the symptoms, the patient received their second of two planned doses of mRNA-1273 (Batch number: unknown) via unknown route in the left arm for prophylaxis of COVID-19 infection. On an unknown date in Feb 2021, the patient reported having a medically significant event, blood clot on his left leg, from his groin to his ankle and is still having it. The patient taking medication for it. The patient received both scheduled doses of mRNA-1273 prior to the events, therefore action taken with the drug in response to the events was not applicable. At the time of this report, the outcome of the event had blood clot on his left leg, from his groin to his ankle was not resolved.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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1173590	4/6/2021	IN	71	M	1/28/2021	2/26/2021	<p>Right ankle swollen; could not walk for several weeks; Leg cramp; pain in right leg that comes and goes; right leg swelled up; This spontaneous case was reported by a consumer and describes the occurrence of GAIT INABILITY (could not walk for several weeks), MUSCLE SPASMS (Leg cramp), PAIN IN EXTREMITY (pain in right leg that comes and goes) and PERIPHERAL SWELLING (right leg swelled up) in a 71-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 022M20A and 022M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Fall from high place (fell off a roof 20 years ago), Coma (for 23 days after a fall), Clot blood (in left leg after being in coma for 23 days) and Nerve damage (left leg). Concurrent medical conditions included Depression (mild), Acid reflux (esophageal) and Disability. Concomitant products included OMEPRAZOLE for Acid reflux (esophageal), ST. JOHN'S WORT for Depression. On 28-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 26-Feb-2021, the patient experienced PERIPHERAL SWELLING (right leg swelled up) (seriousness criterion disability). On 26-Feb-2021 at 8:00 PM, the patient experienced MUSCLE SPASMS (Leg cramp) (seriousness criterion disability) and PAIN IN EXTREMITY (pain in right leg that comes and goes) (seriousness criterion disability). On 27-Feb-2021, the patient experienced GAIT INABILITY (could not walk for several weeks) (seriousness criterion disability). On 01-Apr-2021, the patient experienced JOINT SWELLING (Right ankle swollen). At the time of the report, GAIT INABILITY (could not walk for several weeks), MUSCLE SPASMS (Leg cramp) and PERIPHERAL SWELLING (right leg swelled up) outcome was unknown and PAIN IN EXTREMITY (pain in right leg that comes and goes) and JOINT SWELLING (Right ankle swollen) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Feb-2021, X-ray: normal (normal) no blood clots. Treatment for the events included diclofenac sodium cream and paracetamol. On 06 Mar 2021, a physician</p>

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							told the patient that it was okay for him to do leg presses so he did 350 pounds x100 and he also walked in a pool. He went home and after sitting for a half hour, his leg cramped up again and he needed a crutch to walk. The patient also reported using a cane. The patient stated, stated "now I just exercise leg with movements that seem to help." Very limited information regarding this event/s has been provided at this time. Further information has been requested. Most recent FOLLOW-UP information incorporated above includes: On 01-Apr-2021: City, state and zip code updated; patient's date of birth and race updated; medical history and concomitant medications added; events updated.; Sender's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.
1173347	4/6/2021	ND	68	M	3/31/2021	4/3/2021	Right lower extremity deep venous thrombosis.
1173076	4/6/2021	HI	65	F	3/22/2021	3/23/2021	On 03-23-21, I woke up I felt a pulse and y dialysis access and there was no pulse which indicates that the graft has become clotted. I went to the dialyses center contacted dr. and he said I needed to go to another town, to get surgery to clear the clot with another Dr. I flew there had surgery to clear the surgery, surgery was success. I went to dialysis that night, when I checked the graft again it was clotted. I then had to go make arrangements again to fly to another town to get surgery again with Dr. to clear the clots. Surgery was successful and subsequently and I have had a good pulse on my dialysis access.
1173053	4/6/2021	VA	56	M	3/23/2021	3/24/2021	Patient states that he woke up the next day extremely fatigued. About 3pm, he could not move his arm/right hand and had trouble walking. He called his doctor's office who told him to call 911. At the hospital, he was given emergency medication for a blood clot. He states the ER told him his stoke was from the covid vaccine.

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1173004	4/6/2021	ND	72	F	3/12/2021	3/14/2021	Client reported today, 4/6/21, the day after her first COVID-19 Pfizer vaccine, she was very tired and had some achiness. 2 days post vaccination, she reported some pain in her thigh, pain went from thigh to her knee, to her thigh over the next couple days, then after about 4 days she noticed a bruise on the inside of the right knee without any known trauma. Client reports she continues to have tenderness to touch on thigh and leg. Client denied any swelling. Client has had hx of blood clots in her knees when she was in her 20's.
1172452	4/6/2021	NY	49	M	3/31/2021	4/1/2021	Patient received Johnson&Johnson COVID vaccine in the afternoon on 3/31/21. Patient reported having right arm pain, diaphoresis, chills, nausea, and muscle aches/pain in upper leg/lower back at 5:30am the following morning. Patient took 2 tablets of 500mg naproxen in the morning and in the afternoon. Symptoms did not resolve and patient had to leave work early. Upon getting home patient took 2 tablets of 650mg tylenol and symptoms resolved within 48 hours. On 4/3/21 patient reported mild to severe pain in heel of left foot. The following day the patient went to WellNow urgent care to get his heel examined. During examination provider noticed patient's lesions and patient stated more lesions have appeared since getting the vaccine. 1 on his stomach, 1 on the dorsum of his left foot, 1 on his back, 1 on his left elbow, in between his toes of his left foot, and in between the fingers of his right hand. Patient stated that these lesions cause a burning sensation and can become itchy. Patient was sent to Hopsital ED as provider at urgent care was concerned patient may have purpura. Patient was seen and discharged on 4/4/21 from the ED. The heel pain was determined to be plantar fascitis which was treated with at home exercises with a heel cup. The patient was given clotrimazole for his lesions. The patient had a follow-up visit with his primary care provider at hospital on 4/6/21 in which he explained the clotrimazole only made his lesions worse. Patient was referred to follow up with dermatology on 4/8/21. Primary care provider believes progression of the lesions since getting the vaccine leads to concern of an underlying autoimmune exacerbated by vaccine.



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1172377	4/6/2021	WI	45	M	3/17/2021	3/19/2021	I had an extensive oral surgery about 36 hours after getting the vaccination. I had non profuse bleeding after the surgery. I experience a condition called Liver Clot (currant jelly clot). This condition and the bleeding continued for over 5 days following the surgery or 6.5 days after the vaccine dose 1.
1172285	4/6/2021	PA	62	F	4/1/2021	4/2/2021	patient had headache within the first 15 minutes after administration and was found to be positive for dural venous sinus thrombosis with unknown etiology
1171375	4/6/2021	TX	50	M	3/12/2021	3/25/2021	A perfectly healthy guy, who did not change anything else in his life, got the first vaccination, and 12 days later had a blood clot in his right lung. Went to ER, was diagnosed, and spent 3 days in the hospital. Serious. Doctors so far has no explanation for why this happened.
1173697	4/6/2021	CA	34	F	3/1/2021	3/15/2021	DVT blood clot in leg. Not able to seek care due to high deductible health insurance. Swelling, pain, discoloration, bruising in lower leg below soleus muscle and deep pain in calf. Using compression, ice, elevation, massage and aspirin regimen.
1171097	4/6/2021	NC	37	M	3/3/2021	3/6/2021	Blood clots (still experiencing... undergoing treatment)
1171196	4/6/2021	NC	44	M	3/20/2021	3/21/2021	After the shot, which I received on a Saturday, I developed pain and redness in my right leg. Two days later, on Monday morning, I contacted my primary care physician's office, who told me to go to the ER to be evaluated for a blood clot. At the ER, they performed a doppler ultrasound on my right leg and found a superficial clot in the greater saphenous vein of my right leg. There was no evidence of a DVT in the right leg.
1171343	4/6/2021		81	M	1/29/2021	2/23/2021	Critical lower leg ischemia. Pt had thrombolysis of left lower extremity on 2/23 followed by angiogram. He had complete resolution of the thrombosis. Discharged home with follow up with vascular clinic as well as addition of Plavix. Patient had first dose of COVID vaccine followed by a positive COVID test at the hospital 25 days later.

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1173969	4/6/2021	NC	56	M	3/22/2021	3/24/2021	Leg pain Shortness of breath , rapid heart rate , Dizziness , Nights sweat Symptoms started March 24 .Went to Urgent care April 2, they referred me to the ER . I went to the Hospital ER April 6 , They admitted me at noon after finding Blood Clot down my right Leg and Chest . 2 shots of Lovinox for 3 to for days
1170930	4/6/2021	FL	48	F	1/21/2021		Sx's started a month ago in the arm where she got the first dose of the vaccination. Inflammation and pain. Can not lift the arm up due to pain, have to use the other hand to elevate the arm. Mild tingling and muscle spasm. reports she has been to her PCP office three times. First time she was prescribed steroids and naproxen for pain. Second visit she was prescribed Methylprednisolone and a muscle relaxer. Third visit, which was this afternoon; she was prescribed Gabapentin and told that they could have hit a nerve while giving her the vaccination. CT scan was done to r/o blood clots - scan showed no indications of blood clots. Advised to use cold compress and take Gabapentin. Also advised to see a neurologist to r/u nerve damage/pain.
1173866	4/6/2021	TX	73	M	3/24/2021	3/25/2021	Rash developed on right side the day after the injection. Over several days it expanded to a 14" long 3" wide Red Rash. Dr Advised, NOT SHINGLES. After applying prescribed cream - (Clotrim?Beta 1-0.05% CRE GLE - ) - Clotrimazole/Betamethasone Dipropionate 1% / 0.5% for 14 days. Itching stopped immediately and rash started to heal after 3 days. After 10 days almost gone. Inaddition, Dr. wanted me to report that patient had the Bamlanivimab Intervenous Injection, January 22, after testing positive for Covid-19 on January 13, 2021.

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1168970	4/5/2021	NJ	95	F			<p>ATRIAL FIBRILLATION; INABILITY TO SWALLOW; BLOOD CLOT IN RIGHT ARM; LOW BLOOD PRESSURE; DEATH 4 DAYS AFTER RECEIVING VACCINE; This spontaneous report received from a vaccine facility via a company representative concerned a 95-year-old female. The patient's height, and weight were not reported. The patient's concurrent conditions included atrial fibrillation. The patient received COVID-19 VACCINE AD26.COV2.S (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 2021 for prophylactic vaccination. No concomitant medications were reported. The batch number was not reported and has been requested. It was reported that on an unspecified date in 2021 the patient received Janssen Covid-19 Vaccine and within 6hrs she had a major atrial fibrillation episode, then several the following day. The next day, she lost her ability to swallow. Two days later she was on oxygen. Three days later she developed a blood clot in her right arm, was still on oxygen and blood pressure was falling. On an unspecified date, the patient died 4 days after receiving vaccine. The action taken with COVID-19 VACCINE AD26.COV2.S was not applicable. The patient died 4 days after receiving vaccine on an unspecified date, and the outcome of atrial fibrillation, inability to swallow, blood clot in right arm and low blood pressure was not reported. This report was serious (Death, Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: 20210400509: This spontaneous report received from a vaccine facility via a company representative involved a 95-year-old female with the past medical history remarkable for atrial fibrillation who received the Janssen COVID-19 Vaccine for prevention of COVID-19 infection and within 6hrs had a major atrial fibrillation episode. No concomitant medications were reported. The next day, she lost her ability to swallow. Two days later she was on oxygen. Three days later she developed a blood clot in her right arm, was still on oxygen and blood pressure was falling. On an unspecified date, the patient died 4 days after receiving vaccine. No information was provided regarding the cause of death. Considering the patient's past medical history of atrial fibrillation, the causality for the event of atrial fibrillation, as well the consequent events is assessed not related to the</p>

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							Janssen COVID-19 Vaccine.; Reported Cause(s) of Death: DEATH 4 DAYS AFTER RECEIVING VACCINE
1170312	4/5/2021	FL	55	M	4/1/2021	4/3/2021	I had a sharp pain in my chest and told my wife something was wrong.. I sat down and started sweating, after that my wife said she was asking me if I was ok and she said I was staring straight ahead and moaning then my eyes rolled back in my head and I was unconscious. My wife called 911 and was trying to get me to respond but no response. While she was yelling get an ambulance I came to and I asked my wife who are you calling. She told me I was unconscious for several minutes. I went to the ER via ambulance due to the symptoms. The paramedics thought I had a blood clot or heart attack.
1170033	4/5/2021	CA	86	M	3/5/2021	3/9/2021	The first doze made him tired and got back pain. Went to his Primary Doctor to see if it is okay to get the second dose. He got his blood work done, echo Cardiogram and all the necessary test have been done and he is okay to proceed by his Doctor. On the fourth day after he get the second dose of Pfizer-BioNTech, in the afternoon, he couldn't get up from his bed that he had lay down. He experienced slur, facial droop and left side hand weekness. We called the paramedics right away and they checked him and took him to the nearest Emergency Hospital. They ran tests, did CT scan and diagnosed him with Ischemic Stroke on his right side which has effect on the left side of his body for facial droop and weekness and not being able to get up. He was threatred with Mechanical Thromboctomy to remove the blood clot. He stayed in the hospital for 8 days and is bed bound up until now and is transferred to a re-hab. He still can't stand. Today is the 27th day since the adverse reaction started. His left hand has improved a little bit.
1169809	4/5/2021	MD	51	F	3/22/2021	3/29/2021	DVT / Blood Clot
1169566	4/5/2021	NY	73	M	3/17/2021	3/18/2021	formation of a blood clot in right calf

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1169284	4/5/2021	LA	66	M	3/3/2021	3/19/2021	PT SAYS HE GOT MODERNA VACCINE on 3/3/2021, PT SAYS HE WAS EXPERIENCING HIVES, URGENT CARE DIGNOSED HIM ON 3/19TH AS having DERMATITIS, AND WAS GIVEN CLOTRIMAZOLE-BETAMETHASONE, PT SAYS HE WAS SNEEZING a lot as well
1169237	4/5/2021	CA	88	F	2/26/2021	2/28/2021	Blood Clot, lower leg (left calf muscle). MD. recommed Xeralto 20mg
1170456	4/5/2021	MI	56	F	4/1/2021	4/2/2021	Symptoms began about 5 hours after the application of the vaccine and consisted on: fatigue, headaches and high resting hearth palpitations. During the night and the day after (Friday 04/02) symptoms worsened especially heart palpitations being all day above 120 up to 135 per minute. At moments it was difficult to breath and talk. By the end of the day I also experienced chest pain and signs of low oxygen (blue lips and pale colors) as well as mild fever. After calling paramedics, I was transported to the ER where blood, urine and Covid test were performed. I was told that some values of the blood test could suggest a blood clot so a CTscan was also performed with negative results. After a few hours in observation with infusion of fluids, potassium and magnesium I was sent home. Saturday and Sunday (days 3 and 4 after the vaccine) symptoms improved however heart palpitations were higher than normal and I still experience mild fever (98-99F). Insomnia and fatigue persisted for two more nights. Finally today Monday April 5, I could say that I feel back to normal.

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1168994	4/5/2021	CA	71	M	2/13/2021	2/25/2021	<p>Pulmonary embolism; Spitting out blood clots; Labored breathing; Diarrhea; Body aches; Joint aches; Fever; Exhausted; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Pulmonary embolism) in a 71-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 030M20A) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse reaction (No medical history reported.). Concomitant products included METOPROLOL and LOVASTATIN. On 13-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Feb-2021, the patient experienced OXYGEN SATURATION DECREASED (Oxygen levels have gone as low as 76 and several in the 80's), HEART RATE INCREASED (Heart rate is normally around 60, and has been in the 90's several times), PAIN (Body aches), ARTHRALGIA (Joint aches), PYREXIA (Fever) and FATIGUE (Exhausted). On 07-Mar-2021, the patient experienced DIARRHOEA (Diarrhea). On an unknown date, the patient experienced PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criterion medically significant), HAEMOPTYSIS (Spitting out blood clots), DYSPNOEA (Labored breathing) and VITAL CAPACITY ABNORMAL (Vitals are waked out). At the time of the report, PULMONARY EMBOLISM (Pulmonary embolism), HAEMOPTYSIS (Spitting out blood clots), DYSPNOEA (Labored breathing), OXYGEN SATURATION DECREASED (Oxygen levels have gone as low as 76 and several in the 80's), HEART RATE INCREASED (Heart rate is normally around 60, and has been in the 90's several times), VITAL CAPACITY ABNORMAL (Vitals are waked out), DIARRHOEA (Diarrhea), PAIN (Body aches), ARTHRALGIA (Joint aches), PYREXIA (Fever) and FATIGUE (Exhausted) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In February 2021, Body temperature: 103.7 (High) 103.7. In February 2021, Heart rate: 90s (abnormal) In the 90s several times. In February 2021, Oxygen saturation decreased: 76s (Low) has gone as low as 76 and in 80s. In February 2021, SARS-CoV-2 test negative: Negative</p>

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1168723	4/5/2021	GA	23	M	3/17/2021	3/29/2021	<p>and Negative. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment information was not provided.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> <p>Rash developed on thigh about 2 weeks after the 1st Pfizer vaccine; NOTHING else in life is novel, ie, no new foods, detergents, soaps; no traveling, no guests, and the patient abhors the outdoors so insect involvement is extremely unlikely. Rash was reported to me (Mom) on Thursday, April 1st. There was one spot/lesion that was oval and larger than the others, with a somewhat blanched center. No itch or pain. Friday the 2nd, patient reported around 5:00 p.m. that it had spread to his sides, so I called the nurse healthline.. Saturday a.m. per recommendation I took him to Urgent Care; it had by then also spread to his stomach. The doctor there didn't have any "A-HA!!" moment, but sent us off with a prescription for a clotrimazole/betamethasone topical cream. The rash is now heavily populating his stomach, is on his back and there are a couple spots on his arm. I contacted his primary care manager this morning as we are to receive our 2nd Pfizer vaccines day after tomorrow (Wed, 4/7) and I'm wondering if he should get his as planned or whether that might be a bad idea.</p>

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1168887	4/5/2021	MO	71	M	3/10/2021		<p>UNABLE TO URINATE AT ALL; BLOOD CLOTS THAT WERE BLOCKING CATHETER; PROSTATE INFLAMMATION/ ENLARGED PROSTATE; This spontaneous report received from a consumer concerned a 71 year old male. The patient's weight was 212 pounds, and height was 182 centimeters. The patient's past medical history included urinary tract infection (UTI), enlarged prostate,. The patient's past medication included shingles vaccine for alpha gal syndrome. Concurrent conditions included kidney stones, alcohol user, non smoker, polyethylene glycol allergy, sulfa allergy, alpha gal syndrome and high uric acid. The patient previously experienced drug allergy when treated with polyethylene glycol for unspecified indication. The patient had no illness at the time of vaccination, no history of drug abuse. Because of the inflammation the stones caused when in the process of being passed, the patient also had occasional issues with an enlarged prostate as well as UTIs as a result of the stones. However, the patient never had his prostate enlarged to the point where he could not urinate as a result of passing stone. The patient has passed a small stone unannounced without symptoms approximately 10 days prior to receiving the COVID vaccine. The patient had no side effects after passing the stone, there was no pain, no dis colouration and no trouble urinating. The patient felt 100% with no after effects that would be attributed to passing the small stone. The patient received COVID-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029, and 1805029 expiry: not reported) dose was not reported, administered on 09-MAR-2021 09:30 in left deltoid for prophylactic vaccination. Expiry date was not reported and has been requested. Concomitant medications included allopurinol for high uric acid, and prevention of stones On 10-MAR-2021, 1:00 AM, approximately 15 hours post vaccination the patient experienced pain and trouble urinating. Subsequently, the patient went to urgent care where he was diagnosed with enlarged prostate and sent home. By mid morning, he was unable to urinate at all and went to see the physician. Patient has undergone a bladder scan and catheter was placed. On 10-MAR-2021 01:00, the patient also experienced prostate inflammation/ enlarged prostate On 13-Mar-2021, the patient returned to the emergency room twice</p>



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for blood clots that were blocking the catheter due to overextension of the bladder. On 18-Mar-2021, the patient returned to the physician, got the catheter removed and scope was performed. The patient was noted to have greatly enlarged prostate gland and the physician allowed him to leave the office without catheter. Several hours later, the patient was unable to urinate once again and went to physician's office and the catheter was put back in for additional two weeks, at the end of that time the patient will be reassessed. Laboratory data included: Prostate examination (NR: not provided) Enlarged prostate. On 18-MAR-2021, Laboratory data included: Ureteroscopy (NR: not provided) prostate greatly enlarged. Treatment medications (dates unspecified) included: finasteride to help with urine flow. The action taken with COVID-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from prostate inflammation/ enlarged prostate, had not recovered from unable to urinate at all, and the outcome of blood clots that were blocking catheter was not reported. This report was serious (Other Medically Important Condition) Additional information was received from consumer on 31-MAR-2021 following information was updated and incorporated into case narrative: Patient demographic details (height, weight, date of birth), patient's past medical history ( urinary tract infection (UTI), enlarged prostate), past medication (shingles vaccine for alpha gal syndrome), concurrent conditions (kidney stones, alcohol user, non smoker, polyethylene glycol allergy, sulfa allergy, alpha gal syndrome and high uric acid), COVID-19 vaccine therapy details (vaccination time), additional event of enlarged prostate, reporter details, lab details were added.; Sender's Comments: V2. Follow up information received regarding Patient demographic details, past medical history, past medication, concurrent conditions, vaccine therapy details, additional events , reporter details, lab details were added . 20210323574-COVID-19 VACCINE AD26.COV2.S- Unable to urinate at all, Prostate inflammation. Follow-up received regarding Clinical Details. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically:

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							MEDICAL HISTORY, UNDERLYING DISEASE .
1168314	4/5/2021	TX	67	F	3/10/2021	3/12/2021	pt states that she got the vax that she is in constant pain from her waist down and cannot walk with out a walker. She has knots in the muscles in her hips and legs. She has been taking pain relievers for her symptoms and has had diarrhea since she got this vax so is not sure if it is from the vaccine or the medicine. She went to Hospital ER. Pt was referred to see her orthopedic surgeon. Her Orthopedic surgeon took x-rays(negative results) and scheduled her for physical therapy. She went back to the Hospital ER. They did a sonogram to rule out blood clots in her legs. She starts her physical therapy today 4/5/2021.
1168135	4/5/2021	NY	74	M	2/10/2021	3/1/2021	Pt developed intermittent shortness of breath around 3/7/21. Pt fell and had left arm and leg weakness. Pt had transient ischemic attack, multiple pulmonary emboli and deep venous thrombosis diagnosis on 3/27/21
1169002	4/5/2021	SC		M	3/11/2021	3/12/2021	blood clot in brain/ stroke; A spontaneous report was received from a consumer concerning an 75-year-old, male patient who was hospitalized due to Blood clot in brain and stroke. The patient's medical history was not provided. No relevant concomitant medications were reported. On 11 Mar 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 Batch no: 027A21A for prophylaxis of COVID-19 infection. On 12 Mar 2021, It was reported that the patient experienced Blood clot in brain and stroke and the patient was hospitalized for three days, from Friday 12 Mar 2021 to Sunday 14 Mar 2021. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the event(s) Blood clot in brain and stroke was considered to be resolved.; Reporter's Comments: This is a case of cerebrovascular accident in a 75-year-old male patient with no medical hx provided who was hospitalized after experiencing blood clots in the brain and stroke after receiving first dose of vaccine. Very limited information has been provided at this time. Further information is expected

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1168233	4/5/2021	OK	34	F	3/25/2021	3/31/2021	Fever 103 3/27, stomach pain, vomiting, diarrhea, headache, chest pain, SOB Hospital 3/29, critically low potassium, D-Dimer elevated, chest CT clear, admitted 3/30 HIDA scan, gallbladder removed 3/31 woke with vision issues, seeing multiples of things, slanted hallways, can?t stay awake 4/1 CT and MRI of brain show venous blood clot Started on blood thinners, stopped birth control (had only been on birth control about 5-6 months)

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1165713	4/4/2021	FL	78	F	2/2/2021	2/3/2021	gained weight since COVID,she was 136 pounds and she just weighed herself and weighs 142 pounds; she could not step down on her left leg; Charley horse; This is a spontaneous report from a contactable consumer (patient) reporting for herself. A 78-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EN5318), dose 2 intramuscular route of administration, administered in Arm Right on 02Feb2021 17:00 as SINGLE DOSE for covid-19 immunization. Medical history included breast cancer (additional Information for Other Conditions: 19 radiations and they took out three lymph nodes on the left, she was diagnosed 3 years ago), blood pressure, 19 radiations, shingles shot. Reports she had the shingles shot a few months ago, vein disorder from Sep2020 to an unknown date. Patient was not sure if vein injections might be indicative of something and clarifies that she had vein issues in her legs had vein injections to dispose of the larger veins. She has had the vein injection a number of times throughout the years. The last time she had it done again was in Sep2020. Concomitant medications included losartan; taken for blood pressure abnormal; amlodipine besilate taken for blood pressure abnormal; tamoxifen taken for breast cancer. It was reported that, she has been taking losartan for years for blood pressure and amlodipine besylate about a year ago. The patient previously administered first dose BNT162B2 on 12Jan2021 11:30 (Lot number:EL3246), intramuscular injection in right arm for covid-19 immunization On 03Feb2021, patient experienced charley horse, gained weight since covid, she was 136 pounds and she just weighed herself and weighs 142 pounds, she could not step down on her left leg. Clinical course of events includes, patient was curious, she had her second shot at 5pm on Tuesday. Yesterday morning when she woke up at 6:30 or 7 in the morning, she could not step down on her left leg. For the last day and a half, she has had what had a bad charley horse behind her knee on the upper part of the calf. She was asking if the vaccine has any indications of a blood clot. Reports she was sitting in a car for 5 hours waiting to get the vaccine. She plays golf, stays busy, she does a lot, she was not someone that is very stagnant normally. When she went to get out of bed, she could not put her foot down, she was limping. She cannot step down without being in pain.

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1165637	4/4/2021	PA	51	F	1/29/2021	1/29/2021	<p>She was trying to walk now. Therapeutic measures were taken as a result of charley horse, she could not step down on her left leg. She read walking was good and drinking water, drinking tea, she did a warm compress four times this morning. The outcome for the charley horse, she could not step down on her left leg was recovering and outcome for gained weight since covid, she was 136 pounds and she just weighed herself and weighs 142 pounds and was unknown.</p> <p>Arm soreness; Fatigue; Throbbing headache; Rib and upper back pain; Rib and upper back pain; Axilla pain; Rapid pulse; Temp; This is a spontaneous report from a contactable other health Care Professional. A 51-years-old female patient received first dose of BNT162B2 (PFIZER COVID-19 VACCINE ;solution for injection; Lot Number: EN53185/21) via intramuscular to right arm on 29Jan2021 at 11:00 as single dose for COVID-19 immunisation. Medical history included hypertension, gastrooesophageal reflux disease, anxiety, thrombosis, COVID-19. The patient had Covid prior vaccination. Concomitant medications included labetalol, NORVASC, ELIQUIS, OMEPRAZOLE, ZOLOFT, VIT D and VIT C. The patient experienced Arm soreness, temp, fatigue, throbbing headache, rib and upper back pain, axilla pain, rapid pulse on 29Jan2021 at 20:00. The patient underwent lab tests and procedures which included body temperature with unknown result heart rate with rapid result, viral test with negative on 01Feb2021. Therapeutic measures were taken for the events with Tylenol. The outcome of the events was recovering. Follow-up activities have been completed and no further information is expected.</p>

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1165711	4/4/2021	FL	78	F	1/12/2021		<p>Weight: She has gained weight since covid; This is a spontaneous report from a contactable consumer (Patient). A 78-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot Number: EL3246), via intramuscular, administered on Right arm on 12Jan2021 11:30 (at the age of 78-years-old) at single dose for COVID-19 immunization. Medical history included breast cancer (19 radiations and they took out three lymph nodes on the left, she was diagnosed 3 years ago); blood pressure abnormal (Additional Information for Concomitant Products Losartan: she has been taking for years and Additional Information for Concomitant Products Amlodipine besylate: added about a year ago); vein disorder (She clarifies that she had vein issues in her legs had vein injections to dispose of the larger veins. She was asking if it is possible that may have anything to do with it. She has had the vein injection a number of times throughout the years. The last time she had it done again was in Sep2020) and herpes zoster. No additional Vaccines Administered on Same Date of the Pfizer Suspect reported. Concomitant medication(s) included losartan (MANUFACTURER UNKNOWN, Formulation: tablet), orally at 100 mg, 1x/day (once a day) for blood pressure abnormal; amlodipine besilate (MANUFACTURER UNKNOWN, Formulation: tablet), orally at 5 mg, 1x/day (once a day) for blood pressure abnormal; and tamoxifen (MANUFACTURER UNKNOWN, Formulation: tablet), orally at 20 mg, 1x/day (once a day) for breast cancer. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced weight since COVID-19 infection on an unspecified date. She clarifies that she had vein issues in her legs had vein injections to dispose of the larger veins. She has had the vein injection a number of times throughout the years. The last time she had it done again was in Sep2020. Reports she had the shingles shot a few months ago. She will call her doctor to see if she should get a sonogram or x-ray of her calf to check for blood clot. The patient underwent lab tests and procedures which included that she was 136 pounds and she weighed herself and weighs 142 pounds. The outcome of event was unknown. No follow-up attempts are possible. No further information is expected.</p>

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1165645	4/4/2021			F	1/1/2021		nausea reported around 3am; This is a spontaneous report from a contactable other healthcare professional and contactable consumer. A 47-year-old female patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for COVID-19 immunization; tofacitinib citrate (XELJANZ XR, strength: 11mg), oral from Jan2021 (Batch/Lot number was not reported) and ongoing, at 11 mg, daily for rheumatoid arthritis. The patient's medical history include ulcerative colitis, heart attack 2018, blood clot, high cholesterol, heart -low ejection fraction. Concomitant medications were not reported. The patient experienced nausea reported around 3am. Information on the batch/lot number has been requested.
1166312	4/4/2021	PA	45	M	3/26/2021	3/29/2021	patient developed malaise, abdominal pain and nausea 2 days after the vaccination. It did not improve for a week and he presented to the hospital and was diagnosed with acute superior mesenteric vein and portal vein thrombosis along with pancreatic edema

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1166454	4/4/2021	OH	45	M	3/23/2021	4/3/2021	The patient is a 45 y/o male prisoner who presented 4/3/2021 with 3 days of headache, neck pain and stiffness, sensitivity to light, and nausea. He was found to have extensive dural venous sinus thrombosis causing the symptoms. He has hypothyroidism was taking levothyroxine 150 mcg daily at time of vaccination. On admission on 4/3/2021 his TSH was found to be 12 and levothyroxine dose was increased to 175 mcg on 4/4/2021. He has no prior history of thrombosis and the only family member with thrombosis is his mother who had DVTs associated with lung cancer. He has a history of prior COVID-19 infection in April of 2020 and at that time reported 3-4 days of mild symptoms and was not hospitalized or given anticoagulation. He has not had fevers, chills, or other symptoms of infection. He received his first dose of the Moderna COVID-19 vaccine at the prison on 3/23/2021 which was 9 days prior to symptom on set 12 days prior to presentation at the hospital. He reports 2-3 days of arm soreness at the injection site in his right arm, mild neck soreness, and fatigue after the injection which had resolved prior to his current symptoms starting. He currently remains hospitalized and is being treated with anticoagulation.
1167081	4/4/2021	NY	48	F	3/29/2021	3/30/2021	Arm pain on first day Tendons stiffness on one arm and both wrists on second night 4th day - Early menstrual period ( 2 weeks early); sudden bright red bleeding without usual signs of menstrual periods (no cramps, very unusual), and large clots in the bleeding Nausea, 2nd day
1167217	4/4/2021	NY	78	F	1/31/2021	2/16/2021	Persistent Dry Mouth after dose 1 Oral Candidiasis (yeast tongue) after dose 2 (02/21/2021) Took Clotrimazole lozenges 5 per day for 2 weeks Needed refill prescription of Clotrimazole still on it . Some relief but not gone. Gastric reflux-



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1165645	4/4/2021			F	1/1/2021		nausea reported around 3am; This is a spontaneous report from a contactable other healthcare professional and contactable consumer. A 47-year-old female patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for COVID-19 immunization; tofacitinib citrate (XELJANZ XR, strength: 11mg), oral from Jan2021 (Batch/Lot number was not reported) and ongoing, at 11 mg, daily for rheumatoid arthritis. The patient's medical history include ulcerative colitis, heart attack 2018, blood clot. high cholesterol, heart -low ejection fraction. Concomitant medications were not reported. The patient experienced nausea reported around 3am. Information on the batch/lot number has been requested.
1164900	4/3/2021	CA	73	M	2/9/2021	2/23/2021	Patient started feeling woozy, dizzy, slurring words and fatigued around 11:30am. By the afternoon he was extremely fatigued and barely ate lunch or dinner. He went to bed at 9:30pm. By 1:30am, he woke up and urinated the bed because he couldn't get his urinal in place. He was extremely weak and shaking, and could barely hold his body upright when I used the lift to get him out of bed. He was not making coherent sense when he spoke, though his words and sentences were sensical, it made no sense in context. We sent him to the ER on recommendation of the advice nurse and 4:30am. He was checked in and showed low levels of sodium and potassium. They gave him an IV and he began to feel better very soon, though he remained weak and woozy and nauseous. He returned home in early afternoon, but remained weak for over 2 weeks afterward, slurring words and having trouble lifting his arms, though mental function returned by that same day. The doctors believe that he had a TIA, though no evidence of a clot showed up. They did discover that he has atrial fibrillation, though they had never detected that before on the heart exams following his heart attack.

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1162481	4/3/2021	NY	73	F	2/12/2021	2/15/2021	Two blood clots in my right calf that travelled up to my lungs; Shortness of breath; Pain in my right calf; Had difficulty just walking; This is a spontaneous report from a contactable consumer (patient). A 73-years-old non pregnant female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration in left arm on 12Feb2021 19:30 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included heart (as reported) and known allergies to penicillin. There concomitant medications were not reported. On 15Feb2021 18:30 the patient experienced two blood clots in my right calf that travelled up to my lungs, shortness of breath, pain in my right calf, had difficulty just walking. It was reported that two nights after receiving the vaccine, she suffered shortness of breath and pain in her right calf. She tried to relax the next day, but had difficulty just walking. She went to a walk in medical facility. They sent her to the ER. After testing they found that she had two blood clots in her right calf that travelled up to my lungs. The event two blood clots in my right calf that travelled up to my lungs was considered as serious (hospitalization) and other event were considered as serious (hospitalization). The patient was hospitalized for all events for 4 days. The patient underwent lab tests and procedures which included blood test on 15Feb2021 with showed two blood clots in my right calf that travelled up to my lungs and sars-cov-2 test with negative results on Feb2021. Therapeutic measures were taken as a result of two blood clots in my right calf that travelled up to my lungs, shortness of breath, pain in my right calf and had difficulty just walking. AE treatment included blood thinner. The outcome of the events was recovering. No other vaccine was given to patient in four weeks and two weeks. No Covid prior vaccination. If Covid tested post vaccination: Yes. Patient was covid tested post vaccination in Feb2021 with negative results. AE resulted in: [Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization]. Facility type vaccine was Public Health Clinic facility. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected

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1163369	4/3/2021		84	M	2/12/2021	2/22/2021	Blood clots
1163438	4/3/2021	OH	54	F	2/27/2021	3/1/2021	After the first vaccine on 2/6/2021, I did not have any reaction except a sore arm until 2/10/2021 when developed a bad headache causing me to leave work. When I awoke on 2/11/21 I felt worse as the day went on until I had complete flu like symptoms. On Friday, 2/12, I went to my primary care doctor and they did a COVID-19 test which was negative. Hence, I just waited for the reaction to go away, I was not better and able to resume normal activity until 2/15/21. I did decide to get the second shot as I was not entirely sure it was a result of the vaccine. On 2/27/2021, I received the second vaccination. Again, the immediate side effect was only a sore arm. On the following Monday (3/1/2021) see cont.I began to have what I thought was muscle aches and pains around the mid section on my body but they were manageable. On Tuesday and Wednesday (3/3/2021) the pain and area of the pain spread and intensified. I was unable to sleep or find a comfortable position and was losing strength and knew I needed medical attention as I was afraid it was a heart issue. My husband took me to the ER (3/4/2021). The ER doctor ran a CT scan with contrast and the result was a blood clot in my right lung and pneumonia in my left lung along with pleurisy. I was then admitted to Clinic on 3/4/2021. I remained in the hospital until 3/7/2021. There I was treated with IV antibiotics, warfarin, Lovenox (80mg), and pain medication for the pleurisy. I was also on a full time heart monitor and my heart was checked several times. Since returning home, I finished a dose of two antibiotics and am using an inhaler to help with breathing. I have also just finished a long dose of steroids. My INR is still not regulated to the therapeutic level. Prior to this reaction, I was in the therapeutic range and had been checked. As of 4/3/2021 I am at 1.8 not in the 2-3 range and have increased my dose from before the reaction at 7.5 mg to 9.0 mg daily.

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1163599	4/3/2021	IL	81	F	3/10/2021	4/2/2021	4/2/2021 - pain in right arm starting at injection site. Over next 18 hours pain ran along arm to shoulder to upper back. Pain starts as sharp, then burning. Patient had difficulty sleeping. Started on ibuprofen (1000mg) at 8am on 4/3/2021 and heating pad. Pain dulled a bit. Additional info: on 3/27/2021 Patient woke up with a droopy eyelid that was diagnosed as Horner's Syndrome on 3/31/2021. Sent to ER at Hospital for MRI/MRA/CT, scans showed nothing conclusive - no evidence of stroke, aneurysm, clot, cancer, or anything pressing on optical nerve. Have followup with Dr at Hospital Neurology. Blood work ordered to check for evidence of other conditions that could deteriorate the myelin sheath.
1163634	4/3/2021	IL	73	F	3/9/2021	3/15/2021	patient with abdominal pain, diarrhea, and PORTAL vein thrombosis
1163691	4/3/2021	MN	71	M	3/8/2021	3/10/2021	Breathing problems starting on March 10th. Walk in health care did lung X-ray and other tests on the heart. Had to see regular doctor on the 18th. Doctor did a CT scan and it showed I had blood clots in the lungs. Doctor put me on Xarelto 30mg tablets
1163914	4/3/2021	FL	43	M	4/2/2021	4/3/2021	I have blood and blood clot in my urine.
1163967	4/3/2021	MA	73	F	3/26/2021	3/30/2021	Felt crummy on day one and two better on day three and on day four developed four blood clots on Coumadin with an INR of 4.5 and died the next day on 3/31/2021.
1164319	4/3/2021	MO	68	F	3/5/2021	3/5/2021	Very severe pain in left shoulder. Physician treated me at Urgent Care. He believes I had a blood clot in the muscle. Injection site was one slim finger width below bone. Followed up at Orthopedic Clinic twice. MRI scheduled 4/5/21. Some tingling and numbness going down to hand and pain extending up from shoulder to neck and jaw. Unable to sleep on left side currently.
1164340	4/3/2021	UT	69	M	3/25/2021	3/30/2021	Blood clot developed in the upper arm from arm pit to elbow. This was the same arm as injection site. Clot developed within 4 days. Diagnosed as DVT of axillary vein, acute.

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1164583	4/3/2021	NY	43	M	3/28/2021	3/28/2021	After a few hours of getting the second shot some fever minor headaches and a stuffy nose feel with no mu us present, pain and swollen area of shot and also all my left side from head to toe started to hurt significantly to the point that a walk to the bathroom was difficult. A few of the symptoms fade away after a few days but the left side swollen area on my leg still an issue not letting me continue my workouts, went to my doctor got a sonogram doppler no clots were found and they sent me home. Told me to rest and elevate my legs been doing that nothing has changed and a few minor headaches have made a comeback.
1164847	4/3/2021	AZ	72	M	4/2/2021	4/2/2021	Six hours after receiving a second Moderna shot, while slicing food in the kitchen, my right hand (between the thumb and middle index finger) began to burn and itch. The skin blackened over the right hand area. I immediately took a low dose aspirin for fear of a blood clot. One day later, the blackened area is still present.
1164666	4/3/2021		39	M	3/19/2021	3/29/2021	Blood in urine / urinating blood clots
1164912	4/3/2021	OR	35	F	3/30/2021	4/1/2021	Bloody nose, headache (same as first vaccine). My menstrual cycle started a week early (I've been obsessively charting for fertility reasons? I am like clockwork) and was full of large blood clots and painful.

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1160713	4/2/2021	MI	74	F	3/7/2021	3/16/2021	<p>DETAILS OF HOSPITAL STAY: PRESENTING PROBLEM: Cardiac arrest (HCC) [I46.9] HOSPITAL COURSE: Patient is a 74 year old female who receives care through healthcare clinic and second healthcare clinic with past medical history of HTN, CKD, cardiomyopathy/congestive heart failure, atrial fibrillation on Pradaxa who presented to the ED 3/16 after suffering an out of hospital cardiac arrest at her dentist's office. Per report, patient had SBP in the 80s on arrival but was asymptomatic. Prior to start of any procedure (no reports of being given sedative medications), she became unresponsive. CPR was initiated and was found to be in asystole. She received 3 rounds of CPR with ROSC. CT head without acute abnormality. Chest XR showing mild vascular congestion and interstitial edema. Initial labs showing AKI, elevated liver enzymes, BNP &gt;29,000, troponin 39, lactic acid of 11, INR of 6.6, PTT 62, APTT 87. UA with protein, nitrite, moderate blood. Urine culture ordered. Blood cultures ordered. In ED, patient was hypotensive requiring addition of vasopressors. Targeted temperature management was started. Ceftriaxone and flagyl started for possible urinary tract infection and aspiration. Patient with profound coagulopathy, INR increasing to 12.0 on arrival to the ICU. Two units FFP and vitamin K were given. Patient with escalating pressor requirements at this time so CT t/a/p was ordered showing multiple bilateral rib fractures, nondisplaced sternal fracture with small anterior mediastinal retrosternal hematoma, small right sided hemothorax, right chest wall hematoma, patchy bilateral airspace disease consistent with atelectasis/infiltrate/aspiration, diffuse GGO consistent with interstitial edema, enlarged pulmonary arteries consistent with pulmonary hypertension, cholelithiasis. FDP elevated and 2 units of cryoprecipitate given 3/16. Hemoglobin decreased to 5.9 3/17 with INR of 5.4. Two additional units of FFP and additional dose of vitamin K ordered. Two units RBCs ordered. CTA thorax and abdomen 3/17 re-confirmed hemothorax and chest wall hematoma but no active bleeding noted. CT bilateral LE showed no evidence of hematoma. Trauma consulted who recommended chest tube placement. Overnight 3/16-3/17, patient also noted to have seizure activity on EEG and patient loaded with Keppra. Head CT 3/17 negative for hemorrhage or other acute processes. Patient remained in status epilepticus</p>

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3/17am and additional Keppra load was given and neurology consulted. Received Praxbind for continued bleeding/coagulopathy. 3/17pm went into PEA arrest with 10 minutes of CPR with ROSC. Bronchoscopy following ROSC noted evidence of bleeding from multiple areas, clots removed. MRI brain showing diffuse anoxic brain injury. Propofol stopped 3/19am. After goals of care discussion this morning, all first degree relatives (daughter and son) all in agreement to transition to comfort care measures. I received call from bedside RN that patient had passed away. On exam, no heart or breath sounds appreciated upon auscultation for 2 minutes. No spontaneous movement or chest rise noted. No pulse palpated for two minutes. Pupils fixed and dilated. No response to noxious stimuli. Time of death 1400 3/20/2021.

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1162086	4/2/2021	VA	34	F			<p>Her heart rate in the vaccinated arm had a mark for arrhythmia; inflammation in the vaccinated arm; some aching in the arm but I thought perhaps the stiffness is going to be, the onset of stiffness; If I put my arm bended towards my chest that's when I would feel sort of a pop or some type of spasm and I drop my arm just like shake it off that would stop the static; Some aching in the arm; She thought she felt muscle spasms in the vaccinated arm; This is a spontaneous report from a contactable consumer (patient). A 34-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EN6208), via an unspecified route of administration on an unspecified date (at the age of 34-years-old) as a single dose for COVID-19 immunisation. Medical history included endometriosis from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. The patient received the 1st dose of the Pfizer COVID vaccine on Tuesday (unspecified date). She thought she felt muscle spasms in the vaccinated arm, it felt like it was matching her heart rate. Her heart rate in the vaccinated arm had a mark for arrhythmia. She spoke to a family member who is a medical student, he thought it was caused by pressure on the vessel or pressure on the area. She reported having a rare form of microscopic endometriosis. She also read in a magazine that there were 36 cases of severe reactions after receiving the COVID vaccine. Not sure if it was the Pfizer COVID vaccine, but in one case, a female had heavy vaginal bleeding and her obstetrician found that she had 0 platelets although the week before her platelet count was normal. On 19Mar2021, when probed for the side effects experienced, consumer stated, "Yesterday there was some aching in the arm but I thought perhaps the stiffness is going to be, the onset of stiffness is going to start but it didn't start as stiffness it just started progression to muscle out what I thought, muscle spasm. If I put my arm bended towards my chest that's when I would feel sort of a pop or some type of spasm and I drop my arm just like shake it off that would stop the static. When I work at my desk I keep my arm folded and today this morning is when I started to feel that the spasm in my fore arm sort of matched my heart rate a little bit and I thought do I feel my heart rate in my arm I thought that was impossible but apparently you</p>



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can. I have a blood pressure check machine just to make sure I don't have high blood pressure which I have never had but I just in case you just want to check your 'vital signs'. I put that on, it also checks 'report' and your heart rate. I put it on my right arm which was the non-vaccinated arm because I didn't want to irritate inflammation in the vaccinated arm. When I put it my right arm my 'signs' they were perfectly fine and it was 118 over 66 and pulse rate 85 but I thought, you know I really need to check the arm that I felt the, that was vaccinated but I actually felt the heart beating through the arm 'is due to' muscle spasm so I put the device on that arm that was vaccinated, my left arm and when the results stopped it was completed, it was 107 over 68, 81 Pulse but then it had the notation that I had arrhythmia, I thought that here must be the heart, I don't know if it was skipping and so I thought it is a perhaps a blood clot matter but I keeping think what Pfizer had blood clot side effects so that's where I started to check and when I started to check on maybe compression or maybe inflammation I didn't want to assume blood clot so I checked for inflammation and compression. My sister's husband is a doctor, he said it sounds like Thoracic outlet syndrome and that compression but then there is like the 'veins' one which is the blood clot, then I thought man that does sound like what I have but the fact that it was involved with blood clot but let me check to see if Pfizer did have a blood issue or a blood clot matter, that's when I thought those rare side effects. I have Endometriosis (History) but I have rare type of Endometriosis that's called microscopic (not spelled) and so it travels throughout head to toe of my body and always triggers some sort of inflammatory problem that mimic other type of condition, either trigger finger arthritis and then I don't get also sensation and then it's ruled out and then I don't have it back but it mimics something that's different and that's what I am little concerned because if the vaccine attacks right there." For treatment, consumer stated, "I did immediately because I have heavy blood flow with Endometriosis, it's little bit frightening that the vaccine could be taking out my platelets and if I start bleeding I may just end up hemorrhaging and I went to online because the fastest thing to do on weekend, it's doing online when I did quick diagnostic to do the complete blood count to check my platelet numbers are okay so I

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1162082	4/2/2021	KY	71	M	3/2/2021	3/12/2021	<p>just ran to the store that has a blood diagnostic and they were closing so I explained to them my concern about maybe having ITP and they could be attacking my platelets and if they could just you know stumbles it later and draw the blood they did so I am waiting that may take a day to receive the results." The patient underwent lab tests and procedures which included blood pressure measurement: 118 over 66 and 107 over 68, full blood count: result unknown, heart rate: 85 and 81, SARS-COV-2 test: unknown result and weight: i think i am now 190 on unspecified dates. The outcome of the events was unknown.</p> <p>developed blood clots in my left leg that began swelling some on 12Mar2021 and by Monday 15Mar2021 it was huge and 16Mar2021 big and hurting; developed blood clots in my left leg that began swelling some on 12Mar2021 and by Monday 15Mar2021 it was huge and 16Mar2021 big and hurting; developed blood clots in my left leg that began swelling some on 12Mar2021 and by Monday 15Mar2021 it was huge and 16Mar2021 big and hurting; This is a spontaneous report from a contactable consumer (patient). A 71-year-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot Number: EN6202), via an unspecified route of administration, administered in Arm Left on 02Mar2021 16:00 (at 71-year-old) as single dose for COVID-19 immunization. Medical history included Arthritis in knee. High blood pressure. Patient had no covid prior vaccination and no covid tested post vaccination. Patient has no known allergies. Concomitant medication included hydrochlorothiazide. The patient previously took first dose of BNT162B2 for COVID-19 immunization. The patient developed blood clots in my left leg that began swelling some on 12Mar2021 17:00 and by Monday 15Mar2021 it was huge and 16Mar2021 big and hurting. So he went to urgent care and they sent him to hospital ER. The patient was hospitalized for 3 days. Events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization. Events treatment included Ultra sound, CT scan, heparin blood thinner. The outcome of the events was not recovered.</p>

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1161921	4/2/2021	TN		F		3/1/2018	<p>her heart went back into afib one; feeling tired; numbness in her hands and fingers; tingling in her hands and fingers; lower back pain on the right side/lower back starts to hurt sometimes; weakness in legs/legs are weak; shortness of breath; feeling off; black eye; This is an initial solicited report from a non-Pfizer sponsored program, from a contactable consumer, based on information received by Pfizer. This 79-year-old female patient was involved in a patient support program. The patient received apixaban. The report describes a case of fatigue (feeling tired), hypoaesthesia (numbness in her hands and fingers), paraesthesia (tingling in her hands and fingers), back pain (lower back pain on the right side/lower back starts to hurt sometimes) and muscular weakness (weakness in legs/legs are weak). The occurrence of additional non-serious events is detailed below. The patient's past medical history included High frequency ablation and Hospitalisation. In March 2018, the patient started apixaban (Oral), (unspecified dose, twice a day). On an unknown date, the patient experienced fatigue (feeling tired), hypoaesthesia (numbness in her hands and fingers), paraesthesia (tingling in her hands and fingers), back pain (lower back pain on the right side/lower back starts to hurt sometimes), muscular weakness (weakness in legs/legs are weak), dyspnoea (shortness of breath) and feeling abnormal (feeling off). The action taken with apixaban (Oral) was unknown. At the time of the report, fatigue, hypoaesthesia, paraesthesia, back pain, muscular weakness, dyspnoea and feeling abnormal outcome was unknown. For apixaban (Oral), the reporter did not provide any causality assessments. Patient received apixaban for the indication of Atrial fibrillation. The consumer reported that in Mar-2018 during a trip with her daughter, she began feeling tired and her legs hurt. When she returned home, she was hospitalized and diagnosed with Atrial Fibrillation. Follow-up (18Mar2021): This is a follow-up solicited report from a non-Pfizer sponsored program, from a contactable consumer, based on information received by Pfizer license party for apixaban. This 79-year-old female patient was involved in a patient support program. The patient received APIXABAN. The report describes a case of ATRIAL FIBRILLATION (her heart went back into afib one). The occurrence of additional non-serious events is</p>

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detailed below Co-suspect products included Covid-19 Vaccine. The patient's past medical history included High frequency ablation and Hospitalization. Concurrent medical conditions included AFib. In March 2018, the patient started APIXABAN (Oral), (unspecified dose, twice a day). On an unknown date, the patient experienced ATRIAL FIBRILLATION (seriousness criterion medically significant), FATIGUE (feeling tired), HYPOAESTHESIA (numbness in her hands and fingers), PARAESTHESIA (tingling in her hands and fingers), BACK PAIN (lower back pain on the right side/lower back starts to hurt sometimes), MUSCULAR WEAKNESS (weakness in legs/legs are weak), DYSPNOEA (shortness of breath), FEELING ABNORMAL (feeling off) and EYE CONTUSION (black eye). The patient was treated with Surgery (heart monitor) for Atrial fibrillation. The action taken with APIXABAN(Oral) was unknown. At the time of the report, ATRIAL FIBRILLATION, FATIGUE, HYPOAESTHESIA, PARAESTHESIA, BACK PAIN, MUSCULAR WEAKNESS, DYSPNOEA, FEELING ABNORMAL and EYE CONTUSION outcome was unknown. The patient stated that she had the coronavirus Pfizer vaccine and a few days later she had a black eye. The patient was concerned about this because she takes Eliquis so she asked a healthcare professional for advice they then informed her that the vaccine had caused her black eye. She was told that she cannot miss her second vaccine and that she might have to stop Eliquis. Patient was concerned about having to stop and had some questions. The patient reported that, she had been on Eliquis for a while and she had been doing just fine. She recently took the Pfizer Covid vaccine and a week or two later she developed a "black eye". She described the color around her eye as eggplant purple. She remembered her mother would have blood vessels burst around her eye, so at first, she thought nothing of it. She said the day before yesterday she went with her daughter while she got the Moderna Covid vaccine. She asked the nurse administering her daughters Moderna Covid vaccine if the Pfizer vaccine could cause black eyes. The patient said the nurse did some research and told her the the Pfizer vaccine was known to cause hemorrhaging, and that the vaccine caused the black eye. The nurse told the patient she should go to her HCP as soon as possible and get blood work done. The patient did not

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say anything else was abnormal about her blood work. She told the HCP what happened to her eye after she was given the Pfizer Covid vaccine. The HCP told her that no matter what the patient should get the second Pfizer vaccine, even if she had to stop the Eliquis for a few days. The patient said she did not want to stop the Eliquis because she has been doing wonderful on the medication and did not think the Eliquis was the cause of the black eye. She said she will have a talk with her normal primary care doctor as well as her cardiologist. The patient said she rather not get the second covid then stop the Eliquis. The patient started Eliquis two years ago after her heart went into "full afib" she had an ablation procedure and they shocked her heart three times to get it back into rhythm. Since starting the Eliquis the patient said her heart went back into afib one time. She wore a heart monitor and her heart went back into sinus rhythm on its own. She also mentioned that her HCP prescribed her a diuretic but she said she has a terrible reaction to it. She was prescribed the diuretic to help with the swelling around her ankles. She said the diuretic was also to help "keep congestion from her heart". The diuretic makes her feel "terrible" so her HCP allows her to cut the pill in half or quarters and take as needed to keep swelling down. She said the diuretic makes her feel faint and she even passed out one time while walking in the mall. She said she has not taken it in a while. The patient said she had a lot of allergies to medications, to many to list.

DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Mar-2021, Prothrombin time: 16.2 seconds. For APIXABAN(Oral), the reporter did not provide any causality assessments. Patient received apixaban for the indication of Atrial fibrillation. The consumer reported that in Mar-2018 during a trip with her daughter, she began feeling tired and her legs hurt. When she returned home, she was hospitalized and diagnosed with Atrial Fibrillation. The strength of Eliquis was 5 mg. Most recent follow up information received on 18-Mar-2021 from Non-Health Professional incorporated above includes : New events added, lad data, concomitant drugs and narrative updated.; Sender's Comments: BMS Medical Evaluation Comment: This 79-year-old patient had atrial fibrillation after therapy with apixaban. Elderly age and underlying atrial fibrillation can be associated with increased risk of arrhythmias and

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based on the absence of etiological plausibility; the  
reported event is considered not related to apixaban.

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1162036	4/2/2021	AL	73	M	1/21/2021	2/13/2021	Fluid overload; shortness of breath; Graft clotted off; This is a spontaneous report from the Pfizer sponsored program. A contactable Nurse reported that a 73-year-old male patient (husband) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot Number: EK4176), via an unspecified route of administration, on Right Arm on 21Jan2021 at single dose for COVID-19 vaccination. Medical history included ongoing Diabetes, ongoing Vascular problems, ongoing Congestive heart failure; all (At least 15 years ago), blood thinners, dialysis from Sep2020 (husband has been on Dialysis since Sep2020. last time he was dialyzed was 11Feb2021) and Allergic to seafood and nuts. Concomitant medication(s) included clopidogrel bisulfate (PLAVIX) for blood thinner and acetylsalicylic acid (ASPIRIN) for blood thinner. The patient experienced fluid overload and shortness of breath on an unspecified date, graft clotted off on 13Feb2021. The patient was hospitalized for fluid overload from 16Feb2021 to an unknown date. She stated that her husband is on dialysis in the hospital and is going to miss the second dose appointment for the Pfizer covid 19 vaccine. She wanted to know what to do about the second dose. She wanted to know how long a person has to be off steroids before getting the vaccine and if she can reschedule the second dose appointment as he was hospitalized. Her husband is allergic to seafood and nuts. His appointment is at 10:30 (On 17Feb2021). She reported that he is on dialysis and his graft clotted and he has not had any dialysis in about a week. Her husband had fluid overload and shortness of breath. She said that he had to have an emergency port put in and they dialyzed him in the ER. He typically goes Tuesday or Thursday or Saturday. She said that he had not been dialyzed in over a week and he was getting fluid overload. She said that the last time he was dialyzed was 11Feb2021. She clarified that her husband has been on Dialysis since Sep2020. She said that when he got his Covid vaccine they checked that he was on Plavix and Aspirin. She said that they are supposed to hold the site because he has the tendency to bleed more while on blood thinners, but she does not know if that was the reason. She said that she knows what it was and he had to be dialyzed because of the fluid, but she was not told that her husband had fluid overload by the physician.

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She said that her husband has congestive heart failure as well. The patient was hospitalized due to Fluid overload from 16Feb2021 to ongoing. Outcome of all events was unknown and for remaining event Graft clotted off was not recovered. ; Sender's Comments: The causal association between the suspect, BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) and the events, fluid overload, graft clotted, shortness of breath is unrelated. The impact of this report on benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events.



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1162046	4/2/2021		69	F	1/1/2021	1/1/2021	Lung disorder; Post procedural complication; Shaking; Feeling down; Tiredness; This is a solicited non-interventional study report from the marketing program received from a contactable consumer (patient). A 69-year-old female patient received first dose of bnt162b2 (BNT162B2), intramuscular in Jan2021 (Batch/Lot number was not reported) as single dose, second dose intramuscular on 15Feb2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation; methotrexate sodium (METHOTREXATE SODIUM), route of administration, start and stop date, batch/lot number and dose were not reported for an unspecified indication; adalimumab (HUMIRA, Solution for injection in pre-filled syringe), subcutaneous from 2015 (Batch/Lot number was not reported) to 2020, at 40 mg (40 mg, 1 IN 2- 2), subcutaneous from 2020 (Batch/Lot number was not reported) and ongoing, at 40 mg (40 mg, 1 IN 2- 2) for Moderate To Severe Rheumatoid Arthritis and lupus. Medical history included hatal hernia, blood clots on legs were not worsened with Humira, non smoker, abstains from alcohol, allergy to latex manifested by rash, allergy to Sulfa drugs manifested by upset stomach. Concomitant medications included lisinopril (LISINOPRIL) taken for blood pressure, start and stop date were not reported; ezetimibe (ZETIA) taken for blood cholesterol, start and stop date were not reported; folic acid (FOLIC ACID) taken for rheumatoid arthritis, start and stop date were not reported; esomeprazole magnesium (NEXIUM) taken for hiatal hernia, start and stop date were not reported; apixaban (ELIQUIS) taken for blood clots on legs, start and stop date were not reported; prednisone (PREDNISONE) taken for an unspecified indication, start and stop date were not reported; colecalciferol (VITAMIN D) taken for an unspecified indication, start and stop date were not reported; proline (PROLIN) taken for an unspecified indication, start and stop date were not reported; tramadol (TRAMADOL) taken for pain, start and stop date were not reported. The patient experienced lung disorder on an unspecified date with outcome of not recovered, post procedural complication on an unspecified date with outcome of unknown, shaking on an unspecified date with outcome of not recovered, tiredness in Jan2021 with outcome of recovered in Jan2021, feeling down on an unspecified date with

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outcome of unknown. Clinical course: Solicited report by a consumer of a 69 year old female with events of small tumor on thyroid, blood clot on both legs, coughing and shortness of breath and non-serious lungs issue caused by methotrexate, after surgery shaking a bit, tired and cloudy weather caused to feel down a bit with HUMIRA 40MG/0.4ML (ADALIMUMAB). The patient had a relevant medical history of hiatal hernia and blood clots on both legs. On unknown dates, the patient experienced lungs issue caused by methotrexate, after surgery shaking a bit and cloudy weather caused to feel down a bit. In 2016, the patient experienced blood clot on both legs. In Sep2020, the patient experienced small tumor on thyroid. On 01Sep2020, the patient experienced coughing and shortness of breath. In Jan2021, the patient experienced tired. In Jan2021, the tired resolved. Methotrexate and covid-19 vaccine were also considered suspect. In Sep2020, the patient was admitted in hospital for cough, shortness of breath and was treated with unknown oral and intravenous antibiotics. While she was in the hospital, it was discovered that she had a tumor on her thyroid. She had stayed a week in hospital. She also had a lung issue. It was discovered lots of scar tissue on lungs and according to the physician it might be from patient's lupus, rheumatoid arthritis or methotrexate. The physician said that it was caused by the methotrexate not the Humira. Methotrexate was stopped for her. Patient denied to have pulmonary fibrosis and said that according to her doctor she did not have it and she did not know her diagnosis as it was not discussed with her doctors. For problems in lungs, patient was on oxygen. Patient was off of Humira for three weeks. She had surgery on thyroid biopsy. After the surgery she was shaking a bit. She thought it was because of the anesthesia but she was fine shortly after. The biopsy results were inconclusive which looked like it was not cancerous but physician could not really tell patient if it was or it was not. On unknown date in 2020, patient had restarted Humira again. On 04Dec2020, patient had thyroid tumor removed and was on oxygen until 11Jan2021. Sometimes the cloudy weather caused patient to feel down a bit. She did not have any paper work for the blood test. It was unknown if patient was enrolled in a covid-19 vaccine trial. In Jan2021, patient received 1st dose covid-19 vaccine manufactured by

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Pfizer. On 15Feb2021, patient received 2nd dose covid-19 vaccine manufactured by Pfizer. The reported events except for coughing were serious as medically significant. The patient underwent lab tests and procedures which included biopsy: inconclusive in Oct2020 and in Dec2020, biopsy of tumor: inconclusive in Sep2020, blood test: unknown results in 2020, computerised tomogram of chest: unknown results in Oct2020, COVID-19 TEST: negative in 2020 and in 2020. The action taken in response to the events for bnt162b2 was not applicable, for methotrexate sodium was permanently withdrawn on an unspecified date, for adalimumab was dose not changed. The reporter's assessment of the causal relationship of the events with the suspect products bnt162b2 and methotrexate sodium was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment. Pfizer is a marketing authorization holder of methotrexate sodium in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of methotrexate sodium has submitted the same report to the regulatory authorities. Information on Lot/Batch number has been requested.; Sender's Comments: Considering temporal relationship, a possible contribution role of vaccination with BNT162B2 to the onset of events, cannot be completely excluded. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1162121	4/2/2021	FL	69	M	3/12/2021	3/13/2021	<p>Left leg basically numb and rubbery/ leg had just gone to sleep; Tried to stand up and fell; Urinating almost non-stop; going about every 2 hours and going a lot; he had no strength except a smidgen of strength in the right leg; trying to learn how to walk/ He can't walk to the commode very well; Weight: States 201; then mentions that during the night he thought about how much he was urinating and got on the scale out of curiosity and it said he weighs 191; Afraid he was having a stroke; he had trouble holding his fork/Like a cramp in hand; Sore Arm; This is a spontaneous report from contactable consumer (patient). A 69-year-old male patient received his second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6199) at the age of 69-years-old, via an unspecified route of administration in right arm on 12Mar2021 at single dose for COVID-19 immunization. Medical history included blood clots (reported as blood thinner). Concomitant medication included apixaban (ELIQUIS) from 2019 and ongoing as blood thinner. The patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6199) at the age of 69-years-old, via an unspecified route of administration in right arm on 16Feb2021 at 14:00 at single dose for COVID-19 immunization which gave him severe diarrhea, nausea, gastrointestinal distress, a sore arm and it wore him out. After the second dose of the vaccine on 13Mar2021 which was administered in a public health department, the patient experienced sore arm. He was concerned because around 02:00 on 19Mar2021, he got up to go to the bathroom and noticed his left leg was basically numb and rubbery. As soon as he tried to stand up, he fell. He thought the second vaccine was the one everyone says will be harder than the first. They even gave him a sheet of paper that scared the hell out of him. Thought he was okay after the second vaccine until around 02:00. At first, he thought his leg had just gone to sleep. It was like having noodles for legs. The patient has been urinating almost non-stop which also started around 02:00, this was what woke him up. He had to crawl on hands and knees after falling to get into the bathroom, he had no strength except a smidgen of strength in the right leg. On 18Mar2021, while eating dinner, he had trouble holding his fork and did not think much about it. He had a cramp feeling in right hand. Today, while eating lunch with a fork, he also had a</p>

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1161020	4/2/2021	TX	69	M	2/27/2021	2/28/2021	<p>difficulty. The patient eats with his right hand. The patient has been trying to learn how to walk since early this morning. He has worn out his wife since she was cleaning up after him in the bathroom and helping him walk. He couldn't walk to the commode very well, couldn't hold his water, and has been making a mess all day. He was at first afraid he was having a stroke but had no stroke symptoms. The patient reported that his weight was 201, then mentioned that during the night he thought about how much he was urinating and got on the scale out of curiosity and it said he weighs 191. At this time, his leg weakness persists but he was able to stand and hold his own body weight. Issue with holding fork and cramp feeling in right hand was persisting. Urinating was persisting and stated he was going about every 2 hours and goes a lot. The outcome of the event pain in arm was recovered on 17Mar2021; unknown for stroke, fall, and weight loss; and not recovered for all other events.</p> <p>I seem to have thrown a clot that blocked Right Optic Nerve Artery. Immediate blindness in Right Eye.</p>

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1160456	4/2/2021	MI	71	F	3/24/2021	3/28/2021	Went to bed on fourth night after shot with symptoms from shot seemingly resolved. Woke up the fifth day and got out of bed to discover intense pain in right leg. Nothing like a charley horse cramp. Small nodule about the size of a pea, located 6 inches up from outside ankle bone. ¼ inch beneath skin. Great difficulty putting weight on right leg, created acute feeling of pinching or twisting pain. Level of pain (1-10) was an eight [note: my definition of the "worst pain imaginable" has been altered after being stung by a tarantula hawk wasp]. I hobbled to the bathroom and took two aspirin. Hobbled around on flat surfaces gradually reduced pain to a level 3-4, though I had trouble walking up and down steps for the remainder of the day (level 5-6). Fifth day, the pain level on flat surfaces was down to 1-2, on stairs, 2-3. at end of sixth day, no pain on flat surfaces, 1-2 on stairs. No pain by evening. I took two aspirin in morning and two in afternoon during this period. Seventh day, I woke up to find pain returned as I got out of bed (level 4) but was walked out within in three to four hours. I had talked with my sister (an extreme case of Factor five leiden, which I do not have) and felt this was not a blood clot, but went in to the doctor's because my husband and I were about to leave on vacation. She ordered a Doppler and ultrasound (which showed no blood clot) after telling me this type of muscle/nerve pain was just starting to be reported in patients after the vaccine. She had seen an earlier patient who had swelling and inflammation, which showed no other explanation after testing than post-vaccination reaction. I felt no lump, heat, or tenderness pushing on the skin. Doctor requested I report it on-line.
1160323	4/2/2021	AZ	66	M	3/4/2021	3/6/2021	My Ooxgyen was dipping into high 70s to low 80s with oxygen @4 lpm, Also very dehydrated and went to hospital due to feet and ankles swelling up alot.. In the hospital for 9 days to lower clots from legs and constant high oxygen therapy also hemoglobin and hematocrit went upper range. Im home now doing better, but I dont think I should take the 2nd dose.
1159981	4/2/2021	CA	34	F	1/11/2021	1/11/2021	hemorrhagic bleeding (period), blood clot via bleeding. 1 week of bleeding, required transfusion cbc/esr/crp. now have +factors for antiphospholipid syndrome along CCP. along w/ joint pain in her right hands, fingers and right knee. have swelling to the fingers.

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1159805	4/2/2021	CO	20	F	4/1/2021	4/1/2021	Patient received first dose of Moderna vaccine. Later that day, patient experienced heavy vaginal bleeding that included blood clots and required the use of a sanitary pad. She had her period the previous week and it had since stopped so she does not believe it's her period. At the time of the call to the pharmacy, 8:30am the following day, patient was still actively bleeding. Advised patient to monitor for other signs and symptoms of bleeding such as excessive bruising, nose bleeds, gum bleeds, and to check her stool for the appearance of coffee grounds. Patient was calling to try to find a doctor nearby who could see her. Advised patient that if she could not find a doctor to go to urgent care if the bleeding continued or worsened.
1159544	4/2/2021	NY	55	M	3/1/2021	4/1/2021	Mild abdominal pain and cramping. Blood clot with stool.
1158711	4/2/2021		80	F			Blood clots; This is a spontaneous report from a non-contactable consumer through a Pfizer sales representative. An 80-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number and expiration date were not reported) as a single dose, with route of administration and therapy date unspecified, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient had blood clots. The patient was hospitalized on an unspecified date due to the reported event. The outcome of the event, blood clot, was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.

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1161172	4/2/2021	CO	54	F	3/24/2021	3/26/2021	I was vaccinated last Wednesday, March 24, at 8 pm with the Janssen vaccine. As soon as I was vaccinated (on my left arm), I put on my coat and I felt a brief and sharp pain in my left arm. And nothing else. On Friday night, I felt a very slight tingling in my left hand. And pain in the upper arm, in the region between the place where the vaccine was applied and my elbow. This pain seemed to spread to the forearm. Since then, I have tingling / numbness in my left hand and forearm and pain throughout my left arm, left shoulder, upper left center of the back and neck. And these pains and numbness have been increasing every day. Ten days have passed since the vaccine was applied and the condition only worsens. I took Voltaren in the last 3 days and the pain has not subsided. I am worried and scared. Was it a case of thrombosis or pulmonary embolism? In addition, I saw in the CDC information that, during the JNJ vaccine tests, there was a case of a severe reaction called brachial neuritis; as I didn't know what it was, I did a Google search and, apparently, the symptoms I have coincide with those of this disease. Anyway, what do you advise me to do? I have waited until now imagining that the pain and numbness would lessen. But the opposite happened and everything just makes it worse. I look forward to feedback and guidance. I haven't been to a doctor yet, but it looks like it will be necessary. Thanks.



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1159908	4/2/2021	AZ	60	F	3/6/2021	3/12/2021	She got her vaccine and had no reactions at all. On 3/12/21 she was in her car and started having stabbing pain in the left side of her chest under the rib. She thought it was gas pains and dismissed it, and then it started radiating towards the front and the stomach. On 3/16/21 she went to the ER and they did a CT scan that showed that she had a blood clot on her spleen. With that they gave her the diagnosis of idiopathic splenic infarction. She was then sent by ambulance to another hospital to be admitted in case she was needing surgery. She was given heparin and on that for 2 1/2 days. They determined that 60% of her spleen is dead, blood supply cut off to it, and the other 40% is nonfunctional. On 3/19/21 they gave her vaccines of Prevnar 13, HIB, meningococcal, meningococcal B, and a flu vaccine. She was discharged on the 3/20/21 with Plavix. She saw her regular doctor yesterday and he diagnosed her with functional asplenia and to continue the Plavix. She is no longer having any symptoms after dissolving the blood clot.
1162619	4/2/2021	NV	18	F	3/16/2021	4/1/2021	Superior sagittal sinus thrombosis diagnosed on 4/1/2021. Symptoms started early on April 1, 2021
1162715	4/2/2021	AZ	67	F	3/9/2021	3/9/2021	I was 2 weeks post prolapse surgery and healing quite well. I thought that would be enough time to wait to heal and get my vaccine. I got the vaccine in the afternoon and that night at about 10 pm I started bleeding profusely with blood clots coming out of my vagina. Before this I had no bleeding post surgery or any complications. This lasted all night. I went to the surgeon next day and the bleeding and blood clots had stopped. 2 days later it started again all night long. I refrained, stupidly, to not go to ER because of the virus. It stopped next day and then 2 days later I woke up in blood and clots and it would not stop. I had to go to the ER my surgeon said to stop it. He added more stitches to my previous surgery.

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1159748	4/2/2021	WV	45	F	3/20/2021	3/21/2021	The evening (3/20/21)I received the vaccine I noticed fatigue, headache and chills. The next morning I developed shortness of breath. The day after that my left left began swelling for no reason, was slightly discolored and warm to the touch. As the week went on my shortness of breath became greater and my leg more swollen. On (3/26/21) I sent to the ER by my doctor. Had a ultra sound and discovered an extensive DVT in my left groin down to behind left knee. Had a CT and discovered blood clots in my lungs. I had never had any underlying health conditions or been on medications, don't smoke, no complaints prior. Was transported to hospital spent 2.5 days in ICU before being moved to a regular bed for a total of (4) days hospitalized. The doctor installed two sheaths on each side of groin, injected my lungs with medication to blast/dissolve the clots and installed a filter in the main artery to catch any clots that may break away from leg. I was also put on a Heparin drip while in ICU. The next day the doctor went and the procedure was a success dissolving the clots. He removed the sheaths. I went back to ICU. The next day (3/28/21) a second ultra sound was done to left leg and DVT is still in left leg. Have been described Eliquis blood thinner.

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1162139	4/2/2021	AL		M	2/6/2021		<p>He was diagnosed with multiple blood clots in his lungs/ clots may have appeared in his leg and went to his lung; bed ridden; pain in left side; This is a spontaneous report from a contactable consumer (the patient). A 70 year old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH, COVID-19 MRNA VACCINE)), via an unspecified route of administration on 06Feb2021 (Lot number: UNKNOWN) as a single dose for COVID-19 vaccination. The patient medical history and concomitant medications were not reported. Historical vaccination included BNT162B2 (PFIZER-BIONTECH, COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration on 16Jan2021 (Lot number: UNKNOWN) as a single dose for COVID-19 vaccination. The patient reported that he received the first dose of the Pfizer-BioNtech Covid-19 vaccine on 16Jan2021. On 06Feb2021 he received the second dose of the vaccine. Twelve days later he was diagnosed with multiple blood clots in his lungs, and from "15Feb2021 to 16Feb2021" he was hospitalized. He was prescribed to take Eliquis (Apixaban) a blood thinner, at 5 mg tablets for 6 months. He also reported that during that period (first part of Jan and part of Feb) he was bedridden because he had a lot of pain in his left side and it would not let him get out of bed, so he was on bed for a while. His primary care doctor told him that the clots may have appeared in his leg and went to his lung. The patient would like to know if any participant developed blood clots during the clinical trials of the vaccine. The clinical outcome of the events was unknown. Information on the lot number has been requested.</p>

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1154074	4/1/2021		57	M	2/25/2021		<p>Blood clot/very large blood clot from his thigh to his calf; Joint pain; chills; he can't even walk now; leg pain; This is a spontaneous report received from a contactable consumer (patient's wife). A 57-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number: EN6202), via an unspecified route of administration, on 25Feb2021 (at the age of 57-years-old), at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The consumer stated she's asking on behalf of her husband. He received his first dose of Pfizer-BioNTech COVID-19 Vaccine on 25Feb2021 and had Joint pain and chills after that (on unspecified date in 2021) he was diagnosed with Blood clot (unspecified date in 2021); she stated he had no history of similar health issues and wanted to know if it could be directly linked to this vaccine. The wife further reported that it's dramatically changing his life, he can't even walk now. He had the Covid vaccine on 25Feb2021 and he has no history of blood clots. He developed a leg pain (on unspecified date in 2021) which was odd and they thought that maybe it was some arthritis or something like that. They went to the orthopedist and he was being treated for what the orthopedist thought was a bakers cyst. But then they discovered it was a very large blood clot from his thigh to his calf. They would like to know about this. They have been looking into what he had experienced, and it seems very unusual. It just seems too coincidental that this happened after the Covid vaccine. The emergency room doctor of course shut them down immediately and said that the Covid vaccine never would have done this. But the patient's doctor yesterday said that there are too many unknowns to say for sure that the Covid vaccine didn't cause this. She is not saying that they are against the Covid vaccine, but they are concerned. The patient is on blood thinners now and they just need to know if there is a possible correlation. She had heard on the world news that there is a connection after receiving the (company name) Covid vaccine and now they are shutting this vaccine down in (region name). She saw on the news last night they were asking if there is a correlation with the Pfizer and (company name) Covid vaccines and this. It is very concerning. They have been trying to do research and there is</p>

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							nothing that you can find. The only thing that they did see online was about the doctor that died of a blood disorder in (state name), he had thrombocytopenia. The patient is going to be sent to see a vein doctor. She stated that he has a lot of things ahead of him and he is too young to be dealing with all of this. They are going to be following up with the vein doctor and she would like to have this information when the vein doctor calls later today. The reported adverse events resulted to an emergency room and physician office visit (went to the orthopedist). The patient received corrective treatment as response to the reported events. Outcome of the events was unknown.
1157076	4/1/2021	MO	49	F	3/30/2021	3/30/2021	Anxiety before shot Tingly tongue about 10minutes after Monitored for 30minutes and that went away/Pt feeling fine when left Pt called the pharmacy to report elevated heart rate to 90 bpm at 5pm offered to call paramedics if pt wanted / she decided it might be anxiety so no call better at 7-8pm Elevated during sleep to 151 bpm and still high at work in am 143bpm Called Dr. and advised to ER Checked for Cardiac event and blood clots Tests done EKG/blood work for tropin and d-dimer/ chest xray- results normal except an elevated d-dimer pt monitored until 4pm and released follow up with pcp today 4/1 Dr. and said no treatment at this time / pt to report to doc if pulse rate stays elevated but right now they say since it is fluctuating up and down no tx HA and 99.6fever today at 4:18pm Will follow up with pt and pcp on Friday 04/02
1156984	4/1/2021	PA	68	F	3/27/2021	4/1/2021	I received a phone from patients husband stating patient was in the hospital with blood clots in her spinal cord and the part of the patients brain was dying and patient was in a coma. I called Hospital to get more information but they would not give me information they said it was HIPPA information
1156434	4/1/2021	ME	64	F	3/21/2021	3/22/2021	acute left leg pain and swelling 15 hour after vaccination with subsequent same day ER visit and ultrasound diagnosis of acute left leg DVT (blood clot) diagnosed.

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1156253	4/1/2021	AZ	68	M	3/12/2021	3/12/2021	I didn't have pain in the arm, after an hour I had a slight headache. The headache lasted about a day. After the 3-4 day I had severe diarrhea and stopped taking my supplements. It stopped for a couple days then came back for a day. I had no headache or pain, just 3 bad episodes of diarrhea. On March 24th I went into the Hospital with severe pain in my lower left back side. I thought I was passing a kidney stone, with the pain I was having. When I got there they did a CT scan and blood work and it wasn't kidney stone but I had a blood clot on the lower left side of lung and the right side as well. They immediately put me on blood thinners. I was there for a day and a night. They released and put me on medication. I've had minor pain but nothing like the pain I had before. I have since followed up with a Pulmonologist and PCP. Pulmonologist said I had blood clots but couldn't give me a cause. My PCP said she thought I had or have Covid. I asked to have my blood drawn and she said it was too late for that because I had taken the vaccine already.
1155524	4/1/2021	CA	70	F	3/25/2021	3/26/2021	Pt. states she started to spit blood approximately 12 hours after Covid 19 vaccines. It happened both times. 1st dose given on 2/25/21, reporting second dose from 3/25/21 because pt. sought ER care at . She states the blood was coming from throat area, not vomiting. She just spit out blood and blood clots. Dr. will send her to ENT to rule out lesion.
1155444	4/1/2021	NE	53	F	3/25/2021	3/26/2021	Minor change - cotton mouth at some point in every day since starting 1 hour after vaccination, including slight difference of tongue feeling thicker as in slightly thirsty and dry. MAJOR CHANGE - 12 hours after vaccination, like a faucet turning on menstrual cycle break-through heavier somewhat clotted bleeding starting 4 days early which NEVER happens - convinced is due to the vaccine. Flow for 12 hours then stopped for 12 hours, going on since but now into the regular week. Want to know why. VERY CONCERNED about girls such as 13-year olds and what the vaccine might do to their female bodies and ability to have children and to have normal cycles.

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1155198	4/1/2021	DE	57	F	2/16/2021	2/18/2021	2/18/2021 Post menopausal bleeding LMP 7/2018. No significant gynecological history other than pregnancies/childbirth. No prior h/o abnormal vaginal bleeding, No known history of uterine fibroids. No h/o bleeding/coagulation disorder. 2/18/2021 Onset of vaginal bleeding began with light flow and gradually increased with use of pads and tampons. No clots. Menstrual period lasted until 2/23/2021. This appeared to be similar to menstrual periods in the past except that there was no cramping on the first day and in the past would have expected to end on 2/22) No further vaginal bleed or spotting since 2/23
1155177	4/1/2021	ID	57	M	3/16/2021	3/28/2021	Blood clots in urine
1155130	4/1/2021		64	F	3/16/2021	3/17/2021	Deep vein Thrombosis cot, followed 2 days later by multiple blood clots in her lungs.

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1157488	4/1/2021	NJ		F	3/19/2021		MORE BLEEDING AND PASSING MORE CLOTS THAN NORMAL ONE HOUR POST GETTING THE SHOT; This spontaneous report received from a patient concerned a 79 year female. The patient's height, and weight were not reported. The patient's concurrent conditions included uterine cancer, high blood pressure, seasonal allergy, and thyroid, and other pre-existing medical conditions included the patient had no known drug allergies. The patient had no DM and no cholesterol. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805018, expiry: UNKNOWN) dose was not reported, 1 total, administered on 19-MAR-2021 12:05 to right arm for prophylactic vaccination. Concomitant medications included unspecified thyroid pill. On 19-MAR-2021, one hour post getting the shot the patient noticed more bleeding and passing more clots than normal. The patient denies abdominal pain or any other symptoms of concern. The patient also mentioned that uterine cancer - surgery planned for end of March 2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from more bleeding and passing more clots than normal one hour post getting the shot. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210340677-Covid-19 vaccine ad26.cov2.s-Bleeding. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY, UNDERLYING DISEASE
1154104	4/1/2021	KY		M			Clot blood; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced clot blood on an unspecified date with outcome of unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.



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1155567	4/1/2021	MI	65	M	3/13/2021	3/17/2021	Deep Venous Thrombosis, 5 days of calf/leg swelling, diagnosed 8 days later, treated with Xarelto. Currently being treated.

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1154072	4/1/2021	NY	74	F	3/3/2021		<p>doesn't feel that well; It hurt there at where the needle went in, in the beginning; something is happening to her arm but it is not where the needle went in/it hurts down toward the elbow and it penetrates through the epidermis, endodermis and the muscle and feels like it's at the bone; something is happening to her arm but it is not where the needle went in/it hurts down toward the elbow and it penetrates through the epidermis, endodermis and the muscle and feels like it's at the bone; something is happening to her arm but it is not where the needle went in/it hurts down toward the elbow and it penetrates through the epidermis, endodermis and the muscle and feels like it's at the bone; something is happening to her arm but it is not where the needle went in/it hurts down toward the elbow and it penetrates through the epidermis, endodermis and the muscle and feels like it's at the bone; This is a spontaneous report from a contactable consumer (patient). A 74-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EN6205), via an unspecified route of administration, administered in the left arm on 03Mar2021 (at the age of 74 years old) at a single dose for COVID-19 immunization. Medical history included lumbar spine infusion (operations on spinal cord) from an unknown date and unknown if ongoing. There were no concomitant medications. It was reported that the patient needed the call handler to speak slowly, she doesn't feel that well. She had the first dose of BNT162B2 last 03Mar2021 and the second dose will be on 23Mar2021. She said something was happening to her arm but it was not where the needle went in, that is not where it is. It hurt there at where the needle went in, in the beginning but now it hurts down toward the elbow and it penetrates through the epidermis, endodermis and the muscle and feels like it's at the bone. She hopes it was not a blood clot. She has been looking at the website and they say people could have blood clots and she does not know if this was a blood clot, she can't hardly lift her arm, it was the left side that the shot was in because her right side is partially paralyzed due to effect of lumbar spine infusion and so when she tried to get up sometimes she can hardly lift that arm and so she didn't know what to do if she should call the primary care doctor to see if she has a clot but she read it and it says to call this number if you</p>

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are having compactions and she been on hold over and hour and a half. It was hurting and the feeling like she couldn't hardly raise the arm or get any kind of strength in it. She knew in Europe they have had few people who have had blood clots, and she thought could that be a sign of a blood, like blood not moving through her veins like it is supposed to. It is not moving it has not made it to her heart yet. She says it is associated with the product, this is the only thing she has had in her arm she knows it is the product. She said her birthday just passed. She turned 75 years old but when the issue started in her arm she was 74 years old. It did not start the first week, the first week it was just sore around where the shot went in but then last week it started happening where it was hurting down her arm and she was getting close to the second shot which she doubts she will have but it is the 23rd which is next week. She used to be 5'2" but the operations on her spinal cord, she guesses she might be 4'10 now. She does not know because she can't hold her head up straight because the doctor that fused it, she indented it instead of it being more out and because of that her head is forward and down. It was also reported that she hasn't been to the doctor she only goes to pain management for him to check out her body and everything and renew prescriptions. The outcome of the events was unknown.

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1153985	4/1/2021	KS	70	F	3/10/2021	3/15/2021	Blood clot in the lung; A spontaneous report was received from a consumer concerning a 70-years-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced blood clot in the lung/ Pulmonary thrombosis. The patient's medical history included hyperthyroidism. Products known to have been used by the patient, within two weeks prior to the event, included levothyroxine for hyperthyroidism. On 10 Mar 2021, approximately five days prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Batch number not provided) via unknown route for prophylaxis of COVID-19 infection. On 15 Mar 2021, the patient developed a medically significant event of blood clot in her lung and was hospitalized for 2 days followed by short of breath and cannot walk very far. Treatment for the event included blood thinner. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the event, blood clot in the lung/t Pulmonary thrombosis was not provided.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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1153939	4/1/2021	MA		F	2/13/2021	2/14/2021	<p>clot in lung; pain in her left lower lung from back; Shortness of breath; fever 102F; nausea; very very tired; A spontaneous report was received from a female patient of an unspecified age who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced pyrexia (fever 102F), nausea (nausea), illness (very sick), fatigue (very very tired), dyspnoea (shortness of breath) and back pain (pain in her left lower lung from back). The patient's medical history was not provided. No concomitant product use was reported. On 13 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly in left arm for prophylaxis of COVID-19 infection. On 14-Feb-2021, the patient felt very sick, had fever of 102 degrees Fahrenheit, nausea, pain in her left lower lung which had radiated from the back, shortness of breath and was very tired. On 15-Feb-2021, the patient got hospitalized and underwent laboratory examination findings of which were unknown. On an unspecified date, it was known that the patient had clot in the lungs and was receiving a daily shot of an unspecified drug as a remedy. On 13 Mar 2021, the patient received their second of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly in left arm for prophylaxis of COVID-19 infection. The patient took 2X strength of Tylenol right before receiving the second dose of vaccine as per the Physician's recommendation. Treatment information included Tylenol. Action taken with mRNA-1273 was not applicable. The outcome of the events, pyrexia (fever 102f), nausea (nausea), illness (very sick), fatigue (very very tired), dyspnoea (shortness of breath) and back pain (pain in her left lower lung from back), was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events (pyrexia, nausea, back pain, dyspnoea, and fatigue) a causal relationship cannot be excluded. Very limited information regarding these event (Pulmonary embolism) has been provided at this time. Further information has been requested.</p>

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1153927	4/1/2021	CA	77	F	2/10/2021	2/23/2021	A spontaneous report was received from a consumer who is also the 77-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced blood clots in lung/pulmonary embolism. The patient's medical history was not provided. No concomitant product use was reported. On 10 Feb 2021, the patient received first of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 23 Feb 2021, the patient was admitted to hospital with blood clots in lung. Patient was put on blood thinner. On 26-Feb-2021, the patient was discharged from hospital. Treatment medication included unspecified blood thinners. Action taken with mRNA-1273 was unknown. The outcome of the event, blood clots in lung/pulmonary embolism, was reported as resolved on 26-FEB-2021.; Reporter's Comments: Very limited information regarding the events has been provided at this time and is insufficient for causality assessment. Further information has been requested.

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1153914	4/1/2021	NY	72	M	1/10/2021	1/11/2021	<p>dark blood clot coming out of his penis; Gross Hematuria; dark urine; Redness arm; Sore Arm; Swelling arm; A spontaneous report was received from a healthcare professional who was also a 72-year old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events redness arm/ vaccination site erythema, sore arm/ vaccination site pain, swelling arm/ vaccination site swelling, gross hematuria/ hematuria, dark blood clot coming out of his penis/ hemorrhage urinary tract, and dark urine/ chromaturia. The patient's medical history was not provided. No relevant concomitant medications were reported. On 10 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot batch: 013L20A) intramuscularly for prophylaxis of COVID-19 infection. On 11 Jan 2021, the patient experienced the events redness, sore arm and swelling. On 20 Jan 2021, the patient experienced the events gross hematuria, with dark blood clot coming out of his penis. The patient had urine analysis (no results provided), and was still urinating dark urine. No treatment information was provided. Action taken with mRNA-1273 in response to the events was unknown. The outcomes of the events, vaccination site erythema, vaccination site pain, and vaccination site swelling, were considered recovered on an unspecified date. The outcomes of the events, hematuria, hemorrhage urinary tract, and chromaturia, were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.</p>

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1154148	4/1/2021	CO	51	F	3/1/2021	3/17/2021	DVT (deep vein thrombosis) in right medial subclavian; superficial thrombosis in right proximal basilic vein; right arm swelling in the setting of receiving her Pfizer covid vaccine in the right arm 1 week prior; This is a spontaneous report received from a contactable healthcare professional. A 51-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 intramuscular, administered in arm right in Mar2021 (Batch/Lot number was not reported) as a single dose for COVID-19 immunization. Medical history included hyperlipidemia, acute pancreatitis, May-Thurner syndrome, and allergies: penicillin, IV contrast. Concomitant medications included drospirenone, ethinylestradiol betadex clathrate (YAZ), fenofibrate, and levothyroxine. Patient is not pregnant at the time of vaccination. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. Patient has not been tested for COVID-19 since the vaccination. Patient was seen at the ED for right arm swelling in the setting of receiving her Pfizer COVID vaccine in the right arm 1 week prior. She was found to have a DVT (deep vein thrombosis) in right medial subclavian and superficial thrombosis in right proximal basilic vein. The events started on 17Mar2021 09:00. AE resulted in emergency room/department or urgent care. Patient was recovering from the events. Treatment for AEs include anticoagulation. Information about lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of subject vaccine cannot be excluded for the DVT and other reported events, based on temporal relationship. However the reported events may likely represent intercurrent medical conditions in this patient. There is very limited information provided in this report. This case will be reassessed upon receipt of follow-up information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.



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1157533	4/1/2021			M		3/25/2021	<p>DIZZINESS; FELL; HURT HIMSELF; SOME DAMAGE TO HIS KIDNEYS IN THE PROCESS (BLOOD CLOT); SOME DAMAGE TO HIS KIDNEYS IN THE PROCESS (BLOOD CLOT); CONFIRMED COVID-19 POSITIVE; This spontaneous report received from a patient via a company representative concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 11-MAR-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 15-MAR-2021, the patient became ill with COVID like symptoms, and got tested for COVID on 22-Mar-2021 and received results that he was COVID positive on 25-Mar-2021 and was running high temperatures (fevers over 103), On 27-MAR-2021, the patient became dizzy, fell and hurt himself, was rushed to the hospital and was admitted same day. He did some damage to his kidneys in the process. On 25-MAR-2021, Laboratory data included: COVID-19 virus test positive (NR: not provided) Positive. On 25-MAR-2021, Laboratory data included: Body temperature (NR: not provided) Over 103. Laboratory data included: Oxygen consumption decreased (NR: not provided) 87. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the confirmed covid-19 positive, dizziness, fell, injury to kidney, hurt himself and blood clot was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition) This report was associated with product quality complaint : 90000174591.; Sender's Comments: V0: 20210355610- Covid-19 Vaccine Ad26.Cov2.S-Confirmed Covid-19 Positive. This event is considered Unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event. 20210355610- Covid-19 Vaccine Ad26.Cov2.S - Dizziness, Fell, Hurt himself, Some damage to his kidneys in the process (blood clot). This events are considered Unassessable. The events have a compatible/suggestive temporal relationship, is</p>

*VAERS\_ID RECVDATE STATE AGE\_YRS SEX VAX\_DATE ONSET\_DATE SYMPTOM\_TEXT*

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unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events.

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1157535	4/1/2021	CO	50	F	1/6/2021	1/7/2021	Cellulitis; Clammy skin and hands; Nauseous; Fatigue; fever; chills/teeth chattering; red rash; red mark on their right arm; hot to the touch; tender; Arm swollen and sore; A spontaneous report was received from consumer, concerning a 50-years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced cellulitis, chills, fatigue, nausea, fever/pyrexia, red mark on their right arm/ vaccination site erythema clammy skin and hands/cold sweat, red rash/ rash erythematous ,arm swollen and sore/pain in extremity, red rash, hot to touch/ feeling hot and tenderness. The patient's medical history was not reported. Concomitant medications included bomocriptine, doxycycline, cetirizine hydrochloride, ibuprofen. On 06-JAN-2021, prior to the onset of the events, the patient received mRNA-1273 intramuscularly in Right arm for prophylaxis of COVID-19 infection. On 07-JAN-2021, after receiving mRNA-1273, the patient's arm was swollen tender, and sore. The patient reported that the arm felt better the next day, after sleeping and taking it easy. The patient stated that on 08-JAN-2021, she woke up with more energy after sleeping and taking it easy. The injection site was not treated directly, but she may have taken some Advil for symptom relief. On 19-JAN-2021, the patient started not feeling well. On 20-JAN-2021, the patient noticed a red mark on their right arm where they had received the injection. The patient reported that she had a red rash on the right arm, below the injection site, that was hot to the touch. On 21-JAN-2021, she reported seeing a physician. The physician ordered an ultrasound to rule out a blood clot in the patient's arm. The doctor diagnosed the patient with cellulitis and prescribed an antibiotic (Doxycycline) and cetirizine hydrochloride. The event cellulitis was assessed as medically significant as per IME list. The patient reported feeling very nauseous and fatigued. The patient also reported chills and fever, chattering teeth, clammy hands and feet. The patient is still fatigued and nauseous but is starting to feel better today 28-JAN-2021. The treatment included an antibiotic (Doxycycline) and cetirizine hydrochloride. Action taken with mRNA-1273 in response to the events was not reported. At the time of this report, the outcome of the events cellulitis, chills, fatigue, nausea, fever, red mark on their right arm, clammy skin and hands, red rash, arm swollen and sore,

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1157590	4/1/2021	MN		M	2/8/2021	3/18/2021	red rash, hot to touch and tenderness was resolving.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
							Blood clots in his lungs (After second dose); A spontaneous report was received from consumer, concerning himself, a 71-year -old elderly, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced blood clots in lungs (Pulmonary embolism). The patient's medical history was reported as unknown. Concomitants reported included Metoprolol, Tamsulosin, Gabapentin, Metformin, Fenofibrate and Losartan for unknown indication. On 8 Mar 2021 patient received second of two planned doses of mRNA-1273 (Lot number: 040A21A) via unknown route for prophylaxis of COVID-19 infection. On 18 Mar 2021 patient went to doctor and after some studies that included a CT scan they discovered he had blood clots in his lungs. The event blood clots in lungs (Pulmonary embolism) was medically significant. It was reported that, he was prescribed with a blood thinner for treatment purpose. Action taken with mRNA-1273 in response to the event was not applicable. The outcome of the event, blood clots in lungs was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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1157608	4/1/2021	CO	73	M	1/8/2021	2/26/2021	Stroke; Blood clots in his brain; Limited motion on the left side of the face and arm; Turned my life upside down; A spontaneous report was received from a consumer concerning a 73 -year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and reported events blood clots in brain/ cerebral thrombosis, stroke/ cerebrovascular accident, turned life upside down/loss of personal independence in daily activities and limited motion on the left side of the face and arm/mobility decreased. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. The patient received the first of the two planned doses of mRNA-1273 (lot/batch number: 041L2A) on 08 Jan 2021. On 05 Feb 2021, prior to the onset of the events, the patient received their second of the two planned doses of mRNA-1273(lot/batch: 01020A) via unknown route in the left arm for prophylaxis of COVID-19 infection. On 26 Feb 2021, the patient experienced blood clots in brain, stroke and he patient woke up in the morning with limited motion on the left side and was subsequently hospitalized for two days. The patient's life upside down. Treatment information included blood thinners, small dose of acetyl salicylic acid, rosuvastatin, CoQ and Vitamin D3. The patient received both scheduled doses of mRNA-1273 prior to the events therefore, action taken with the drug in response to the events was not applicable. The outcome of the events blood clots in brain, stroke, turned life upside down and limited motion on the left side of the face was not reported.; Reporter's Comments: This case concerns a 73 -year-old, male patient, who reported cerebral thrombosis, stroke, loss of personal independence, and mobility decreased. Very limited information regarding these events has been provided at this time. Further information has been requested.

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1157825	4/1/2021	MD	42	F	1/15/2021	1/21/2021	I took Tylenol prior to vaccination. About 5 or 6 hrs later, I had heaviness in my arm and mild headache. I took Tylenol again and I was fine. I started having headaches, so I checked my BP. It started spiking to like 168/100 and 180/110. I went to cardiologist and he did an ECHO, checked the carotid in my neck and a doppler to check for blood clots. Everything was normal. He prescribed a new BP med (Losartan - 50mg once a day) and diuretics (HCTV - 12.5 mg once a day in the morning). My BP was stabilized, but then it started to increased again, so he increased my Losartan to twice a day. Now it's stabilized.
1158135	4/1/2021	TX	39	M	3/17/2021	3/20/2021	Got a sudden heart attack after developing chest pain/discomfort while walking outside on 3/20 afternoon time. Went to ER and shifted to hospital. Treated with 2 stents in heart. Arteries were found blocked and blood clot was removed.
1155485	4/1/2021	OK	65	F	1/14/2021	1/17/2021	About 3 days after the vaccine my daughter mentioned to me that I was not breathing right. It was harder to breathe and I could not even take a shower that I would be out of breath. My daughter checked my pulsox and it was 85. I couldn't really walk or do anything so my daughter transported me to ER and lots of labs were done so since my D Dimer was too high they did a CT scan and it showed some blood clots in my lungs. They admitted me because they were concerned with the location of one of them. They did some heart tests too and put me on Eloquis and then sent me home. I stayed for 2 days. Then they scheduled me FUs with a heart doctor and a pulmonologist.

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1157508	4/1/2021	MA	68	F	3/1/2021		HYPOCHROMIA; HIGH WHITE BLOOD CELLS; DVT WITH INFLAMMATION AND SWELLING OF RIGHT LOWER LEG; RUNNY NOSE; BILATERAL WATERY EYES; LEFT ARM TENDERNESS POST IMMUNIZATION; URINARY TRACT INFECTION; LOWER BACK PAIN; This spontaneous report received from a patient concerned a 68-year-old female. The patient's height, and weight were not reported. The patient's concurrent conditions included baker's cyst, and reflux sympathetic dystrophy. The patient experienced drug allergy when treated with gabapentin, and prednisone, drug intolerance when treated with codeine, and ibuprofen. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805031, expiry: UNKNOWN) once a total dose was not reported, administered on 10-MAR-2021 at right arm for prophylactic vaccination. No concomitant medications were reported. On MAR-2021, the subject experienced urinary tract infection. On MAR-2021, the subject experienced lower back pain. On 10-MAR-2021, the subject experienced left arm tenderness post immunization. On 11-MAR-2021, the subject experienced runny nose. On 11-MAR-2021, the subject experienced bilateral watery eyes. On 14-MAR-2021, the subject experienced deep vein thrombosis with inflammation and swelling of right lower leg. On 23-MAR-2021, Laboratory data included: Diagnostic ultrasound (NR: not provided) confirmed DVT right lower leg, Urinalysis (NR: not provided) Unknown, and White blood cell count high (NR: not provided) 10.35 increased and was previously 9.23 not reported. Treatment medications included: ciprofloxacin for urinary tract infection. On 24-MAR-2021, the subject experienced hypochromia. On 24-MAR-2021, the subject experienced high white blood cells. Additional treatment medications (dates unspecified) included: rivaroxaban for deep vein thrombosis. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from runny nose, and bilateral watery eyes on 12-MAR-2021, and left arm tenderness post immunization on 11-MAR-2021, had not recovered from deep vein thrombosis with inflammation and swelling of right lower leg, high white blood cells, and hypochromia, and the outcome of urinary tract infection and lower back pain was not reported. This report was serious (Other Medically Important Condition).; Sender's

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							Comments: V0 20210348648-Covid-19 vaccine ad26.cov2.s-Deep vein thrombosis. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
1151450	3/31/2021	CA	61	M	2/24/2021	2/27/2021	Deep Vein Thrombosis/he have numbness , tingling on his left foot. It was also swollen; CT scan shows he have PE; This is a spontaneous report from a contactable consumer (patient) reported that a 61-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in arm left on 24Feb2021 10:15 as a single dose (at the age of 61-years-old) for covid-19 immunisation. The vaccine was administered at the hospital. Medical history included back pains, acid reflux and chest pain; all from an unknown date. Concomitant medication included esomeprazole sodium (NEXIUM [ESOMEPRAZOLE SODIUM]) taken for an unspecified indication, start and stop date were not reported. The patient reported that after several days of getting his first shot, he have numbness , tingling on his left foot. It was also swollen, he went to the Emergency and they found out he have deep vein thrombosis and CT scan shows he have PE on 27Feb2021. The reported events resulted in emergency room/department or urgent care. The patient received treatment for the events which was a blood thinner, Eliquis. The outcome of the events was not recovered. Information on the lot/batch number has been requested.



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1150476	3/31/2021		79	F	2/11/2021	3/12/2021	Discomfort and pressure felt in the bladder; Bleeding from her bladder; Passing clots; A spontaneous report was received from a consumer concerning a female patient who received Modern's COVID-19 vaccine (mRNA-1273) and experienced discomfort and pressure felt in the bladder, passing clots, and bleeding from the bladder. The patient's medical history is unknown. Concomitant medication includes blood pressure medication, cholesterol medication, thyroid medication and aspirin were reported. On 11-FEB-2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: 031L20A) for prophylaxis of COVID-19 infection. No adverse events after the first dose were reported. On 10-MAR-2021, the patient received their second of two planned doses of mRNA-1273 (lot/batch: 031L20A) for prophylaxis of COVID-19 infection. On 12-MAR-2021, the patient experienced discomfort and felt pressure in the bladder. She was also passing clots and had CAT scanning which reports as she has many clots in the bladder. She took medicine and was on observation for 48 hours, after which the clots were gone in the scanning and the bleeding stopped. Laboratory tests included CAT scanning, which found that there were more clots in the bladder. The treatment details were not provided. Action taken with mRNA-1273 in response to the events was not applicable she completed both the doses. At the time of this report, the outcome of the events were resolved on 14-MAR-2021.; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.

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1150488	3/31/2021	FL	80	F	2/26/2021	3/15/2021	mini stroke; still weak; A spontaneous report (United States) was received from a consumer concerning an 80 years old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced event mini stroke/transient ischaemic attack and still weak/asthenia. The patient's medical history was not provided. The concomitant medications on use were also not provided. On 26 Feb 2021, approximately 17 days prior to the onset of the events, the patient received their first of two planned doses of mRNA (Batch number: 011A21A) through unknown route of administration for prophylaxis of COVID-19 infection. On 15 Mar 2021, patient experienced mini stroke. The patient was hospitalized on the same day till 17 Mar 2021. It was serious event which required hospitalization. Laboratory tests performed included ultrasounds, cat scan of the brain, MRI of brain, ultrasound of arteries, and chest x-ray. The findings of lab tests were not provided. The patient was given acetylsalicylic acid and an injection in the belly to prevent blood clots. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events was unknown; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded

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1151065	3/31/2021	TX	69	M	1/5/2021	2/5/2021	Stroke; Blood clot on the brain; I Just sort of zoned out on them; Arm soreness; I Just kept getting tireder; A spontaneous report was received from a consumer, concerning a 69-years old male patient, who received Moderna's COVID-19 vaccine and experienced stroke, blood clot on brain, arm soreness without redness and swelling, he just kept getting tireder, he just sort of zoned out on them. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 05 Jan 2021, prior to the onset of events, the patient received the first of two planned doses of mRNA-1273 (lot number 037K20A) via unknown route for COVID-19 infection prophylaxis. On 05-FEB-2021, prior to the onset of events, the patient received the second of two planned doses of mRNA-1273 (lot number 032L20A) via unknown route for COVID-19 infection prophylaxis. On 05 Feb 2021, after the second dose of vaccine, the patient experienced arm soreness and fatigue, He did not get any medication or treatments for his arm soreness without redness and swelling and and just kept getting tireder events. On10-MAR-2021 patient experienced just sort of zoned out of them, stroke, blood clot on brain. An ambulance was called for him and he was taken to the hospital where he received MRIs, and CT scans. He states they think it was a stroke. No treatment medication was reported. Action taken with mRNA-1273 in response to the event was not applicable. The outcome of the events (arm soreness without redness and swelling and he was just kept getting tireder) was recovered but the events (stroke, blood clot on brain, he just sort of zoned out on them) not resolved at the time of this report.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
1151097	3/31/2021	NY	56	M	3/14/2021	3/16/2021	Reports that 2 days after vaccine, patient noticed L neck pain and warmth with possible rash. Says that while the rash/warmth improved, he noted that a vein was very prominent on that side and he came to my office (I'm his PC doctor) to show me it. I felt a cord, and suspected a superficial neck vein thrombosis L side, which was confirmed on US.

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1151417	3/31/2021			M	3/2/2021	3/1/2021	blood clots in his left legs and also some in his lungs.; blood clots in his left legs and also some in his lungs.; This is a spontaneous report from a contactable consumer (patient) received via Medical Information Team. A 64-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 02Mar2021 (Lot number was not reported) as single dose for COVID- 19 immunisation. The patient medical history and concomitant medications were not reported. The patient reported that he had to go to the emergency room (ER) where they discovered blood clots in his left legs and also some in his lungs in Mar2021. The events were serious, the patient was hospitalized for 2 days. Therapeutic measures were taken as a result of the events and the patient was placed on blood thinners. The patient outcome of the events was unknown. Information on the lot/batch number has been requested.

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1151420	3/31/2021	MN	67	F	2/12/2021	2/15/2021	blurry vision- right eye; BRVO; A localized clot (thrombus) development in a branch retinal vein.; This is a spontaneous report from a contactable consumer (patient). This 67-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9266) on 12Feb2021 02:15 PM in left arm at single dose for COVID-19 immunisation. Medical history included slight asthma, known allergies: sulfa, penicillin. No COVID prior vaccination. Concomitant medications included Vitamins (over-the-counter, other medications in two weeks). No other vaccine in four weeks. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9262) on 22Jan2021 03:30 PM in left arm at single dose for COVID-19 immunisation at the age of 67-year-old. The patient was not pregnant, was not pregnant at time of vaccination. No COVID tested post vaccination. On 15Feb2021, within a few days of receiving second dose of vaccine, the patient developed blurry vision of right eye. After seeing a retina specialist, patient was diagnosed with BRVO (retinal vein branch occlusion). The cause of BRVO is a localized clot (thrombus) development in a branch retinal vein. The events resulted in disability or permanent damage. The patient received treatment as anti-VEGF drug - Avastin for the events. Outcome of the events was not recovered.

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1150394	3/31/2021	UT	77	M	2/26/2021	3/3/2021	Two blood clots in left leg; This is a spontaneous report from a contactable consumer. A 77-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in left arm on 26Feb2021 (Batch/Lot Number: EN6203) as single dose for COVID-19 immunisation. Medical history included back disorder, ATTR amyloidosis, and allergies: caffeine from an unknown date. Concomitant medication included allopurinol (ELAVIL); meloxicam; tizanidine; tafamidis (VYNDAMAX) all taken for an unspecified indication, start and stop date were not reported. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9269), on 05Feb2021, administration time: 06:00 PM, vaccine location: Left arm for COVID-19 immunisation. The patient experienced two blood clots in left leg on 03Mar2021 23:00. Treatment for the event includes Aspirin. The event resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The patient had no COVID-19 prior vaccination. The patient was not tested for COVID-19 post vaccination. The outcome of the event was resolved on an unspecified date.

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1151440	3/31/2021	CA	30	F	3/2/2021	3/2/2021	cardiac arrhythmia; dizziness/lightheadedness; nausea; muscle weakness; extreme fatigue; lost consciousness/She is in and out of consciousness; extreme weakness; extremely low blood pressure; tachycardia when resting/heart rate is high/HR gets up to 135; One foot and leg became very cold and turned blue; One foot and leg became very cold and turned blue; other foot warm and hot; This is a spontaneous report from a contactable consumer (patient's sister). A 30-year-old non-pregnant female patient received the second dose of bnt162b2 (BNT162B2 reported as PFIZER COVID 19 VACCINE; lot number: EN/ EW 6198; expiration date: unknown), at vaccination age of 30-year-old via an unspecified route of administration in the left arm on 02Mar2021 as a single dose for covid-19 immunisation. The patient medical history was not reported. The patient was not diagnosed with covid prior to vaccination. The patient received the first dose of bnt162b2 (BNT162B2 reported as PFIZER COVID 19 VACCINE; lot number: EN6198), at vaccination age of 30-year-old via an unspecified route of administration in the left arm on 09Feb2021 as a single dose for covid-19 immunisation but had weakness, fainted, lost consciousness and concussion. There were no concomitant medications. The patient did not receive other vaccine in four weeks. The reporter mentioned that on the next day after vaccination (03Mar2021), the patient's one foot and leg became very cold and turned blue other foot warm and hot started cardiac arrhythmia, dizziness, lightheadedness, nausea, muscle weakness, extreme fatigue, extremely low blood pressure and tachycardia when resting. The reporter stated that since 02Mar2021, she hasn't been able to get out of bed due to extreme weakness. The reporter also mentioned that her heart rate (HR) gets up to 135 [unit unspecified]. The reporter also stated that the patient was wearing a heart monitor and was waiting for data. They went to the emergency room (ER) on 12Mar2021 due to concerns of blood clot, ruled out blood clot. The doctors can't explain what is happening to her. She was extremely healthy and fit, no previous cardiac or energy issues. No blood pressure issues or family HX. She says she "feels like she's dying". The adverse events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care,

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							hospitalization, and life-threatening illness (immediate risk of death from the event). The hospitalization was reported as 1 day. It was unknown if the events received treatment. The patient was not tested post vaccination. It was further reported that her sister had the second Covid shot 02Mar2021 and a few hours later she lost consciousness. She has been in the hospital ever since. She was in and out of consciousness, her blood pressure is low, and her heart rate is high. One of her legs is blue and cold, the other is hot. She cannot get out of the bed. The doctors don't know what is wrong. It was mentioned that the patient was healthy and not taking any medication. The outcome of the events was not recovered.
1148732	3/31/2021	FL	83	M		3/18/2021	Blood clots in urine; Chills; A spontaneous report was received from a consumer concerning an 83-years-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced blood clots in urine/haemorrhage urinary tract and chills. The patient's medical history was not provided. Concomitant product use provided by reporter included baby aspirin. On 18 Mar 2021, prior to the onset of the events, the patient received first of two planned doses of mRNA-1273 (lot/batch number: 030A210) intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, the patient experienced blood clots in urine and chills. The event blood clots in urine was medically significant. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events blood clots in urine and chills was resolved on an unspecified date.; Reporter's Comments: Although a temporal association exist, there is not enough information to assess the events of blood clots in urine as the patient's medical history is lacking. However, chills is consistent with the known safety profile of the vaccine. Further information has been requested.



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1151451	3/31/2021			F	3/5/2021	3/1/2021	if it was a lung issue or blood issue, such as blood clots; nervous system was affected; weakness on her leg; had very tight calf muscles; eye pain; have difficulty breathing; she was dragging her feet, could not take the next step.; had "such a tight feeling" of the calf, and a little bit of pain to it; nauseous; if it was a lung issue or blood issue, such as blood clots; whether the injection was done in the wrong location; her arm was very itchy and a red papule-like round rash developed, it was pigmented.; her arm was very itchy and a red papule-like round rash developed, it was pigmented.; her arm was very itchy and a red papule-like round rash developed, it was pigmented.; it was "highlighted" and "dot-like"; had a sharp pain, and tingling or pain-like sensation at the fingertips/she was going "through a world of pain", and from the arm down to the side of body.; had a sharp pain, and tingling or pain-like sensation at the fingertips; a fever too, 99.4°F at one time and over 100°F for a day or so; This is a spontaneous report from a contactable consumer. This consumer (patient) reported for self that the female patient of an unspecified age received second dose of bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EN6200, Expiration Date: 30Jun2021) via an unspecified route of administration on 05Mar2021 at single dose for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient previously took first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot#: EL9262, expiration date: 31May2021) for covid-19 immunization for covid-19 immunization, rabies vaccine and experienced pain. The patient experienced if it was a lung issue or blood issue, such as blood clots on Mar2021 with outcome of unknown, nervous system was affected on Mar2021 with outcome of unknown, weakness on her leg on Mar2021 with outcome of unknown, had very tight calf muscles on Mar2021 with outcome of unknown, eye pain on Mar2021 with outcome of unknown, have difficulty breathing on Mar2021 with outcome of unknown, she was dragging her feet, could not take the next step on Mar2021 with outcome of unknown, had "such a tight feeling" of the calf, and a little bit of pain to it on Mar2021 with outcome of unknown, nauseous on Mar2021 with outcome of unknown, if it was a lung issue or blood issue, such as

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blood clots on Mar2021 with outcome of unknown, whether the injection was done in the wrong location on Mar2021 with outcome of unknown, her arm was very itchy and a red papule-like round rash developed, it was pigmented on Mar2021 with outcome of unknown, her arm was very itchy and a red papule-like round rash developed, it was pigmented on Mar2021 with outcome of unknown, her arm was very itchy and a red papule-like round rash developed, it was pigmented on Mar2021 with outcome of unknown, it was "highlighted" and "dot-like" on Mar2021 with outcome of unknown, had a sharp pain, and tingling or pain-like sensation at the fingertips/she was going "through a world of pain", and from the arm down to the side of body on Mar2021 with outcome of unknown, had a sharp pain, and tingling or pain-like sensation at the fingertips on Mar2021 with outcome of unknown. The patient underwent lab tests and procedures which included body temperature: 99.4 fahrenheit on Mar2021, body temperature: 100 fahrenheit on Mar2021. The consumer reported that "Who makes the vial label? What syringe did they use to give her the vaccine? How big was it? Where is the vaccine administered? Did we make a second batch with "much less" side effects? She thought there was an earlier version which should have more side effects. Did she have to share a vial with other people? Is it multiple doses? How much is the dose of a vaccine?" Consumer stated the lot number was a "so vague looking thing" to come with the Pfizer vial. Upon clarification, said she did not see the lot number on the vial, but on the vaccination card, where the lot number was very small. She would include 5 labels with lot numbers to split to each person who gets the dose from the same vial. The clinical course was reported as follows: She got the second dose of Pfizer's COVID-19 vaccine on 05Mar2021 and has developed side effects. Her nervous system was affected, she has weakness on her leg, had very tight calf muscles, eye pain. When she was working, she started to have difficulty breathing, she was dragging her feet, could not take the next step. This was 2 weeks ago and went away for a while. Today she had "such a tight feeling" of the calf, and a little bit of pain to it, she was nauseous. She was wondering if it was a lung issue or blood issue, such as blood clots. She had a fever too, 99.4°F at one time and over 100°F for a day or so. The

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1151601	3/31/2021	PA	78	M	3/11/2021	3/28/2021	<p>first dose didn't give her any side effects. She was also concerned about whether the injection was done in the wrong location, she thought it was in the deltoid, but 10 days later her arm was very itchy and a red papule-like round rash developed, it was pigmented, she wondered if it was a hair, it was "highlighted" and "dot-like". It was located in the 2/3 lower to the elbow from the shoulder, she thought it was "really low" and they missed the deltoid muscle, she had no idea if the nurse didn't know the exact location and putting it "in the skin" was the cause of her symptoms. Stated they put a bandage in the wrong location, there was nothing there. She additionally had a sharp pain, and tingling or pain-like sensation at the fingertips, yesterday she was going "through a world of pain", and from the arm down to the side of body. With the first dose she didn't have any pain, but it was "very weird", afterwards she had some "sharp pain" under the scapula and didn't know why. She thought it was "echo" through the nervous system. Stated when she got the vaccine, she saw 3 dark marks on the syringe and two thirds were filled with the liquid. She wanted to know if this dosage was correct. Mentioned a lot of people had side effects, a lot of times they are given in the wrong location, in an entirely different place. She thought there was an earlier version of the vaccine which should have more side effects. She had a "very bad bad" experience 4 years ago when she got a rabies vaccine, it was given at 45°, the nurse gave the injection "cutaneously", after 5 min she was "so in pain".</p> <p>Copious bleeding from left nostril, running down throat to the point patient was choking on it. Clott-like material in the sputum. Copious bleeding lasted for fat least 1.5 to 2 hours, slowed down only when treated an packed in the hospital ED. Chemical cauterization with Silver Nitrate at approximately 10:30 PM. ENT follow up scheduled for April 1.</p>

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1151636	3/31/2021	PA	85	M	2/3/2021	2/12/2021	<p>My father received his first Pfizer vaccine on 02/03/21. On 2/12/21 I rushed him to the ER. He was vomiting uncontrollably and had shortness of breath. Once arrived at ER, they immediately put him on oxygen. Vomiting lasted several hours. They tested him for Covid and did a chest x-ray. Tested positive for Covid. Chest x-ray showed Covid pneumonia. Was admitted. Stayed in hospital for 5 days and was then released to nursing home for physical and occupational therapy. He was very weak and on days experienced what they called Covid fog. After 2 weeks of therapy, he was released on 03/06/21 to go back home to his apartment, with extended visiting nurse therapy. On 3/10/21, was the first visiting nurse appointment. At 12:00 an RN came to his apartment from Home Health Care. She checked his vitals. She said his blood pressure was good, lungs sounded good and oxygen level was 98. She said he was doing good and that she would not need to continue to come out and check on him weekly. She left. At 2:30 the same day, a Physical Therapist from Home Health Care came. She asked him lots of questions and adjusted my fathers' walker for him. He showed her how he was doing using the walker. Walked approximately 15-20 feet in his apartment. She checked his vitals before she left. His oxygen level was now at 91. She had him take a few deep breathes until his oxygen level was up to 93. She left and said she would be back on Friday the 12th to begin the actual physical therapy then. Within 10 minutes after she left my father started shaking uncontrollably and was having difficulties breathing. I called 911. Paramedics arrived. My fathers' oxygen level was all the way down to 74. They took him to the ER. When getting him out of ambulance he began vomiting. Vomiting lasted for hours just like when he went to the hospital back in February. They tried 3 different drugs to control the nausea. They did EKG, chest and abdomen scans. Was found that he had multiple blood clots and inflammation in his lungs and a bacterial infection in his blood. After testing, bacteria was found to be E Coli. Treated him with heparin for clots and antibiotics for infection and had him on oxygen in nose. Every day thereafter, he felt worse. They switched him to a high flow oxygen mask to keep his oxygen levels up. By Saturday night (early morning Sunday) on 03/14, they had taken the high flow oxygen mask off and hooked him up to a BiPap oxygen machine</p>

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because his oxygen levels were dropping too low. We were then told by the lung doctor, that the damage to his lungs was extreme and that the next step would be to put him on a ventilator and feeding tube. My father did not want this per his will and his discussion with Dr earlier in the week. Dr indicated that he would not get better just being on the BiPap machine and we then chose to have them take him off of the machine because he did not want to go on life support. My father passed away on Sunday, March 14th around 6:30pm.

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1151439	3/31/2021	WI	79	F	2/18/2021		<p>Pain in my legs; I developed really bad pain in my legs and one leg is black and blue like all black and blue bruise; Left leg is all bruised; It is all swollen and black and blue and it is like I had tingling going from the ankle bone up to kind of half way in to my calves; Left leg is all bruised; It is all swollen and black and blue and it is like I had tingling going from the ankle bone up to kind of half way in to my calves; there is a little nodule; This is a spontaneous report from a contactable consumer (patient). A 79-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; Lot Number: EN6198) via an unspecified route of administration, at the age of 79-year-old, on 18Feb2021, as SINGLE DOSE for covid-19 immunisation. Medical history included high blood pressure. Concomitant medication included losartan. The patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; Lot Number: not reported) on an unspecified date, as SINGLE DOSE for covid-19 immunisation and did not have any reaction. On an unspecified date in 2021, like the last week or so, the patient had some pain in legs. The left leg is all bruised and the patient did not hit it, the patient did not remember hitting it but it is all swollen and black and blue and it is like the patient had tingling going from the ankle bone up to kind of half way in to calves. The right leg it is like the ball, the top of it is all kind of shiny and swollen and it is very painful. The patient did not have that before. The patient clarified almost all over the side of legs where the bone is and like to the toes and above the ankle, it is like there is a little nodule that is little sore and same thing is on the right leg. But on right leg, the patient can barely put any weight on it. The left leg tingles and its tender, like the patient have tingling above the ankle up to like half way in to the leg. The patient would like to know if it is possible to have blood clots from the vaccine, it actually looks like a little nodule. The patient underwent MRI on an unspecified date with unknown result. The patient did not receive treatment in response to the events. Outcome of the events was unknown.</p>

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1150385	3/31/2021	VT	67	F	3/1/2021	3/4/2021	I had a return of a superficial thrombophlebitis on my left arm above where a catheter had been when I had surgery 7 weeks before. The blood clot returned again to the same level of pain and the same; I had a return of a superficial thrombophlebitis on my left arm above where a catheter had been when I had surgery 7 weeks before. The blood clot returned again to the same level of pain and the same; This is a spontaneous report from a contactable consumer (patient). A 67-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in right arm on 01Mar2021 13:30 (lot/batch number was not reported) as single dose for COVID-19 immunisation. The patient's medical history included high blood pressure. The patient had no known allergies. The patient's concomitant medications were not reported. On 04Mar2021 07:30, the patient had a return of a superficial thrombophlebitis on her left arm above where a catheter had been when she had surgery 7 weeks before. The blood clot returned again to the same level of pain and the same. No treatment was received for the events. Patient was not pregnant at the time of vaccination. Patient had no COVID prior to vaccination and not tested for COVID post vaccination. Vaccine facility type was other. There was no other vaccine in four weeks and there was other medications in two weeks. The outcome of the events were not recovered. Information on the lot/batch number has been requested.

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1150383	3/31/2021	PA	50	F	3/5/2021	3/5/2021	blood clots in arm/Blood Clots in Left Arm; swollen lymph nodes /Swollen Lymph Nodes in Left Arm; nodules were found on her lungs/Nodules in Lungs; arm swelling /Left Arm Swelling; Left Arm Redness; Left Arm Discomfort; Soreness at the Injection Site; This is a spontaneous report from a contactable consumer (Patient's Mother) calling on behalf of daughter. A 50-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, batch/lot number and expiration date unknown), via an unspecified route of administration, administered in Arm Left on 05Mar2021 13:30 at age of 50 years old at single dose for covid-19 immunisation. There was no medical history. There were no concomitant medications. The patient did not have prior vaccinations within 4 weeks. No adverse events following prior vaccinations. There were no additional vaccines administered on same date of the Pfizer suspect. The patient experienced the following after first dose. The patient experienced arm swelling /left arm swelling (hospitalization) on 09Mar2021 with outcome of recovering , blood clots in arm/blood clots in left arm (hospitalization) on 11Mar2021 with outcome of not recovered , swollen lymph nodes /swollen lymph nodes in left arm (hospitalization) on 11Mar2021 with outcome of not recovered , nodules were found on her lungs/nodules in lungs (hospitalization) on 11Mar2021 with outcome of unknown , soreness at the injection site on 05Mar2021 with outcome of not recovered , left arm discomfort on 08Mar2021 with outcome of not recovered , left arm redness on 09Mar2021 with outcome of not recovered. The patient was hospitalized from 11Mar2021 to 12Mar2021. On 05Mar2021 she began to have arm pain. 48 hours later, patient's arm started really hurting her, something about her arm being sore on the day of injection and reporter said she was going to be sore and when she got back from going away for the weekend, she thought uh oh, there was a problem here, this was not normal, not right. On 10Mar2021, she experienced swells arm swelling and went to urgent care which was diagnosed with swollen lymph nodes and given Cheplex prescription at urgent care. 11Mar2021, daughter was admitted to hospital by her provider. Daughter was found to have blood clots in arm and continued swollen lymph nodes. Daughter was given IV cheplex and Eliquis while in hospital. Daughter will have



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to be on Eliquis for next 3 months per reporter. The patient had her first vaccine, Pfizer, and became ill with blood clots, swollen lymph nodes, and wound up in the hospital. Reporter stated that she and the patient were worried about her getting the second shot. The patient was on blood thinners and was seeing a pulmonary doctor and hematologist. She didn't know about her getting the second shot and thought this should be reported. The patient was due for the second vaccine next week on 26Mar2021 and she was still sick, should it be postponed or what? The patient went the night before the hospitalization to the Urgent Care and the doctor prescribed Keflex, an antibiotic and saw her primary care doctor the next morning and she put her in the hospital. Reporter stated they were getting nervous and wanted to report for side effects. She stated the patient was home from the hospital but still sick really bad. The patient went to Urgent Care 10Mar2021, saw her primary care 11Mar2021 and was sent to the hospital 11Mar2021. Reporter later clarified that the patient was sent to the Emergency Room and after a few hours, she was sent upstairs to be admitted for a 24 hour hospital stay. The patient received Eliquis; Keflex as treatment. Fluids at the hospital, unknown type. Reporter stated they decided the patient wasn't doing really well and went to the Urgent Care that night and were given Keflex because they felt there was an infection. When they discovered it further that there were blood clots, the patient was told to stay on the antibiotic and given fluids and put on blood thinner, Eliquis, states patient had never been on a blood thinner before. Patient was admitted on 11Mar2021 for 24 hours. Reporter stated that they kept the medicine going and then felt she was stable enough to be discharged the next night at around 18:00 to continue with Keflex antibiotic and Eliquis for 3 months. Reporter stated they were told to contact a hematologist and pulmonary doctor for the nodules in her lungs and to contact her primary doctor if not doing better in one week, but they will probably contact her tomorrow. Reporter clarified that the patient had a chest x-ray a couple of months ago and everything appeared fine, so she thinks that the nodules developed after the vaccine. The patient had a chest x-ray on 11Mar2021 and nodules were found on her lungs, scheduled to follow up with lung doctor. Reporter stated whether they were there before

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or not was unknown. No follow up X ray yet. Reporter would like to know if daughter should get second dose? Second dose was scheduled 26Mar2021. Adverse events required visit to emergency room: Urgent Care the night before, follow up the next morning with primary doctor, the doctor got her in right away and said she needs to go to the hospital. Yes, patient went through the ER, doctor said that she would be coming and then after there a while, she was admitted to the hospital. Adverse events required visit to physician office. Patient saw the doctor on 11Mar2021 and was sent to the hospital. Information about lot/batch has been requested.

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1148710	3/31/2021	KS	57	M	2/3/2021	2/3/2021	<p>blood clot in lower leg; achy; Pain in the back of leg that would not go away; body ache/ache; headache; A spontaneous report was received from a consumer concerning a patient age ,57 years old male patient who developed Blood clot in lower leg/Thrombosis, Body ache/Myalgia, Headache/Headache and pain in the back of the leg that would not go away/pain in extremity. The patient's medical history included Central Retinal vein occlusion (CRVO). Concomitant product use was not provided/unknown by the reporter. The patient received their first of two planned doses of mRNA-1273 (Batch number not provided) on unknown date. The patient received their second of two planned doses of mRNA-1273 (Batch number not provided) on 03 Feb 2021, intramuscularly in the (unknown injection site) for prophylaxis of COVID-19 infection. On the same day as receiving the vaccine 03 Feb 2021 patient reported as having pain in back of the leg that would not go away. Patient also had body aches, felt achy and had headache. Patient went to Emergency room on 03 Feb 2021 and was diagnosed a blood clot in lower leg. The event blood clot in lower leg was assessed as medically significant based on IME list. Treatment information was not provided/unknown. Patient is following up with a hematologist. The patient received both scheduled doses of mRNA-1273 prior to the event(s); therefore, action taken with the drug in response to the event(s) is not applicable. The outcome of the event(s), Blood clot in lower leg/Thrombosis, Body ache/Myalgia, Headache/Headache and pain the was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events (pain, myalgia, and headache) a causal relationship cannot be excluded. A very limited information regarding these event (Thrombosis) has been provided at this time. Noting the history of central retinal vein occlusion may remain as a risk factor for thrombosis. Further information has been requested.</p>

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1148725	3/31/2021	PA		F	2/4/2021		<p>blood clot in her leg/clots in upper thigh on inside of thigh which were very sore; more lumps in crease of leg/knee/lump red and raised/ones behind the knee in the crease are still there and hard as a rock; lump was red and raised; Patient reports it was really sore up toward groin; A spontaneous report was received from a consumer concerning herself, who is 68-years old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced thrombosis, mass excision, groin pain, skin swelling, developed more clots in upper thigh on inside of thigh which were very sore. No medical history was reported. No concomitant medications were reported. On 04-Feb-2021, the patient received their first of first planned doses of mRNA-1273 (Lot number: 031120A) was administered intramuscularly with unknown site for prophylaxis of COVID-19 infection. On an unknown date, an unspecified amount of time, the patient developed a blood clot in her leg, her lump was red and raised. She went to the doctor and they told her to put a warm compress and keep her leg up. The lumps did not start to go down. She started to develop more lumps in crease of leg/knee. Patient went to vascular doctor who did an ultrasound and diagnosed superficial thrombophlebitis. Patient then went to get second Moderna vaccine on 10MAR2021(lot#036021A). She developed more clots in upper thigh on inside of thigh which were very sore. Patient reports it was really sore up toward groin. She went to doctor again and they put her on Xarelto, and Aleve as directed on box. Symptoms are ongoing. Original lumps were no longer sore to the touch, ones behind the knee in the crease are still hard as a rock. New lumps after second dose are tender. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the events were not recovered. The reporter did not provide an assessment for the events; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1148782	3/31/2021	OK	38	M	3/1/2021	3/4/2021	Pain in left calf leading to development of blood clot above left knee cap near inside of quad; Pain in left calf leading to development of blood clot above left knee cap near inside of quad; This is a spontaneous report from a contactable consumer. A 38-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in Arm Left on 01Mar2021 12:00 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. Medical history included U/L fasciatomy in same leg with nerve damage, Blood transfusion, previous clot in femoral during recovery, Shellfish (allergy). The patient has not had COVID prior vaccination. The patient received first dose of BNT162B2 for COVID-19 immunization on an unspecified date (lot number: unknown) at 38-years-old. Concomitant medication included sulfamethoxazole, trimethoprim (BACTRIM) taken for an unspecified indication, start and stop date were not reported. On 04Mar2021 16:00, the patient experienced Pain in left calf leading to development of blood clot above left kneecap near inside of quad. AE resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The patient received treatment for the events: Originally treated as cellulitis with doxy. The outcome of the events was recovering. The patient was not tested for COVID post vaccination. Information about Lot/Batch number is requested.

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1148785	3/31/2021	CA	68	M	3/3/2021	3/15/2021	Chills; seems to have some kind of hypothermia/kept reading 94.7; hemorrhoids; pulmonary embolism in his right lower lobe; This is a spontaneous report from a contactable pharmacist (patient). A 68-year-old male patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on 03Mar2021 (Batch/Lot Number: EN6198; Expiration Date: 30Jun2021), at the age of 68-years at vaccination, as SINGLE DOSE for COVID-19 immunisation. Medical history included paraplegic, he has been paralyzed for 45 years. The patient received first dose of the vaccine on 10Feb2021 with lot number: EN5318, expiration 31May2021. There were no concomitant medications. The patient went on Monday to the ER for an unrelated condition and they did a CT scan and found a blood clot, a pulmonary embolism in his right lower lobe. He confirms the pulmonary embolism was diagnosed on Monday, 15Mar2021. He got home that night and read the headline in the (Withheld) times that said several European countries are pulling the Astra Zeneca vaccine over concerns about blood clots even though there has not been any causal relationship found. He thought that with the drug companies, they should be able to have data regarding potential adverse effects for Pfizer so he was calling report that. He discusses it with the ER doctor and he couldn't really figure out why he had a blood clot, it was incidental to what he was being scanned for, it surprised him. They put him on Eliquis so he is on an anticoagulant, which will cost him a fortune. Today will be the third day he has been on the Eliquis. He is at home and he would say his only concern is that he does have hemorrhoids so when he has bowel movement tomorrow, because he doesn't go every day, but when he goes he is concerned if he starts to bleed that the anti-coagulant might cause the bleeding to be more significant than it usually is. No further information provided. His only other concern is he seems to have some kind of hypothermia, he is not entirely sure because of his thermometer is not very good. That is the reason he went into the Emergency Department because it kept reading 94.7 and he googled it and it said if it is below 95 it is a medical emergency and go to the ER so he got to the Emergency Department and it was 97.6 and now he checked his temperature again with the thermometer and it was 96.8 so either he has a faulty thermometer or something but

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1149738	3/31/2021	MA	49	F	3/29/2021	3/29/2021	<p>he is experiencing some kind of chills. The outcome of the events was unknown.</p> <p>Patient presented to Medical center with right sided MCA stroke (proximal M1) occlusion. She underwent tPA therapy and is recovering. She has a history of breast cancer that was treated in 2017. It?s unclear to us whether or not these events are related. However, given the thrombosis occurred on the same day as the vaccine was administered, we felt it was a reportable event</p>

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1149915	3/31/2021	WI	86	M	2/3/2021	2/3/2021	<p>her husband's pain is more in his right elbow and right shoulder/pain is more like a joint pain; right arm pain started with the COVID-19 Vaccine injection site/pain is in his right (dominant) arm; husband is experiencing a sore arm, husband's arm has been sore as worsened; This is a spontaneous report from a contactable nurse. A 86-year-old male patient received first dose of BNT162B2, (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Batch/Lot Number: EL9269), via intramuscular route of administration, administered in Arm Left on 03Feb2021 14:15 as single dose for covid-19 immunization. Medical history included was none. Concomitant medication was not reported. Upon follow-up (16Mar2021): it was reported that, first dose of Pfizer covid-19 was shot on an unspecified date at 14:15 PM via intramuscular route of administration in right arm of Batch/Lot number: EL9269. She said her husband's arm has been sore for 8 days. Her husband's arm has been sore for 8 days was reported as worsened. She said her husband tried Advil, Tylenol, hot packs, cold packs, and nothing seems to help his sore arm, and pain was in his right (dominant) arm, the pain was more in his right elbow and right shoulder, and her husband's pain is more like a joint pain. She said her husband has a high tolerance for pain, and normally doesn't take anything for pain. She said her husband can't put his jacket on because he is unable to lift his arm due to the pain in his right elbow and right shoulder. She said her husband has been trying everything, and nothing seems to help his right elbow and right shoulder pain much. Clarified her husband's right arm pain started with the COVID-19 Vaccine injection site and then the pain moved into his right shoulder and then into his right elbow. Reported her husband had a CAT scan of his head and neck on 01Feb2021 checking for blood clots. She said the results of the Head and Neck CAT (Computerised tomogram) Scan were normal. Reported her husband's second COVID-19 Vaccine dose is scheduled for 24Feb2021. The reporter classified the event husband is experiencing a sore arm and husband's arm has been sore as worsened as disability and other events was not reported and assessed the causality between the event husband is experiencing a sore arm and husband's arm has been sore as worsened the vaccines as Related. Upon follow-up, it was reported that, the patient has a very sore arm</p>



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							for about 8 days but then it resolved and no trouble since then. His second shot did not have much of a reaction and both are fine now. Therapeutic measures were taken as a result of husband is experiencing a sore arm and husband's arm has been sore as worsened and included treatment with ADVIL at a dose of 200 mg (Lot Number: W36210, Expiration Date: Nov2019), TYLENOL, at a dose of 500mg, hot packs and old packs. Upon follow-up (16Mar2021), the outcome for the events were recovered on 11Feb2021. Follow up (16Mar2021): This is a follow-up spontaneous report received from a contactable nurse includes, updated information about the first dose of Pfizer vaccine, route of administration for the second vaccine and the outcome for the events. Follow-up attempts are completed. No further information is expected.; Sender's Comments: Considering temporal relationship and known safety profile, the reported pain in arm was likely causally related to the vaccination with BNT162B2. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
1150166	3/31/2021	MD	87	F	2/27/2021	3/16/2021	Stroke (blood clot in right brain), resulting in slurred speech and left-side weakness
1150203	3/31/2021	FL	63	F	3/23/2021	3/26/2021	pain in left arm, numbness. Then developed a itchy rash and a lump in the cubital fossa and swollen lymph nodes. Initially took benadryl, then went to the ED. An ultra sound showed a clot located in her left cubital fossa. Transferred to Med center started on eliquis and released from the hospital. Now complaining of pain in the left leg. Adv caller to follow up with her pcp about the pain.

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1150377	3/31/2021	MI	62	M	3/10/2021	3/12/2021	Superficial blood clot on left calf at the lower end of some varicose veins two days after injection; Superficial blood clot on left calf at the lower end of some varicose veins two days after injection; This is a spontaneous report from a contactable consumer (patient). A 62-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot: EN6207), via an unspecified route of administration in right arm on 10Mar2021 14:30 (at the age of 62-years-old) as single dose for covid-19 immunisation. The vaccine facility type was a pharmacy or drug store. The patient had no other vaccine in four weeks. The patient did not have Covid prior vaccination and was not Covid tested post vaccination. Medical history included macular. Concomitant medication included amitriptyline. The patient previously took erythromycin and statins and experienced drug allergies from these. The reported adverse events were superficial blood clot on left calf at the lower end of some varicose veins two days after injection (on 12Mar2021 at 10:00). It may be unrelated, but the patient wanted to let know. The events resulted in emergency room/department or urgent care. AE treatment included hot compress, support stockings and ibuprofen (MOTRIN). The outcome of the events was recovering.; Sender's Comments: Varicose veins most probably was a preexisting condition, unrelated to BNT162B2 vaccine. The reported superficial blood clots are considered a complication of varicose vein and unlikely related to BNT162B2.

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1150382	3/31/2021	OH	82	F	1/23/2021	1/24/2021	<p>After her 1st dose, she had an allergy so bad; Swelling and hives all over body; Swelling and hives all over body; This is a spontaneous report from a contactable nurse, the patient. An 82-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the arm on 23Jan2021 (at the age of 82-years-old) as a single dose for COVID-19 immunization. Medical history included the patient was on blood thinner therapy; allergy to a lot of medications, mold and cut grass; operation to remove clots in Nov2020 (two months prior to vaccination); thyroid disorder. Concomitant medications included unspecified thyroid pills and apixaban (ELIQUIS) as a blood thinner. The patient previously took moxifloxacin (AVELOX) and experienced allergy and rash and was in the hospital. On 24Jan2021 (the next day after vaccination), the patient experienced an "allergy so bad", swelling and hives all over her body. The patient went to the emergency room due to the events and was "hooked up" with intravenous (IV)s for an hour before she could go home. The reactions were assessed as related to the vaccination by the patient. The patient was scheduled for her second dose on 23Mar2021. She was not given the Pfizer-BioNTech COVID-19 Vaccine fact sheet for recipients and caregivers until after being administered the first dose of the vaccine. If she had been given the fact sheet for recipients and caregivers before being administered the first dose, she would not have gotten the vaccine because the sheet says not to get the shot if you are allergic to other medications or other reasons for allergies or on blood thinners. The patient questioned whether she should get the second dose as her physician said she should not get the second dose while on apixaban. The clinical outcome of "after her 1st dose, she had an allergy so bad" and "swelling and hives all over body" was unknown. Information on lot number/batch number has been requested.; Sender's Comments: Based on temporal relation and known safety profile of the vaccine, a causal relation between events allergy to vaccine, swelling, hives and BNT162B2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any</p>

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							safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
1152023	3/31/2021	MN	61	M	3/25/2021	3/27/2021	developed a blood clot in right leg DVT
1152698	3/31/2021	NC	68	M	2/19/2021	2/21/2021	stroke -venous thrombosis

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1148712	3/31/2021	GA	64	F	2/14/2021		<p>bleed heavily again; a feeling of pins and needles in their face/tingling sensation in face; A spontaneous report was received from a consumer who was also a 64-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced heavy bleeding/ postmenopausal bleeding, a feeling of pins and needles that began on the left side of the face and radiated down to the bottom of the chin with sensitivity on the nose and lips/ paraesthesia oral. The patient's medical history was not reported by the reporter. Concomitant medications taken by the patient were not provided. The patient received the first of two planned doses of mRNA-1273 (Lot number: 031M20A) intramuscularly in the left arm on 14 Feb 2021. On 13 Mar 2021, prior to the onset of the event, the patient received their second of two planned doses of mRNA-1273 (Lot number: 026A21A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 18 Feb 2021 four days after the first dose of vaccination, patient began to bleed as if their menstrual cycle began. Patient reported that she was at a menopausal phase in life to typically do not bleed not or if they do there was a light pink blood excreted, the last time this had occurred was in November. Patient had a bleeding that was very heavy and contained large blood clots. The event heavy bleeding/ post menopausal bleeding was a medically significant event. Patient stated that this bleeding lasted 7 consecutive days until 25 Feb 2021. The bleeding then stopped 26 Feb 2021 for 2 days, and then heavy bleeding episode came back again on 28 Feb 2021 for 2 days lasting until 02 March 2021. On 03 March 2021, patient reported that she had a fever of 102F which lasted for 24 hours. Patient also reported that she had very sore gums and swelling inside of mouth. Patient reported that she was not sure if these events were due to the vaccination. On 13 Mar 2021, after the 2nd dose patient had begun to bleed heavily again. Patient also reported that after the first and second dose immediately afterwards there was a feeling of pins and needles in their face. This tingling sensation began on the left side of face down to the bottom of the chin with the most sensitivity on the nose and lips. This tingling sensation was far more pronounced after the second dose than the feeling of the first dose. Patient reported that the heavy bleeding and feeling pins and needles in face were present on 15 March 2021. Treatment</p>

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							activities for event was not provided. The patient received both scheduled doses of mRNA-1273; therefore, action taken with the drug in response to the events is not applicable. The outcome of events, heavy bleeding and tingling sensation that began on the left side of face down radiating to the bottom of the chin with the most sensitivity on the nose and lips were not recovered/not resolved.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
1153501	3/31/2021		51	F	3/3/2021		blood clot in her lungs; shortness of breath; chest pain; This is a spontaneous report from a non-contactable consumer. A 51-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 03Mar2021 as single dose for COVID-19 immunisation. Medical history included obesity and inactivity. The patient's concomitant medications were not reported. On an unspecified date, patient experienced blood clot in her lungs and was hospitalized on 14Mar2021. Patient also experienced shortness of breath and chest pain on an unspecified date. She was treated with anticoagulant therapy for the event "blood clot in her lungs". Outcome of event "blood clot in her lungs" recovered on an unspecified date while for all other events was unknown. No follow-up attempts are Possible. Information on lot/batch cannot be obtained.
1152079	3/31/2021	KY	46	F	3/10/2021	3/18/2021	Patient developed calf pain in the morning of 3/18/21, pain for 2 days and then the pain went away. Right lower leg started swelling on or around the 19th and patient went to the urgent care on the morning of 03/22/21. Patient was sent to imagining center to have venous doppler where they in turn sent her to the ER after having a positive venous doppler study. Blood clot noted behind right knee.
1154610	3/31/2021	AL	64	M	3/15/2021	3/16/2021	DVT Blood clot, followed by pulmonary embolism

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1154606	3/31/2021	FL	69	F	3/3/2021	3/10/2021	Patient began having symptoms 7 days after vaccination: chest pain, shortness of breath, feeling like a lump in the throat. Over several days symptoms worsened, and included upper back pain and some pain in the upper left arm. Patient went to urgent care clinic on the morning of March 15, where staff decided to send patient by ambulance to the hospital. She was admitted to the hospital and diagnosed with having 5 blood clots in her lungs. She was discharged March 16 in the evening on Eliquis 5mg twice a day. She states the hospital did not know what caused the blood clots, and were aware she had been vaccinated recently. She has not had a doctor visit in years, but is now established with a primary care physician for follow-up care. The second Moderna dose was given today 3/31/21.
1152349	3/31/2021	IA	47	F	3/18/2021	3/21/2021	developed a blood clot in left calf
1153533	3/31/2021			M	1/15/2021	3/5/2021	blood clots in the lungs; certain cardiac problems; On 05MAR2021, he tested positive to COVID; On 05MAR2021, he tested positive to COVID; This is a spontaneous report from a non-contactable consumer (patient). A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose via an unspecified route of administration on 15Jan2021 (Batch/Lot number was not reported), first dose via an unspecified route of administration on 25Dec2020 (reported as 25Dec2021; Batch/Lot number was not reported); both as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. On 05Mar2021, he tested positive to COVID. It's now been 16 days he has COVID. He stated he has blood clots in the lungs and certain cardiac problems on an unspecified date. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on 05Mar2021. The outcome of the events was unknown. No further follow up excepted. Batch/lot number cannot be obtained.

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1153367	3/31/2021	UT	77	M	2/26/2021	2/26/2021	left leg was cold/left foot was 79-82 degrees Celsius; blood clots in his left leg/he had three/first one on 02Mar, second one 13Mar and the third one yesterday; he had the Pfizer vaccine on 15Feb and 26Feb; he had the Pfizer vaccine on 15Feb and 26Feb; This is a spontaneous report from a contactable consumer (patient). A 77-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose via an unspecified route of administration on 26Feb2021 (Batch/Lot Number: EN6203) as single dose for covid-19 immunisation; tafamidis (VYNDAMAX), route of administration, start and stop date, batch/lot number and dose were not reported for an unspecified indication. The patient took the first dose of PFIZER-BIONTECH COVID-19 VACCINE on 15Feb2021 at age of 77 years old for covid-19 immunisation. The patient medical history and concomitant medications were not reported. A patient taking Vyndamax medication who stated that he had experienced blood clot in his left leg. Clarified that he had the Pfizer vaccine on 15Feb2021 and 26Feb2021. Clarified that on 02Mar2021 that he had blood clots in his left leg. Stated that he had three. Stated that he had the first one on 02Mar2021, second one 13Mar2021 and the third one yesterday (15Mar2021). Stated that he was told left leg was cold. Stated that he took his temperature with a thermometer and his left foot was 79-82 degrees Celsius. Stated that the right foot is 95-96 degrees Celsius. Stated that he filled it out for the Covid vaccination. Stated that he reported Vyndalink when it asked what other medications that he took. The action taken in response to the events for tafamidis was unknown. The outcome of events was unknown.



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1153487	3/31/2021	WV	65	F	3/3/2021	3/12/2021	Blood clots; This is a spontaneous report from a contactable consumer (reported for herself). A 65-years-old (non-pregnant) female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Solution for injection, Lot Number: EN6199, expiry date not reported), via an unspecified route of administration, administered in left arm on 03Mar2021 10:45 at a single dose for covid-19 immunisation. Medical history included known allergies to sulpha. The patient had no Covid prior vaccination. Concomitant medications included atorvastatin (LIPITOR) and lisinopril, both taken for an unspecified indication, start and stop date were not reported. The patient had no other vaccine in four weeks. The patient had the vaccination on a public health clinic/veterans administration facility. On 12Mar2021, patient experienced blood clots that resulted in doctor other healthcare professional office/clinic visit, and emergency room/department or urgent care. The patient was not tested for Covid post vaccination. Therapeutic measures were taken as result of the event which included that the patient was put on blood thinners. The event blood clots recovered with lasting effects.

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1153425	3/31/2021	CA	45	F	1/15/2021	1/15/2021	<p>Deep vein thrombosis in right calf; received bnt162b2, dose 2 on 15Jan2021/first dose on 29Dec2020; received bnt162b2, dose 2 on 15Jan2021/first dose on 29Dec2020; This is a spontaneous report from a contactable physician (patient). A 45-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in the left arm on 15Jan2021 (Batch/Lot number was not reported) at a single dose for covid-19 immunisation. The patient received the first dose on 29Dec2020 in the left arm for covid-19 immunisation. The patient did not receive any other vaccines in four weeks. Medical history included allergies: Sulfa. Patient was not pregnant at the time of report. The patient has not had COVID prior vaccination and was not tested post vaccination. Concomitant medication included ethinylestradiol, levonorgestrel (SEASONIQUE) taken for birth control. The patient experienced deep vein thrombosis in right calf on 13Feb2021 with outcome of recovering. The event deep vein thrombosis in right calf resulted in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The patient received aspirin regimen as treatment for the event deep vein thrombosis in right calf.; Sender's Comments: Based on the information currently available, the event deep vein thrombosis most likely represents an intercurrent medical condition and was unrelated to Bnt162b2 vaccine. A possible contributory role of concomitant drug ethinylestradiol, levonorgestrel to the event can not be totally excluded. Case will be re-assessed upon the additional information provided. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.</p>

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1153367	3/31/2021	UT	77	M	2/26/2021	2/26/2021	left leg was cold/left foot was 79-82 degrees Celsius; blood clots in his left leg/he had three/first one on 02Mar, second one 13Mar and the third one yesterday; he had the Pfizer vaccine on 15Feb and 26Feb; he had the Pfizer vaccine on 15Feb and 26Feb; This is a spontaneous report from a contactable consumer (patient). A 77-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose via an unspecified route of administration on 26Feb2021 (Batch/Lot Number: EN6203) as single dose for covid-19 immunisation; tafamidis (VYNDAMAX), route of administration, start and stop date, batch/lot number and dose were not reported for an unspecified indication. The patient took the first dose of PFIZER-BIONTECH COVID-19 VACCINE on 15Feb2021 at age of 77 years old for covid-19 immunisation. The patient medical history and concomitant medications were not reported. A patient taking Vyndamax medication who stated that he had experienced blood clot in his left leg. Clarified that he had the Pfizer vaccine on 15Feb2021 and 26Feb2021. Clarified that on 02Mar2021 that he had blood clots in his left leg. Stated that he had three. Stated that he had the first one on 02Mar2021, second one 13Mar2021 and the third one yesterday (15Mar2021). Stated that he was told left leg was cold. Stated that he took his temperature with a thermometer and his left foot was 79-82 degrees Celsius. Stated that the right foot is 95-96 degrees Celsius. Stated that he filled it out for the Covid vaccination. Stated that he reported Vyndalink when it asked what other medications that he took. The action taken in response to the events for tafamidis was unknown. The outcome of events was unknown.

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1153225	3/31/2021	CT	45	M	2/17/2021	2/17/2021	headache; left arm pain; chills; body aches; This is a spontaneous report from a contactable consumer. A 45-years-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, formulation: Solution for injection), via an unspecified route of administration, administered in Arm Left on 17Feb2021 11:30 (Batch/Lot Number: EL3247) as single dose for covid-19 immunisation. Medical history included irritable bowel syndrome and GERD (gastroesophageal reflux disease) from an unknown date and unknown if ongoing. Concomitant medication(s) included probiotics taken for an unspecified indication, start and stop date were not reported; clotrimazole taken for an unspecified indication, start and stop date were not reported; diphenhydramine taken for an unspecified indication, start and stop date were not reported; colecalciferol (VITAMIN D) taken for an unspecified indication, start and stop date were not reported. The patient previously administered first of BNT162B2 (lot number :EL3247) on 27Jan2021 11:30 AM administered in Left arm for covid-19 immunisation. The patient experienced headache, left arm pain, chills and body aches on 17Feb2021 11:45. The patient did not received prior vaccination and covid tested post vaccination and also reported known allergies as no. Therapeutic measures were taken as a result of headache, left arm pain, chills and body aches and included treatment with acetaminophen 500 mg x 2 tablets. The outcome of the events was reported as not recovered.

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1153172	3/31/2021	FL	89	M	2/24/2021	3/8/2021	Ischemic stroke; Right side of brain and blood vessels affected badly and found blood clots because of ischemic stroke; A spontaneous report was received from a consumer concerning an 89-years-old male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) experienced ischemic stroke and right side of brain and blood vessels affected badly and found blood clots because of ischemic stroke/thrombosis. The patient's medical history included hearing issue. Concomitant medication included losartan. On 24 Feb 2021, approximately 12 days prior to onset of the events, the patient received their first of two planned doses of mRNA-1273 (batch number: 001A21A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 08 Mar 2021, the patient got ischemic stroke. The patient was in hospital for 3 days and doctor put him on blood thinner. MRI (magnetic resonance imaging) of his upper body revealed his right side of brain and blood vessels affected badly and found blood clots because of ischemic stroke. Treatment for the event included blood thinner. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events ischemic stroke and right side of brain and blood vessels affected badly and found blood clots because of ischemic stroke was not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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1153166	3/31/2021	AR		F	2/26/2021	3/3/2021	back was hurting; chest was hurting; Couldn't breathe; very high potassium levels; A spontaneous report , was received from a consumer, concerning herself an 81 - year-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced Couldn't breathe, back was hurting , chest was hurting, very high potassium levels. The patient's medical history was not reported by the reporter .miralax , Flonase nitroglycerin , ondansetron hydrocodone , ranolavine, floresimide, loretedine, clotigogrel, Tamsulosin, gabapentin,sadrovastadin, sertraline , sinoxidil for drug use for unknown indication. On 03 MAR 2021, the patient received the first of two planned doses of mRNA-1273 (Batch number: 012A21A) intramuscularly in left arm for prophylaxis of COVID-19 infection. On 03 MAR 2021, the patient couldn't breathe, hurting back, hurting chest ,high potassium levels .The patient took nitroglycerin and was admitted to hospital, vitals were ok. The patient was administered with breathing treatment. The action taken with the first dose of mRNA-1273 in response to the events was not reported. The outcome of the events Couldn't breathe, back was hurting , chest was hurting, very high potassium levels was resolving .; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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1153142	3/31/2021	WV	69	F	2/4/2021	2/14/2021	bleed on her stomach; blood clot on her leg; A spontaneous report was received from a consumer concerning a 69-year-old female patient who received Moderna (mRNA-1273) vaccine and experienced blood clot on their leg/Deep vein thrombosis and bleed on their stomach/Gastric hemorrhage. The patient's medical history was not provided. No Relevant concomitant medications were reported. On 4 Feb 2021, prior to the onset of symptoms, the patient received their first of two planned doses of mRNA-1273 (Lot number: 013M20A) in the left arm for prophylaxis of COVID-19 infection. On 14 Feb 2021, the patient had a blood clot on their leg for which the patient was hospitalized. While on treatment the patient had a bleed on their stomach. The patient was in ICU for 2 weeks and another week on a regular room. The event, bleed on their stomach, was considered life-threatening. On 4 Mar 2021, the patient was sent to a rehabilitation facility and on 16 Mar 2021, the patient was sent to their home. No Treatment information was provided. Action taken with mRNA-1273 in response to the event(s) was unknown. On an unknown date, the outcome of the events, blood clot on their leg and bleed on their stomach were considered unknown.; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. Critical details such as the patient's medical history, list of concomitant medications, diagnostic findings and hospitalization details are lacking. Further information has been requested.

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1153139	3/31/2021		65	F	3/13/2021	3/14/2021	Mind wonderings at night, like visions or hallucinations; Misspelling issue; Arm sore; Burning aches, not just joint aches; Chills; Burning aches, not just joint aches; A spontaneous report was received from a consumer concerning a 65-years-old female patient, who received Moderna's COVID-19 vaccine (mRNA -1273) and experienced events, arm sore/pain in extremity, chills, burning aches/pain not just joint aches/arthralgia, Mind wonderings at night, like visions or hallucinations/ hallucinations visual and misspelling issue/aphasia. The patient's medical history provided included allergy to sulfa drugs, shrimps, enthesitis and has non- alcoholic fatty liver and hypertension. Also, her grandmother experienced a condition with platters bleeding without clots. Concomitant medications reported included lutropin alfa, rosuvastatin calcium, bisoprolol HCPC, vitamin D3 and calcium. On an unknown date, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Batch number: unknown) unknown route for prophylaxis of COVID-19 infection. On 13 Mar 2021, prior to the onset of the symptoms, the patient received their second of two planned doses of mRNA-1273 (Batch number: 048A21A) intramuscular in the left arm for prophylaxis of COVID-19 infection. On 14Mar 2021, the patient reported having arm sore, chills, burning aches not just joint aches, mind wonderings at night, like visions or hallucinations. Before falling sleep or waking up, patient had images of black and white live photos. She sees image with one eye, and they are not like a dream. When she opens the eyes, the photos disappear, but when closing again, the shots are in color and like cartoons or childish videogames. patient states that this is like a sleep pattern and that she has never been on drugs. She also has misspelling issues. She reported that while writing things down, she notices that are wrongly written and that letters are not coming easy to her mind. The patient states that she does crosswords all the time, so this was very strange for her. The event hallucinations was considered medically significant. No treatment information was provided. The patient received both scheduled doses of mRNA-1273 prior to the events, therefore action taken with the drug in response to the events is not applicable. At the time of this report, the outcome of the events, arm sore, chills, burning aches not just joint aches, mind wonderings at



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1153133	3/31/2021	LA		M	2/21/2021		<p>night, like visions or hallucinations and misspelling issue were unknown.; Reporter's Comments: This case concerns a 65 Y/O F with a serious unexpected event of visual hallucinations along with nonserious unexpected aphasia, pain, pain in extremity, and expected chills and arthralgia. Event onset with unknown latency after first dose mRNA-1273. Event outcomes unknown. Based on current available information and temporal association between use of the product and the start date of the event, a causal relationship cannot be excluded.</p> <p>Blood clot; Swelling in lower leg; A spontaneous report was received from a consumer concerning a male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced swelling in lower leg and blood clot . The patient's medical history was not provided. Concomitant medications reported included blood thinners Xarelto. On 21 Feb 2021 prior to the onset of the events, the patient received his first of two planned doses of mRNA-1273 (Lot number: unknown) for prophylaxis of COVID-19 infection. Treatment for the events was unknown. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, swelling in lower leg and blood clot was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1153319	3/31/2021	CA	70	M	3/11/2021	3/1/2021	blood clot formation that went to my brain; stroke; numbness; paralyzed; vision is messed up; trouble concentrating; This is a spontaneous report from a contactable consumer (patient) . This 70-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: unknown, may be EN8199 or EN6199), via an unspecified route of administration on 11Mar2021 at single dose in right arm about 16:00 for COVID-19 immunisation. Medical history included ongoing probably overweight and blood clot about 20 years ago. The patient's concomitant medications were not reported. It was reported that, the patient who was administered the first dose of Pfizer-BioNTech COVID-19 Vaccine on 11Mar2021. He reported on 14Mar2021 he got a blood clot and had a stroke. He asked if he should or should not still get the second dose of the Pfizer-BioNTech COVID-19 Vaccine related to these events. He had in the hospital from 14Mar2021 to 15Mar2021. He was supposed to have an appointment with his Family Care Physician, Doctor next Monday or Tuesday. He had to go to the emergency room because of these events where he was admitted to the hospital from 14Mar2021-15Mar2021 when he was discharged home under family care. They let him go so soon on 15Mar2021 because he insisted on it, if he was just going to be laying in the hospital he could be laying at home. There was not much they could do in the hospital except observe him, monitoring symptoms of when his numbness and the being paralyzed like in the face for improvement, then they figured the clots were clearing up. They put him on an Aspirin and other unknown things to keep events from reoccurring soon after these events. He was still does not feel 100%, his vision was messed up, he has trouble concentrating, vision was blurred sometimes; that was what happened, he knew he had a stroke when his vision went south on him on 14Mar2021. While in the hospital they did everything except no x-rays; he had CT scan, lots of bloodwork and stuff like that. He does not have further information on those tests or results. The seriousness of the events blood clot formation that went to my brain, stroke, numbness and paralysed was reported as serious (hospitalized). The outcome of events was reported as unknown. Information about lot/batch number has been

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							requested.
1154356	3/31/2021	SC	72	M	2/17/2021	3/22/2021	Developed a blood clot behind the left knee. Symptoms started on 3/22/2021. Saw physician on 03/23/2021 for tests and diagnosis
1146300	3/30/2021	MN	91	F	2/27/2021	3/10/2021	Systemic: blood clots-Medium, Systemic: Nausea-Medium, Systemic: Neurological Disorder (diagnosed by MD)-Medium, Systemic: Stroke-Severe
1148182	3/30/2021	OH	78	F	3/19/2021	3/19/2021	pt stated that about an hour after she got the vax she had severe headache, extremely tired and pain in right leg muscle. On 2/20/21 all symptoms were gone except the pain the the right leg between her hip and knee on the outside of the leg. On 2/26/2021 she went to the ER. They did Covid Test, EKG, Chest X-ray and blood work. All test were negative. She was released to go home. On 3/4/2021 she woke up and her right leg had turned black and blue. She call 911 and taken to the ER where they did blood test, EKG, Chest Xray, CT, Spine Xray and US to see if she had any blood clots. She did not have any blood clots and all test were negative. Pt was released to FU w/ her PCP on 3/12/21. He took more blood work. Pt was told to drink water take more vitamin D. Pt still has some pain.
1146205	3/30/2021	NY	67	F	2/9/2021	3/13/2021	My wife had several blood clots in both lungs. She is now on blood thinners after spending 1 week in the hospital.
1147922	3/30/2021	OR	38	F	3/22/2021	3/23/2021	Off-cycle menstrual/vaginal bleeding. Today is 7th day of heavy bleeding, about twice as heavy as a heavy flow day for a normal menses. Many large blood clots through the day and night.

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1147839	3/30/2021	IN		F	3/10/2021	3/10/2021	Per clinical pharmacist internal report: Adverse Drug Reaction Vaccine: COVID vaccine (unclear if 1st or 2nd and which manufacturer) Reaction: Unclear if associated with vaccine but wanted to report in case it is Patient presented to hospital via EMS with a CC of dizziness and nausea. She was found to have increase O2 demands (4L O2, 3L O2 at home) but was ready for discharge when she developed aphasia, bilateral grip weakness, and staring into space. Oxygen was increased to 10L and a Code Stroke was called. Subsequent workup was negative for a stroke (MRI, CT). The following day, another episode occurred and MRI did show an acute left frontal stroke determined to be embolic in nature per neurology in a patient with a below goal INR and atrial fibrillation. The patient has a past medical history of atrial fibrillation (CHADS VASC 5 prior to CVA this admission) and is on warfarin at home. INR at admission was 1.79 (previously stable with home regimen per hospital ACC notes, no missed doses were noted PTA). Due to NPO status, the patient was soon placed on full-dose enoxaparin at 0346 on 3/11 when admitted. This was continued and no doses were missed prior to CVA being diagnosed. The patient's husband states that she was in normal health until her COVID vaccine the morning of admission. Unclear if COVID vaccine could have decreased INR or put patient at a higher clot risk. Of note she was found to have Ulceration and infection of left 2nd toe however systemically she was not exhibiting signs of infection. Pfizer COVID-19 Vaccine - lot number: EN6199 Given at hospital on 03/10/2021

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1147755	3/30/2021	CT	64	F	3/27/2021	3/29/2021	I have tinnitus...so loud I can not get away from it. I noticed it when I went to sleep last night. I had the shot at 3Pm Saturday. I woke up at 3:47 and started to feel terrible. Chills, severe congestion, head hurt so bad, nauseous, ached all over. I have never felt so badly EVER. at 3pm Sunday I took two tylenol and everything got better. I was fatigued but functioning. I still had a slight headache but was able to eat a light dinner. Monday I was so fatigued I could not drive or go to work. I had severe brain fog. Monday night I noticed how loud my ears were when I went to bed. I could not get away from the noise. today the brain fog seems to be lifting but I am still drained and not feeling great. no energy. I have heart palpitations and shortness of breath. At one point I had a pain in my chest and was concerned about a blood clot. That seems to have passed the palpitations remain.
1147735	3/30/2021	CA	21	F	3/27/2021	3/27/2021	Few hours after I got the vaccine I experienced sinus pressure in my left nostril. I went to blow my nose and a blood clot came out. I tried to blow my nose again but nothing came out. I went to sleep and the next day (the day after I got the vaccine) I still felt the same sinus pressure. I showered about mid-afternoon that day and after I got out of the shower my nose was bleeding, but it was a mild nose bleed. The rest of the day, I experienced a headache that felt like it was coming from the place I experienced the sinus pressure. The head got progressively worse as the day went on, I took Advil to get rid of the pain and went to sleep early. The next few days I experienced a headache that would be mild when I woke up in the morning, then got progressively worse as the day went on. Right now (4 days after the vaccine as I'm submitting this report) the pain of the headache has somewhat subsided, but the pain is still present.
1147604	3/30/2021	WV	45	F	1/29/2021	1/30/2021	L JUGULAR AND UE DVT LEFT UPPER EXTREMITY SWELLING ACUTE THROMBOSIS OF LEFT BRACHIAL VEIN ACUTE THROMBOSIS OF LEFT BASILIC VEIN ACUTE THROMBOSIS OF LEFT INTERNAL JUGULAR VEIN

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1147110	3/30/2021	OH	66	M	2/17/2021	2/18/2021	Arm hurting at the injection site; Slight headache; This is a spontaneous report from a contactable consumer (patient). This 66-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; lot number EL9266) via an unspecified route of administration in the left arm on 17Feb2021 at 11:00 (at the age of 66-years-old) as a single dose for COVID-19 immunisation. Medical history included deep vein thrombosis (DVT), gout, high blood pressure (HBP), high cholesterol, focal segmental glomerulosclerosis (FSGS), rheumatoid arthritis, and penicillin allergy, all from unknown dates and unknown if ongoing. Prior to vaccination the patient had not been diagnosed with COVID-19. The patient reporting taking concomitant medications. The patient previously received moxifloxacin hydrochloride (AVALOX) from an unknown date for an unknown indication and experienced drug allergy. The patient had not received any other vaccines in the 4 weeks prior to the COVID vaccine. The patient experienced arm hurting at the injection site and a slight headache for a couple days on 18Feb2021 at 06:00. The events were reported as non-serious and did not require hospitalization. No treatment was received for the events. The clinical outcomes of arm hurting at the injection site and slight headache were recovered in Feb2021. It was also reported that since vaccination the patient had not been tested for COVID-19.
1146214	3/30/2021	WA	28	F	3/17/2021	3/28/2021	Was 5 weeks pregnant at time of vaccine with strong HCG levels, approximately 2 weeks after vaccination patient suffered a miscarriage. Vaginal bleeding, cramping and passed large clots including a sac like tissue.
1147267	3/30/2021	CO	74	M	3/20/2021	3/21/2021	Had vaccine about 9:35 am on 3/20/21. In the middle of the night about 2:30 am 3/21/21 He should signs of paralysis on right side of his body and was not able to walk. Went to the emergency room on 3/21/21. Admitted to the hospital. MRI was done about 8:00 pm on 3/21/21 and results were blood clot on left side of the brain caused a stroke. Paralysis of right side of his body and changes in speech. Transferred Rehabilitation Hospital 3/24/21. Possibility of second stroke, and another scan done 3/29/21. Waiting for results

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1147964	3/30/2021	ID	46	M	3/18/2021	3/18/2021	Within an hour of receiving the vaccine I felt a sharp pain shoot down the back of my knee to my heel. I continued to work with the pain. The next day my knee and calf was sizeably larger. I went to the urgent care on March 19, 2021. Then to the Emergency room on March 20, 2021. They performed an ultrasound of my leg and found a blood clot. It is in a superficial vein. Followed up with a vein doctor and will go again in three months for another follow up.
1143483	3/29/2021	WA	49	M	3/9/2021	3/1/2021	Blood clot; Unable to use arm at all; This is a spontaneous report from a contactable consumer (patient, self-reported). A 49-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiry dates were not provided), via an unspecified route of administration, in arm left, on 09Mar2021 02:15 AM, as single dose for COVID-19 immunization. Patient's medical history included Fibromyalgia. Concomitant medications were not reported. Patient was not diagnosed with COVID, prior vaccination. Patient has not been tested for COVID, post vaccination. Patient did not receive other vaccine in four weeks of vaccination. On an unknown date in Mar2021, patient had Blood clot and patient was unable to use arm at all. Patient resulted in Emergency room/department or urgent care, Disability or permanent damage in Mar2021. Patient did not receive treatment for adverse events. Seriousness of the events reported as hospitalization and disability. Outcome of the events was not recovered. Information about lot/batch number has been requested.
1144314	3/29/2021	CA	81	M	3/14/2021	3/26/2021	patient complained of shortness of breath of 3/22/2021 to primary care physician approximately 1 week post covid vaccine. CT Scan was ordered. Confirmed on 3/26/2021 as Left Lower lobe occlusion and diagnosed with Pulmonary embolism. On 3/26/2021 at Emergency department, he also showed bilateral PE with large clot burden. Patient is hospitalized a this point since 3/26/2021 and has been treated for PE since. He was discharged on 3/28/2021 and continue treatment as appropriate with Rivaroxaban.

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1144204	3/29/2021	TX	23	F	3/17/2021	3/17/2021	Pt vaccinated @1430. 1436 pt c/o Itching, tingling to mouth and nose and one side of throat, nausea. Pt given Benadryl 50mg PO. Bp 166/81, P 98, SPO2 99%, mild wheezing auscultated. Car seat leaned back, MD consulted. Pt has hx blood clot Oct 2021, currently on Lovenox BID. Pt used her personal inhaler she had in car. Hx of anaphalaxis with bee stings, Fentanyl, Hydrocodone. EMS called, on site <5min, care transfered, pt being taken to local ER. Pt advised to consult PCP to determine if she should get 2nd dose. RN
1143895	3/29/2021	KS	55	F	1/13/2021	1/18/2021	13th of January received first Moderna shot. 18-19th began to have headaches 22nd headaches worsened 25th at the doctor's (tested negative nose swab) home till 28th (28th tested positive for corona after having her first shot at Advent) stroke symptoms at school 28th Advent did CT scan MRI venous thrombosis diagnosis, from front to back, hemorrhage in the northern hemisphere 29th blood thinner administered to attempt to drain clot, seizures 31st passed away
1143602	3/29/2021		63	F	2/26/2021	3/1/2021	Shortly after 2nd vaccine patient developed local reaction with lymphadenopathy, then developed within a week a roply painful vein extending to the wrist. Seen 1 month later, ultrasound in clinic with peripheral thrombosis of Left arm, no axillary or deep venous system thrombosis. No history of same. Given extent of thrombosis 45 days of anticoagulation for peripheral thrombosis prescribed.
1145050	3/29/2021	PA	78	F	1/21/2021	2/2/2021	2/2/2021 red scaly skin rash dorsum right hand. Next day pinpoint hemorrhagic 2-4 mm sized lesions on palmar surface of fingertips and sides of fingers, 21 in all. Diagnosed as clots by cardiologist and dermatologist on 2/25. Gradual resolution and healing by 3/14/2021.



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1143485	3/29/2021			F	3/13/2021	3/14/2021	woke up with a blood clot lying in her mouth; This is a spontaneous report from a contactable consumer (patient's parent). A 23-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 13Mar2021 (Batch/Lot number was not reported) as single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient received her first dose of the Pfizer COVID-19 vaccine yesterday (13Mar2021), and this morning (14Mar2021) she woke up with a blood clot lying in her mouth. The reporter wanted to know if this side effect had been reported or of this could be associated with the Pfizer COVID-19 vaccine. The outcome of event was unknown. Information on the lot/batch number has been requested.
1145194	3/29/2021	IN	55	M	3/21/2021	3/23/2021	Patient had Moderna covid vaccine #1 on 3/21/21. Patient presented to the emergency dept on 3/23/21 complaining of a discolored right arm (turning purplish) and swollen. Patient had a blood clot in Sept 2020 and was on anticoagulation until Jan 2021. Ultrasound of the RUE found an occlusive thrombus, R subclavian and right axillary vein as well as a nonocclusive thrombus within the inferior R internal jugular. Patient was initiated on apixaban anticoagulation. Patient was seen back in the office and had a repeat ultrasound due to lack of improvement on 3/26, thrombus was unchanged. Patient continued on apixaban. Patient called the office on 3/29 with no improvement in his arm. Patient to be re-evaluated

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1143474	3/29/2021			M	2/24/2021	3/1/2021	blood clots in couple of toes near nails; observed swollen; This is a spontaneous report from a non-contactable consumer. A 55-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EL3247), via an unspecified route of administration, administered in arm left on 24Feb2021 15:15 as a single dose for covid-19 immunisation . The patent has no medical history. The patient has no known allergies. The patient's concomitant medications were not reported. In Mar2021, the patient was observed with swollen and blood clots in couple of toes near nails. The events was not treated. The outcome of the events was not recovered. The patient has not had covid prior to vaccination and was not testes for Covid post vaccination. No follow-up attempts are possible. Information about Lot/Batch cannot be obtained.

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1143469	3/29/2021	FL	66	F	2/9/2021	2/1/2021	<p>phlebitis in my Right leg; small blood clot; This is a spontaneous report from a contactable nurse (patient). A 66-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in right arm on 09Feb2021 (Batch/Lot Number: EL9269) as single dose for covid-19 immunisation. Medical history included many allergies. The patient has no COVID prior to vaccination. The patient had other medications in two weeks but no other vaccine in four weeks. The patient previously had the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot: EL9263) on 20Jan2021 at 10:00 administered in the right arm for Covid-19 immunization. On 20Feb2021 at 12:00 (also reported as "in February"), the patient had a phlebitis in her right leg, a week later (Feb2021) a vascular surgeon office did an ultrasound and found a small blood clot. The events resulted in doctor or other healthcare professional office/clinic visit. The events were treated with Eliquis BID (twice a day) for 45 days. The patient was not tested for COVID post vaccination. The outcome of the events was not recovered.; Sender's Comments: A causal relationship between BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) and the event thrombosis cannot be excluded based on temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate .</p>

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1143465	3/29/2021	MI	82	F	1/19/2021		<p>Superficial blood clot in the leg/area is sore to touch; A spontaneous report was received from a consumer (patient), concerning a 82-years-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced superficial blood clot in the leg/area is sore to touch (thrombosis). No medical history was reported. No concomitant medications were reported. On 19 Jan 2021, the patient received the first of two planned doses of mRNA-1273 (Lot number: not provided), on 15 Feb 2021, the patient received the second of two planned doses of mRNA-1273 (Lot number: 027L20A) intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, the patient experienced a superficial blood clot in her leg (medically significant). She also reported that the area was sore to touch. The doctor prescribed medication to treat her problem, but they said to wait a week to see if it solved on its own before taking it. She was also applying ice pack on the affected area. No further information as reported. The patient received both scheduled doses of mRNA-1273 prior to the event, therefore action taken with the drug in response to the event is not applicable. The event of superficial blood clot in the leg/area is sore to touch (thrombosis) was unresolved. The reporter did not provide assessment for the event of superficial blood clot in the leg/area is sore to touch (thrombosis).; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p>

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1142935	3/29/2021	NV	87	M	2/17/2021	2/24/2021	1 week after second dose I developed a blood clot behind my left knee, in hospital for 9 days; This is a spontaneous report from a contactable consumer (patient). An 87-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 17Feb2021 09:00 (Lot Number: EN6201) as SINGLE DOSE for COVID-19 immunization. Medical history included high blood pressure, controlled from an unknown date and unknown if ongoing and penicillin allergy from an unknown date and unknown if ongoing. The patient previously had first dose of BNT162B2 in the left arm (lot number: EL3244) on 20Jan2021 for COVID-19 immunization. Concomitant medications included apixaban (ELIQUIS), metformin, caredevil and fish oil; all taken for an unspecified indication, start and stop date were not reported. On 24Feb2021 12:00 PM, it was reported that the patient 1 week after second dose, developed a blood clot behind left knee, in hospital for 9 days that also resulted in emergency room/department or urgent care. The event was treated with blood thinners. The patient had no COVID prior to vaccination and has not tested for COVID post vaccination. The outcome of the event was recovering.

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1142915	3/29/2021	WA	54	F	1/2/2021	1/20/2021	Blue/black blood clot on middle finger right hand; Burning in middle finger on right hand; Itchiness on middle finger on right hand; Pain in middle finger on right hand; A spontaneous report was received from a Consumer concerning a 55-years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events burning in middle finger on right hand/burning sensation, itchiness on middle finger on right hand/pruritus, pain in middle finger on right hand/pain in extremity, blue black blood clot on middle finger right hand/thrombosis. The patient's medical history was not provided. No relevant concomitant medications were reported. On 2 Jan 2021, prior to the onset of the events the patient received their first of two planned doses of mRNA-1273 (lot batch: 037K20A) intramuscularly for prophylaxis of COVID-19 infection. On 20 JAN 2021 1.00 pm, after taking mRNA-1273, the patient felt weird sensation in right hand middle finger. She felt burning, itchiness, pain and had a dark blue/black blood clot on inside of finger. 2 hours later it started to fade down (purple in color). In the evening it was considerably lighter. On 21 Jan 2021 there was a light imprint of the blood clot. Blood clot went away later that day. Patient did not received treatment. Action taken with mRNA-1273 in response to the events was not reported. On 20 Jan 2021 the outcome of events burning in middle finger, itchiness on middle finger on right hand, pain in middle finger on right hand was resolving. On 21 Jan 2021 the outcome of event blue black blood clot on middle finger right hand was resolved.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.

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1142665	3/29/2021	TN	36	F	2/12/2021	2/14/2021	Working full time during this post injecting time but 2days later sarterd with nausea and vomiting and then itching and then next day asthma started to flare up and by the next day it developed into full blown exacerbation. As everything worsened and couldn't control anymore with inhaler and even tried nebulizer, I went to hospital. I went to ER that day on 2/17. They did breathing treatments, several Blood tests, chest xrays, Epi injection, IV steroids and several other meds, oxygen, and was admitted. As it worsened I had to be intubated 3 different times, where I would get to point they thought could be weaned off and for a day or two and would be a little better and then would worsen again requiring me to be reintubated for a total of about 10 days on the ventilator. During this time on vent second time I developed pneumonia, staph/MRSA, UTI. After being put on vent 3rd time I had to be life flighted to bigger hospital ICU. Then after a few days they were able to wean of ventilator but during which time I developed laryngospasms. I continued to improve with breathing but mentioned I had leg pain and the said probably due to low sodium and lack of mobility. I was finally released on 3/5 and discharged home with home health but sent home in supplemental oxygen due to says dropping and poore tolerance without sitting O2 stay at hospital prior to DC home. After getting home the next day or two right leg pain worsened along with breathing worsenining and HH sent me to PCP who discovered blood clots and sent me to local er, that day which was 3/8. That hospital evaluated breathing issues and took blood work and chest xrays, started me on heparin drip and sepsis protocol and then called in life flight to send me to bigger ICU hospital within a few hours after arrival which they debated on ventilator or bipap but ended up on bipap and flown to hospital. There I was treated for breathing issues, infection, clot, vocal cord dysfunction from the multiple intubations then sent home when stable again with home health RN, PT, PT and ST. Also during all this hospital stay I was treated 4x for covid and all negative. Then after coming home this last time on 3/13 i had 15-20lb with gain in a little over a week and in 3 of those last days almost 9lbs with abdominal distension and chest pain/ nausea/ dizziness/low BP but fluctuating high at times / high Hr, so referred back to PCP 3/23 who sent me to ER that day concerned of abd blessed, kidney and

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or liver issues/sepsis/etc. PCP sent to ER. They did blood work and Abd CT and xray not showing anything and blood levels of liver slightly elevated, with blood in urine and so they said nothing of concern even though I went from looking normal to 6/7 months pregnant in less than a week. Followed up with pulmonologist who said bases of lungs hypoventilated, PFT very poor, wheezing and tight and WBC still up and gave me more steroids and asthma meds. Went to urologist due to blood in urine and also having urinary retention. They advised me to self cath and I will follow up in 1 month to determine if they need to do more tests to look into it more. PCP still concerned about these new abd. And other symptoms, and referring to specialists (cardiologist, Gastroenterologist, and Nephrologist) along with others already seeing too find the root of what are causing these new problems and if other organs are being affected with this whole immune response. I work full time, had 3 kids and works out with no limitations in my daily activities or ability to function, however since all this and being the hospital for pretty much most of laar month, the ongoing breathing issues (which I'm still requiring O2 at home) and all the other medical issues and the physical weakness/ lack of cardiopulmonary endurance I am unable to work (on short term disability/FMLA) and limited to home with ability to do much at all. Now I'm left with decreased income and tons of medical bills to come which is very concerning in itself how I will even pay since i can't work right now, but the most concerning is I'm still in this waiting game to figure out why things are not improving that much and why these other symptoms are arising. I have worked my whole life and love my work and my life and was trying to protect from this horrible virus by doing my part and getting vaccinated. But it seems that my life went from nothing wrong to one crazy medical reaction to another after this 2nd covid-19 moderna injection.



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1143491	3/29/2021	VA	51	F	2/19/2021	3/5/2021	heavy bleeding with lots of blood clots; extended and heavy menstrual period/ heavy bleeding with lots of blood clots; This is a spontaneous report from a contactable consumer (patient). A 51-year-old non-pregnant female patient received second dose of BNT162B2 (Pfizer product), lot no. EN5318, via an unspecified route of administration (left arm) on 19Feb2021 at a single dose for COVID-19 immunisation at a workplace clinic. Medical history included high cholesterol and anxiety. No known allergies. No COVID prior to vaccination. Concomitant medications were not reported. Historical vaccine included first dose of BNT162B2 (brand: Pfizer, lot no. EL9261, left arm) for COVID-19 immunisation on 30Jan2021 at age of 50 years old. No other vaccine in four weeks. The patient was experiencing extended and heavy menstrual period. Her cycle began on 05Mar2021 and was still happening as of today 16Mar2021. She had heavy bleeding with lots of blood clots. This was not normal for her at all. She is calling her doctor tomorrow. No treatment received for the events. No COVID test post vaccination. The outcome of the events was not recovered.
1145352	3/29/2021	IL	32	F	3/5/2021	3/23/2021	Acute Splenic Artery Thrombosis
1145963	3/29/2021	NY	73	F	2/24/2021	3/17/2021	bilateral pulmonary emboli; ER ultrasound of legs (no clots); CT scan showed PEs; administered 2 shots Lovenox; Rx 10 mg Eliquis 2x/day for 1 week, then 5 mg 2x/day.
1144446	3/29/2021	WA	79	F	1/26/2021	1/28/2021	Received vaccine on 01/26/2021 and unknowingly experienced event. Early morning of 01/28/2021 had fainting spell and thought it was caused by low blood pressure. Felt fine for remainder of day. On evening of 01/29/2021 I started having strange symptoms. Could not concentrate, vision impaired and couldn't figure out what evening meds I needed to take. Decided to go? to hospital on 01/30/2021. Getting ready, I passed out and husband called emergency services. Husband learned later in the day that I had a stroke. Doctors i;nfo?rmed that had blood clots in heart and lungs. Doctors advi;se not to get second vaccine shot.

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1141687	3/28/2021	IL	59	F	2/24/2021	3/14/2021	Blood clots a few weeks after 2nd dose. Currently being treated with Xarelto. No other changes in patient medical or prescription history. Covid vaccine was the only thing that was new. Patient had no prior history of blood clots.

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1140696	3/28/2021	MI	69	F	2/2/2021	2/4/2021	Multifocal Intracerebral Hemorrhage; Disseminated Intravascular Coagulopathy; strokes, Ischemic and Hemorrhagic; strokes, Ischemic and Hemorrhagic; AML; Leukemia; Blood clot diagnosis; Sore lower leg; RDW Stand. Dev. H/RDW Coeff Var H; Platelet Count L, Platelet Vol L; Neutrophils L; Band Neutrophils H; Monocytes H; Metamyelocytes H; Myelocytes H; Absolute Neutrophils L; Other Cell Type Blast Like Cells H; This is a spontaneous report from a contactable consumer. A 70-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) lot number: EL9261, via an unspecified route of administration, administered in Arm Right on 02Feb2021 08:30 (Batch/Lot Number: EL9261) as SINGLE DOSE for covid-19 immunisation. Medical history included breast cancer (8 years ago no chemo just radiation). Historical vaccine included first dose of BNT162B2 (lot number: EL0140) on 11Jan2021 for Covid-19 immunization. Concomitant medication included vitamin c [ascorbic acid] (VITAMIN C [ASCORBIC ACID]), calcium citrate, colecalciferol (CALCIUM CITRATE + D3), glucosamine, magnesium citrate, docosahexaenoic acid, eicosapentaenoic acid, tocopheryl acetate (OMEGA 3 [DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID;TOCOPHERYL ACETATE]) and curcuma longa (TURMERIC [CURCUMA LONGA]). On 04Feb2021, the patient's blood work result showed red cell distribution width (RDW) stand. dev. high; RDW coeff var high, platelet count low, platelet vol low; neutrophils low; band neutrophils high; monocytes high; metamyelocytes high; myelocytes high; absolute neutrophils low; other cell type blast like cells high. On 15Feb2021, the patient experienced sore lower leg. On 16Feb2021, the patient was diagnosed with blood clot. On 19Feb2021, the patient was diagnosed with leukemia. On 20Feb2021, the patient was diagnosed with acute myeloid leukemia (AML). On 21Feb2021, the patient had tow types of stroke, ischemic and hemorrhagic, the patient was intubated. On 23Feb2021, the patient was extubated and died due to multifocal intracerebral hemorrhage, disseminated intravascular coagulopathy, acute myeloid leukemia with blast crisis. The patient received chemotherapy and leukapheresis as treatment. The patient died on 23Feb2021. An autopsy was not

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							performed.; Reported Cause(s) of Death: Disseminated Intravascular Coagulopathy; Acute Myeloid Leukemia With Blast Crisis; Multifocal Intracerebral Hemorrhage
1141723	3/28/2021	NY	67	M	2/1/2021	3/18/2021	My leg and foot swelled on Thursday. We elevated and treated with heating pad & Advil. The swelling went down, so we started for home, drove 4hrs. My leg & foot swelled back up. We went to the ER they gave me an ultrasound, and said I had 2 blood clots in my leg. They prescribed, Eliquis.
1142097	3/28/2021	PA	50	M	3/13/2021	3/20/2021	1. Around March 20th, 7 days after the vaccination, felt mild pain between left ear and temple. Pain was more if the head is shaken or if I jump. This pain disappeared on 27th March. 2. On March 26th both the feet are swollen , left foot more than the right. I still feel slight numbness in the feet today on March 28th. 3. On March 27th , around noon, a blood clott showed up on my left palm , it caused intense pain in the arm for 10 minutes before starting to subside itself. I felt a lump in my palm , it was visible in dark color ,about 1 cm in size. I still feel it in my palm today on 28th March.
1142211	3/28/2021	CA	19	M	3/26/2021	3/26/2021	Unknown relation to vaccine but since I was vaccinated, I have had about three nosebleeds per day with unusually heavy bleeding (lasting more than 20 minutes). They seem to be random with no obvious cause. Treatment was per the usual, folded tissue paper in nose and tilt head forward to allow the blood to clot.

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1140686	3/28/2021	OH		M			throwing blood clots within a few weeks of final vaccine.; This is a spontaneous report from a contactable consumer (patient's daughter) via a Pfizer-sales representative. A male patient of an unspecified age received the second dose (reported as final dose - pending clarification) of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date as SINGLE DOSE for COVID-19 immunisation. Medical history included history of blood clots and transient ischemic attacks (TIAs). The patient's concomitant medications were not reported. Historical vaccine includes first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on an unspecified date for COVID-19 immunisation. On an unspecified date, the patient experienced throwing blood clots within a few weeks of final vaccine. The patient and the daughter are concerned about the vaccine having this effect. The outcome of the event was unknown. Information about the batch/lot number has been requested.
1139202	3/27/2021	TX	76	F	1/16/2021	2/20/2021	02/20/2021Shortness of breath on climbing 15-20 stairs, 02/24/2021/D-dimer test very high, 02/24/2021Admitted to hospital. CT Angiogram showed blood clots in lungs. Administered IV Hyperin. scans of legs-no blood clots, Scan of heart and arteries. 02/26/2021Released with perscription of Eliquis. 03/04/21 Blood test by Hematologist Normal; 03/08/21 CT Scan of body-Normal-no tumors/cancer detected
1139635	3/27/2021	KY		U			I have had a heavy period every other week with large quantities of clots and pain. Periods also last much longer. Currently on period, 7th day, and still no sign of stopping.

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1140235	3/27/2021	FL	69	F	2/20/2021	3/14/2021	Couple of days after first Vaccine my left leg just above my ankle on underneath the skin it felt like the blood getting very hot and feverish for a few minutes then go away for awhile then do it again and happening constantly. Then in my 3rd week it jumped to middle of leg and then up to lower knee (all left leg), then go back down to ankle. It just feels like hot blood under the skin. I then called my primary doctor and they had me do in as I was concerned it could be a blood clot, but he checked and assured me it wasn't. Dr. said they have been seeing patients with same issue I am having, having the Pfizer shots but those people have in both legs or both arms and he really couldn't give me a answer but to report to CDC. He said to proceed with second shot which I did and still having same issue. I called my primary doctor back again this week as this continues with "Hot Spots" and I was experiencing numbness in two small toes on left leg and next 2 toes tingling and concerned for these "Hot Spots" (no rashes). He is now setting me up for a sonogram to reassure me it isn't a blood clot. I was never sick with the shot, just minor soreness in arm for following day and tired on first round. Called me a prescription in for Gabapentin 300mg.
1139939	3/27/2021	IL	63	F	3/13/2021	3/14/2021	PT CALLED ON 3-27 TO REPORT A BLOOD CLOT IN HER EYE AFTER RECEIVING THE VACCINE ON 3-13, STILL PRESENT
1139882	3/27/2021	GA	40	F	3/22/2021	3/24/2021	I started my period two days after receiving the shot, which was two weeks earlier than expected. Flow was unusually heavy and very clotted - all abnormal for me. While I may have felt some fatigue from the shot, I never felt ill in any way. I also never felt any of the points of pain I might feel with my normal period, such as sore breasts prior to my period and cramps in my upper legs when it arrived. I only had a sore arm for a day where I received the shot.
1139742	3/27/2021	GA	59	F	3/16/2021	3/22/2021	Extensive dural venous sinus thrombosis, SAH, acute ischemic thalamic infarct. Headache, lethargy, diplopia, right arm weakness

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1139599	3/27/2021	FL	72	M	3/10/2021	3/14/2021	<p>Patient was found deceased in his own home on Monday, March 15, 2021. He was found on the floor in a sitting position with three fingers of his right hand on his right carotid. It appeared that he was getting ready for church, which was a routine event. Although patient was a diabetic, he never had episodes that were life threatening, and was always able to manage to remediate with insulin or food. Patient last spoke to a neighbor at 2:30 a.m. on Sunday, March 14th, who said he appeared to be just fine and they scheduled a date with their dogs on Sunday afternoon. A sheet of instructions found on the kitchen counter at the home informed us that he had a COVID vaccine at the VA Hospital on Wednesday, March 10th. He was documenting side-effects of very sore right arm and low blood sugars. that was unusual because if he was able to manage he wouldn't have noted it. It was apparent that something sudden happened such that he was unable to get to help and his heart rate must have been of concern. We believe that patient suffered onset of some sort of cardiac event, blood clot, high heart rate, or heart attack, that was associated with the vaccine on Wednesday and 4 days later he was suddenly gone, unable to call for help (he has family close by in this community). We want healthcare providers and individuals to be able to make informed decisions about giving/taking the vaccine when there is another health issue such as diabetes to consider. We lost a brother, a father, a friend and a dedicated veteran unnecessarily.</p>
1139491	3/27/2021	NY	45	F	3/22/2021	3/25/2021	<p>I had my second vaccine on Monday, 3/22, and woke up at 1am on Thursday 3/25 with extreme chest pain, shortness of breath, sweating and chills. I went to the ER, and they discovered two blood clots in my lungs. I've never had pulmonary embolisms before, so this is a very strange coincidence. I am in cancer treatment, so my risk of PEs is higher, but the timing is too close for me not to think that the second vaccine traumatized my immune system, causing the PEs.</p>

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1137221	3/26/2021	CO	79	F	1/30/2021	2/27/2021	<p>Blood clots in both legs; Cramps and spasms on her right and left legs; Painful nodules under both arms and shoulders; Itching down to her toes and left side of the body; Injection site itching; A spontaneous report was received from a consumer concerning a 79-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced Cramps and spasms on her right and left legs, injection site itching, itching down to her toes and left side of the body/pruritus, painful nodules under both arms and shoulders/nodules and blood clot in both legs/Thrombosis. Medical history was not reported. Concomitant medications included losartan, cetirizine hydrochloride and pantoprazole. On 30 Jan 2021, the patient received her first planned dose of mRNA-1273 (batch number: 007M20A) intramuscularly for prophylaxis of COVID-19 infection. On 27 Feb 2021, she had her second planned dose of mRNA-1273 (batch number: 01021A) intramuscularly on left arm. Soon, she developed itching at injection site down to her toes and left side of the body. She developed painful nodules on shoulders as well as both under arms and it was mentioned that the one on left side was severe. On 09 Mar 2021, she began experiencing cramps and spasms on her right and left legs. She was diagnosed with blood clots in both legs while in the emergency room (ER). She was treated with hydroxyzine and apixaban. The event blood clot in both legs was considered to be medically significant. The action taken with mRNA-1273 in response to the events injection site itching, itching down to her toes and left side of the body, painful nodules under both arms and shoulders and blood clot in both legs was unknown. The outcome of the events Cramps and spasms on her right and left legs, injection site itching, itching down to her toes and left side of the body and blood clot in both legs was unknown whereas painful nodules under both arms were still sore but better.. The reporter did not provide any causal relationship between mRNA-1273 and the events injection site itching, itching down to her toes and left side of the body, painful nodules under both arms and shoulders and blood clot in both legs.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p>



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1138552	3/26/2021	WI		M			<p>vaccine may be linked to the patient's ITP/the ITP became clinically apparent following the vaccine; A 22-year-old healthy male with no medication use received the Pfizer-BioNTech BNT16B2b2 mRNA vaccine through his work as an emergency department employee. On day three, post-vaccination, he experienced widespread petechiae and gum bleeding, which prompted his presentation. He was current on his vaccines, including yearly influenza, with no history of adverse reactions. He denied respiratory and gastrointestinal complaints or a history of infection. He had no personal or family history of bleeding or autoimmune disease. Vital signs and the remainder of his exam were normal. Laboratory tests revealed normal white-cell count, hemoglobin, and severe thrombocytopenia with a platelet count of <math>2 \times 10^9/L</math>. Two months prior to receiving the vaccine, the patient was evaluated at an outpatient clinic for upper respiratory symptoms. His PCR assay returned negative for SARS-CoV-2, and complete blood count was unremarkable with a normal platelet count of <math>145 \times 10^9/L</math> (reference range, <math>140-400 \times 10^9/L</math>). The upper respiratory symptoms resolved within a few days, and the patient had no further complaints. However, as a precautionary measure, one-week post outpatient evaluation, he was again tested for SARS-CoV-2, which returned negative. At the emergency department on day 3, post-vaccination, the following labs were normal or negative: prothrombin time, partial thromboplastin time, fibrinogen, BUN, creatine, electrolytes, bilirubin, LDH, alkaline phosphatase, albumin, globulin, total protein, and haptoglobin. The aspartate aminotransferase and alanine aminotransferase were mildly elevated; however, they normalized the next day. Additionally, he tested negative for HIV, Hepatitis B, Hepatitis C antibody, and Epstein Barr Virus serology. A nasopharyngeal swab also returned negative for SARS-CoV-2 antigen. The patient was then admitted and given dexamethasone 40 mg daily for 4 days, a platelet transfusion, and intravenous immunoglobulin at 1 g/kg for 2 days. Immunologic studies performed on day 6 for Rheumatoid factor, antibodies for Cyclic Citrullinated Peptide, Anti Centromere, Chromatin IgG, dsDNA, Jo1, Ribosomal P Protein, Ribonucleoprotein, Scleroderma, Smith, Sjogren's Syndrome B, Sm/Rnp IgG, Antinuclear Antibody (<math>&lt;1:80</math>, normal <math>&lt;1:80</math>) were normal. However,</p>

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Sjogren's Syndrome A antibody (2.8) was elevated (normal <1 AI). On day six, post-vaccination, petechiae and oral bleeding decreased, and the patient was discharged with a platelet count of 28 x 10<sup>9</sup>/L. Based on the presentation, a platelet count <100 x 10<sup>9</sup>/L, and the exclusion of alternative causes, a diagnosis of ITP was made. At follow up, on day 11, the patient's platelet count normalized to 173 x 10<sup>9</sup>/L, and the patient tested positive for plasma IIb/IIIa and Ia/IIa platelet autoantibodies. Sjogren's Syndrome A antibody decreased from 2.8 on day 6 to 1.5 (normal <1 AI). Moreover, complement C3 (94) was normal (reference range, 79-152 mg/dL), while complement C4 (10.9 mg/dL) was low (reference range, 16-38 mg/dL). On day 34 a repeat of the patient's abnormal immunologic studies showed a normal value of both Sjogren's syndrome A antibody (SSA AB: <0.2) and Complement C4 (27.6 mg/dL). Additionally, SARS-CoV-2 IgG antibody testing was performed to rule out that a previous COVID-19 infection elicited the ITP experienced on day 3. However, SARS-CoV-2 IgG was negative. As of 16Feb2021, and since the patient's discharge on day 6, he remains healthy without any evidence or symptoms of autoimmune disease. [Correction added on 22Feb2021, after first online publication: 11Feb2021]. Previous studies reported only mild or moderate adverse events following the Covid-19 vaccine. To the author's knowledge, outside of a report in the press, this is the first case published in the medical literature of an individual, with no other cause identified and no associated illness, experiencing ITP after receiving the Pfizer-BioNTech vaccine. The temporal relationship of the patient's presentation 3 days post-vaccine administration suggests, but does not prove, the vaccine may be linked to the patient's ITP. Additionally, the rapid and severe drop in platelet count to 2 x 10<sup>9</sup>/L is reminiscent of the abrupt onset observed in drug-induced thrombocytopenia, which further suggests a recent etiology. However, it must be noted that the incidence of ITP is about 3.3 per 100 000 adults/year.<sup>8</sup> Therefore, it is also plausible that this patient's diagnosis was purely coincidental, given that over 12 million vaccines administered to date. Additionally, 43 448 participants were included in the Pfizer-BioNTech trial, and no ITP was reported. Moreover, considering the low complement C4 (10.9 mg/dL), mildly elevated SSA Ab (1.5), and 2

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months prior, the platelet count (145 x 109/L) was near the lower limit, it is difficult to exclude alternative causes, such as an underlying autoimmune condition with pre-existing ITP. In this scenario, the ITP became clinically apparent following the vaccine, though this patient never manifested symptoms suggestive of autoimmune disease. This case was reported to the FDA's Vaccine Adverse Events Reporting System (VAERS) and is valuable both for post-approval pharmacovigilance and as a foundation for clinicians to evaluate future patients with suspected ITP. Rare vaccination events are important, but do not diminish the enormous utility of vaccination and the well-documented safety profile of the Pfizer-BioNTech BNT16B2b2mRNA vaccine. No follow-up attempts are needed; information about batch/ lot number cannot be obtained.; Sender's Comments: The causal relationship between the reported event immune thrombocytopenia and BNT16B2b2 vaccine cannot be excluded based on a plausible temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

1137940	3/26/2021	FL	84	M	3/12/2021	3/15/2021	About 11:30 PM on 03/15/2021, started gasping for breath when laying down, sat up in lazy boy for a hour and half, beathing returned to normal. About 3:30 PM on 3/16/2021, started gasping for breath again. Called my daughter and she transported me to Hospital. They tested for covid - results negative. They did a C-Scan of my chest and saw a blood clot in each lung. While hooked to the monitors, they found I had Afib. They also did an ultra-sound of my legs and found a small clot in each leg below the knees in a small vein. I have never had any record of clots or Afib. They transferred me to Medical Center early on 3/17/2021. They started a heparin drip to soften the clots. In the afternoon of 3/17/2021, they performed a Suction Thrombectomy to remove the clots from my lungs. On 3/19/2021, they put me on Eliquis Tab. I was released from the hospital in the evening of 3/20/2021.
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1137756	3/26/2021	GA	69	F	3/2/2021	3/25/2021	Vaccine 3/2/2021. Presented to ER 3/25/2021 with chest pain and found to have acute MI with completely occluded left main coronary artery with clot causing cardiac arrest, cardiogenic shock. Currently Critically ill, intubated, high risk mortality.
1137739	3/26/2021	OH	39	M	3/18/2021	3/20/2021	2 DAYS AFTER SM RECIEVED HIS MODERNA VACCINE IN HIS LEFT ARM HIS RIGHT ARM TURNED BLUE. HE WENT TO THE EMERGENCY ROOM TO FIND OUT HE RECIEVED A BLOOD CLOT WHICH THEY THINK WAS CAUSED BY THE VACCINE. HE WAS PUT ON BLOOD THINNERS THAT DAY AND SENT HOME 6 HOURS LATER. HE WILL BE ON BLOOD THINNERS FOR UP TO 6 MONTHS.
1137686	3/26/2021	IL	48	F	3/9/2021	3/25/2021	Patient presented to a local ED on 3/25/2021 & was diagnosed with a deep vein thrombosis in the right lower extremity. She is convinced it is related to the vaccine she received on 3/9/21 and cancelled her appt for her second vaccine.
1138571	3/26/2021	CA	32	F	3/5/2021	3/5/2021	Patient had Pfizer dose #1 on 3/5/21, same night she started to develop left leg swelling and pain. Patient went to ER on 3/8/21, showed superficial venous thrombosis with occlusion of left greater saphenous vein, currently on Eliquis

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1137224	3/26/2021		83	F		2/26/2021	Develop a blood clot on their left knee; Left leg kept swelling up; A spontaneous report was received from a physician concerning a 83-year-old, female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced a blood clot on her left knee and left leg kept swelling up. The patient's medical history included cholesterol unspecified. Products known to have been used by the patient, within two weeks prior to the event, included vitamin D and medications for cholesterol. On 26 Feb 2021, prior to the onset of the symptoms, the patient received her first of two planned doses of mRNA-1273 (Batch number: 038K20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On an unspecified date after the vaccination patient developed blood clot on left leg, leg also kept swelling. Relevant treatment for the event included blood thinners and aspirin. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events, blood clot on their left knee and left leg kept swelling up, was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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1135720	3/26/2021	LA	63	F	2/25/2021		blood clots in upper thigh down to foot; swelling of the foot; tingling; clot was burning and hot; A spontaneous report was received from a consumer concerning a 62-years-old patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events blood clots in upper thigh down to foot, swelling of the foot, tingling, and clot was burning and hot. The patient's medical history included insertion of a blood clot filter. Concomitant medications reported were Xarelto for drug use for unknown indication. She is also taking 17 other medications (not provided) and has other medical issues (not provided). She also has a blood clot filter inside her body (location not provided). She also wears compression and diabetic socks. On 25 Feb 2021, prior to the onset of the events the patient received the first of two planned doses of mRNA-1273 (lot/batch: L014M20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On an unknown date, the patient experienced the event(s) blood clots in upper thigh down to foot, swelling of the foot, tingling, clot was burning and hot. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of event(s), blood clots in upper thigh down to foot, swelling of the foot, tingling, clot was burning and hot was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
1137173	3/26/2021	IA	72	M	3/12/2021	3/12/2021	Superior mesenteric vein thrombosis. No known cause at this time. Hypercoag panel negative. patient hospitalized and currently on Xarelto for 6 months. Received vaccination dose 2 1 week prior.
1136780	3/26/2021	FL	80	M	3/21/2021	3/21/2021	Blood clots in lungs

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1135723	3/26/2021	FL	70	F	1/21/2021	2/1/2021	Blood Clot in Leg; A spontaneous report was received from consumer concerning a 70-years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced blood clot in leg. The patient's medical history was not reported by the reporter. Concomitant medications taken by the patient included blood thinners for blood clot. On 21-Jan-2021, the patient received her first of two planned doses of mRNA-1273 (Lot number: 013L20A) through intramuscular route on left upper arm for prophylaxis of COVID-19 infection. On 18-Feb-2021, prior to the onset of the event, the patient received their second of two planned doses of mRNA-1273 (Lot number: 013M20A) through intramuscular route at right upper arm for prophylaxis of COVID-19 infection. On 23-Jan-2021, after the first dose patient developed leg pain. The patient reported of having the leg pain linger for about 2 weeks before seeing a healthcare professional. The healthcare professional had later found that the leg pain was related to the development of a blood clot. Relevant Treatment for the event was with blood thinner. The patient received both scheduled dose of mRNA-1273; therefore, action taken with the drug in response to the event is not applicable. The outcome of event, blood clot in leg was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.



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1135716	3/26/2021	WV		M		3/4/2021	Blood clot in lungs; Pneumonia; A spontaneous report was received from a consumer concerning her husband, male patient who developed blood clot in lungs/pulmonary embolism, pneumonia/pneumonia. The patient's medical history included Parkinson's. Concomitant product use was not provided by the reporter. The patient received their first of two planned doses of mRNA-1273 for prophylaxis of COVID-19 infection. On 4 Mar 2021 the patient was admitted due to blood clot in lungs and pneumonia. The medically significant event caused hospitalization. Treatment of the event included blood thinners. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events blood clot in lungs and pneumonia was not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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1135692	3/26/2021	VA		M	1/28/2021	1/28/2021	Pneumonia; Thrombus; Incoherent; dehydrated; threw up; Fever; A Spontaneous report was received from Consumer concerning 73-year-old of male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and fever, incoherent, threw up, dehydrated, blood clot and he was diagnosed with Pneumonia. The patients relevant medical history included. The concomitant medication was not reported. On 28 Jan 2021, prior to the onset of the event, the patient received their first dose mRNA-1273 (Lot number: 012M20A, Expiration date: not provided) via unknown route in the left arm for prophylaxis of COVID-19 infection. On same day, after vaccination patient experienced fever, incoherent, threw up, dehydrated. Few days later he went to the hospital because of shortness of breath, the hospital diagnosed him with a blood clot (on 31 Jan 2021), Then on 09 Feb 2021, he went to see his family doctor because he still did not feel well and he was diagnosed with Pneumonia. Treatment was included as Eliquis and Antibiotic. Action taken with the mRNA-1273 in response to the events was not provided. On 29 Jan 2021 the outcome were recovered for fever, incoherent, threw up, dehydrated. The outcome were unknown for pneumonia and shortness of breath. On 01 Feb 2021 the outcome blood clot was recovered.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events of pyrexia, vomiting, dehydration , incoherent and thrombosis, a causal relationship cannot be excluded. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the event of pneumonia is assessed as unlikely related. Further information has been requested.
1137624	3/26/2021	FL	56	F	1/11/2021	1/24/2021	I noticed increasing episodes of SOB, dizziness, and PVCs. My blood pressure continued to increase. After 4 weeks of increasing symptoms I reported to the ED. I was admitted for Right Lower Lobe blood clot, hypertension, and PVCs.
1138841	3/26/2021	IL	48	M	1/28/2021	2/27/2021	Common iliac vein thrombosis

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1139147	3/26/2021	WA	68	F	2/27/2021	3/1/2021	I went into DKA, my left eye bled, my left arm has a blood clot I was in hospital 9 days and a rehabilitation place for 11 days.
1138686	3/26/2021	CA	62	M	2/23/2021	3/1/2021	Pt developed a RT Leg DVT Deep Vein Thrombosis and Pulmonary embolus. Started having symptoms of dyspnea. , low oxygen saturations in the 80s and RT pleuritic chest pains one week after getting the shot. He had never had a DVT or PE before. Was seen in Emergency on 03-23-2021 . He was admitted on 02-23-2021. Started on anticoagulation and went to the cath lab to have intraarterial administration of TPA in pulmonary arteries.
1135707	3/26/2021	UT		F		3/11/2021	Blacked out; Multiple blood clots; inflammation in spine; A spontaneous report was received from a consumer, concerning a female patient of unspecified age, who received Moderna's COVID-19 vaccine and experienced multiple blood clots/ thrombosis, inflammation in spine/inflammation, blacked out/loss of consciousness. The patient's medical history included blood clots. Concomitant product use was not provided by the reporter. On an unspecified date, prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 via unknown route for COVID-19 infection prophylaxis. On 11 Mar 2021, the reporter stated that her sister received the Moderna vaccine and she had multiple blood clots, inflammation in spine and blacked out. The events multiple blood clots and blacked out were assessed as serious based on IME list. Treatment information was not reported. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events multiple blood clots, inflammation in spine and blacked out was reported to be unknown at the time of this report.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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1133011	3/25/2021	WA	57	M	1/12/2021	1/1/2021	<p>Diagnosed with DVT; Leg got really swollen/swelling of the lower calf area; Sore arm; Sore arm; Pulled a muscle; A spontaneous report was received from a consumer concerning a 57-years-old male patient, who received Moderna's COVID-19 vaccine (mRNA -1273) and experienced events, DVT/ deep vein thrombosis, pulled a muscle/myalgia, swelling of the lower calf area(leg got really swollen)/peripheral swelling and calf pain(sore arm)/pain in extremity. The patient's medical history was not provided. No relevant concomitant medications were reported. On 12 Jan 2021, prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number: unknown) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 09 FEB 2021, prior to the onset of the symptoms, the patient received their second of two planned doses of mRNA-1273 (Batch number: 013M20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 12 Jan 2021, after receiving the vaccine the patient had sore arm. On an unspecified date in Jan 2021, the patient had experienced a pull in his muscle in his calf and lower calf area got swollen. On 09 Feb 2021, after receiving the second dose of vaccine he had experienced a sore arm. On 11 Mar 2021, his leg got really swollen and on 12 Mar 2021, he visited hospital where it got diagnosed as DVT in his right lower calf. Treatment for the events included blood thinner Apixaban. Patient is concerned about possibility of indirect relation of events to the vaccine. The patient received both scheduled doses of mRNA-1273 prior to the events, therefore action taken with the drug in response to the events is not applicable. The outcome of the event DVT, leg got really swollen, swelling of the lower calf area and calf pain were unknown at the time of this report. The event pulled a muscle is not resolved. The event sore arm which the patient experienced for both the doses got resolved on 13 Jan and 14 Jan 2021, respectively.; Reporter's Comments: Based on the information provided which includes a strong temporal association a causal association between the event of sore arm and the administration of mRNA-1273 cannot be excluded. The evens of DVT , pulled muscle and swelling of lower calf is assessed as unlikely related to mRNA-1273. Events were all attributed to muscle strain.</p>

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1135306	3/25/2021	PA	71	F	2/5/2021		<p>Clot on the lower left leg; foot and ankle swollen; A spontaneous report was received from a physician concerning a 72-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced foot and ankle swelling (joint swelling) and clot on the lower left leg (deep vein thrombosis). The patient's medical history was not provided. No relevant concomitant medications were reported. No information on allergies were provided. The reported stated that the patient was physically and mentally healthy before vaccination. On 5 Feb 2021 , prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 012M20A) via intramuscular route on left side for prophylaxis of COVID-19 infection. On 5 Mar 2021 prior to the onset of the events, the patient received their second planned dose of mRNA-1273 (Lot number: 036A21A ) via intramuscular route on left side for prophylaxis of COVID-19 infection. Doctor found a clot in her lower left leg. Patient said that on Feb 2 before receiving the first dose on Feb 5 needed to have an x ray and blood work due to foot and ankle got swollen. Patient said they checked it for different things and that the doctor thought It would be a pseudo gout. As the ankle was still swollen patient went to her family doctor and doctor insisted to have a test for deep vein thrombosis. They have found a clot on the lower left leg. The patient had stated she have not a had a surgery or an injury and that it happened between doses. Treatment drug used for the event included was apixaban. Action taken with mRNA-1273 in response to the events was not applicable. The outcome for the events, foot and ankle swelling and clot on the lower left leg, was considered unknown.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested. It was reported that the patient had an x ray and blood work due to foot and ankle swelling before receiving the first dose of vaccine and that the doctor thought it to be a pseudo gout.</p>

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1135298	3/25/2021	KS	31	M	1/26/2021	1/26/2021	blood clot; Fever; sick feeling; chills; nausea; night sweats; A spontaneous report was received from a healthcare professional concerning a 31-year-old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sick feeling/illness, chills, nausea, night sweats, blood clot/thrombosis, and fever/pyrexia. The patient's medical history included Cystic Fibrosis and only has half of their liver. No relevant concomitant medications were reported. On 26-JAN-2021, prior to the onset of the events the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) intramuscularly for prophylaxis of COVID-19 infection. On 26JAN2021, the patient began experiencing symptoms including sick feeling, chills, nausea, and night sweats. The patient had blood clot and fever on 21-FEB-2021. Patient was admitted into the hospital on 22-FEB-2021 and discharged on 26-FEB-2021. He received the following tests while in the hospital: MRI, Bone Density, and LABS. Treatment of the events included Eliquis. Action taken with mRNA-1273 in response to the events was not reported. On 25 Feb 2021 the outcome of event, fever was resolved. The outcome of events, sick feeling, chills, nausea, night sweats, blood clot were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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1135288	3/25/2021	SC	84	M	2/2/2021	2/8/2021	Dizziness; A spontaneous report was received from a consumer (patient), concerning himself, an 84-years-old male patient, unknown race and ethnicity, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced dizziness. The patient's medical history included major brain surgery one year ago due to a major fall off a ladder, a blood clot in his head, seizure and a pacemaker placement several years ago. Current condition included needs cane or walker. Concomitant medications reported were levetiracetam, pantoprazole, allopurinol, apixaban, carvedilol and rosuvastatin. On 02 Feb 2021, prior to the onset of the event, the patient received first of two planned doses of mRNA-1273 (lot/batch: 012M20A), intramuscular for prophylaxis of COVID-19 infection. On 08 Feb 2021, the patient experienced dizziness that was pretty severe and needs cane and walker when standing. Patient stated that he was feeling better today on 10 Feb 2021, than past two days. Reportedly, patient was inquiring about his second dose scheduled on 02 Mar 2021. Treatment details were not provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome of event, dizziness was recovering.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
1134435	3/25/2021	VA	29	F	3/18/2021	3/19/2021	A 100+ degree fever developed approximately 36 hours after vaccination and lasted for 8-12 hours. I developed extreme fatigue that lasted for 48 hours after the fever began. Approximately 36-48 hours after the fever began, my period started, and I had severe cramps, blood clots, and bleeding that were notably abnormal for me. I am on birth control and have very minor, if any, withdrawal bleeding.

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1133516	3/25/2021	OH	85	F	2/20/2021	2/1/2021	<p>Atrial fibrillation; heart rate was erratic, but not as much as yesterday and today.; Her blood sugar is steady in 160s where it is normally lower in the 120s, 130s, and 140s.; This is a spontaneous report from a contactable consumer (patient). An 85-year-old female patient received second dose bnt162b2 (BNT162B2, Solution for injection) via an unspecified route of administration on 20Feb2021 (Batch/Lot Number: EL9266; Expiration Date: 31May2021) as single dose for covid-19 immunisation. Medical history included ongoing diabetes mellitus, thyroid, ongoing bone strength. Concomitant medications included ongoing insulin lispro (HUMALOG) (over 150 take two units) for Diabetes, ongoing insulin (30 units of insulin) taken for diabetes, ongoing levothyroxine sodium (SYNTHROID) (25mcg one tablet in the morning) taken for thyroid, ongoing Lisinopril (40mg one in the morning) for Blood pressure and ongoing Nifedipine (90 mg two and half hours after lisinopril) for blood pressure abnormal, ongoing Atorvastatin (one 20mg tablet at night), ongoing colecalciferol (D3) (25mcg one in the morning), cyanocobalamin (VITAMIN B12) (1,000mcg time release in the morning), Magnesium oxide at 400mg, ongoing calcium carbonate, colecalciferol (CALTRATE 600+D3) taken for bone strength. Historical vaccine included BNT162B2 (30mcg/0.3mL, lot: EL9265, expiration: 31May2021) on 30Jan2021 at 85 years for Covid-19 immunization. It was reported that, she has not had any problems. She goes to the doctor regularly. She has an apple watch, and she does check her heart. She also walks and tracks her steps. The last two weeks, she has noticed something knew. She has developed atrial fibrillation on an unspecified date in Feb 2021. She was concerned. She will do whatever her doctor suggests. She has read that two of the side effects are blood clots and t cells and a changing heart. She has not had atrial fibrillation in the past. She does check her heart. It was just something she does. She has had heart tests before. They checked her out last year 2020. On an unspecified date in 2020, they did a stress test and everything was fine. Everything was fine until last week. Everything was normal before that. The atrial fibrillation started last week. She decided to wait another week to see what happened. Then yesterday, the atrial fibrillation started again with all sort of swiggles. Her watch shows afib or inconsistency. It has been off the wall yesterday and today. She didn't</p>



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							have a prescribing doctor. The health department put up a screen on their website for people 80 and over so she signed up. She goes to the doctor this Thursday. She has diabetes, but it was under control. She takes insulin and Humalog for extra coverage. Her blood sugars have steadily been higher than normal. She took her heart rate on and off last week. It was over a couple of days. Her heart rate was erratic, but not as much as yesterday and today on an unspecified date in Feb2021. Her blood sugar was steady in 160s where it was normally lower in the 120s, 130s, and 140s on an unspecified date in Feb2021. The outcome was not recovered for atrial fibrillation, and unknown for erratic heart rate and blood sugar levels increased. No follow-up attempts are possible. No further information is expected.
1133506	3/25/2021	IN	54	F	3/8/2021	3/1/2021	Had a major nosebleed with blood clots; Had a major nosebleed with blood clots; This is a spontaneous report from a contactable consumer (the patient). A 54-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1, intramuscular on 08Mar2021 (Batch/Lot Number: EN6199; Expiration Date: 30Jun2021) as single dose for COVID-19 immunisation. Medical history was not reported. There were no concomitant medications. The patient had a major nosebleed with blood clots on an unknown day in Mar2021. The patient reported that he never got nosebleeds before. There was no treatment taken for the event, it stopped on itself. The outcome of the events was unknown.

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1133490	3/25/2021	MO	73	M	3/4/2021	3/1/2021	<p>had really low energy; tired; lethargic; terrible cramps; very cold sweat; diarrhea; Belly ache; bloody stools; broke into a sweat; Dull ache in stomach; Tried to move his bowels 2-3 times/No more bowel movements; soreness; soreness was in right arm; started having dark thoughts; had not eaten much/Had coffee this morning and he barely touched it yesterday morning; did pass gas and that was all that happened; This is a spontaneous report from a contactable consumer (the patient). A 73-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EN6204), via an unspecified route of administration in the right arm on 04Mar2021 11:15 (at the age of 73-years-old), at 0.3 mL (30 mcg), single dose for COVID-19 immunization. The patient's medical history included: service connected disability diagnosed from the (name withheld) for a lower back injury; last Spring and early Summer (2020) he went through treatment for 45 days with External beam radiation therapy (EBRT), which was 405 doses of radiation from a machine called FORD, had radiation treatment for early stage prostate cancer last year (2020); had anaphylactic shock, rash, awful case of hives when in military service in response to shots then and stayed for half an hour until okay (The patient was unable to provide names of vaccines given in past in service since that was in 1969-1970's. At that time, they got the shots in big air guns and was shot 3-4 at a time. Had those 3-4 shots during his basic training. During that time, he woke up around midnight and had awful case of hives and was taken to the base hospital and was given adrenaline in one arm and diphenhydramine hydrochloride (BENADRYL) in the other); allergies to sulfa drugs; diagnosed allergies (unspecified); compromised immune status; respiratory illness; genetic/chromosomal abnormalities; endocrine abnormalities (including diabetes and obesity); blood stools, rare occasion; glasses. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had no concomitant medications. The patient did not receive any other vaccines within four weeks prior to the vaccination or on the same day as the vaccination. The patient received the first dose on 04Mar2021 at about 11:15. He had not had much of a reaction, just a little soreness and soreness (04Mar2021). The soreness started that afternoon of getting the vaccine. When he</p>

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went to sleep, he noticed the soreness was in right arm, so he didn't lay on that side. He noticed it enough to sleep on the other side. On 07Mar2021, the patient had bloody stools, which were a rare occasion in the past. The patient stated the blood was significant enough to draw his attention, almost felt like a blockage in the system. The patient "sat on the pot" for 15-20 minutes and broke into a sweat (07Mar2021). The patient did not know if he had bloody stool then, because he didn't turn on the light, but ever since then, it has been bloody. No BM's (bowel movement) since yesterday (09Mar2021). The patient was tired yesterday (09Mar2021). He just laid around all day on a heating pad. He had a dull ache in stomach since it started (07Mar2021). Still there today, but not that bad. The patient stated he had radiation treatment for early stage prostate cancer, they tried to prevent burning or damaging the rectum, but this could be related to that. On Sunday night (07Mar2021), about midnight, he got an awful, awful stomach pain that woke him up about midnight. He tried to move his bowels 2-3 times Sunday night (07Mar2021) and on Monday morning (08Mar2021) he was able to move them a little bit. His underwear he had from Sunday night had lots of red stains in them, and all day Monday (08Mar2021) he was having a bellyache. Every time he managed to move his bowels and it was bloody and seemed to get bloodier pretty much all day. Yesterday (09Mar2021), he laid on a heating pad and went to bed early about 20:30, he usually goes about 22:00. He managed to stay in bed for about 9 hours, and he usually can't sleep that long. He slept on his side. He started having dark thoughts (unspecified date Mar2021), stating that last Spring and early Summer he went through treatment for 45 days with external beam radiation therapy (EBRT). On Monday night (08Mar2021), the patient had terrible cramps about midnight, with very cold sweat and diarrhea. The next morning (09Mar2021), every bowel movement was very bloody. Then all day Tuesday (09Mar2021) very lethargic. No more bowel movements until the following Friday. The patient stated he felt like I was trying to pass a blood clot. The patient stated he seemed to have problems with bowels all day yesterday (09Mar2021) and was not much better; he had really low energy (09Mar2021). Today (10Mar2021), he seemed to feel better, but not much. He had not eaten much (Mar2021)

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							and was hesitant to put food in his system, since his system was not functioning very well. The patient had not been seen by doctor or in an emergency room. His wife was a retired nurse, and they have discussed if he was not better, they were going to call his primary care provider and urologist. The patient had coffee this morning (10Mar2021), and he barely touched it yesterday morning. So far, no bloody discharge, no discharge or bowel movements today. Three to four times in the night he did pass gas (Mar2021), and that was all that happened. The patient knew side effects were rare with this (vaccine) and unsure if these side effects were something reported; this was certainly unusual for him. The clinical outcome of bloody stools, dull ache in stomach, had really low energy, terrible cramps, very cold sweat, diarrhea, tired, and lethargic was recovering. The outcome of belly ache, decreased appetite, and gas, was not recovered. The outcome of other events was unknown. It was also reported that since the vaccination, the patient had not been tested for COVID-19.
1133212	3/25/2021	MO	38	F	3/8/2021	3/17/2021	The patient was experiencing headaches 1 week ago. She also had aphasia later in the week. She went to an outside hospital on 3/24/2021 and was found to have intraparenchymal hemorrhage in addition to venous sinus thrombosis. She is being treated for the venous sinus thrombosis with heparin.
1135458	3/25/2021	NM	70	M	2/12/2021		Severe pancreatitis with no specific cause identified followed by complications of peritonitis, fluid in lungs of 80%, deep leg vein thrombosis, and multiple episodes of coronary arrest and systemic inflammation.
1132787	3/25/2021	MO	32	M	3/6/2021	3/10/2021	Within a week of getting the vaccine I developed a blood clot in the lining of my stomach
1132430	3/25/2021	PR	86	F	2/24/2021	2/25/2021	The daughter of the patient stated that her mother is a cardiac patient and has a stent. The patient always has edemas on her legs but the day after the vaccination she observed edema and report pain on the left thigh. The following Monday she visited the MD and he order a venous Doppler. The result was a thrombosis on the right leg . The patient was put on medication (Xarelto)

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1132399	3/25/2021	FL	69	M	3/22/2021	3/22/2021	He received his vaccine, had a sore arm and that evening around 7 hours later it was as if a switch flipped he was not able to breath, and his wife noticed on his body she could see all his veins like a track on his trunk and everywhere. He could not talk. He said that he was burning up, was hot and clammy. He got in the shower to cool himself down, and was told that the oxygen was not getting to where it was supposed to go. His wife called 9-1-1 and the EMT's said that his oxygen had dropped down into the 60's. He went to the hospital and they said he had pulmonary edema that filled his lungs that quickly. He was not intubated, and is on a BiPAP. He was given Lasix, steroids, antibiotics trying to pull the fluid off of his lungs. He has had so many different scenarios from people at the hospital right now and at one time one of his nurses said that his blood work showed a possible blood clot. They looked at his lungs and they said that they did not see it in his lungs. Then they said that he had a heart attack and that he needed a valve replacement. Today, 3/25/21 they told him that he did not have a heart attack, did not need a valve replacement. Last night they said that his BP was dangerously high and today, his BP is fine. He also had an adverse reaction to the steroids and had a ROID rage from that as well giving the nurses and his wife a hard time, hanging up the phone on her, and said that he was leaving the hospital. He was fine prior to the vaccine, and does not have any other issues for him to have this reaction. He is in ICU and they keep saying that they are going to put him in a cardiac care unit. He has a lot of IV lines and his 2nd COVID test came back negative. He feels like they are just running test to get money out of him. They said that he may be able to go home tomorrow.

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1131206	3/25/2021	GA	64	F	2/14/2021	2/18/2021	feeling of pins and needles in their face; swollen and sore gums; swollen and sore gums; fever of 102F; heavy bleeding; A spontaneous report was received from consumer concerning a 64 years old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced heavy bleeding/ postmenopausal bleeding, and contained large blood clots/postmenopausal bleeding, fever of 102F/ pyrexia, swollen and sore gums/gum swelling, swollen and sore gums /gum pain. The patient's medical history was not reported by the reporter. Concomitant medications taken by the patient were not provided. On 14 Feb 2021, prior to the onset of the event, the patient received the first of two planned doses of mRNA-1273 (Lot number: 031M20A) through intramuscular route at left arm for prophylaxis of COVID-19 infection. On 13 Mar 2021, prior to the onset of the event, the patient received their second of two planned doses of mRNA-1273 (Lot number: 026A21A) through intramuscular route at left arm for prophylaxis of COVID-19 infection. On 18 Feb 2021 four days after the first dose of vaccination, patient began to bleed as if the menstrual cycle began. Patient reported that she was at a menopausal phase in life to typically do not bleed or if they do there was a light pink blood excreted, the last time this had occurred was in November. Patient had a bleeding that was very heavy and contained large blood clots. The event heavy bleeding/ post menopausal bleeding was a medically significant event. Patient stated that this bleeding lasted 7 consecutive days until 25 Feb 2021. The bleeding then stopped 26 Feb 2021 for 2 days, and then heavy bleeding episode came back again on 28 Feb 2021 for 2 days lasting until 02 March 2021. On 03 March 2021 patient reported that she had a fever of 102F which lasted for 24 hours. Patient also reported that she had very very sore gums and swelling inside of mouth. Patient reported that she was not sure if these events were due to the vaccination. Treatment activities for event was not provided. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of events, experienced heavy bleeding, bleeding was very heavy, and contained large blood clots was resolved on 02-MAR-2021. The outcome of events, swollen and sore gums were unknown and fever of 102 F was resolved on an unknown date.; Reporter's

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Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

1131203 3/25/2021

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3/4/2021

3/9/2021

blood clots that had apparently broken up and gotten stuck in my lungs; A spontaneous report was received from a consumer who is a male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced blood clots that had apparently broken up and gotten stuck in lungs/thrombosis/pulmonary embolism. The patient's medical history was not provided. No relevant concomitant medications were reported. On 04 Mar 2021, prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Lot number: not provided) intramuscularly for prophylaxis of COVID-19 infection. On 09 Mar 2021, five days post-vaccination, the patient reported he had a significant event in which his wife had to call an ambulance and rush him to the hospital. It was discovered that he had blood clots that had broken up and got stuck in his lungs. The patient reported he was put on heparin and apixaban blood thinners. The patient stated he is scheduled for further testing. Treatment included, heparin and apixaban. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, blood clots that had apparently broken up and gotten stuck in my lungs/thrombosis/pulmonary embolism, were considered unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1131197	3/25/2021	NY	70	M	2/10/2021		<p>blood clot in his left leg; A spontaneous report was received from a consumer concerning a 70-year-old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and developed a blood clot in his left leg/thrombosis. The patient's medical history was not provided. No relevant concomitant medications were provided. On 10 Feb 2021, approximately two weeks prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 030M20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. Two weeks after the vaccination, the patient developed a blood clot in his left leg. He got his second vaccine on 10 Mar 2021. Treatment information was not provided. There was no change planned to the dosing schedule of mRNA-1273 in response to the event. The outcome of the event blood clot in his left leg was not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the event, a causal relationship cannot be excluded.</p>



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1131196	3/25/2021	PA		F	2/5/2021	2/17/2021	<p>blood clot; Vertigo; Nausea; Vomiting; A spontaneous report, was received from a consumer concerning a 53 year old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273), and experienced vertigo , nausea, vomiting and also developed a blood clot (thrombosis) during hospitalization. Patient had no medical history. The concomitant medication included were zolpidem tartrate 10mg nightly, allopurinol 100mg daily, duloxetine 50mg daily, multivitamin, vitamin d and acetylsalicylic acid 81mg. On 05 Feb 2021, prior to the onset of events, the patient received the first of two planned doses of mRNA-1273 (Batch no- 010MZ0A), intramuscularly in the left upper arm for prophylaxis of COVID-19 infection. On 17 Feb 2021, few days after administering the vaccine, the consumer experienced vertigo related nausea and vomiting. The patient was hospitalized for two days and experienced a blood clot during hospitalization. Patient was treated with only diazepam on first two days of treatment. In hospital, patient was given meclizine, diazepam and other anti-nausea medication whereas at home, patient was treated with ondansetron 8 mg, meclizine and diazepam. On 05 Mar 2021, the patient received the second of two planned doses of mRNA-1273 (Batch no- 036A21A), intramuscularly in the left upper arm for prophylaxis of COVID-19 infection. The action taken with the second dose of mRNA-1273 in response to the event was not applicable. The outcome of the events, vertigo, nausea, vomiting was not recovered whereas the outcome of blood clot was unknown at the time of the report.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1133481	3/25/2021	CO	78	M	2/11/2021	2/14/2021	<p>Blood clot in his left lung and right lung; Blood clots in his right groin; Terrible pain on the left side of his upper body, It hurts so much; A spontaneous report was received from a consumer concerning a 78 years old male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced terrible pain on the left side of his upper body, it hurt so much, blood clot in his left and right lung and blood clots in right groin. The patient's medical history was reported by the reporter as high blood pressure, prediabetes and hepatitis C due to a bad blood transfusion (treated with Mavyret).</p> <p>Concomitant medication was not reported. On 11 Feb 2021, three days prior to the onset of the event, the patient received their first of two planned doses of mRNA-1273 (Lot number: 031L20A) through an unknown route at left arm for prophylaxis of COVID-19 infection. On 14 Feb 2021, 3 days after vaccination, patient had a terrible pain on the left side of his upper body and was hospitalized, the tests revealed blood clot in his left and right lung as well as in right groin, which was treated by Eliquis. Patient was observed overnight and discharged with a follow up in 3-6 months. Action taken with mRNA-1273 in response to the events was unknown. The reporting physician assessed the events as not related to the product, but did not recommend second of vaccine. The outcome of events was unknown.; Reporter's Comments: Based on reporter's causality and history of diabetes and Hepatitis C infection, the event is assessed as unlikely related to mRNA-1273.</p>

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1135473	3/25/2021	PA	71	M	3/1/2021	3/1/2021	I scratched my leg and it would not clot. I am not on a blood thinner so I thought this was strange.; facial paralysis; This is a spontaneous report received from a contactable consumer (patient). The consumer reported for himself that the 71-year-old male patient received first dose of bnt162b2 (BNT162B2), via an unspecified route of administration, administered in Arm Right on 01Mar2021 09:30 AM at single dose for covid-19 immunisation. Medical history included hypertension from an unknown date and unknown if ongoing. Family medical history relevant to ae(s) was none. Concomitant medication(s) included ongoing amlodipine 5 mg taken for an unspecified indication from an unspecified start date and ongoing; ongoing simvastatin 20 mg taken for an unspecified indication from an unspecified start date and ongoing; ongoing ascorbic acid/betacarotene/ biotin/ calcium/ chloride/ chromium/ copper/ folic acid/ iodine/ lycopene/ magnesium/ manganese/ molybdenum/ nickel/ nicotinic acid/ pantothenic acid/ phosphorus/ potassium/ pyridoxine hydrochloride/ riboflavin/ selenium/ silicon/ thiamine/ vanadium/ vitamin b12 nos/ vitamin d nos/ vitamin e nos/ vitamin k nos/ xantofyl/ zinc taken for an unspecified indication from an unspecified start date and ongoing and Hypertension drug. The patient experienced facial paralysis 45 minutes after the administration on 01Mar2021 10:15AM with outcome of recovered , "i scratched my leg and it would not clot. i am not on a blood thinner so i thought this was strange." on 02Mar2021 with outcome of recovered on 02Mar2021. The report was assessed as srious and seriousness criteria of the events was medically significant. Facility where the most recent COVID-19 vaccine was administered was School or Health Clinic. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No treatment was received for the adverse event. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The other vaccinations within four weeks prior to the first administration date of the suspect vaccine(s) was none. The clinical course was reported as follows: On the drive home from receiving the vaccine, I experienced facial paralysis that lasted about an hour. The next day, I scratched my leg and it would not clot. I am not on a blood thinner so I thought this was strange. Information

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1135488	3/25/2021	NC	82	F	2/6/2021	2/16/2021	<p>on the lot/batch number has been requested.</p> <p>blood clots right nostril; pain/discomfort right side at waistline going toward back; pain/discomfort right side at waistline going toward back; This is a spontaneous report from a contactable consumer (patient). An 82-year-old female patient received the 2nd dose of bnt162b2 (BNT162B2, Lot Number: EL9581), as single dose in left arm on 06Feb2021 10:30 for COVID-19 immunisation, administered at hospital. Medical history included artificial mitral valve. No known allergies. The patient was not pregnant. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient received concomitant medications in two weeks but were not reported. No other vaccine in four weeks. The patient received the 1st dose of bnt162b2 (BNT162B2), on an unknown date for COVID-19 immunisation and experienced pulsatile tinnitus right ear. The patient experienced blood clots right nostril, pain/discomfort right side at waistline going toward back on 16Feb2021. The patient was hospitalized for blood clots right nostril. She went to Dr. for tinnitus, had MRI and CAT scan in 2021. All tests were negative. She received no treatment. COVID was not tested post vaccination. Right side got better after several days in 2021. Blood clots in nose lasted one morning and recovered on 06Feb2021.</p>

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1135578	3/25/2021	CO	68	F	3/6/2021	3/7/2021	Developed DVT blood clots in legs and clots in lungs.; Developed DVT blood clots in legs and clots in lungs.; This is a spontaneous report from a contactable consumer. This 68-year-old female consumer reported that she received 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EN6198) on 06Mar2021 12:30 PM at left arm for COVID-19 immunisation. Medical history included known allergies: Clindamycin and high blood pressure. Historical vaccine was 1st dose of BNT162B2 (lot number EN6201) on 14Feb2021 01:15 PM at left arm for COVID-19 immunisation. Concomitant drugs included hydrochlorothiazide, triamterene (TRIAMTERENE AND HYDROCHLOROTHIAZIDE), omeprazole, nortriptyline hydrochloride (NORTRIPTYLIN). The patient developed DVT blood clots in legs and clots in lungs on 07Mar2021 08:00 AM. Event resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). Patient was hospitalized for 3 days and received treatment. The patient had computerised tomogram (CAT) scan, ultrasound, echocardiogram. Event outcome was not resolved.

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1135581	3/25/2021	MN	66	M	2/23/2021	3/11/2021	multiple bilateral DVTs; pulmonary embolus; This is a spontaneous report from a contactable Physician (Patient). A 66-year-old male patient received second dose of bnt162b2 (BNT162B2, Solution for injection, Lot number: EN6200, Expiration date was not reported), via an unspecified route of administration, in Arm Left on 23Feb2021 13:15 as single dose, the first dose via an unspecified route of administration, a in Arm Left on 02Feb2021 13:15 as single dose for covid-19 immunization. Medical history included Subarachnoid hemorrhage (SAH), hypertension (htn), degenerative discs, malignant melanoma and prostatectomy (2 years 3 months). Concomitant medications included atorvastatin calcium and lisinopril taken for an unspecified indication, start and stop date were not reported. The patient previously took cephalosporin for allergies. After receiving the second dose patient experienced pulmonary embolus on an unspecified date in 2021 and multiple bilateral DVTs diagnosed on 11Mar2021. As per the reporter seriousness criteria reported as emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event). Patient did not receive any other vaccine in four weeks. Patient did not have Covid prior vaccination. Patient was not tested Covid post vaccination. Therapeutic measures were taken as a result of pulmonary embolus multiple bilateral dvts. The outcome of the events was not recovered.; Sender's Comments: Based on the temporal relationship, A possible contributory role of the suspect product to the development of Pulmonary Embolus and Deep Vein Thrombosis cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1135376	3/25/2021	CA	73	M	1/31/2021	2/15/2021	I am writing this to let you know that two weeks after receiving my first COVID 19 vaccination I developed a severe blood clot from my right ankle to my right groin. I am Factor 5 deficient, and believe that the vaccine caused the clot. I had no symptoms at all until I noticed my right calf was swollen (no pain). My wife insisted I go to emergency because I am Factor 5 deficient and inclined to thickening of the blood. I have not been on a plane or taken a long trip by car. I walk 3 miles a day, play golf and am very active. I strongly believe the vaccine caused the clot. I will be on blood thinners the rest of my life..
1135371	3/25/2021	MA	37	M	3/20/2021	3/23/2021	Patient developed myalgias and chills the day after vaccination. Three days after vaccination, awoke from sleep with burning upper chest and neck pain lasting several hours. Came to the ED. ECG notable for lateral ST elevation. Troponin I elevated. CRP elevated. COVID PCR negative x2. Treated with aspirin and intravenous heparin infusion. Echocardiogram revealed left ventricular systolic dysfunction (EF 48%). Cardiac catheterization revealed no coronary obstruction or thrombosis. Cardiac MRI revealed late gadolinium enhancement and myocardial edema consistent with acute myocarditis. Max temperature during hospitalization 37.4C.
1128546	3/24/2021	CT	69	M	2/8/2021	2/9/2021	Patient was admitted to the ED with left deep peroneal vein thrombosis on Feb. 9 2021 after patient noticed prolonged edema in both ankles. Patient started taking 10 mg of Eliquis twice a day on Feb. 11, 2021. And on Feb. 17 2021, 2 more blood clots were found in the patient's peripheral veins within the limbs. Patient decreased dose of Eliquis to 5mg twice a day on Feb. 18 2021. Patient continues to take 5mg of Eliquis twice a day.

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1131365	3/24/2021	CO	71	F	2/25/2021	3/6/2021	On March 6, I woke up feeling like I had a Charlie horse in my left calf. I tried to walk and it was sore but I felt it would go away in a day or two. By Wednesday, March 10, I called my doctor and after telling them my left calf hurt , they had me come right in. After seeing dr I was sent to get a sonogram immediately and was told I had a blood clot inside my left knee. I was sent back to Dr and was given Xerelto 15 mg twice a day for 21 days and the 20 mg once a day until gone. Today,, it is still sore. I am asking if I should take my second shot on March 29 or not.
1131317	3/24/2021	WI	69	M			I was breaking down existing blood clot in my right leg when after getting the 1st shot got a red rash & my right leg swelled up producing a blood clot in my right leg .
1130597	3/24/2021	VA	37	F	3/18/2021	3/23/2021	A medical provider and myself already reported an allergic reaction that started about 24-30 hours post vaccination (rash on chest, high blood pressure, feeling unwell, chest tightness). On 3/23 in the afternoon, my right knee started suddenly swelling and became painful. I went to the ER to rule out a blood clot- which was not indicated. It was determined the lymph node in the back of my knee (same side as my shot arm) was swelling due to moderna. I was given naproxen to treat it for one week.
1130573	3/24/2021	AZ	67	F	3/9/2021	3/14/2021	I woke up at 1 am and needed to urinate. I did but then immediately felt the urge to go again but I could only go a small amount. This continued on for every 5 to 10 minute until 2am. My urine was tinged pink and then continued to get worse. By 2am, it was the color of tomato juice with several clots. I went the the emergency room and was given 1 liter of IV solution and an IV antibiotic. I was released around 4am and returned home. I was prescribed a 7 day regimen of oral antibiotics. I did not feel any pain, only the discomfort from the urge to urinate which lasted about 18 hours. By 9am, my urine was clear and in normal amounts. I have never had a UTI in my life which is why I am reporting this.



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1130407	3/24/2021	IN	67	F	3/2/2021	3/3/2021	Reported side effects of fever, chills and headache that began within 24 hours, also reports burning in throat. Was evaluated by a specialist after 1 week due to continued burning and pain in throat. Reports was diagnosed with edema around vocal chords. Approximately 2 weeks after vaccination developed swelling in left arm. She was seen by her physician who sent her for an ultrasound and they found a blood clot. Patient called to report these symptoms.
1130395	3/24/2021	PR	70	F	3/4/2021	3/7/2021	Swollen upper arm and tender for 2 days after the injection. The ringworm rash seemed to spread like wildfire on the third day and within a couple of days, both my legs were covered with the blotches. I had continued using the tolinaftate but on Saturday the 13th of March I went to get medical advise at the local ER and was told to take Allegra and Clotrimazole-Betamethazone cream. The rash got worse and I called Dr. and he told me to continue to take the Allegra but stop the cream and start with Lotrimin because the Betamethazone in the cream counteracts the positive effects of the Clotrimazole.
1130191	3/24/2021	IN	58	F	3/18/2021	3/23/2021	Developed extreme pain in my left leg. Went to emergency room. Ultrasound showed I have a blood clot in left calf. Doctor prescribed a blood thinner, told me to elevate my leg and apply moist heat.

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1129691	3/24/2021	NY	72	F	2/26/2021	3/9/2021	<p>Deep Vein Thrombosis in both legs; eye was completely black/veins in the back of eye are completely black; eyes started to go very blurry; scared to sleep at night, scared to move/afraid to live life, petrified with this; arm is sore and puffed up; arm is sore and puffed up; A spontaneous report was received from a consumer, concerning a 72-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and developed deep vein thrombosis (DVT) in both legs/deep vein thrombosis, one clot from groin to mid chest and one behind knee to groin, quite large and very risky, extremely large thrombus, scared to sleep at night, scared to move, afraid to live life, petrified with this/ fear, eyes started to go very blurry/ vision blurred, left eye was completely black and veins in the back of eye are completely black/ eye contusion and arm was sore/ pain in extremity and puffed up/ peripheral swelling. The patient's medical history included being a cancer survivor twice. No relevant concomitant medications were reported. On 26 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 014M20A) intramuscularly in left arm for prophylaxis of COVID-19 infection. On 09 Mar 2021, approximately ten days after receiving vaccine, the patient's eyes started to go very blurry, her left eye was completely black and veins in the back of eye were completely black. On 10 Mar 2021, she had one clot from groin to mid chest and one behind knee to groin, quite large and very risky, extremely large. She was afraid to live her life and was petrified. She developed a DVT in both legs and was taken to the emergency room. She was hospitalized on 10 Mar 2021 and had positron emission tomography (PET) scan, doppler, echocardiogram with pictures of face and neck. Her lung was dyed, she had 3 types of dye, had PET scan for brain, chest, blood draws from finger and shots of blood thinner in stomach. She was scared to sleep at night and scared to move. Her arm was sore and puffed up. On 13 Mar 2021, she was discharged from the hospital. Treatment of the events included Eliquis. Action taken with mRNA-1273 in response to the events was unknown. The outcome of the events, deep vein thrombosis, fear, vision blurred, eye contusion, pain in extremity and peripheral swelling were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of</p>

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1128838	3/24/2021	NV		F	2/12/2021	2/13/2021	<p>the product and the start date of the events, a causal relationship cannot be excluded.</p> <p>lost appetite; so tired, thought could not get out of bed; Big/ huge clots, came out in a spit; had 3 nose bleeds; A spontaneous report was received from a 77-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced 3 nose bleeds/ Epistaxis, big/huge clots, clot came out in a spit/ Thrombosis, tiredness/ Fatigue, and loss of appetite/ Decreased appetite. The patient's medical history was not provided. No concomitant product use was reported. On 12 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly for prophylaxis of COVID-19 infection. On 13-Feb-2021, the patient experienced 3 nose bleeds with huge blood clots. The bleeding was persistent throughout the day, stopping at the intervals and later on the same day it was reported the patient had a huge clot come out in spit. On 14 Feb 2021, the patient was tired, could not get out of bed, and had lost appetite. On 18-Feb-2021, the patient woke up feeling normal. Treatment information was unknown. Action taken with mRNA-1273 in response to the events was not provided. The outcomes of the events were not provided.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p>

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1129682	3/24/2021	NY		M	12/31/2020	3/1/2021	<p>a blood clot in his leg behind his knee; blood clots on both of his lungs; leg pain and cramps that got worst as time went by; A spontaneous report was received from a consumer concerning a 65 year old male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced leg pain and cramps that worsen as time progressed, a blood clot in his leg behind his knee, and blood clots in both lungs. The patient's medical history include high blood pressure. The relevant concomitant medications are Lisinopril, Paroxetine, and Multivitamins. On 31 Dec 2020, the patient received the first of two planned doses of mRNA-1273 (lot/batch: 026i20a) intramuscularly for prophylaxis of COVID-19 infection. On 28 Jan 2021, prior to the onset of the events, the patient received the second of two planned doses of mRNA-1273 (lot/batch: 004m20a) via unknown route in left arm for prophylaxis of COVID-19 infection. On 01 Mar 2021, the patient experienced leg pain and cramps that worsen with time. 03 Mar 2021, the patient developed a blood clot in his leg behind his knee and blood clots on both lungs. The seriousness criteria for the events, blood clot in the leg behind the knee and blood clots in both lungs was were life threatening and medically significant. The Laboratory findings include an ultrasound showing a blood clot in the leg behind the knee on 03 Mar 2021. On unknown day of Mar 2021, chest CT showed blood clots in both lungs. Treatment medication included rivaroxaban prescribed earlier by his physician. Action taken with mRNA-1273 in response to the events was not applicable. At the time of this report, the outcome of the events, leg pain and cramps that got worst as time went by and a blood clot in his leg behind his knee was unknown. The event, blood clots on both of his lungs was considered recovering on an unknown date.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>
1128196	3/24/2021	CA	74	M	2/24/2021	3/9/2021	<p>Deep Venous Thrombosis: DVT extending from the right common femoral to the popliteal vein. Swelling of entire Rt Leg and Numbness</p>

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1131417	3/24/2021	MI	47	M	3/4/2021	3/14/2021	Fever, headache, chills, night sweats. All on same day. 3 days later swollen knees. 10 days later blood clot in right leg.
1128059	3/24/2021			M	2/2/2021	2/1/2021	blood clots found on his arm and lung; blood clots found on his arm and lung; valve blockage; This is a spontaneous report from a contactable consumer (patient's friend) via Medical Information team. A male patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; batch/lot number and expiration date were not reported), via an unspecified route of administration on 02Feb2021 as a single dose for COVID-19 immunization. Relevant medical history included COVID-19 infection from Sep2020 to an unknown date. The patient's concomitant medications were not reported. The reporter stated that the patient was due to receive his second dose the day prior reporting on 02Mar2021, and wanted to know if the patient should receive the second dose of the vaccine if he stayed longer than 3 weeks in the hospital. The patient was currently hospitalized; he received medical attention 2 weeks prior reporting on an unspecified date in Feb2021 due to some blood clots found on his arm and lung. The patient went into the hospital because he had a valve blockage on an unspecified date in Feb2021 and that the patient still had to go to rehab and might miss that 3 week window. The reporter wanted to know if a patient should restart the vaccination series if he could not receive the second dose 42 days after the first one. The patient was hospitalized for the events "blood clots found on his arm and lung and valve blockage" from an unspecified date in 2021. The outcome of the events was unknown. Information on the batch/lot number has been requested.

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1129669	3/24/2021	NY	71	M	2/14/2021	2/15/2021	Blood clot in my left leg; A spontaneous report was received from a consumer concerning a 71-year-old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced deep vein thrombosis. The patient's medical history was not provided. Concomitant medications was not reported. On 14-FEB-2021 prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Lot number: 030M20A) in the left arm for prophylaxis of COVID-19 infection. The next day after receiving mRNA-1273, the patient developed a blood clot in left leg and extended from upper left leg down into his lower leg. He went to the emergency room and was treated for the event with Xarelto. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the event deep vein thrombosis was not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
1131580	3/24/2021	ND	70	M	3/12/2021	3/20/2021	After second Moderna covid vaccine , 1 1/2 weeks after second vaccine I ended up with blood clots in right leg and right lung - hospital overnight stay. Outcome is not good thanks to the covid vaccine
1131644	3/24/2021	NE	82	F	1/26/2021	2/17/2021	2 large Blood Clots in the lungs
1131671	3/24/2021	LA	51	F	3/13/2021	3/15/2021	Following the vaccine injection which was provided by the personnel, I have developed minor fainting spells and angina for the past 10 plus days. A large dried blood clot was noted on the first day of my period which occurred on March 16th. I continue to pass large blood clots while I was having my period. I also want to point out that a personnel who gave me an injection was incorrectly injected the vaccine outside of the area of the preferred injection zone. I have reported this event to the supervisor who was on site. I have not yet contacted my health care provider at this time but plan to contact her tomorrow as these symptoms have been persisting.
1129475	3/24/2021	VA	39	F	3/9/2021	3/10/2021	Early onset of menstrual period-14 days early-lastest 11 days versus normal 5 and heavy bleeding including large clots for 10 days.

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1131574	3/24/2021	NC	42	F	3/19/2021	3/19/2021	Weird headache at top of head which would come on quickly for a minute or two then vanish and repeat every 10-15 minutes or so. Very tired. Had started menstrual cycle on March 17, but post vaccine it was lighter than normal and then on the 22nd it became very heavy and there were lots of large blood clots. This has lasted an additional three days. My cycle usually lasts 5-7 days but day 2/3 are the heaviest and it's usually very light by day 6/7. I have not had blood clots in several years. These are very large.
1126059	3/23/2021	PA	80	F	2/5/2021	3/9/2021	Bilateral pulmonary emboli; A spontaneous report was received from a physician concerning an 80-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) experienced shortness of breath and oxygen level low. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. The patient received her first of two planned doses of mRNA-1273 (LOT: unknown) on 05-Feb-2021. On 05-Mar-2021, approximately 1 day prior to the onset of the symptoms, the patient received their second of two planned doses of mRNA-1273 (Batch number: 048A21A) intramuscularly for prophylaxis of COVID-19 infection. On 06-Mar-2021, the patient developed shortness of breath and her oxygen level was low. On 09-Mar-2021, she was diagnosed with bilateral pulmonary embolisms. No hospitalization was required. The reporter stated that the patient had no history of blood clots. Treatment for the event included apixaban. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. The outcome of the events was considered unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded

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1127071	3/23/2021	CA	71	M	2/13/2021	2/25/2021	Feb 25th afternoon I started feeling pretty yucky. As the evening progressed I had chills, body aches, and fever. I thought I had covid. On the 26th I was worse. on the 27th I went to the ER, and the diagnosis was "unknown virus" I continued to get worse. On March 3rd I called the nurse and she said "I need to go to the ER, don't go to the ER, go to the closest ER to you". I received the same diagnosis. I thought maybe my CPAP machine had bacteria and they tested for bacteria and it was negative. I went home. On march 8th I was really bad off, I had 103.7 fever still and O2 was 70-80. I was admitted to the hospital. they tested me again and I had bacterial pneumonia. 3 days later they were going to send me home but when I woke up that morning I felt like I had been kicked in the ribs on my right side. I sat in a chair and if I coughed, hiccuped or anything It felt like a knife through my chest. a CT scan showed a massive blood clot in my lung. I was put on medications and I was discharged on March 17th. My left lung had 100% pneumonia and the blood clot was in the right lung and my lungs were unable to help each other. With any exertion, my heart rate jumps and my O2 drops. I can only sit. The theory they had at the hospital is that the Moderna vaccine had the full attention of my immune system which allowed other infections to come into my body unchecked. Since the pandemic started I have left my house on my bicycle to the store and that is it. I have had almost no exposure.
1126935	3/23/2021	FL	50	F	3/9/2021	3/19/2021	Patient came to emergency room complaining of pain, intense, severe locating in epigastric area and diffuse all over the abdomen associated with nausea and vomiting. While admitted it was identified that Pt had Subacute thrombosis of the main trunk of the superior mesenteric artery with no flow distal, 3 cm from the ostium with no flow identified in the right-sided branches or jejunal branches. MD thinks is due to Moderna Vaccine as Pt has no history or clots.



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1126577	3/23/2021	VA	62	F	2/8/2021	3/18/2021	Patient reported the following: I went to the ER last Thursday because my left leg was red and swollen. They did a sonogram and the results came back as tendentious and a superficial blood clot. The ER physician at Health suggested that I report the blood clot because it is of unknown origin and I did receive both vaccines.
1126561	3/23/2021	CA	74	M	2/3/2021	2/5/2021	basal ganglionic hemorrhagic stroke; basal ganglionic hemorrhagic stroke; This is a spontaneous report from a contactable consumer. This 74-years-old male consumer (Patient) reported for himself that he received first dose of bnt162b2 (BNT162B2) (Batch/Lot Number: EN9581), via an unspecified route of administration in Arm Right on 03Feb2021 at single dose for covid-19 immunization. Medical history included asthma, atrial fibrillation (A-fib), hypertension (HTN), ischaemic stroke (Ischemic CVA). Concomitant medications included amlodipine; atorvastatin; doxazosin; apixaban (ELIQUIS); lisinopril (LISNOP). No other vaccine in four weeks. The patient experienced basal ganglionic hemorrhagic stroke (hospitalization, disability, life threatening) on 05Feb2021 08:00 with outcome of not recovered. The patient was hospitalized for basal ganglionic hemorrhagic stroke from 05Feb2021 to 21Feb2021. Clinical course reported as follow: Early in the morning hours of 05Feb2021, patient had a basal ganglionic hemorrhagic stroke. He was found 10+ hours later and airlifted from local emergency room to neuro ICU unit. He spent 16 days in hospital then was d/c home for hospice care. Treatment for event included factor ii (prothrombin);factor ix;factor vii (proconvertin);factor x (stuart power factor);protein c (coagulation inhibitor);protein s (KCENTRA). No covid prior vaccination. No covid tested post vaccination.

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1127265	3/23/2021	NY	17	F	3/23/2021	3/23/2021	17 YEAR OLD PATIENT: AFTER RECEIVING VACCINE PATIENT SAT IN OVERVATION AREA, UPON SITTING DOWN EXPERIENCED DIZZINESS, SHORTNESS OF BREATH, FATIGUE. PATIENT DEMONSTRTING RAPID EYE MOVEMENTS, RESPONSIVE TO DIRECET QUESTIONS AND TO PAINFUL STIMULI THOUGH UNABLE TO SPEAK IN FULL SENTENCES. DENIED CHEST PAIN, COUGH NAUSEA, VOMITING. MOTHER STATES SIMILIAR BEHAVIOR WHEN SHE DEVELOPED BLOOD CLOT IN THE PAST. PATIENT THEN STATED FELT LIKE THROAT WAS SCRATCHY.
1126263	3/23/2021	TX	24	F	1/13/2021	2/13/2021	Bilateral pulmonary embolism. No clots detected in legs. Treatment: removed from birth control, Eliquis (10mg) for 3 months
1125931	3/23/2021	VA	53	F	3/2/2021	3/2/2021	Left leg started hurting, and swoll up from my knee to my foot, and the next day was told to go to hospital. They found a blood clot in my leg .
1125625	3/23/2021	NH	78	F	3/7/2021	3/11/2021	3/11/21- pt was feeling fine. She stood up got dizzy and seamed to have a seizure. when she came to she did not know that it had happened. about 5 hours later she stood up again got dizzy and seamed to have had another seizure. her husband called 911. EMTs took her vitals but did not detect anything to be wrong at the time and was advised to see PCP. Next day 3/12/21 she went to her PCP. She had blood work which showed high enzymes for heart failure so was sent to hospital to be admitted. Pt had blood work, chest xray which showed blood clots in both lungs. She was administered blood thinner. MRI of head was clear. Echocardiogram was clear. Pt stayed about 4 days. Enzymes for heart failure was clearing up. Pt was released and had a FU appt w/ PCP on 3/22/21. Pt found out that she also had bilateral deep vein thrombosis in both legs while she was in the hospital. Pt is improving and is almost back to normal.

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1125249	3/23/2021			F	2/9/2021	2/12/2021	Two blood clots in the posterior lobes of her lung; heart rate was really fast; A spontaneous report was received from a 69 year-old female consumer who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced two blood clots in the posterior lobes of her lung and heart rate was really fast. The patient's medical history included diverticulitis. Consumer mentioned that she was recovering from diverticulitis when she received the first Moderna vaccine. Products known to have been used by the patient, within two weeks prior to the event, included flagyl, bactrim, clindamycin (for a dental procedure one day after her vaccine), famotidine, lorazepam and elavil. On 09 Feb 2021, four days prior to the onset of the events, the consumer received their first of two planned doses of mRNA-1273 (lot/batch: 030M20A) intramuscularly in left arm for prophylaxis of COVID-19 infection. On 12 Feb 2021, the consumer experienced really fast heart rate and went to urgent care. The patient was referred to the hospital where it was found that the patient had two blood clots in the posterior lobes of her lung and she was hospitalized. Treatment for the event included heparin bolus (dose and duration) not specified. The patient was discharged on 13 Feb 2021 and started on Eliquis 5 mg twice a day. Action taken with mRNA-1273 in response to the events was unknown. The outcome of the events was resolved. The assessment for the events was not provided.; Reporter's Comments: Very limited information regarding the events has been provided at this time. Further information has been requested.
1126277	3/23/2021	ME	39	M	12/22/2020	3/18/2021	STEMI on 3/18/2021. Thrombosis in LAD. Minimal coronary artery disease on cath.
1121937	3/22/2021	OH	56	F	3/18/2021	3/20/2021	Bloody nose on March 20th - threw up blood clot. Bloody nose again on March 21st, same clot formed. lasted about 15 minutes each time. Seeing my PC doctor today March 22nd.
1123395	3/22/2021	WA	32	F	3/14/2021	3/15/2021	~~increased fatigue, mild cough shortness of breath, headache and then some isolated left leg pain. Patient denies any trauma, any swelling, nonpainful to the touch no difficulty walking or specific joint pain. Patient has no prior history of blood clots or DVTs, not currently on OCPs~~

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1123131	3/22/2021	NC	85	F	2/25/2021	2/26/2021	hard of hearing; Headache and then I had muscle aches/Achy and headachy; Headache and then I had muscle aches/Achy and headachy; Little bit of discomfort; Kind of stiff; Trouble in seeing; Used to be 5'7" but now I am 5'4"; she noticed bright red bleeding in her urine when she emptied her bladder; I just had a taint little bit till the day when I got it and then the next day I went to the bathroom to empty my bladder again and I had bright red bleeding again with some blood clots in it; Skin dry; slept a lot; she felt tired and so rotten; mild low-grade fever; body aches and pains; This is a spontaneous report from a contactable consumer (patient herself). An 85-year-old female patient received her second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EM9810) via an unspecified route of administration on 25Feb2021, 11:00 am as a single dose for COVID-19 immunisation. Medical history included hypertension, stroke, heart attack, COVID-19 in Aug2020 (actually had COVID this summer in August, had the mild case), and emergency surgery in Aug2020. Concomitant medications included ajmaline (CARDIA), isosorbide, and levothyroxine sodium (SYNTHROID) taken for cardiac disorder; and losartan. The patient her first dose on 04Feb2021 and experienced headaches, muscle aches and pains, chills, other flu-like symptoms, heart conditions, and sensitivity to eggs. She mentioned that this was normal and nothing unusual. She received her second dose on 25Feb2021 at 11:00 am. She was still kind of stiff but was okay. The next day on 26Feb2021 at 11:00 am, she noticed bright red bleeding in her urine when she emptied her bladder. After a few hours it faded. On the next day on 27Feb2021, she experienced the bright red bleeding in the urine again. The red blood did not hurt and patient was achy and headachy, "you know muscles." So, that kind of happened and it just kind of eased off. She slept a lot because she felt tired and so rotten from Friday, Saturday, Sunday after getting the shot. She also had a mild low-grade fever, headaches, and body aches and pains which she considered normal. Patient was hard of hearing and did not have a bright red bleeding, just had a taint little bit till the day when she got it and then the next day, she went to the bathroom to empty her bladder again and had bright red bleeding again with some blood clots in it. Then she did not really have that much the rest of the day and since then it

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							seems to be clear. She did have a little bit of discomfort and her skin was dry. She have never had that experience before so she was just not sure was that connected with that shot? She wanted to know if there were any other patients that have had that. Patient also stated, "I have a bit trouble in seeing. So, I am going to have my magnifying glass" when asked about the product details. She will be getting her annual check up on 24Mar2021 so she will also check with her doctor. She mentions that she doesn't take that much flu-shots because she is sensitive to eggs. Her urine seems to be clear as of the time of report. She wants to know if the bright red bleeding in the urine has been reported. Patient stated, "I used to be 5'7" but now I am 5'4". I think I am weighing about 158 now. I am sorry like I said because of my hearing and with a language difference a little bit. I was having a trouble hearing you." The patient did not have treatment for the events. Outcome of the events was unknown.
1122738	3/22/2021	WV	62	F	2/27/2021	3/5/2021	blood clot formed in left arm; This is a spontaneous report from a contactable consumer (patient). A 62-year-old female patient, not pregnant at time of vaccination, received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: EN6198), via an unspecified route of administration, on right Arm on 27Feb2021 0100, SINGLE DOSE for covid-19 immunisation. Medical history included Diabetic, High blood pressure, both from an unknown date. Concomitant medications included glipizide, metformin, fenofibrate. The patient previously took sumatriptan succinate (IMITREX) and experienced drug allergy. After vaccination 6 days later (05Mar2021) a blood clot formed in left arm. Shot was given in right arm. Hospitalization followed and now on blood thinners. AE resulted in: Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). The patient was hospitalized for 2 days. The outcome of the event was not recovered. Eliquis was given as treatment for the event. No covid prior vaccination. Not covid tested post vaccination.

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1122533	3/22/2021	KY	58	F	3/9/2021	3/17/2021	Blood clot in right arm. 3/17/21 right arm sore for no reason 3/18/21 soreness continues no reason 3/19/21 redness appears on arm 3/20/21 redness, soreness, spot warm to touch Went to emergency room. Diagnosed with clot. Given Levonox shot to thin blood. 3/21/21 Began taking Eliquis starter pack at home.
1121598	3/22/2021			U	3/5/2021		Blood clot in my bowel movement; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on 05Mar2021 15:45 as single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that when the patient had a bowel movement, the patient had a blood clot in the bowel movement on an unspecified date. The patient was asking if it was a normal side effect or should that be something to be concerned about. The outcome of the event was unknown. Information about Batch/Lot number has been requested.

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1121604	3/22/2021	MO	68	F	2/12/2021	2/12/2021	<p>Pain radiating from chest to left side of neck and left arm; Sore Swollen Lymph Nodes; Pain chest; Arm Pain, Left; Can't hardly use her left arm, it is so sore; This is a spontaneous report from a contactable nurse reported for herself. A 68-year-old female patient received her first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), from lot# EL9261, via unknown route on 12Feb2021 12:00 (at the age of 68-years-old) at left arm for COVID-19 immunization. The patient had not medical history. Concomitant medications were not reported. Vaccination Facility Type: Hospital. On 12Feb2021 the patient experienced left arm pain, pain chest, can't hardly use her left arm, it is so sore and on 14Feb2021 Pain radiating from chest to left side of neck and Swollen Lymph Nodes. Caller stated that she was thinking needs to go to the Emergency Room because it could be her lymph nodes, a blood clot, or her heart. She stated that she has been experiencing this since day one and nobody else has had side effects but her. She stated that this was out of the ordinary and according to the list she was given, it was not listed as a side effect. She was supposed to go tomorrow to get second shot, but she didn't think that she was going to be able to do it. No emergency room or physician office required. The outcome of the events at the time of last observation was reported as not recovered. Treatment was none. The events were assessed as serious, important medical events.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. There is limited information provided in this report. This case will be reassessed upon receipt of follow-up information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>

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1122273	3/22/2021	MO	74	F	2/22/2021	2/24/2021	She started have swelling and weight gain starting 2 days after immunization. She has a history of DVT and had more swelling and redness in one leg leading to ultrasound to rule out a DVT and labs significant for an elevated D-dimer which then led to a CTA of her chest because of additional complaints of breathlessness. The ultrasound and CTA were negative for any clots. She was prescribed furosemide for the swelling. D-dimer was 2.26 micrograms/mL. Due to the temporal nature of events, I felt filing a report was necessary.



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1121620	3/22/2021	FL	67	M	2/23/2021	2/23/2021	chest pains; chest pains; blood clot; light headedness; low fever; blacked out for about 5 minutes; onset of major body ache and fatigue; onset of major body ache and fatigue; Body aches at injection site and into upper back; Body aches at injection site and into upper back; This is a spontaneous report from a contactable consumer (patient). A 67-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EN6200), via an unspecified route of administration, administered in left arm on 23Feb2021 10:30 AM (at age of 67 years old) as single dose for COVID-19 immunisation. Medical history included high cholesterol. Concomitant medications included atorvastatin; levobunolol (eye drops); latanoprost (LATANO). The patient previously received his first dose of BNT162B2 on 05Feb2021 for COVID-19 immunisation (brand=Pfizer; lot number: EL9269; administration time 03:30 PM; vaccine location=Left arm; dose number=1). 6 hours after injection on 23Feb2021, the patient experienced body aches at injection site and into upper back. After 24 hours after injection on 24Feb2021, started light headedness, low fever, blacked out for about 5 minutes, onset of major body ache and fatigue. Spent the next 36hrs in bed. 72hrs after injection recovered back to normal slowly. On 04Mar2021 at 8pm, started with chest pains called, admitted to Hospital with heart attack, immediately taken to Cardiac Cath Lab for coronary catheterization in both legs, to partial remove blood clot and insert continuous balloon pump, IV Heparin infusion Troponin 6542.3 ng/l (critical), NO previous health issues for blood clots. Discharged 07Mar2021, Apixiban 5mg twice a day, Clopidogrel 75 mg /day. AE resulted in: Emergency room/department or urgent care, Hospitalization, Prolongation of existing hospitalization (vaccine received during existing hospitalization), Life threatening illness (immediate risk of death from the event. Number days hospitalization: 3 days. The outcome of events was unknown.
1122253	3/22/2021	TX	28	F	3/16/2021	3/16/2021	Stroke (blood clot in vein in left side of brain), occurred Wednesday March 17 at 5:15 pm. Immediately admitted to emergency room/stroke unit and given blood thinner IV and anti-seizure medicine

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1121972	3/22/2021		35	F	3/18/2021	3/19/2021	Chronology of Events: March 19th 2021-One day post vaccine, severe headache developed along with flu like symptoms and pronounced malaise March 20th 2021-Continued symptoms from previous day and additionally bleeding vaginally (had cycle end over a week prior to vaccine dose 1) March 21st 2021-Severe hemorrhaging vaginally with large amounts of clots developed. Completely saturated overnight pads at a rate of about 1 per hour. Began at 7pm. Had never had bleeding like this before with other cycles. Unable to control so went to local Emergency Department in the where we are stationed. Unable to determine a cause for the bleeding, was put on TXA to help control. Discharged at 0400 March 22nd. March 22nd 2021-Continued to have excessive bleeding, and continued TXA treatment during day at home with Rx. Follow up made with GYN doctor for Wednesday March 24th. Headache has continued this entire time.
1122044	3/22/2021	MI	73	M	2/25/2021	2/26/2021	Patient stopped at the health department on 3/18/21 and spoke with the secretary stating that he had a blood clot on 2/26/21 after receiving the covid vaccine. She took his information and RN followed up with him on 3/19/21. Patient states he had a blood clot in his left leg a few years ago and on the 26th he experienced the same pain as with his original blood clot. He said it was 10/10 pain in his left leg from just above the knee to right above the ankle around the whole leg. He states it felt warm. He did not speak with his doctor or seek any medical attention. He states he "suffered through it" and it went away after a couple days.

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1122080	3/22/2021	PA	46	F	3/12/2021	3/19/2021	<p>Patient's received 2nd dose of Moderna vaccine Friday 3/12. Her husband reported she had not unexpected fatigue, malaise, and fever for 1 day but better after that. On Monday she began complaining of shortness of breath. This progressively worsened and she started having presyncopal episodes. On Saturday she was unable to come down the stairs in the house so husband planned to take her to the hospital but she stood up and passed out and woke up quickly. He decided to call EMS. By the time she presented to our hospital she was cyanotic and agonal breathing. On moving her from EMS stretcher to ED bed she had PEA cardiac arrest. She underwent mechanical device CPR with only brief (&lt;1 min) ROSC x1. She at some point did have a shockable rhythm. Cath lab was notified and she was taken emergently to the cath lab with ongoing mechanical device CPR. Peripheral VA ECMO was placed after about 1.5 hours. Pulmonary angiogram was done which showed massive saddle PE with near complete obliteration of the right pulmonary tree and some filling defects in the left tree as well. At that time she had severe mixed respiratory and metabolic acidosis with a lactate of 24. She also had no gag or corneal reflex, minimally responsive pupils, and no response to noxious stimuli. Mechanical thrombectomy was attempted with some result. She was transferred to the SICU with increasing pressor requirement, and DIC. Ultimately, the venous catheter of the ECMO circuit malfunctioned thought to be secondary propagating IVC thrombosis. Family decided to withdraw care and she passed away.</p>

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1122195	3/22/2021	PA	65	M	2/21/2021	3/1/2021	My husband had a stroke one week after his 2nd dose. The blood clot affected his occipital lobe. Ten years ago he had a stroke in the same area below this area. On that Monday around 7 PM, he took our refuse out to the curb in front of our home. When he came in he did not recognize me or his surroundings. I took him to the hospital by car as I was not sure what happened to him. After testing the doctors said he had a minor infarct. The stroke affected his memory. He was very confused and did not remember anything from the moment of the incident until moments before exiting the MRI machine, approximately 2 hours later. He still cannot recall anything surrounding the incident. We questioned if this was related to his recent vaccination and the doctors stated no, however, we believe it is something that should be reported since it occurred a week after the vaccination.
1122238	3/22/2021	IN	53	F	1/9/2021	1/9/2021	1/9 vaccination 2.5 hours later, my arm was swollen, itchy, raised, heated, increased HR, chills, weakness. Symptoms lasted for 2 days. Fatigue lasted for 4-5 weeks after; 'washed out' 1/13 days later, I could barely walk due to the swelling. I thought my foot was going to collapse due to the crackling sound. Sent to urgent care for xray, swelling and inflation, no breaks. 1/21 I had to go to a foot and ankle specialist 1/25 I was referred to have a doplar to make sure I didn't have a clot. I had to get fitted for a special foot brace, had to get a second one. My retina, on my L side, started to see flashes of light. Dr. stated it was prob going to tear. The specialist said could be a autoimmune; fighting off the vaccine. 1/28 urgent care. Foot was infected. Prescribed 500 mg x3 Cyclo x 7 day; probiotic, as well. I removed my name for 2nd vaccine. Swelling lasted till March 13. Told body was fighting off vaccine.

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1123595	3/22/2021	WA	57	F	3/19/2021	3/20/2021	I began to have several very severe nose bleeds starting Saturday and into Sunday night. It was nothing I had ever experienced. It took 30 minutes to an hour to get them to stop. Then it would randomly start again. Just sitting quietly and it would start again. I am hoping they do not continue into today. I have had one real nose bleed in my life and it was a broken nose. These were as bad if not worse than the broken nose. During the time when I was trying to stop them, huge clots would form but they would just fill the gap and the blood would drain out the other side or down my throat and into my mouth. Soon the clots would get a little smaller and finally After getting the clots all out it would finally subside.

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1121607	3/22/2021	NC	72	F	1/27/2021	2/6/2021	<p>she was hospitalized with pulmonary embolism and they also found blood clots in her spleen (she had both venous and arterial clots).; she was hospitalized with pulmonary embolism and they also found blood clots in her spleen (she had both venous and arterial clots).; she was hospitalized with pulmonary embolism and they also found blood clots in her spleen (she had both venous and arterial clots).; This is a spontaneous report from a contactable Nurse. A 72-year-old female patient (Reporter's mother, not pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 27Jan2021 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunization. Medical history included hypertension (HTN), hyperlipidemia and high cholesterol. The patient's concomitant medications were not reported. No other vaccine in four weeks. 2 weeks after the immunization, 06Feb2021 the patient was hospitalized with pulmonary embolism and they also found blood clots in her spleen (she had both venous and arterial clots). Follow up with hematologist after discharge, MD reported unable to determine cause of clots. AE resulted in Emergency room/department or urgent care, Hospitalization. The patient hospitalized for three days. The patient received treatment blood thinners. The patient tested Covid post vaccination on 06Feb2021 with negative result. The outcome was Recovered with Sequel. Information on the lot/batch number has been requested.; Sender's Comments: The causal relationship between BNT162B2 and the reported events cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.</p>

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1122233	3/22/2021	IL	40	F	3/4/2021	3/7/2021	Two days after the vaccine, my right foot started to feel weird - felt wet sometimes or felt tingly. My foot was not swollen. I still have those weird sensations 18 days after getting the vaccine. Also, I had many small blood clots during my first menstruation after the vaccine (13 days after vaccine), which is not normal for me.
1124370	3/22/2021	WA	59	M	2/10/2021	2/15/2021	nonocclusive left sigmoid venous sinus thrombosis without ischemic stroke
1124590	3/22/2021	IN	65	M	2/7/2021	2/20/2021	Swollen right lower leg. Doppler study revealed multiple blood clots. Stared on Eliquis. Continues on Eliquis at this time and leg still swollen
1124682	3/22/2021	NY	34	F	3/17/2021	3/17/2021	No pain or adverse event for the first 4 hours after vaccination. Starting at 2pm, which was 4 hours after my vaccine, , my chest began to tighten. It was not severe; I took a normal walk and was just mildly uncomfortable. It escalated hourly for about 10- 12 hours. At 8pm, the pain, pressure, and tightness around the chest went from mild to moderate, from a pain level of 2 to about 3 or 4. The sensation was one of a stack of books on my chest. There was pressure and mild pain (again, not severe), about 8-10 inches horizontally across my chest, from about the bottom of my sternum to the collarbone. I also felt some pressure in my lower throat, perhaps the bottom third of my neck. I did not have any shortness or breath, swelling, or difficulty swallowing. At about 9 pm, I became itchy on my neck, ankles, and flank. I developed some red spots, which were not large enough to be hives, They mostly became red from my itching, though they were more moderately itchy than seriously itchy. I have had hives before, and they did not appear to be hives, more just isolated red spots. Once I became itchy, I went to the ER. They worked me up for cardiac issues and a blot clot, but all tests were negative. I did not take any medication other than my standard Oxcarbazepine 8pm dose of 300 mg. The itchiness went away at about 11pm (two hours after onset), and the chest pain did not worsen. The following morning, it was significantly better, and about 36 hours after I first received the vaccine, it was gone entirely.
1124727	3/22/2021	IN	86	M	2/24/2021	3/21/2021	Pulmonary Embolism Multiple blood clots in legs and lungs

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1124798	3/22/2021	AZ	87	M	2/13/2021	3/4/2021	Blood Clot in the lower right
1124134	3/22/2021	MI	73	F	3/13/2021	3/15/2021	On Sunday 2/14, pt notes that she experienced chills and "just felt out of sorts." On 3/15 at 1:30pm, she was scheduled for a wellness exam with her primary care provider. She notes that when staff took her vital, they were concerned because she seemed short of breath. Pt notes that she is overweight and does have dyspnea on exertion at times, but staff were concerned because she had been at rest for some time and they considered the shortness of breath unusual. Pt reports that her blood pressure was normal and her O2 sats were running 97-98% on room air. However, her pulse was 150. An EKG was done and the physician voiced concern over how long her pulse had been elevated. She was transferred to the ED, where per her report another EKG showed that she was in atrial flutter. Pt reports that she was treated with IV Cardizem and given and IV bolus of magnesium. At approximately 4:30pm, a CT with contrast was completed to rule out blood clot or PE. A third EKG done in the ED revealed that she had returned to normal sinus rhythm. She was discharged home at 6:30pm. Pt reports that she was seen for follow up on 3/20. At that time, her physician ordered repeat labs - CMP, potassium, magnesium, and thyroid - all of which were normal per her report. He changed her medication from baby aspirin 81 mg to Zarelto 20 mg, noting that she is at high risk for stroke. Cardiology has been alerted and she has an ECHO scheduled. Since her discharge from the ED, pt has been monitoring her pulse daily and it have ranged from 66-72 bpm/



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1121114	3/21/2021	PA	48	F	3/11/2021	3/13/2021	The next day after the shot, I had a small rash on my wrist. It disappeared during the day. Saturday evening, my right thigh felt like it received a trauma like a hit, but I did not have an injury. An area the size of my hand is slightly pink on the thigh. On Tuesday, I tried starting ibuprofen, but it did not really remedy the pain. I went to urgent care Wed. evening. They sent me for an ultrasound to rule out blood clots. No blood clots, but lymph nodes were visible in ultrasound. They suggested I follow-up with PCP. On Thursday and Friday, the leg felt crampy but less painful. Friday night the pain traveled down my right leg to ankle as well as right lower lung had dull ache. Returned to urgent care. They are treating the leg for cellulitis (1000mg daily of generic Keflex.) They said if the leg felt better in 24 hrs, probably cellulitis, but if not, it might be a response to vaccine. There is no relief after 3 doses and 24 hr + later.
1120882	3/21/2021	MI	54	F	3/13/2021	3/21/2021	This morning, a week after my shot, my arm started itching incessantly. The area has become red, hot, itchy, and now my whole shoulder hurts. I'm currently trying to get an online appt. to see if I should go to the hospital as I have a history of blood clots.
1120842	3/21/2021	AL	72	M	2/1/2021	2/1/2021	this is all per family, 4 to 5 days after 2nd COVID vaccine he was acting unusual and was taken to the hospital. He had a clot in his brain and underwent brain surgery. He experienced seizures after the surgery, but it was ultimately reported the surgery went well. He remained intubated and on a ventilator after surgery. He developed complications of his lungs and kidneys while on the ventilator. Ventilator was removed 3/16/2021 and he passed away that day. The hospital providers thought the clot in the brain may have been from hitting his head over a month ago. From my understanding he was A&O, independent with ADLs, and lived in his private residence prior to these complications.

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1120490	3/21/2021	CA	43	M	1/18/2021	3/13/2021	I had experience of muscle cramps of left calf muscle in Feb / march and observed 3-4 times over a period of 2 months . I was thinking that could be due to dehydration . On 03/ 14 /21 morning , I got severe left leg pain and could not able to walk. I took pain killers and did not subside and that end up going to hospital emergency . I was diagnosed with 2 blood clots in left leg . I do not have family history of clots nor any h/o major medical issues . All my previous and recent blood reports normal . I am currently in use of blood thinners
1121213	3/21/2021	CA	73	F	3/13/2021	3/13/2021	Extreme unremitting weakness, unable to walk without aid for 8 days. blood tests negative on 4th day. On 8th day neighbor said mother also collapsed and her ER said it was blood clots from the vaccine and gave her aspirin. Exactly one hour after my wife took 325 mg of aspirin, all of her vigorous strength had been restored.
1119938	3/21/2021	WI	70	M	2/2/2021	2/4/2021	Rash on torso/rash on bicep; This is a spontaneous report from a contactable consumer. A 70-years-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration in Arm Right on 02Feb2021 (Batch/Lot Number: EL9264) at single dose for covid-19 immunisation. Medical history included he contracted Covid in late Oct2020, blood clots from Nov2020 to an unknown date. Concomitant medication included apixaban (ELIQUIS) taken for blood clots from Nov2020 and ongoing. It was reported that patient received the first dose of Covid-19 vaccine 2 days ago. He has a red rash on each side of his torso and a little rash on his right bicep. This is the same type of rash he developed when he contracted Covid in late Oct2020. Typically, he has a rash when he gets a virus. Patient's weight was between 158-160lbs. The rash does not itch. He wouldn't know that he has it other than seeing it. Outcome of the event was unknown.

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1120515	3/21/2021	NE	84	F	3/3/2021	3/7/2021	Patient had vaccine Wednesday and felt a little dizzy after the shot. Sunday morning she woke up very dizzy and ended up passing out in her kitchen while getting her morning coffee. She hit her head and was taken to the ER. Her blood pressure was found to be very high (systolic 218). CT scans revealed 2 blood clots in her lungs per pt. She was hospitalized for 2 days. She reports trouble walking now.
1119815	3/21/2021	WY	72	F	1/28/2021	3/4/2021	Feeling terrible; Feeling tired; Blood clot in knee; A spontaneous report was received from a nurse who was a 72-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and developed a blood clot in her knee, feeling terrible and feeling tired.. The patient's medical history was not provided by the reporter. No relevant concomitant medications were reported. On 25 Feb 2021, the patient received her second of two planned doses of mRNA-1273 (Lot number: 031M20A) intramuscularly for prophylaxis of COVID-19 infection. On 04 Mar 2021, a week after vaccination, the patient was seen at the hospital and was diagnosed with a blood clot in her knee of unknown origin. She also reported that she has continued feeling terrible and feeling tired. Lab details were not provided by the reporter. Treatment for the events were unknown. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, blood clot in her knee, feeling terrible and feeling tired, were considered unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
1120117	3/21/2021	WI	82	M	2/17/2021	2/19/2021	Blood clot in his lung

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1120144	3/21/2021	FL	46	M	12/31/2020	2/12/2021	12 Feb 2021 at 17:00 patient report electrical shoot pain felt from left foot to left knee. Pain lasted for approximately 10 sec. Pain repeated twice during the night, waking from rest. 13 Feb 2021 painful episode repeated at 7:30 am. Painful episode repeated at 7:00 pm and continued for every 20 minutes. Pt reported to ER on 13 Feb 2021 at 10:30 pm. Facility conducted ultrasound on 14 Feb 2021 and identified left popliteal near occlusive blood clot. Prescribed Eliquis 5 mg and discharged home; f/u with PCP and Hematology. Continued course of treatment: Continue Eliquis as prescribed for 6-8 wks, f/u with PCP and Hematology.
1118872	3/20/2021	FL	56	F	3/8/2021	3/19/2021	Pt started having muscle pain in left leg on 3/18/2021 went to hospital on 3/19/2021 had doppler done and confirmed blood clot in left leg. Pt has been started on Eliquis. Currently out of hospital and at home.
1117769	3/20/2021	MA	70	M	2/25/2021	3/16/2021	Just under 3 weeks after last dose, development of left popliteal/distal femoral vein deep venous thrombosis with several small bilateral pulmonary emboli. Symptoms were about 4 days of increasing discomfort left calf, edema, pain in region of left gastrocnemius muscle, depend erythema, all not responsive to NSAIDS. I was hospitalized overnight for assessment and treatment. Started on heparin, switched to Eliquis. So far, no complications.
1117838	3/20/2021	FL	80	F	3/3/2021	3/5/2021	Blood clot in lower right leg
1117927	3/20/2021	CO	77	M	1/30/2021	2/3/2021	Blood clot running from ankle to groin; entire leg swollen; still swollen after 6 weeks; received shot of heparin and put on Xarelto; blood clot was just short of where it could break off and go to heart or lungs.

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1117950	3/20/2021	TN	58	F	1/2/2021	1/2/2021	A few minutes after the shot, I became dizzy, watery eyes, blurry vision, resolved in a few minutes and I drove home, woke up to severe pain in my right eye, foggy brain, sharp/shooting pain in left side of chest and left breast, headache (very rare for me to have a headache), toes began to hurt and brown spots with excessive dry peeling skin appeared with pain (more on right toes than left) and was unable to wear closed toe shoes, hit my thumb and a blood clot appeared (never had a blood clot in my life). Both the toes and clot is just now beginning to get better ( and is just now starting to get better). I continue to have blurry vision and occssional foggy brain,
1118031	3/20/2021	ID	32	F	3/18/2021	3/18/2021	Period started 6 hours before 1st dose, and since 1st dose at 10am period has become painful, intense cramping, and increased number of blood clots.
1118058	3/20/2021	CA	72	M	3/16/2021	3/17/2021	Besides expected head ache and slight fatigue, I woke up on the night of 3/17 (day 2 following 2nd vaccine dose) with extreme pain in my right big toe and foot, with some cramping in the right calf. It was difficult to walk. I stayed in bed most of the next day with right leg elevated, and using ice to help pain and swelling. My wife and I suspected Gout, however it would have been a first for me to have it. By 3/19 it felt a little better, but right foot still swollen, and my wife and I noticed a pronounced vein from the right knee down. She got scared that it could be a blood clot, so we called Dr and he ordered ultra sound, which was done on 3/19 in afternoon, but technician said that saw "nothing". Today (3/20) foot still sore and it's hard to put wight on it still.
1118197	3/20/2021	CA	85	M	3/15/2021	3/17/2021	2 days after receiving the second moderna vaccine my father experienced a stroke. He was transported to the emergency room medical center where he went thru a procedure to remove a clot in his left side brain. Prior to this vaccine my father was in good health and was very active and still works and owns and operates a restaurant. He has never had any problems like this before the vaccine. One day after the vaccine he was complaining about a pain on the left side of his neck area. He was doing paperwork at approx 7:40pm when he experienced the stroke. I had to call 911. My father is currently at the medical center recovering from the incident.

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1118428	3/20/2021	SC	39	F	3/19/2021	3/19/2021	Unusually heavy menstrual bleeding with very large clots. Atypical for patient. Low back pain associated with menstrual cycle. Also atypical for patient. Began day 1 of vaccine dose 2. Continuing into day 2 after vaccine dose 2.
1118563	3/20/2021	TX	69	F	3/5/2021	3/7/2021	Patient reports having severe pain while urinating and notices blood clots in urine. First noticed this adverse reaction on 3/7/21
1118702	3/20/2021	TN	66	M	3/15/2021	3/16/2021	Had a stroke 36 hours after getting second vaccine. Lost ability to speak and see clearly, had word salad. Was identified quickly by my wife and was taken by ambulance to hospital where they gave me TPA clot buster infusion after identifying a clot in my left back side of brain and luckily I responded well and have all speech function back we believe so far.
1119074	3/20/2021	CA	48	F	3/14/2021	3/19/2021	Acute deep vein thrombosis of femoral vein of left lower extremity.
1118591	3/20/2021	GA		F	2/20/2021	3/6/2021	Hospitalized March 6th 2021. Numbness, loss of use left foot, leg, L-ARM, HAND. DAZED, COULDN'T CONCENTRATE, FUNCTION. TOOK TO EMERGENCY ROOM at Piedmont Athens Reg Med Ctr and admitted. Had cat scans, MRI's, ultrasounds, EKG's. Blood clots etiology unknown, caused by COVID 19 VACCINES. PFIZER
1119208	3/20/2021	CO	50	F	3/6/2021	3/16/2021	10 days after my second shot of the Covid vaccine, I was short of breath and my heart rate was elevated. I went to the hospital and they found blood clots in both lungs and I had to be hospitalized.
1114702	3/19/2021	NY	56	M	3/13/2021	3/15/2021	amaurosis fugax. Temporarily lost vision in top half of right eye - lasted about 15-20 seconds - blood clot in right eye. No past history of blood clots
1115965	3/19/2021	WI	63	F	3/10/2021	3/17/2021	Pt developed a new onset, acute deep vein thrombosis approximately 6-7 days after vaccination in the R lower extremity with extreme pain and inability to bear weight.
1115774	3/19/2021	AZ	77	M	2/17/2021	3/3/2021	Blood Clots in both legs Extreme weakness

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1115659	3/19/2021	MA	76	M	3/8/2021	3/10/2021	Patient states he had a fever "a day or two" after he received the 2nd Moderna vaccine. The fever reached 101.7 degree F and resolved within 24 hours. A few days after that the patient states he had a "minor stroke." Patient states the doctor told him that there was a small clot on the left side of his brain. Patient has resulting numbness of the right side of his body. Per the patient the doctor says the clot had nothing to do with the stroke. When asked if the doctor had thought that the vaccine had anything to do with either stroke or clot the patient said the doctor said he didn't think so but also kind of ignored the question.
1115461	3/19/2021	MD	89	F	2/16/2021	3/9/2021	Deep vein thrombosis

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1115248	3/19/2021	OH	65	F	1/5/2021	1/1/2021	Localized discomfort where they gave her injection of first dose; both of her feet were only slightly swollen; This is a spontaneous report from a contactable consumer (patient). A 65-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the upper left arm on 05Jan2021 around 11:00-11:30 at SINGLE DOSE for COVID-19 immunisation. The patient had no prior vaccinations within 4 weeks prior to the first administration of the vaccine. Medical history included ongoing thyroid condition (Over 25-30 years ago. Ongoing controlled with Synthroid), breast cancer (2019 treatment and surgery. Presumed resolved with radiation treatment, but no treatment within a year prior to getting Pfizer COVID-19 Vaccine. Has no history of blood clots. She had full genetic testing for breast cancer and the results came back unremarkable for everything; every gene they could test they tested and they had nothing come back), lyme disease from 2002 (20 years ago; Has some suppressed immunity from Lyme Disease). The patient had no family medical history. Concomitant medication included ongoing levothyroxine sodium (SYNTHROID) taken for thyroid condition. In the evening on 05Jan2021, the patient experienced localized discomfort where they gave her injection of first dose. The event lasted maybe a day. It was also reported that about 3 or 4 days (Jan2021) after she was administered her first dose of Pfizer COVID-19 Vaccine both of her feet were only slightly swollen. She considered this event insignificant at the time. She drank water and this event went away after about 2 days. Event was not uncomfortable. Recovered completely to her awareness at that time. On 06Jan2021, the patient recovered from localized discomfort where they gave her injection of first dose and recovered on an unspecified date from the event both of her feet were only slightly swollen. Information on the lot/batch number has been requested.



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1114911	3/19/2021	MI	81	F	2/3/2021	2/3/2021	sore arm; This is a spontaneous report from a contactable consumer (patient herself). A 81-years-old female patient started to receive bnt162b2 (BNT162B2) (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection)via an unspecified route of administration from 03Feb2021 to 03Feb2021 at SINGLE DOSE for covid-19 immunisation .Medical history included thrombosis from Feb2020 to an unknown date Verbatim: blood clots. Concomitant medication included varicella zoster vaccine rge (cho) (SHINGRIX), aspirin [acetylsalicylic acid] (ASPIRIN [ACETYLSALICYLIC ACID])). The patient previously took eliquis for thrombosis. The patient experienced sore arm on 03Feb2021 and The patient underwent lab tests and procedures which included investigation was unknown results and Consumer calling about Pfizer COVID-19 vaccine who says she just had a question since she had the first dose of the vaccine yesterday. She says that the first dose went fine, and she had no ill effects at all other than a sore arm, but she didn't know that Ibuprofen shouldn't be taken before getting the vaccine and she takes low dose Aspirin every day. She says yesterday she took her dose of Aspirin, and she doesn't know should if she should continue to take her low dose Aspirin. and Caller took a low dose aspirin before taking the first dose. She is asking if that is okay. .

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1115043	3/19/2021	PA	68	M	2/13/2021		<p>Blood Clot in Leg; Tenderness; A spontaneous report was received from a consumer concerning a 68-year-old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced blood clot in leg and tenderness. The patient's medical history was not provided by the reporter. Concomitant medications reported included diltiazem hydrochloride, atorvastatin calcium and acetyl salicylic acid. On 13-Feb-2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number:031M2QA) through intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 13-Feb-2021, following administration of the vaccine, the patient had tenderness in his leg that continued until he sought out medical treatment. After medical treatment is was concluded that the patient has a blood clot in his leg and has to receive medical treatment to resolve that condition. The treatment information included rivaroxaban. Action taken with mRNA-1273 in response to the events was not applicable. The events, blood clot in leg and tenderness were considered recovered.; Reporter's Comments: There is not enough information to assess the causa association between the reported event of blood clot in leg and the administration if the mRNA-1273 vaccine. Critical details such as the patient's medical history is lacking. Additional information has been requested. Howe ever, based on temporal association between product administration and the event of tenderness, a causal relationship cannot be excluded.</p>

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1114705	3/19/2021	OH	86	F	2/16/2021	2/17/2021	In the afternoon after getting the vaccine she was eating an ice cream bar and had a time trying to eat it, it did not go down and it did not go down. She ate dinner and at 10:30 she had terrible burning that went through to her back, had shortness of breath like she could not catch her breath. Her daughter took her to the ER as the pain was so severe she thought she was having a heart attack. In the ER they ran a bunch of tests, did an EKG and took blood, she did not have a heart attack. She was admitted and monitored her. She did have a chest x-ray in the ER as well. Nothing showed blood clots in her lungs, nothing in her lungs, but she still had the SOB and the pain went away. She thinks they may have given her some medicine and the pain was gone, but she still was shortness and still is today 3/19/21. She has an appointment next week to have an echocardiogram. She has had check ups with the cardiologist and her PCP since coming home from the hospital. Her PCP gave her an inhaler to use but she has not used it. She did not have any reaction to the injection site itself. Ever since this has happened has had no appetite, brain fog, shortness of breath, fatigue and nothing sounds good to eat. She can taste okay, but nothing tastes good to her. She said she doesn't think she can handle this much longer, it's been over a month.
1113954	3/19/2021	IL		F			tends to have blood clots; This is a spontaneous report from a Pfizer-sponsored program, patient. A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that the patient was scheduled to get the second shot this afternoon (02Mar2021), on a blood thinner and tends to have blood clots. Outcome of the event was unknown. Information on Lot/Batch number has been requested.

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1114379	3/19/2021	CA	50	F	1/30/2021	2/22/2021	I was transported by ambulance and admitted to the hospital with numerous blood clots in my lungs after I could not breathe.; I was transported by ambulance and admitted to the hospital with numerous blood clots in my lungs after I could not breathe.; This is a spontaneous report from a contactable consumer (patient). A 51-year-old female patient (not pregnant) received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9265) on 30Jan2021 09:00 (age at vaccination was 50-year-old) on left arm for COVID-19 immunisation. Medical history included hypothyroidism. No Known allergies. Concomitant medications in two weeks included thyroid (ARMOUR THYROID), ethinylestradiol, levonorgestrel (SEASONALE) and cetirizine hydrochloride (ZYRTEC). No other vaccine in four weeks. The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3246) on 07Jan2021 14: 15 (age at vaccination was 50-year-old) on left arm for covid-19 immunization. Facility type vaccine was Hospital. She was transported by ambulance and admitted to the hospital with numerous blood clots in her lungs after she could not breathe on 22Feb2021 09:45 AM. AE resulted in Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). Treatment received as Angioplasty to remove bigger clots. No covid prior vaccination. Nasal Swab test (PCR) on 22Feb2021 was negative. The outcome of the events was recovering.

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1114378	3/19/2021	TX	68	F	2/6/2021	2/10/2021	multiple blood clots in lungs; multiple blood clots in legs; feeling chest pain; short of breath; This is a spontaneous report from a contactable consumer (patient). A 68-year-old female patient (pregnant: No) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9269), via an unspecified route of administration in left arm on 06Feb2021 at 18:00 at single dose for covid-19 immunisation. The relevant medical history included DCIS Breast cancer from 2016, Known allergies: penicillin from an unspecified date. Concomitant medications included levothyroxine sodium (SYNTHROID). The patient previously received first dose of BNT162B2 on 16Jan2021 at the age of 68 years old (lot number: EL3249, at 06:15 PM, in Left arm) for covid-19 immunisation. The patient received 2nd Pfizer vaccine dose on Sat, 06Feb2021. On Wednesday 10Feb2021 she became short of breath. On 11Feb2021, she began feeling chest pain. On 12Feb2021, she was advised by primary care Dr to go to the emergency room. She was admitted on 12Feb2021 to ICU with multiple blood clots in her lungs and legs. She was told by the emergency Dr this was a sign of Covid, they did a Covid test, came back negative. She remained in the hospital till 18Feb2021. She was at the time of the report on Eliquis (10 mg/d). A hereditary blood clot test was done that came back negative. She had never had an issue before the vaccination with blood clots nor anyone in her family and she was in good health before the vaccination. Dr didn't think the vaccine caused the blood clots but her primary care Dr thought it did-which was why she was reporting it. The patient also stated that event multiple blood clots in her lungs and legs resulted in Emergency room/department or urgent care, Hospitalization and Life threatening illness. The patient had hospitalization for 7 days. Treatment Heparin 25,000unit in .45% NaCl Premix, Narcan received. No covid prior vaccination. The patient underwent lab test included Nasal Swab which showed negative on 12Feb2021; Hereditary blood clot test which showed negative on an unspecified date in 2021. Therapeutic measures were taken as a result of all the events. The outcome of the events was recovered with sequel.

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1115425	3/19/2021	KY	28	F	1/13/2021	1/14/2021	the day after the vaccine around midday I started feeling aches tired chills, persisted through that Saturday, all symptoms resolved the 16th. That weekend I had heart palpitations, the Monday after my standing heart rate chest xray, ddimer - possible lung collapse, any exertion my heart rate would elevate, they performed an MRI with contrast, there could be a blood clot in the lung so I went to see a cardiologist, They put me on epinolol and did an echocardiogram, everything else checked out in my tests. I have not recovered my breathing still bothers me and my heart rate still elevates with exertion.

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1114275	3/19/2021		75	F	2/3/2021	3/8/2021	<p>Difficulty breathing; Chest pains; Blood clots in both of her lungs; Blood clots in both legs; Tired/ wiped out; A spontaneous report was received from a consumer (patient's daughter), concerning a 75-years-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced difficulty breathing (dyspnoea), chest pains, blood clots in both of her lungs (pulmonary embolism), blood clots in both legs (deep vein thrombosis), tired/ wiped out (fatigue). No medical history was reported. No concomitant medications were reported. On 03 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: not provided). On 03 Mar 2021, the patient received their second of two planned doses of mRNA-1273 (Lot number: not provided) intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, the patient was completely wiped out for a couple of days following the vaccine. She was very tired and out of it. On an unknown date, over the weekend, the patient had difficulty breathing. On 08 Mar 2021, in the morning, the patient was hospitalized for chest pains and difficulty breathing. On the same day lab data revealed that she had blood clots in both of her lungs. On an unknown date, the patient had clots in both legs as well. She was hospitalized for a week and was in rehabilitation being monitored. The reporter also informed that the patient will be hospitalized until 18 Mar 2021 for the clots in both legs. The patient received both scheduled doses of mRNA-1273 prior to the event, therefore action taken with the drug in response to the event is not applicable. The outcome of the events of difficulty breathing (dyspnoea), chest pains, blood clots in both of her lungs (pulmonary embolism), blood clots in both legs (deep vein thrombosis), tired/ wiped out (fatigue) was unknown. The reporter did not provide assessment for the events of difficulty breathing (dyspnoea), chest pains, blood clots in both of her lungs (pulmonary embolism), blood clots in both legs (deep vein thrombosis), tired/ wiped out (fatigue). Follow-up received on 16 Mar 2021 included hospitalization end date, date of first dose of vaccine.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p>

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1115977	3/19/2021	MD	62	F	1/30/2021	1/30/2021	I had arm pain, aches, tired and vomited a few time. I felt weird all over. I had pain in my upper abdomen, legs and lower back. Chills and anxiety. On 2/8, I had a tele visit with my doctor. I took Tylenol as instructed to make sure that I didn't develop a fever. My doctor said that it could be from the vaccine. My left leg and foot were swollen on 2/13, so I called my doctor again and he sent me for a Doppler to check for a blood clot. I saw him on 2/15 in person. I have lower back pain and weakness in my legs at times, but it doesn't prevent me from doing anything. They feel heavy, especially if I walk for an extended period of time.
1114806	3/19/2021	VA	45	F	3/6/2021	3/12/2021	Diagnosis: Cortical vein thrombosis, massive intracerebral hemorrhage with tentorial herniation, thrombocytopenia. Clinical Presentation and Course: 1 week after receiving Janssen COVID19 vaccination, patient developed gradually worsening headache. On March 17th, patient presented to Hospital with dry heaving, sudden worsening of headache and L sided weakness. Evaluation with head CT revealed a large R temporoparietal intraparenchymal hemorrhage with 1.3cm midline shift. She ended up getting intubated for worsening mental status. On evaluation at arrival in Medical Center, she was noted to have extensor posturing. Repeat imaging revealed worsening midline shift to 1.6cm. CTA showed cortical vein thrombosis involving the right transverse and sigmoid sinus with tentorial herniation. Patient developed brain herniation and brain death was pronounced on March 18th, 2021.



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1114245	3/19/2021	GA		F	2/13/2021	2/13/2021	<p>Pulmonary embolism in her lungs; DVT in her leg; Chest pain in her right chest; Breathing was labored; Breaking out in hives; Chills; Dull Headache; A spontaneous report was received from a consumer concerning a female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced chest pain, breathing was labored, pulmonary embolism in lungs, DVT in leg, chills, dull headache, heartbeat is up and stayed up , D-dimer levels were high and breaking out in hives, and shortness of breath. Relevant medical history included cancer involving lungs . Relevant concomitant medication was not reported. On 13 FEB 2021, the patient received their first dose of two planned dose of mRNA-1273 (lot/batch: 015M20A) intramuscularly for prophylaxis of COVID-19 infection. On 13 FEB 2021, the patient experienced chills, headache, and heart rate increased. On 27 FEB 2021, the patient experienced chest pain, dyspnea, urticaria, pulmonary embolism, deep vein thrombosis, for which she required hospitalization. Relevant laboratory investigations included increased D-dimer. Treatment for the events included Heparin and oral blood thinner. Action taken with mRNA-1273 in response to the events was unknown. On 16 FEB 2021, the outcome of the event's chills, headache was considered as resolved. At the time of this report, the outcome of the event's chest pain, dyspnoea, pulmonary embolism, deep vein thrombosis, heart rate increased, fibrin D dimer increased and urticaria were considered as unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, the events Pulmonary embolism, DVT, is Unlikely related to mRNA-1273 and a very limited information regarding these events has been provided. Further information has been requested</p>

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1114709	3/19/2021	GA	30	F	2/12/2021	2/13/2021	I was 30 + 2 weeks at the time of my second Moderna vaccine. My due date is 4/22/2021. Pregnancy has been uneventful until the second Moderna vaccine. At 3:00 am (14 hours post vaccine), I woke up with the urge to go to the bathroom. I went, urinated, and had a small amount of diarrhea. I laid back down and within 30 second had urge to go again. I repeated this six times back to back. I began to have severe lower abdominal cramping and could not sleep again. I didn't know if I had to urinate or defecate but the urge was extremely severe and constant. My temperature began to rise, and I was shaking/aching severely. I took 500 mg tylenol at 5:45 am and that kept my temperature around 99.5 (normal 97.5). Around 7:30 am I called my OB and they told me to go to emergency/labor and delivery ward of the hospital. At this time, my diarrhea and urge to defecate to stop and it turned to a constant urge to urinate with near constant, severe, lower abdominal cramping. At the labor and delivery ward, they monitored the baby (stable and moving the whole time), did a fetal fibronectin (normal), did a CBC (normal except preexisting mild anemia), and a urinalysis (normal). Hospital determined I was not in labor and did not have UTI so they sent me home. I continued to have temperature raises (up to 100.4 but always took tylenol at this point), severe lethargy, no appetite, severe abdominal cramping, constant urge to urinate, severe shaking, etc. until approximately 8 or 9 pm that evening (32 hours post vaccine). Everything except the constant urge to urinate resolved. Three days post vaccine (evening of 2/15/2021), I began to urinate large blood clots. I scheduled an appointment with my OB for a repeat urinalysis and urine culture. I had the appointment on 2/16/2021 and the only abnormality was hematuria. Urine culture was negative. Doctor prescribed 7 days of antibiotics just in case (while waiting for urine culture). My symptoms finally resolved on 2/19/2021 (7 days after vaccination), with slow improvement after urinating the large blood clots. I have not had any symptoms since then and my baby appears healthy still in utero. I have no history of UTIs.

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1116221	3/19/2021	NJ	47	F	2/19/2021	2/26/2021	Woke up with pain in left leg lower calf on February 26 one week after my second vaccine. Had pain and throbbing in leg couldn't sleep with pain so on the evening of March 3rd I went to urgent care . Doctor didn't think it was blood clot because I had no swelling or redness in my leg but gave me a script for ultrasound. I couldn't get an appointment until the morning of March 5th . Was diagnosed with a very large blood clot in lower leg going up past my knee. I am now in Eliquis blood thinner for 3 months while they run tests
1116566	3/19/2021	WA	39	F	3/9/2021	3/15/2021	Pt was admitted for right lower extremity swelling. has had DVT and pulmonary embolism. Pt found to have thrombosis of right popliteal vein. pt following up with hematologist.
1116753	3/19/2021	OR	65	M	3/4/2021	3/17/2021	Developed a DVT in right calf on 03/17/2021. Doctor told me it was a significant clot that had developed , after review of ultrasound exam

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1116991	3/19/2021	MN	85	M	3/2/2021	3/4/2021	<p>Patient is a very pleasant 85-year-old male who presented to the emergency department first on 3/8/2021 via private vehicle accompanied by his spouse in no acute distress with complaints of left arm pain and swelling after receiving his Pfizer COVID vaccination on 3/2/2021. Medical history includes hypertension, heart failure, CAD, GERD, diaphragmatic hernia, chronic left shoulder pain, among others. Patient states he received his vaccine on Tuesday and began to develop pain, swelling, and bruising at the injection site on Thursday. Since that time all of his symptoms have worsened. 9/10 pain this morning has lowered to a 4/10 after 2 tylenol, which he took approximately one hour prior to arrival. Is not anticoagulated but takes baby aspirin daily. He did stop this when he first noticed the bruising. Denies recent trauma, including falls. His chronic left shoulder pain is unchanged from baseline; the pain he presents to the ED for is located lower at the injection site. Further notes pain patches helpful with his pain. Seen again on 3/15/2021 for persistence and involvement of his forearm with the bruising and pain. Over the last week the purple discoloration has migrated down his arm towards his hand. He denies any new numbness or weakness in the arm. Exam reveals impressive and extensive ecchymosis that involves both his upper and lower arm and is circumferential in nature. There is no area of discrete swelling or tenderness. Good peripheral pulses and capillary refill. Normal strength of hand. An ultrasound done showed no clot.</p>
1117082	3/19/2021	SC	31	F	1/27/2021	3/17/2021	<p>Pregnancy with EDC of 5/7/2021. On 3/17/2021 infant was not moving as expected, went to hospital and emergency c-section performed due to failure of BPP score. Score was 2. Infant delivered @ 32 week. Wt. was 4#4 oz. Infant had blood in urine. After numerous studies my baby was found to have thrombosis in the intrahepatic IVC. Treatment has started.</p>

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1117090	3/19/2021	PA	79	F	1/24/2021	1/25/2021	I HAD HEADACHES, CHILLS, DIARRHEA, ACHES AND TIREDNESS BUT MY BIGGEST CONCERN IS THE FACT THAT I WOUND UP IN THE HOSPITAL ON FEB 8 WITH BLOOD CLOTS DOWN MY ENTIRE RIGHT LEG AND IN MY LUNGS. I NEED TO KNOW IF THE MODERNA CAUSED THESE OR MADE THEM WORSE. I HAD NO IDEA I HAD BLOOD CLOTS BUT MY FOOT, LEG WERE SWOLLEN AND I ACHED FROM MY HIP DOWN THAT LEG. I ACTUALLY THOUGHT IT WAS SIADACA.
1117313	3/19/2021	SC	55	F	3/6/2021	3/9/2021	Blood clot perpendicular to injection site

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1115064	3/19/2021	VA	46	F	3/5/2021	3/12/2021	<p>On March 5, I received my first dose of the Covid shot. Later that day, I was fatigued. Six days later, however, sometime early morning on March 12, (I was in and out of sleep because of it), I had pain swallowing my saliva on my left side (also the side of my vaccine in my arm). It was hard to pinpoint but the pain came from somewhere at the back of my throat and my ear. If I had to guess what time it was, it probably was around 1-2am that the pain began. March 12, I went to see my primary care doctor. He checked my ears &amp; didn't see any concern. He saw a little redness at the back of my throat but couldn't definitively say what I had. He thought it was a virus but didn't discount a reaction to the vaccine (although he said it was unlikely since reactions usually happen within 3 days). He ran no tests and didn't prescribe anything. March 13, I was feeling worse. I suddenly had a fever (101 was the highest it ever got), swollen lymph nodes, a white tongue. I went to the local ER at 9am who said I might have oral thrush but he didn't sound convinced because my tongue wasn't as white or thick as thrush would present (he said for example that typically when you have thrush, you could scrap it off and it would bleed). He diagnosed me with Thrush and Lymphadenopathy. He prescribed anti-fungus medication Clotrimazole 10 mg Troche, five times a day. On Sunday, March 14, my throat pain got worse (it was constant pain v.s. pain only swallowing) so I called the on-call doc who told me to get tested for Strep. The next day, on March 15, I could swallow easier so my doctor didn't think it was necessary. My lymph nodes were still swollen, I had a bit of a fever, and it was still a bit hard to swallow but I was recovering. I had some lingering ear pain. By March 15 I was much better. Today, March 19, I still have a sensation on my left ear/throat area after swallowing but I am much better. Please note that while the ER doctor thought it was fungal and my primary care doctor thought it was viral, neither were sure/thought it was the vaccine. ** Also please note, this is the second time I am completing this because the system booted me off after 20 min the first time and it was erased. It takes times to complete. Just a thought for future reference, it might be helpful to allow for more time.**</p>
1112424	3/18/2021	PA	74	F	3/5/2021	3/7/2021	DVT blood clot in leg

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1112006	3/18/2021	CA	48	F	2/24/2021	2/25/2021	I received the first does of the Pfizer vaccine and within 24 hours had started developing a superficial thrombophlebitis on the inside calf of my left leg. By Sunday, February 28th, I was in the emergency room getting an ultrasound to rule out a blood clot. By March 11, I had developed a DVT. I have been put on blood thinner and had catscans, ultra sounds, and am under a physician's care weekly.
1111727	3/18/2021		71	M	2/16/2021	2/23/2021	Developed extensive deep vein thrombosis and pulmonary embolism
1111720	3/18/2021	IL	65	M	2/17/2021	2/22/2021	Pulmonary embolism: multiple blood clots in all five lobes of lungs
1111680	3/18/2021	OH	72	F	1/27/2021	2/8/2021	Developed severe back pain. which she went to the ER to have evaluated. Upon evaluation, she was diagnosed with a PE and blood clots in her spleen
1111554	3/18/2021	MA	80	F	2/27/2021	3/10/2021	Multiple strokes resulting from blood clots starting 10 days past 2nd shot. Fuzzy headed with headache prior to strokes.

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1111371	3/18/2021	CO	65	F	2/15/2021	2/16/2021	Alt is at 148; my INR level went from 2.9 to 4.3; This is a spontaneous report from a contactable consumer, the patient. This 65-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: unknown), dose 1, single dose via an unspecified route of administration in the left arm on 15Feb2021 at 12:00 PM (at the age of 65-years-old ) for COVID-19 vaccination. Relevant medical history included asthma and chronic blood clot in heart. The patient was not pregnant. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient had no allergies to medications, food, or other products. Concomitant medications included amiodarone and warfarin. On 16Feb2021 at 15:00 the patient experienced alanine aminotransferase (ALT) at 148 and international normalized ratio (INR) went from 2.9 to 4.3. The events were reported as non-serious and required a doctor or other healthcare professional office/clinic visit. Treatment received for events alanine aminotransferase (ALT) at 148 and international normalized ratio (INR) went from 2.9 to 4.3 included reducing dosage of warfarin still working on the liver. The clinical outcome of alanine aminotransferase (ALT) at 148 and international normalized ratio (INR) went from 2.9 to 4.3 was unknown. Since the vaccination, the patient has not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.
1111026	3/18/2021	CO	60	F	3/16/2021	3/18/2021	Presents with chief complaint of left chest wall swelling. The patient states that she has a history of Covid prior and received a Madera vaccine 2 days ago. This was the first vaccine. She states that she had a significant amount of redness and swelling at the vaccine site on her left arm initially. Yesterday she started noticing some swelling above the clavicle on the left-hand side and was concerned that this could be a blood clot given her history of Covid. She states it is tender to the touch. She has not had a fever and denies any redness. No history of similar in the past and no prior venous thromboembolism.



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1111014	3/18/2021	NJ	44	F	2/7/2021	2/7/2021	Felt heat up my chest immediatley-then it subsided . I sat for 30 minutes. I went home and had severe pain in stomach, nausea, fevers etc. I felt chest pressure had fevers and diarrhea for two weeks. I was admitted to the hospital for the chest pressure and high heart rate and possible dehydration. My D-dimer elevated however, no clot was fount on Cat Scan of chest.
1112605	3/18/2021	PA	78	M	3/14/2021	3/14/2021	Received the Vaccine Shot, waited 15 minutes with no issues. Went home, in about 15 minutes had extreme chest pain. Quickly moved to emergency room. Was given nitroglycerin paste on chest, Asprin to chew, Heprin and cardiac cautherization. Cautherization showing no real issues. Eventually the pain was gone. Cardiac doctor mentioned heart possibly being highly stressed earlier. I have some thoughts that it may have been a temporary blood clot, but not proven. Chest pain was very bad until emergency room starting getting it under control. never had that much pain before with previous heart attacks in 2004-05
1110877	3/18/2021	PA	61	M	1/14/2021	3/18/2021	EE admitted to hospital 3/18/2021 with "blood clots~~
1111566	3/18/2021	TN	63	F	2/24/2021	2/28/2021	Developed extensive DVT with pulmonary emboli 4 days after receiving Covid vaccine. Clot was evacuated with thrombectomy but reaccumulated 1 day later, despite being treated with Eliquis.
1110612	3/18/2021	NC	42	F	1/4/2021	2/9/2021	EDC: 25 APR 2021 AE1: Superficial Venous Thrombosis: On 10 Feb 2021, patient presents with RLL pain and swelling. Dopplers with non-occlusive Superficial Venous Thrombosis. Started on 40 Lovenox qd. On 23 Feb, had worsening pain and repeat doppler showed occlusive SVT. Her Lovenox was increased to 40 mg BID and referred to Hematology. Her hematologist increased her lovenox to 80 mg bid. SAE: Pulmonary Embolism: On 3/9 patient developed Shortness of breath and chest pain and went to ED where she was diagnosed with Bilateral pulmonary emboli. She was admitted to the hospital and started on an heparin drip. AE2: SVT: Patient developed a second SVT after discharge from hospital on 17 Mar 2021 that is located away from original SVT site.

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1110391	3/18/2021	IN	61	M	2/25/2021	3/6/2021	Received vaccine, and no reactions. Nine days after the vaccine slowly had drooping on the right side of his face, numbness on the right side of his face, mainly around the mouth, a little on the eye, hard to close the right eye. General soreness around his mouth when he tries to eat or talk a lot. Limited movement of his face do to swelling, difficulty closing his eye, and headache. Went to the ER on 3/7/21 and admitted him as they believed he had a blood clot, diagnosed him with Bell's palsy on Monday 3/8/21. Was given corticosteroids for 9 days Prednisone 60 mg. The symptoms are slowly improving but still has the Bell's palsy.
1110042	3/18/2021	PA	61	F	1/28/2021	2/2/2021	blood clot (superficial) developed four days after vaccine.. No prior history of blood clots.
1110945	3/18/2021	IA	71	M	2/7/2021	3/17/2021	Saddle pulmonary embolism, increasing shortness of breath, COVID positive test but seems to have symptoms from the pulmonary embolism and not COVID, no ground glass opacities in lungs seen on imaging., still currently in the hospital getting treatment for clots, currently day two
1112628	3/18/2021	AZ	60	F	3/7/2021	3/12/2021	I received my vaccine on Sunday March 7 and in the morning of March 12, I woke up to a large bruise with a hard clot on the inside of my right forearm measuring 7cm x 4cm with a large clot in the bruise. I also have a smaller spot which has a firm bump under the skin. I did not hit my arm or injure it during my sleep or before going to bed.
1112683	3/18/2021		73	F	2/19/2021	3/15/2021	Extremely tired for the next month, and then was hospitalized with 2 blood clots in lungs and severe anemia (cause not determined yet, as to whether not making platelets or losing blood). Had two blood transfusions and iron transfusion.
1112775	3/18/2021	MN	56	F	3/10/2021	3/12/2021	blood clot leading to brain stem stroke, intubation, shortness of breath and chest pain

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1112779	3/18/2021	CA	65	F	2/26/2021	2/28/2021	Just 38.5 hours after receiving my 2nd dose of the Pfizer Covid-19 Vaccine I suffered a Cerebral Vascular Accident, a CVA, a Stroke @ 5:05a.m. in our home. My entire right side was paralyzed & unable to speak. My husband alerted #911 & fortunately @ the hosp. I received immediate life saving care. I had a C.T. Scan which revealed #2 blood clots in the left side of my brain. Intravenous T.P.A. was administered & then a thrombectomy was performed. Hospitalized approx. 5:45a.m on Sun., Feb. 28th, 2021 till my discharge on Wed., March 3rd, 2021@ 5:30pm.
1111548	3/18/2021	NY	59	M	2/20/2021	3/12/2021	Pfizer-BioNTech COVID-19 Vaccine EUA Approximately three weeks after this injection, I began to feel a pain in my left leg. I assumed it was a cramp. I then received a second dose (Lot # EN6206) on 3/13/21. Over that weekend the pain in my leg grew worse and the leg began to swell. on 3/15, I went to my primary care physician who said it looked like a blood clot. He sent me to a radiologist for an ultrasound (?) of the leg. After confirming the clot, I went to a local ER. They started me on Eliquis to treat the clot
1112614	3/18/2021	RI	78	M	3/13/2021	3/15/2021	Blood clot in urinary track
1107421	3/17/2021	VA	75	M	12/30/2020	1/6/2021	I had sudden malaise, lost consciousness and my wife says was not breathing briefly. I revived and was taken to the hospital, and treated for 2 1/2 days with heart catheterization and TPA injected into my clot in the pulmonary arteries with good resolution. I did have cor pulmonale with acute severe right heart failure as part of that. Dr. thought the clot came from my right calf by his examination. Diagnosis was confirmed by CAT scan cardiac Echo and right heart catheterization.
1109422	3/17/2021	CO	71	M	1/29/2021	3/7/2021	Client received first dose of Moderna vaccine on 1/29/21. Client presented for a second dose on 3/12/21 and reported that he had 'blood clots in the lungs' on 3/7/21 and was hospitalized. The cause of the blood clots is unknown. Client has since recovered and spoke to his doctors and they advised that he receive the second dose of Moderna as scheduled on 3/12/21.

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1108750	3/17/2021	NE	52	M	2/18/2021	2/19/2021	No reaction to first shot. Received the second shot the morning of 18 Feb, noticed some minor joint stiffness, minor pain and tiredness mid morning 19 Feb. Laid down at 16:30 and remained asleep until 0530 the next day. Unusual to sleep 13 hours. Later that weekend I noticed a bruise on my leg. I rarely bruise and had not hit my leg on anything. I ignored the bruise a couple weeks, but as it did not heal, continued to hurt and had swelling I went to my primary doctor on 4 March who thought it was a blood clot and sent me for imaging. They determined it was superficial thrombophlebitis and treated with antibiotics and heat.
1108656	3/17/2021	CO	70	F	1/13/2021	1/14/2021	The next day, I had short term memory loss. I went to the hospital, and they said I had some type of heart episode. I was taken by ambulance to the hospital and was told I had a blood clot in my brain and had suffered a mini stroke. I was hospitalized for 4 nights. I was given blood thinner and I improved.
1108465	3/17/2021	UT	50	F	3/11/2021	3/12/2021	Heart was in A-fib, blood clot formed and had a Left Posterior Parietal Stroke
1108193	3/17/2021	WA	72	F	3/1/2021	3/11/2021	Pain in calf of left leg. Two blood clots lower left leg, being treated with blood thinner Xeralta
1107735	3/17/2021	OH	90	M	2/19/2021	3/7/2021	Death on March 8 due to a large blood clot at the base of his brain. This was 16 days after inoculation.
1109714	3/17/2021	SC	75	M	3/2/2021	3/6/2021	Headache. Blood clot. Passed the blot clot in urine four days after getting the second dose of the Moderna COVID vaccine.
1107356	3/17/2021	AZ	94	F	2/4/2021	2/6/2021	Blood clot in blood vessel in the left hand at the base of the middle finger causing darkening in the lower part of the finger and numbness in the whole finger.
1107342	3/17/2021	OH	81	M	1/22/2021	2/26/2021	Blod clot, stroke

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1107202	3/17/2021	NJ		F	2/14/2021	2/14/2021	Migraines have become more frequent and more intense to the point of were she could not function; Developed a welt at the injection site that she describes as COVID arm which was a 3-4inch raised circle underneath the injection site; Pain under lymph nodes; Developed thrombosis on her head, but it went away; A spontaneous report was received from a consumer on 04 Mar 2021 concerning a 45-years-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed thrombosis on her head, but it went away, migraines have become more frequent and more intense to the point of were she could not function, developed a welt at the injection site that she describes as COVID arm which was a 3-4inch raised circle underneath the injection site, lymph nodes pain, which she still has. The patient's medical history was not reported. Current conditions included migraine. The patinet had allergy to latex and pineapple. No relevant concomitant medications were reported. On 14 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (lot: not provided) intramuscularly in right arm for prophylaxis of COVID-19 infection. Since 14 Feb 2021, patient's migraines had become more frequent and more intense to the point of were she could not function. She also developed thrombosis on her head, but it went away. The patient also developed a welt at the injection site that she described as COVID arm which was a 3-4 inch raised circle underneath the injection site. She also developed pain under lymph nodes, which she still had. No treatment information was provided. Action taken with mRNA-1273 in response to the events was unknown. The event of migraines have become more frequent and more intense to the point of were she could not function and pain under lymph nodes which she still has were unresolved, the event of developed thrombosis on her head but it went away was resolved, while the outcome of the event of developed a welt at the injection site that she describes as COVID arm which was a 3-4inch raised circle underneath the injection site was unknown. The reporter did not provide an assessment for the events thrombosis on her head, but it went away, migraines have become more frequent and more intense to the point of were she could not function, developed a welt at the injection site that she describes as COVID arm which was a 3-4inch raised circle underneath the

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							injection site, Pain under lymph nodes, which she still has.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
1107853	3/17/2021	CA	55	F	2/1/2021	2/17/2021	Patient developed intense bilateral leg pain, right greater than left. Physical exam consistent with acute arterial thrombosis of both lower extremities.
1107187	3/17/2021	OH	89	F	2/5/2021	2/11/2021	Blood clots on her legs; Blood clots on her lungs; A spontaneous report was received from a consumer concerning 89-year-old, female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and who experienced blood clots on legs and lungs. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 05 Feb 2021, approximately 7 days prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number not provided) via an unknown route in the right arm for prophylaxis of COVID-19 infection. On 11 Feb 2021, the patient was hospitalized for blood clots on legs and lungs for 7 days and was discharged on 17 Feb 2021. Treatment include unknown injections. Action taken with mRNA-1273 in response to the event was not provided. The outcome of the event was not reported.; Reporter's Comments: Very limited information regarding this events has been provided at this time. Further information has been requested
1109729	3/17/2021	ME	62	M	2/27/2021	3/8/2021	03/07/21: Onset of dyspnea upon exertion 03/09/21: Worsening dyspnea and non-productive cough 03/11/21: Primary care visit for diagnosis/tests 03/12/21: Elevated BNP levels noted; chest X-ray 03/13/21: Further worsening of dyspnea 03/15/21: D Dimer test elevated (positive) 03/15/21: ED visit; CTA scan indicates pulmonary emboli (lots of clots); admitted to hospital; Heparin IV drip 03/16/21: (evening) Discharge on Eliquis 03/17/21: Moderately severe dyspnea upon exertion and non-productive cough continues Event: Pulmonary emboli

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1109200	3/17/2021	CA	73	M	3/1/2021	3/9/2021	PATIENT NOTICED BLOOD CLOT IN URINE 8-9 DAYS AFTER SECOND DOSE OF COVID VACCINE GIVEN. BLOOD CLOT IN URINE OCCURRED ONLY ONCE AND CLEARED AFTERWARDS.NO OTHER SIGNIFICANT POSSIBLE ADVERSE REACTIONS NOTED BY PT
1105661	3/16/2021	CA	61	M	3/2/2021	3/5/2021	Blood Clot's small in distal region of lungs bilateral 3 days after injection of vaccine
1105602	3/16/2021	IL	74	F	2/15/2021	2/15/2021	2/15-2/19 nightly headaches increasing in intensity each night. 2/20-2/25 nightly headaches with stabbing pain in left eye 2/26.. 2/22- saw Dr. /had CT. 2/24-returned to Dr. and was sent to ER due to high BP. Hospital admission that evening. 2/26 Steroid treatment stopped headaches and eye pain. 2/27 released from hospital after BP was <160. Diagnosis-migraines possibly triggered by vaccine. Pain/nausea elevated BP and decreased food intake which caused low blood sodium levels. IV treatments to increase sodium and lower BP. Dizziness from low sodium and high BP created fall risk, so bed had alarm. Bed confinement necessitated daily injections to prevent blood clots. Twice daily blood tests done to monitor sodium and potassium levels + kidney function.
1105535	3/16/2021	NY	63	M	1/5/2021	1/15/2021	Multiple blood clots in right leg (DVT) and multiple blood clots in lungs (PE)
1105500	3/16/2021	WA	62	F	3/5/2021	3/6/2021	Pfizer-BioNTech Covid vaccine, first shot developed a blood clot in a superficial vein the day after the vaccine, was diagnosed by a doctor as "superficial thrombophlebitis, pain swelling in leg. Treatment of ibuprofen started. Wondering if I should take my second shot which is scheduled for March 26
1105496	3/16/2021	IN	67	M	3/10/2021	3/13/2021	you got second Moderna vaccine on March 10, Wednesday. Saturday night began with left leg swelling and pain. Thought it was a side effect of the vaccine. Tuesday, march 16 the pain got so bad he went to ER. Has bleed clots in main artery in leg femoral artery. Pt. was transferred to larger hospital.

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1105456	3/16/2021	FL	77	F	2/26/2021	2/27/2021	Lymph gland under left arm size of golf ball, smaller glands swollen underarm, (soft), neck swollen, left foot swollen, weakness, small blood clot in myopic of middle finger, small modules in upper thigh, sore on lower lip right side
1105441	3/16/2021	KS	74	M	2/26/2021	2/26/2021	Pt developed RUE erythema and edema. RUE US demonstrated clot in 1 of 3 brachial veins in mid-portion of RUE. Pt prescribed Eliquis x 6 weeks ( 5 mg PO BID once. 10 mg PO BID x 7 days. Then 5 mg PO BID x 5 weeks) followed by repeat RUE US.
1105216	3/16/2021	OH	32	F	3/12/2021	3/13/2021	The first day about 10 hours later I got flu like symptoms. I had nausea, chills, stiff muscles- it lasted 14-15 hours. I woke up Sunday morning and had shortness of breathe and have been ever since. I seen my PCP and he sent me for testing to rule out Blood clots and that came back ok, but I'm still having the shortness of breathe. If I get worse he advised me to go to the ER and if im not feeling better to call him in three days.
1105195	3/16/2021	MI	74	M	2/16/2021	2/17/2021	Pain in upper right thigh on day after vaccine and next day. Badly swollen calf on third day after vaccine. Hospitalized with "Right femoral acute thrombosis; no compression; no flow detected.~~
1104607	3/16/2021	NJ	74	M	2/8/2021	2/11/2021	Stroke on 2/11/2021 caused by a blot clot



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1106299	3/16/2021	PA	59	F	2/25/2021	2/25/2021	arm was very sore when she got up it was swollen and red and hurt terribly; arm was very sore when she got up it was swollen and red and hurt terribly; arm was very sore when she got up it was swollen and red and hurt terribly; This is a spontaneous report from a contactable consumer (patient). A 59-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 59 years of age), via an unspecified route of administration in the left arm on 25Feb2021 14:15 (Batch/Lot Number: Unknown) as a single dose for COVID-19 immunisation. Medical history included chronic blood clot in left leg from an unknown date and unknown if ongoing and environmental allergies. The patient's concomitant medications were not reported. The patient did not receive any other vaccine in four weeks prior to covid vaccine. She was not pregnant. The patient had not had covid prior vaccination and she had not been tested post vaccination. It was reported that during the night of 25Feb2021 at 11:00 PM, the patient's arm was very sore when she got up it was swollen and red and hurt terribly. So she went to the ER because she had a chronic blood clot in her left leg; there was no clot in her arm but it was still swollen, red and it hurts. She added that she have very bad environment allergies and queried if she should get the second shot. No treatment received for the events. The outcome of the events was unknown; the events resulted to emergency room visit. Information on the lot/batch number has been requested.
1104565	3/16/2021	AZ	74	M	1/19/2021	1/21/2021	BLOOD CLOT. Began feeling ill 2 days after 1st vaccine...headache, cold and tired. Developed pain in my abdomen area quite noticeable 4 days later. 6 days later had major pain, vomiting, bloody diarrhea. Went to ER morning of the 7th day....spent 4 days in hospital. Had a blood clot--Portal Vein Thrombosis. Put on Heparin drip in hospital...and Eliquis blood thinners after released. I have never been sick like that...never been on any prescription...always been healthy, walking 3-5 miles per day. My family feels that there must be a connection with the vaccine. One of my doctors said no...another said didn't think so, but unknown at this time.

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1104554	3/16/2021	PA	77	F	2/1/2021	2/14/2021	I had quite an adverse reaction to the second MODERNA vaccine. That afternoon and evening I developed symptoms. I was experiencing chills, fever, body aches, headache, sore throat, shaking and nausea. As the week went on, my reaction became worse. I was sweating profusely and had shortness of breath accompanied with burning pain on the top of my hands and feet and a rash. On Friday morning, 5 days after the vaccine, I collapsed and had a stroke. I was rushed to hospital and was admitted. It was confirmed that I had a stroke. through a Cat Scan and MRI. On Saturday, I had another stroke. This time I was transferred to hospital. I had a huge blood clot on the left side of my brain which has effected my speech and walking. My entire life has been effected and changed. I had a plethora of tests done, MRI, CAT SCAN, EKG, BLOOD WORK etc. I also have to have speech therapy, physical therapy and occupation therapy. I spent about weeks in the hospital. The doctors think it is a possibility that the 2 Moderna vaccine caused my two strokes. What can be done about this? I will have problems for the rest of my life.
1104499	3/16/2021	VA	54	F	2/2/2021	2/4/2021	Developed numerous blood clots in left saphenous vein and likely pulomary embolism (did not do test for embolism b/c I am allergic to the contrast but I was very short of breath for several weeks). Not sure if this is related to the vaccine since I was post bone surgery and also on estrogen therapy (ovaries removed 5 years ago) but I have not ever developed a problem before after surgery and while on estrogen.

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1104327	3/16/2021	FL	68	F	2/10/2021	2/12/2021	68 yo WF in excellent health with prior history of intermittent benign positional vertigo for seven years and a cerebral concussion two years ago from which she recovered uneventfully in 6 weeks with no residual neurologic or physical issues. Patient received first dose 1/19/2021 with only mild fatigue and arm soreness at injection site. 16 hours after the second dose, Patient developed a dull total cranial headache and fatigue , retiring to bed , taking no medicines. She had taken only her premarin 0.625 mg for the last week. Patient awoke at 4:30 am with severe headache, nausea and vertigo, being unable to stand without assistance. urinary incontinence also occurred, but most likely occurred as she was unable to to get to the bathroom due to vertigo and pronounced vomiting of clear yellow fluid. incontinence never occurred again throughout the illness. examination at this time showed nystagmus on bilateral lateral gaze and vertical nystagmus. no other neurological signs or symptoms were present. On return to bed, Patient continued to have vertigo headache and nausea even supine with eyes closed. Vetigo and standing instability did not respond to epley manuevers. Headache remained mild to moderate, along with persistent vertigo and nystagmus for 4 days, becoming slightly less each day. On the fifth day, Patient was able to ambulate unaided by holding onto walls furniture etc. vomiting did not reoccur after her initial bout. Headache abated on the fifth day. Patient remained "fuzzy" and imbalanced for the next 14 days with occasional mild posterior cranial headache. Rotary nystagmus abated on the 7th day. Note is made that no abnormalities of the tympanic membranes were noted. no cardiac symptoms or irregularities were noted HR 60 BP 110/70 several attempts at epley manuevers only resulted in symptom worsening. Patient felt well enough to traveled by airplane day 8 post dose, having still some "fuzziness 'and slight imbalance, being unable to walk briskly due to gait instability..symptoms worsened slightly after air flight, and on return to home, slight barotraumatic changes were noted in the tympanic membranes, slight fluid levels and some small streaky membrane hemorrhages noted. her gait became slightly more unstable, but she was able to walk unaided. symptoms improved daily and by day 14 symptoms seemed to be much lessened, no nystagmus being noted. vertigo was present only on

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							<p>rapidly standing , position change and vertical looking up., vertigo abating quickly after each motion at rest. Patient traveled by plane on 3/4/21-3/8/21, vertigo escalated to mild to moderate..no response to epley maneuvers. Vertigo worsened daily and Patient again developed mild gait instability and nystagmus bilaterally and vertically. Ear exam was unchanged. no headache was present during this time. Patient was taken for balance training to a specially trained Physical therapist on 3/10/21 for evaluation , Patient being markedly symptomatic, examination showing both right and left ear abnormalities as well as vertical nystagmus. driving was prohibited. The constellation of symptoms for the even are most consistent with acute vestibular neuronitis or central vertigo.. Neuologic localizing signs suggestive of cerebral thrombosis, etc were not present , so MRI was not performed. Patient had Had a Notmal CT scan with here cerebral concussion two years prior. As the symptoms weer worsening and the result of the balance training session on 3/10/21 resulted on significant worsening on awakening on 3/11/21 with moderate gait instability, bilateral horizontal and vertical nystagmus, Prednisone 40MG po was administered. Approximately 8 hours after the prednisone dose, Patient was able to stand unaided, and vertigo was almost totally cleared. 30mg prdnisone was administered on 3/12/21 with Patient being totally asymptomatic. No nystagmus could be detected and epley maneuvers done by the physical therapist resulted in no symptions or evoked nystagmus. Predinsone dose was deescalated by 10 mg daily, Patient remaining totally asymptomatic. today 3/16/21 Patient will take 5mg of prednisone, still assymptomatic, prednisone to be discontinued tomorrow.</p>
1104152	3/16/2021	KS	61	M	3/10/2021	3/13/2021	Developed 3 small blood clots in his left lower leg on Saturday, 3/10/2021 - swelling and slight redness along with pain

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1103782	3/16/2021	TX	63	F	3/4/2021	3/4/2021	Site: Bruising at Injection Site-Medium, Site: Pain at Injection Site-Mild, Site: Redness at Injection Site-Mild, Site: Swelling at Injection Site-Mild, Systemic: Allergic: Rash (specify: facial area, extremities)-Mild, Additional Details: Mostly injection site reaction, large yellow bruise( 5.5 cm long and 2.5 wide) at site of injection with clotted blood/dark bruise near immediate areameasuring 11.5 cm long and 6 cm wide, pale-pink radiating ring area surrounding bruise. Also has a nearby knot in area that is throbbing.

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1103636	3/16/2021		78	M	2/24/2021	2/24/2021	He has had a friable capillaries, so sometimes when he urinate, he urinate blood or little blood clots; This is a spontaneous report from a contactable consumer. A 78-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EN6198), via an unspecified route of administration on 24Feb2021 at a single dose for COVID-19 immunization and apixaban (ELIQUIS), via an unspecified route of administration from an unspecified date to an unspecified date at unknown dose for Atrial Fib (atrial fibrillation). Medical history included prostate cancer from about 10 years ago and was treated by radiation, the radiation has caused capillaries in the penis to be fragile (friable capillaries) and there were times when he bleeds and has some clots and it usually resolves itself; and bloody urine in the past. The patient's concomitant medications were not reported.. Radiation has caused capillaries in the penis to be fragile and there are times when he bleeds and has some clots. The patient has had a friable capillaries, so sometimes when he urinates, he urinate blood or little blood clots. The patient was on Eliquis, so yesterday when they came home after he got the vaccine, he was bleeding with the clots which he has done in the past. The reporter asked if it is possible that the vaccine can precipitate a bleeding episode in someone that is on Eliquis and had on and off had bloody urine in the past. After the shot, he was bleeding with the clots and with the bloody urine. The patient got the first dose of the Pfizer COVID-19 vaccine on Wednesday. He had radiation for prostate cancer 10 years ago. He had a bloody urine periodically and the doctors were aware. He had a blood urine one hour post vaccination in 24Feb2021. It would take at least a few hours for the medication to get in the system before having any kind of reaction. It resolved on its own he doesn't have a blood urine anymore. The second dose of the vaccine is due on 16Mar2021. The action taken in response to the events for apixaban was unknown. The outcome of the events was recovered on unspecified date in Feb2021.

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1103625	3/16/2021	MI	75	M	2/3/2021	2/3/2021	dizzy; BP dropped to 117/79.; This is a spontaneous report from a consumer. A 75-years-old male patient started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number: EL9265, via an unspecified route of administration in left arm,from 03Feb2021 as a single doseE for COVID-19 immunization . Medical history included a stroke and high blood pressure . Concomitant medication included oral clopidogrel (CLOPIDOGREL), 75 mg once a day for a storkeand apixaban (ELIQUIS) 5 mg 2x/day oral for blood clots. On 03Feb2021Patient had a reaction with the first dose of the Pfizer vaccine. He got a little dizzy and his BP dropped to 117/79. He wants to know if it is safe to take the second dose.. Patient states that he had a mild reaction to the COVID shot on 03Feb2021. Patient states that he got kind of dizzy, and his blood pressure dropped to 117. Patient states that his reaction lasted about an hour, and he had no other problems. Patient is wondering if he should get the second dose, or if he should not take some of his blood thinning medications on the same day as his second dose. Patient got his first dose of the product on 03Feb2021, and the side effects occurred that same day, just after the patient left the clinic, about 15 minutes later. Patient reports that he got kind of dizzy and he checked his blood pressure which was 117/79. Patient states that the dizziness lasted about an hour, and he did not check his blood pressure again after that. The outcome of the events was not reported.

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1104841	3/16/2021	AZ	76	M	2/3/2021	2/10/2021	My husband received the first injection on Feb 3, 2021 he developed a cough afterwards, cough would come and go. He was scheduled to receive 2nd dose on March 11 and I was concerned about having a cough at the time of 2nd vaccine. He went to walk-in clinic and got a covid test was negative, he said his exam was normal, they gave him prescription of Benzonatate 100mg he took one and it did not help so he never took any more. On March 5 while working in the yard he collapsed, paramedics arrived and he was in cardiac arrest, they started CPR, they used AED was in vfib, he was taken to Hospital then transferred to second hospital. I was told he had blood clots in both lungs, one in his leg, and possible clots in the mesenteric area of abdomen. His heart stopped due to the blood clots in his lungs. He remains in the hospital in the Intermediate Coronary Care Unit. He has not yet gained full consciousness.
1106925	3/16/2021	MI	53	F	2/1/2021	2/17/2021	I received my first vaccination on February 11, 2021. On February 17th I was rushed to my local ER with a massive heart attack. I was rushed by helicopter to second hospital where I underwent an emergency Heart Catherization. It was discovered that I will need a triple bypass surgery. However, there is a HUGE blood clot that formed in my heart, and further treatment is on hold for now, until the massive clot has safely dissolved.



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1106802	3/16/2021	CA	75	M	2/23/2021	3/2/2021	One week after 2nd Moderna, started coughing periodically in day and night chest congestion started to build at night. After three days of cough periodic and each night became more congested with problem being to not inhale deeply, and lower right side adobonem pain. Sought medical appointment March 20 but did not get appointment until March 9 with medical facility due to increasing pain and not sleeping from congestion. March 10 doctor visit ordered blood and urine tests and CT scan. Early Mar11 test B type natriuretic protein was high (CHF), Doctor ordered chest xray, ekg and echogram. CT scan found clot in right lower lung. Told to go to ER Mar 10 evening, ER ordered Ultrasound images of the legs.BILATERAL LOWER EXTRE BILATERAL LOWER EXTREMITY DEEP VEINS: Nonocclusive thrombus in the distal right femoral vein and popliteal vein extending into the tibioperoneal trunk. Thrombus is hypoechoic and expansile consistent with acute thrombus.Left lower extremity veins are patent and compressible. Left common femoral vein demonstrates normal waveform without loss of respiratory phasicity.Positive for right lower extremity DVT of the distal femoral vein, popliteal vein, and tibioperoneal trunk. CT;LUNG BASES: Small right pleural effusion with overlying compressive atelectasis and consolidation. There are addition, there are apparent filling defects within the subsegmental pulmonary arterial branches suggestive of emboli. Many /multiple blood tests March 9, 10 ,11 , 12 and 16 available to examine details..one perhaps low Platelets count 151 K/uL (range) 140 - 400 K/uL. I can give permission for these tests results to study to correlate lung and leg clots . This is unique because hospital data available to diagnose in detail my reaction after 2nd Moderna shot. Please look into it with experts..Did Moderna cause my clots I never had before?

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1103636	3/16/2021		78	M	2/24/2021	2/24/2021	He has had a friable capillaries, so sometimes when he urinate, he urinate blood or little blood clots; This is a spontaneous report from a contactable consumer. A 78-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EN6198), via an unspecified route of administration on 24Feb2021 at a single dose for COVID-19 immunization and apixaban (ELIQUIS), via an unspecified route of administration from an unspecified date to an unspecified date at unknown dose for Atrial Fib (atrial fibrillation). Medical history included prostate cancer from about 10 years ago and was treated by radiation, the radiation has caused capillaries in the penis to be fragile (friable capillaries) and there were times when he bleeds and has some clots and it usually resolves itself; and bloody urine in the past. The patient's concomitant medications were not reported.. Radiation has caused capillaries in the penis to be fragile and there are times when he bleeds and has some clots. The patient has had a friable capillaries, so sometimes when he urinates, he urinate blood or little blood clots. The patient was on Eliquis, so yesterday when they came home after he got the vaccine, he was bleeding with the clots which he has done in the past. The reporter asked if it is possible that the vaccine can precipitate a bleeding episode in someone that is on Eliquis and had on and off had bloody urine in the past. After the shot, he was bleeding with the clots and with the bloody urine. The patient got the first dose of the Pfizer COVID-19 vaccine on Wednesday. He had radiation for prostate cancer 10 years ago. He had a bloody urine periodically and the doctors were aware. He had a blood urine one hour post vaccination in 24Feb2021. It would take at least a few hours for the medication to get in the system before having any kind of reaction. It resolved on its own he doesn't have a blood urine anymore. The second dose of the vaccine is due on 16Mar2021. The action taken in response to the events for apixaban was unknown. The outcome of the events was recovered on unspecified date in Feb2021.

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1106326	3/16/2021			M			<p>acute severe ITP; The initial case was missing the following minimum criteria: literature report without causality. Upon receipt of follow-up information on 01Mar2021, this case now contains all required information to be considered valid. This is a literature report. A 22-year-old healthy male with no medication use received the Pfizer-BioNTech BNT16B2b2 mRNA vaccine through his work as an emergency department employee. On day three, post-vaccination, he experienced widespread petechiae and gum bleeding, which prompted his presentation. He was current on his vaccines, including yearly influenza, with no history of adverse reactions. He denied respiratory and gastrointestinal complaints or a history of infection. He had no personal or family history of bleeding or autoimmune disease. Vital signs and the remainder of his exam were normal. Laboratory tests revealed normal white-cell count, hemoglobin, and severe thrombocytopenia with a platelet count of <math>2 \times 10^9/L</math>. Two months prior to receiving the vaccine, the patient was evaluated at an outpatient clinic for upper respiratory symptoms. His PCR assay returned negative for SARS-CoV-2, and complete blood count was unremarkable with a normal platelet count of <math>145 \times 10^9/L</math> (reference range, <math>140-400 \times 10^9/L</math>). The upper respiratory symptoms resolved within a few days, and the patient had no further complaints. However, as a precautionary measure, one-week post outpatient evaluation, he was again tested for SARS-CoV-2, which returned negative. At the emergency department on day 3, post-vaccination, the following labs were normal or negative: prothrombin time, partial thromboplastin time, fibrinogen, blood urea nitrogen, creatine, electrolytes, bilirubin, Lactate dehydrogenase, alkaline phosphatase, albumin, globulin, total protein, and haptoglobin. The aspartate aminotransferase (42) and alanine aminotransferase (90) were mildly elevated; however, they normalized the next day. Additionally, he tested negative for HIV, Hepatitis B, Hepatitis C antibody, and Epstein-Barr Virus serology. A nasopharyngeal swab also returned negative for SARS-CoV-2 antigen. The patient was then admitted and given dexamethasone 40 mg daily for 4 days, a platelet transfusion, and intravenous immunoglobulin at 1 g/kg for 2 days. Immunologic studies performed on day 6 for Rheumatoid factor, antibodies for Cyclic Citrullinated Peptide, Anti</p>

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Centromere, Chroma-tin IgG, dsDNA, Jo1, Ribosomal P Protein, Ribonucleoprotein, Scleroderma, Smith, Sjogren's Syndrome B, Sm/Rnp IgG, AntinuclearAntibody (<1:80, normal <1:80) were normal. However, Sjogren's Syndrome A antibody (2.8) was elevated (normal <1 AI). On day six, post-vaccination, petechiae and oral bleeding decreased, and the patient was discharged with a platelet count of 28 x 109/L. Based on the presentation, a platelet count <100 x 109/L, and the exclusion of alternative causes, a diagnosis of ITP was made. At follow up, on day 11, the patient's platelet count normalized to 173 x 109/L, and the patient tested positive for plasma IIb/IIIa and Ia/IIa platelet autoantibodies. Sjogren's Syndrome A antibody decreased from 2.8 on day 6 to 1.5 (normal <1 AI). Moreover, complement C3 (94) was normal (reference range, 79-152 mg/dL), while complement C4 (10.9 mg/dL) was low (reference range, 16-38 mg/dL). On day 34 a repeat of the patient's abnormal immunologic studies showed a normal value of both Sjogren's syndrome A antibody (SSAAB: <0.2) and Complement C4 (27.6 mg/dL). Additionally, SARS-CoV-2 IgG antibody testing was performed to rule out that a previous COVID-19 infection elicited the ITP experienced on day 3. However, SARS- CoV-2 IgG was negative. As of 16Feb2021, and since the patient's discharge on day6, he remains healthy without any evidence or symptoms of autoimmune disease. This is the first case published in the medical literature of an individual, with no other cause identified and no associated illness, experiencing ITP after receiving the Pfizer-BioNTech vaccine. The temporal relationship of the patient's presentation 3 days post-vaccine administration suggests, but does not prove, the vaccine may be linked to the patient's ITP. Additionally, the rapid and severe drop in platelet count to 2 x 109/L is reminiscent of the abrupt onset observed in drug-induced thrombocytopenia, which further suggests a recent etiology. However, it must be noted that the incidence of ITP is about 3.3 per 100 000 adults/year. Therefore, it is also plausible that this patient's diagnosis was purely coincidental, given that the country has administered over 12 million vaccines to date. Additionally, 43 448 participants were included in the Pfizer-BioNTech trial, and no ITP was reported. Moreover, considering the low complement C4 (10.9 mg/dL), mildly elevated SSA Ab (1.5), and 2 months

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prior, the platelet count (145 x 109/L) was near the lower limit, it is difficult to exclude alternative causes, such as an underlying autoimmune condition with pre-existing ITP. In this scenario, the ITP became clinically apparent following the vaccine, though this patient never manifested symptoms suggestive of autoimmune disease. This case was reported to the FDA's Vaccine Adverse Events Reporting System (VAERS) and is valuable both for post-approval pharmacovigilance and as a foundation for clinicians to evaluate future patients with suspected ITP. Rare vaccination events are important, but do not diminish the enormous utility of vaccination and the well-documented safety profile of the Pfizer-BioNTech BNT16B2b2 mRNA vaccine. No follow-up attempts possible. No further information expected.; Sender's Comments: The young adult having extremely low platelet 3 days presented with skin/subcutaneous bleeding following vaccination, a contributory role of the vaccine use therefore cannot be fully excluded in triggering the event onset. Meanwhile, the adult experienced upper respiratory symptoms prior to the vaccination having positive autoimmunological biomarkers positive including Sjogren's Syndrome A antibody elevated, tested positive for plasma IIb/IIIa and Ia/IIa platelet autoantibodies, complement C4 low, a underlying autoimmune condition with pre-existing ITP might not be completely ruled out. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1106640	3/16/2021	WA	78	M	3/3/2021	3/8/2021	During my earlier years working in an industrial area I had inhaled asbestos which caused me to have plural thickening in my lungs. Every year since that diagnosis I have been required to annual Pulmonary (lung and heart) testing. On February 11th I had my 30th annual Pulmonary exam consisting of EKG, Stress Test, and Chest X-ray. As in the past, results were all good. On March 3rd I had my 1st Pfizer vaccination. Five days later on March 8th I collapsed, was taken to the hospital by ambulance having suffered a massive Pulmonary Embolism affecting my heart and right lung. During my 2 hour operation, Surgeons used a flexible suction tube inserted thru my groin to remove a large blood clot (embolectomy). Pieces totaling about 14cm long, 2cm wide and 1/2 cm thick. I was discharged 3 days later and instructed to take blood thinning medication probably for the rest of my life. I am now 78 years old.
1106515	3/16/2021	UT	39	M	2/2/2021	2/21/2021	Severe middle back pain beginning February 21. Initially thought it was a kidney stone, but a visit to a urologist on February 25, determined it wasn't a kidney stone. The urologist ordered some blood work and that indicated that I most likely had blood clots. Went to the ER on the 25th and had further tests that determined that I indeed did have blood clots in my lungs.
1106505	3/16/2021	MI	74	F	2/25/2021	2/27/2021	Ocular stroke. A black curtain dropped down over right eye. Went to ER on the 28th, and was admitted. Had a blood clot in the right eye. Carotid artery right side did not have stenosis, they do not know why she had a stroke. Doctor can't say that it was caused by the vaccine. She now has a permanent blind spot in right eye.
1106428	3/16/2021	FL	68	M	2/18/2021	3/10/2021	Sub-Clavian Vein Blood Clot
1106403	3/16/2021	NV	50	F	2/9/2021	2/11/2021	Blood clots in the left leg, same side as the vaccine was given. Woke up approximately two days afterward (2/11/21) with muscle pain in the left thigh. The pain did not lessen over the week, assumed it was just muscle. The pain migrated down to my calf and then was too painful to stand on or walk on 2/18/21.

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1106331	3/16/2021	SC	70	M	2/4/2021	2/19/2021	developed two blood clots in his right calf; pain in his leg; This is a spontaneous report from a contactable consumer reporting for himself. A 70-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number EN9581/expiration date: not provided), via an unspecified route of administration, on 04Feb2021 (at the age of 70 years old) as a single dose for COVID-19 IMMUNIZATION. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number EL3249/expiration date: not provided), via an unspecified route of administration, on 15Jan2021 (at the age of 70 years old) as a single dose for COVID-19 IMMUNIZATION. Relevant medical history included was not provided. Concomitant medication included acetylsalicylic acid (BABY ASPIRIN), meloxicam, an allergy medication and anti-depressants. On 19Feb2021, the patient reported that he developed two blood clots in his right calf, one towards his ankle and one towards his knee and pain in his leg which required hospitalization on 22Feb2021. The patient was discharged on the same day, 22Feb2021. Relevant lab data included: blood test on 22Feb2021 were done to determine what medication to put him on. The results of the blood test was unknown. Treatment received for the event thrombosis included abixaban (ELIQUIS) tablets as a blood thinner. The patient reported he never had blood clots in his life. The outcome of the events thrombosis and pain in leg was unknown.

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1101152	3/15/2021	TN	72	F	2/2/2021	2/17/2021	<p>Blood clot on right lung; soreness in arm; A spontaneous report was received from a 72 year old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced blood clot on right lung (pulmonary embolism) and myalgia. The patient's medical history was not provided. The patient had family history of blood clot (mother and brother). No concomitant product use was reported. On 02-Feb-2021, the patient received her first of two planned doses of mRNA-1273 (Lot number: 011M20A) intramuscularly for prophylaxis of COVID-19 infection. The patient had soreness in the right arm which subsided couple of days later. The patient also experienced shortness of breath for a week after vaccine administration. On 17-Feb-2021, the patient went to the hospital and underwent COVID-19 virus test, the results of which were negative. On 17-Feb-2021, the computerized tomography scan on chest showed moderate size blood clot on right lung. On 18-Feb-2021, the patient was discharged from the hospital on recommendation to initiate and continue lifetime treatment with Eliquis (apixaban, 5mg every 12 hours). According to the physician, moderate size blood clot on right lung of the patient could be attributed to the genetic history (patient's mother and brother also had blood clot). The patient also followed up with primary care physician, who informed that it was genetic and not related to vaccine. Action taken with mRNA-1273 was not reported. The outcome of the events, pulmonary embolism was unknown. The outcome of the event, myalgia was considered as recovered/resolved.;</p> <p>Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>



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1102512	3/15/2021	TX	34	F	3/9/2021	3/9/2021	I received my first dose Pfizer vaccine on 03-09-2021. I have a history of blood clot, 10 years ago. I am currently 9 weeks pregnant. I called my doctor's office who encouraged me o go to the ER since I was having symptoms of a blood clot. I went to the emergency room at Hospital where they did some blood testing. I then went to Hospital where they did more lab work and blood testing, they did an D-dimer test ad my level was at 3.23 and explained to me it could be due to my pregnancy. They ran some more tests showing I have a clot in the superficial femoral/ popliteal vein. They placed me on Lovanox medication for two days. I will be seeing a maternal fetal doctor tomorrow for further evaluation. They also monitored my baby and baby is doing fine.
1102925	3/15/2021	CA	70	F	1/14/2021	2/25/2021	I started to have tingling sensation to my left leg. I have history of DVT, hemochromatosis, hyperthyroidism but is all managed. The issue is that the tingling sensation I was experiencing was moving in my left leg, was painful but then it went away. I went to the emergency room 02-25-2021 that started with a blood clot and they placed me on Xarelto medication. My PCP encouraged me to go to the ER. they did an U/S of my left lower extremity which showed blood clot. I am already on blood thinner medication and no one can explain or give me an answer as to why I have a blood clot after my vaccine when i am on blood thinner medication.
1102909	3/15/2021	AZ	43	F	2/5/2021	2/24/2021	Starting on February 24, 2021, I started to have shortness of breath. This slowly got worse until on March 2, 2021 I was unable to breathe in all the way and was getting a sharp pain in my side/back when I tried to breathe in more than half way. I then went to the emergency room recognizing the symptom as likely being a pulmonary embolism, as I had experienced one four years earlier. It was, in fact, a PE. I was in the hospital for five days as they treated the clots with blood thinners. I slowly got my breathing more back to normal and was discharged. They are still runnyng myriad tests to try to determine the cause or causes, but I thought it wise to report here in case the vaccine is a factor. I received my second dose on 2/26/21, a few days before I went to the hospital but my symptoms started a few days before that.

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1102813	3/15/2021	MI	79	F	2/11/2021	2/14/2021	Developed an Acute nonocclusive DVT in left leg 10 days after my first vaccine. Decided to decline my second vaccine. I do have a history of having blood clots, but last one was 32 years ago.
1102699	3/15/2021	LA	44	F	1/16/2021	1/19/2021	First Vaccine Dose on 12/26/2020 felt extremely fatigued. After 2nd vaccine dose on 01/16/2021 developed fever, chills, weakness, fatigue, body aches approximately 10 hours after received the 2nd dose. This all lasted about 24 hours. Then on 01/19/2021 which was the 2nd day of mine menstrual cycle, I had a very abnormal menstruation. I was passing "fist" size blood clots which made me very weak. this lasted again about 24 hours then it stopped. I had some labs drawn on 02/27/2021 which came back with very low Iron, Hematocrit and Hemoglobin levels. I usually do show signs of anemia in previous blood work but this time the levels dropped lower so i was referred to see a Hematologist.
1103001	3/15/2021	UT	59	M	2/22/2021	3/9/2021	Development of blood clots in lower right leg causing swelling and pain. Pt. visited doctor who prescribed an ultrasound which revealed the clots. Doctor has now put pt. on blood thinners indefinitely.
1102328	3/15/2021	MA	51	F	3/12/2021	3/12/2021	BLOODY LEFT EYE CHILLS/FEVER BODY ACHE HEADACHE INDUCED MENSURATION WITH HEAVY BLEEDING AND PASSING LARGE BLOOD CLOTS . I TOOK ONLY TYLENOL 1,000 MG TWO 3 TIMES AND FELT BETTER BUT STILL BLEEDING AND HAS RED EYE
1102279	3/15/2021	MD	71	M	3/3/2021	3/6/2021	Diagnosis of a deep vein thrombosis in the left leg.
1102241	3/15/2021	FL	78	F	1/12/2021	2/7/2021	First dose was on 01/12/2021 at 9:30 am. No reaction until Feb.7. 2021, when left leg began to swell, but not seriously. Feb.8, 2021 leg was continuing to swell. went to doctor's office where he prescribed an ultrasound. Was told there was a clot behind my left knee and in some of the smaller veins. I had the chills, joint pains all over, which lasted about the three weeks, but was slightly different every day. When I began the 20 mg dose of Xarelto, every symptom cleared up and I felt great. I am continuing on the 20 mg Xarelto.

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1101157	3/15/2021	OH	78	F	2/10/2021	2/10/2021	<p>blood clot in left forearm; Sore arm; A spontaneous report was received from a consumer concerning a 78, year, old, female patient who developed a blood clot in the left forearm. The patient's medical history included hypertension, high cholesterol and hypothyroidism. On 19-JAN-2021 the patient had two stents placed in her heart. Products known to have been used by the patient, within two weeks prior to the event, included clopidogrel bisulfate (One 5 milligram AM and PM) and apixaban (One 5 milligram AM and PM) and Aspirin. On 10-FEB-2021, approximately six days prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number not provided) intramuscularly in the left arm for prophylaxis of COVID-19 infection. The patient had a sore arm for about a day after the vaccination. Six days later the left arm was red and swollen, inside forearm four inches down below the elbow it was stinging, slightly swollen, just to a soft touch she felt lumps of swelling. The patient went to the emergency room and had blood work and an ultrasound. The emergency room doctor told her that she had a blood clot in the left forearm four inches down below the elbow. The lab test done at the emergency were blood work and ultrasound. Treatment for the event included changing her current medication to one clopidogrel bisulfate 5 milligrams AM and PM and apixaban two tablets of 5 milligrams AM and PM and to discontinue the Aspirin for one week. There was no change planned to the dosing schedule of mRNA-1273 in response to the event(s) and is scheduled to get her second vaccination 10-MAR-2021. The outcome of the events were considered as unknown. Follow up: No follow up information received.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p>

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1103401	3/15/2021	PA	33	F	3/8/2021	3/10/2021	I received my second Moderna vaccine on 3/8/21. On 3/10/21 I started spotting (bleeding: a menstrual period). This was 12 days ahead of my normal cycle. Today, 3/15/21 I am still experiencing mensuration bleeding. The blood is mostly brown, but also red, and has small clots. It comes and goes throughout the day unlike my normal period.
1100924	3/15/2021	NC	63	F	1/22/2021	2/8/2021	DVT blood clot in left calf verified via ultrasound on 2/17/2021. Symptoms: pain in left calf and foot proceeded by chills/fever and right fingers/hand inflammation. Symptoms began 2/08/2021.
1100271	3/15/2021	WI	82	F	2/8/2021	2/10/2021	Lost control of muscles; ended up blacking out; could not move; could not talk; A spontaneous report was received from a Consumer concerning about a 82 years old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced Paralysis, Syncope, Mobility decreased and Aphasia. The patient's medical history was provided as diabetes, dementia as current illness. Relevant concomitant medication was reported as blood thinner for blood clots. On 08 FEB 2021, prior to the onset of event, the patient received their first dose of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 10 FEB 2021, the patient experienced Paralysis, Syncope, Mobility decreased and Aphasia. Due to these events patient's required hospitalization and on oxygen. Laboratory details was not provided. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was unknown. The outcome of the event's Paralysis, Syncope, Mobility decreased, and Aphasia was as unknown.; Reporter's Comments: The events were consistent with increased risk of cerebrovascular complications associated with elderly age of patient. Company assessed the events to be unlikely related to company product.

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1100197	3/15/2021		78	M	2/24/2021		<p>On Eliquis and on and off had bloody urine; This is a spontaneous report from a contactable consumer, based on information received by Pfizer from Bristol-Myers Squibb (manufacturer control number US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-020443), license party for apixaban (ELIQUIS). This spontaneous case was reported by a patient family member or friend and describes the occurrence of haematuria (On Eliquis and on and off had bloody urine) in 78-year-old male patient who received apixaban (Eliquis) for Cerebrovascular accident prophylaxis. Co-Suspect Products included Covid-19 Vaccine for COVID-19 immunization. The patient's past medical history included Prostate cancer (about 10 years ago), Radiation therapy and Capillary fragility. On an unknown date, the patient started Eliquis (unknown route). On 24-Feb-2021, the patient started Covid-19 Vaccine (unknown route). On an unknown date, the patient experienced haematuria (On Eliquis and on and off had bloody urine). The action taken with Eliquis (Unknown) was unknown. At the time of the report, haematuria resolved. Event reoccurred on 24-Feb-2021 For Eliquis (Unknown), the reporter did not provide any causality assessments. The reporter stated that the patient got the Covid vaccine the previous day, he had a history of prostate cancer from about 10 years ago and was treated by radiation, the radiation had caused capillaries in the penis to be fragile and so sometimes when he urinate, he urinate blood or little blood clots, neurologist was aware of it, cardiologist was aware of it but they did not treat it, they just waited for it to resolve itself. He was also on Eliquis for a Atrial fib so the previous day when we came home after he got the vaccine, he was bleeding with the clots and with the bloody urine which he had done in the past. He had a blood urine one hour post vaccination. She was shocked. It would take at least a few hours for the medication to get in the system before having any kind of reaction. It resolved on it's own he did not have a blood urine anymore. The second dose of the vaccine was due on 16-Mar-2021.</p>

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1101995	3/15/2021	OR	64	F	1/13/2021	1/13/2021	A few hours after shot I felt achy and had joint pain. The following day in the morning I had a nosebleed which is unusual for me. I had had a blood clot and anemia six months prior to vaccine. I had two episodes of diarrhea. I had the second dose of vaccine and had no symptoms.
1103410	3/15/2021	CA	72	F	3/9/2021	3/9/2021	Developed a DVT blood clot in right leg calf area -after the shot-
1103572	3/15/2021	UT	62	M	12/29/2020	12/30/2020	Chills, blood clot R DVT, Dizzy, balance difficulty, itchy upper torso, sleeplessness
1103171	3/15/2021	MA	78	F	2/3/2021	2/7/2021	Pain in left leg - outside 2/7/21 went to clinic 2/8/21 Given an ultrasound Diagnosis: Blood Clot (Dvt) Given immediate shot in belly And prescription for Eliquis Followed up with Dr. (internist) 2/11/21
1103049	3/15/2021	NV	79	F	2/18/2021	2/18/2021	On my right leg down close to the ankle I have a swelling that is showing bruising and a lump that is painful. I am not sure if it is a clot or not. I have not been to Urgent care . I informed people giving me vaccine I was on blood thinners. Nobody seem to show concern about that. I have already received 2nd shot, which I got very sick after, but symptoms seem to happen to others. My concern is the lump on my leg if it is a clot and concern if I will get more now that I took the 2nd vaccine.
1098030	3/14/2021	VA	44	F	2/27/2021	3/9/2021	Woke up with sore upper right thigh Tuesday March 9. Very tender to the touch. Visited Dr. Wednesday March 10, ordered ultrasound which was completed on Thursday March 11 and diagnosed a superficial blood clot. Prescribed Xarelto 10mg.
1098455	3/14/2021	FL	28	F	3/11/2021	3/13/2021	vein thrombosis
1098715	3/14/2021	NY	66	M	2/13/2021	2/26/2021	My 1st Covid-19 vax was on Saturday 02/13/2021. On Friday 02/26/2021 I had pain in my right ankle and foot and thought it was possibly just another bruise. Saturday evening 02/26/2021 I realised it was a blood vessel popping out. On Tuesday 03/02/2021 I had an ultrasound and it was diagnosed as a "superficial thrombosis". It goes from the inside of my right foot to the top of the foot. Then it can be seen on the inside of my ankle, skip a spot, and is again visible on the inside of my calf. It ends mid-calf on my right leg.

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1098953	3/14/2021	FL	79	M	1/11/2021	1/19/2021	<p>KEY POINTS Had the first dose of the Moderna vaccine on Mon. Jan 11. Symptoms started Tuesday, January 19, 2021 1st hospitalization, January 27, 2021 o Discharged, January 29, 2021 o Diagnosis: High leukocytes, inflammation. Diagnosis, acute pancreatitis. 2nd hospitalization, February 2, 2021. o Discharged February 4, 2021. o Diagnosis: Diagnosis, Deep vein thrombosis (DVT) of popliteal vein and pneumonia Details in notes section. NOTE This is an updated and correctly filed version of a form that I attempted to email to the regulatory authority. No evidence that it went through. Use this version if you have the earlier version. DETAILED DESCRIPTION OF EVENTS AFTER VACCINATION PROGRESSION OF SYMPTOMS TUES. JAN 19: At night, felt like hunger pangs – but not really relieved by eating. In the morning tried 2 Tums. Had temporary relief for about an hour. Had symptoms for the last three days. Chronic, varied between almost negligible to mildly annoying. Bowel habits usually very regular. WED. JAN 20. Had major bowel movements in the middle of the night THUR. JAN 21. Had major bowel movements in the middle of the night FRI. JAN 22. Extremely mild feelings of bloatedness over the last couple of weeks (0.5 on 1 to 10). A slight loss of appetite, but did not interfere with eating. Sometimes slightly nauseous. (0.5 on 1 to 10) SAT. JAN 23. Extremely mild feelings of bloatedness over the last couple of weeks (0.5 on 1 to 10). A slight loss of appetite, but did not interfere with eating. Sometimes slightly nauseous. (0.5 on 1 to 10) SUN. JAN 24. Extremely mild feelings of bloatedness over the last couple of weeks (0.5 on 1 to 10). A slight loss of appetite, but did not interfere with eating. Sometimes slightly nauseous. (0.5 on 1 to 10) MON JAN 25. Extremely mild feelings of bloatedness over the last couple of weeks (0.5 on 1 to 10). A slight loss of appetite, but did not interfere with eating. Sometimes slightly nauseous. (0.5 on 1 to 10) TUES. JAN 26. Problems persisted and got worse. On Jan 26, Daughter GP suggested getting blood analysis to test for inflammation. WEDS, JAN. 27. Hospitalized. Findings: High leukocytes, inflammation. Diagnosis, acute pancreatitis. THURS. FRI. JAN 28. Hospitalized. FRI. Jan 29. Discharged. Wt 193 lbs! Usual, ~176-183. MONDAY FEB 2. Readmitted to hospital. Felt</p>

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1099190	3/14/2021	OR	44	F	3/9/2021	3/9/2021	<p>feverish, easy fatigue, bilateral stiffening of the calves, some edema. Diagnosis, DVT of popliteal vein and pneumonia. Given an iv bolus of a broad spectrum antibiotic. Started on Eliquis two 5mg pills twice a day for one week and the one tablet am and one pm. Given Lasix bolus and then started on 5 mg Lasix/day. Swallowing tests more or less OK WEDNESDAY FEB. 4. Discharged. MONDAY, MARCH 8, Check up with GP, Blood pressure 127/76. Lasix discontinued. THURSDAY, MARCH 11, Check up with GI doctor, Blood pressure consistently 150/90. Sent to adjacent cardiologist's office (next door). High BP reading confirmed and reconfirmed the next day. Dose of Metoprolol succinate increased to 5 mg 2xday. Note 1: Still have the DVT. Note 2: Received 2nd dose of Moderna vaccine on Feb 11. Note 3. All medical records available either through hospital, GP or by contacting me. Note 4: This is not a crank report. I have had 50 years teaching and doing funded research in 3 medical schools rising to the rank of full Professor in each.</p> <p>After waiting my 15 min, and left the facility about 10 min later my left side of face tingled. Then about 1 hour after getting the shot I had a horrible leg crap in left leg to the point it was hard to walk. Went to ER and ruled out blood clot and I also developed sores in my mouth. That night I started feeling warm sensation down both arms and tingling in both hands and this had been going on each day throughout the day where I have a warm sensation down my arms and through my upper chest and is not going away, today 3/14/21 I went to urgent care again as now left side has swelling in my lymph nodes in my chest and I still have the tingling in my face and my head does not feel right. Urgent care did a neurological base test and I seem fine in that department but told me to report the warming sensation as it's not my skin but I feel it inside.</p>



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1096852	3/13/2021	TN	72	M	3/3/2021	3/4/2021	About 27-28 hours after injection felt strong pain in left lung area. Got progressively worse, especially at night when lying in horizontal position. The pain became extreme, could hardly breathe (inhalation causing extreme pain) and couldn't really walk on morning of March 6 (about 66 hours after vaccination. Called General Practitioner and he said to go to Emergency Rm. A catscan showed a small blood clot in each lung. Given blood thinner injection. Subsequent Ultrasound of legs showed no clots there. Released 48 hours later, put on Eliquis -- 5mg -- two each time, twice a day for 6 days, then one each time twice a day. for 3 months.
1097794	3/13/2021	FL	52	F	3/7/2021	3/7/2021	15 min. after shot, my neck became warm and flushed, slightly red. By 30-40 minutes after shot, my face was also flushed and the inside of my mouth (mostly roof of my mouth) and lips were itchy/tingly. Then, I took 2 Zyrtec 10 mg. as instructed by my allergist if I had a reaction. Within an hour, the flushing and itchiness were gone. 2 days later - had strange pain, swelling, and warmth in upper left shin below knee. Worried about possible blood clot, I took 2 baby aspirin. Pain and swelling went away. Not sure if related to vaccine but unaware of anything else that could have been different.
1097807	3/13/2021	OR	41	M	2/7/2021	2/27/2021	2/27/21 Sudden cardiac arrest due to thrombosis in the LAD
1097745	3/13/2021	NY	30	F	3/1/2021	3/10/2021	I had a migraine for three days starting on wed and burning tingling and numbness in my hands feet back of my calf also, my veins in my wrist hurt and felt tight and by Friday night my face was starting to get numb. I also have a bad sore throat. I went to the hospital they ruled out blood clot and stroke. My Covid test was negative.
1096940	3/13/2021	CO	75	M	2/27/2021	3/10/2021	lost total vision in left eye, took about 2 seconds from onset. Recovered within 30 minutes. Suspect small clot. No other symptoms. No detectable lasting vision impact.
1096774	3/13/2021	TX	69	F	3/13/2021	3/13/2021	superficial blood clots in left leg.

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1096672	3/13/2021	FL	46	F	1/11/2021	1/11/2021	About 16 hours later I had a heart attack, 20% plaque and the rest was a blood clot that acute my artery. I was in the Hospital for two days. I ended up having angioplasty and a stent. When I went home I had post heart attack issues and a sore arm for about 3 weeks.
1097013	3/13/2021	NC	66	F	2/26/2021	3/8/2021	Saddle blood clot in lung. Place in ICU for 1 day. Then regular room. Heparin drip to Apixaban. No activity. All medical tests indicated no cause of blood clot. Vitals great. Past out twice and threw up night it started
1094591	3/12/2021	CT	64	F	3/5/2021	3/7/2021	Woke at 32hrs with severe pain in Rt hip joint and Rt knee joint. later in day rt leg was numb, unable to bear weight, go up stairs without assist or sleep. Next day #3, severe pain in Rt hip, Rt knee and femur. Not responding to Motrin 800mg Q6-8hrs, Tylenol 1gm Q6-8 hours. Day #4 pain now radiating down rt leg through both joints and into Rt calf. Now Monday- called PCP, advised symptoms and would be starting perocets for 2 days of severe pain post vaccine. Also took ASA 325mg for blood clot risk know with virus even through pain was hip to ankle now (not ascending but descending) Percocet Q6hours without improvement but could sit and sleep with pain (dulled brain response to pain). Day #5- leg completely numb, pain now following sciatic nerve, stopped meds as no improvement and developed headaches, stomach aches and constipation from meds. Day#6 Pain severe in am, from hip to ankle- leg and heel of Rt foot numb. Today #7 pain on awaking, Rt hip all along sciatic nerve to foot which remains numb in heel.
1095915	3/12/2021	NY	27	F	2/14/2021	2/22/2021	I got a blood clot in my left leg, as well as numerous blood clots in both my lungs. I have never had a blood clot before, and my family does not have a history of them.

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1095766	3/12/2021	IL	66	F	2/28/2021	3/5/2021	My mother felt pain increasing in her back. On Saturday the 6th she went to her clinic Dr. He gave her a ex-ray. He saw a mass and told her to ho to the hospital for more test. She went to hospital where they per f order a CT scan and many other test and found a blood clot on her lungs. She was advised to be admitted immediately. She was there getting many test taking blood thinners to shrink the clot. Monday after all her test came back the doctors could not find a source of the clot. She was sent home with blood thinner prescriptions and follow up appointments.
1095030	3/12/2021	MA	54	M	2/11/2021	3/8/2021	After 1st injection (1/11/21) experienced severe shortness of breath with minimal activity with accelerated heart rate and drop in O2 stat. within 2 days of injection then developed wheezing cough. Primary MD prescribed Augmentin nd prednisone with eventual success. With normal blood work, chest x-ray and negative Covid test all done by 1/15. On 3/9/21 (28) days after second dose (2/11/21) experienced burning and swelling on right leg. Went to Hospital, ER and found extensive blood clots in right leg and saddle pulmonary embolism . Also had 50% Platelet blood count decrease since the 1/15 bloodwork Admitted for 3 nights on heparin dip. Discharge on home Lovenox injections for 30days.
1094645	3/12/2021	OH	70	F	3/4/2021	3/11/2021	Patient is a 70 year old female that is post-menopausal. Her first Moderna vaccine dose was given on 2/4/21. Exactly one week later on 2/9/21, the patient had vaginal bleeding that lasted one day. There were small clots in the blood that was discharged. The patient went to the doctor where a urinalysis was performed. The patient had a positive urinalysis and was started on antibiotics. The patient's second dose was on 3/4/21. Exactly one week later on 3/11/21, the patient had vaginal bleeding that lasted a day. Patient usually takes aspirin 81mg daily, however she stopped this medication prior to both doses being administered. She restarted the aspirin after each Moderna dose.

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1093498	3/12/2021	RI	68	M	3/2/2021	3/9/2021	Site: Swelling at Injection Site-Severe, Systemic: DVT-Severe, Additional Details: Patient presented to office with swelling of right upper extremity occurring after first COVID 19 vaccine dose. Was sent for duplex study which revealed acute deep vein thrombosis in right subclavian and axillary veins and superficial thrombophlebitis of basilic vein in right arm. Pharmacy was contacted 3/10/2021 by MD at hospital to report vaccine adverse event
1093491	3/12/2021	MO	83	F	3/2/2021	3/2/2021	Blood clot, swelling noticed a few hours after vaccine. Probably coincidence but felt it should be reported. Im not sure if the doctor she saw for blood clot knew she got the vaccine. It was a different clinic.
1093361	3/11/2021	CA	45	M	1/12/2021	1/13/2021	Acute right index finger digital ischemia after initial complete numbness from PIP joint distally absent any previous symptoms ever. Recurrence Jan 20 of same symptoms. Suspect antibody complex clot blocking terminal branches of digital arteries.
1090733	3/11/2021	CO	65	M	3/4/2021	3/9/2021	The patient is a very pleasant 65 year old gentleman with a history of hypertension who presents to the hospital reporting a fever, cough, and chest pain starting two weeks ago. He states that he has had flu-like symptoms for the previous two weeks with a prominent nighttime fever and sweats. He states that he had a similar episode approximately one year ago. He reports that since Saturday he became short of breath. He states that when he goes and feeds the horses and walks back he is short of breath and needs to rest. He denies any myalgias, nausea, vomiting, diarrhea, or abdominal pain. He reports that he has chest heaviness. In the emergency department he was diagnosed with pulmonary emboli with large clot burden. He states that he has never had a blood clot. He has no family history of cancer, deep venous thrombosis, or pulmonary embolus. He denies any melena or hematochezia. He states he has not had a colonoscopy. He reports that over the past two weeks he has not been moving around much, saying that he has been largely confined to his chair due to his illness

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1090965	3/11/2021	CO	80	F	2/26/2021	3/9/2021	Patient is a very pleasant 80 year old female with a history of hypertension and recent pelvic fracture approximately two months ago who presented to the emergency department reporting right sided chest pain. She states that her symptoms started on Sunday. She has pain with a deep breath and also with exhaling. She reports it is a sharp pain. She states that she has had no lower extremity edema or calf pain, however, she did have a shooting pain down her right leg recently. She denies any history of personal or family history of deep venous thrombosis or pulmonary embolus. She reports that she has not had any hemoptysis. She denies feeling short of breath. She denies abdominal pain, nausea, vomiting, or diarrhea. She states that she has not had any COVID exposures or known symptoms. She has received two COVID vaccine doses. She reports that she has not been sick and denies fever, chills, or cough. In the emergency department she was diagnosed with an acute pulmonary emboli in the right main pulmonary artery with extension into the segmental pulmonary arteries. There is concern for early pulmonary infarct. This has prompted admission to the hospital.
1091169	3/11/2021	TX	67	F	2/8/2021	2/18/2021	ACUTE STEMI HEART ATTACK - VENTRICULAR FIBRILLATION - 99.9% BLOOD CLOT IN RIGHT CORONARY ARTERY
1091908	3/11/2021	IL	83	M	1/27/2021	2/12/2021	DVT blood clot in the right foot, then spread to lower leg and knee and thigh, groin
1091986	3/11/2021	NV	29	F	1/9/2021	1/11/2021	I had just finished my cycle the day before. I woke up Mon morning to thick, clotted blood. I contacted my provider and I was instructed to take a pregnancy test, which was positive. I went in for an exam on the 12th and they confirmed that I was indeed pregnant. They tested my Beta Hcg twice. I didn't get my results immediately due to one site being closed due to COVID. I could've gone to the hospital and received the results immediately, but my doctor didn't want to take the chance due to the hospital having a lot of COVID. They confirmed that I was pregnant on the 19th or 20th. I bled for a few days after that. The final Beta Hcg was done and my level was 0.

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1092316	3/11/2021	VA	66	F	2/26/2021	2/27/2021	Received report that client was admitted to the hospital on Feb 27th with persistent tachycardia. Called client on March 11 to inquire. Client shared that she has felt weak since having COVID-19 in September 2020 and was hospitalized for 3 months. She shared she has felt weak since having COVID-19. She shared that on the morning after receiving the vaccine she was getting out of her bed, which is on the floor, and she hit her head. She shared that her daughter was concerned and took her to the emergency department (ED). While there in the ED her blood work ?wasn?t right? and they thought she might have a small blood clot in her lung and she was admitted. While in the hospital she received eliquis which she had a reaction to. She shared she was in the hospital for 1 day. Recommended she see her PCP for these health concerns as well as before receiving the 2nd dose of a COVID-19/Moderna vaccine.
1092438	3/11/2021	PA	45	M	3/1/2021	3/10/2021	Spontaneous Pain in inside left foot just above heel, pain radiates all over back of foot when standing or walking. Feels like blood clot / ruptured blood vessel. Not sure if this is attributable to vaccine
1092477	3/11/2021	FL	83	F	2/17/2021	3/7/2021	Pericardial effusion; multiple blood clots in portal vein.
1092490	3/11/2021	MO	99	F	2/9/2021	2/10/2021	Patient became lethargic, extremely tired, unable to care well for self. Patient had no appetite, refused most food and spent many hours simply sitting in her chair. She felt that she was having a heart attack and called 911 using her emergency response button on 2/21/2021. Doctors indicated that the patient's life was in serious danger, but because of age they were hesitant to try to remove the clot pressing on her heart. She was only allowed to go back home because we utilized Hospice. When asked about her life expectancy, we were told she could die any minute or might live a few more months, but that she was not expected to live much longer. SHE WAS IN GOOD HEALTH PRIOR TO THE IMMUNIZATION!

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1092507	3/11/2021	MA	51	F	3/11/2021	3/11/2021	Vax Clinic note: Approximately 10 minutes after receiving J&J vaccine c/o lips tingling and tongue feeling thick. Medicated with 10 MG cetirizine. VS o2Sat 97%, Pulse 84, BP 146/74. Pt states has had allergic reactions to IV contrast that involved tongue swelling. staets this feels similar but not as bad. o2Sat continues at 97%, Pulse 58, BP 128/68, pt trying to relax, c/o slight headache. Swellig has spread to her lips, and cheeks feeling heavy, O2Sat 97%, Pulse 75, medicated with 50mg benadryl. 911 called to transfer pt to ED for further eval. States throat is feeling tighter. And unable to swallow Epi given 11:18, daughter aware and will meet her at ED. BP 148/82, PULse 75, O2Stat 97% swelling in tongue decreasing, throat n o longer tight, tongue still feels thick, has some hives between her eyes, and forehead. Pt transported via EMS to ED Intake ED note: 51 y.o. F here after getting J&J vaccine and 10 min. After she c/o her tongue feeling thick and lips tingling Pt given zertec Then 15 min later pt felt lips swelling and had hives around eyes and forehead Pt c/o difficulty swallowing and was rx'd with epi pen Pt has no stridor, or resp issues on arrival, able to speak in full sentences. Pt denies COVID sx 2nd ED note: Pt arrived to ED via EMS from community health center S/P Covid vaccination. About 15 minutes after receiving vaccine - felt nausea and smelled "medicine" followed with upper lip swelling and numbness to tongue associated with difficulty swallowing and redness to forehead. Pt alert and oriented at this time. Speaking in full sentence, drinking bottled water without any difficulty. No drooling noted. Denies SOB, chills or fever. Emergency Department Attending Attestation Note See resident/PA/student note for further details of HPI, history, exam, ED course, and diagnoses. Briefly, this is a 51 y.o. female with PMH reviewed in chart and w/ patient notable for insulin dependent diabetes, depression, prothrombin mutation, migraine, p/w concern for allergic reaction. Emesis or change in Covid vaccine today. 10 minutes after receiving the vaccine, patient reports feeling thick in her tongue with tingling in her lips. Patient was given Zertec. The minutes later, her lips began to swell up and was also noted to have new erythematous rash between her eyes and forehead. Patient was given 50 mg of Benadryl. Patient felt like she could not swallow with worsening lip swelling. She was given EpiPen and 911

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was called. No stridors. No wheezing. Reports continued tingling and the numbness in her mouth but no lip swelling or tongue swelling. Denies any difficulty swallowing at this time. No wheezing. No abdominal pain or nausea. No rash at this time. Of note, patient also notes left-sided facial, arm, and leg numbness starting about 10 minutes prior to arrival to the emergency department. She reports that she has had recurrent numbness on the left side in the past, which was thought to be due to migraine versus TIA. She has had extensive work-up and multiple hospitalization for this symptom. She reports that she is allergic to iodine and gadolinium containing contrast. Denies any headache at this time though she had a mild headache after receiving the vaccine. Denies any blurry vision. Denies any weakness in her bilateral upper and lower extremities. Assessment and Plan: Vital signs notable for O2 sat of 96 to 98% on room air without tachypnea. Patient is mildly hypertensive. Patient is well-appearing speaking full sentences without any dysarthria. Pupils are equal and reactive to light. Extraocular movement intact. She notes diminished sensation to her left face, left upper extremity, and left lower extremity. Tongue is midline. Hearing is intact bilaterally. No facial droop. She has 5 out of 5 strength in bilateral upper and lower extremities. No pronator drift. Normal gait. No tongue swelling or lip swelling. No stridors. No uvula swelling. No pharyngeal or erythema. Lungs are clear to auscultation bilaterally without wheezing or rhonchi. Cardiac exam without murmurs rubs or gallops. Regular rhythm. No abdominal distention or tenderness on palpation. No CVA tenderness. 51-year-old female who is presenting to the emergency department with improving lip swelling and numbness in her mouth, raising a concern for anaphylaxis related to her Covid vaccine. Reassuringly, status post EpiPen, her symptoms are improving. However, she has new onset left-sided numbness, with without any headache. She reports that she has had this numbness in the past the last time she had the numbness on the left side was approximately 10 years ago. Her neurologic exam is only notable for diffuse numbness on her left side including her face. Differential diagnosis include migraine headache and TIA. Stroke is possible though less likely given the patient has had the same symptoms in the past



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1092549	3/11/2021	CA	72	F	2/17/2021	2/19/2021	with negative work-up. Will defer code stroke at this time but will emergently consult neurology. Will get labs including BMP and CBC. We will continue to monitor her from the anaphylaxis perspective. We will also give her a dose of steroid. Prednisone 60 mg by mouth given 12:29 PM NEUROLOGY CONSULT NOTE Assessment: Formulation- Diagnosis is guarded. Localization structurally would suggest subcortical (thalamic) or small brain-stem in a sensory territory on the right. Etiologies could be stroke given her vascular risk factors but seems unlikely given there is stereotypy of earlier symptomatology. Demyelinating would be another possibility as well, but again, the stereotype. Seizure unlikely because of the timing of rush from toes to body was minutes and duration of some occasions being days. Complicated migraine possible, has some risk factors, but should be treated as dx of exclusion. She does make complaint of headache, which could support. Some FND elaboration on her anxiety-ridden allergic reaction is also possible, but no objective non-structural signs to support.
							blood clots dx'd via ultrasound on 2-20-21

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1090240	3/11/2021	NY	71	M	2/10/2021	2/1/2021	Cardiac arrest; Pulmonary embolus; Renal failure; Fever; Dehydration; Not eating or drinking; COVID-19 confirmed by positive COVID-19 test / COVID pneumonia; blood clot; blood pressure was low; Respiratory arrest; Respiratory failure; Hypoxemia; ventricular tachycardia; This is a spontaneous report from a contactable nurse reporting on behalf of the husband. A 71-year-old male patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EL9264) on 10Feb2021 at about 19:00 (at the age of 71 years), in left deltoid, for COVID-19 immunisation. No other vaccines were given on the same day or within 4 weeks. The patient declined flu vaccine and pneumococcal vaccine (PNEUMOVAX), he had never had another vaccine except maybe his childhood vaccines. Medical history included rotator cuff surgery and cataract removed in 2020. The patient exercised regularly, he was healthy, he walked for miles and didn't eat any non-sense, he did not eat out, he did not smoke. The patient's mother was 100 years old and fully competent. The patient had two sisters older than him, the oldest one had hypertension the second sister did not have anything that they were aware of. The patient's father lived until he was 98 years old. The patient concomitant medications were none. The patient was told to take vitamin D 50,000 units but didn't even take them (he still had 9 of them in the bottle and they gave him 13). The patient experienced fever on 11Feb2021, renal failure on 14Feb2021, pulmonary embolus on 28Feb2021, cardiac arrest on 04Mar2021, dehydration and not eating or drinking on an unspecified date in Feb2021. These events required ER visit and were reported as serious as involved hospitalization from 14Feb2021 to 04Mar2021 and as fatal events. The patient died on 04Mar2021. Clinical course of the events included the following information. The patient received the first vaccine on 10Feb2021, the next day he developed a fever. The reporter spoke with the patient's doctor who told to give the patient paracetamol (TYLENOL) thinking the fever was from the vaccine. On 12Feb2021 and 13Feb2021, the patient's temperature was 102. Then the doctor advised to take the patient to the hospital. The patient's temperature was still 102, he was in renal failure, and they had to dialyze him. The patient was otherwise healthy, the patient's last physical was in Dec2020 and the only thing it showed

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was that his A1C was 5.7. The patient had no cholesterol or hypertension. The doctor advised the patient to decrease sugar and carbs because the holidays were coming up. The patient's follow up was scheduled on Mar2021. The reporter felt that the vaccine has something to do with the patient renal failure. The reporter spoke with the doctors at the hospital who didn't want to commit to anything. The reporter believed this was an adverse event. The caller mentioned that she had her vaccine before and she was fine. The patient was admitted on 14Feb2021 and by Wednesday he was not eating or drinking, he was dehydrated. The patient's admitting diagnoses was elevated temperature and ruling out COVID. The patient tested positive for Covid on 14Feb2021 (COVID-19 PCR test). The patient's temperature was 99.8 and then kept creeping up, on Saturday it was 102. The caller gave the patient Tylenol cold and flu (lot T0CL001021, expiry date Oct2021) took the edge off but in three hours the temperature was back up again. The patient never complained of pain and didn't want to take Tylenol. On 15Feb2021 the patient's numbers were getting better after the fluid challenge and then his numbers kept creeping up after that. The patient had the fever a week until they had it under control. The fever went away, it was gone for like 5 days, then it spiked again. The patient was started on piperacillin/tazobactam (ZOSYN) for like 3 or 5 days and the fever went away but then it kept getting worse. On 28Feb2021, the medical personnel thought the patient had a pulmonary emboli but because of the renal failure, they couldn't do a computerized tomography on the patient. The doctors mentioned that the patient was in renal failure and they thought they heparinized the patient and he had a blood clot who led to pulmonary embolus, cardiac arrest, and death. The patient was diagnosed with a pulmonary emboli on 28Feb2021. The patient started de-saturating and the doctors intubated and sedated him that whole time until this. Dialysis was started on 01Mar2021 and the patient received it every day except 04Mar2021. The patient's blood pressure was normal, it hardly ever went above 120. The patient was on the medical floor from 22Feb2021 to 04Mar2021. When the patient was on the medical surgical floor, he was on high flow 5 liters. After the patient started desaturating, he went to the intensive care unit and was

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put on a non-rebreather on 45%. The patient's highest heart rate was after intubation was 135, but the patient's blood pressure was low so they started him on some vasopressors. They did the fluid challenge on the patient and his labs were a little better than the labs kept creeping up until the doctor inserted a shiley catheter for dialysis. Respiratory: Respiratory arrest and then cardiac arrest. Respiratory failure, they intubated the patient. The reporter assumed dyspnea because the patient was intubated. Tachypnea was when the patient was in the intensive care unit already intubated. Hypoxemia, they intubated the patient so the caller guessed it was for the oxygen saturation drop. Covid pneumonia: yes. Chest x-ray showed mild pneumonia. The caller requested a follow up x-ray and the doctors said they were going to do another one but the caller is unsure if they did or when. The patient received additional therapies for COVID-19: remdesivir. Other radiological investigations: unable because of the patient's kidney function. They were looking at the D dimer and BMP to come up with the embolus since the patient couldn't have the scan. ARDS: no. Cardiovascular: The patient had a heart attack on 04Mar2021. The reporter thought it was from the pulmonary embolus which led to cardiac arrest. Arrhythmia: the caller guessed so, the patient was being worked on for 10 minutes before the caller got there. The caller saw a rhythm strip which showed a flat line and then she noticed ventricular tachycardia, then a flat line. The patient did not have SARS-CoV2 antibodies at diagnosis. Gastrointestinal/Hepatic, neurological, hematological, dermatological: none. Vascular: pulmonary embolus: yes, deep vein thrombosis, limb ischemia, vasculitis: no. Renal: renal failure: yes, acute kidney injury: no. The patient was scheduled for his second vaccine dose on 03Mar2021 at 04:15 but did not receive it. Time of death was 4:15 in the afternoon on 04Mar2021. The reporter considered renal failure, fever, dehydration, not eating or drinking, cardiac arrest and pulmonary embolus as fatal and related to the suspect vaccine. The outcome of the other events was unknown. Cause of death was unknown. No autopsy was performed.; Sender's Comments: Based on current information available, the company considered there is a possibility that all reported events are consequence of COVID-19 pneumonia on the basis of advanced age.

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							The positive COVID-19 test occurred 4 days after the first injection of suspect vaccine BNT162B2. No complete effect can be achieved for short time interval. The COVID-19 is more likely pre-existing colonization or intercurrent condition, unrelated to suspect vaccine BNT162b2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Renal failure; Fever; Dehydration; Not eating or drinking; Cardiac arrest; Pulmonary embolus
1092762	3/11/2021	AL	48	F	3/1/2021	3/8/2021	I experienced a runny nose with mucus, blood running from nose with blood clots four to five times a day from March 8th 2021 up to March 10th 2021. It is unknown rather I have blood clots within my body.

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1090229	3/11/2021	MI	63	F	2/1/2021	2/1/2021	pulmonary embolism/Blood clots in the lung; heart attack; Shortness of breath; headache; jaw hurt; Shin hurt; heart burn; This is a spontaneous report from a contactable consumer (patient's son). A 63-year-old female patient (mom) received the second dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine), via an unspecified route of administration in arm in Feb2021 (reported as in the first week of Feb2021) at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient previously received the first dose of BNT162B2 in Jan2021 for COVID-19 immunization. Reporter (patient's son) received his first dose of Pfizer COVID vaccine on Wednesday and wanted to know if this vaccine could cause blood clot. He stated his mom (patient) in the hospital due to pulmonary embolism from 24Feb2021, 2.5 weeks after her second shot. He stated his anxiety levels were higher than normal. He had strong response to flu vaccine this year and experienced chill, shakes, fever, received antibiotic, and loss sense of taste from the flu vaccine. Reporter read online that some people commented that they have DVTs (deep vein thrombosis) and blood clots from the Pfizer COVID vaccine. Patient experienced blood clots in the lung in Feb2021 and hospitalized on 24Feb2021. Patient got her second shot about 2 weeks before and she ended up in the hospital with pulmonary embolism. They looked at her lungs and found all the blood clots. Patient had really bad shortness of breath, headache, her jaw hurt, and her shin hurt. She was helping out at vaccine clinic and she was out of breath, she said the old people in strollers were passing her. Patient began to make complaints about how she was feeling in mid of Feb2021. Patient said in rare cases 2 weeks after the second dose reactions could happen. Patient got done working in ICU, and helped with PPE, then at 11 she left work at the hospital, she was experiencing heart burn for 3 days and so she thought had a heart attack drove to an ER (emergency room) on the way home, and then was admitted to the hospital on that same day 24Feb2021, she was supposed to be discharged today (26Feb2021). Patient had been feeling out of breath for past 2 month, it was possible it might seem like it was related to the vaccine but it could also not be related. Reporter stated that on the internet he saw how a 1000 deaths happened after the vaccine, it

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was all old people, but in the autopsies there was no link to the vaccine, they were going to die regardless. Lab data included: She did get a test before for Factor 5 Leiden but it was negative. They did test for COVID, it was negative, while in the hospital. In the hospital they were also testing her again for the Factor 5 Leiden, the results hadn't come back yet. They did test for blood clots, they did an MRI (magnetic resonance imaging) in Feb2021, it was positive for blood clots (blood clots in the lungs). When she was admitted her oxygen was 85%. Outcome of the events was unknown. Information on lot and batch number has been requested.

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1090223	3/11/2021		70	F			<p>SV for unstable angina; CAD; Tachycardia; Nausea; Belching; SOB; Chest heaviness, chest pressure, chest tightness; Pain; This is a spontaneous report from a non-contactable other HCP. A 70-year-old female patient received the first dose of bnt162b2 (lot number EN6205) via unspecified route of administration on unspecified date at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications was not provided. Upon 15 minutes after injection, she noted nausea with belching and had some SOB. Symptoms worsened as she ambulated over to the medical bay along with her chest pressure. She denied rash, hives, welts, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. Patient reported recently admitted for unstable angina and CAD with tachycardia. Patient had elevated d-dimer and blood clot was ruled out. Patient discontinued on new medication, beta blocker. Since discharge this Sunday 21Feb2021, she reported chest heaviness as if she has "cardboard on chest." Can slightly increase with going up and down stairs or increased activity. She states she had reached out to her cardiologist via an online site but has not heard back. Patient stated her pain is about the same today. Patient complains of chest tightness and shortness of breath. The outcome of events was unknown. No Follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on temporal association, the contribution of the suspect drug to the onset of events unstable angina and tachycardia cannot be excluded. The patient's age and suspected cardiac condition are risk factors. The event CAD, given its progressive nature, is most likely an underlying condition, thus unrelated to the suspect drug. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.</p>



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1092640	3/11/2021	CT	38	F	1/21/2021	1/25/2021	atrial flutter pain in right arm , pain kept going up arm but only if you touched it, got on xartorl ( blood thinner) . right forearm was really swollen , tingling and turned blue, went to hospital they did a ultrasound to check pressure in veins. if she had hand at 90 degree angel it wouldnt turn blue but if I drop it it would turn blue. next day ran more test. MRI on arm. taped vitamin c to spot where pain was in arm. developed blood clot. told her to put heat on arm and take pain meds. felt better until she stopped blood thinner feb22, 2021. two days later had more blood clots on arms, veins were showing huge in breast and foot, pants got tighter. feb 27veins in lower leg and neck started appearing more. feb28 my left hand was cold and the veins were showing more and u could see veins. right back veins started appearing , got period but after 12 hours it stopped. march 3 veins started appearing again. march 4 right arm swelled and tingling in fingers and right right arm was so painful. Nerve pain. put back on blood thinner. march 4 in evening was put on new meds. I'm still dealing with pain and different issues. march 9 had a Val moment but had tingling from butt to brain . next morning felt miserable, nauseous , throwing up and couldnt control it. 3/11 neck is swollen. referring her to university because no doctor can figure out what it is.
1089580	3/10/2021	TX	67	M	1/27/2021	2/3/2021	Injection to shoulder went in vein rather than muscle; bleeding. A week later left ankle swelling, turned worse, calf starting cramping and swelling. On next Monday went to Hospital for ultrasound. Diagnosis: 2-foot long blood clot, DVT. CT Venogram taken February 11 no cause found. Went to hematologist did full blood panels. No cause found. Diagnosis: only alternative cause: COVID-19 vaccine.

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1089267	3/10/2021	AK	65	M	2/12/2021	2/19/2021	One week after getting the first Pfizer vaccine, my superficial vein thrombosis returned with a vengeance. I had gotten the vein ablation treatment several years ago for varicose veins, and the problems I had went away, but one week after the first shot, my calf muscle was swollen and felt sore and aching, and the rest of the leg was in pain, just like it was before getting the vein operation. The varicose veins returned and my leg now has prominent black and blue areas on it, like it had before my surgery. I'm returning to the vein clinic in two weeks for them to look at it. My leg still hurts. I should also add that my arm is still sore where they gave me the shot. My strength has not yet fully returned, even though I work out in the gym regularly.
1088646	3/10/2021	FL	73	F	2/24/2021	2/25/2021	following evening back pain lower left side for 2 days. Moved to stomach on left side and back. At this time urine was orange in color and had a foul odor for 3 days followed by stomach pain still but more intense and dysentery. Called Dr office when I had blood clots the size of quarters or better, Nurse suggested I go to emergency. I did not, this continued for 3 days and then subsided. I still am having chills and a temp of 96.7.. At this point I am concerned to get the second vaccine on the 29 th of this month.
1088409	3/10/2021	MD	46	F	2/8/2021	2/16/2021	I started hem morning from my nose for over a hour and my blood wouldn't clot. My nose was profusely bleeding while it was constantly running down my throat and bleeding out my right eye.
1088297	3/10/2021	PA	61	M	3/3/2021	3/4/2021	Next day developed right leg pain. Following day diagnosed with a new deep venous thrombosis of the popliteal vein, right leg
1087827	3/10/2021	PA	67	F	3/8/2021	3/8/2021	Modern a COVID-19 Vaccine EUA After 12- 36 hours- slight nausea, 101.5 degree F. fever, sore arm and muscles, fatigue, bone pain, blood clots in nose, sweating, headache

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1087308	3/10/2021	PA	92	F	2/15/2021	2/18/2021	her mother didn't want anything to eat; her mother wasn't making any sense when she talked; Dizzy; Weakness; shaky; stomach became upset; her mother had a pretty severe headache come on; Nose bleeds; Blood pressure increased; her mother's comprehension is not at the same level as prior to being hospitalized; This is a spontaneous report from a contactable consumer. A 92-years-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on left arm on 15Feb2021 12:30 at SINGLE DOSE for covid-19 immunisation. Medical history included blood pressure high, high cholesterol. Caller stated her mother has had high blood pressure for around 15 years. She said her mother's blood pressure medicine has changed over the years, providing her current blood pressure medication as: Ramipril 2.5mg capsule, once a day, Bisoprolol 5mg tablet, once a day. Reported her mother has had high cholesterol for at least 30 years. She said her mother's cholesterol is controlled with Simvastatin 40 mg, once a day. She said her mother has been on Simvastatin for at least 10 years and her mother's Simvastatin dose has been bumped up gradually over that time. She said the Simvastatin 40mg is dispensed in a pharmacy bottle with no NDC, Lot, and expiration date. Concomitant medication included omeprazole (OMEPRAZOLE), simvastatin (SIMVASTATIN) for high cholesterol, ramipril (RAMIPRIL) for blood pressure high, bisoprolol (BISOPROLOL) for blood pressure high. The patient experienced nose bleeds on 18Feb2021 with outcome of recovered on 22Feb2021, her mother had a pretty severe headache come on on 18Feb2021 with outcome of not recovered, blood pressure increased on 18Feb2021 with outcome of recovering, dizzy on 20Feb2021 with outcome of unknown, weakness on 20Feb2021 with outcome of not recovered, shaky on 20Feb2021 with outcome of unknown, stomach became upset on 20Feb2020 with outcome unknown, her mother didn't want anything to eat on 21Feb2021 with outcome of unknown, her mother wasn't making any sense when she talked on 21Feb2021 with outcome of not recovered, her mother's comprehension is not at the same level as prior to being hospitalized on an unknown date with outcome unknown. The patient was hospitalized from 21Feb2021 to an unknown date. Reporting on her 92 years old

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mother who received her first Pfizer COVID-19 Vaccine dose last Monday, 15Feb2021. She said the first couple days her mother was fine after receiving the COVID-19 Vaccine. She said on Thursday, 18Feb2021, her mother had a pretty severe headache come on. She said her mother normally doesn't have headaches. She said her mother began having nose bleeds that started on Thursday (18Feb2021), and continued on Friday (19Feb2021), and Saturday (20Feb2021). She said her mother's blood pressure was up during that time, as well. She said on Saturday night (20Feb2021) at 9:00 PM she took her mother to the Emergency Room because her mother's blood pressure was very high. She said a CT scan of her mother's head was done and was negative for a stroke. She said her mother was kept in the Emergency Room and monitored. She said her mother's blood pressure was gotten under control with given blood pressure lowering medication in the Emergency Room and her mother was discharged home at around midnight. She said she does not know the name, dose, NDC, Lot, and Expiration Date for the blood pressure medication. Reported her mother takes Warfarin for blood clots. She clarified her mother is monitored monthly and her mother's Warfarin is adjusted accordingly. She said her mother takes a Warfarin 1mg tablet daily on Monday through Friday, and a 1/2 Warfarin 1mg tablet (0.5mg) on Saturday and Sunday. She said the Warfarin is dispensed in a pharmacy bottle with no NDC, Lot, and Expiration Date. She said her mother has been on Warfarin for around 20 years, since her mother had a blood clot. Reported her mother takes a stomach medication, clarified as Omeprazole 20mg capsule once a day. She said her mother has been on Omeprazole for years. She said the Omeprazole 20mg capsule was dispensed in a pharmacy bottle with no NDC, Lot and Expiration Date. She said her mother's stomach had been fine. She said her mother didn't get sick to her stomach, until the night she was released from the Emergency Room (20Feb2021). She said when her mother sat up and tried to stand while she was in the Emergency Room on Saturday night (20Feb2021), her mother was dizzy, and felt weak and shaky. She said her mother was given some orange juice and peanut butter crackers at the time. She said her mother's stomach became upset then. She said she thinks her mother's

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stomach upset had more to do with having the orange juice and peanut butter crackers than anything else. She said her mother has never had nose bleeds or headaches before. She said her mother has blood pressure issues that she takes blood pressure medicine for. She said she thinks the COVID-19 Vaccine may have exasperated her mother's issues. Reported on Sunday (21Feb2021), her mother didn't seem much better to her. She said her mother's blood pressure was up, her mother was dizzy, weak and had a bad headache. She said her mother has a healthy appetite for 92 years old and her mother didn't want anything to eat. She said she ended up calling 911 because her mother wasn't making any sense when she talked. She clarified her mother was picked up by the ambulance at 9:00PM on Sunday (21Feb2021); and admitted to the hospital. She said her mother is still in the hospital as of today, Tuesday, 23Feb2021. She said her mother had a CT scan, a MRI, and an EEG. She said the CT scan, and MRI were negative, and the EEG results were not back yet. She said her mother may be released home today, 23Feb2021, depending on the EEG results. Reported her mother has never had nose bleeds or headaches before. Reported on Sunday, 21Feb2021, she took her mother's blood pressure. She said her mother was very weak and incoherent. She said her mother was unable to comprehend the way she usually does. Reported her mother has had no more nose bleeds since yesterday 22Feb2021. She said her mother is still quite weak, but her blood pressure is now under control. She said her mother has been on a stroke watch while at the hospital, and her mother has not been allowed to get up out of bed as of last night (21Feb2021). She said the hospital staff are supposed to let her mother walk today (23Feb2021) to see if her mother's blood pressure stays stabilized. She said her mother's comprehension is not at the same level as prior to being hospitalized. She clarified her mother still drives a car at 92 years old and takes care of her own check book. She said she doesn't know if her mother will still be able to do that at this time. Reported her mother was checked for a UTI while at the hospital. She said the hospital went ahead and treated her mother for a UTI without knowing if her mother had a UTI. She said because her mother is elderly, a lot of times the elderly have UTIs. She said the hospital didn't want to

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waste time and went ahead and treated her mother for a UTI because her mother hadn't been on antibiotics recently. The caller stated she did not have any information on the medications her mother has been given while at the hospital. Reported at first she did not think her mother's symptoms had to do with her mother's first COVID-19 Vaccine dose, but then there was a new part to her mother's story that made her think her mother's symptoms had to do with the COVID-19 Vaccine. Caller stated she is apprehensive for her mother to go get her second COVID-19 Vaccine shot. The patient underwent lab tests and procedures which included blood pressure abnormal: up on 18Feb2021, Head CT: negative on Feb2021, Head CT: negative for stroke on 20Feb2021, EEG: unknown results on Feb2021, MRI brain: negative on Feb2021. Therapeutic measures were taken as a result of nose bleeds, blood pressure increased, dizzy, weakness, shaky.



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1086928	3/10/2021	CA	50	F	1/16/2021	2/1/2021	<p>showed no acute intracranial process Identified. No evidence of enhancing lesion. Patient had not completed laboratory at this time. It was unknown if the patient had doctor or other healthcare professional office/clinic visit. The outcome of the event was not recovered. No follow-up attempts are possible. No further information is expected.</p> <p>Chose not to get second shot; Deep Vein Thrombosis; A spontaneous report was received from a consumer, concerning a 50 year-old, female who received Moderna (mRNA-1273) and developed deep vein thrombosis, and chose not to get second shot. The patient's medical history was not provided. Concomitant product was not provided. On 07Jan2021 (previously reported as 16Jan2021), approximately one week prior to the onset of symptoms, the patient received their first of two planned doses of mRNA-1273 (batch number: 025L20A) intramuscularly for prophylaxis of COVID-19 infection. A week post vaccination, she had a thick painful cord down injection arm and was misdiagnosed with tendonitis. After a second opinion, she was diagnosed with deep vein thrombosis. On 01FEB2021, an ultrasound confirmed a blood clot and subsequently, she went to the ER. A computerized tomography (CT) of the lungs ruled out pulmonary embolism. Based on these events, the patient chose not to get the second shot. Treatment included rivaroxaban and follow-up with hematologist. The second dose of mRNA-1273 was discontinued in response to the event. The outcome of the events deep vein thrombosis and chose not to get second shot were unknown. Follow-up information received 08Feb2021 included additional event, date of first dose was updated from 16Jan2021 to 07Jan2021, diagnostic test and treatment.; Reporter's Comments: This case concerns a 50 year-old, female who experienced deep vein thrombosis. Treatment included rivaroxaban and follow-up with hematologist. Very limited information regarding this event has been provided at this time. Further information has been requested. The causality for the event of intentional dose omission is assessed to be not applicable.</p>



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1089057	3/10/2021	CA	90	M	3/3/2021	3/5/2021	Acute Pulmonary Embolism, and Acute Deep Vein Thrombosis. He is active every day doing arm exercises and walking in place for exercise, and moving about his house with his walker, and this day was no different. He finished making breakfast and went to sit down on the couch, and had sudden-onset pleuritic chest pain. No other recent risks such as long car ride, illness, plane ride, or other immobility. Patient says the vaccine was Moderna second dose, given at pharmacy.
1086136	3/9/2021	CA	49	F	2/27/2021	2/28/2021	Within 6 hours I had overwhelming headache with injection site pain that radiated up to my ear and down to my elbow. I had lymph node pain and swelling. The next 36 hours I felt general malaise with a bad headache which continued to linger throughout the week. A few days later on Feb 4 at 3am I woke up with extreme chest pain and trouble breathing. I was rushed to the hospital where I had an NSTEMI event resulting in a cardiac cath/thrombectomy removing a rope-like blood clot in an otherwise healthy heart.
1084084	3/9/2021	IN	54	F	3/8/2021	3/8/2021	Profuse bloody nose with clots for approximately 5 minutes
1084197	3/9/2021	AL	66	F	2/24/2021	2/24/2021	Initial reaction of splotchy, itchy rash over body which diminished but returned on 3/4/21 with severe pain and swelling in legs and rash from feet to buttocks/back area. Patient went to hospital on 3/7/21; negative for blood clots, lab work was normal; Prescribed Hydroxyzine, PCN-(for mild sore throat), Multi V, Areds 2
1084432	3/9/2021	MN	57	F	2/17/2021	2/22/2021	hospital visit, increased b/p, pain in center of sternum, tingly limbs, bottom of feet felt burned, dx of Epigastric abdominal pain, vomiting 48 hours, dr visit, hospital visit for dehydration, lack of smell and taste, tingly limbs gone but severe pain behind right knee, ruled out blood clot, smell back, taste not all the way returned, pain continuous

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1084516	3/9/2021	VA	81	M	2/27/2021	3/4/2021	4 days after second short arm of shot ballooned such that no features can be distinguished. Visited Doctor twice but they had not seen anything like this. They ordered scan on left arm for possible blood clots; negative. Prescribed Benadryl every 8 hours, taken for three days but no relief from sever swelling. It is now 7 days since the arm first swelled up.
1085254	3/9/2021	NJ	90	M	3/1/2021	3/1/2021	Severe abdominal pain unable to eat or sleep for 36 hours. He went by ambulance to the Hospital emergency room. They tried to pump his stomach but he aspirated and went into cardiac arrest. He was revived but never regained consciousness. (The ICU Dr said that he had blood clots in his abdomen from a recent stroke. We were unaware of him having a stroke other than in 2026. The same Dr. said that he had necrosis in his lungs from aspirating. The necrosis was from his bowel dying) He was put on a ventilator and given drugs to increase his heart rate. On 3-5-21 the heart drugs were reduced and he died. I was with him when he recieved the vaccination and he was healthy, just old. I think that the shot killed him.
1085298	3/9/2021	PA	59	F	2/27/2021	3/3/2021	She got the vaccine, started feeling like she thought was muscle pain and now that she thinks about it was menstrual cramps. Then some dark menstrual discharge. She thought it had stopped, but this afternoon had dark bloody clots/discharge when wiping. She is not having as bad of cramps. Sunday and morning were definitely worse days than today. She has not had a menstrual cycle in over 15 years, she is 60. She did not take anything for the pain. She is still having the symptoms, and actually worse than it was earlier.

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1085423	3/9/2021	NY	37	M	3/2/2021	3/4/2021	2 days after my 1st vaccine (Thursday, 3/4), I started to feel a slight shortness of breath...it was not severe but felt pretty constant regardless if I was still or moving...not a full catching of breath but the sensation was there I went to Urgent Care on Friday 3/5 to get tested for COVID, and that came back negative on Rapid (3/5) and PCR (3/7) The symptom continued into Monday 3/8, and I went back to Urgent Care to get a Chest X-Ray and Blood work. The Chest X Ray came back normal, but the D Dimer showed an elevated level and they recommended I go get a CT Scan to check for Blood Clots I went to NY Presbyterian ER to get a CT Scan with Contrast, which came back clean. They also did a ECG 12 Lead and Troponin I Test, all came back clean I was discharged on 3/8, with Hospital potentially diagnosing the issue as Pueris. This could be from a common cold, but also concerned that the vax caused some internal inflammation Still feeling the sensation on 3/9, have a follow up appointment with GP on Friday 3/12 to go over all tests
1085435	3/9/2021	TX	67	M	2/27/2021	3/3/2021	Onset of leg pain began four days after vaccination (vaccination on 2/27 onset of leg pain 3/3). DVT behind left knee confirmed with ultrasound on 3/8 and started on apixiban 3/9. No history of clots and no activities that would contribute to an elevated risk: no family history, no recent injuries or surgeries, not sedentary, nonsmoker, and drink only in moderation.
1086059	3/9/2021	CO	92	F	2/21/2021	2/25/2021	DVT in right leg discovered after swollen foot on 2/25/2021 via ultrasound. Clot extends from mid thigh to mid calf. Placed on Xarelto 15 mg 2x/day until next imaging appointment on March 30, 2021. First incident of blood clot for mother.

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1086384	3/9/2021	TX	36	F	1/5/2021	1/5/2021	On the following day after receiving my first dose of the vaccination, my arm was throbbing, completely swollen, decreased ROM and skin was RED and severely tender to the touch. Took OTC Tylenol (2) po and had no signs of relief. Pain , swelling, and skin redness lasted for 3 days. On February 10th, 2021 I had a positive pregnancy test (confirmed by bloodwork and urine) which indicated I was 6-7 weeks pregnant and had a miscarriage on March 2021, after giving live births 3 prior times. The cause of the miscarriage is unknown. I also developed a blood clot on the arm that was inserted for an IV. I have no family history or personal history of needing blood thinners.
1086484	3/9/2021	CO	27	F	2/13/2021	2/18/2021	I got the Covid vaccine on 2/13/21, I lost a small clot and started to bleed on 2/19/21. I was due around Oct 4th, at the time of the vaccine I was 6 weeks pregnant. I miscarried at home on 2/25/21- I lost a very large clot and was bleeding heavily for a week. Doctor confirmed with HCG test that I miscarried. This was my second pregnancy, I had my first child 1/10/20.
1086527	3/9/2021	NY	74	F	2/13/2021	2/22/2021	The night of my 1st COVID Vaccine, I developed fever that lasted 2 days. Next day had chills, and sweats, and nausea, Next day fever 102, headache, chills. Next day Tuesday, 2/16, fever 100, started to feel less achy. Then felt better on the 17 of February. The rash, pain and swelling began on the 22 of February. Red rash, swelling, upper thigh, both legs radiating down to ankles. As days went on the swelling increased , along with pain, and redness.Difficulty walking . Ankles swollen, skin shiny, very painful. Called Dr. he advised give it a few more days, not knowing why this was happening. My Rheumatologist suggested it was an allergic reaction of some kind. She discontinued my Lamisil and Fosomax. Redness continued along with swelling , and pain . On March 9, went to my physician. Saw the PA, she said she would speak to Dr. He wanted to make sure I didn't have DVTs. He wanted me to get a Doppler for clots. I went to Hospital and had Doppler and it was Negative for deep vein thrombosis.

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1086033	3/9/2021	OH	67	F	2/15/2021	2/15/2021	Blood clots in arm; Arm was sore; A spontaneous report was received from a healthcare professional concerning a 67-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sore arm/pain in arm and blood clot in her arm/thrombosis. The patient's medical history, as provided by the reporter included diabetes. Concomitant medications were not included. On 15 Feb 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 031M20A) in the left arm for prophylaxis of COVID-19 infection. On 15 Feb 2021, post vaccination the patient experienced sore arm and her condition got worse. She was then taken to emergency room with blood clots in her arm. Action taken with mRNA-1273 in response to the events were not reported. The outcome of the events, sore arm and blood clot in her arm, were not known.; Reporter's Comments: This case concerns a 67-year-old, female patient, who experienced thrombosis and pain in arm. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. The patient's medical history of diabetes is a risk factor. Further information has been requested.

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1081108	3/8/2021	CA	72	F	2/1/2021	2/1/2021	Cellulitis in left leg may be acting up/Might have an infection in area of cellulitis in left leg; Cellulitis in left leg may be acting up/Might have an infection in area of cellulitis in left leg; Questioned if she might have a blood clot in left leg; Might have an infection in area of cellulitis in left leg; pain in the left leg; This is a spontaneous report from a contactable consumer. A 72-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL9262, expiration date 31May2021), via an unspecified route of administration on 01Feb2021 at left upper arm around 19:00 or a little later at single dose (at the age of 72-years-old) for covid-19 immunization. Medical history included bad knees and got injections for this and recurrent cellulitis of legs (cellulitis was not active at time of vaccine; but anytime her leg swells with bad knees she had a little episode with the cellulitis down around her ankles on both legs but left leg was more predominant. She had been keeping it at bay), mineral supplementation, bad knee pain, blood pressure medication (abnormal), urine output control (abnormal), dehydrated and dizzy. Concomitant medication included lisinopril as blood pressure medication, potassium for Mineral supplement, solifenacin succinate for urine output control, paracetamol (TYLENOL 4) for bad knee pain. She had taken potassium before and it calmed it down: she was little dehydrated, little dizzy, so was drinking some Pedialyte, water, and taking potassium. The patient had it once before but it kind of snuck up on her again. The patient called to ask if anyone had reported any type of blood clot on the same side of the body that the Pfizer COVID-19 Vaccine was administered. She questioned if she might have a blood clot in her left leg after having been administered the Pfizer COVID-19 Vaccine. She had recurrent cellulitis in both legs prior to Pfizer COVID-19 Vaccine. The doctor thought the cellulitis in left leg may be acting up and that she might have an infection in that area of cellulitis. She reported pain in the left leg when she rested her leg on a pillow; but did not feel any pain when she was standing and walking. The pain became a little too hard for her to bear so the doctor prescribed her Cephalexin 500m capsule every 12 hours-she was on the 3rd capsule now. Onset date for the events was approximately 03Feb2021 or 04Feb2021. The events were better since started

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							Cephalexin. Second dose date scheduled for 22Feb2021 but did not give her time. The outcome of the events was recovering. Follow-up (23Feb2021): New information received from the product quality complaint group includes confirmation of lot number (EL9262) and new expiry date.
1081226	3/8/2021	IN	75	M	2/25/2021	2/26/2021	Left leg-knee started swelling, knee was sore, fluid around knee appeared, unable to lift leg, and large contusion appeared on back of thigh. Xray done and showed a large area of arthritis. Blood work was done US of left leg was done and test show negative for blood clot. As of today (3/8/21) there is still a lot of swelling in knee, lower leg and foot
1080646	3/8/2021	NM	38	F	3/1/2021	3/1/2021	- Headache: starting about 12 hours after the vaccine and continuing for 2 days - Fatigue: starting about 12 hours after the vaccine and continuing for about 2 days - Chills: starting about 16 hours after the vaccine and intensifying until 24 hours after the vaccine administration - Fever: starting about 16 hours after the vaccine and intensifying until 24 hours after the vaccine administration - Blood clots: expulsion of clots during the same period as the fever and chills. Had completed menstruation 2 weeks prior, so not related to that.
1081909	3/8/2021	MN	42	F	1/29/2021	2/12/2021	DVT blood clot and surface blood clot in lower left leg diagnosed at the ER on 2/12/21. Levonox injections and warfarin have been started. Twice weekly INR checks. No longer need the injections; warfarin is continued. Next INR check is scheduled for Thursday March 11, 2021. Warfarin may need to continue life-long.
1082154	3/8/2021	FL	33	F	3/4/2021	3/7/2021	Early menstrual cycle (two weeks after the start of the last cycle) with unusually heavy bleeding and menstrual clots.

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1082674	3/8/2021	MI	72	M	2/26/2021	2/27/2021	Patient received Covid19(Pfizer) vaccine on 02/26/2021 at 3.55pm and on 02/27/2021 in the morning he had swelling in his left leg ( patient had knee replacement in same leg 9 months ago). He waited 2 days and still no improvement. He went to Beaumont urgent care on 03/03/2021 and he was referred to emergency room at hospital. He was admitted due to blood clot in left leg and lungs, where he had leg surgery. He was prescribed Eliquis 5 mg twice a day.
1083227	3/8/2021	NC	47	F	3/1/2021	3/2/2021	Stayed home on 3/2, was very weak. Wed went to work. Friday, menstrual cycle started 12 days early, which she had thick blood clots and noticed greyish color piece of tissue. Saturday and Sunday, she started to move around after being in bed. Today, she feels about 90% better.
1083391	3/8/2021		71	M	3/3/2021	3/4/2021	71yo M received first Moderna COVID vaccine 5d ago. 24hrs following pt started having fatigue, vertigo, body and joint aches, intermittent runny nose, PND, throat irritation and gravelly voice, decreased smell, loss of taste, chills, and fever to 104.2. Chronic dry cough which pt is unsure if has recently been worse. No ear or sinus pressure/pain. no respiratory concerns at present. +nausea, no vomiting, no diarrhea/loose stools, + decrease in activity, +decrease in appetite. Also yellow/rust colored urine x4d getting darker esp today w/ decreased urinary frequency. No burning or urgency. No urine blood clots. No BM for 4d w/ decreased appetite but did have BM today which was normal w/o blood, black, or tarry stool. Pt had heart stent placed 1mth ago and started on plavix along w/ his daily ASA and atorvastatin increased from 10 to 40mg. No CP or SOB. Pt found to have elevated LFTs, alk phos, and bili w/ hepatitis reaction.



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1080222	3/8/2021	NM	72	M	2/10/2021	2/18/2021	Pulmonary embolism; Multiple clots in his lungs; Shortness of breath; This is a spontaneous report from a contactable consumer (patient wife). A 72-years-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number unknown and expiration date not reported), via an unspecified route of administration on 10Feb2021 at a single dose for Covid-19 immunization. The patient medical history was not reported. Concomitant medication included levothyroxine. The patient previously took first dose of bnt162b2 (EL8982) on 19Jan2021. The reporter (wife) stated that she and her husband both took the Covid vaccine. The patient (husband) is the one who have the adverse reactions. On 19Jan2021, she and her husband had the first shot, the Pfizer Covid shot. On 10Feb2021, they had the second shot. Just today she picked her husband from the hospital, they dismissed him for today because on 18Feb2021, she had to take him to emergency room because he had pulmonary embolism. He has multiple clots in his lungs. This is nothing that they dealt before with him. The reporter is afraid that it might be related to have taken the vaccine. Reporter stated that when she took him to the emergency room, it was 18Feb2021. Now he had a little shortness of breath for few days before the 18th but they didn't realize that he was having a big problem. He fully developed this on 18Feb2021. The reason for hospitalization was pulmonary embolism and blood clots in his lungs. He is little bit slow like the reporter said she got him to the hospital where he stayed 3 days she guess with pulmonary embolism, from 18Feb2021 to 21Feb2021. He had lot a of lab work while he was in hospital on these days the wife described. He had blood work, Echocardiogram, CAT scan, Ultrasounds, Chest X-ray, Covid rapid test, they haven't got back the result yet. Outcome of the events was unknown.
1079045	3/7/2021	MA	83	F	2/12/2021	2/15/2021	Initially, a UTI developed. As the UTI resolved, double pneumonia took hold. At the hospital they then discovered multiple clots in the legs.
1078458	3/6/2021	VA	31	F	2/22/2021	2/26/2021	Blood clot in lung

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1077988	3/6/2021	CO	38	F	1/28/2021	2/11/2021	# AKI with non-nephrotic range proteinuria and microscopic hematuria # Neutrophilia # Fevers # Normocytic anemia # Thrombocytosis # Coagulopathy # RUE Superficial venous thrombosis # Subconjunctival hemorrhage # Flame hemorrhage R fundus # Mild iridocyclitis # CRP elevation # Procalcitonin elevation # D Dimer elevation # Anasarca # Elevated BNP # Hypoalbuminemia # Small pericardial effusion # Elevated alk phos, bilirubin (direct predominant), and AST # Elevated lipase # Hypocomplementemia with low CH50 # Elevated IL2 Receptor (8540) # Aseptic meningitis w CSF with lymphohistiocytic predominant pleocytosis (25 nuc cells with 49% lymphs, 35% histiocytes, 16% pmn, glucose 41, protein 155 with neg meningoencephalitis panel)

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1076717	3/5/2021			F			<p>Thrombocytopenia (diffuse petechiae, easy bruising, bleeding gums); Polychromasia; Petechiae; Easy bruising; Mild headache; Anisocytosis; A spontaneous report was received from a literature article concerning a 36, year old, female patient who experienced thrombocytopenia, headache, polychromasia, anisocytosis, petechiae and easy bruising. The patient's medical history included thrombocytopenia and allergy to acetaminophen. Products known to have been used by the patient, within one week prior to the event, included ibuprofen and sumatriptan. A vaginal ring containing etonogestrel-ethinyl estradiol, was place one week prior to hospitalization. Approximately one week prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number not provided) on unknown date, intramuscularly in the for prophylaxis of COVID-19 infection. The patient presented to the hospital on unknown date with diffuse petechiae, easy bruising, bleeding gums and mild headache. Vital signs were within normal limits upon arrival at hospital. Physical exam was notable for diffuse petechiae of the extremities and trunk along with oral ecchymosis of 1-2 cm; no focal neurological deficits were observed, and no hepatic or splenic enlargement was noted. Blood work was significant for white blood count of 13.1 L/uL, hemoglobin 13.6 g/dL, heamatocrit of 42.1%, and platelet count of 3000/uL. Prothrombin time and activated partial thromboplastin time were within normal limits. SARS-CoV2 swab was negative but the SARS-CoV2 IgG antibodies were reactive. Peripheral smear showed thrombocytopenia without clumping along with polychromasia and anisocytosis appreciated with some mature neutrophils. A CT scan of the head did not show acute infarction or hemorrhage. Treatment for the event included, dexamethasone 40 mg intravenously daily for four days, intravenous immunoglobulin (IVIg) 1 mg/Kg for three days and was place on the Health Stroke Scale monitoring. Platelet count improved to 28000/uL within 3 days and oral lesions disappeared through some petechiae remained. The patient's contraception ring was not removed. The patient was discharged with outpatient hematology follow up. Action taken with mRNA-1273 in response to the event(s) was not provided. The outcome of the event(s) was not reported. According to the abstract, the temporal sequence of the events suggests</p>

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1075784	3/5/2021	CA	71	M	2/23/2021	3/2/2021	<p>an exacerbation of the patient's chronic thrombocytopenia related to the receipt of the mRNA-1273 Covid-19 vaccine. The abstract also stated that it is possible based on reviews of reported side effects unlikely, that the patient's headache medications and contraception were triggers for this event. Follow up: No follow up provided.; Reporter's Comments: Very limited information regarding the events has been provided at this time.</p> <p>About a week after receiving my second Moderna Covid shot I felt shortness of breath. 9 days after the shot I had a mild fever (100.5f), severe shortness of breath and chest pain (level 5+) and went to the emergency room. They found D/Dima was elevated and sent me for a CT scan. This showed a significant blood clot in the right lung and a lesser clot in the left. I am usually extremely health, walking 2 miles at least 5 days a week and bicycling about 50 miles per week</p>

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1075247	3/5/2021	WI	54	M	2/12/2021	2/12/2021	Deep vein thrombosis left calf; Difficulty breathing; Pulmonary Embolism; Felt doggy, sluggish, punky; Arm hurt; A spontaneous report was received from a nurse concerning a 54-year-old, male patient who experienced pulmonary embolism, deep vein thrombosis, vaccination site pain, sluggishness and dyspnoea. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 12-Feb-2021, approximately 2 days prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number: unknown) intramuscularly in the left arm for prophylaxis of COVID-19 infection. The patient received his vaccine on 12-Feb-2021 and reported that his arm hurt a little for a few days. On 14-Feb-2021, he reported that he started feeling sluggish and on 20-Feb-2021 he began to have difficulty breathing and pain in the right lower base of rib cage. He went to urgent care where he was diagnosed with a pulmonary embolism for which he received treatment. On the evening of the same day, he again started having difficulty breathing with pain upon inhalation. He returned to urgent care and was subsequently admitted at 12:30 AM on 21-Feb-2021. That Monday, 22-Feb-2021, a doppler ultrasound revealed a deep vein thrombosis in the left calf. Patient was treated with heparin intravenously (IV). He was discharged 22-Feb-2021. Treatment for the event included Xarelto 20mg twice per day for two weeks and Heparin IV. Action taken with mRNA-1273 in response to the events was not provided/unknown. The outcome of the events, pulmonary embolism, deep vein thrombosis and dyspnea, was considered recovering/resolving as of discharge on 22-Feb-2021. The outcome of the events, vaccination site pain and sluggishness, were considered recovered/resolved.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
1074843	3/5/2021	SC	69	M	3/4/2021	3/4/2021	Right arm parathesia, hx of blood clots

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1074304	3/5/2021	ND		U			PE; DVT; A spontaneous report was received from a pharmacist concerning patient (age and gender unknown) who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced a pulmonary embolism (PE) and deep vein thrombosis (DVT). The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On an unknown date, the patient received the first of two planned doses of mRNA-1273 (Batch number not provided) intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, the patient experienced a PE and DVT. Treatment information was not provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the events, PE and DVT, were not reported.; Reporter's Comments: Very limited information regarding the reported events have been provided at this time. No additional information is expected as consent to follow up was denied.
1075857	3/5/2021	NJ	56	F	2/26/2021	3/2/2021	Blood clot on thigh

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1075308	3/5/2021	CA	61	F	1/20/2021	1/21/2021	<p>still have sore muscles in my shoulders; still feeling bad with all the above symptoms; 23Jan2021 went to get covid test but due to blood in my nose received antibody test which was neg; bad headache; winded; vomited; diaherria; coughing/cough; large clots gushed from my rt nostril went to er stopped bleeding after 2 hrs; large clots gushed from my rt nostril went to er stopped bleeding after 2 hrs; This is a spontaneous report from a contactable other hcp (patient). A 61-year-old female patient received their first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EL1283, expiry date not reported), via an unspecified route of administration on the left arm on 20Jan2021 18:45 at single dose for COVID-19 immunization. Medical history included diabetes mellitus and high BP from an unknown date and unknown if ongoing. Concomitant medications included levothyroxine, losartan potassium and sodium fluoride (CREST CAVITY PROTECTION). The patient previously took septria and experienced allergies. The patient reported that on 21Jan2021, they woke up and brushed their teeth then at 6:40am blood with large clots gushed from their right (rt) nostril. The patient went to ER and stopped bleeding after 2 hrs. On 22Jan2021, the patient woke up with bad headache, winded, vomited, diaherria (as reported), coughing. On 23Jan2021, they went to get covid test but due to blood in their nose, they received antibody test which was negative. On 24Jan2021, the patient was still feeling bad with all the above symptoms. Then on 25Jan2021, they went to ENT doctor who cauterized their nose and stated that since antibody was negative to take the moderna vaccine since they have no antibody in their system, the Pfizer vaccine did not work. From 26Jan2021 to 13Feb2021, the patient felt same started feeling better 14Feb2021 but still have sore muscles in their shoulders and cough. The patient underwent lab tests and procedures which included sars-cov-2 antibody test: negative on 23Jan2021. The action taken in response to the event(s) for bnt162b2 was not applicable. Therapeutic measures were taken as a result of epistaxis and clot blood which include the doctor cauterized their nose. The patient recovered with sequel from the events.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the epistaxis and other reported events due to</p>

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							temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including CBC and coagulation panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
1073786	3/4/2021	IL	35	F	2/17/2021	2/18/2021	The following day, she complained of headache, fatigue, dizziness, and lightheadedness for 3 days. On 2/19/2021 she experienced hives on her abdomen and back that were itchy. No medicine was taken. On the 2/20/2021, she complained of further headache, fatigue, dizziness. She also had shortness of breath. The next day, she presented to the urgent care. She was given an intravenous fluid bolus for dehydration. She was given a "migraine cocktail." She was told that her D-dimer was positive. She had a CT scan that showed sinusitis and her chest was clear. The following day, she complained of progressively worsened ascending pain in her left arm. She had red patches of a rash in her left arm as well. One week later, she went back to the urgent care. An ultrasound was performed and a blood clot was found at. She is now taking Eliquis daily.
1071607	3/4/2021	OH	75	F	2/20/2021	2/22/2021	Cellulitis left arm - red and swollen, 2 pulmonary embolism, right tibial blood clot
1071744	3/4/2021	MI	38	M	1/11/2021	1/15/2021	superficial thrombophlebitis left greater saphenous vein with blood clot formation almost entire length of the vein



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1071748	3/4/2021	WI	71	F	3/4/2021	3/4/2021	Patient received second Moderna COVID vaccine. While waiting in waiting area, alerted staff that she was feeling SOB. States h/o asthma. Just used inhaler prior to arrival for vaccine. States h/o COVID and now has blood clots in lungs. On a blood thinner. C/o chest pain. States h/o MI. Pt was somewhat diaphoretic in face. C/o some dizziness. RR elevated. AA&O. First responder called with prompt arrival. Pt transferred to ED immediately. Transported via wheelchair. Pt was AA&O when leaving the observation area, still symptomatic. VSS.
1071927	3/4/2021	TX	74	F	12/28/2020	1/11/2021	It started out with just stiffness in my legs and back. Then at night I couldn't put my legs down they hurt and my shins felt like I had shin splines. This lasted about a week or more. I went to a Dr. because my left knee and shin were hurting so bad. The Dr. was not sure and did a Doppler to see if I had a Blood clot in my left knee but I didn't. She put me on an antibiotic, that I really didn't need I don't think. I took that for a few days and stopped because it wasn't helping any. On the 14th I went to see another Dr. and he put me on Prednisone, at this time I could barely walk my right hip was hurting so much. I was taking little bitty steps. The prednisone has been helping, it's allowed me to walk and to function. I was to the point it was getting so bad. I'm still having some stiffness, my left elbow gets inflamed at times, my left hand and knuckle swell and get stiff at times too. It seems to move around at effect different places. The medication helps me move better, I have been off work for 7 weeks, I plan to go back and try half days.

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1072549	3/4/2021	IL	83	F	2/17/2021	2/17/2021	<p>Pounding in head; Heart pounding; Elevated BP; bouncing off the walls, and going from side-to-side when she tried to walk; oxygen saturation level kept dropping; shaking; cold; Weakness; Tiredness; Throat tightness; Dry mouth; This is a spontaneous report initial from a contactable nurse and follow up from a Pfizer-sponsored program. This Nurse (patient) reported for self that the 83-year-old female patient received first dose of bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6200), via an unspecified route of administration on 17Feb2021 09:30AM on right arm at single dose for covid-19 immunization. Medical history included rheumatoid arthritis from an unknown date and unknown if ongoing Reported she was diagnosed with Rheumatoid Arthritis about 10 years ago, fibromyalgia from an unknown date and unknown if ongoing and stated when the doctor couldn't figure out what was causing her pain, the doctor said she had Fibromyalgia, carotid endarterectomy from 2014, pain in extremity from an unknown date and unknown if ongoing She said she has rheumatoid arthritis, and has had terrible leg pain for a long time. Family Medical History Relevant to AE(s) was not provided. Concomitant medication included cortisone (CORTISONE) for Pain in leg from 10Feb2021 and stated her doctor gave her a Cortisone shot in her right knee to help with her right leg pain. Reported she received a Cortisone shot in her right knee on Wednesday, 10Feb2021. She said the doctor gave her the Cortisone shot in her right knee to see if it would help her right leg pain. She said she has a problem with Cortisone, clarifying the Cortisone keeps her awake. She said the doctor wanted her to have another Cortisone shot in 3 months, and she is not going to take the Cortisone shot because she doesn't like how the Cortisone makes her feel. The patient experienced pounding in head (hospitalization, medically significant), heart pounding (hospitalization, medically significant), elevated bp (hospitalization, medically significant), bouncing off the walls, and going from side-to-side when she tried to walk (hospitalization, medically significant), dry mouth (medically significant) all on 17Feb2021 with outcome of recovering, throat tightness (medically significant) on 18Feb2021 with outcome of recovering, weakness (medically significant) on 19Feb2021 with outcome of not recovered, tiredness (medically significant) on 19Feb2021 with outcome of not recovered.</p>

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significant) on 19Feb2021 with outcome of not recovered, oxygen saturation level kept dropping on an unspecified date with outcome of unknown, shaking on an unspecified date with outcome of unknown, cold on an unspecified date with outcome of unknown. He experienced terrible pain in the leg after the 1st dose and took a marijuana cookie and she was rushed to the ER because she was shaking and cold. The patient was hospitalized for events pounding in head, heart pounding, elevated bp and bouncing off the walls, and going from side-to-side when she tried to walk from 17Feb2021 to 18Feb2021. The nurse states that "I told her up until a Month ago, she was taking care of a huge house and husband that is blind. I've been having the pain in my legs for over a month, doppler was done, and I had an injection in my knee with cortisone, I won't do that again, it keeps me awake at night. There is no diagnosis yet on the pain, have an orthopedic appointment coming up. Caller states, I got the first Pfizer vaccine shot on Wednesday at 9:30 am in right arm. Never so much have felt it. or have not felt anything else since. My friend talked me into eating a marijuana cookie about 5pm that day, and at 6 or 6:30pm, I started feeling terrible, my head was feeling terrible, my heart was pounding, I could hardly walk, my mouth was dry as a bone. we called paramedics, we found out on Friday before the shot that I have a right bundle block. Woke up 4:30 in the morning the Friday before with chest pain. EKG found right bundle block, my blood pressure was 245/105, that night in the ER, they got my blood pressure down and sent me home. Wednesday, I had the covid shot in right arm, at 9:30am, that day about 4:30 - 5:00 had the cookie thing, about 6pm, had to call the paramedics, they kept me in the hospital overnight. because my oxygen saturation kept dropping, down in the 86% or 89%, I don't know. Gave me breathing treatments, CT scan for blood clots in lungs was done, Doppler for blood clots in legs, and a HgbA1C. They did an echo of my chest. I don't know all of the results yet. Even yesterday, in the hospital I felt better, but feel week and tired, while walking the hall in the hospital my Blood pressure went up a little bit. I told the nurse, my head feels like this when my blood pressure is up. They sent me home last night. Today, I am feeling okay. My mouth is still a little dry, got a little better yesterday. My legs are still killing me, I have an

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appointment with my Cardiologist and Rheumatologist, I have Rheumatoid Arthritis. My question is , the doctor didn't know if it was from the cookie or from the vaccine. I am wondering if I should get the second vaccine." She stated she never had a sore arm after getting the COVID-19 Vaccine. She said she did something stupid after she received the COVID-19 Vaccine. She said she has rheumatoid arthritis, and has had terrible leg pain for a long time. She said her friend talked her into having a cookie that had marijuana in it. She said her leg pain was so severe at the time, she took the cookie with marijuana in it around 4:30PM-5:30PM on 17Feb2021. She said at 7:00PM she was bouncing off the wall (clarified as unsteady, and going from side-to-side when she tried to walk), her head was pounding, her heart was pounding, she was dizzy and shaky. She said she went to the hospital emergency room. She said the hospital kept her overnight because her oxygen saturation level kept dropping. She said she got home from the hospital last night (18Feb2021), clarifying she was discharged from the hospital at 6:00PM. She said she noticed her mouth was very dry when she went to the hospital on 17Feb2021, and her mouth continued to stay very dry all night. Caller asked if she should get the second COVID-19 Vaccine shot after experiencing what she did after receiving the first COVID-19 Vaccine. Reported her leg pain became severe about a month ago, clarifying she has had leg pain for a long time. Reported her blood pressure was up while she was at the hospital, clarifying she had one blood pressure reading of 145/82 that she recalls. She said her blood pressure is pretty normal, and she takes blood pressure medications. She said she believes her heart rate was up too, but was unsure what her heart rate was. Reported a couple days before receiving her first Pfizer COVID-19 Vaccine, she went to her doctor on 12Feb2021 because she was having severe chest pain. She said her doctor did an EKG and told her she had a right bundle branch block. She said her doctor sent her to the hospital Emergency Room. She said while she was in the Emergency Room she had an extremely high blood pressure of 245/105. She said she came home from the Emergency Room on 12Feb2021, and had a couple spells, but was OK. She said she was OK when she went to get her first COVID-19 Vaccine shot on Wednesday, 17Feb2021. Reported

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she had difficulty reading her COVID-19 Vaccine Immunization Card. She said the Pfizer COVID-19 Vaccine Lot Number looked like EN6200, and there was no NDC Number, or Expiration Date listed on the card. Reported she had blood work done at the hospital. No further details provided. Treatment included she was given Albuterol breathing treatments while in the hospital, along with some other things that she can't remember. Reported she believes her symptoms were medically significant because she was nervous from recently being to the Emergency Room for her severe chest pain a few days before. Reported she did not think her symptoms were from the COVID-19 Vaccine. She said she thought the cookie with marijuana in it caused her symptoms because the symptoms happened about 1-1/2 to 2 hours after she had the cookie with marijuana in it. Reported she feels very weak and tired. Reported yesterday (18Feb2021) while she was in the hospital, her head felt like it was going to explode when the hospital staff tried walking her around. She said she asked the hospital staff to check her blood pressure because her head will feel like that when her blood pressure is up. She said when the hospital staff checked her blood pressure, her blood pressure was elevated. Reported the pain in her legs is driving her crazy, so she called for an appointment with an orthopedist today. Reported she is feeling better, but is still experiencing a tightness in her throat. She clarified she felt the throat tightness on Wednesday, 17Feb2021. She said she has no problem swallowing or eating, but her throat feels tight. Vaccination Facility Type was Hospital. History of all previous immunization with the Pfizer vaccine considered as suspect (or patient age at first and subsequent immunizations if dates of birth or immunizations are not available) was none. Additional Vaccines Administered on Same Date of the Pfizer Suspect was None. AE(s) required a visit to: Emergency Room (admitted to hospital), no Physician Office. Prior Vaccinations (within 4 weeks) was none.; Sender's Comments: The 83-year-old female patient had medical history included rheumatoid arthritis, fibromyalgia and carotid endarterectomy, and was on multiple concomitant drugs. Considering temporal relationship, a possible contribution role of vaccination with BNT162B2 to the onset of the reported events, cannot be completely excluded. The impact of this report on the benefit/risk

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1072556	3/4/2021	IN	70	F	2/11/2021	2/11/2021	<p>profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> <p>right leg showed blood clot in lower back of leg from ankle to knee; right leg calf was red swollen and throbbled; Right leg ankle still hurt; flu symptoms appeared; Left arm, muscles, joints hurt; Left arm, muscles, joints hurt; Left arm, muscles, joints hurt; tired; chills; not feeling well; This is a spontaneous report from a contactable consumer (patient). A 70-year-old female non-pregnant patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EM9810), via an unspecified route of administration on 11Feb2021 10:00 at single dose in arm left for COVID-19 immunisation. There was no medical history and no known allergies. Concomitant medication included colecalciferol (D3) and multi vitamin. The patient did not have COVID prior vaccination. There was no other vaccine in four weeks. After about 4 hours after first Pfizer shot on a Thurs (11Feb2021), the patient experienced flu symptoms appeared, Left arm, muscles, joints hurt, chills, tired, not feeling well, on 11Feb2021 16:00. Right leg ankle still hurt after 24 hours Friday and Saturday by Sunday. Right leg calf was red swollen and throbbled on 14Feb2021 16:00. Monday (on 15Feb2021) the patient called physician and had sonogram on right leg which showed blood clot in lower back of leg from ankle to knee. Doctor put immediately on rivaroxaban (XARELTO) blood thinner for blood clot. Blood work has been done on 15Feb2021. The patient would follow up on 02Mar2021. She was concerned about taking second COVID vaccine dose on 04Mar2021. The adverse events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. Covid was not tested post vaccination. The event outcome was unknown.</p>

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1072810	3/4/2021	NC	72	F	1/1/2021	1/1/2021	SOB and HTN on 1/30/21, 3 wks after 1st Covid shot. Submassive acute saddle pulmonary embolism. Pt was sent by ambulance to ER. On arrival, CT revealed a saddle embolism. Heparin was initiated and pt was transported to hospital. Admitted to ICU and bil thrombolytic catheters were placed. On 1/31/21 thrombosis has dissolved. on cessation of thrombolysis and removal of lytic stents on 1/31/21 pt was placed on Xarelto. Pt was D/C on 2/1/21.
1073554	3/4/2021	TX	30	F	1/13/2021		itching (itching affected her upper body, face, shoulders and torso).; This is a spontaneous report from a contactable nurse (patient) received via Medical Information Team. A 30-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3249), via an unspecified route of administration at arm left on 13Jan2021 at 12:00 (at the age of 30 years) at single dose for COVID-19 immunization. Medical history included pregnancy from an unknown date to an unknown date, dual venous thrombosis post pregnancy (from two years and four months ago) and blood thinner from an unknown date and ongoing. Concomitant medication included warfarin oral at 7.5 mg once a day from an unknown date and ongoing for blood thinner. The patient experienced itching (itching affected her upper body, face, shoulders and torso). The patient outcome of the event was not recovered.
1073807	3/4/2021	UT	72	M	2/11/2021	2/17/2021	blood clots on lungs 2 days in hospital on blood thinner for the last 10 days
1074082	3/4/2021	OK	40	F	3/3/2021	3/4/2021	My stomach was hurting while urinating and there was blood in my urine. At another instance, there was a small blood clot.
1074118	3/4/2021	TX	53	M	2/10/2021	2/19/2021	Renal artery blood clot causing renal infarction

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1073412	3/4/2021	FL	79	F	2/23/2021	2/24/2021	Initial flulike symptoms with fever Tues -Friday. Had a right side stroke 6 AM Saturday morning . Rushed to hospital and had a procedure involving a catheter through the body to the clot in the brain. Came out of that with a weekend left side and was medicated through Sunday night. At 10:30 PM Sunday night had a second stroke on the right side. Did not wake from that. Now I?m not expected to survive.
1068013	3/3/2021	KY	42	F	1/29/2021	1/30/2021	Extreme muscle aches; fever; chills; headache; vomiting; This is a spontaneous report from a contactable healthcare professional reporting for herself. A 42-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in the left arm on 29Jan2021 17:15 (at the age of 42-years-old) at single dose for COVID-19 immunization in the workplace clinic. Medical history included endometriosis, acid reflux, and history of blood clots. The patient had no known allergies. The patient was not pregnant. The patient did not have COVID prior to vaccination. Concomitant medication included methyldopa hydrochloride (ALDOMET [METHYLDOPA HYDROCHLORIDE]), omeprazole (PROTONIX [OMEPRAZOLE]), probiotics (PROBIOTICS), cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]) and vitamins. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly in the left arm on 08Jan2021 at 06:15 PM (at the age of 42-years-old) for COVID-19 immunization. The patient did not receive other vaccines in four weeks. The patient experienced extreme muscle aches, fever, chills, headache, vomiting on 30Jan2021 at 11:00 AM. The patient did not receive treatment for the events. The patient was not tested for COVID post vaccination. The outcome of the events was recovered in Jan2021. Information on the Lot/Batch number has been requested.



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1067981	3/3/2021	TX	64	F	1/29/2021	1/1/2021	very active stomach, diarrhea due to problem (nervous)/bowel movement really often; very active stomach, diarrhea due to problem (nervous)/bowel movement really often; Stool being dark is concerning; This is a spontaneous report from a contactable consumer (patient). A 64-year-old female patient received second dose of bnt162b2 (BNT162B2 also reported as PFIZER-BIONTECH COVID-19 VACCINE, lot EL8982), intramuscular in right arm on 29Jan2021 at SINGLE DOSE for Covid-19 immunisation. Medical history included high blood pressure and had insulin resistance. She had her first dose of BNT162B2 on 03Jan2021. Concomitant medication included metformin. She also mentioned 'Candistan Clotrimazole' (not clear nor clarified) something like that, and also took 'Premarin' (not clear nor clarified) it's hormone for menopause. She got the vaccine instead of 21 days it was 26 days. Since when she had the vaccine, her stomach was really active, diarrhea due to problem (nervous). She informed having bowel movements like really often. Today (Jan2021), she already went twice but the thing was she was going and it was like too dark, mentioned that stool being dark was concerning. She took Libertrim S11 Trimebutine Simethicone, for diarrhea. The outcome of events was unknown.

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1068151	3/3/2021	NC	73	F	1/22/2021	1/23/2021	When I cough it was blood in that cough couple of times; Left leg swell up from my feet to all the way up; When I woke up, I didn't know what time, what date, nothing; I was all confused; Feeling achy/ body ache; This is a spontaneous report from a contactable consumer (patient). A 73-year-old female patient received first dose of BNT162B2 (Pfizer COVID vaccine), lot no. EL347, via an unspecified route of administration on 22Jan2021 at a single dose for COVID-19 immunization at a health department because she was at high risk and she was 73. Medical history was not reported. Concomitant medications included unspecified medications. The patient had an injection done 2 weeks, not this last Friday, the Friday before that. They had to make her wait for half an hour before she left and she was okay. Then Saturday (23Jan2021), she started feeling achy but to she was okay. Then Sunday (24Jan2021), she had a very bad experience, she went and start watching TV and she fell asleep. When she woke up, she didn't know what time, what date, nothing. And she looked at the time on her TV and it said 6:45, she didn't know if it was am or pm. And it was dark outside and she didn't know if it was Monday or Sunday. She was all confused, she called someone to make sure what day and time and all and still she was still confused. And then she had to call her aunt and then she told her no it's Sunday and it's night time and so on. Then she got better. Then during the week she didn't have that much body ache, she expected that because that was in that papers. Then today is Sunday, Friday morning (29Jan2021) she got up and she coughed, when she coughed it was blood in that cough couple of times. Then her daughter came over and took her to the hospital (hospitalization details were not clarified). She had lab work the day they took her in the emergency room. At the hospital, they did all kind of tests, on top of that her leg, her left leg swelled up from her feet to all the way up, all the way up. They thought that it could have been some blood clot. And they took test and all and nothing, everything was okay. They couldn't find out why her whole leg was swollen. On top of that, they did chest x-ray and they did something else she can't remember, another test. And they took all kind of blood work and all. And they did to see if she had the virus, the COVID. And yesterday they called her from the hospital and they said that she didn't have the virus. And

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she asked them about the blood work and they told her if there was anything more than they would call her. So, she thinks all this came from that injection. She called because this was not guaranteed if this was from injection. When confirmed that COVID test was negative and blood work report was not out, she stated they haven't called her that meant her blood work was okay. The swollen leg has been gone down and blood once in a while she sees a little bit. They gave her 2 prescriptions, one was antibiotic and one is steroid. Due date for the next shot is 12Feb2021. The outcome of the events was recovering.

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1068231	3/3/2021	PA	70	F	1/3/2021	1/1/2021	wrist pain; wrist pain and it locked up.; little bumps on the back of her hand; Headache; This is a spontaneous report from a contactable consumer (patient). A 70-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE;lot EJ1686) on 03Jan2021 in the morning before 12:00 pm (at 70 years) at single dose in right arm for COVID-19 immunization.Medical history included hypertension from 2002. Concomitant medication included enalapril for hypertension from 2002 (she tried several things-unspecified-before enalapril, took a number of months before she found something to tolerate). The patient on 24Aug2015 (at 65 years) took varicella zoster vaccine live (oka/merck) (ZOSTAVAX) for immunization and experienced shingles (it started a couple months after the shot, she had skin discoloration, black spots over the skin, caused by her bathing suit and the pool water, and it stayed for about 1.5 years, she was using a cream. It was maybe 2 years before it disappeared). Patient received first dose of the vaccine on 03Jan2021, after in Jan2021, she had a headache, a week and half later pain in wrist and wrists locked up, pain floated up to the back of her hand, continued since, locking of wrist stopped, pain continued, little bumps came on the back of hand.Patient added she may have had headache the second day (as reported), it came and went, she didn't pay attention, she had a headache morning and it gone as of 15Feb2021, but still came and went. Wrists locking up recovered before 24Jan2021. Bumps on back of hand started the same time, it came and went, stayed most of last week, still had it this week, about the same.No blood tests done since this happened.Final outcome of headache was unknown. Wrists locking up recovered in Jan2021. Bumps on back not recovered. wrist pain was recovering.Patient took the second dose of the vaccine (lot EN5318) on 24Jan2021 in the afternoon (maybe 2 or 3:00PM) at single dose in left arm for COVID-19 immunization. On 12Feb2021 patient lost part of mobility in the small finger of the right hand, can't lift it all the way above. Patient was scheduled to go to the doctor on 15Feb2021 in the afternoon. Patient saw joint pain listed on contraindications, would like to know the nature of the joint pain described from side effects of the covid vaccine. She was concerned of a blood clot, unsure what happened or what can cause it, was unsure if it was

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muscular or something. Patient would like to know whether blood clots and muscle pain have been reported as a side effect of the covid vaccine.

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1068079	3/3/2021	NY	66	F	1/30/2021	1/30/2021	migraine with flashes of light in left eye; migraine with flashes of light in left eye; gets IBS stuff; has had diarrhea; diarrhea, had a mild version of the diarrhea that seemed to get worse after the vaccine and still ongoing; vessels in hands really dilated and dark blue; This is a spontaneous report from a contactable consumer (patient). A 66-year-old female patient received the first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number EL9264), via an unspecified route of administration (arm left) on 30Jan2021 14:00 at SINGLE DOSE for to have some protection against COVID, at 66 years old. Medical history included connective tissue disorder and anti-cardiac lipid antibody problem; she is prone to blood clots from 2001. At that time, she was sent to the hospital and no one could figure out what it was. She was seeing the Rheumatologist and another person, and they knew something was going on and was given Prednisone (from 2001) because her tissues in the joints were swelling and she had trouble with speech. Patient also reported this as some weird connective tissue disorders already and some anti-cardiac lipid antibody problem. It was really weird and had not changed a bit since so she was kind of checking to see if anyone has reported anything like this. She reported that with this weird antibody problem, she is more prone to blood clots and has to be careful with medications with her blood she knows that some breast cancer medicines can do that. She stated this immune thing was never diagnosed. She also had migraine with globes of flashes of light, left eye (does not typically get migraines and has only had 1 in her life and she saw globes of lights in both eyes and had to go to the emergency room and was told it was an ocular migraine and this was also only in the left eye. This was long ago) from an unspecified date. Concomitant medication included low dose steroid (unspecified). The patient previously received flu vaccine on Sep2020 (AE none). No other vaccines were administered on the same day. On 30Jan2021, the patient experienced vessels in hands were really dilated and dark blue 5 hours after vaccination. On 30Jan2021, the patient also experienced IBS stuff and has had diarrhea the last couple of days after getting the COVID vaccine. She took Pepto Bismol to help and had a mild version of the diarrhea that seemed to get worse after the vaccine and still ongoing.

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On 01Feb2021, the patient experienced migraine with flashes of light in left eye. It was further described as having a weird migraine with flashes of light in the left eye and she got the shot in her left arm and not sure if that makes any difference. She does not typically get migraines and has only had 1 in her life. The migraines started in the morning and lasted about an hour (as reported) and now they are gone and hopes they stay gone (reported as recovering). She wanted to know if she can take TYLENOL or ibuprofen for vaccine. She heard about people getting symptoms after the second dose not the first dose. Events did not require visits to the emergency room or physician office, but stated that if her vision become worse, she would go to the eye infirmary close by. The outcome of the events diarrhea and vessels in hands really dilated and dark blue, gets IBS stuff was not recovered. Outcome of the events migraine with flashes of light in left eye was reported as recovering.

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1068264	3/3/2021	FL	82	M	2/2/2021	2/1/2021	<p>bilateral blood clots in legs that then went to lungs then went into BLAST crisis; bilateral blood clots in legs that then went to lungs then went into BLAST crisis; bilateral blood clots in legs that then went to lungs then went into BLAST crisis; Patient with myeloid leukaemia (CML) and WBCs abnormal received BNT162B2; Patient with myeloid leukaemia (CML) and WBCs abnormal received BNT162B2; This is a spontaneous report from a contactable consumer (patient). An 82-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection (lot number and expiration date unknown) via an unspecified route of administration in the left arm on 02Feb2021, 13:00PM (at 82 years old) at a single dose for COVID-19 immunization. The patient was vaccinated in the Nursing Home/Senior Living Facility. The patient's medical history included myeloid leukaemia (CML) diagnosed a few months earlier, WBCs abnormal, blood pressure, and heart surgery valve repair. The patient has no known allergies. Concomitant medications included atorvastatin, carvedilol, vitamin d nos, dasatinib monohydrate (SPRYCEL) from an unknown date to help get WBCs back in normal range; cyanocobalamin (VITAMIN B12), and cetirizine hydrochloride (ZYRTEC), all were received within 2 weeks of vaccination. At 82 years old, the patient received the first dose of BNT162B2 (lot number and expiration date unknown) via an unspecified route of administration in the left arm on 12Jan2021 at a single dose for COVID-19 immunization. The patient was not diagnosed with COVID prior to vaccination and did not receive any other vaccines within 4 weeks prior to BNT162B2. It was unknown if patient was tested for COVID post vaccination. On Friday (unknown date in Feb2021), patient's WBC was 150,000 and on Saturday (unknown date in Feb2021), patient had bilateral blood clots in legs that then went to lungs then went into BLAST crisis. The adverse events resulted in emergency room/department or urgent care as well as hospitalization due to life threatening illness (immediate risk of death from the events). The patient was hospitalized for 12 days. Therapeutic measures which include steroids, blood thinners, and lots of other meds were administered. Outcome of the events "patient's WBC was 150,000" and "bilateral blood clots in legs that then went to lungs then went into BLAST crisis" was</p>



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							recovering. Information on the lot/ batch number has been requested.
1069009	3/3/2021	PR	94	M	1/21/2021	1/30/2021	Several days after vaccination his left arm turned red. He was taken to the hospital where he was evaluated and admitted with a diagnosis of left axillary vein thrombosis. A chest X-ray was taken and he presented bibasilar atelectasis and pneumonia with pleural effusions.
1069054	3/3/2021	NY	66	F	1/14/2021	1/16/2021	Anxious; Tired; Blood clots in left leg, right leg and brain; A spontaneous report was received from a consumer who was also a 66-year-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and developed blood clots in the left leg, right leg, and brain, anxious and tired. The patient's medical history was not provided. Concomitant medications reported included vitamin D, magnesium, lisinopril, and vitamin B12. On 14 Jan 2021, approximately 3 days prior to the onset of symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number not provided) intramuscularly in the left deltoid for prophylaxis of COVID-19 infection. On 16 Jan 2021, the patient experienced immense pain in the middle of the night, and subsequently saw her primary physician. An ultrasound revealed blood clots in her left leg, right leg and brain. A hematologist and vascular surgeon were consulted. Patient was treated with apixaban while they are doing blood work. The patient also became tired and anxious. She noted that she never had comorbidities before and was upset that her life has completely changed. A repeat ultrasound was scheduled for 19 Feb 2021. The mRNA-1273 dose was discontinued in response to the event of blood clots in the left leg, right leg, and brain, anxious and tired. The outcome of events, blood clots in the left leg, right leg, and brain was considered unknown at the time of this report. The outcome of the events, tired and anxious were considered not resolved at the time of this report.; Reporter's Comments: Very limited information regarding the events has been provided at this time. Further information has been requested.

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1070714	3/3/2021	CA	77	F	2/1/2021	2/1/2021	she was hospitalized 2.5 days after having symptoms of a "massive heart attack" 2 days after the vaccine; blood clot; pain on the left side/pain so bad/ pain was so severe couldn't bent over and couldn't get up; pain was in the heart and underneath the rib; pain was in the heart and underneath the rib; had a little trouble breathing; broke out in a sweat; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect from a contactable consumer (patient). A 77-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number/expiration date unknown), via an unspecified route of administration on an unspecified date in Feb2021 at a single dose for COVID-19 immunization. Medical history included asthmatic, had double pneumonia years ago, has ongoing atrial fibrillation and a pacemaker to control it as the only problem she has in her heart. The patient's concomitant medications were not reported. On an unspecified date in Feb2021, the patient was hospitalized for 2.5 days after having symptoms of a massive heart attack two days after the vaccine. It was reported that two days post vaccination, the patient was rushed to the hospital by ambulance as they thought she was having a massive heart attack. She added her symptoms lasted for hours, she had pain so bad that she was bent over and had a little trouble breathing. She said the pain was in the heart and underneath the rib, on the left side. She later mentioned she did not feel like it was AFib. She said they did every test possible and listed the following ones: ultrasound, stress test, x-ray (unknown results), and blood work in Feb2021. She specified that her blood work indicated a blood clot. She mentioned she was told by her personal friend, who was a doctor, that by having the shot sometimes it indicated you have blood clots when you really don't. The patient also specified that she broke out in a sweat, the pain was so severe that she could not bend over and could not get up; therefore, they treated her as if she was having a massive heart attack for 12 hours at the hospital. It was reported that they kept giving her stuff to stop the effect with her heart. She mentioned her second dose was scheduled on 25Feb2021. She asked if her experience was reported as a side effect to the vaccine and should she get the second dose of the vaccine. She explained the doctors did not know what

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she had, and she needed to determine if she can receive the second dose. She also asked if we could notify her if a similar reaction is reported. The outcome of the events was unknown. Information on lot/batch number has been requested.

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1070763	3/3/2021	CA	66	F	2/18/2021	2/18/2021	<p>large knot right above the injection site/size of a half dollar/size of a silver dollar and where the needle went in was right at the base of that knot/like egg under the skin or clot; felt like she got a flu shot and could tell her arm was very sore; swelling started almost immediately after the shot/swelling was exactly underneath the injection site, just in the pronounced area/about 4 inches wide and about 2 inches high; thought maybe someone has hit a vein because it did bleed and ran down her arm; This is a spontaneous report from a contactable consumer. A 66-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection, lot number: EN6201, unknown expiration), via an unspecified route of administration on 18Feb2021 at 04:30 at a single dose for COVID-19 immunization. Medical history reported as none. Concomitant medications included tolterodine and adalimumab (HUMIRA). The patient reported that she received the COVID vaccine on 18Feb2021 at around 4:30. Firstly it was fine, she felt like she got a flu shot and could tell her arm was very sore. What concerned her was the swelling started almost immediately after the shot on 18Feb2021. She knew that was one of the symptoms. This morning and yesterday though (18Feb2021), she noticed some of the symptoms. She got a large knot that was right above the injection site. Yesterday, it was about the size of a half dollar, today it is about the size of a silver dollar and where the needle went in was right at the base of that knot. It feels like an egg under the skin or a clot. Like a knot (a hard spot underneath the skin). The patient was wondering if it was something she should be concerned about because the swelling was exactly underneath the injection site, just in the pronounced area. It was a rectangle and is about 4 inches wide and about 2 inches high and then right above that was where the needle went in. The large circle or knot was right above that and she was thinking possibly when she was given the injection she has never really bleed before. So, she thought maybe someone has hit a vein because it did bleed and ran down her arm. She got no problem. That happens at times, but she started thinking if this was a clot or it was something that is right above there because it is so pronounced, and it really hurts. The patient stated that she took some Aspirin last night and is going to take an ibuprofen in a little while. She mentioned that she</p>

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1065433	3/2/2021						
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takes this one pill and it has nothing to do with anything. The patient had lab work done (unknown results) that was about 3 weeks ago (2021). She also stated that she also take Humira which is a shot every 2 weeks and it said in the fact sheet that she should be concerned or be sure that she did not take any medicine that affects the immune system and Humira does weaken the immune system but she was not ask that prior to. The patient wanted to know if is that something she should be concerned about. Outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.

stroke; blood clot in the heart; Hospitalization with racing and irregular heart beat; Hospitalization with racing and irregular heart beat; loss of motor function; This is a spontaneous report from a non-contactable consumer. A 46-year-old male patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) (brand=Pfizer) on an unspecified date at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. If other vaccine in four weeks was unknown. Other medications in two weeks was unknown. If covid prior vaccination was unknown. If covid tested post vaccination was unknown. Known allergies was unknown. Historical vaccine included the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) (brand=Pfizer) on an unspecified date for COVID-19 immunization. Patient experienced hospitalization with racing and irregular heartbeat, blood clot in the heart, stroke, loss of motor function on an unspecified date. Treatment included intubation. The outcome of the events was unknown. Events resulted in hospitalization, life threatening illness (immediate risk of death from the event). No follow-up attempts are possible; information about lot/batch number cannot be obtained.

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1064684	3/2/2021	OR	88	F	2/11/2021	2/19/2021	Deep vein thrombosis (DVT) of left lower extremity She reported swelling of her left leg and was seen at Family Medicine Urgent Care on 2/19/2021 and was diagnosed with a thrombosis of the left popliteal vein. She was treated with Xarelto for anticoagulation and compression stockings. Her treatment course was uncomplicated when I saw the patient at follow up and was made aware of her condition at her appointment with me on 3/1/2021.
1065160	3/2/2021	TN		F	2/10/2021	2/13/2021	Stroke; This is a spontaneous report from a contactable consumer reporting on behalf of the mother. An approximately 81-year-old female patient received the second single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EL9264) on 10Feb2021, for COVID-19 immunisation. The patient received the first dose of BNT162B2 vaccine on 23Jan2021 (Batch/lot number: EL3302). Medical history was not reported. Concomitant medications included two unspecified prescriptions. On 13Feb2021 the patient experienced stroke which required hospitalization on the same day. The reporter was not sure of the name but they did a 'CAT' where they went up and pull the clot out of the brain. Event outcome was unknown. The patient was still in the hospital at the time of report. No investigation was performed before the event.

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1065435	3/2/2021	NC	81	F	1/19/2021	1/19/2021	blood clot; death cause: Heart Problems; tired; nauseous; This is a spontaneous report from a contactable consumer. An 81-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number EL3248), via an unspecified route of administration at single dose in the left arm on 19Jan2021 14:00 for covid-19 immunisation. Medical history included heart problems, pacemaker. Concomitant medication included heparin. The patient experienced death cause: heart problems on 20Jan2021, blood clot on an unspecified date with outcome of unknown that required hospitalization, tired on 19Jan2021 with outcome of unknown, nauseous on 19Jan2021 with outcome of unknown. The patient was hospitalized for blood clot from 16Jan2021 to 18Jan2021. The patient died on 20Jan2021. An autopsy was not performed. The events were described as follows: The patient was tired and nauseous about 3 hours after her vaccine. She had been in the hospital 16Jan2021 to 18Jan2021 for a blood clot. The patient died at her home on 20Jan2021 between 4 and 7 pm. No treatment required. The vaccine was administered at Hospital Facility. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19.; Reported Cause(s) of Death: death cause: Heart Problems
1065921	3/2/2021	LA	87	F	1/30/2021	1/31/2021	right middle cerebral stroke due to clot in brain; right middle cerebral stroke due to clot in brain; This is a spontaneous report from a contactable consumer or other non hcp. A 87-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EL9265), via an unspecified route of administration right arm single dose on 30Jan2021 15:00 for covid-19 immunisation. First dose was received on 09Jan2021 03:00 PM, right arm, lot # EK9231. Medical history included diabetes mellitus, hypertension, hyperthyroidism, glaucoma, drug allergy (to Sulfites). The patient's concomitant medications were not reported. The patient experienced right middle cerebral stroke due to clot in brain from 31Jan2021. The patient was hospitalized from 31Jan2021 to 01Feb2021. The events outcome was not recovered.

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1067083	3/2/2021	MA	49	M	2/23/2021	2/24/2021	Early Wednesday morning (2/24) around 5:00AM, I woke up to extreme pain in my left arm, primarily along the upper forearm, inside of my elbow, and lower bicep. There was no trauma or unusual behavior prior to onset of pain. It came on suddenly and worsened with extension of the arm. Symptoms worsened over the next few days, with pain intensifying and extending down into my hand and up into my armpit and shoulder. I tried ice, Ibuprofen, Acetaminophen, and Vicodin for pain relief, but nothing really helped other than the ice. On Saturday morning (2/27), I visited Urgent Care and was diagnosed as brachial plexis neuritis, aka Parsonage-Turner Syndrome by Dr and prescribed Prednisone and rest. On Sunday evening (2/28), I went to the ER seeking pain relief and second opinion. On Monday (3/1) morning, I was seen by ED doctors, and then three different neurologists. After doing an ultrasound which ruled out vein/artery thrombosis, the neuro team diagnosed Parsonage-Turner Syndrome. They've prescribed Gabapentin, Acetaminophen, and Ibuprofen for pain relief, a follow-up neuro consult, an MRI for next Friday, and an EMG in a few weeks. Last night while sitting and reading, the same pain began in my right arm, similarly to how it presented in my left arm last week. The right arm pain is less than the left arm pain, but at this point seven days later, I am experiencing neuropathic pain in both arms.
1068762	3/2/2021		76	M	1/11/2021	3/2/2021	DEATH Narrative: patient's wife reported he had gone in an outside hospital, had held his brilinta as advised anticipating shoulder surgery "and he threw a big clot and died.~~



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1067148	3/2/2021	IL	61	F	1/8/2021	1/9/2021	The next day, when I woke up I was unable to stand on my left leg. Pain in the posterior knee. Felt like I was walking through mud. Joints were all loose. Just a really bad left knee pain. They a lower extremity doppler to that leg - to look for blood clot and that was negative. Physical therapy - taped my knee; pain was so bad I had to stay home a couple of times. My hands (both) were so painful. Like I had frostbite. Occupational therapy did hand massage and paraffin for the pain. And isotoner glove at night and that helps with the buzzing. I am 2 months out today from the vaccine and I'm starting to feel like normal. Took two months to fade away. It may have been because I was still having COVID antibodies. COVID antibodies on August started at 6.95. I'm not totally recovered right now but I'm close to normal. Doctor visit - January 29, 2021 and February 5, 2021, and February 19th. They put me on high dose of Steroids - 20 mgs Prednisone daily and another round of blood thinner -ELIQUIS mg which helped me with pain and joints.
1065118	3/2/2021	WA	58	F	1/23/2021	1/30/2021	Blood clot in lower left leg; This is a spontaneous report from a contactable consumer (patient herself). A 58-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), via an unspecified route of administration on the left arm, at age 58 years, first dose on 23Jan2021 14:00 at single dose for COVID-19 vaccination. Medical history was reported as none. Patient had no known allergies. The patient is not pregnant. There were no concomitant medications. There were no other vaccines administered in four weeks and no other medications taken in two weeks. On 30Jan2021, patient experienced blood clot in lower left leg. ER doc indicated that patient had no reason to have formed a clot given the medical history, health, weight, age, diet, no surgeries, no prior injury, etc. Facility type vaccine was administered at a Public Health Clinic/Veterans Administration facility. Event resulted in emergency room/department or urgent care. Therapeutic measures were taken as a result of the event includes rivaroxaban (XARELTO) as blood thinner. The outcome of the event was not recovered. Information about lot/batch number has been requested.

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1066342	3/2/2021	SC	33	F	2/4/2021	2/15/2021	I ended my normally scheduled menstrual cycle on 02/06/2021, and exactly 6 days later (02/15/2021) I had severe menstrual bleeding with blood clots that has continued to this day (03/02/2021). I went to urgent care and was prescribed Provera to stop the bleeding to no avail. I then proceeded to go to urgent care again because the bleeding had not stopped. At my second Doctors visit, I had an abdominal and a transvaginal ultrasound done, and both of them came back completely normal. I have now scheduled an upcoming obgyn appointment, but cannot be seen until 03/09/2021.
1062101	3/1/2021	TX	56	F	1/26/2021	1/26/2021	Sinus pain congestion; Sinus pain congestion; coughing; tiredness; headaches; chills; muscle pain; feeling unwell; back pain; achy all over; very dizzy; nausea; This is a spontaneous report from a contactable consumer (patient). A 56-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EN5318 and expiry date: unknown), via an unspecified route of administration on the left arm, on 26Jan2021 18:45 at a single dose for COVID-19 immunization. Medical history included High BP, diverticulosis, vertigo and blood clot in artery (healing), allergy to red licorice, hayfever dogs and cats. Patient was not pregnant at the time of vaccination. Concomitant medication included doxycycline, aspirin [acetylsalicylic acid], Multi vit, fiber gummy, and BP meds. There was no other vaccine in four weeks. The patient previously took hydrocodone and prednisone, and experienced allergies. The patient experienced sinus pain and congestion, coughing, tiredness, headaches, chills, muscle pain, achy all over, nausea, feeling unwell, very dizzy and back pain on 26Jan2021 19:30. No treatment was received for the events. Outcome was unknown. Patient was not diagnosed with COVID-19 prior to vaccination and had not been tested since the vaccination.

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1062122	3/1/2021	NC	81	F	1/26/2021	1/26/2021	itching at her head, face and shoulders and the back; This is a spontaneous report from a contactable consumer (patient). An 81-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE lot#: EL9261), via an unspecified route of administration on the right arm on 26Jan2021 10:30 at SINGLE DOSE as COVID-19 immunization at the hospital. Medical history heart attack, ongoing bone disorder (reported as bone), ongoing blood pressure abnormal (reported as blood pressure), ongoing pain in leg, ongoing blood cholesterol abnormal (reported as cholesterol), ongoing allergy, and ongoing blood clots in leg. The patient was also allergic to sulfa. Ongoing concomitant medications included hydrochlorothiazide, triamterene (MAXZIDE) since 2011 (taking for 10 years) and for blood pressure, cetirizine hydrochloride (Zyrtec) from unknown date (taking for long time) for allergy, losartan (LOSARTAN) since 2016 (taking for 5 years) for cholesterol, potassium (POTASSIUM) from unknown date (taking for long time) for pain in leg, metoprolol tartrate (LOPRESSOR) since 2011 (taking for 3 years) for blood pressure, omeprazole (PROTONIX) since 2011 (taking for 3 years) for blood clots in leg, fish oil (FISH OIL) from unknown date and indication, acetylsalicylic acid (ASPIRIN) since 2001 (taking for 20 years) for heart attack, colecalciferol (D3) since 2016 (taking for 5 year) for calcium supplementation reported as (calcium and body build up), and calcium (CALCIUM) from unknown date for bones. The patient first dose of the Pfizer COVID 19 vaccine on 26Jan2021 at 10:30AM in the right arm. She noticed about 9PM last night, she started itching at her head, face, shoulders and back. The itching only lasted for a little over an hour (26Jan2021 10:00 PM). She took some diphenhydramine (BENADRYL) and it helped, gave her some relief. She was fully recovered today 27Jan2021. She was scheduled for the next dose 16Feb2021.

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1062457	3/1/2021	WI	81	M	2/2/2021	2/9/2021	<p>Patient admitted for fatigue, dry throat, generalized weakness, dyspnea on exertion. During hospitalization was identified to have an acute ischemic CVA -- unclear time of symptom onset, possibly evening of 2/9 or morning of 2/10. Time course suspicious for possible COVID vaccine adverse event. He received his first Moderna COVID vaccine on 2/2/21 per WIR. Per PCP note on 2/9/21: Patient is here today accompanied by his wife with concerns for fatigue, headaches, head pressure and tremors. Received vaccine last Tuesday. Around 10 PM that evening he developed pressured in the head. On Wednesday morning, he states he got out of bed and was in a cold sweat - he states he pajamas were soaked in sweat and he felt chilled. He experienced brief numbness of the left arm down to his fingers. On Thursday, he felt fine - he went out to snow blow. Friday he developed headaches and head pressure. At night, he felt his breathing was labored as he was "gasping for air." On Saturday and Sunday, he sat and laid around all day. On Monday, he wakes up at 125 AM and his blood pressure was 165/104 and it remained elevated for 3 separate readings. Patient was then admitted on 2/10/21 with weakness and confusion, then on 2/11 MD noted ?word finding difficulty, slurred speech, possible subtle right upper lip droop, and possibly some mild right hemineglect? with MRI showing likely embolic source of infarcts and cerebral MRA with possible acute thrombus. His symptoms the day after the vaccine seem a bit suspicious for TIA. Per Drug Policy Manager call to Moderna, no current reports of TIA/stroke secondary to COVID vaccine, so time course may be incidental. Patient had echocardiogram without right to left shunt or clot identified, no known history of atrial fibrillation. Was monitored on telemetry for the duration of his hospitalization without any noted arrhythmias, discharged on e patch for 14-day outpatient monitoring.</p>

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1064041	3/1/2021	PA	46	M	1/6/2021	1/9/2021	I woke up on 1/9/2021 with my lower left leg swollen and red and DR said it could be a superficial blood clot. January 9 - ER - Diagnosed cellulitis - round of Ceflex for a week - things got worse. Since January 9, I've had two other separate ER visits and three rounds of CEFLEX. Was referred to Dermatology - Arrhythmia Nodusem - so now I'm off Ceflex and on a steroid regimen now. I just started it today. It hurts to even touch my skin and it hurts to walk. I'm in a lot of pain. I have no open wounds so no reason for this to happen.
1064361	3/1/2021	MI	86	F	2/20/2021	2/21/2021	Four blood clots in left leg
1060991	2/28/2021	CA	82	M	2/23/2021	2/25/2021	Blood clot in left leg, inside next to the knee
1061209	2/28/2021	CA	83	F	2/17/2021	2/20/2021	Sharp pain behind right knee. Subsided by evening. Went to The ER Sunday morning, Feb. 21. They x-rayed leg and found nothing unusual for a woman my age. Then they conducted a scan and discovered a blood clot behind my knee. Since then, I have had intermittent pain. The Doctor referred me to a hematologist which I will see this week. Prior to the vaccination have never had a blood clot. It occurred three days after the vaccination. Coincidence? I think not.
1060112	2/27/2021	UT	58	F	2/5/2021	2/10/2021	I have had 3 bloody noses lasting about a half an hour every 5 to 7 days. I had never had a bloody nose in my life up to this vaccine. They are hard to clot.
1059327	2/27/2021	TX	71	M	1/1/2021	1/28/2021	Moderna COVID-19 Vaccine EUA. PT - Multiple blood clots both lungs (no other presentable causes i.e. diagnosed as unprovoked).

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1059874	2/27/2021	MO	27	F	1/21/2021	2/2/2021	My last period started Tuesday Feb 2nd and did not stop until 14 days later, more than double my usual menstrual cycle. It seemed pretty normal and painless, but then on 8th day I was surprised to find myself still bleeding . It was a darker color around then, but then became brighter and I noticed myself passing clots when I went to the restroom that were loose, but about the size of a quarter or half dollar. I did not bleed through any menstrual pads, but the return of bright red after it being a darker red that im used to at the end of a period had me concerned. I was in slight discomfort around my uterus/bowels and I couldn't tell if it's my body recovering from the vaccine, or something else. I received my second dose of the COVID-19 vaccine 2/11/21 (Pfizer) and stayed home from work as I had a fever/headache/chills (this was not unexpected to me, my coworkers had the same symptoms). Family medical history: grandmother (dad's mom) in remission from stage 4 uterine cancer about 5 years ago. Mom had endometriosis at 45 and had a hysterectomy.
1060219	2/27/2021	OH	89	F	2/5/2021	2/10/2021	Trouble breathing, severe fatigue, blood clots in lung and leg.

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1059465	2/27/2021	CO	77	M	2/25/2021	2/26/2021	Dramatic drop in %SpO2: from a range of 94 - 97, to 88 - 89, with occasional drops to 87. I checked it because I found, even on waking, that I needed to make an effort to breathe more deeply - which did make enough of a difference. In a setting where it would have been available, I am sure I would have received O2. I also had a fever of up to 101.3, and felt "rotten", but not dire. In 2017, I had some sort of incident - I was traveling at the time, and it was never "determined" - that may have been a "scatter" pulmonary embolism - where the clot breaks apart before distributing into the lung. Initially, I did have quite low %SpO2 readings, but over the years that has improved. But these readings were even lower than I had ever seen. I have two oximeters, to, um, verify each other, so I am reasonably confident of their readings. I have a background in physics so I have some experience with instrumentation. This situation continued for perhaps 6 hours, then the fever slowly went down and the %SpO2 increased to 90 ? 91, which was ?manageable?, then slowly higher. It is still lower than it had been, but feels normal enough. Since this dramatic drop in %SpO2 seemed a part of COVID-19 symptoms, I thought this might be significant, and that is why I am reporting it.
1057786	2/26/2021	TN	53	F	1/26/2021	1/27/2021	Within 12 hours of receiving my second vaccine, My left leg felt like it internally rotated and started to hurt and feel like lead. On January 28, 2021, I went to the ER and an extensive blood clot (DVT) was found.
1056011	2/26/2021	TX	75	M	2/7/2021	2/10/2021	My grandpa had a stroke on the 15th of February. He claimed he had been feeling "off" for a few days, but didn't say anything. A blood clot had formed in his brain. He was doing better and about to go to rehab to strength his right side of his body. On the 22nd he took a turn for the worst. He was having trouble breathing and they sedated and partially paralyzed him to put a tube in his mouth. I believe another blood clot had formed and oxygen wasn't properly going through his body. They could not stabilize him, and he passed away the same day.

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1056626	2/26/2021	NC	94	F	1/23/2021	1/23/2021	Vertigo last week that stayed for five days; pain at the injection site; 2 stroke like symptoms/ like she was having a TIA (Reporter confirmed TIA as Transient ischemic attack); Blood Pressure 170/130; Fatigue; Joint ache; Nausea; Vomiting; Fever 100.1; Stress; 2 stroke like symptoms/numbness in her lip; Pervasive aching; Momentary confusion; , like she was having a TIA; Not able to answer questions; she still has not recovered her strength; This is a spontaneous report from a contactable consumer (patient's daughter). A 94-year-old female patient (mother) received 1st dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot# EL1283), via an unspecified route of administration on 23Jan2021 13:00 at a single dose for COVID-19 immunisation. The patient's medical history included ischaemic stroke, haemorrhagic stroke in Aug2019, pulmonary embolism, deep vein thrombosis (DVT), cholesterol, myalgia condition, blood pressure, thyroid, sleep and vertigo. The patient concomitant medications included amlodipine for blood pressure, calcium carbonate/colecalciferol (CALCIUM + VITAMIN D), rosuvastatin calcium (CRESTOR) for cholesterol, levothyroxine for thyroid, eszopiclone (LUNESTA) for sleep medication, ascorbic acid, cupric oxide, dl-alpha tocopheryl acetate, xantofyl, zeaxanthin, zinc oxide (PRESERVISION AREDS 2), prednisone for myalgia condition, and escitalopram. The patient experienced fatigue, joint ache, nausea, vomiting, blood pressure 170/130, fever 100.1, stress, stroke like symptoms, numbness in her lip, momentary confusion; like she was having a TIA; not able to answer questions, tired, pervasive aching, all on 23Jan2021 19:00. Events reported as follow: patient had the Pfizer vaccine on Saturday around 1 pm and Saturday (Clarified 23Jan2021) night she had severe side effects for about 4 hours. When probed for side effects, the reporter stated it increased gradually over time. So, first patient had joint achiness and then she experienced nausea and vomiting. The reporter took her blood pressure. It was 170/130 and so reporter called EMS and they came up and her blood pressure had gone back down to normal and they recorded she had a fever of 100.1. EMS believed that the combination of the 'violence' of the onset and the fever caused her blood pressure to spike but she had a history of ischemic and hemorrhagic stroke. So, the reporter was concerned that the stress



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and whatever that was going on the reaction, the reporter was concerned that it was going to cause her a stroke. Patient had 2 stroke like symptoms, one was that she had numbness in her lip and the second was that she had momentary confusion, like she was having a TIA (reporter confirmed TIA as Transient ischemic attack). The only symptom of that was when the reporter asked her the name of her children she gave the names of her grandchildren but that confusion cleared up quickly and she was fine for a while but not able to answer questions, sharply. By the time that EMS got there patient was sharp again, no problem. For treatment, the reporter gave patient aspirin. The reporter put some Salonpas patches on her joints. It was like the analgesic patch. It was an external patch that patient put on. Patient usually does not need them that was why she was taking the prednisone to treat that kind of pervasive aching. The reporter also gave her the fluids, Gatorade kind of stuff to replace her fluids from throwing up and that kind of stuff. One more thing, it all started with an extreme fatigue but that seem normal but it seemed to lead into the other symptoms. Like it was a big day to go out and get the vaccine. So, she was a little bit tired. This was a very deep fatigue that was part of it too. Reporter stated only 81 aspirin (later clarified as treatment) as she could not go back on blood thinners because she had the hemorrhagic stroke. As of 11Feb2021, it was reported that patient still has not recovered her strength since 23Jan2021 19:00 and was reported as ongoing but improved. On 03Feb2021, the patient had vertigo that stayed for five days and was now improved. The patient was scheduled for the second dose on 13Feb2021. The immediate effects her mother had after the first dose of the vaccine were pain at the injection site; fatigue; fever; nausea. Mentions she also had some confusion and they were worried that the patient might be having another stroke. But all of this cleared up; all of this in a violent episode that lasted about four hours. Today she wants to report that her it took her a week for her mother to recover. Adds her mother could walk for half an hour before the vaccine but since the vaccine she still has not recovered her strength. Adds her mother has only been able to walk about 15 minutes with a walker and resting a lot, for a couple time in three weeks and this was their main way of maintaining her health. Adds her mother

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also had some vertigo last week that stayed for five days but she has had that in the past. Adds actually she still has the vertigo a little and she can tell when her mother bends her head. Outcome of blood pressure 170/130, she still has not recovered her strength and vertigo was recovering, outcome of events pain at the injection site, fatigue, fever, nausea and confusion was recovered on 23Jan2021 23:00; other events was unknown. No investigation assessment. Follow-up (11Feb2021): New information received from the same contactable consumer (patient's daughter) includes: reporter details, medical history, reaction data and course of events.

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1056640	2/26/2021	FL	71	M	1/22/2021	1/26/2021	<p>Lt parietal occlusion; DVT; Right paralysis; This is a spontaneous report from a contactable Nurse reporting for her husband. A 71-years-old male patient received the first dose of bnt162b2 (BNT162B2; Lot # EL 1284) vaccine , intramuscular in the left deltoid on 22Jan2021 17:00 at single dose for Covid-19 immunisation . The patient medical history was not reported. Concomitant medication included apixaban (APIXABAN), acetylsalicylic acid (ASPIRIN) atorvastatin (ATORVASTATIN), cyanocobalamin (CYANOCOBALAMIN), metoprolol tartrate (METOPROLOL TARTRATE) , pantoprazole (PANTOPRAZOLE), sumatriptan (IMITREX [SUMATRIPTAN]), triazolam (TRIAZOLAM). The patient experienced DVT (deep vein thrombosis) on 26Jan2021 with outcome of not recovered , left parietal occlusion (ischaemic stroke) on 26Jan2021 05:30 with outcome of unknown , right paralysis on an unspecified date with outcome of unknown. The patient was hospitalized for DVT (deep vein thrombosis) and stroke from 26Jan2021 to 30Jan2021. The patient underwent lab tests and procedures including blood pressure diastolic: 84 mmhg on 30Jan2021 , blood pressure systolic: 141 mmhg on 30Jan2021 , body mass index: 26.4684 kg/m2 on 26Jan2021 , body temperature: 98.2 °F on 30Jan2021, heart rate: 55 bpm on 30Jan2021 , magnetic resonance imaging: acute left parietal lacunar infarct, Lower extremity ultrasound: left popliteal vein DVT, oxygen saturation: 95 % on 30Jan2021 , respiratory rate: 18 br/min on 30Jan2021. The reporter considered the reported events to be possibly related to BNT162B2 vaccine. Follow up information has been requested.;</p> <p>Sender's Comments: Based on the limited information currently available, a possible contributory role of the suspect drug in the reported events cannot be completely excluded given the known suspect drug profile and/or implied temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>

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1056972	2/26/2021	ME	77	F	1/29/2021	2/4/2021	5-6 days after receiving first Moderna covid vaccine pt. began not feeling well. On 02/10/2021 she saw a provider in an office for eval of abdominal pain and diarrhea and sent home. On 02/15/2021 she presented to a local ED with continuing symptoms, transferred to Medical Center, She is currently an inpatient there with a diagnosis of multiple blood clots in abdomen and brain and antiphospholipid syndrome.

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1058169	2/26/2021	OH	65	F	1/23/2021	1/23/2021	Diagnosed with May-thurner syndrome; Deep vein thrombosis; Both of her feet were only slightly swollen; Dull minor headache; Off-label use; Inappropriate schedule of vaccine administered; Localized discomfort where injection of second dose of Pfizer COVID-19 Vaccine was given; This is a spontaneous report from a contactable consumer (patient). A 65-year-old female patient (weight: 77.56 kg, height: 157 cm) received the second dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) at single dose, in the upper left arm, on 23Jan2021, for COVID-19 immunisation. Relevant medical history included thyroid condition from an unspecified date (over 25-30 years before this report) and ongoing, controlled with levothyroxine sodium (SYNTHROID); and breast cancer from an unspecified date, in 2019 (treatment and surgery on an unspecified date, in 2019. Presumed resolved with radiation treatment, but no treatment within a year prior to getting Pfizer COVID-19 vaccine). The patient previously, on 05Jan2021 (18 days before the second dose), received the first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) for COVID-19 immunisation. After the first dose, the patient experienced localized discomfort at the injection site and swelling of feet. Concomitant medication included levothyroxine sodium (SYNTHROID) from an unspecified date and ongoing, 0.88 mg, daily, for thyroid condition. On 23Jan2021, the patient experienced injection site discomfort described as "localized discomfort where injection of second dose of Pfizer COVID-19 Vaccine was given". On 24Jan2021, she had dull minor headache. On an unspecified date, the patient was hospitalized after the second dose and was diagnosed with May-thurner syndrome. She clarified that May-Thurner syndrome was where the iliac artery collapses and crushed the iliac vein in the upper abdomen; from that point down it started creating a blood clot. She developed a deep vein thrombosis (DVT) from her left ankle up to her right rib cage area; it was a monster. On 10Feb2021, the patient experienced deep vein thrombosis and thrombectomy was performed on the same day (outpatient thrombectomy surgery, performed 10Feb2021. It was a great surgery, very corrective. She never did have any pain or discomfort which confused everyone. She felt fine this whole time, no issues). On an unspecified date, both of her feet were

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only slightly swollen. Relevant laboratory test, performed on an unspecified date, in 2021, included computerised tomogram (CT scan with contrast of her abdomen and chest) that showed deep vein thrombosis: left ankle-right ribcage area. The adverse events May-Thurner syndrome and deep vein thrombosis were assessed as serious, hospitalization required from 02Feb2021 to 10Feb2021. The patient recovered from deep vein thrombosis on 10Feb2021, recovered from headache on 26Jan2021, recovered from swelling of feet and vaccination site discomfort on an unspecified date, while clinical outcome of the other events was unknown. Her vascular surgeon said he did not believe these events were vaccine related but cannot rule it out; her Primary Care Physician absolutely believed the events were vaccine related. The information on the lot number has been requested.

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1058182	2/26/2021	FL	69	F	2/5/2021	2/8/2021	3 days after vaccine started coughing up blood clots. Started off as a couple small clots then within a half hour later I coughed up the size of a quarter Went to ER and then was admitted.; This is a spontaneous report from a contactable consumer (patient). A 69-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number: EL9269), intramuscular at the right arm on 05Feb2021 13:30 at single dose for COVID-19 immunization. The patient's medical history included rheumatoid arthritis (RA), transient ischaemic attack (TIA), atrial fibrillation (AFib), thyroid nodules, and back surgery. The patient's concomitant medications included methotrexate, atorvastatin, rivaroxaban (XARELTO), ergocalciferol (VIT D), and zinc. The patient was not pregnant at the time of vaccination. The patient previously took sulfur and acetylsalicylic acid;oxycodone hydrochloride (PERCODAN). The patient previously received the first dose of BNT162B2 (lot number: EL8982) on 15Jan2021, 01:30 PM at left arm for COVID-19 immunization. On 08Feb2021 23:45, 3 days after vaccine started, patient experienced coughing up blood clots. It started off as a couple small clots then within a half hour later, she coughed up the size of a quarter. She went to the emergency room (ER) and then was admitted for 3 days. The patient underwent lab tests and procedures which included nasal swab: negative on 09Feb2021. The patient had Cat Scans and broncoscopy as treatment for the event. Facility were the most recent COVID-19 vaccine was administered was reported as other. The outcome of the event was recovered on Feb2021.

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1056656	2/26/2021	FL	65	F	1/29/2021	1/29/2021	blew a blood vessel under her eye lid; stroke; tasted rubber band taste in her mouth; This is a spontaneous report from a contactable consumer (patient). A 65-year-old female patient received the second dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EN5318), in a clinic, intramuscularly in the right arm on 29Jan2021 at 14:00 at 65-years-old at a single dose for COVID-19 immunization. There were no prior vaccinations within four weeks of the bnt162b2. Medical history included ongoing fibromyalgia from an unknown date, reflex sympathetic dystrophy from an unknown date and unknown if ongoing, irregular heart beat from an unknown date and unknown if ongoing, ongoing hemangioma from an unknown date, thyroid problems from an unknown date and unknown if ongoing, low white blood cell counts from an unknown date and unknown if ongoing, ongoing pinched nerves in her neck and back from an unknown date, migraines from an unknown date and unknown if ongoing, diastolic heart failure from an unknown date and unknown if ongoing (diagnosed about 5 years ago.), abdominal pains from an unknown date and unknown if ongoing, numbness in her nose, foot from an unknown date and unknown if ongoing, nausea from an unknown date and unknown if ongoing, vomiting from an unknown date and unknown if ongoing. Concomitant medications were not reported. The patient previously received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EL1283) for COVID-19 immunization on 08Jan2021 at 64-years-old and experienced metallic taste (Recovered), carbamazepine (TEGRETOL) from an unknown date to an unknown date and experienced white count was down to 1, influenza vaccine (MANUFACTURER UNKNOWN) in Jul2020 at 64-years-old for immunization. The patient experienced the following events and outcomes: stroke (medically significant) on 29Jan2021 at 14:10 with outcome of unknown, blew a blood vessel under her eye lid (medically significant) on 31Jan2021 with outcome of recovering, tasted rubber band taste in her mouth (non-serious) on 29Jan2021 with outcome of unknown. The clinical course was reported as follows: The patient reported a history of migraines/ weather migraines, that cause numbness in nose and foot as well as gastro-



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intestinal symptoms. The patient received her first dose of the Pfizer COVID vaccine on 08Jan2021 and felt a metallic taste in her mouth (said that the metallic taste lasted about three hours; ate to get rid of the metallic taste). On 29Jan2021, the patient received her second dose; after 10 minutes her face went numb; her nose, forehead, and under her eyes all the way up felt numb. Also, the patient's systolic blood pressure was at 150. The patient reported that she also tasted rubber band taste in her mouth. The patient's neighbor that was there with her getting the vaccine told the nurse and they called the paramedics. The paramedics stated that they thought she had a stroke. She said that her blood pressure was 150 systolic (usually 107-110/79). The patient had diastolic heart failure which was diagnosed about 5 years prior. The numbness stayed with her until about 22:00 on 29Jan2021. The patient had a history of "migraines and gets abdominal pains, numbness in her nose, foot", and she experienced "nausea and vomiting and stuff with her migraines." The patient thought the vaccine just gave her a big migraine. The patient took sumatriptan succinate (IMITREX) and it did nothing. The patient said that on 31Jan2021 her eye felt weird. The patient blew a blood vessel under her eye lid. The patient's eye looked like a blood clot in the corner of her eye then it dispersed throughout the eye and then now it was just below the pupil of her eye. The patient called the doctor on 01Feb2021, but they were out because of the snow. On 02Feb2021, the patient received a call from the doctor's office saying that the physician assistant would call her back, but the patient had not heard anything yet. The blood circulated around her eye and now it was just only under her pupil. The patient said that her daughter sent her something that said that some people have gotten Bell's palsy after getting the vaccine. The patient said that she was concerned about this with the facial numbness. The patient said that every once in a while, her face felt weird; her cheeks feel weird and her nose. The patient said that it comes and goes. The day after she got the second shot, she felt like she got run over by a truck and like someone beat her up. The patient's migraines were under control with magnesium. The migraine came on so quick it was like a boom. The patient said that was why she was concerned. The patient said that she declined going to the hospital; and

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1055819	2/25/2021	AZ	83	F	1/26/2021	1/27/2021	there was no trip to the emergency room or physician office. The patient underwent lab tests and procedures which included blood pressure: 150 systolic on 29Jan2021 (usually 107-110/79). Therapeutic measures were taken as a result of stroke.  On January 1, 2021, patient was admitted to Medical Center with COVID. Tested positive on January 2, 2021. Spent 10 days in hospital. Once recovered from pneumonia and fever gone, on January 10, 2021, she was transferred to Rehabilitation Center for continued treatment. She spent 16 days there. She developed UTI and CDIF infections and was on/off oxygen. She started physical therapy. She was scheduled to be released to go home on January 27, 2021. On January 26, 2021, the day before going home, Rehabilitation Center gave her the Moderna vaccine. On January 27, the day she went home, she started feeling very weak and couldn't walk. My dad tried lifting her and they both fell to the ground. My dad called 911 and she was taken to Medical Center, with high fever and possible stroke symptoms (which later was negative). Two days later, she had difficulty breathing and was put on a ventilator. She was on a ventilator for about three days. They took it off and she slowly started recovering. The doctors did all kinds of tests (blood clot in lung, heart, etc.) and all was negative. The only thing they could trace it to was an adverse reaction to the vaccine. After spending 11 days at hospital and treating her for various infections, her heart stopped and she passed away suddenly.
1053724	2/25/2021	OR	73	M	2/8/2021	2/1/2021	Within a few days after receiving the vaccination I noticed a significant blurring of vision in my left eye. Consulted my ophthalmologist, who diagnosed a central retinal vein occlusion, confirmed with an OCT., and referred me to a retina specialist. Primary care physician started me on Xarelto and referred me to a hematologist. I do not have any history of blood clots.

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1053897	2/25/2021	IA	43	F	1/15/2021	1/15/2021	Pfizer COVID-19 Vaccine EUA Pt received 2nd dose of COVID vaccine 1/15/21. A few hours after receiving vaccine, pt developed shoulder and neck pain. She felt feverish, chills that night but did not check temperature. Over next few days, she developed increasing generalized body aches, joint aches, headaches, weakness, fatigue. On 1/21/21 pt noted SOB and chest tightness, so she reported to ED. She checked her pulse ox and was 99%, was tachycardic to 140-150. She takes propranolol for essential tremor, so she took propranolol 40 mg PO x 1 and presented to ED on 1/21/21. In ED, pt was no longer tachycardic. Pt also states her concern for blood clot (mother had DVT in her 30s). She presented with moderate chest pain and tightness, as well as headache, weakness, SOB. Pt given APAP 1000 mg PO x 1, ibuprofen 800 mg PO x 1, orphenadrine 100 mg PO x 1. Nitroglycerin 0.4 mg SL x 1 ordered, but not given on MD's orders. Pt discharged home. 1/22/21: Pt f/u with hospital. DO says her elevated WBX and Cr were likely d/t vaccine and dehydration. DO offered to schedule f/u BMP and CBC on Monday 1/25. Pt also scheduled for outpt fluids at infusion center on Monday 1/25 in case BMP and CBC still indicate dehydration.
1054106	2/25/2021	CA	69	F	2/16/2021	2/16/2021	2 hours after injection left leg from the knee down started to swell and the muscle turned rock hard Severe pain made it impossible to walk The swelling is not going down and is causing great discomfort went to the doctor yesterday and it was determined there is a blot clot
1054390	2/25/2021	MN	36	F	1/13/2021	1/20/2021	After the first dose I had muscle soreness and a headache the first day, and then it resolved, but, one week later I developed a rash about 4 inches below the injection site that was red, hot to the touch, hard, and painful. It was about 1inch by 4inches. I called my doctor thinking it may have been a blood clot, but she said it will likely go away in a couple days. It did, but, wanted to report it. After the second dose I had the same red rash, but it showed up within the first 12 hours of the vaccine. I was rotating ibuprofen and and Tylenol every 3 hours, so I didn't have a fever, but, I had muscle pain and night sweats for about 5-7 days, with the second night being the worst.

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1054591	2/25/2021	IN	47	M	1/8/2021	1/20/2021	Stroke on January 20th, 2021. Unknown cause for blood clot.
1054874	2/25/2021	KY	61	M	1/15/2021	1/16/2021	Blood clot large in leg DVT and PE both lungs
1053621	2/25/2021	IL	40	F	12/21/2020	12/31/2020	Irregular menstrual cycles (3 periods in 6 weeks); Irregular menstrual cycles (3 periods in 6 weeks) and extremely heavy bleeding; This is a spontaneous report from a contactable nurse reported for herself. A 40 years old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685) via an unspecified route of administration on 21Dec2020 02:45 PM at age of 40 years old in left arm at single dose for covid-19 immunisation. Medical history included there was no known allergies. No covid prior vaccination. And no other medical history. Patient was not pregnant. Concomitant medications were none. Previously there was no other vaccine in four weeks. No other medications in two weeks. Patient experienced irregular menstrual cycles (3 periods in 6 weeks) and extremely heavy bleeding with several clots starting one week after first vaccine. The adverse events started date was on 31Dec2020. Patient had the doctor or other healthcare professional office/clinic visit. There was no treatment. No covid tested post vaccination. Outcome of events were unknown. Patient received the second dose of BNT162B2 (lot number= EL1283) on 11Jan2021 09:15 AM in left arm for covid-19 immunisation.

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1054900	2/25/2021	KS	70	F	2/25/2021	2/25/2021	<p>Progress Notes Family Medicine 2/25/2021</p> <p>Date: 2/25/2021</p> <p>Subjective Is a 70 y.o. female who was seen at a vaccine Clinic today for her first dose of the COVID 19 vaccination. She was given the Pfizer vaccination in the left deltoid muscle. During her 30 minute waiting period after the injection, the patient began to experience nausea, belching, sob. She denied rash, hives, welts, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to blood pressure abnormality , rapid progression of symptoms, respiratory distress and vomiting. PMH: pt reports recently admitted for unstable angina and CAD with tachycardia. Had elevated d-dimer and blood clot was ruled out. Pt dc'd on new medication, beta blocker. Since discharge this Sunday, she reports chest heaviness as if she has "cardboard on my chest." Can slightly increase with going up and down stairs or increased activity. She states she had reached out to her cardiologist via my chart but has not heard back. States her pain is about the same today. Upon 15 minutes after injection, she noted nausea with belching and had some sob. Symptoms worsened as she ambulated over to the medical bay along with her chest pressure.</p> <p>ALLERGY REVIEW OF SYSTEMS: Patient complains of chest tightness and shortness of breath Patient denies chills, malaise/fatigue, sore throat, frequent throat clearing, eyes watering, eyes itching, puffy eyes, eye redness, cough, wheezing, rash, hives, eczema, itching of skin, abdominal pain, muscle aches, dizziness and headaches + nausea and belching: Previous Reactions: none Objective Vitals Vitals: 02/25/21 1000 02/25/21 1008 02/25/21 1013 BP: (!) 157/102 (!) 144/86 (!) 169/94 Pulse: 72 SpO2: 97%</p> <p>Physical Exam Vitals and nursing note reviewed.</p> <p>Constitutional: General: She is not in acute distress. Appearance: Normal appearance. She is well-developed. She is not ill-appearing, toxic-appearing or diaphoretic.</p> <p>HENT: Mouth/Throat: Mouth: Mucous membranes are moist. Eyes: General: Right eye: No discharge. Left eye: No discharge.</p>

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1055374	2/25/2021	MI	30	F	2/23/2021	2/24/2021	<p>Conjunctiva/sclera: Conjunctivae normal. Neck: Thyroid: No thyromegaly. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Breath sounds: Normal breath sounds. No wheezing. Skin: General: Skin is warm and dry. Capillary Refill: Capillary refill takes less than 2 seconds. Findings: No rash. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. Thought Content: Thought content normal. Judgment: Judgment normal.</p> <p>Assessment/Plan Treatment included: She has nitro on hand. We gave that at 10:03 am. Follow up response to treatment: fair. Patient discharge: Transported to ED by ambulance. Differential Diagnosis: Red flag symptoms (CP, SOB, NVD, Visual/Neuro concerns) Firefighters responded first at 1008 Arrived at 1011. EKG done, no acute findings. Pt reports pain at 0 after nitro administration. Belching and nausea reduced. Pt taken to ED for further evaluation. ED called and given report at 1020 Electronically Signed 2/25/2021 10:24 AM</p> <p>Severe pain in my upper back and shoulders. Went to the ER in case of blood clots. Had X-rays and blood/urine tests. Was given Toradol and Norco, but nothing changed. At home switching between heat/ice, and taking prescribed muscle relaxer. Not feeling much better after 12 hours.</p>

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1053606	2/25/2021	MI	53	M	1/21/2021	1/1/2021	Within a week after receiving the first round of vaccine I have developed two blood clots in my left leg.; This is a spontaneous report from a contactable consumer (patient) A 53-year-old male patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EL3248) on 21Jan2021 at single dose via an unspecified route of administration on right arm for COVID-19 immunization. The patient didn't have medical history or concomitant medications. On an unspecified date in Jan2021 within a week after receiving vaccine patient developed two blood clots in his left leg. As treatment patient was currently on blood thinners. At the time of the reporting event outcome was unknown.
1055755	2/25/2021	WA	28	M	2/23/2021	2/24/2021	On 02/24 wake up to fever of 101.4 and severe body aches and took day off from work. On next day woke up to nose bleeding with lot of clots coming out of my nose. Only medication i took was OTC ibuprofen that i took month ago as well for fever.
1051015	2/24/2021			F			a heart attack; I had a blood clot in my lung; stabbing pain in chest; This is a spontaneous report from a contactable consumer. A 76 years old female patient first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) on an unspecified date at single dose via an unspecified route of administration for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. About 30 hours after 1st dose of vaccine the patient experienced stabbing pain in chest wall, quite persistent. At first she thought was having an heart attack. Hurt too much to move. Had to lay down. Thought she had a blood clot in her lung severe for 2 days, moderate for 2 day. It was dissipated after 6 days. The patient was scheduled for second dose on 20Feb2021. The patient recovered from the events on an unspecified date. Information about Batch/Lot number has been requested.

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1051429	2/24/2021	OH		U	2/1/2021	2/1/2021	bad nose bleed/It's bleeding in the back of my nose; the clots are so big that I gag when I expel them; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 on 01Feb2021 at single dose for covid-19 immunization. Medical history was not reported. Concomitant medications included warfarin sodium (COUMADIN). On 02Feb2021, patient had a bad nose bleed which patient stopped. On 03Feb2021 patient was ok and on 04Feb2021 patient got a nose bleed that patient could not stop and still have to be careful and not do anything as it starts all over again. It's bleeding in the back of nose also and the clots are so big that patient gag when patient expel them. The outcome of the event was not recovered. Information on batch/lot number was requested.
1052373	2/24/2021	PA	38	M	1/23/2021	2/3/2021	Blood clot on lung after experiencing chest pain; This is a spontaneous report from a contactable consumer reported for himself. A 38-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 23Jan2021 14:00 on Arm left at single dose (Lot # EK9231) for covid-19 immunisation. Prior to vaccination, was the patient did not diagnose with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient with confirmed blood clot on lung after experiencing chest pain/chest tightness/left sided, thought that he was having a heart attack, shortness of breath on 03Feb2021, reported as non serious. Emergency room/department or urgent care. Blood thinner received for the events. Outcome of the events was unknown.



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1051004	2/24/2021		50	F			blood clot; This is a spontaneous report from a contactable consumer. A 6-decade-old female patient (in her 50's) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose as vaccine. Medical history and concomitant medications were not reported. It was noted that one of the reporter's co-worker developed a blood clot after receiving the first dose of the Pfizer vaccine on an unspecified date. Any information or data on someone developing blood clots? The outcome of the event was unknown. Information on the lot/batch number has been requested.
1052845	2/24/2021	CA	73	M	2/1/2021	2/1/2021	Blood clot in left arm.
1053127	2/24/2021	CA	82	M	2/13/2021	2/14/2021	patient developed unprovoked deep venous thrombosis in left leg one day after receiving 2nd Moderna vaccine
1285007	2/24/2021	MA	82	M	2/2/2021	2/6/2021	Diagnosed with CML few months ago and taking Dasatinib daily with great response and normalized WBCs. Had second dose of Pfizer vaccine 2/2. Blood work on 2-5 WBCs 150K and 2/6 bilateral blood clots in legs which then became pulmonary blood clots.
1053191	2/24/2021	IN	67	F	2/8/2021	2/11/2021	Vaccine administered 02/08/2021 , by Thursday 02/11/2021 patient almost nonverbal, by Monday 02/15/2021 patient went to the hospital with bruising, sores on her stomach and clots reported as thrombocytopenia, deceased by Friday 02/19/2021.
1052711	2/24/2021	WI	92	F	1/27/2021	2/24/2021	The patient has developed an acute deep venous thrombosis in the right popliteal and trifurcation vessels of the calf. She has an elevated d-dimer of 14,738 and acute hypoxic respiratory failure due to pulmonary embolism.
1052023	2/24/2021	CT	70	M	2/10/2021	2/20/2021	large lower extremity deep venous thrombosis and small pulmonary embolus; outcome: responded well to anti-coagulants, with decreased pain, swelling and improved oxygenation

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1048211	2/23/2021	NY	64	M	1/16/2021	1/24/2021	<p>a genitourinary infection (UTI)/diagnosed with a gram negative urinary tract infection; iron level was low at 21. He said a normal iron level for a male is 35; couldn't walk afterwards; Tiredness; another soft tissue injury; Headache; left eye was totally blurry/ one eye blurriness; has severe eye dryness; Injection site pain; Injection site redness; injection site puffiness; stated he noticed at around 2:30PM-3:00PM he had a rash on his hip and back; shingles/ shingles pain; a fever of 100.4 Degree F/Fever; This is a spontaneous report from a contactable pharmacist (patient) reported similar events for two patients. This is the first of two reports. A 64-year-old male patient receive first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3246), at same age intramuscular in arm left on 16Jan2021 11:00 at single dose for COVID-19 immunization. Medical history included fallen at work and landed on his left side, hitting his head and left knee, a knot on the left side of his head, bleeding from above his left eyebrow, had a left black eye, all on Nov2020, subarachnoid hemorrhage, cataract surgery, using crutches when he walks, in the hospital from Nov2020 to 17Nov2020, pacemaker implanted while he was in the hospital on Nov2020, he couldn't walk on 19Nov2020, 6 stents, 3 cardiac stents on Oct2020, and chicken pox as a young adult. Concomitant medication included aspirin [acetylsalicylic acid], clopidogrel bisulfate (PLAVIX) from unspecified date to 27Jan2021 for 6 stents, paracetamol (TYLENOL, 500 mg, caplets, NDC Number: 5058044936, Lot Number: SJA066 and Expiration Date: Jul2024). The patient said he received his first COVID-19 Vaccine dose on 16Jan2021. He said at the time he pre-medicated with 2 paracetamol. He said he had read afterwards that it is not recommended to pre-medicate with Tylenol before receiving the COVID-19 Vaccine. On 24Jan2021 he developed a fever of 100.4 Degree F (body temperature). He stated his fever was 8 days after receiving his first COVID-19 Vaccine dose. On 27Jan2021, he was urinating blood/blood clots and was admitted to the hospital and treated for a UTI. He was diagnosed with a genitourinary infection (UTI). He clarified on the morning of 27Jan2021 his urine looked darker than normal. He said he went to physical therapy (PT) on 27Jan2021. He said when he came back from PT, and went to the bathroom, there was blood and blood clots in his urine.</p>

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He said he called his urologist, and his urologist saw him on 27Jan2021. He said his urologist took a urine sample, and his urine sample was clear and negative for nitrites. He clarified his urologist did a digital prostate exam, and his prostate was fine. He said his urologist wanted him to make an appointment for a cystoscopy, and a CAT scan of his abdomen and pelvis. He said after he got home from the urologist, he went to the bathroom, and again had blood and blood clots in his urine. He went to emergency room. While he was in the Emergency Room, he was set-up on CBI (Continuous Bladder Irrigation). He said the urologist did not seem concerned about the amount of blood in his urine. He clarified he was admitted to the hospital, and had in place for approximately 16 hours. Next day (28Jan2021) he was diagnosed with a gram negative urinary tract infection. He said he was given a daily dose of IV Ceftriaxone 1gram on 29Jan2021 and 30Jan2021. He said he was also given a daily dose on 29Jan2021 and 30Jan2021 of IV Ferlecit 125mg because his iron level was low at 21. He said a normal iron level for a male is 35. On 31Jan2021 he had injection site pain in his left arm, he said the COVID-19 Vaccine injection site was red and puffy. He said the COVID-19 Vaccine injection site pain, redness, and puffiness resolved on the same day, 31Jan2021. He said his second COVID-19 Vaccine dose was given in the same arm (left) on 06 Feb2021. He stated he asked that the second COVID-19 Vaccine dose be given in the same arm (left) because his left arm is his non-dominant arm. He was discharged from the hospital on 30Jan2021, and was given a prescription to take 1 Levaquin 250mg orally for 3 days starting on 31Jan2021. He said the Levaquin 250mg was dispensed in a pharmacy bottle, and did not have the NDC, Lot, and Expiration Date. He said he was also prescribed oral Feosol 325mg, twice a day, starting on 31Jan2021. He provided the Feosol 325mg, NDC Number: 12451-10-17 (unsure if he provided the correct NDC), Lot Number: 201167, and Expiration Date: Jul2022. At around 2:30-3:00PM on 31Jan2021, he developed a rash on his hip and back, saying the hip and back rash were along the same pathway. He said he spoke to a PA (physician assistant) about his rash. He said on 31Jan2021 he had taken 1 oral dose of the Levaquin 250mg. He said the PA discontinued the oral Levaquin 250mg, and changed his

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prescription to Macrobid 100mg, twice a day, for 5 days. He said he started the Macrobid 100mg, twice a day, on Monday, 01Feb2021. He said he completed the Macrobid 100mg prescription on Sunday, 07Feb2021, and did not have the Macrobid 100mg NDC, Lot and Expiration Date. He clarified his rash was raised, oozy, and looked weird, like a pimple that came to head. He said he spoke to his dermatologist on a video call Sunday, 31Jan2021. He said his dermatologist told him he had shingles and prescribed Valtrex 1gram, three times a day, for 7-10 days. He stated the Valtrex 1gram was dispensed in a pharmacy bottle. He said he took his first Valtrex 1gram dose on Sunday evening, 31Jan2021, and was still taking the Valtrex 1gram as of today (08Feb2021). He had an appointment to see his dermatologist in person on Wednesday, 03Feb2021, but woke up with a wicked headache that morning, so he took paracetamol and went back to sleep. He said when he woke, he still had headache, and his left eye was totally blurry. He said back in Nov2020 he had fallen at work and landed on his left side, hitting his head and left knee. He said his fall left him with a knot on the left side of his head, and he had bleeding from above his left eyebrow, and had a left black eye. He said he also had a subarachnoid hemorrhage. He said he had a CT scan of his head that showed the subarachnoid hemorrhage was contained, so the doctors wanted to just monitor him. He said he was on Effient at the time and the doctors changed him to Plavix. He said he also was taking Aspirin 81mg. He said he was taken off of Plavix on 27Jan2021 when he was admitted to the hospital for having blood and blood clots in his urine. He said he continues to take the Aspirin 81mg daily. He clarified he has been on compensation since his fall in Nov2020. He said he also had cataract surgery 2 years ago. He said he immediately called his eye doctor, and then went to the hospital Emergency Room because he thought he had a stroke. He said the Emergency room did a CAT scan and CTA of his head, which were both normal. He said a neurologist saw him in the Emergency Room, and said since it was a headache with one eye blurriness, he should see his eye doctor. He said the neurologist told him if he had a headache and both eyes were blurry, it would more likely have been a stroke. He stated when he was discharged from the Emergency Room on

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03Feb2020, he went directly to his eye doctor. He said his eye doctor did several tests: field of vision, a sonogram, pictures of his left eye, and a dilation of his eyes. He said he had an eye test where he looked at a half circle and clicked a counter when he saw dots, and another eye test where he stared at something that looked like a hot air balloon, while the eye doctor took measurements. He said the eye doctor also measured his eye pressure, which was normal. He said he was at his eye doctor's office for a good couple of hours. He said his eye doctor told him that he has little white dots on the background area of his eyes that indicates he has severe eye dryness. He said his left eye is much worse than right eye. He said his eye doctor asked him if he took Crack, or Cocaine, or any kind of opioids in the last few weeks. He said he told his doctor he took 1 dose of an opioid on 31Jan2021 because of the shingles pain. He clarified he had a Percocet prescription leftover from his hospitalization in Nov2020. He said he took another dose of the Percocet the week before 31Jan2021 for pain in his knee from the fall he had in Nov2020. He said his eye doctor told him his dry eyes could be caused by the Percocet. He said his eye doctor prescribed lubricating eye drops (Refresh Optive Mega 3, UPC Number: 0023577330, Lot Number: T095, and Expiration Date: Aug2022), that he is to use in both eyes every hour, and an eye ointment in his left eye only at bedtime. He had been using crutches when he walks because of the problem with his right knee since he fell in Nov2020. He said on 06Feb2021, he took a shower, and when he went to get out of the shower, his right leg gave out. He said he didn't fall, but he couldn't walk afterwards. He said he went to the Emergency Room on 06Feb2021, and an x-ray and sonogram were done of his right knee. He said he was told he had another soft tissue injury like he had when he fell back in Nov2020. He said he was given a leg immobilizer to use. He said when he first fell in Nov2020, he originally fell on his left knee. He said he has had PT since being discharged from the hospital on 17Nov2020. He said he also had a pacemaker implanted while he was in the hospital in Nov2020. He said after his discharge from the hospital on 17Nov2020, he went to take shower at home on 18Nov2020 and his left knee gave out. He said he was able to lower himself to the floor in the shower stall, but he couldn't get out of the

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shower stall. He said he was left sitting on his left leg and he couldn't use his right leg. He said he finally got himself to bed, and iced his right knee because he sat on it for over an hour. He said the next day (19Nov2020), he couldn't walk and had to have an ambulance take him to Emergency Room. He said he hasn't had PT since 27Jan2021, and needs clearance from his doctor before he can restart PT. He said he has been without PT for 2 weeks now. He said on 06Feb2021 he was unable to get a MRI on his knee because he had too much swelling that would have made the MRI imaging cloudy. On 06Feb2021 he was due for his second COVID-19 Vaccine, so before he was discharged from the Emergency Room he was given his second COVID-19 Vaccine dose. He was using the Refresh Optive Mega 3 eye drops constantly now. He said he had no fever, but is more tired than in the past. He said the last couple of days he can sleep for hours, and wake up and feel like he can go right back to sleep. He said he and his cardiologist are concerned because since 27Jan2021, he has only been on Aspirin 81mg. He said he has 3 cardiac stents since Oct2020, and should be on dual therapy. He said he had a CT of his abdomen and pelvis while he was in the hospital. He said he has been off of Plavix since 27Jan2021, and can restart the Plavix until he has a cystoscopy. He wants to know if UTIs in men are common after getting the COVID-19 Vaccine, so he can decide if he should cancel the cystoscopy and restart his Plavix. The second COVID-19 Vaccine Lot number as EL9261 or EI9261. He stated the vaccine lot number was handwritten on his COVID-19 Vaccine immunization card and was difficult to read the handwritten vaccine lot number. The patient underwent lab tests and procedures which included bacterial sepsis: gram negative urinary tract infection on 28Jan2021. Clarified he had no pain, burning, or urgency with the UTI. He said he was told by the hospital he had gram negative rods in his urine, when he was started on the IV Ceftriaxone on 29Jan2021. He stated he has never had a UTI before. Clarified his body temperature is rarely 98.6 degrees, and is normally 98.2 degrees and he had never had shingles before. He said he had chicken pox as a young adult, and he only had 1 spot of chicken pox. He had never had dry eyes before. Reporter seriousness for fever, UTI, injection site pain, injection site redness, injection site puffiness, rash,

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shingles were medically significant. For other events were unspecified. The outcome of event injection site pain, injection site redness, injection site puffiness was recovered on 31Jan2021, dry eye, tiredness was not recovered, while the outcomes of other events were unknown.; Sender's Comments: Based on the temporal association and the known possible local reaction, a possible contributory role of BNT162B2 to the development of injection site pain, redness, and puffiness cannot be excluded. The other events are considered as due to underlying or intercurrent conditions and unrelated to the use of BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021134924 same reporter/drug, different patient, similar event

1049150 2/23/2021 MI

85 M

1/31/2021

2/9/2021

Feb 9, patient was light-headed, as if he was going to faint. He did not have appetite. Evening of Feb 9, started vomiting large amounts of blood. Ambulance took him to hospital. CT scans showed abnormally enlarged pancreas. Patient aspirated blood and was put on a ventilator for 48 hrs. Endoscopic ultrasound showed ulcers in stomach that appear to have been bleeding, which were clipped and shot with epinephrine. After being treated for ulcers, patient developed blood clots in leg and lungs. It is almost two weeks since initial emergency, and patient is still showing sings of internal bleeding (low blood pressure, low hemoglobin, blood in stool). Still no firm explanation for continued bleeding. Before adverse event on Feb 9, patient did not report other symptoms from shot, however, he did show unusual signs of large bruising on his arm. Patient is currently at Hospital. Blood thinners are being discontinued, but patient still has blood clots.

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1049328	2/23/2021	CO	61	F	1/13/2021	1/22/2021	sudden onset pain left armpit radiating down to elbow and into left breast and back. Severe. Treated at ER with percocet and turadol and aspirin. Tested for blood clots, heart attack, lymph node anomaly. Everything tested came back as normal. Sent home. Used naproxen and hydrocodone and ice at home. discomfort continues but is bearable now (next day) with drugs and ice. Note: Took monthly Cosentyx shot on Feb 20, 2021.
1049931	2/23/2021	NM	66	F	1/22/2021	1/24/2021	2 days after vaccination right thighs and right leg started to have pain similar to pain I got with polymyalgia rheumatica that I have had in past and I thought it was a flare up. A couple of days after that right leg started to swell and was warm. Went to ER on 1/29/2021 and had doppler which showed blood clots from groin area to below the knee. I was placed on Xarelto at that time. Got 2nd dose and about 24 hours latter back of thighs started to hurt again. Called doctor and applied heat and elevation and had no new swelling but I remain on Xarelto. Not sure if it was related but I have had no history of blood clots. 2 years previously broke my right patella and was with brace and no weight bearing for about 8 weeks and brace for 12 weeks without clot issues. Traveled by car a couple thousand miles last year and no issues.
1049991	2/23/2021	CT	96	M	2/12/2021	2/16/2021	4 days after receiving the vaccine in his left arm, my father developed a blood clot in his left arm that required emergency hospitalization and large doses of blood thinners.
1050154	2/23/2021	AZ	77	M	2/3/2021	2/13/2021	Pulmonary Embolism right lung and blood clot in right leg. No travel or other events or activities are known that might have contributed to blood clots in leg and lung. Symptoms of embolism first appeared about 10 days following 2nd dose of Pfizer vaccine.



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1048814	2/23/2021	FL	81	F	1/20/2021	1/27/2021	DELAYED LOCAL REACTION AT INJECTION SITE, WITH MUSCULAR INVOLVEMENT, STILL PRESENT FIVE (5) WEEKS.AFTER INJECTION 1- SEVERE PAIN IN LEFT ARM, INCREASING OVER TIME, LIMITING MOVEMENT; 2-SWELLING IN THE AREA AROUND INJECTION SITE; 3- AREA WARM TO THE TOUCH; 4-RUBOR IN THE AREA. SYMPTOMS SUGGESTED DEEP VENOUS THROMBOSIS, BUT ULTRASOUND FOUND NO CLOTS.. ANOTHER POSSIBILITY COULD BE BICEPS TENDONITIS, BUT ETIOLOGY NOT CLEAR. MEDROL GIVEN FOR 5 DAYS DECREASED SYMPTOMS, BUT SWELLING, RUBOR, AND PAIN PERSIST FIVE WEEKS AFTER INJECTION. SEVERE LOCAL REACTION TO INJECTION, AFFECTING MUSCLE?
1049035	2/23/2021	OH	81	F	2/13/2021	2/21/2021	On Sunday, February 21 at 07:42 AM I received a call from patient advising me she had called for an ambulance, she was awoken from her sleep with a rapid heart beat and was also suffering from shortness of breath. Patient was taken to Hospital where she was admitted due to a Pulmonary Embolism, a small clot was found in her lung.

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1048691	2/23/2021			M		2/7/2021	<p>White blood cells went up greatly; Blood clots in his legs; oxygen went down/oxygen levels went down; This is a spontaneous report from a contactable consumer (patient's daughter). A male patient of an unspecified age received second dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot/batch number and expiry date were not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. Medical history included he had Leukemia and was on treatment. The patient's concomitant medications were not reported. The patient took first dose bnt162b2 for COVID-19 immunization. Caller says that her father got his second COVID vaccine from Pfizer. He wound up in the hospital 3 days later. His white blood cells went up greatly and he has blood clots in his legs. They do not know what is happening. They are very worried about him. He is getting a bone marrow test today (08Feb2021). His oxygen went down yesterday (07Feb2021) and is now on oxygen. She is freaking out about it. She really thinks it has to do with vaccine. It was asked if there was any information on other people with Leukemia getting the vaccine. If what research there was on this. They need all the help and information they can get. Every minute counts as everything getting worse. He is now on oxygen as his oxygen levels went down. He is getting worse every hour. The patient underwent lab tests and procedures which included oxygen saturation: his oxygen went down yesterday/oxygen levels went down on 07Feb2021, white blood cell count: his white blood cells went up greatly on an unknown date, biopsy bone marrow: unknown results on 08Feb2021. Reporter seriousness for White blood cells went and Blood clots in his legs up greatly was hospitalization. Therapeutic measures were taken as a result of oxygen went down. The outcome of the events was not recovered. Information on the lot/batch number has been requested.</p>

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1048205	2/23/2021			M	2/2/2021	2/1/2021	he has chronic myeloid leukemia - white blood cell count is higher; His oxygen is low; Blood clot in his legs; first dose on 19Jan2021 and second dose on 02Feb2021; first dose on 19Jan2021 and second dose on 02Feb2021; This is a spontaneous report from a contactable nurse reported for her father that an 82-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 02Feb2021 at single dose for covid-19 immunisation. Medical history included chronic myeloid leukemia (CML). Concomitant medications were not reported. Patient previously received first dose of BNT162B2 on 19Jan2021 at single dose for covid-19 immunisation. Patient received Pfizer-BioNTech COVID-19 Vaccine first dose on 19Jan2021 and second dose on 02Feb2021. Two days after second dose (04Feb2021) he had to go to the hospital - he had chronic myeloid leukemia - white blood cell count was higher (Feb2021), he had been in the hospital for the last 3 days as of 08Feb2021, his oxygen was low, had a blood clot in his legs, had a bone marrow biopsy, all on an unspecified date in Feb2021. The nurse is taking its related to this vaccine and assessed this case as not serious. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
1047820	2/23/2021	OR	37	M	1/7/2021	1/12/2021	37yo male with no cardiac risk factors had spontaneous dissection of rt coronary artery 5 days post vaccination w associated MI requiring 3 drug eluting stents and "extreme" clot burden on cath requiring tPA.
1048812	2/23/2021		74	F	2/11/2021	2/19/2021	8 days after vaccination - stroke/full right side of body paralyzed - clot buster drug at ER

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1047631	2/22/2021	NE	42	F	1/11/2021	1/13/2021	Two days after the 2nd injection I started to have chest pain and not feel right. I went to the Station where I volunteer. I did and EKG which showed Anterior Infarct. I went to the ER. They gave me 4 baby aspirin to take and some blood work. I was told the blood work showed elevated levels consistent with a blood clot as well. I had a CT scan to rule out a clot in my heart or lungs. Which it was negative. I was released and told to see a cardiologist in the next few days. I saw the cardiologist two days later who said I ended up with Pericarditis and that it should resolve on its own. I was feeling better until two days ago when I developed chest pain again. I again went to my fire station I volunteer for and did an EKG which showed Anterior Infarct. I am currently waiting for treatment from my cardiologist.
1047576	2/22/2021	CA	67	F	1/29/2021	1/29/2021	diarrhea            low gas pain            chills / sweating            dry mouth            sleepy no apatite            cough with phlegm            dizzy loss of bladder control blood clots in nose mucus
1046979	2/22/2021	OH	30	F	1/26/2021	1/27/2021	Extremely short of breath O2 was in low 90s and pulse was 130+ . Labs drawn and D-dimer was elevated . No active clot was found by the time I got to ER and seen . Due date June 11th 2021
1045951	2/22/2021	OH	65	F	1/29/2021	2/2/2021	Stroke in third branch of middle cerebral artery and intramural clot of right carotid artery

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1045548	2/22/2021	CA	87	F	1/16/2021	1/17/2021	blood clot in the lungs; UTI; COVID-19; Fatigue; Loss of appetite; A spontaneous report was received from a consumer concerning an 87 years-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced blood clot in the lungs/MedDRA PT: pulmonary embolism, loss of appetite/MedDRA PT: appetite lost, UTI/MedDRA PT: urinary tract infection, COVID-19/MedDRA PT: COVID-19, and fatigue/MedDRA PT: fatigue. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. The patient received their first dose of two planned doses of mRNA-1273 (Lot# 041L20A) in left arm (route of administration not provided) on 16 Jan 2021 for prophylaxis of COVID-19 infection. On 17 Jan 2021, the patient experienced fatigue and loss of appetite. On 24 Jan 2021, patient experienced UTI and tested positive for COVID-19. On 31 Jan 2021, the patient was hospitalized and was found to have a blood clot in the lungs. Treatment details were unknown. Action taken with mRNA-1273 was unknown. The outcome of events blood clot in the lungs, loss of appetite, UTI and COVID-19 were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
1047435	2/22/2021	OR	41	F	2/14/2021	2/15/2021	deep vein thrombosis in lower left leg; mild fever; fatigue; body aches all in the day following injection DVT persists and was diagnosed 6 days later; all other symptoms resolved within 24 hours

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1044020	2/21/2021	IN	70	F	2/11/2021	2/11/2021	Flu like symptoms about 4 hrs after vaccine(Thurs)...left arm, muscles, joints hurt, chills, tired, not feeling well. most symptoms disappeared after 24 hr however right ankle and leg continue to hurt (FRI and SAT) and by Sun. calf on right leg hot red and swollen. Mon called my physician and went to hospital for sonogram on right leg. Results were a blood clot on the back of my leg from ankle to knee. Xarelto was prescribed as blood thinner and taken. Tuesday appt. with Doctor for consultation and blood work was prescribed with follow up appointment March 2 . My concern is taking second dose of Pfizer vaccine on Mar 4. My doctor and I will discuss. On internet others have reported this same side affect of blood clots from 2 days to 2 wks after. This needs to be addressed.
1044071	2/21/2021	NE	38	F	12/16/2020	12/25/2020	I had a major stroke on 12/25/2020, 9 days after receiving the vaccine. I had a clot in my MCA. My left arm was completely flaccid, with left facial droop and garbled speech. Thankfully I was able to receive TPA that day, which resolved all of my symotoms.
1044102	2/21/2021	OH	77	M	2/9/2021	2/15/2021	Shortness of Breath causes by multiple large blood clots, put on blood thinners, seems to be fine, but has follow up appointment in March
1044799	2/21/2021	CA	73	F	2/8/2021	2/8/2021	Blood clots in left leg diagnosed in Hospital, , emergency room 02/08/2021, about 5 hours after first vaccine. Treated with eliquis. History of prior embolus and blood clots. Referred to primary physician who referred me to a vascular surgeon and a hematologist. For about 3 days extremely tired and slept quite a bit. I already have rotator cuff injury of arm where I got shot so pain was not able to be separated from rotator cuff pain. No temperature, rash, redness or swelling of injection site.
1040874	2/19/2021	MN	65	M	1/30/2021	2/6/2021	Within one week of receiving vaccine, experienced shortness of breath and chest tightness on exertion, lightheadedness, tachycardia. Became increasing worse over next 5 days. Visit to ER on 1/18/21. Diagnosed with many bilateral pulmonary emboli with clots in both pulmonary arteries. Admitted to hospital and started on Eliquis. Had doppler on legs which showed DVT.

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1040920	2/19/2021	FL		F	1/8/2021	2/5/2021	Do not feel that the medication was delivered into arm; Heard a click as withdrew the needle, fluid squirted; Do not feel that the medication was delivered into arm; A spontaneous report was received from a consumer concerning a 73-year-old female patient who experienced heard a click as withdrew the needle, fluid squirted and do not feel that the medication was delivered into arm. The patient's medical history included cancer. Products known to have been used by the patient, within two weeks prior to the event, included blood pressure medication, rapid heartbeat medication, medication for a blood clot in their lung, vitamins and minerals The patient received their first of two planned doses of mRNA-1273 on 08 Jan 2021. On 05 Feb 2021 the patient received their second of two planned doses of mRNA-1273 (LOT #031L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. Patient had their first dose of the Moderna vaccine on 08Jan2021 in their left arm, and their second dose on Friday 05Feb2021 in their right arm, both at the Health Department. During the administration of the second dose, the patient heard a click noise, and as the syringe was pulled out they noticed some fluid came out. Patient wants to know if they got the full dose, or not, and what to do regarding this. Patient provides consent for Safety to follow up Lot# for the second dose is 031L20A. Treatment information was not provided/unknown. Action taken with mRNA-1273 in response to the event(s) was unknown. The outcome of heard a click as withdrew the needle, fluid squirted and do not feel that the medication was delivered into arm was considered as resolved on 05 Feb 2021.; Reporter's Comments: This report refers to a case of Vaccine underdose and Wrong technique of vaccine administration for mRNA-1273, lot number 031L20A, with no associated AEs.

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1041402	2/19/2021		21	F	1/26/2021	1/26/2021	Pt reports receiving dose #1 of the COVID-19 vaccine (Moderna) on 1/26/21. She reports feeling intense abdominal cramping that evening into the next morning, and she reports starting her menstrual period that morning. The pt continued to have 2-3 days of heavy menstrual bleeding then 2-3 weeks of intermittent passage of menstrual blood and clots with continued cramping. The pt has been receiving depo provera injections on time for approximately two years, and she reports that she has not had her period during this time. After receiving the COVID-19 vaccine was when she resumed her menstrual period after a long time. She reports to her primary care clinic today to receive her depo injection on time, and she reports having some menstrual bleeding today. This RN consulted with a provider on site who encouraged use of tylenol for abdominal cramping, maintaining hydration and rest. This RN asked pt to call back next week after her 2nd dose of the COVID-19 vaccine to report status of menstruation and any side effects from depo injection or covid vaccine. It is also important to note that the pt has a hx of dysmenorrhea, but the two years of depo injections have suppressed her regular menstrual cycle.
1041297	2/19/2021	VA	32	F	1/2/2021	2/7/2021	I started bleeding on the 4th, doctor stated threaten miscarriage. I had blood clots and vomiting'. I was taking to emergency room. I was giving a DNC because I had a miscarriage.
1040386	2/18/2021	CO	38	F	2/3/2021	2/8/2021	got a pain in my left side of my neck right after shot. Had some headaches and chills and feeling fatigued for two days. The noticed the pain in my neck increase and my vein protruding. Went to get a neck ultrasound. they found many swollen lymph nodes and a blood clot. Diagnosis Thromophlebitis superficial.



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1037837	2/18/2021	CA		F	1/20/2021	1/25/2021	ultrasound revealed blood clots at right leg; Swollen ankle and foot after 5-6 days of first dose; Swollen ankle and foot after 5-6 days of first dose; This is a spontaneous report from a contactable consumer reported for herself. A 73-year-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in left arm on 20Jan2021 11:00 at single dose for COVID-19 immunisation. The patient was vaccinated in nursing home/senior living facility. Medical history included high blood pressure, monitored for lymph node growth. The patient had no known allergies. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included high blood pressure medication and clonazepam. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced swollen ankle and foot on 25Jan2021 12:00 AM after 5-6 days of first dose, ultrasound revealed blood clots at right leg. Doctor ordered to take apixaban (ELIQUIS) immediately during second week. The events resulted in Doctor or other healthcare professional office/clinic visit. Since the vaccination, the patient had not been tested for COVID-19. The outcome of events was not recovered. Information on the lot/batch number has been requested.

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1038250	2/18/2021	NY	73	F	12/24/2020	12/25/2020	<p>Saddle embolism in lungs; DVT in left leg; Slight fever; Extreme fatigue; Shortness of breath, struggling for every breath; Low o2 sat; A spontaneous report was received from a health care professional, who was a 73-year-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced shortness of breath, slight fever, extreme fatigue, left leg deep vein thrombosis (DVT), and saddle pulmonary embolism (PE). The patients' medical history was not provided. No concomitant medications list was provided. On 24 Dec 2020, prior to the onset of symptoms, patient received the first of two planned doses of mRNA-1273 (Batch number 011J20A) for the prophylaxis of COVID -19 infection. On 25 Dec 2020, patient experienced shortness of breath with low oxygen saturation levels. On 26 Dec 2020, the patient's oxygen saturation levels were down to 89% with slight fever and extreme fatigue. On 27 Dec 2020, patient's energy was back to normal. On 28 Dec 2020, the patient woke up in the morning with symptoms of almost could not breathe, could not walk across the room. The patient's vital signs included oxygen saturation 83%. The patient was struggling for every breath. The patient tested negative for COVID-19. On 30 Dec 2020, another COVID-19 test was negative. On 31 Dec 2020, patient's vital signs included oxygen saturation closer to 90%, and she reported getting better. Symptoms remained the same for about a week. On 08 Jan 2021, the patient experienced left ankle and foot swollen. The patient was seen by physician and then sent to emergency room where it was determined that the patient had DVT in the left leg. A computerized tomogram (CT) scan found clots in the left lung, or saddle PE. On 09 Jan 2021, the patient was discharged from the hospital. Treatment for the events experienced included intravenous heparin and blood thinners. Action taken with planned second dose of mRNA-1273 in response to the events was not provided. The event, extreme fatigue, was considered resolved on 27 Dec 2020. The outcome of the events, shortness of breath, slight fever, DVT and saddle PE were not provided. Follow-up received on 19 Jan 2021 included updated events (DVT and saddle PE), updated event details, treatment, and hospitalization details.; Reporter's Comments: This spontaneous report refers to a case of 73- year-old female patient who experienced serious</p>

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event of pulmonary embolism and deep vein thrombosis and non-serious events of shortness of breath, oxygen saturation levels were down to 89% with slight fever and extreme fatigue the next day after administration of the first dose of mRNA-1273, lot # 011J20A, expiration date-unknown. Based on temporal information provided and the known safety profile of the vaccine and the absence of any other etiology factors, a causal association between the vents of shortness of breath, oxygen saturation levels were down to 89% with slight fever and extreme fatigue and the administration of mRNA-1273 vaccine cannot be excluded. Fever and fatigue are consistent with the known safety profile of mRNA-1273 vaccine. There is no enough information t clinically assess the causal association between the events of pulmonary embolism and deep vein thrombosis as the patient's medical history and list of concomitant medications were lacking. Main field defaults to 'possibly related'

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1038305	2/18/2021	TX	50	M	1/6/2021	1/21/2021	<p>On January 21, 2021 I started feeling pains in my right shoulder (1st shot was left shoulder) and the following day it had spread across my body, shoulders, chest, arms, legs and calves. I also had a severe headache along with the muscle pains and woke up each day since in a pool of sweat with the sheet soaked to this day. Due to the severe muscle pains, I started taking Tylenol and all the symptoms pointed to the virus itself. I was tested for the virus on Monday, January 25th with negative results on the morning of the 26th. I continued to self-medicate with Advil every four hours to remove the severe muscle pains noted above. To back track slightly, I had a colonoscopy on January 19, 2021 and one large polyp was removed without issue. Due to the full body muscles pains and taking the Advil, it likely caused bleeding from the polyp site of the colonoscopy and went to the ER and they transferred me back the hospital on January 28, 2021, the location of the colonoscopy, and hospital found nothing wrong with the colonoscopy during my 2.5 day stay there. The did an x-ray of my chest to test for the flu and related items and found everything to be clear. They also a CT of my abdomen to look for any abnormalities and found none. Through all this the muscle pains continued when I would move, the muscles would fire up and intense pain persisted until I could calm them down after about 30 mins of intense pain. Hospital also tested me twice for the COVID virus and each turned out negative. Overall, I've been tested for the virus nearly 12 times and all were negative. From the visit to Hospital, with the colonoscopy and no additional bleeding occurring, Hospital gave me a steroid called Prednisone to mask the pain on Saturday, January 30, 2021 at about 1pm and by 4pm they fully released me with no idea what was causing the severe muscle pain across my body when I moved. I literally just walked out of the hospital since the steroid masked the muscle pain issue. The steroids worked but I was still walking up in a pool of sweat and very clammy and wet each morning from 1am until I woke up. On February 2, 2021 I had 3 bowel movements that were all dark purple and full of blood clots which led me back to Hospital and the ER could not get in touch with the Hospital Doctors for transfer so they admitted me to the Hospital, thank God. On February 4, 2021 Methodist performed an emergency colonoscopy to</p>

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clamp the polyp site, took two additional polyps out and did an endoscopy to ensure my upper and lower GI track were clear, and it was and the two additional polyps were benign. Through all this the serve muscle pains persisted and Hospital moved me to a patient room and out of the ER. Over the next several days, February 4 thru the 11th Hospital cleared me of everything they could test for, over 85 different tests were ran based on MyChart. All my blood counts were all over the place, WBC were 19,000, Platelets were nearly 700, my sedimentation rate reached 64+ and the server muscle pains persisted and I was basically incapacitated during my entire stay at Hospital. Hospital had several specialists seem me from Internal Medicine, Infectious Disease, Neurology to Rheumatoid ologist and none of them found anything wrong with me other than my COVID anti-bodies were enormously high with not signs of slowing down. The conclusion by each of the specialist is that my symptoms all point to an Adverse Level 3 Inflammatory Reaction to the first COVID Vaccine shot. The Infectious Disease specialists emphasized that I DO NOT get the second vaccine shot since it would like have killed me. (We had cancelled my 2nd shot, scheduled for February 3, 2021 via Cancer Center the week of January 30, 2021.) Hospital concluded that they could not do anything further for me since all their extensive testing all came up negative other then the COVID antibody levels and started me on the same steroid via IV on February 10, 2021 and on February 11, 2021 I was released from Hospital with a 28-day gradual reduction of the steroid over that timeframe to see if the COVID antibody production would simply stop. They had no other recourse or follow up with for any of the specialists. I?m on my own at this point and scared. To help with the inflammation the only thing my wife and I saw we could do is see a health and well Doctor to try and purge myself of the inflammation and assist my bowel and liver health with trying to rid me of the vaccine and hopefully the antibody production. I?m on a strict diet and taking supplements to assists in the reduction of inflammation and cleaning my system out. Starting today, February 18, 2021 I start stepping back on the steroids prescribed by Hospital and praying that the symptoms and pain simply go away but I?m still having night sweats, weak and shaky.

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1038473	2/18/2021	NY	71	F	1/26/2021	2/5/2021	1 week after receiving first dose of Pfizer COVID vaccine (received 1/26/2021), develop worsening shortness of breath. Presented to ER on 2/4/2021. Found to have submassive pulmonary embolism with evidence of right heart strain, US showed left lower extremity DVT. Also found to have descending aortic thrombus with extensive clot burden. Was hypoxic 89% on room air.
1039071	2/18/2021	CT	77	M	2/11/2021	2/13/2021	Two leg blood clots DVT and also phelbitis same leg..Never had blood clots prior
1039396	2/18/2021	PA	32	F	2/14/2021	2/16/2021	Miscarriage: vaginal bleeding with clots and tissue within 1 week of a positive home pregnancy test, two days after vaccination. Blood HCG take once vaginal bleeding commenced was <5.
1039940	2/18/2021	CA		F			Blood clot in her leg; This is a spontaneous report from a non-contactable consumer (patient). This female patient of unspecified age (reported only as 72) received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unknown date, for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient believed she may have a blood clot in her leg since an unspecified date. She had the second vaccine dose scheduled on an unknown date. Event outcome was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

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1040119	2/18/2021	ND	43	F	1/26/2021	2/4/2021	I didn't notice any symptoms right away. When they started, I didn't think it was abnormal at first. I am female and still have my menstrual cycle. This time it appeared to be heavier than usual and had some blood clots. However, before I was on birth control it was always that way. Sometimes it is a little heavier when I have more stress or the weather is not ideal. My cycle started around 2/4/21. On 2/8/21, I combed my one cat. She scratched and bit me and has done so in the past. She and I both are vaccinated and I've never developed any infections because of it in the past. On 2/10/21, I noticed a cluster of red pinpoint dots underneath my skin on my arms and chest. They weren't bumpy, warm to the touch, itchy or anything. It just looked odd and I didn't know how it happened. I work with a Nurse Practitioner and she suggested I go into to a clinic as those usually indicate an infection is developing. I went to the Urgent Care and was treated. He did blood work on me and informed me that my glucose was a little low. It was supertime so that didn't surprise me. He told me there was no signs of infection in my blood work but was prescribing two antibiotics in case one developed. When I was getting my meds at the pharmacy, a call was coming through that I didn't recognize so do to phone scams, I didn't answer it. I started the antibiotics. Then over the course of 2/13/21 and 2/14/21 weekend days, I felt more fatigued than usual, nauseated, had a decreased appetite and still had my menstrual cycle. I still didn't think much about it as a side effect of the antibiotics was nausea and decreased appetite and the fatigue could be related to it being so cold and winter usually affects my depression symptoms. Then on 2/14/21 I noticed my lower abdomen was covered in those red, pinpoint blood dot clusters and there were unexplained bruises on my body. I took a shower and when I went to wash my legs, my pelvic area was completely bloody and a blood clot dropped into the bathtub. Never has that occurred when I have my period. It looked like I had just given birth it was so much blood. I became nauseated and dry heaved several times. On 2/15/21, I sent a message to Dr asking what was happening to me. He called me and informed me that he had tried to call me the night he saw me because he saw my platelet count was only 11,000 and should be a minimum of 140,000. Dr asked that I return to Urgent

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1035850	2/17/2021	NC	67	M	2/4/2021	2/6/2021	<p>Care as soon as possible. I arrived there around 12:30 pm that day. He had bloodwork done again on me. My platelets went down to 9,000. I explained that my menstrual cycle would not stop and it should've but I just keep bleeding. Dr contacted a Hematologist that informed him that recently the blood disorder Immune Thrombocytopenia (ITP) has been linked with the COVID19 vaccination in rare cases. I was scheduled to be seen by a Hematologist and put on the medication prednisone to build up my platelet count. I returned to Urgent Care for blood work again on 2/16/21. My platelets went up to 30,000. I met with Hematology on 2/17/21 and had blood work again, platelets 28,000. All providers looked over my medical record and noted that since my gastric bypass surgery in 2015, my health has been good, my blood work has been normal and I live a clean lifestyle. Again, the only issue showing up in my bloodwork was that my platelets were extremely low. Now I have weekly blood draws, take 80 mg of prednisone and have a Hematologist when just a few weeks ago my health was good.</p> <p>Patient woke up on the morning of 2/6 with symptoms of a stroke. Rushed to hospital where clot found in brain. Recovered from initial stroke but then had another major stroke on 2/8 and never recovered.</p>



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1035003	2/17/2021	NV	74	F	2/1/2021	2/1/2021	Atrial fibrillation; This is a spontaneous report from a contactable consumer (reported for herself). A 74-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number: EN5318; expiry date: not known), via an unspecified route of administration in the left arm on 01Feb2021 10:45 at single dose for COVID-19 immunization. Medical history included deep vein thrombosis (DVT) and allergies to sulfa drugs. The patient's concomitant medications were not reported. The patient is not pregnant. The patient did not receive any other vaccines within 4 weeks prior to COVID vaccine. The patient previously took amoxicillin, clavulanate potassium (AUGMENTIN) and experienced allergies. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The patient experienced atrial fibrillation on 01Feb2021 17:45. No treatment received for this event. The outcome of the event was recovered on an unspecified date in Feb2021.
1036912	2/17/2021	KY	51	F	2/5/2021	2/10/2021	Initial injection site pain for two days. Around day five, both armpits were discolored significantly. On day nine I was in the ER with left side abdominal cramps that was diagnosed after a CT Scan as a splenic infarction caused by a blot clot. I have not had a blot clot previously and have always been healthy with no surgeries or prescription medications except propranolol for anxiety (since the pandemic started).
1036464	2/17/2021	TX	40	F	1/8/2021	1/8/2021	Headache, nausea, vomiting, sore arm, temp 102.8, chills began 1/08/2021 @ 9pm and lasted for 24 hours The next menstrual cycle was very heavy period, soaking heavy flow tampons every hour, large clots, and lasted 6 days from a typical mild flow 3 day period

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1035867	2/17/2021	OH	41	F	1/23/2021	2/13/2021	Noticed swelling in my left hand around Feb 6th, but by Feb 13th entire left arm was swollen and warm and observed blue/purple skin coloring on upper arm and lower arm was red. Went to ER on Feb 15th, and ultrasound revealed a blood clot near the junction of the subclavian vein and cephalic veins. Diagnosis was idiopathic subclavian deep vein thrombosis (DVT). Started on enoxaparin and warfarin on Feb 15th. Referred to hematology and coumadin clinic to monitor INR.
1034259	2/16/2021	MT	93	M	1/25/2021	2/9/2021	hospitalized with extensive bilateral pulmonary emboli and right leg deep vein thrombosis after 1st vaccine dose. Required high-flow nasal canula for oxygen support. ultimately discharged on hospice
1034221	2/16/2021	WA	44	M	2/8/2021	2/8/2021	Reported palpitations which is a feeling of a single strong heart beat w/ associated catching of his breath and feeling of startle and mild anxiety which started w/ other post COVID vaccine symptoms of f/c, fatigue, and body aches. Other symptoms resolved but not startle symptoms and pt now also having cough and nasal congestion. Normal exam other than congestion. EKG NSR w/ no feeling of the startle while here and no CP or SOB. CXR normal. Full lab eval also normal including neg CRP, Trop, BNP, and D dimer. CBC and CMP also normal. TSH mildly elevated but normal T4 so likely c/w pt's prior minor thyroid abn but unlikely to be source of current symptoms. Given normal exam and w/u do not feel myocarditis, pericarditis, or clots or other significant process associated w/ current symptoms. Pt retested for COVID since not fully immune prior to symptom onset.
1033861	2/16/2021	NY	77	F	1/19/2021	1/21/2021	I developed all the symptoms of Covid, except fever. The cough was the worst. Had taste, but it is still off; nothing tastes right. I had a Covid test on 01/24/2021 that came back negative. I had two more tests in the hospital on 2/9/2021 that also came back negative. I went to hospital on doctor's orders due to some blurry vision and concern about blood clots, which I did not have. Symptoms persisted until 2/12/2021.

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1033682	2/16/2021	WI	95	M	2/4/2021	2/5/2021	L hand edema, hematoma which burst and caused bleeding sending pt to the ER for pressure dressing and 2 stitches. L hand and arm progressively got more edematous and bruised looking (severely black/blue/purple) and the hand continued to bleed and swell on 2/6/21. Severe arterial and venous issues and apparent blood clots. On 2/7/21 there were also lumps noted on left inner thigh. Pt. stopped eating or drinking on 2/8/21 and expired on 2/12/21.
1032868	2/16/2021	NC	35	F	2/9/2021	2/12/2021	Developed nose bleed around 8am, took 18 minutes to completely stop (held pressure x8 min, then clot dislodged, held pressure again x10 min). Got lightheaded, heart rate increased to 120 bpm, felt palpitations, got I-watch and took EKG. Then felt stronger palpitations, had to sit down, 2nd EKG read 172bpm. 911 called, felt very dizzy, laid down in floor with legs up, pursed lip breathing. Ambulance arrived and had SBP of 100. HR in ambulance on way to hospital was around 120.
1033516	2/16/2021	MN	32	F	1/29/2021	2/15/2021	At the time of administration of the first dose of Moderna vaccine, I was 6 weeks pregnant. I had confirmed pregnancy with home positive test and missed period. I had an estimated due date of 9/24/2021. This was my 4th pregnancy. I have had two uncomplicated pregnancies to term. In September 2020 experienced a chemical pregnancy with early pregnancy loss at 5 weeks. The first 24 hours after 1st dose of vaccine I experienced extreme arm soreness in the arm that was vaccinated, causing headache and unable to sleep. After 24 hours I felt "normal". 2 weeks and 3 days following the first dose of Moderna, I had a miscarriage. On the night of 2/15/21 I lost the pregnancy with vaginal bleeding, bright red blood, passing tissue, clots/ sac. I had an uneventful pregnancy up to that point, feeling well as I had with prior pregnancies.

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1032596	2/16/2021			M			On Saturday little blood clot, no liquid blood, and this morning this same; a little blood in the urine; This is a spontaneous report from a contactable consumer (the patient). A male patient (Age: 77, Unit: Unknown) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number not provided), via an unspecified route of administration on an unspecified date (age at vaccination unknown) as a single dose for COVID-19 immunization. The patient's medical history included little blood clot, no liquid blood, 7 years ago (unspecified date in 2014). The patient's concomitant medications included fish oil and acetylsalicylic acid (ASPIRIN). The patient stated he received the first dose of the COVID shot on Thursday (unspecified date). The next morning, there was a little blood in the urine. On Saturday, little blood clot, no liquid blood, and this morning the same. The patient had this before 7 years ago. The patient asked if anyone else reported this and for information. The clinical outcome of little blood clot and a little blood in urine was unknown. Information on Lot/Batch number has been requested.
1032994	2/16/2021	AZ	74	M	2/10/2021	2/10/2021	Received 1st. Pfizer vaccine shot at 10:00 am Thursday 2/10/2021 At approximately 6:00 pm same day I started to have severe pain in my side shortness of breath and could not lie down to go to sleep. Had to go to bed sitting up with three pillows on my back. The next morning went to doctor who ordered blood test and chest X-Ray. Chest X-Ray indicated Pulmonary Embolism. Doctor started me on Eliquis blood thinner to hopefully dissolve the blood clot on my lung. Doctor suggested I report Pulmonary Embolism occurring same day as my first vaccine shot. Do not know if shot caused Pulmonary Embolism or just a coincidence. In addition doctor found blood in my urine and a CT of Bladder has been ordered
1033349	2/16/2021	IN	70	F	2/11/2021	2/13/2021	Pt initially had diffuse joint pain, then worsening pain and swelling in RLE. Had DVT u/s + for DVT No history of blood clots, no prior risk factors Cannot be certain that she did not have clot prior to vaccine, although she never had pain or swelling to this degree (1-2 mo prior thought skinny jeans were slightly tighter on R than L, but no visible swelling. Now with RLE 2x size LLE)

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1034428	2/16/2021	CO	46	F	2/4/2021	2/13/2021	I have an extremely big hive on my right arm, same area I got the shot. I was very worried about having an infection or developing blood clot. I saw my family doctor this morning, she hasn't seen such a reaction in any other patient. She prescribed Benadryl and hydrocortisone cream. and a follow-up on Friday. If there is no change she said she might have to prescribe antibiotics. She told me to contact her if any changes develop, and yes it has I will be contacting her in the morning because the hive is getting much bigger. I am very worried any my health right now since the hive is spreading and its itching, burns and looks very inflamed. I hope to hear from someone very very soon. Thank you.
1031674	2/15/2021	NC	71	M	2/2/2021	2/5/2021	Early morning of the 3rd day, Friday, the left wrist and hand became inflamed, swollen and movement became restricted in both the wrist and fingers. Pain was associated with movement. Symptoms increased through the weekend.. Video consult with Dr. Monday AM and advised to take Zertac and elevate arm. Tuesday, no relief. Advised to continue for several days and monitor. Wednesday, sought help at Mt. View Urgent care. Did Ultrasound for possible clot. Negative. Advised as to possible options. Decided for a single does steroid injection. Thursday, some relief in swelling and pain. Friday was give a 6 day treatment pack of Prednisone Oral. Hand and wrist swelling are down, pain almost gone. Movement of

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1030030	2/15/2021	CA	61	M	12/18/2020	12/1/2020	the swelling and extreme tenderness of the site of injection; the swelling and extreme tenderness of the site of injection; headache; I couldn't sleep last night because I have headache, throbbing headache and back pain; Nausea; I had like metallic taste; Dizziness; The initial case was missing the following minimum criteria: suspect drug. Upon receipt of follow-up information on 27Jan2021, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable physician. A 61-year-old male patient received his first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EJ1685, expiration date Mar2021) on his left arm, intramuscular on 18Dec2020 at 0.3 mL, single for COVID-19 immunization. Medical history included hypertensive, 2 stents in heart in 2016, Hyperlipidemia, hypothyroidism, coronary artery disease in 2016 and Allergic (Allergic rhinitis + Chronic sinusitis). Concomitant medication included acetylsalicylic acid (ASPIRIN), clopidogrel bisulfate (PLAVIX). It was reported that the patient had swelling and severe tenderness left his arm. He couldn't sleep last night because he had throbbing headache and back pain on 18Dec2020. Initially, he had nausea. Patient stated further stated that Headache and swelling and extreme tenderness of the site of injection, that is the swelling, no redness but the swelling and tender and painful. Initially, he had till now the mild back pain. He patient said she took Tylenol. She also mentioned that initially she had like metallic taste and then disappear. The patient also had dizziness a little bit. The outcome of the event vaccination site swelling, dysgeusia and tenderness was recovered on unspecified dates, headache and back pain was not recovered, recovering for nausea while unknown for the remaining events.
1030521	2/15/2021	WI	77	M	1/28/2021	1/29/2021	I am 77 yrs old, male , , 150# and 5ft 6inches...Within 24 hours of receiving the shot, my body thru-up clots in my left leg. and I spent 4 days in the hospital ( 3 days in surgical ICU), breaking up the clots to save the leg. This is too much of a coincidence to ignore and I will not receive the 2nd shot.

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1031553	2/15/2021	OR	58	M	1/8/2021	1/21/2021	Developed upper extremity Deep Vein Thrombosis (DVT) with complete occlusion of the Axillary and SubClavian veins of the right arm. Swelling, redness of the right arm and hand. Pain in the right axilla. Visibly distended veins near the right clavicle, upper arm, forearm and hand. This occurred 2 weeks following 2nd dose of COVID vaccine. Patient has no risk factors or other known causes of DVT.
1031884	2/15/2021	HI	82	F	1/25/2021	1/31/2021	7 days post COVID #1 vaccine, onset of bilateral leg claudication (1/31/21). Subsequently dx'd with acute bilateral arterial clots in both legs requiring thrombolysis, bilateral popliteal/artery thromboembolectomy, heparin. Acute clot per vascular surgeon. Surgery performed 2/12/21.
1031519	2/15/2021	WA	72	F	1/22/2021	2/2/2021	Deep Vein Thrombosis, both legs below knee 11 days after first vaccine injection
1032269	2/15/2021	IN	91	F	2/9/2021	2/15/2021	Blood clot right thigh
1029515	2/14/2021	OH	80	M	1/25/2021	2/5/2021	Superficial blood clot in right lower leg
1029556	2/14/2021	IA	51	M	1/8/2021	1/16/2021	Deep Vein Thrombosis; Superficial Thrombophlebitis. Treatment: Xarelto. Outcome: Resolved
1028722	2/13/2021	WA	39	F	2/5/2021	2/10/2021	Very uncomfortable ache in arm for 3 days several days (after initial expected and familiar post-injection soreness that only lasted 24 hours). New ache impacted sleep and daily activities. Feels like what I would imagine a blood clot would feel like but did not notice redness and heat. Discomfort currently focused near inner elbow and underarm area. Discomfort increases with applied pressure to area. Massage has not helped. Sx have diminished since insert but still present after 3 days.
1031120	2/13/2021		57	F	12/29/2020	1/20/2020	Fever, Diarrhea, 1/20/21 SYMPTOMS BEGAN. ADMITTED TO HOSPITAL & CONTACTED EOH 1/27/21 WITH FEVER, CHILLS,SOB, COUGH., DIARRHEA, BLOOD CLOTS, FLUID AROUND HEART. Narrative: Other Relevant History:

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1028144	2/13/2021	CA	65	F	2/9/2021	2/10/2021	After receiving the first shot on Jan 19 I had a nosebleed. It was mild and happened about an hour after the shot. When I received the 2nd shot on Feb 9 I had a very severe nosebleed about 24 hours after the shot. It took about 45 minutes to stop and I passed several clots. It was very frightening.
1026681	2/12/2021	IA	32	F	2/12/2021	2/12/2021	9 minutes after receiving 1st dose of vaccine, client states "I feel different than I did before the shot". When asked to explain, client reports headache, dizziness, chilled and face and neck were visibly flushed and warm. VS were taken. Client was 98-99% on RA with no respiratory distress. HR was elevated at 110. Denied chest pain. Blood pressure was initially 130's/80's. Client was assisted to sit to lie down and reports less dizziness at that point. HR did return to 70-80's and blood pressure to 120's/70's. Client continued to deny issues with breathing or chest pain. Due to continued weakness, headache and dizziness, client was taken to ER at Hospital for evaluation
1026980	2/12/2021	OH	80	M	1/22/2021	1/23/2021	Patient reported to Emergency room on 01/23/2021 with complaint of nausea. According to ER record patient reported he received a COVID 19 vaccine Pfizer the day before. Work up in the ER (CT ABD PELVIS) reveal a clot of SMA. CT CHEST REVEALED BILATERAL PULMONARY EMBOLUS. THE PATIENT WAS TRANSFERRED TO THE STATE HOSPITAL. HE WAS SCHEDULED FOR EMERGENT VASCULAR SURGERY WHICH WAS CANCELLED AS THE PATIENT DIED SHORTLY AFTER HIS ARRIVAL.



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1026850	2/12/2021	MA	76	M	2/5/2021	2/6/2021	On Saturday 2/6/21 in the morning on the left side under armpit felt like he had a pulled muscle or something. It eventually radiated over up into the left quadrant of his chest where he could not push down on it. It was extremely painful by Monday. He has a history of esophageal spasms and exacerbated them to where he thought he was having a heart attack. He called his Cardiologist and told him to go to the ER. He went to the hospital Monday evening, he had two EKG's, had blood drawn 3 times, did sonograms looking for blood clots. He did inform them that he had the vaccine on Friday and they told him it was due to that. He went to nuclear medicine to get his lung checked for blood clots as well. All tests were negative. He saw his PCP today who told him that the lymph nodes were affected due to the vaccine. He has improved greatly, still has some slight discomfort which his PCP said would go away in time.
1026801	2/12/2021	CO	30	F	1/27/2021	1/29/2021	Central venous sinus thrombosis
1026203	2/12/2021	SC	56	F	1/25/2021	1/27/2021	1/25 L sore shoulder. 1/26 L sore shoulder. 1/27 L burning sensation running down arm from shoulder to wrist. 1/28 L forearm and wrist began to swell and be very painful, complete loss of all wrist range of motion this continued thru Monday 2/8 This was so painful that I sought medical treatment from a MUSC health, Lanc MD on 2/5. He examined my wrist and sent me for an X-ray, X-ray was negetaive. Monday 2/8 the pain was subsiding from my wrist and began to start in my L shoulder. Wed 2/10 The pain had moved under my breast radiating from my L front around my back, severe along with shortness of breath. I went to ER for a complete work up including a CT to rule out a blood clot. All test negative all blood work normal. Except it did reveal that I had a UTI. I have never had a UTI in my life. I was started on a anitibiotic for the UTI. I still have the pain under my L breast. Unknown reason.

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1026016	2/12/2021	KY	45	F	1/6/2021	1/6/2021	possible case of cellulitis; arm feeling heavy; hot to touch; swelling; rash developed that was 3-4 inches diagonal that appear to spread to upper arm in couple of days; redness; shower with itchiness at the site of injection that was round in shape; thrust from antibiotics bactrim and Amox/Clav; on and off adverse event with feeling left ear on fire; A spontaneous report was received from a healthcare facility staff member concerning a 45-years-old, female patient who experienced possible case of cellulitis, on and off adverse event with feeling left ear on fire, hot to touch, redness, swelling, arm feeling heavy, thrust from antibiotics, rash developed that was 3-4 inches diagonal that appear to spread to upper arm in couple of days and shower with itchiness at the site of injection that was round in shape. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 06-Jan-2021, prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 [Lot number 012L20A] intramuscularly in the right upper arm for prophylaxis of COVID-19 infection. On 06 Jan 2021, the patient started experiencing on and off adverse event with "feeling left ear on fire". Eight days later the patient noticed itchiness at the site of the injection that was round in shape. Rash developed that was 3-4 inches diagonal that appeared to spread to upper arm. The injection site was hot to touch, redness, swelling and arm feeling heavy. On 13 Jan 2021 or 14 Jan 2021, the patient was recommended Bactrim (sulfamethoxazole, trimethoprim), amox/Clav (amoxicillin, clavulanic acid) and clotrimazole lozenges because the primary care physician (PCP) was believing she possible has a case of cellulitis. The patient went to the emergency room (ER) on 17 Jan 2021, in which an ultrasound was performed and did not suspect any blood clot or cellulitis. Upon discharge, the patient experienced thrust from antibiotics. Treatment for the event included Bactrim (sulfamethoxazole, trimethoprim), amox/clav (amoxicillin, clavulanic acid), clotrimazole lozenges and Benadryl (diphenhydramine hydrochloride). Patient informed that the symptoms are on-going where the swelling and redness comes and goes. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events possible case of cellulitis, on and

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							off adverse event with feeling left ear on fire, hot to touch, arm feeling heavy, thrust from antibiotics, rash developed that was 3-4 inches diagonal that appear to spread to upper arm in couple of days and shower with itchiness at the site of injection that was round in shape was considered as not recovered and for redness and swelling outcome is considered as unknown.; Reporter's Comments: This case concerns a 45 year old female subject with a serious unexpected cellulitis, with NS unexpected burning sensation, feeling hot, limb discomfort, thrush, and NS expected Vaccination site events of erythema, swelling, pruritus, and rash. Event onset same day as first dose mRNA-1273. US without blood clot or cellulitis. Based on the current available information and temporal association between the use of mRNA-1273 and the start date of the events, a causal relationship cannot be excluded.
1025635	2/12/2021	SC	71	F	1/28/2021	1/30/2021	I presented at ER with burning, throbbing right leg pains at upper calf and upper thigh area. The ER doctor said it was not a blood clot, but was the beginning of Shingles on the back of my right thigh, buttock and downward just below the back of my knee. I was prescribed Acyclovir, Hydrocode with Tylenol and suggested topical creams. I was unable to find the Zostrix suggested so began with Caladryl and Terrasil cream as well as baking soda/water soaks a couple times a day. As of today, February 12, I still have leg pain, markings from the lesions and am unable to sleep more than a couple of hours a night without throbbing, burning pain especially at 2 lesion sites. Now taking Tylenol alternating with Tramadol for the pain.

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1025460	2/12/2021	CA	72	M	1/19/2021	2/3/2021	Patient went to bed totally fine and woke up saying he could not see in one eye. I rushed him to the emergency hospital they ran cat scans, MRI, heart tests etc. He stayed overnight while they checked. The next day we went to eye doctor who told him he had a eye stroke. He would regain some of his site not all of it. Something to do with blood clot or loss of blood to the eye. I was not satisfied with that so made another drs appointment for the next day with a different eye doctor. The first eye doctor gave us some blood test to do so we did it then. Later that evening we got an emergency call form the first eye doctor to get back to the hospital right away he could lose sight in the other eye.. They found some high c-reactive protein. Normal is 8 his was over 40. They put him on heavy steroids and did biopsy on both temples of his eyes. This started last Wednesday morning. He was released from the hospital Monday Morning to see his regular doctor that afternoon. Test results for the eye would be Tuesday and all other vital tests came back fine thank goodness. On Tuesday the biopsy tests also came back negative so they are stopping steroids. I think they were looking for auto immune issues. Today we are going to Rheumatologist
1025335	2/12/2021	MN	94	M	2/8/2021	2/9/2021	Excessive bleeding from a small scratch, blood appeared very thin and did not want to clot
1026582	2/12/2021	PA	79	M	1/27/2021	2/8/2021	Pt developed pain and swelling in his leg on 2/8/21. Sent to the emergency room on 2/10/21 and found to have DVT. No history of clots in the past.
1026574	2/12/2021	CA	43	F	1/21/2021	1/27/2021	On 1/27/21 Client felt pain and lump to right underarm. Client went to ED and MD said not sure if lump was related to vaccine. Client was advised to self-monitor. On 01/30/21 client went back to ED due to red/hot/itchy rash below injection site and numbness to right hand. ED MD ordered an ultrasound and CBC. MD stated no infection or blood clot. PMD prescribed an antibiotic, Cephalexin, for possible cellulites. Client has completed antibiotic. Today, 2/12/21, area is itchy and discolored at injection site. Client advised to get a note from PCP or health care professional before having 2nd dose of vaccine. Client was agreeable.

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1023403	2/11/2021	SC	48	M	1/6/2021	1/8/2021	bakers cyst behind my right Knee; pain and swelling in my right knee/ calf and ankle/in the right leg/in left hand; pain and swelling in my right knee/ calf and ankle/in the right leg/in left hand; pain and swelling in my right knee/ calf and ankle/in the right leg/in left hand; pain and swelling in my right knee/ calf and ankle/in the right leg/in left hand; This is a spontaneous report from a contactable consumer (patient). A 48-years-old male patient received the first dose of BNT162B2 Pfizer-BioNTech COVID-19 Vaccine, lot number EH9899, via an unspecified route of administration in left arm on 06Jan2021 at 09:00 at single dose for COVID-19 immunization. The patient received vaccination in Doctor's office/urgent care. Medical history included bladder cancer from an unknown date, cancer treatment with tumor vaccine therapy BCG (Bacillus Calmette Guerin) on 23Dec2020, bone spur in right thumb from an unknown date, COVID-19 from an unknown date and drug allergy to amoxicillin/clavulanate potassium (AUGMENTIN). The patient has not been tested for COVID-19 since the vaccination. Concomitant medication included doxycycline. On 08Jan2021 (also reported 3 days after the vaccine) at 05:45 the patient experienced pain and swelling in his right knee/calf and ankle. Pain and swelling in the right knee, calf and ankle continued until 14Jan2021 when the patient went to the urgent care. He was sent to the emergency room with a suspected blood clot and ultrasound proved no clot was in the leg. On 15Jan2021 the patient went to a hematologist and had an additional ultrasound which found a bakers cyst behind his right knee. He continued to have pain and swelling in the right leg and left hand which had already arthritis and he suspected it was an immune response to the vaccine. Rest, ice, compression and elevation were suggested as therapeutic measures to treat the events. The reported events had not resolved yet at the time of the report.

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1024378	2/11/2021	WA	55	F	1/10/2021	1/16/2021	6 days after first covid vaccine I ended in the ED with a mild heart attack and a spot on lungs for possible pneumonia. Tests ran showed no blockage or issue with heart and no blood clot found. Tests are still being run, but no cholesterol issues, low BP rate always, and no history of heart issues for myself or family members. 2nd dose caused shortness of breathing starting at 24 plus hours and increased heart rate for 7+ days and starting to decrease. Lungs cleared up after 6 days from 2nd dose.
1023638	2/11/2021	MO	58	F	1/25/2021	1/28/2021	Dose #2 - Nose bleeds following the 2nd Pfizer COVID-19 vaccine beginning a few days later and lasting at least (1) one week; on 2/2/2021 this patient coughed up a pea-sized bright red blood clot; no blood clots noted since that one time and no petechiae noted; severe body and joint aches and pain beginning the next day and lasting 24 hours. No fever noted on any day. Dose #1 - Nausea / diarrhea beginning a few days later and lasting two and one-half (2 1/2) weeks; sore arm same day and lasting at least 3 days. No fever noted on any day.
1024728	2/11/2021	CA	67	M	2/9/2021	2/9/2021	On 2/11/2021, after about an hour the vaccine was administered to the patient and with about minutes left of his dialysis treatment. , the patient reported to staff that he was feeling nauseous and then spit out a 3/4 quarter sized blood clot. Pt was almost done with his dialysis treatment and his time was cut short by 3 minutes. Pt then verbalized that he felt "fine." The RN working with the patient notified the on-call nephrologist and 911 was called. Pt refused to go to the hospital. On following up with patient and RCM on 2/10/2021, patient reported he notified his nephrologist and CXR was scheduled. As of 2/11/2021, pt stated he is not feeling well and did not arrive for scheduled hemodialysis. RCM aware.

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1024780	2/11/2021	FL	60	F	2/2/2021	2/2/2021	The skin on my arms and legs (mostly noticed arms) looked marbled red immediately after vaccine. It is still there but not as bad as it was initially. I googled skin conditions and it looks like Livedo reticularis. I went to my Cardiologist on 2/5/21 and he took bloodwork CBC, Prothrombin Time and bloodwork was normal. Cardiologist told me to go to a dermatologist. My arm was sore also where the injection was and it was hard to lift my arm. That lasted one day. I also had aches and pains and was fatigued on 2/3/21 for 24 hours.
1023351	2/11/2021			F	1/26/2021	1/1/2021	She has concerns that it could be a blood clot as it is on her left side (pain) and near her neck.; Clavicle pain; Swelling of her lymph nodes; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 26Jan2021 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. On an unspecified date in Jan2021 the patient experienced clavical pain and swelling of lymph nodes and she had concerns that it could be a blood clot as it was on her left side (pain) and near her neck. The final outcome of the event was unknown.Information about lot/batch number has been requested.
1024013	2/11/2021	NY	81	M	1/18/2021	2/4/2021	Had a stroke, blood clot removed from brain

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1019015	2/10/2021	FL	86	M	1/11/2021	1/18/2021	eye lid infection; This is a spontaneous report from a contactable consumer reported for her husband. An 86-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Pfizer product; Batch/lot number: EL3246) via an unspecified route of administration on 11Jan2021 at a single dose for COVID-19 immunization. Medical history included pulmonary embolism (PE) diagnosed 3 years ago, treated at (university name) hospital for about 3 weeks and the clot was gone and he went back to his normal routine. Other products were reported as no. Caller stated she and her husband got the first dose of the Covid vaccine 2 weeks ago today, 11Jan2021, stated they were scheduled to get 2nd dose next week 01Feb2021. Caller stated her husband had developed, unrelated to vaccine, an eye lid infection on 18Jan2021 with outcome of not resolved, stated he went to doctor had been treating it with topical antibiotics and anti-inflammatory eye drops, infection was improving but persistent, doctor wanted to put him on an oral antibiotic, they were very reluctant to do so, stated that they considered doxycycline but they read not to be taken with vaccines, stated he would not take that one, caller wanted to know did he need to ride the infection out and possibly end up with an incision and drainage or if he can take an antibiotic. Stated the main concern was that could an antibiotic possibly diminish the efficacy of either the first or second doses of the Covid vaccine and wanted to know if this was possible. Stated her husband was a retired orthopedic surgeon.; Sender's Comments: Eyelid infection is considered unrelated to the vaccine use representing a coincidental skin/ subcutaneous infectious condition.



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1019152	2/10/2021	CA	71	F	1/21/2021		<p>had like sort of a hard time breathing; got really weird smell; lips and her tongue were all this kind of swelled and then like it was steamed; lips and her tongue were all this kind of swelled and then like it was steamed; her arm, both of her arms went numb; could not go to sleep; This is a spontaneous report from a contactable consume r(patient). This 71-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 21Jan2021 at single dose (Lot # EL8982) for covid-19 immunisation. Medical history included stated, the only thing was got the susceptible to blood clots, had that gene so that is one of the reasons took the vaccine other than that did not take any meds. The patient didn't even take any blood thinners because did not need them." (not clarified further). No concomitant therapy included. The patient did not know if it is the vaccine but she got really weird smell and then her lips and her tongue were all this kind of swelled and then like it was steamed. The patient stated, "In the tongue and my lips, it was like when you get chilli on them and a distinct type of smell. " And then her arm, both of her arms went numb and she had like sort of a hard time breathing. Now, that it went away but she just waited and waited and it lasted almost in the most of the night and then she could not go to sleep but it was something she had never had before and it was very strange. She did not know if you have that kind of reaction from people or you know if it has come up but she thought she better report it because she had not had my second dose yet. She had to get the second dose on 09Feb. No treatments were received. Outcome of the events was recovering.</p>

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1019946	2/10/2021	FL	81	M	2/1/2021	2/1/2021	Wife calling, sitting with her husband an 81 yo m currently in the Neuro ICU. He went Pharmacy Monday morning 11:30 AM for a covid shot. No immediate issues, no symptoms that day. 8 PM that night she noted facial asymmetry and slurred speech, called 911. He's still in hospital, improving mentation today, more aware to person than before. Had surgery to remove the clot. She doesn't currently have all the information on her person (ex, unsure exact meds, CDC card at home. She isn't certain it's related but wants to report this, just in case. Reviewed with Dr., no reports of this type of ADR, most likely issues unrelated, but Relayed to patient also that it's great that she had the presence of mind to report this, because this is how we can best assess vaccine safety. PCC will Check back in a week for patient status, missing report information. Slurred speech, facial asymmetry/other neuro, confusion, blood clot, - still ongoing but improving
1019741	2/10/2021	CT	50	F	1/26/2021	1/28/2021	I developed a itchy oval raised rash that started on my lower abdomen and has spread to most of my body. My physician is treating as it Pityriasis Rosea and prescribed Clotrimazole-Betamethasone cream to help with the severe itching.
1019785	2/10/2021	TX	49	F	1/5/2021	1/11/2021	1 week after the first dose patient started to have her period. The period consisted of heavy clots and would go through 6-8 pads /day. Period lasted 3 weeks and went to see GYN and they prescribed Provera, which helped stop the bleeding.
1020333	2/10/2021	CA	91	F	1/22/2021	1/31/2021	Had swelling in leg for a couple of days prior to the early morning of 1/31 where the knee and entire lower leg was swollen and painful and made it very painful to walk. After sending photo to primary care physician had mom evaluated for a blood clot. It was determined based on blood test, vascular ultrasound that right non occlusive (mid) Femoral vein DVT.

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1020860	2/10/2021	TX	69	M	2/4/2021	2/7/2021	I went to my doctor yesterday because my left calf muscle had acute pain. He did an ultrasound to verify that it was not the result of a blood clot which was negative; so he gave me pain pills and instructions to use hot/cold compresses. After getting out of a tub of warm water I noticed blotches of redness (rash) above my right knee which had already begun to swell. I also noticed that my right calf muscled is beginning to be sore and a rash was developing on my arm below my elbow.

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1018790	2/10/2021	NY	88	F	1/19/2021	1/1/2021	high blood pressure/blood pressure was sky high; she didn't feel well/not being well; dizzy; nausea; sharp pain in stomach; This is a spontaneous report from a contactable consumer (patient's daughter). An 88-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL3247), via an unspecified route of administration on 19Jan2021 at 14:00 into left arm at single dose so she wouldn't die from COVID-19, she is 88. Medical history included cancer survivor, patient had one kidney, that kidney was stage 4 kidney disease and was not on dialysis, the one kidney was kidney cancer in 2010; high blood pressure; had blood clots from 2017; heart disorder; iron was low; having problems with memory. Concomitant medications included amlodipine started taking it years ago and hydralazine both for high blood pressure, bupropion, iron started a year and a half before (in 2019) for iron was low, all ongoing; donepezil started taking it in 2011 or 2012 as memory medication, apixaban (ELIQUIS) started taking two years before (in 2019) for blood clots, isosorbide started it so many years for heart, quetiapine from 2011 for having problems with memory. The patient previously took another medicine for blood clots. The patient went to hospital for the following side effects: dizzy and nausea on 23Jan2021, sharp pain in stomach in Jan2021, high blood pressure on 24Jan2021. Reporter would like to know if this side effects were reported or what should she do for her mom. Patient had just not being well in Jan2021 after received bnt162b2. Reporter had to take her mother to the ER 24Jan2021, and right now patient was dizzy, had nausea, and reporter took her to the ER yesterday and they couldn't find anything, and reporter was trying to find: was this due to the vaccine. Patient said she didn't feel well, since Saturday (23Jan2021). Patient now had a lot of stomach pain, so reporter took patient to the ER on 24Jan2021, and did a lot of tests, and her blood pressure was sky high, reporter wondering did the vaccine affect blood pressure. Patient was just not herself, and reporter knew the patient, patient had been doing pretty good, but was not herself. Reporter stated they let patient came home from the hospital on 24Jan2021, clarified she was in the ER on 24Jan2021, was not admitted to hospital. The outcome of event nausea was not recovered, outcome of the other events was unknown.

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1017556	2/9/2021	IL	84	M	1/21/2021	1/28/2021	Patient has been weak and having difficulty urinating for the few days. Was unable to urinate this morning and made an appointment. On the drive to the appointment, he felt the urge to urinate and urinated in a urinal he had with him. The urine looked like blood with clots. Patient admits that he has had some clots in his urine for past week, so he had taken plavix to break up the clots (plavix is not his medication). Given weakness, difficulty urinating, and gross hematuria, patient was sent to the ER. ER nurse was called and given report
1017107	2/9/2021	IN		F			anaphylactic shock; bleeding disorder (blood clots); atrial fibrillation; little sore arm; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer reported that a female patient of an unspecified age started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient calling-in because she received her 1st shot of vaccine earlier today. She claims that it is too late when she reads the fact sheet. she called-in because she has bleeding disorder (blood clots) or atrial fibrillation and taking xarelto. She also reported that she had anaphylactic shock. Reporter stated she never experienced an anaphylactic reaction just a little sore arm, she just called to obtain information as she currently takes an anti-coagulant. Therapeutic measures were taken as a result of bleeding disorder (blood clots), atrial fibrillation. The outcome of the events was unknown.

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1017602	2/9/2021	MD	54	F	1/4/2021	1/5/2021	On Tuesday went to work and at around 1:30 she told her boss that she was not feeling good. Felt achy in her body, her arm was hurting and was not feeling like herself. She went home, sat on the sofa and drank something and went to sleep and felt drained, and slept for 4 hours. She then woke up with runny nose, low grade temp, and felt really weak. The next day, 1/6/21 her body ached bad. She slept a lot that day and drank a lot of water, didn't eat and just felt really sick. Then on Saturday evening, she looked at her leg and felt cold chills and her leg was hot. She looked at her leg and had an area that was like a red dot, and she then realized that her leg was about to be inflamed. She went to bed, woke up and her entire leg was blotchy red, swollen and hot. She then called her family and around 12:00 on Monday 1/11/21. She went to the hospital, and they treated her like she had COVID, isolated her and was negative. Sent her to vascular and did not have a blood clot in her leg, and told her she had an cellulitis flair, and she started being treated with IV antibiotics. Was in the hospital for 5 days. She was discharged and went home after infectious disease team told her to go home with a nurse on IV antibiotics. She came home on 1/15/21, and was off the IV antibiotics on 1/22/21. She has been home and unable to work. She is going to therapy for her legs. They changed her hypertension medications, and put back on her antibiotics last week as they told her that the swelling was not going down. Her kidney function is low and told today, 2/9/21 that she is concerned about her kidney function. She is to have more labs drawn on Monday, 2/15/21.
1016653	2/9/2021	CT	56	M	1/24/2021	1/29/2021	5DASY AFTER RECEIVING 1ST DOSE OF COVID 19 VACCINE, PATIENT DEVELOPED GENERALIZED BODYACHE, ACUTE SOB, HYPERGLYCEMIA(BG RUNS 500-600'S), AND LOWER EXTREMETIE PAINS FOUND TO HAVE STENT THROMBOSIS.

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1016218	2/9/2021	TX	41	F	1/27/2021	2/3/2021	Vaccine was on 1/27 and although I experienced local reaction ok arm, it eventually began to fade. One week after injection I began feeling my arm burn and itch, and on Thursday 2/4 it started getting red again as if I were just injected. It has spread each day and the rash is over a large part of arm. I went to urgent care on 2/6 and they checked CBC and D Dimer to ensure there was no infection or blood clot. I was advised to return if it did not go away in 2 days, apply ice packs, and to keep an eye on how it was spreading. If it continued to go around the arm vs upwards, it was simply a reaction to vaccine. (As opposed to infection) I also emailed my PCP w pictures of progression and was advised to wait it out. It is almost a week later and it continues to grow slowly. Extremely hot to touch, painful, constant burning itch. Some days it is hard around injection site like at beginning. The redness seems to calm down at times throughout the day,, but come back. The redder it is, the hotter the skin is. Believe it may simply be a sign my body is working, but even doctor was surprised it went away and came back worse. Realize this isn't life threatening,, but VSafe stopped texting me on 2/3 so I have not been able to submit this reaction to them. Feel it is important this side effect is recorded.
1016123	2/9/2021	IN	38	F	2/7/2021	2/8/2021	Day after (2/8/21): Severe chills, tiredness, body aches, headache, loss of appetite, fever (101.4), bloody nose w/blood clots (left nostril only). 2 days after (2/9/21): Intermittent headache, aches in joints, bloody nose w/blood clots (left nostril only), hive around injection site.

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1015672	2/9/2021	MA	65	F	1/8/2021	1/13/2021	my body collapsed and I had a Pulmonary embolism/I have clot in my lung; I have behind my knee like a deep wide black spot and it is hard; This is a spontaneous report from a contactable consumer (patient). A 65-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 08Jan2021 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medication included amlodipine, metformin and propranolol. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization and experienced severe headache and diarrhea. On 13Jan2021, the patient reported that: "my body collapsed, I had a pulmonary embolism. I had to go to the hospital in ambulance. When I was there, they find out that I have clot in my lung. I was in an intensive care for 2 days or 3 days and about 5 days in the hospital (from 13Jan2021 to 17Jan2021). I have behind my knee like a deep wide black spot and it is hard, my body did not have anything like that". Therapeutic measures were taken as a result of event pulmonary embolism/ clot in lung and included treatment with "some medications", one of which ELIQUIS. The patient outcome of pulmonary embolism and "clot in lung" was recovered on an unspecified date and of deep wide black spot was unknown. The information on the batch number has been requested.



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1015660	2/9/2021	IL	49	M	1/11/2021	1/19/2021	swollen left calf that was DVT, deep vein thrombosis; This is a spontaneous report from a contactable Other Health Professional. A 49-year-old male patient received 2nd dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EL3248), via an unspecified route of administration on 11Jan2021 at single dose on left arm for COVID-19 immunisation. Medical history included hypothyroidism and high cholesterol. Patient had no known allergy. No COVID prior vaccination. No COVID tested post vaccination. Historical vaccine included 1st dose of bnt162b2 (lot: EK5730) via intramuscular on 23Dec2020 at 15:30 at single dose on left arm for COVID-19 immunisation. Concomitant medication included levothyroxine and atorvastatin. 1 week after receiving the 2nd dose, patient woke up with a swollen left calf. Ultrasound the same day (19Jan2021) showed that was DVT, deep vein thrombosis. Patient started taking apixaban (ELIQUIS) (blood thinner) the same day. Event resulted in doctor or other healthcare professional office/clinic visit. Outcome of the event was resolving. No follow-up attempts are possible. No further information is expected.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported event cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

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1015638	2/9/2021	WA	64	F	1/5/2021	1/26/2021	Deep vein thrombosis; pulmonary embolism; A spontaneous report was received from a 64-year-old female consumer who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed deep vein thrombosis and pulmonary emboli. The patient's medical history was not provided. Concomitant product use was not provided. On 05 Jan 2021, approximately 3 weeks prior to the onset of the events, the patient received first dose of mRNA-1273 (Lot number: 037K20A) intramuscularly for prophylaxis of COVID-19 infection. On 26 Jan 2021, the patient reported she was hospitalized for deep vein thrombosis and pulmonary emboli. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, deep vein thrombosis and pulmonary emboli, were considered unknown.; Reporter's Comments: This case concerns a 64-year-old, female patient. The patient's medical history was not provided. The patient experienced serious, unexpected event of Deep vein thrombosis and pulmonary embolism. The events occurred 22 days after the first dose of mRNA-1273 (Lot number: 037K20A) administration. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Additional information has been requested for further assessment.
1017129	2/9/2021	NV	65	M	12/17/2020	12/28/2020	Sudden cardiac death. Autopsy report: right coronary artery thrombosis.
1017411	2/9/2021	TX	82	F	1/27/2021	2/3/2021	patient developed blood clot in her left groin one week after getting first COVID19 vaccine.

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1017716	2/9/2021	IL	62	F	1/6/2021	1/8/2021	On 1/8/2021 2 days after I received the Covid vaccine I started to have SOB and coughing. I started to used my inhalers and it would give some relief but I was using it more than normal. I had not had asthma attack for more than a year. My asthma is very controlled that I don't use any inhalers whether daily or as needed. I went to work as usual since at that time my symptoms weren't getting worse but also not getting better. On 1/19/21, I was feeling more out of breath and having more dry hacking cough that when I called EH I was told to do the Covid testing. That same day I called my Asthma doctor and did a video call and was prescribed Breo inhaler, spiriva inhaler, xopenex nebulizer treatment and xopenex rescue inhaler. I couldn't go to work because of my shortness of breath and coughing. The treatment didn't work. On Tuesday 1/26/21, I called my asthma doctor again and another video call was made. She changed my inhaler to symbicort, still continue spiriva inhaler and nebulizer treatment. I also contacted my primary doctor who asked that I schedule an appointment with him so he can see me. On 1/28/21, I saw my primary doctor who did blood works to see if I have any blood clot and to see how my heart was doing. I was given phenergan with codeine to help with my coughing and it did help me to go to sleep. My blood works came out negative and he ordered CAT scan of my chest since I can't get rid of my SOB and coughing. I had the CAT scan on 2/3/21. He called me the next day and I was told that I had mucous plugging. He told me to go home and he prescribed Duoneb nebulizer treatment 4x a day and spiriva inhalers 2x a day. I started to get rid of the mucous that I had and started to breath better. It took 4 days of 4x a day nebulizer treatment and inhalers before I started to feel
1015212	2/8/2021	IL	27	F	1/30/2021	2/2/2021	Deep Venous Thrombosis of Right Axillary and Subclavian vein. Treated with IV Heparin Drip.

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1010678	2/8/2021	TX	60	F	1/22/2021	1/23/2021	Nausea; This is a spontaneous report from a contactable consumer (patient). A 60-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: En5318; Expiration date was not reported) on 22Jan2021 (10:45) at a single dose on the left arm, with route of administration unspecified, for COVID-19 immunization. Medical history included multiple (MS), blood clots and pulmonary embolism. Concomitant medications included rivaroxaban (XARELTO) and omeprazole. The patient previously took clarithromycin (BIAXIN), and had drug allergies. The patient was not pregnant at the time of vaccination. On 23Jan2021 (16:00), the patient had nausea. The patient did not receive any treatment for the event, nausea. The outcome of the event, nausea, was not recovered. The patient was not diagnosed with COVID-19 prior to vaccination, and was not tested post-vaccination.
1012962	2/8/2021	CA	43	M	1/26/2021	1/27/2021	On Wednesday 1/27 the day after my second dose I felt a minor pinch/discomfort on my lower leg. I did not think much of that is reason I did not report it right away. Day by day the discomfort and pain got worse. Exactly one week after my second dose I was not able to sleep due to the pain. On Wednesday 2/3 I decided to go urgent care. From there I was referred for an ultra sound a few hours after. After the ultra sound I was contacted by my doctor, letting me know that the results showed I had a blood clot on my left leg. I was put on Eliquis medicine right away. On 2/5 I was able to physically see my doctor who told me that this was caused by the second dose of the moderne vaccine that I took on 1/26.
1014720	2/8/2021	AZ	49	F	2/3/2021	2/6/2021	Very heavy menstrual cycle. Numerous clots. Severe cramping. All unusual for me

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1014871	2/8/2021	OK	50	F	1/11/2021	1/11/2021	CENTRAL RETINAL VEIN OCCLUSION RESULTING IN LOSS OF SIGHT TO RIGHT EYE I WAS ON COMPUTER AND HAD BRIGHT FLASHES OF LIGHTS THE LOST VISION IN THE EYE ABOUT 2 1/2 HOURS AFTER RECIEVING VACCINE. CRVO IS RARE IN MY AGE WITH NO HEALTH PROBLEMS. SAW ER DOCTOR THAT NIGHT THEN OPHTHAMOLOGIST THE NEXT MORNING WHO DIAGNOSED ME. I AM CURREENTLY PRESCRIBED A BABY ASPIRIN AND WILL HAVE TO GET INJECTIONS IN MY EYE WHEN MACULAR EDEMA OCCURS, AN EXPECTED OCCURRENCE WITH A BLOOD CLOT IN THE RETINAL VEIN

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1009473	2/7/2021	VA	38	F	1/28/2021	1/28/2021	<p>Moderna shot #2: About 6-8 hours in, I got the expected serious joint aches, chills, headache, and fever (101F). This lasted for about 2 days, managed well by alternating Motrin and Tylenol. A mild rash occurred a few days after shot #2. Thought I was done since most of my colleagues bounced back after 2-3 days. Then 48 hours in, I developed a racing heart (HR in the 110-120s), sweating palms/soles, tingling/numbness in the feet/arms, warm flushes over my chest, nausea, and a few loose stools. No position or relaxation method would resolve these symptoms. All I could do was lie down perfectly still with an ice pack on my forehead and hope this was short-lived and would pass. I could not sleep. I had no appetite. Over the 8 days this has been occurring, I lost 3 pounds. I could not find any literature of anyone else having any cardiac/dysautonomia symptoms. It scared me. I have no prior cardiac history and no history of anxiety. I went to the ER. Labwork showed an elevated D-dimer (luckily the CT scan showed NO blood clots), elevated WBC/neutrophils, and low potassium. Thyroid labs (which I had tested a few days later) were normal. The ER assumed the abnormal labs were due to the immune response to the vaccine and referred me to a cardiologist. I did a virtual visit with the cardiologist the next day. He suggested a heart monitor and scheduling an echo. The heart monitor was mailed to me. I started wearing it on 2/4/21 (3 days ago). I am supposed to wear it for 7 days and then mail it back. My echo is scheduled for 3/4/21. Again, I have had no previous cardiac history. I am an active, healthy 38 y/o F. These symptoms (racing heart (HR in the 110-120s), sweating palms/soles, tingling/numbness in the feet/arms, warm flushes over my chest, nausea, and a few loose stools) have continued to last for another 8 days and are debilitating. I have not been able to work. On day 7 of these symptoms, I called my PCP's emergency line. They suggested calling the cardiologist to see if they would consider prescribing a beta blocker for symptomatic relief. I called the cardiologist last night. They prescribed Metoprolol. I haven't taken it yet. It's officially day 8. I thought I was in the clear and had not had symptoms since last night, but then just now another episode of these cardiac/dysautonomia symptoms have occurred but less intense than previously. At this point, I have had had 10 days of symptoms post Moderna</p>

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							vaccine #2 but 8 of those days are specifically the cardiac/dysautonomia symptoms. Although a little better, these symptoms have NOT resolved and continue. I realize I am probably an outlier in terms of how I have reacted to this vaccine. I would love a call back to know if other people have had a similar experience, so I can understand if this is ?normal.? I understand 7% of patients in the Moderna vaccine trial had ?symptoms? lasting longer than 7 days. Were they symptoms similar to mine? Will this go away completely? Any help is appreciated. Of note, I did develop a nice rash below my injection site on Moderna shot #1. Does that mean I?m more ?reactogenic? and would potentially have a harder time with shot #2? Does size matter in how you will react? Moderna is 100 mcg (instead of Pfizer?s 30 mcg) I am petite (5?2? and am now 106 lbs since I?ve lost weight).
1016143	2/6/2021		23	F			23 y.o. female presents with shortness of breath x 1.5 weeks. States in the last 4 days she had increased shortness of breath and feeling like she cant get a deep breath. States it does hurt when she breaths as well and radiates to her back. States she also feels like her heart is racing and intermittent palpitations. Denies calf or leg pain. No recent travel. She does take OCP. Denies other medical problems. Denies drug use. Only occasional etoh use. No headache, nausea, vomiting, cough, fever. No history of CA, blood clots. She works at dermatology office and got the COVID vaccine 3 weeks ago.
1004777	2/5/2021	TN	53	M	1/18/2021	1/19/2021	Headache the next morning after receiving vaccine that hasn?t gone away, fluid in left lung, blood clots in right lung and leg.
1004784	2/5/2021	KY	76	F	1/14/2021	1/21/2021	About a week after receiving the vaccine soreness in my arm which lasted for about 3 days. About 5 days after the soreness went away I developed a rash on my arm. My arm was hot and swollen. I went to an urgent care the same day I noticed the rash, they put me on steroid and antibiotic Cephalexin. They also sent me to the ER for an ultrasound to make sure I didn?t have a blood clot. It is normal now. Besides the rash I felt fine otherwise.

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1006210	2/5/2021	TX	27	F	1/8/2021	1/15/2021	<p>The Moderna vaccine administration was painful at the time the shot was received. I experienced symptoms of fatigue and body aches for 24 hours after receiving the vaccine. My left arm was extremely sore and knotted for over a week after administration. The vaccine site was red and splotchy for the first 7 days after getting the shot. By the early morning of the 8th day (01/16/21), the splotches had joined together to make a large red area surrounding the vaccine site, that was raised and hot to the touch. During that entire day, pain was shooting down my left arm to my fingers (particularly the left middle finger) in a manner that felt like how severe arthritis pain is described. The pain became worse as the day went on. I texted a picture of my arm to my boss, who is a physician, to see what he thought I should do. He stated that from the photo, it looked like Cellulitis, and offered to send in an antibiotic to my pharmacy. Soon after, the pain was so intense (especially with movement of the arm) that I had someone drive me to ER &amp; Urgent Care around 8:30pm. The physician there marked my arm and prescribed 2 antibiotics to begin taking immediately (Bactrim &amp; Amoxicillin) with the instructions to come back in 48 hours. By the next day, the redness was spreading by the hour, which was marked &amp; tracked via photos that documented the progression. By Monday morning, the redness had continued to spread &amp; take up most of my left upper arm. The skin was hot to the touch and swollen. I had my boss look at my arm in the morning and mark the redness, then I had another physician at my office look at it in the afternoon and do the same. Their analysis was that the antibiotics were not working, and I went back to ER after I got off work at 5pm, which was around the 48-hour mark when I was supposed to return. ER gave me several IV antibiotics and ordered an Ultrasound of the left arm to make sure there was no blood clot hidden beneath the swelling. They also took several different lab and blood culture samples. I ended up having a reaction to one of the IV antibiotics (Vancomycin), where they had to counteract the reaction with IV steroids &amp; antihistamines, and decided to hold off on giving me the third IV antibiotic that was initially planned. I was sent home with Clindamycin 900mg, a Medrol dosepack, and told to discontinue the Bactrim, but continue the Amoxicillin. I continued to check back over the following days, and ended up receiving another</p>



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							IV antibiotic (Clindamycin) and more lab tests. The provider that saw me on Monday said that she was close to admitting me to the hospital, and if I did not improve by the following day, she would proceed with sending me. By the 5th/6th day, the redness seemed to be improving and becoming smaller.
1007295	2/5/2021	WA	65	F	2/3/2021	2/3/2021	INTENSE CHILLS, BODY ACHES, NAUSE, FATIGUE, SLEEPINESS, LOSS OF APPETITE. FAINTED-YES FAINTED FALLING BACK AND HITTING MY HEAD ABOUT 3 AM IN MORNING. I AM ON WARFARIN FOR BLOOD CLOTS
1007360	2/5/2021	AZ	35	M	2/1/2021	2/1/2021	I had the normal symptoms of pain at injection site, headache, fatigue, chills, muscle aches. I did get a fever for a short duration. The main thing I wanted to report is that I feel my heart and blood flow had been compromised from the vaccine. The reason I say this is that I have been getting pains in my chest and the blood flow in my body just feels not right. Lastly, I do feel it affected my cognition but I hope this will resolve soon as the fatigue dissipates. I also easily get skin reactions (skin reactivity increased such as redness and I got one red bump that looks like a hive but went away the next day). Not sure, but I feel this vaccine may be a cause for a potential blood clot. I do wonder if it has any effect on the characteristics of the blood. This is so far my experience and I hope as time goes on things become better.
1000489	2/4/2021			M	1/20/2021		I may have a blood clot in my leg.; This is a spontaneous report from a contactable consumer (patient). A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not provided), via an unspecified route of administration on 20Jan2021 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the first dose of the vaccine on 20Jan2021 and is going to visit his doctor because they think that he may have a blood clot on his leg on an unspecified date. He wanted to know if it was okay if they give him a shot of something like contrast to see the ultrasound. The outcome of the event was unknown. Information about lot/batch number has been requested.

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1003445	2/4/2021	NY	77	F	2/4/2021	2/4/2021	Administered vaccine into patient left deltoid, patient began to bleed and not clot quickly. Patient was dripping blood from vaccine site for 2 minutes, EMS was called in to confirm patient was feeling well and not pass out. Patient began to bruise and swell at injection site. Patient was coherent entire time, able to walk and move and stay for monitoring for 30 minutes. Patient denied medical transport.
1011163	2/4/2021		51	F	1/4/2021	1/5/2021	hematuria Narrative: Employee stated that she had hematuria with clots the morning after her vaccination, It was recommended that she see her private physician
1002073	2/4/2021	TX	73	F	1/25/2021	1/25/2021	Extreme pain in L arm injection site immediately after injection, followed by extreme fatigue, constant L arm pain, ache in body, on Tuesday-Friday, Saturday felt weak and extremely nauseous, at 2:00 pm experienced a embolic stroke on the right side of the brain and paralysis on the left side of body, rushed to ER, administered TPA clot buster and had a removal of the clots by Dr.
1001141	2/4/2021	WV	42	M	12/22/2020	1/6/2021	going to throw up; dizziness; This is a spontaneous report from a contactable consumer from a Pfizer sponsored -program, Pfizer First Connect. A 42-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231), intramuscular on 22Dec2020 15:15 at a single dose to prevent COVID. Medical history included retinal blood clot in his retina which was why he was tested for RA, and Meniere's disease for which he was asked to try meclizine which was for inner ear but he did not start taking meclizine, and six years ago, they did blood work and he was told he may have rheumatoid arthritis (RA) or he may have markers for RA but he has had no further issues and does not take any medication for this. The patient's concomitant medications were not reported. The patient experienced dizziness on 06Jan2021. The dizziness was increasing and he felt it most of the time. On 07Jan2021, he started feeling swimmy headed and he left work on 11Jan2021 since he was told he looked horrible. He never leaves work. He went to the clinic on the 11th since he felt like he was dizzy and going to throw up. The next day he did not feel better. The outcome of the events was not recovered.

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1000670	2/4/2021	AL	87	F	1/19/2021	1/1/2021	she was hurting at her chest/ Chest pain; on her left arm hurt real bad that's what the clot on her left arm; on her left arm hurt real bad that's what the clot on her left arm; She passed away; heart attack; This is a spontaneous report from a contactable consumer. An 87-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Jan2021 at single dose for COVID-19 immunisation. Medical history included diabetes mellitus, for which she was taking a pill like an hour before she would take her meal. On Monday (Jan2021) the patient experienced was hurting at her chest/ chest pain, her left arm hurt real bad as she had a blockage in her left arm/clot on her left arm, and they wanted to put in a stent and after the surgery it went well and she all go home in two days. The patient was hospitalized in Jan2021 due to the events. She had a heart attack and that the chamber between the dividers had a hole in it and her heart tissue was too thin so much thin she couldn't repair it. The patient passed away on 26Jan2021. The patient was tested negative for COVID-19 on unknown date. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: She passed away

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1000580	2/4/2021	TX		F	12/30/2020	12/1/2020	pain at injection site; This is a spontaneous report from a non-contactable consumer, the patient. A 5-decade-old female patient (late 40's) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: unknown), via an unspecified route of administration on 'approx' 30Dec2020 as a single dose, for COVID-19 vaccination. The patient medical history includes ongoing rheumatoid arthritis, ongoing blot clots (previously hospitalized for treatment of blood clots ). Concomitant medication included adalimumab (HUMIRA) and on 'blood thinners for prevention of blood clots'. On Dec2020, the patient experienced pain at injection site (kind of dull pain, very similar to a tetanus shot). 'Just the first day, took some Tylenol so I could sleep and woke up next day feeling fine.' Therapeutic measures were taken as a result of pain at injection site included Tylenol. The clinical outcome of pain at injection site was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

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1000581	2/4/2021	TX		F	1/19/2021	1/1/2021	<p>pain at injection site; mild headache; some fatigue; This is a spontaneous report from a non-contactable Consumer via social medica site. This female Consumer (patient) of unknown age reported for herself that she received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot number/Exp. date unknown), via an unspecified route of administration on 19Jan2021 at single dose for an COVID-19 immunisation. The patient medical history included rheumatoid arthritis, on blood thinners for prevention of blood clots (she has been previously hospitalized for treatment of blood clots). Historical vaccine included first dose of BNT162B2 on approximately 30Dec2020 and experienced pain at injection site (kind of dull pain, very similar to a tetanus shot) on first day of vaccination and took some Tylenol so patient could sleep and woke up next day feeling fine. Concomitant medication included adalimumab (HUMIRA). On 19Jan2021, the patient received her second dose of BNT162B2 and experienced the same kind of pain at injection site, mild headache, some fatigue. The patient took Tylenol again and stated that she was still able to do her normal daily household activities (laundry, tidying up, plying w/ dogs, vacuuming, and making sure (son) actually does his school work). Therapeutic measures were taken as a result of events pain at injection site, mild headache, some fatigue included Tylenol. No follow-up attempts are possible. Information regarding Lot/Batch No. cannot be obtained. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021058015 Same patient, different dose</p>

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1000666	2/4/2021			U			confirmed about a blood clot/check me for a blood clot, I didn't have one but it was kind of like a thrombosis kind of thing; Both of my legs, lower part of my legs were swollen that night when I went to bed and they got really red, almost purply red; Both of my legs, lower part of my legs were swollen that night when I went to bed and they got really red, almost purply red; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The consumer stated that after the first vaccine and it might be coincidental, the patient was not sure because the patient didn't know what to expect. Both of the patient's legs, lower part of the patient's legs was swollen that night (unspecified date) when the patient went to bed and they got really red, almost purply red and the patient stayed that way for a couple of days. The patient went to see the doctor two days later and doctor confirmed about a blood clot, so they did check the patient for a blood clot; the patient didn't have one, but it was kind of like a thrombosis kind of thing. So, the doctor put the patient on antibiotics for that. The patient asked if it is related to the shot, the patient didn't know it happened the same day the patient got the shot; so, the patient didn't know about that. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.
1003685	2/4/2021	FL	51	F	1/6/2021	1/7/2021	I was post menopausal - 16 months without a period, then got a period the day after my 1st vaccination. The day after my second dose I started another extremely heavy period. The worst I had in years which included many painful clots.

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1000097	2/4/2021			F			she couldn't work, she couldn't function. It was like she was two steps behind she was in a brain fog; This is a spontaneous report from a contactable other health professional (patient). A female patient of an unspecified age received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date: not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date: not reported) on an unspecified date for COVID-19 immunization and the lower part of her legs got swollen and really red, almost purply red. Patient went to see the doctor two days later to confirm about a blood clot so they did check her for a blood clot, and she didn't have one but it was kind of like a thrombosis kind of thing and was put on antibiotics for that. After the patient took the second dose of vaccine, she was sitting in her office trying to work and she couldn't work, she couldn't function. It was like she was two steps behind she was in a brain fog. It was kind of like the feeling of being drugged. She couldn't make herself do anything. She couldn't think, she could feel herself hearing people talk but couldn't respond correctly, couldn't speak quickly, she was talking really slow. She was assisted by a doctor and told her that she needs to go to the ER. She thinks they were afraid she was getting ready to have a stroke or something. So, she went to the ER and while she was sitting in the ER it kind of started to go away and she was coming back to herself. They went ahead and did a CT and everything was okay. The outcome of the event "she couldn't work, she couldn't function. It was like she was two steps behind she was in a brain fog" was recovering. Information on the lot/batch number has been requested.
999170	2/3/2021	CA	49	M	1/27/2021	1/31/2021	3 days after vaccine I developed edema in left hand and wrist, unable to make a tight fist+ swollen left neck supraclavicular lymph nodes+ left side/flank/chest (muscular) tightness. Visited PCP. Clear chest Xray, scheduled arm ultrasound to rule out blood clot

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996743	2/3/2021	NM	39	F	12/17/2020	1/15/2021	some numbness on the right side of face; early Bell's Palsy; This is a spontaneous report from a contactable pharmacist. A 39-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EJ1685), intramuscular in the left arm on 17Dec2020 16:15 at a single dose for COVID-19 immunization. Medical history included allergic rhinitis, deviated nasal septum, Factor V Leiden, GERD (Gastroesophageal reflux disease), DVT (deep vein thrombosis), hypertension, neck pain on left side, rhinitis, and rhomboid muscle strain. Concomitant medication included fluoxetine, acetylsalicylic acid, caffeine, paracetamol (EXCEDRIN MIGRAINE), fluticasone nasal spray, hydrochlorothiazide, lisinopril, loratadine, meloxicam, omeprazole, oxycodone, and sodium chloride nasal spray. The patient had no other vaccines in four weeks before covid vaccine. The patient had no prior vaccination and she had not been tested post vaccination. The patient noticed some numbness on the right side of face after receiving the first dose of vaccine on an unknown date. She was concerned for early Bell's Palsy on 15Jan2021 at 09:00 AM. She will be treated with valganciclovir and prednisone. The events resulted in doctor or other healthcare professional office/clinic visit. The outcome of the events early Bell's Palsy and some numbness on the right side of face was recovering.; Sender's Comments: Based on temporal association, a possible contributory role of BNT162B2 cannot be excluded for reported "concerned for early Bell's palsy". The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.



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999121	2/3/2021	PA	55	M	1/26/2021	1/26/2021	Multiple adverse events. Most serious is the Swelling of the left knee cap area starting on Day 4 (1/29/2021), extremely swelling and pain left knee 1/30/2021, 1/31/2021, 2/1/2021 and reduced swelling 2/2/2021. Went to PCP on 2/2/2021 was referred to hospital for x-rays of left knee. Also right foot and leg were swelled on 2/2/21 and 2/3/21 the same area of prior Achilles Tendon surgery May 2018 and history of DVT Blood Clots June 26, 2018. Still experiencing swelling to left knee and, left ankle now and right ankle swelling. 1/26/2021 at 4:05 pm had charley-horse pain at right posterior thigh area left of hamstring from 4:05 pm to 4:15 pm then it disappeared. 1/26/2021 8:00 pm to 10:00 pain to right quadricept area then disappeared. 1/26/2021 around 4:30 pm to 1/29/2021 10:00 pm had random Itchyness episodes for 15 seconds then ok for a minute then 15 seconds itchy someplace else. The worst of the itchyness was for the first 48 hours.
997550	2/3/2021	MA	54	F	1/27/2021	1/30/2021	First three days was just muscle soreness and fatigue. On day 4 I started having tight chest and SOB while snowshoeing, which I did not have the day before on same activity. That night I woke up with SOB and tightness in my chest and severe pain in area of my heart. I could not lay on my left side. It seemed like I was having heart attack symptoms. Barley slept but upon waking my heart rate was 94 and the pain remained in LT Axilla area. Took it easy for day and that night again had trouble sleeping, SOB but not as bad. Woke up with excrutiating pain radiating up the base of my RT skull. Was concerned about blood clot potential?? Had SOB when walking up stairs. My throat hurt when bending over, as if my esophagus was crushing. Friends said my face looked puffy and I felt bloated. Landed up reporting to ER at the Hospital on Monday, Feb. 1st as directed by my PCP. Hospital was told I had just had 2nd dose of vaccine, but did not think it was related. I will mention all tests below, but upon arriving home on Feb. 2nd, I discovered a rash breaking out on underside of my LT upper arm, LT inner thigh and LT lower leg.

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996224	2/2/2021	MS	56	F	1/4/2021	1/9/2021	Swelling of left forearm and elbow requiring vascular study for blood clot, Joint injection to left elbow . Swelling of entire upper extremity, US elbow. prednisone 20mg for 5 days and doxycycline 100 mg 10 days . Severe overall join pain , right knee swelling 9 days after injection. Six days after injection the left arm started swelling with burning pain at injection site to left arm.
993497	2/2/2021	FL		M	1/11/2021	1/11/2021	Blood clot; Swelling at the injection site; Redness at the injection site; A spontaneous report was received from a consumer concerning a 85-year old, male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced swelling at the injection site, redness at the injection site and blood clot. The patient's medical history was not reported. The patient current condition included chronic obstructive pulmonary disease (COPD). No relevant concomitant medications were reported. On 11 Jan 2021, approximately 0 days prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 11 Jan 2021, the patient's wife called his doctor as he was experiencing swelling and redness. They were referred to the emergency room (ER) by their doctor for a suspected infection. In the ER they were told it may be a blood clot and the patient was given prednisone. Treatment for the events included prednisone. Action taken with mRNA-1273 in response to the events was not reported. The outcomes of the events swelling at the injection site, redness at the injection site and blood clot were unknown.; Reporter's Comments: This case concerns a 85 year-old, male patient, who experienced events of swelling at the injection site, redness at the injection site and blood clot. The events occurred the same day after the first and last dose of mRNA-1273 vaccine administration. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded and the events are assessed as possibly related.

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993639	2/2/2021	NM	39	F	1/6/2021	1/15/2021	Early Bell's Palsy; Facial numbness on the left side of her face; Facial numbness on the left side of her face; Facial numbness and increased sensitivity on the left side of her face; This is a spontaneous report from a pharmacist. A 39-years-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EL0142), intramuscular at left arm on 06Jan2021 17:00 at single dose for covid-19 immunization. Medical history included allergic rhinitis, deviated nasal septum, factor V leiden, gastroesophageal reflux disease (GERD), history of deep vein thrombosis (DVT), hypertension, neck pain on left side, rhinitis, rhomboid muscle strain and pain. No known allergies. Concomitant medication included fluoxetine, acetylsalicylic acid, caffeine, paracetamol (EXCEDRIN MIGRAINE), fluticasone, hydrochlorothiazide, lisinopril, loratadine, meloxicam, omeprazole, oxycodone for pain, sodium chloride. The historical vaccine included the first dose of BNT162B2 (Lot number: EJ1685) via intramuscular at left arm on 17Dec2020 04:15 PM and the patient did notice some numbness on the right side of face after receiving the first dose of vaccine. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced facial numbness and increased sensitivity on the left side of her face. There was no facial droop or lid lag. Other cranial nerves are stable. Concern for early Bell's Palsy would be treated with valganciclovir and prednisone. The adverse events (AE) started from 15Jan2021 09:00. AE resulted in doctor or other healthcare professional office/clinic visit. The patient received treatment valganciclovir 1gm q8h, prednisone 20mg 3-day taper for AE. The events outcome was recovering. No COVID prior vaccination, since the vaccination the patient hadn't been tested for COVID-19.; Sender's Comments: Based on the temporal relationship, the association between the event early Bell's paly with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

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993749	2/2/2021	WV	42	M	1/13/2021	1/1/2021	Cholesterol little elevated; Vitamin D two points low; just about face planted; dizziness worsened; This is a spontaneous report from a Pfizer sponsored program from a contactable consumer (patient). A 42-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EL8982 or E68982), intramuscular on 13Jan2021 16:00 at single dose in left deltoid for COVID-19 immunisation. Patient age at time of vaccination was 42 years. Medical history included retinal blood clot in his retina which was why he was tested for rheumatoid arthritis (RA), and Meniere's disease for which he was asked to try meclizine which was for inner ear but he did not start taking meclizine, and six years ago, they did blood work and he was told he may have RA or he may have markers for RA but he has had no further issues and does not take any medication for this. The patient's concomitant medications were not reported. Historical vaccine included influenza immunisation (flu shot) in Sep2020 and first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EK9231) administered on 22Dec2020 around 15:15 at single dose intramuscular injection in left deltoid, and on 06Jan2021 he started to experience dizziness/feeling dizzy and going to throw up on 11Jan2021. He received the second dose of the Pfizer's COVID-19 vaccine on 13Jan2021 and for the last days it seems that the dizziness is being incrementing, reported as worsened. His physician recommended him to perform laboratory tests and the results came back without abnormal findings except for cholesterol and vitamin D. He was told his cholesterol was a little elevated and his vitamin D was two points low, regarding his lab work. He got a vitamin D supplement which he started to take. He will start on his cholesterol medication today that was prescribed. Reportedly he has a Roomba and when he went to go press the button for it, he just about face planted. He looked online and could not find anything about the dizziness aside from dizziness could be a sign of a severe allergic reaction. He does not have hypotension or anything like that. Dizziness was not resolved, while outcome of other events was unknown. It was stated dizziness is not reported as a side effect of the vaccine.

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995232	2/2/2021	FL	70	F	1/12/2021	1/13/2021	arm soreness/Arm hurt; headache; swollen glands; head "felt stuffy"; very weak muscles (had to be helped to the bathroom); very weak; not feeling well; very sick; This is a spontaneous report from a contactable consumer (patient). This 70-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 12Jan2021 at single dose for COVID-19 immunisation. Age at vaccination was 70-year-old. Medical history included Sars-Cov-2 infection (Mar2020), sick for 5 or 6 days, who knowingly has antibodies, and has donated plasma on multiple occasions, asthma but does not report respiratory symptoms, mild hypertension, migraines, vascular problems, and chronic portal vein thrombosis (PVT). Concomitant medications included linacotide (LINZESS), hydrochlorothiazide, rosuvastatin, montelukast, levothyroxine, clopidogrel. On 13Jan2021 at night, she reports arm soreness/arm hurt, and that when she woke up the next day she 'felt like she had Covid all over again' with: headache, swollen glands, head 'felt stuffy', very weak muscles (had to be helped to the bathroom), no fever but caller did state that she took a Tylenol. From Wednesday to Saturday she didn't feeling well, but every day she felt a little better. She has asthma - drug out my peak flow meter (as reported). No asthma sx during this whole thing. She reported adverse events and thinks some might have been stunted by the Tylenol she took after the first dose. She reported she was very sick, she still had like waves of not feeling well. She had most of the symptoms that she had was when she had Covid. She was sick, she was in bed and could not move. The most severe symptoms were on 13th and slowly each day felt better and it was until Saturday was when she really started to feel a 100 percent herself. Events were reported as non-serious. She had recently lab test within the last month or so. She had two or one and blood and everything was negative, everything was normal. Outcome of very sick and not feeling well is not recovered, while the outcome of the other events is recovering. She should receive the second dose on 02Feb2021. Information about lot/batch number has been requested.

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992155	2/1/2021	NY	55	F	1/13/2021	1/14/2021	The day after the vaccination I had redness around my whole shoulder and arm. On the third day I developed swelling of my shoulder and neck with horrible pain when I breathe. I went to urgent care and had an x-ray which was clear and they were treating me for myalgia with Motrin. I refused any narcotic pain medication or a Toradol shot. The pain never stopped on the 19th I went to Work Force Safety and reported it and I was examined by the nurse practitioner who saw all the swelling and the pain that I was in. That nurse practitioner told me if it wasn't better in a few days to go to the emergency room to be examined. On January 23 , I developed swelling and pain went underneath my armpit it's a burning pain that's constant since the third day after my injection. My blood pressure was 153/104 and I was having nausea and not feeling well at all. On January 25 the pain and swelling were still there I went to work for a few hours and I went to the emergency room. They gave me lidocaine patch and Zofran for the nausea my blood pressure was 159/103 and I had an ultrasound to rule out a blood clot there was no blood clot but there was lymphadenopathy under my arm hurt and swelling and inflammation around the shoulder. The chest x-ray showed left pleural effusion / Pneumonia. My oxygen saturation was 93 and they wanted to admit me but I am a single mom with a new diabetic 14-year-old at home so they let me go home with a pulse oximeter and a prescription for doxycycline For 10 days. They called me the next day from the emergency room to follow up with a pulmonologist and cardiologist. On January 28 I saw the pulmonologist who did an ultrasound in his office and saw the fluid on my left lung. He said that most likely because the technique of the injection was so high in my shoulder that they probably had a nerve and I did have the swelling in the lymphadenopathy and all the pain and it hurt when I breathe so I wasn't breathing correctly and I was splitting my arm against me and that's how I probably developed plural effusion and pneumonia. I am following up with him on February 4. I still have shortness of breath and my oxygen saturation is 93. I am also on two inhalers that the pulmonologist ordered.

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992245	2/1/2021	AZ	59	M	1/11/2021	1/19/2021	Superficial and deep vein thrombosis was diagnosed on 27th of January. Symptoms had been going on for around 2 weeks.
992810	2/1/2021	FL	68	F	1/19/2021	1/22/2021	Concern comes from a pulmonary Embolism and DVT diagnosed within a week of the first shot. Realize this could be a coincidence, I have no history of clots.
992022	2/1/2021	MN	64	F	1/19/2021	1/27/2021	Superficial blood clot in right medial knee area. Aspirin, elevate right leg, compression and heat.
991754	2/1/2021	MO	32	F	1/27/2021	1/28/2021	Started with fever, chills, lethargy, headache and nausea around 0900 on 1/28/21. By 1500 I had severe nausea which resulted in vomiting (water and dry heaving) with a small amount of blood (small clots) with first time vomiting. Then at 1700 I could barely move with severe body aches and headache. Attempted to drink some water and eat soup, but intestines burned too much. Slept from 0800 on 1/28/21 through till 0830 on 1/29/21 with very minimal waking. Only left my bed to throw up one time and use the restroom one time. Took Tylenol around the clock. Upon waking on 1/29/21 noticed a petechiae type rash on both sides of my face, sore throat and mild headache (took tylenol). 1/30/21 no symptoms and facial rash slowly disappearing.

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990624	2/1/2021	GA	60	F	1/14/2021	1/15/2021	nose bleed/kind of "blew like a quarter size of blood clot"; congestion in her throat; headache; tired, very tired and just wanted to sleep; nausea, some nausea; feeling unwell; This is a spontaneous report from a contactable consumer (patient). A 60-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number EL0140 and expiry date unknown) via unspecified route of administration on 14Jan2021 at single dose for Covid-19 immunization on her job (nursing home). Medical history included blood pressure high. Concomitant medications vitamins. The patient took that COVID-19 vaccine shot yesterday (later clarified the date as 14Jan2021) on her job. The patient informed that she was okay the first day, but yesterday (15Jan2021) last night she had some new problems and she wanted to talk about and see it's a clinical sign. The patient informed that it was headache, tired, very tired and just wanted to sleep. The patient had no swelling/no swelling in arm, nausea, some nausea and even she has been just feeling unwell. The patient informed that today (16Jan2021) this morning, she was having nosebleed until the last time she felt like congestion in her throat and she kind of "blew like a quarter size of blood clot". The patient blew her nose and it bled a while, but then a quarter size blood clot come out and since then it wasn't bleeding, her nose was not bleeding. The patient did not receive treatment due to the events. The patient underwent lab tests and procedures which included COVID testing; swab the nose: negative on 13th or maybe 14th (Jan2021). The outcome of the events headache, tired, very tired and just wanted to sleep, nausea, some nausea, feeling unwell, nose bleed/kind of "blew like a quarter size of blood clot", congestion in her throat was unknown.



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990361	2/1/2021	IN		F	1/14/2021	1/14/2021	<p>blindness in left eye; stroke in back of the eye; blood clot; A spontaneous report was received from a consumer concerning an 83-year-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced blindness in left eye, blood clot, and stroke in back of the eye. The patient's medical history was not provided. Concomitant medications reported included comerdol, losartan, hydrocortisone, meloxicam, and unspecified stomach pills. On 14 Jan 2021 at 10:15 am, approximately 3 hours and 45 minutes prior to the onset of the events, the patient received a dose of mRNA-1273 (Lot number: 013L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 14 Jan 2021 around 2:00 pm, the patient lost sight in her left eye as a result of a blood clot and stroke in the back of her eye. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, blindness in left eye, blood clot, and stroke in back of eye, was unknown.; Reporter's Comments: This case concerns an 83-years-old female patient, who experienced a serious unexpected event of blindness unilateral, retinal artery occlusion, and thrombosis. The event of blindness unilateral and retinal artery occlusion occurred 3 hrs. after first dose of mRNA-1273, lot # 013L20A. The event of thrombosis occurred on an unspecified date after first dose of mRNA-1273, lot # 013L20A. Treatment included details were not provided. Concomitant medications included Comerdol, Losartan for blood pressure, Hydrocortisone, Meloxicam and stomach pills. Very limited information regarding this event has been provided at this time. Based on the current available information and temporal association between the use of the product and onset of the event a causal relationship cannot be excluded.</p>

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990355	2/1/2021	NY	60	M	1/7/2021	1/11/2021	DVT blood clot; A spontaneous report was received from a 60-year-old male consumer who received Moderna's COVID-19 vaccine (mRNA-1273) and developed deep vein thrombosis (DVT) blood clot. The patient's medical history, as provided by the reporter, included factor V Leiden, enlarged prostate, DVT, pulmonary embolism and hypertension. Concomitant medications reported included valsartan, alfuzosin, and acetylsalicylic acid. On 07 Jan 2021, approximately four days prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 011J20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 11 Jan 2021, the patient developed DVT blood clot and experienced leg pain so intense that he could not walk. A doppler exam showed the DVT was from the top of the calf to mid-thigh. Treatment for the event included a rivaroxaban starter pack with dose tapering. Action taken with mRNA-1273 in response to the event deep vein thrombosis (DVT) blood clot was not reported. The outcome of the event, DVT blood clot, was unknown.; Reporter's Comments: This case concerns a 60-year-old male patient with a relevant medical history of factor V Leiden, DVT, pulmonary embolism and hypertension who received their first of two planned doses of mRNA-1273 (Lot number: 011J20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. Patient experienced the medically significant unlisted event of Deep vein thrombosis approximately four days after administration of vaccine. Treatment for the event included rivaroxaban. Based on the temporal association between the use of the product and the event occurring after receiving the vaccine, a causal relationship cannot be excluded and the event of Deep vein thrombosis is possibly related to the product. Of note, the patient's underlying Factor V Leiden which predispose to developing abnormal blood clots, and prior medical history of DVT with pulmonary embolism are considered risk factors to the occurrence of the event.

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989360	1/31/2021	NE	31	M	1/26/2021	1/27/2021	Gross hematuria with clots. AKI with elevated creatinine to 2.18 (Baseline <1.0). UA with moderate blood, positive nitrite, moderate LE, >50 rbc's Urine lytes WNL, Pr:Cr 3.3, Al:Cr 1,245 C3/C4 WNL US with mildly echogenic kidneys, a nonspecific indicator of medical renal disease. No hydronephrosis. Thick-walled nondistended urinary bladder. Hgb decreased to 12.9 from 15 Pt underwent a kidney biopsy, pathology is still pending. He received aggressive IVFs and was monitored for 2 days. He was discharged following the kidney biopsy. At that time he was still having hematuria although it was improving and his hemoglobin was stable.
988967	1/31/2021	IN	84	M	1/15/2021	1/21/2021	No immediate reaction to Moderna COVID-19 Vaccination 01/15/2021. Swelling, tenderness, at vaccination site started on 01/21/2021. Increasing discomfort over few days included swelling, tenderness, and increasing bruising / hematoma on upper arm extending past elbow. Ultrasound of neck to wrist ordered by on Monday, 01/25/2021, revealed no venous blood clots. Swelling, tenderness, discomfort, range of motion limitation, though somewhat less intense, continuing through today (01/31/2021).
989737	1/31/2021	CT	36	F	1/4/2021	1/16/2021	Received vaccine on 1/4. Started menstrual cycle on 1/16 which was 1 week early. 3 days into the cycle, heavy vaginal bleeding with large blot clots (golf ball size) starting on 1/20/2021 and continuing until now 1/31, bleeding still going on.
989466	1/31/2021	MI	46	F	1/15/2021	1/21/2021	Deep vein thrombosis right gastrocnemius vein and superficial venous thrombosis in right small saphenous vein diagnosed January 15, 2021. Symptoms began with acute onset right lower extremity calf pain and swelling on January 14, 2021. Treatment with Xarelto began January 15, 2021.
990853	1/30/2021	NC		F	1/7/2021	1/24/2021	Pfizer Covid 19 vaccine treatment under Emergency Use Authorization(EUA): My menstrual cycle has changed and I have started with old brown bleeding with clots 10 days prior to my normal cycle. I have never had this happen and have never had any issues with my periods. Will be seeking medical treatment on 1/27/21 with OBGYN.

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988076	1/30/2021	NY	59	M	1/13/2021	1/16/2021	<p>On day 04 After receiving the 2nd Covid 19 Pfizer vaccine, I experienced a deep pain in my upper inner right thigh around 0600 am of the 16th of January. At the same time my calf muscle of that same right leg was in pain. I thought it to be muscular pain as I was told by the reading material regarding symptoms of the covid 19 vaccine there could be aches an pains attributed to the 2nd shot. I used a deep heating rub on both areas of my right leg and put heat on them to treat the soreness. This occurred over the next few days feeling this pain in my right leg and treated the same way applying heat. Within about 24 hours of the pain in my legs I started experiencing a shortness of breath while walking up and down st. On day 04 After receiving the 2nd Covid 19 Pfizer vaccine, I experienced a deep pain in my upper inner right thigh around 0600 am of the 16th of January. At the same time my calf muscle of that same right leg was in pain. I thought it to be muscular pain as I was told by the reading material regarding symptoms of the covid 19 vaccine there could be aches an pains attributed to the 2nd shot. I used a deep heating rub on both areas of my right leg and put heat on them to treat the soreness. This occurred over the next few days feeling this pain in my right leg and treated the same way applying heat. Within about 24 hours of the pain in my legs I started experiencing a shortness of breath while walking up and down stairs as part of my daily activities. The symptoms of shortness of breath only seemed to appear when I was on any form of extended walking activity or physical movements or exercise this would of have been starting around the 17th of January. The right leg pain was masked by the heating rub while the shortness of breath continued for the next few days. On the 19th of January, I went to an Urgent Care Facility at 0800 am to see a Medical professional to discuss my symptoms I was previously experiencing and to figure out why I was having a shortness of breath and the pain in my right leg. The on staff Physician's Assistant had a Nurse conduct a Covid 19 Rapids test (negative) and a second swab was administered and sent to the Lab. Which produced a (negative for Covid 19) on the 20th of January. An Xray was not taken to determine my shortness of breath. The Dr listened to my lungs and heart, though I did let the PA know I had received both Pfizer shots and when they were administered. I was carrying My Shot record for the</p>

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vaccine with the dates and lot number. He didnt appear to be interested in further diagnosis and made sure I had the paperwork to track the results of my Covid swab sent to the lab. The visit was completed and I was released to go back to work/home. I carried on the symptoms of the shortness of breath from the 19th of January to the 22nd of January monitoring my O2 (oxygen levels) with a pulse oximeter. They ranged from 90-93. On the evening of the 22nd of January I was becoming very uncomfortable with my breathing climbing the stairs in my home and monitored my O2 readings with the oximeter on my finger when walking upstairs and they dropped down to 60-65. My wife drove me to the emergency room at Hospital. I walked into the ER and checked myself in for shortness of breath and leg pain in my right leg. I was admitted into the emergency room and put on 15 litres of oxygen. The emergency room Dr ordered a chest Xray, Cat Scan of my chest and heart and a sonogram of my right leg. The testing results came back with a noted large pulmonary emboli on my lungs/heart area and blood clots throughout my right leg (right lower extremity DVT). Surgery was performed to remove the pulmonary emboli and I was put on a Heparin Drip to thin out my blood for the remaining clots in my chest and my right leg. The attending physician ordered a T.E.E. (transesophageal Echocardiogram) to observe my heart functions. I was told the TEE did not demonstrate any further recommend surgeries. I was administered a test for my cardio and heart functions prior to my discharge on 27 January 2021. I was prescribed Eloquis for maintenance medication to be monitored by followup visits to my cardiologist and Hemotologist within the next few weeks. I have not family or personal history of Blood Clots. I do perform administrative duties as part of my job, which requires sitting and working on a computer. Note however I move around very often during a work day and operate a farm tractor and have an active life style. I have not recently had any extended trips more than 2 hours nor have I flown within the past year or so.

988302 1/30/2021 TX

41 F

1/1/2021

Very heavy period. Passed multiple golf ball sized clots for several hours.

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984641	1/29/2021	IN	35	F	1/16/2021	1/16/2021	Nausea; Slight temperature 99.7; Fatigue; General feeling of aches and pains; Sore throat; Throat seemed red; Sick; Feeling heavy with her chest. She went to the ER; This is a spontaneous report from a contactable nurse. This nurse reported for a 35-year-old female patient (Daughter) received 2nd dose of BNT162B2 (COVID-19 Vaccine lot number: EK9231, Expiry date: Apr2021) on 16Jan2021 at single dose for covid-19 immunization. Medical history reported was She was positive, our whole family had COVID and we all came down which was about the same time which was 29Dec. Concomitant drug were not reported. Retired Nurse stated, "I am calling for my daughter. She received her 2nd vaccination yesterday morning and she had some side effects. Like about 6 o'clock this morning she came in, she came in 6:35, she came and woke me up and said that she felt some of the reaction she is having. She has nausea, she has slight temperature 99.7, fatigue. Just a general feeling of aches and pains. It does not seem like it's an emergency. She was treated in the ER with steroids and since that point we have all recovered until she went for the 2nd. She works in a hospital, she got her 2nd dose of vaccine like I said yesterday morning. "Retired Nurse stated, "I am not sure causality. I mean it is not an emergency. She was feeling fine yesterday. We all are feeling better now. She had the vaccine and last night she said she had a sore throat when I looked at her throat. Her throat seemed red but there was no angioedema or anything like that, she went to sleep and she came in 'feeling really' (voice distortion) sick. So, I do not know. Did they have relapses from the COVID? I do not know." Treatment was "Tylenol." Like I had said that she was feeling heavy with her chest. She went to the ER. She was at her work. She went to the ER." "Probably close to 10 days ago, they did lab work I think they might have been looking for a clot. They did do some lab work at the hospital with unknown results." Outcome of the event was unknown. No follow-up attempts possible. No further information expected.

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985379	1/29/2021	FL	38	F	12/28/2020	1/2/2021	12/28 vaccination 1/2 afternoon started feel swelling in armpit, pain, L arm. Monitored 1/3 pain increased. Worried it was blood clot. Ultra sound @ urgent care. Put on antibiotic as precaution for 10 days. Lasted for 14 days.

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985625	1/29/2021	CA	59	F	12/23/2020	12/23/2020	<p>Blg black thing; Big scar; Felt like chemical burn; Peeling; Cellulitis; Extravasation in tissues; Bruising from upper arm down to elbow; Arm was hot and tender; Swelling from upper arm down to elbow; Arm hot and tender; Bump/clot at injection site; Unsure if it was given intramuscularly; A spontaneous report was received from a physician who was also a 59-year-old female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced a bump/clot at the injection site, swelling, bruising from upper arm to elbow, feeling hot, tenderness, extravasation in tissues, vaccination site cellulitis, a big blackened area, scar, chemical burn, unsure whether it was intramuscular and peeling. The patient's medical history was not provided. Concomitant medication use was not provided by the reporter. On 23 Dec 2020, immediately prior to the onset of symptoms, the patient received the first of two planned doses of mRNA-1273 (Lot number unknown) intramuscularly in the left arm for prophylaxis of COVID-19 infection. The physician reported that she was injected with the vaccine abruptly and roughly. She noticed a bump at the injection site right away. The nurse applied a cold compress. Later that day, she realized it was a clot. On 24 Dec 2020, she had swelling, bruising from her upper arm to her elbow, and the area was hot and tender. On 30 Dec 2020, she went to the emergency room where an ultrasound showed extravasation in the tissues. She was treated with cephalexin for cellulitis. On 01 Jan 2021, the bump began to subside; however, there was a large black area that started to peel. The reporter stated it looked like a chemical burn. On an undisclosed date, there was a large scar in its place. Treatment for the events included a cold compress and cephalexin. The reporter stated she is unsure whether it was intramuscular. Action taken with mRNA-1273 in response to the events was not provided. The event, scar, was not resolved. The outcome of the events, bump/clot at the injection site, swelling, bruising from upper arm to elbow, feeling hot, tenderness, extravasation in tissues, vaccination site cellulitis, a big blackened area, chemical burn, and peeling, were considered resolving. The event, unsure whether it was intramuscular, was resolved.; Reporter's Comments: This report refers to a case of incorrect route of administration for mRNA-1273 and concerns a 59 year-old, female</p>



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patient, who experienced the events of bump/clot at the injection site, swelling, bruising from upper arm to elbow, feeling hot, tenderness, extravasation in tissues, vaccination site cellulitis, a big blackened area, scar, chemical burn and peeling. The event of bump/clot at the injection site occurred the same day after the first and only dose of mRNA-1273 vaccine administration. The events of swelling, bruising from upper arm to elbow, feeling hot, tenderness occurred the next day after the vaccine administration. The events of extravasation in tissues, vaccination site cellulitis occurred 7 days after the vaccine administration. The events of a big blackened area, scar, chemical burn and peeling occurred 9 days after the vaccine administration. Based on the current available information and temporal association between the use of the product and the start of the events, a causal relationship cannot be excluded and the events are assessed as possibly related.

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986092	1/29/2021	NM	39	F	1/12/2021	1/12/2021	the right side swelling, swelling underneath armpit, swelling of collarbone and neck; This is a spontaneous report from a contactable Nurse reporting for herself. A 39-years-old female patient received the second dose of bnt162b2 (BNT162B2; Lot # EL0142) vaccine, intramuscular on 12Jan2021 15:30 at single dose for Covid-19 immunisation. Medical history included deep vein thrombosis, provoked DVT, and moderate asthma . There were no concomitant medications. The patient received the first dose of BNT162B2 vaccine on 23Dec2020. The patient experienced right side swelling on 12Jan2021 some hours after injection. On 13Jan2021 swelling underneath armpit was significant, swelling of collarbone and neck was also present. The reported event was considered Important Medical event. The outcome of the event was recovering. The event was treated with Round the clock Ice pack. Antihistamine and NSAIDs. Followup information has been requested. Lot number already provided.; Sender's Comments: Based on the compatible temporal association, a contributory role of suspect vaccine BNT162B2 in the development of "the right side swelling, swelling underneath armpit, swelling of collarbone and neck" cannot be excluded. The impacts of this report on the benefit/risk profile of the product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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986100	1/29/2021	LA	71	M	1/13/2021	1/15/2021	Raspy voice in the morning; The right side of his mouth is droopy. The droopiness is not excessive, but it is odd.; Right eyelid puffiness/ on the right side of patient's face, the eyelid was puffy; Right eye full of fluid/Under that eyelid is full of fluid; Can't hardly see out of right eye due to swelling; This is a spontaneous report from a contactable consumer. A 71-year-old male patient (reporter's husband) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3299) via an unspecified route of administration on the left arm on 13Jan2021 14:00 at a single dose for COVID-19 immunization at a clinic/ used empty offices. Medical history included being diabetic, had heart attacks and blood clots on unspecified dates. It was confirmed that all of this occurred years ago prior to COVID-19 vaccination. The patient had no relevant family medical history and no relevant tests. The patient takes a number of medications (unspecified). The patient previously received Flu shot at least six weeks ago in Nov2020 and had no adverse events. The patient had no additional vaccines administered on the same date as BNT162B2. The reporter and her husband (patient) got their shots on Wednesday afternoon. That morning, on 15Jan2021 at 08:00, on the right side of patient's face, the eyelid was puffy/ right eyelid puffiness. He can hardly see out of it. He can see. Under that eyelid was full of fluid/ right eye full of fluid. The right side of his mouth was droopy. The droopiness was not excessive, but it was odd. The reporter also stated that the "patient had a raspy voice in the morning anyways." The outcome of the events was unknown.
986749	1/29/2021	FL	71	M	1/22/2021	1/26/2021	5:30 am I found husband by bed, babbling, Called 911, Had Lt Hemi Stroke. Aphasic, Rt side limp, given TPA. Sent to ICU. Recovered within 2hrs, speech, movement of extremities. It hemi clot found on ct angiogram & mri. 2nd mri found clot busted with residual. transfered to telemetry next nite. echo unclusive. 02 sats low, venogram done 3days later show lt dvt, lung ct wnl. Id asa & b/p meds were given. blood work to be drawn for baseline prior to anticoagulant therapy. possible d/c 9/30.

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986130	1/29/2021	GA	57	F	12/17/2020	1/4/2021	increased heart rate after that it started getting worse; a warm feeling in her chest like tingling; kind of short of breath; left hand start swelling up first a little bit and then her left arm start swelling up/ her right hand start very, very mild swelling in her right hand; Chills; Fatigue; GI problems; still have some issue, did not feel good, off and on; SARS Covid antibodies test says positive; This is a spontaneous report from a contactable other nurse (patient) from a Pfizer sponsored program Pfizer First Connect. A 57-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at single dose (lot number: EJ1685) on Deltoid Left for covid-19 immunisation. Medical history included Paroxysmal supraventricular tachycardia. The patient's concomitant medications were not reported. The patient experienced a warm feeling in her chest like tingling; kind of short of breath, it went away like she said it was just breath it was like for couple of minutes and then it went away and then she was just fine till it's been long here honestly about 3 or 4 days later; got shot in her right arm but left hand start swelling up first a little bit and then her left arm start swelling up and it's just and then that's the base and then her right hand start very, very mild swelling in her right hand. The hospital think there as some clot or something weird but she did not and then that started going down after that it just started going down and went away and never had swelling since then but this was going to long but this was something weird happened to her. She got chills, She got fatigue. She had increased heart rate after that it started getting worse. She had Paroxysmal supraventricular tachycardia, she had that always but it's been control. She walked 5 miles daily a day, she was in shape, she had lot since then, so it's been under control, she never had problem with it until after she got the shot, her heart rate was she had to add medication, she never have to add. She took metoprolol (Treatment) so she added that and she added more and that's thing get it under control and then she take herself back off because she felt like it was under control but she had GI problems since, now she was getting better now, still have some issue, did not feel good, off and on. The patient underwent lab tests and procedures which included blood test: good on 04Jan2021 (blood work to see if something was going on

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to her heart, because she had short breath, and everything was good), weight: 166 or 164, SARS Covid antibodies test IgM on 04Jan2021: positive. Treatment: Nurse stated, "No, not now, I had a heart-rate monitor, it's what for see what is my heart rate, to locate and see what's going on." Outcome of left hand start swelling up first a little bit and then her left arm start swelling up/ her right hand start very, very mild swelling in her right hand was recovered.; Sender's Comments: There is not a reasonable possibility that event heart rate increased is related to BNT162B2. The event is most likely due to underlying paroxysmal supraventricular tachycardia. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

986118 1/29/2021 WA

81 F

12/14/2020

12/14/2020

She was cleaned out, pretty much cleaned out of her bowels, but she kept getting pains and started passing blood clots; She kept getting pains; Bad stomach cramps; Diarrhea; This is a spontaneous report from a contactable consumer. An 81-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EL0142, expiration date unknown), via an unspecified route of administration, on 14Dec2020 10:00 at a single dose for COVID-19 immunization. Medical history included hypertension from an unknown date. Concomitant medication included atorvastatin, losartan, alprazolam, mirtazapine, and several medications because of her age and she has hypertension. The patient had her vaccine on 14Dec2020 at about 10 o'clock and a couple of hours later she began getting really bad stomach cramps and had diarrhea for most of the day and about 11 o'clock of 14Dec2020 she reported she was cleaned out, pretty much cleaned out of her bowels, but she kept getting pains and started passing blood clots. Treatment for the events include Some Pepto-Bismol (as reported). The outcome of the event "bad stomach cramps" was not recovered, and for other events was unknown.

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986116	1/29/2021	IN	85	M	1/12/2021	1/14/2021	like a blood clot; All around eye is real swollen and puffy and in corner/don't know if it looks like a bruise or it's like a blood clot or something; like a bruise; a red, dark red spot/not on the eye but up on the eyelid it looks like; all around his eye was real swollen and puffy and in the corner, not on the eye but up on the eyelid it looks like; This is a spontaneous report from a contactable consumer. An 85-year-old male patient (reporter's husband) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number like EL1283), via an unspecified route of administration on 12Jan2021 at single dose for covid-19 immunization. Medical history included slightly elevated blood pressure from an unknown date. Concomitant medication included clopidogrel besylate (CLOPIDOGREL) for blood pressure; hydrochlorothiazide, losartan potassium (LOSARTAN + HIDROCLOROTIAZIDA) as blood thinner and several of drugs. The patient had the Covid vaccine on the 12Jan2021 and yesterday (14Jan2021) as they noticed his eye, all around his eye was real swollen and puffy and in the corner, not on the eye but up on the eyelid it looks like, the reporter didn't know if it looks like a bruise or it's like a blood clot or something and it's still there, it hasn't gone away and they didn't know if this was from the vaccine, the reporter didn't know if it's bruise or if it's a clot the reporter didn't know, it's a red, dark red spot. after we had the vaccine they gave us a paper that had some information on it and it said on there they should advise them if on blood thinners, they did not told beforehand and the patient was on blood thinners. No treatment was received. The outcome of the events was not recovered. Information about lot/batch number has been requested.

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980676	1/28/2021	CA	45	F	1/14/2021	1/14/2021	half of my legs feel uneasy; had bad taste like metal; This is a spontaneous report from a contactable nurse (patient). A 45-years-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL8482, expiration date: unknown), via an unspecified route of administration on the left arm on 14Jan2021 at 12:00 at a single dose for COVID-19 immunization. Medical history included history (Hx) of blood clots. The patient has no known allergies. The patient is not pregnant. The patient's concomitant medications were not reported. The patient had no other vaccine in four weeks and no other medication in two weeks. The patient had no COVID prior vaccination and had not tested post vaccination. On 14Jan2021 at 1315, the patient experienced half of her legs felt uneasy, no pain, just like she worked out. The patient also reported that after the vaccine, she had a bad taste, like metal. No treatment was administered for the events. The events had not resolved.

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980727	1/28/2021			F			Tiredness; Headache; Nausea; Swelling; Feeling unwell; Nose bleed; Coughed up a blood clot; Congestion; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced tiredness, headache, nausea, swelling, feeling unwell, nose bleed, coughed up a blood clot and congestion on an unspecified date. The patient underwent lab tests and procedures which included sars-cov-2 test: unknown results on COVID test close to that time too where they swabbed my nose. Details were as follows: patient got the vaccine on 19th (month and year unspecified), and the COVID test with unknown results close to that time, where they swabbed her nose. She has had had tiredness, headache, nausea, swelling, feeling unwell, and the last night she had a nose bleed and coughed up a blood clot out of her throat. She also had a lot of congestion since taking the injection, and did not know if it was from the injection or the COVID Test. The outcome of tiredness, headache, nausea, swelling, feeling unwell, nose bleed, coughed up a blood clot and congestion was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.
982241	1/28/2021	IN	89	M	1/13/2021	1/14/2021	After I received the vaccination that evening I went to bed and woke up about midnight felt water in the bed and it was coming out of my arm, I dried it off went back to sleep. The next morning my arm was swelling, and it?s gotten worse and worse, the top of my had is so swollen I cannot make a fist. My doctor sent me to the hospital and blood work was alright the echocardiogram showed heart is alright no blood clot and there?s no other reason. My doctor thinks it?s because of the vaccination.
983350	1/28/2021	ND	57	F	1/7/2021	1/11/2021	Patient experienced a blood clot on January 11th. She is unsure if it is related to the vaccine or not.



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983906	1/28/2021	FL	85	M	1/19/2021	1/20/2021	<p>Patient received Pfizer-BioNTech Covid-19 vaccine, first injection, in the afternoon of Tuesday, 1/19/2021 - administered by pharmacy staff. All residents and staff of the facility were vaccinated (except one resident). Wednesday afternoon (1/20/2021), patient was noted to have a open area on his 3rd left toe with digital edema and blackening of toe, 2nd toe had a fluid filled blister as did area superior to left medial knee. There was also an open area inferior to left medial knee. Bruising or blackened areas to 3rd left toe and bottom of left foot (pad below toes 1-3). Patient was placed on Keflex 500 mg BID for 10 days, Clotrimazole 1% topical cream for ring worm middle of left foot, and ammonium lactate 12% lotion for dry skin. By Saturday, 1/23/2021, multiple blisters had erupted on patient's left medial knee area and 4th left toe. Some of the prior blisters were now gone, but new blisters were larger. On Thursday, 1/28/2021, patient now has blisters and open areas on bilateral feet, legs, and hands. He has a red rash on his right lower leg just superior to the medial ankle. Patient was placed on a 10 mg Medrol Dose Pak. There have been no changes to the patient's diet or medications. Patient is confined to the facility due to dementia. He goes from his bedroom to a sitting area, right outside of his bedroom door. He ambulates with assistance using a cane, only to the bathroom in his room. He has a private room.</p>

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983883	1/28/2021	AZ	50	F	1/20/2021	1/28/2021	Got booster shot on Wednesday the 20th, came home and was fatigued. Thursday had horrible headache that would not be relieved with tylenol. I took a plane and arrived at 1130 pm. I went to bed shortly after arriving at my daughters house. Friday morning, I was unable to be woken up and my daughter called 911. I was in a coma. I suffered cardiac arrest during a CT to check for clots. I was resuscitated and put on life support. CT scan for clots, strokes, heart attacks were all clear. I was admitted to the C-ICU and on life support, on the ventilator, and was on 3 different medications at max dosage to keep my blood pressure barely surviving. The doctors told my daughter not to expect me to survive because they had no idea why I was suddenly so ill. A doctor then told my daughter that my kidneys were failing, and my liver was damaged. I also developed a high fever and had a high white blood cell count. They gave me Vancomycin and another antibiotic, and then the next the day a kidney doctor gave me lasix to flush out all of the excess fluid. I woke up on Saturday not knowing what had happened and was completely terrified and confused. My daughter was allowed into the ICU to see me and keep me calm, thankfully. She explained to me what happened. I am still in the hospital, as they are keeping me for observation and trying to determine if my kidneys will start working properly again. Prior to this, I have only ever had a kidney infection, and I thought before I might have had the start of a UTI. I do have chronic high blood pressure as well, a long term side effect from open heart surgery 10 years prior for an aneurysm, but aside from that I am relatively healthy 50 year old.
979775	1/27/2021	CA	47	F	1/11/2021	1/12/2021	Employee states that she received Dose #2 the day after the end of her menstrual cycle and that she began bleeding again after receiving her second dose and that it was a heavy and clotted cycle. She was advised to contact her OB/GYN

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976797	1/27/2021	MI	43	F	1/12/2021	1/12/2021	hot sensation/weird very hot rush down her right arm that was vaccinated and went up the back of her neck only on the right side; dizzy; Heart racing; Her arm was very sore- it was difficult to lift it; Her arm was very sore- it was difficult to lift it; She did feel a little out of it, as it produced a little bit of anxiety; A mild allergic reaction; This is a spontaneous report from a contactable Other Health Professional (patient). A 43 years old female patient received 1st dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EL3248, Expiration Date: Apr2021), via an unspecified route of administration on 12Jan2021 at 13:22 at single dose on right arm for covid-19 immunisation. Medical history included vasovagal (she did have a history of vasovagal. She talked to her doctor about this prior to the vaccine. At first when she had it her previous doctor felt a little confused. She was unsure if it was vasovagal or a blood clot in her lungs. She did get it checked out with a cat scan and there was no clot. They had to have tested her for anaphylaxis at that time. It was not a clear diagnose. Then she saw a cardiologist. She was diagnosed with vasovagal at that time. It lasted only a few months and she was fully recovered). Concomitant medications included ongoing ergocalciferol (VIT D) and ongoing vitamins NOS (MULTIVITAMIN). Patient received the vaccine on Tuesday, 12Jan2021. Her appointment was at 12:54, but she got the vaccine at 13:22. She was looking at her phone to re-schedule her second dose. She felt totally fine. At 13:27 she had this weird very hot rush down her right arm that was vaccinated and went up the back of her neck only on the right side. She looked up from her phone and was very dizzy. She stood up and as she did her heart started to race. It was a really weird feeling that she has never felt. She was a little out of it. She had no trouble breathing. Within 30 seconds she was completely fine. She did feel a little out of it, as it produced a little bit of anxiety. She had no other symptoms. She stayed at the facility for 30 minutes. As she was leaving one person asked how she felt and she was told to let the EMTs know. She let them know what happened. One woman working there said it could have been an anxiety attack. She did not have a lot of anxiety but she did have some. It did not feel like that. She had never had the warm sensations or heart racing. She was totally fine when talking to the EMTs. They did not seem concerned and

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they let her schedule her second shot. She read on Pfizer about allergic reactions. She was assuming this was what happened. A mild allergic reaction. She had no breathing issues or hives. Her arm was very sore- it was difficult to lift it. She had also never had this type of soreness with vaccines. Dizziness: She has had the dizziness a couple of times. Twice now. One when she had gotten home. It was very mild and nothing compared to what she had when she got the vaccine. Then another last night at bedtime. It was a woosh of dizziness. Arm soreness: very improved now. felt like she would normally have after getting a vaccine. The first day was intense but after a few hours was less. The next day she woke up and it was pretty much gone. She still had a little but it has mostly improved. Caller stated she would still like to get the second dose but she was a little nervous. She had it maybe once or twice since then and it has been mild with no extreme pressure drops. They thought maybe it was a virus that affected her. Her reaction to the vaccine was different. The difference was pretty significant. Vasovagal felt like her heart will stop and she will pass out. After the vaccine she felt dizzy but didn't feel faint, and had a racing heart. Nobody seemed concerned about her reaction and getting the second dose. But she read that Pfizer does not recommend getting the second dose even if you had a mild reaction. She was wondering what she should do. Her second dose is scheduled for 02Feb2021. Outcome of hot sensation/weird very hot rush down her right arm that was vaccinated and went up the back of her neck only on the right side and heart racing was resolved on 12Jan2021, dizzy was resolved on 13Jan2021, outcome of anxiety was unknown, outcome of her arm was very sore- it was difficult to lift it and a mild allergic reaction was resolving.

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977081	1/27/2021	NY	31	M	1/12/2021	1/12/2021	Moderna COVID-19 Vaccine. Headache and nausea onset 12 hours after vaccine was given. Chills/body aches and fever were present 18 hours after injection. Fever remained between 101.2 and 102.4, with a spike of 103.4 on 1/14/2021. Headache and nausea lasted approximately 24 hours, while fever and chills/body aches lasted for 5 days after vaccine was administered. An Emergency Room visit to Hospital was made on 1/15/2021 into 1/16/2021 for these symptoms since they had lasted over 48 hours. Negative on all tests, with elevated inflammation levels. X-ray and CT scan of chest revealed no pneumonia or blood clots.
978002	1/27/2021	GA	77	M	1/19/2021	1/20/2021	The morning of Jan 20, 2021, Patient was disoriented, could not communicate well, and fell when he tried to get out of bed. He was taken to The Hospital by ambulance about 11:30 am. He is still hospitalized. Emerging symptoms include: passing a blood clot from his mouth, slight pneumonia, high white count, low kidney values, high fever, all of which fluctuated. A blood transfusion was given because of blood in the urine. He has been confused and disoriented until this morning.
978544	1/27/2021	CA	60	F	1/19/2021	1/20/2021	First vaccine small bruise at her left knee and extreme pain in her neck, shoulder and left arm and missed work. Second vaccine she has 4 bruises and clots on her inner leg from ankle to thigh. So painful she can't sleep and she is having a hard time walking. Her left shoulder is limited due to extreme pain. She sought care from her physician and he is sending her for scans that the facility is requiring a deposit.
979630	1/27/2021	NJ	46	F	1/11/2021	1/15/2021	blood clot in lungs, PE,

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979352	1/27/2021	IN	24	F	1/3/2021	1/6/2021	I began menstruating in the evening of Tuesday January 5th, 2021 (on schedule). However by the morning of January 6th, my flow had increased in a way I had never experienced before. And until midday on January 9th, I was going through 1 "super" tampon every 2-3 hours. My menstruation flow resembled blood, and was not as clotted as my regular flow. On January 9th, the bleeding slowed and normalized. I contacted my doctor's office and was directed to take 1000mg of acetaminophen twice daily, and call back if my flow had not slowed down by Monday because I would have to come in. I followed the recommendations for one day (on January 8th) and took a total of 2000mg of acetaminophen.
974068	1/26/2021	DE	67	M	1/16/2021	1/20/2021	Sudden onset of severe abdominal pain with diarrhea and bloody stool/fluid on Wednesday 1/20/21. Very weak/lightheaded. To ER on evening of 1/21 - CT noted 2 Thrombi in each branch of portal vein and ischemic colitis of descending colon. No risk factors determined. Only change in life was Covid-19 Moderna vaccine. Other side effect from vaccine was only a sore are at injection site. Seen by surgery and hematology. Rapid Covid test was negative and wife's pcr Covid test was negative. As of today is feeling significantly improved but not yet taking PO and remains on heparin drip.
974464	1/26/2021	MI	35	F	1/19/2021	1/22/2021	PRESENTING PROBLEM: Bilateral pulmonary embolism (HCC) HOSPITAL COURSE: 35-year-old female came in with shortness of breath and pleuritic chest pain who was found to have bilateral pulmonary embolism with moderately extensive clot burden. Her BNP and troponins were normal and no signs of right ventricular dysfunction on CT scan. Patient was placed on heparin drip and her symptoms improved. Ultrasound Doppler of bilateral lower extremities were negative. This was an unprovoked PE. Patient was switched to and discharged with Xarelto. She will benefit from a hypercoagulable workup once she is off of anticoagulation. After vaccine: patient reported difficulty breathing and fast heartrate

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975020	1/26/2021	NY	73	F	12/24/2020	12/28/2020	Had normal side effects the day after, 12/25/20 slight fever, lethargy, not even sore arm. on the 27th, felt fine. On 12/28/20, woke up not able to breath, oxygen saturation 83%, could not walk across the room without gasping for air, which lasted for about 2 days. Could not reach her PCP due to holidays, was convinced she had COVID. Went to drive-thru facility and got the COVID test on 12/28/20, negative on 12/29/20. Then made another APT, went back on 12/30/20 had negative test again. On 12/30/20 started feeling better, was not great but her O2 SAT's were about 90. Stayed that way until 1/8/21, had FU from lumpectomy with surgeon, when she got up her left ankle/foot were very swollen and red looking. Saw that Dr., and discussed the postop business and showed her the foot/leg told her to have it looked at. Her PCP was closed, she went to radiology Dept in Hospital and found DVT in her left leg. She was then told to go to the ER and ordered a CT scan, which showed pulmonary emboli in both lungs. Put on heparin IV right away, later transferred to another hospital where CV surgeon on staff. By that evening they decided that she was walking , talking and checking blood levels, kept her overnight and sent her home the next day. Needed to be on blood thinners, and saw pulmonologist. Has APT with hematologist this week. Pulm told her to call and report adverse reaction. Today, 1/26/21 her O2 SAT's are in the 99%, leg is still swollen, and is able to breath better. On Eliquis which will prevent new clots, but the others should be absorbed. Got 2nd dose on 1/21/21 and had only the classic side-effects for about 30 hours but was then fine. Had fever, chills, nausea, sore arm, cough, but then was fine. Same lot # as dose 2.
975052	1/26/2021	MI	33	F	1/19/2021	1/24/2021	Blood clot, DVT of a ill art vein acute left
972101	1/25/2021	CO	64	F	1/12/2021	1/19/2021	On Jan. 19th, 2021, right arm suddenly became sore again at injection site. This was 1 week after vaccine injection. Next day, upper right arm was red, rashy, tender to touch and hot to touch. Red area on arm spread during the day. No fever. Called my Doctor and went in for check. Suspected blood clot, but ultrasound was negative. Suspected Cellulitis. RX given for Keflex 5 day regimen. Symptoms ceased on Jan. 23rd, 2021.

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970593	1/25/2021	TN	75	M	1/22/2021	1/25/2021	This morning at about 745am we were about to begin our dialysis treatment and my husband had to blow his nose and when he did there was blood in the tissue, so I got him more tissue and there was more blood in the tissue. I then got a cold compress and had him lay back with feet up and put cold compress on his nose and a small ice bag on his forehead and for a little bit when I took the tissue from left nostril that is where the blood was coming from and i saw that there was clotted blood. After changing the cold compress on his head the nosebleed began to subside and he continue to sit with his head back but when he sat up after about a half hour it started to bleed again out of the left nostril and that is what he has began experiencing. whenever he sits up it begins again it begins but no clotted blood.



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971534	1/25/2021	CA	60	F	1/11/2021	1/1/2021	<p>Temperature 101.7; Back pain/pain in her back; Right upper jaw pain that felt like sinus; Heart rate 130's; Oxygen Saturation dropping; Headache/head felt like it would explode; Ringing in the ears; Thighs are burning; calf pain/Calves were sore in back; Calves were sore in back and felt like DVT; Chest pressure; she sound like a hypochondriac; flu like symptoms; can barely walk; Nausea; Shivering; weak; felt miserable; dry hives; This is a spontaneous report from a contactable Nurse reporting for herself. A 60-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Batch/lot number: EL1283, Expiry Date: 30Nov2021, intramuscularly into right deltoid on 11Jan2021 07:15 at single dose at the hospital for Precaution as frontline healthcare worker. Medical history included Wolff-Parkinson-White (WPW) syndrome from 2000, heart surgery in the past on unknown date, had surgery that was in 2000. Years of chest pain and PVC after that; allergic to Sulfa with hives: One time she mixed it up with a medication of her sons and took it by mistake and did not realize it and she did not have any reaction, she has not had in years. It was an injection and she doesn't have the name, lot or expiration. Family medical history included Mother was diabetic and sister was prediabetic and was 61. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot E49899) on 18Dec2020 at 10:30 am injected in Right Deltoid for COVID-19 immunisation and experienced shivering; same body aches, she took TYLENOL; had major headache all night long, all over her head; It was a pressure headache; Someone gave her MOTRIN and within 3 hours she was totally fine. The patient stated she received the Pfizer COVID vaccine second dose on 11Jan2021 and has had problems since then. She has been miserable, took paracetamol (TYLENOL), headache, have ringing the ears, head was exploding, back aches, calf pain, temperature at 8 am 101.7 and 101.7 at 10:40 on 12Jan2021, feeling very weak, nausea, dry hives, Right upper jaw pain that felt like sinus, all in Jan2021. Her heart rate was in the 130's at 3:30-4:00 on 12Jan2021 and now down to 115-108. Her Oxygen saturation has been 91-95 %. She just had a miserable night (Jan2021). She had this pressure in her chest. Her heart rate was 130 and O2 was 93%. Her O2 saturation</p>

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last night (on 11Jan2021) was 91-94%, mostly about 93%. Chest Pressure began around 3am on 12Jan2021. She called healthcare provider and was waiting to get advice from them if she needs an EKG. She was still having a little bit of mild pressure. She noticed that her oxygenation was 93% when this was happening. It went up to 95% for a second last night. Her heart rate was now between 112-115. When she walked, it went to 125-130. It started around 3:30-4:00 this morning (on 12Jan2021) and was mildly improved. she was feeling the chest pressure back pain had less, but had pain in the upper jaw, flu like symptoms on 12Jan2021. she said she could not get out of the bed right. She did have a heart surgery in the past, her legs were burring, and week. she said after the first dose she did had a reaction but took MOTRIN and went to work the next day. The patient wanted to know about the heart rate being high and ringing in the ears. She wanted to know if it was supposed to drop your saturation and increase your heart rate. Is she just behaving like the norm or should her O2 be much higher. Her first shot was not as bad as this reaction. There was no prescriber. The temperature just began now as she just took it. Oxygen Saturation dropping began when she woke up in middle of night around 3:30- 4:00. She used her pulse oximeter and noticed it then. It was associated with her ears ringing and her head felt like it would explode at 3:30 on 12Jan2021. She felt better with headache but still had it. She was so weak on 12Jan2021, she did not want to go anywhere. Her oxygenation had worsened to 93% on average. She had a headache last time but did not have ringing in her ears. She woke up about 3:30 with it. The headache now was all over head from front to back and comes and goes. Last time she went to work after receiving the first one and today (on 12Jan2021), there was no way she could go to work. She took TYLENOL when she got home because she was shivering and took more at 3:30 because she felt miserable because of her chest. She took 1 gram. Her headache did not go away. She got to sleep after she took the TYLENOL. Her back and jaw was bothering her. It felt like the flu. She had upper jaw pain and pain in her back. She didn't have a good back and just aches. After the first one, it took 10 hours for the shivering to start. This time it was very similar. The shivering started about 10 hours later, at

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9pm on 11Jan2021. Back pain starting at 05:00 on 12Jan2021 was stated as being sharp on right side scapula and feel like the flu. It is to the right of spinal vertebrae. She thought she would go to bed and lie down. She has had back pain before. The jaw pain started around 05:00 on 12Jan2021. She felt it in her cheek. It was a little bit better. Nausea started at 11:00 pm on 11Jan2021 and got worse at 03:30 when she got up to go to the bathroom around midnight. She felt like she could vomit and felt better, but she couldn't. Her thighs were burning at 03:30 on 12Jan2020. It was persistent weak and burning. She can barely walk. The areas that have hurt like when you get the flu, she was having now in the same places, so she thought it was from the shot. Calves were sore in back and felt like a DVT (Deep vein thrombosis), started at 03:30 of 12Jan2021 and was still sore. She said she sound like a hypochondriac. It was in back of calf towards knee. She did not think it was a blood clot. It was feeling better. It was still sore but nothing like it was at 03:30. It is just an odd pain. She did not want to leave the house and surprised that her oxygen saturation was low. She just wanted to go back to sleep for a bit. Oxygen Saturation dropping was reported as worsened. The outcome of events Chest pressure, Heart rate 130's, Headache/head felt like it would explode, Right upper jaw pain that felt like sinus, calf pain/Calves were sore in back and Calves were sore in back and felt like DVT was recovering. The outcome of events Oxygen Saturation dropping, Ringing in the ears, Shivering, Back pain/pain in her back, Nausea, and Thighs are burning was not recovered. The outcome of events Temperature 101.7, she sound like a hypochondriac, dry hives, flu like symptoms, weak, felt miserable and can barely walk was unknown. The reporter considered events Heart rate 130's, Temperature 101.7, Oxygen Saturation dropping, Right upper jaw pain that felt like sinus and Thighs are burning were related to BNT162B2. The reporter considered events Chest pressure, Heart rate 130's, Temperature 101.7, Oxygen Saturation dropping, Headache, Ringing in ears, Shivering, Back pain, Nausea, Thighs are burning, Right upper jaw pain that felt like sinus and Calves were sore in back and felt like DVT as serious due to Medically significant.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on

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reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

972784	1/25/2021	FL	73	F	1/11/2021	1/16/2021	STROKE SYMPTOMS 5 DAYS LATER. SEVERE HEADACHE, DIZZINESS , SLURRED SPEACH, TROUBLE REMEMBERING SOME WORDS, DIFFICULTY SIGNING NAME, HIGH bp WAS ADMINISTERED EMERGENCY CLOT BUSTING DRUG IV AND THEN TRANSFERRED TO NEUROLOGY HOSPITAL. SYMPTOMS OF SLURRED SPEECH, DISAPPEARED NEXT DAY, WRITING HAND RETURNED TO NORMAL RAPIDLY AFTER IV. SLIGHT HEADACHE REMAINED FOR A COUPLE OF DAYS
974753	1/25/2021	IL	68	F	1/16/2021	1/17/2021	Experienced shortness of breath upon minimal exertion 24 hours after having received the vaccine. Called MD 72 hours vaccine received - MD advised hospital ER. Admitted with pulmonary embolism and deep vein thrombosis. Remains short of breath and is on 4L of oxygen. Receiving anti-coagulants.

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971549	1/25/2021	NY	52	F	12/23/2020	12/1/2020	<p>Pneumonia; Left Arm Swelling / her arm and shoulder became swollen; Left Arm Swelling / her arm and shoulder became swollen; she also has something else going on in her shoulder; achy all over in her neck, arm, and shoulder; achy all over in her neck, arm, and shoulder; Felt sick to her stomach; her arm was sore that evening; This is a spontaneous report from a Pfizer Sponsored Program made from a contactable consumer (patient). This 52-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot#: EK5730) at single dose on left arm on 23-Dec-2020 for COVID-19 immunization. Medical history included sleep apnea; high blood pressure; COPD (chronic obstructive pulmonary disease). Concomitant Medication was nothing new, her normal medication, she took vitamins, and high blood pressure medication. She had had no positive test for Covid prior to the vaccine, she had had no antibody test, she had had no issues with vaccine in the past. The patient experienced left arm swelling in Jan2021 and pneumonia on 08Jan2021. The patient worked in a hospital and received her first dose on 23Dec2020 and she was supposed to get the second dose today but she was not at work today. She was wanting to know if she should go ahead and take the second dose because her arm was still swollen. The product was the Covid vaccine. She stated that her arm was still swollen, when she got shot she was fine, her arm was sore that evening (Dec2020) and then nothing, then a weekend after new years her arm and shoulder became swollen (Jan2021) and she had been to the ER and the doctor thought the swelling was because of the shot, but she also had something else going on in her shoulder (Jan2021). So in the meantime she went to the ER and they took X rays, and they told her that she was starting to develop pneumonia. She was going back to work tomorrow, being that she was on the antibiotics now, still had swelling in the arm, and had pneumonia, should she still get the 2nd shot. She noticed the swelling Saturday after New Years. She was also achy all over in her neck, arm, and shoulder (Jan2021). She felt sick to her stomach, this was all the first Week of Jan2021. She went to the ER, she was not admitted and came home the same day. She went to the ER on 08Jan2021. 08Jan2021 was also when the pneumonia was diagnosed. The name of antibiotic she</p>

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was prescribed was doxycycline. She started it on Saturday 09Jan2021, she was prescribed 100 mg 2 pills a day for 10 days. When they did the X ray, they said that the pneumonia had showed up, or she was just starting to get pneumonia. Patient stated that she didn't believe because they made a comment about the way she was laying however she had been taking the medication and feeling better. She was schedule for the second dose today. She did reschedule for Friday, and wanted to know if she should still get it. In the ER, they said it could have been a blood clot and so they did a scan to find blood clots but it was negative. The outcome of event pneumonia was resolving; events left arm swelling and shoulder became swollen was not resolved. The outcome of rest evens was unknown..

969230	1/24/2021	FL	63	M	12/29/2020	1/6/2021	Developed blood clot in left leg (DVT)
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968026	1/23/2021	TX	32	F	1/21/2021	1/23/2021	Patient states he started having sudden onset of left facial droop, left-sided arm and leg 15 minutes prior to arrival on 1/23 while driving. Pt got the Moderna vaccine second dose 2 days ago (1/21). Patient denies any history of stroke, DVT, PE. tPA was administered. Found to have clot in the Right MCA territory and taken for mechanical thrombectomy to remove the clot. Patient remains hospitalized and further workup is going.
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968400	1/23/2021	LA	43	F	1/6/2021	1/11/2021	Injection site soreness for about 2 days. Day 5 developed bilateral calf pain. Not unbearable, it just felt like I had worked out my calf muscles at the gym the day before or something & I hadnt done any exercise at all that week and not at the gym in years. It seemed worst when I first started moving snd seemed to get better as I warmed up and moved around. Lasted about three days. I do vascular ultrasound and so checked myself for blood clots and I was negative. The last symptom that I dont think Ive had before is this weird pulsing or rapid twitching sensation on the back/left side of my head. Like a nerve firing maybe? I dont know. Felt like one small focal area, like fluttering.. It was very fast. It would last for like a minute or two and then stop . That happened about 3-4 times. On different days, not sure what day. It was so short lived I didnt pay much attention to it. It happened sometime between 1/18/21 & 1/22/21. It only happened one time a day.
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967025	1/22/2021	MO	78	F	1/21/2021	1/22/2021	When I awoke this morning and was getting dressed, I noticed a soreness in the back of my left leg (on the right side of the left leg). I felt a lump, It was about 2-3 inches above the knee. It was what I would describe as a medium-sized lump. I called my doctor to leave a message about my symptoms. My doctor called a few minutes after 11 am and asked me to immediately come in so he could see the lump. He thought I might have a blood clot. This lump was not present late last night because when I put lotion on my legs after my shower, I felt no lump or soreness. I worked out this morning and by 11:00, it seemed to me the lump was not as big as it was when I was getting dressed earlier this morning.
967200	1/22/2021	IA	37	M	12/31/2020	1/5/2021	Spontaneous bleeding from the mucosa of the underside of superior left eyelid at approximately 130 am. I awoke from sleep at that time with mattering in my left eye making it difficult to open. Upon examination in the mirror it was obvious the mattering was due to blood. The blood was obviously coming from my left eye. There was no bleeding from my nose. I had apparently been bleeding for sometime as pooled and clotted blood was also present on my face, arm, pillow, and sheets. Uncertain exactly how much blood total but I would estimate 20 ml of blood. The bleeding stopped spontaneously a few minutes after I awoke. There as an additional scant bleeding the following morning. I was later evaluated by an ophthalmologist who did identify a small punctuate superficial capillary on the mucosal side of my left eyelid which was thought to be the source of bleeding. I have not had further events since.
966606	1/22/2021		27	F	1/18/2021	1/18/2021	Heart rate elevated to 150 and above, shortness of breath. Went to emergency room. Admitted with blood clot in lung. Previously had COVID in 2020, and we are unsure if this is related to previous illness.
966862	1/22/2021	CA	30	F	1/14/2021	1/16/2021	pt had a normal mense without clots between 01/04/2021 and 01/10/2021 but 2 days after receiving Pfizer covid vaccine had second onset of menstrual bleeding which is much heavier leading to leakage around the cup used to retain menstrual bleeding associated with clots (metromenorrhagia). pt on contraceptive and not attempting to conceive pt denies purpura or any other sx

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967151	1/22/2021	GA	28	F	1/15/2021	1/21/2021	Heavy vaginal bleeding with golf ball size clots started 01/21/21 received Covid-19 vaccine 2nd dose on 01/15/21. Started period 2 days prior 1/13/21) to getting vaccine, cycle should've ended on the 18th but has had it for a week with excessive heavy bleeding
960318	1/21/2021	FL	61	M	12/31/2020	1/4/2021	have a persistent severe headache; feverish; I feel very light headed; unsteady with difficulty maintaining balance when I walk; This is a spontaneous report from a contactable healthcare professional (patient). A 61-year-old male patient received the first dose of BNT162B2 (Pfizer, lot number: EH9899), via an unspecified route of administration in left arm on 31Dec2020 12:00 at single dose for COVID-19 immunization. Medical history included known allergies: penicillin, and deep vein thrombosis (DVT). Concomitant medications in two weeks included dabigatran etexilate mesilate (PRADAXA) at 150 mg twice a day, and hydrochlorothiazide/losartan potassium (LOSARTAN + HIDROCLOROTIAZIDA) at 100-25 mg. On 04Jan2021, patient felt very light headed, unsteady with difficulty maintaining balance when I walk, had a persistent severe headache and feverish. However, he did not have a fever. Temperature was 97.5. Blood pressure (BP) was normal. Pulse was normal. No soreness at the injection site from day one. Treatment was not received. Patient was not recovered from all these events.



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960293	1/21/2021	VA	26	F	1/8/2021	1/8/2021	headache; sweating; severe chills; fatigue/more fatigue; fever 100.6 F/fever peaked at 102 F/fever down to 100.4; felt like had the flu.; This is a spontaneous report from a contactable pharmacist (patient). A 26-year-old female patient (not pregnant) received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number= EK4176), via an unspecified route of administration at left arm on 08Jan2021 07:45 AM at single dose for covid-19 immunization. The COVID-19 vaccine was administered at Hospital. The patient's medical history included Deep vein thrombosis (DVT) from 2017. Concomitant medication included naproxen, doxycycline and women's multivitamin. The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number= EK5730) via an unspecified route of administration at left arm on 18Dec2020 09:15 PM at single dose for covid-19 immunization. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. 14 hours after second dose, the patient experienced severe chills and fatigue, fever 100.6 F, felt like had the flu. 16 hours fever peaked at 102 F, 26 hours, chills gone, fever down to 100.4, new onset headache and sweating, more fatigue. Onset date of events chills, fatigue, fever and felt like flu was provided on 08Jan2021 at time of 08:00 PM. Onset date of events headache and sweating was provided 09Jan2021 09:45 AM. No treatment received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was recovered in Jan2021.

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961282	1/21/2021	MA	49	F	12/29/2020	12/30/2020	<p>Felt like a restless leg or blood clot but not as severe.; Felt like a restless leg or blood clot but not as severe.; Left below knee pain and discomfort. Some to the right leg as well.; Left below knee pain and discomfort. Some to the right leg as well.; Checked back of leg for warmth or bruising lasted day 2 and day 3.; Checked back of leg for warmth or bruising lasted day 2 and day 3.; Did feel some discomfort to left arm as a result of the shot in left arm, tender and could feel when holding arm up some discomfort; This is a spontaneous report from a contactable nurse reporting for herself. A 49-years-old female patient started to receive bnt162b2 (BNT162B2; Lot: ECO142) vaccine , intramuscular in the left arm on 29Dec2020 15:45 at single dose for Covid-19 immunisation . Medical history included hypertension, anaemia, blood cholesterol increased , depression, food allergy (whey casium) (taking doxepin for it with relief). Concomitant medication included doxepin (DOXEPIN), metoprolol (METOPROLOL), calcium ascorbate (VITAMIN C [CALCIUM ASCORBATE]), tocopherol (VITAMIN E [TOCOPHEROL]), cyanocobalamin (VITAMIN B-12) , atorvastatin (ATORVASTATIN), sertraline (SERTRALINE). The patient experienced felt like a restless leg or blood clot but not as severe. on 30Dec2020 07:00 with outcome of recovered , left below knee pain and discomfort. some to the right leg as well. on 30Dec2020 07:00 with outcome of recovered , checked back of leg for warmth or bruising lasted day 2 and day 3. on 30Dec2020 07:00 with outcome of recovered , did feel some discomfort to left arm as a result of the shot in left arm, tender and could feel when holding arm up some discomfort on 30Dec2020 07:00 with outcome of recovered. The event blood clot was considered serious (Important Medical Event). Course of the events The patient reported left below knee pain and discomfort. Some to the right leg as well. She checked back of leg for warmth or bruising lasted day 2 and day 3. She felt like a restless leg or blood clot but not as severe. She felt better to stand instead of sitting. Did feel some discomfort to left arm as a result of the shot in left arm, tender and could feel when holding arm up some discomfort. No shortness of breath, no nausea, no dizziness, no increased fatigue (baseline - not enough sleep - working 3 jobs).; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported leg</p>

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							thrombosis cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
961879	1/21/2021	TX	81	M	1/13/2021	1/13/2021	My 81-year-old father, and my brother received the first dose of the Pfizer covid vaccine at the Hospital on Wednesday January 13, 2021. Within a couple of minutes of them returning home, my father collapsed. As it turns out, he'd had a silent heart attack. He is still in the medical center area Hospital this morning. A cardiologist who was filling in for my father's primary cardiologist thought maybe my father had a blockage and might have needed a stent. But when Dr. performed a cardiac catheterization, he only found a little plaque. Medical personnel are not too sure what caused the heart attack. My was very dehydrated when he was admitted, and he has underlying health conditions including diabetes, high blood pressure, dementia and a history of blood clots. Those are just a few of his health issues. His primary cardiologist, Dr is back in town. He plans to see if my father has AFib before they release him. I believe Dr. an internist at Hospital, said my father's INR on admitting was 1.2. My father's hematologist, Dr., had told us to let the person administering the vaccine know that my father is on blood thinners. I was not present when my father and brother received the vaccine, but I assume my brother passed that information on to them.
959549	1/20/2021	MO	58	F	1/2/2021	1/13/2021	1/4/21- Patient stated she had tenderness on the back of her left lower leg with redness then 1/8/21 started to have shortness of breath and made a doctor's appointment for 1/13/21. Seen by provider on 1/13/21 and was sent to ED and admitted to the hospital [ICU] with NSTEMI, acute deep, occlusive venous thrombosis left femoral vein and saddle embolus of pulmonary artery. Transferred to another acute care hospital for removal of thrombosis. Patient started on Eliquis and no intervention for removal of the thrombosis.

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957555	1/20/2021	NY	38	M	10/2/1982	1/1/2021	I am a registered nurse at hospital. On 12/25, seven days after receiving the shot I started to get right lower leg pain and I kept complaining about it till New Years Day. I had no symptoms of a DVT. I triaged on 1/1/21 and the doctors ordered labs/imaging and the results were as followed: D-Dimer biomarker (+) , Ultrasound of the Rt lower leg ( - ) , CTA showed a PE (segmental right upper lobe pulmonary artery consistent with pulmonary embolus). I was discharged on Xarelto and advised to follow up with a hematologist. On 1/5/2021, I went to hematology and they did a whole bunch of labs. I was sent to get a ultrasound of the leg because the pain persist and they found a clot hidden by my soleus. The plan is to continue on the Xarelto for 6 months. Come back in 3 weeks to scan my leg again and get my lab results. On 1/12/2021, I received the 2nd shot of the Pfizer vaccination.
957860	1/20/2021		49	F	1/13/2021	1/14/2021	~~I received the Pfizer Covid vaccine Wed afternoon around 4pm. Thursday morning around 9:30 I started with severe pain in my left leg. The pain worsened through the day and my leg began swelling. No other symptoms at all. This morning my leg was twice the size of my right leg so I went to the ER. I live in so I'm at ED. I have a massive blood clot running the the length of my leg - from my thigh to my ankle. I'm very lucky I got here so fast! I?m a very healthy 49 year old with no history of DVT or blood clots so they dug further to find out why. A cat scan showed I have a congenital condition called May Thurner Syndrome. I?m so relieved to have an answer and it?s fixable! The vascular doctors are not 100% convinced that?s not all that was going on as I was born with the syndrome and I?ve gone this long without a clot. So they are doing lots of labs to see if anything else shows up. This is where we are at. I?m being admitted to take care of the clot.~~

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958057	1/20/2021	PR	40	F	12/30/2020	1/4/2021	On January 4 at 2:00 pm I suddenly started to bleed from the nose from the left nostril and then from both. The event lasted more than 35 minutes so I had to go to the ER. The diagnosis was Epistaxis. I was discharged because at the time of the medical evaluation I removed a large clot from my mouth and the bleeding stopped. Appointment with primary physician for diagnosis and appointment with ENT was ordered. On January 5 at 4:15 am I had another episode of nasal bleeding lasting 25 min. After removing a clot through the mouth, the bleeding stopped. At 4:00 pm I presented Epistaxis again so I had to return to the Emergency Room. I was reevaluated and the instruction was to visit the ENT and Afrin prescription for three days and Claritin D q 12 hrs PRN. From January 6 to 9, I began to eliminate a serous-bloody vaginal discharge. That began with the elimination of a clot and progressively diminished day by day. January 11, 2021, the ENT evaluated me and indicated that it did not observe polyps or anatomical problems. I had not previously prolonged nosebleeds. Previously two minor episodes happened to me, a year ago that resolved in less than 7 minutes. I didn't have a cold or any other symptoms. I want to raise the flag because it was a strange event that occurred after the vaccination and that I had not experienced before in that way. My next dose is January 29, 2021. I am awaiting clot test results
958945	1/20/2021	WA	50	F	1/4/2021	1/5/2021	tried to use a cream Dr prescribed for hemrrhoids, had to have them surgically cut, drained of blood clotts, sent home. went back to urgent care 4 day later still in a lot of pain, was given a surgical consult, waiting for a appointment. Rash Dr prescribed prednisone and topical cream 2x daily on rash, still having rash issues spreading.

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959270	1/20/2021	NJ	57	F	1/13/2021	1/14/2021	Painful joints started at 430PM 1/14/21 started in hands and progressed to entire body. By 630 PM I was in bed with muscle aches, chills, headache, nausea, extreme fatigue, slept 12 hours. Got up 1/15/21 in AM still no relief felt heart palpitations and some dyspnea on exertion with noted drops in pulse ox levels. SpO2 fluctuated from high 90s, then hovered in low 90s and had intermittent irregular drops to as low as 84%. Went to Urgent care at Primary's recommendation, O2 91%, CXR negative, Covid PCR done. SpO2 increased to 96% on ambulation, sent home. Symptoms resolved 1/16 except for O2 drops. Covid negative report 1/17/21. SpO2 still fluctuating, Primary called 1/18/21 referred me to ER r/o PE. DDimer drawn, slightly elevated, CTA done negative for clot, discharged home.
959645	1/20/2021	MN	25	F	1/7/2021	1/15/2021	I started having cramps Friday night and Saturday morning I started bleeding, by Saturday evening I was passing clots and tissue. ER doctor and nurses did tests and found I was having a miscarriage.
959492	1/20/2021	IA	31	F	1/12/2021	1/15/2021	Employee received her 2nd Pfizer vaccine on 1/12/2021. Twelve hours after her vaccine she developed a fever with a T-max of 102 degrees. The fever lasted 18 hours. She also complained of severe malaise and fatigue lasting 36 hours. On day 3 (Friday, January 15, 2021) she developed left lower extremity pain that persisted over the weekend. She was seen in Urgent Care today where she was diagnosed with a deep vein thrombosis of the proximal vein. She also came to the ETC and was ruled out for a PE. The employee does have a family history of antiphospholipid in her mother. She has a follow up with her PCP and will also receive a work up in hematology as she had never been tested for any genetic coagulation conditions after her mom's diagnosis.

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959469	1/20/2021	IA	31	F	1/12/2021	1/15/2021	Employee received her 2nd Pfizer vaccine on 1/12/2021. Twelve hours later she developed a fever with a T-max of 102 degrees. The fever lasted 18 hours. She also complained of severe malaise and fatigue lasting 36 hours. On day 3 she developed left lower extremity pain that persisted over the weekend. She was seen in Urgent Care today where she was diagnosed with a thrombosis. She also came to the ETC and was ruled out for a PE The employee does have a family history of antiphospholipid in her mother. She has a follow up with her PCP and will also receive a work up in hematology as she had never been tested for any genetic coagulation conditions after her mom's diagnosis.
954804	1/19/2021	MA	48	F	1/8/2021	1/10/2021	Started with severe chills, body aches and feverish. The. Slight leg pain which worsened with time , swelling on the right leg calf, warm to touch and difficulty breathing. Got hospitalized on 1/16 21 with multiple clots in my right leg and clot in the lung. Still in the hospital now.
955565	1/19/2021	OH	19	F	1/7/2021	1/14/2021	One week after the shot (1-14-2021) Patient (19 y.o.)reported side pain and appeared constipated, Laxatives given along with Tylenol, on further assessment Patient was noted to have left leg redness and abdominal fullness. Dr. was updated and we had orders for close monitoring, the next day when she got up, her leg appeared better, and she had passed a small BM, but by lunch she had developed significant pain and edema in her left leg, and the color of her leg was reddened again. She was sent to the emergency room with her symptoms. She was admitted back to our facility yesterday, her diagnoses included Acute provoked left external iliac, femoral, popliteal, and peroneal DVT. Elevated Factor II levels, Elevated APC resistant, May-Thurner Syndrome, history of developmental disabilities, fecal impaction and urinary retention - suspected related to her fecal impaction. Vascular surgery was consulted, and pt. was started on a heparin drip, and mechanical thrombectomy was needed for both legs due to multiple clots. She was started on Eliquis and Plavix, and thigh high compression stockings were ordered, ace wraps being used until these are supplied. Her Fecal impaction was addressed also and the urinary retention resolved.

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956642	1/19/2021	CO	44	F	1/9/2021	1/14/2021	Visited Provider appx 500 pm 1.14.2021 DVT - left calf - 2 clots via ultrasound on Eliquis now
952872	1/18/2021	IL	80	M	1/4/2021	1/11/2021	80YO male who htn, cva, epilepsy, ckd, cerebral avm s/p repair, cad s/p cab, cva (left sided hemiplegia) , hx of prostate cancer recent admission for pna on abx presents to ED on 1/11 with dizziness, hypoxia. CT with Bilateral PE "Large bilateral pulmonary artery emboli in the right and left main pulmonary artery extending into the right and left main pulmonary artery branches bilaterally. Findings are associated with right-sided heart strain." "Patchy alveolar airspace disease within the lungs highly suspicious for COVID pneumonia" Covid negative. Patients wife recovered from Covid-19 infection within last month. Patent thus far has tested negative. Doppler lower extremity revealed Acute occlusive vein thrombosis of the entire course of the gastrocnemius vein and soleal vein. Patient received covid vaccine on 1/4/21. Patient has several risk factors for clot - age, previous CVA, hx of prostate cancer. Also had positive covid exposure though tested negative
950996	1/17/2021	NJ	57	F	1/15/2021	1/15/2021	Constant headache began approximately 1 hr after receiving vaccine. Awoke this morning with blood clots on my tongue
951789	1/17/2021	CA	67	F	1/15/2021	1/16/2021	Blood and small blood clots in urine.
951560	1/17/2021	FL	33	M	12/19/2020	1/3/2021	Severe Right sided chest pain, right sided muscle spasms and difficulty breathing two weeks after vaccine was administered Diagnosis of bilateral pulmonary embolism was made on presentation to ER. No personal or family history of clots in arteries or deep veins or any risk factors in patient. Received heparin drip, pain medications, muscle relaxants inpatient. Pain progressively improved over days. Was discharged after 6 days on admission. Was discharged on oral anticoagulant (Rivaroxaban aka xarelto)
947660	1/15/2021	OH	52	M	12/30/2020	1/7/2021	I developed a left Internal Jugular vein thrombosis with supraclavicular inflammation and pain. I was diagnosed by CT scan and Doppler ultrasound. I have been started on Xarelto 1/11/2020. Symptoms were localized and are slowly resolving.



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949555	1/15/2021	NY	71	M	1/13/2021	1/14/2021	Received Pfizer vaccine, first dose on Wed. 01/13/21 between 12 and 1 P.M. Thurs. 01/14/21 in the afternoon he began to note that he had difficulty walking. Went to bed when he woke up at 5:48 A.M. he reported he had ataxia. Patient reported having to walk in tiny steps to stay upright. He went to the emergency room. Had CT scan of head and found blood clots. MRI performed. Stroke found in right PCA territory, but no loss in strength in left lower extremity. Sensation and vision intact. Strength in all four extremities is 5 out of 5.
946819	1/15/2021	IL	37	F	1/5/2021	1/11/2021	Patient developed headache and nausea on 1-11-2021. She was hospitalized on 1-14-2021 at Hospital. Found to have dural sinus thrombosis of the superior sagittal and right transverse/sigmoid sinus on MRV brain. Currently admitted to ICU at Hospital, getting injectable blood thinners. Neurology and hematology have been consulted.
947044	1/15/2021	MI	49	F	1/12/2021	1/12/2021	Patient had headache with dizziness about 30" after injection. 90" later had sudden onset left-sided Chest pain with difficulty breathing. Patient's chest pain was so bad she thought she was going to die. Was transported to ER via ambulance, had cardiac workup, blood clot workup (had left leg pain the day before incident). Was discharged home on zanaflex and motrin with diagnosis of Chest Wall pain about 4 hours later. Follow up on 1.15.2021 at 1000 and patient doing better but still has chest pain. Will not be getting 2nd COVID vaccination.

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946978	1/15/2021	FL	49	M	12/29/2020	1/3/2021	Onset of shortness of breath and cough on 1/3 that progressively got worse. Clinical diagnosis of pneumonia without fever was made, patient started azithromycin on 1/5 and albuterol treatments every 4-6 hrs. Initially he improved, but then worsened. chest xray on 1/6 was negative for pneumonia, PCR covid test was negative, albuterol treatment did not bring much relief. He started respiratory distress on 1/10 and was taken by car to the local ER where another covid test was negative and chest CT revealed multiple bilateral pulmonary emboli. The leg US revealed blood clots in both of his legs. He had an emergency catheter-delivered thrombolysis and was discharged home from the ICU on 1/12 on oral anticoagulants. He is gradually improving, but very weak. He tires easily and gets a drop in oxygen to 90- 93%, as well as an increase in the heart rate to 120 when walking less than half a mile. He runs out of breath with exertion.
947573	1/15/2021	FL		F	1/4/2021		really extreme high blood pressure (202/104); feeling very sick; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 04Jan2021 at a single dose for COVID-19 immunization. Medical history included strokes and bleeding disorder (gene that makes blood clot). The patient's concomitant medications were not reported. The patient experienced really extreme high blood pressure (202/104) and feeling very sick on an unspecified date. The clinical course was reported as: The patient received the vaccine on 04Jan2021 and experienced a lot of side effects, the most concerning of which was really extreme high blood pressure. The patient went to the emergency room (ER) on an unspecified date and her blood pressure was 202/104 on an unspecified date. The patient stated that she had been very sick and in bed for days. The patient had a follow-up appointment with her doctor on the day of the report. The clinical outcome of really extreme high blood pressure (202/104) and feeling very sick was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.

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946780	1/15/2021	FL	33	F	12/4/2020	1/12/2021	#Right parietal/temporal subarachnoid hemorrhage and right intra-axial hemorrhage CT brain (1/12/21): Right parietal intra-axial hemorrhage toward the convexity measuring 2.3 x 1.1 x 1.7 cm with decompression into the subarachnoid space, mild right predominantly temporal and parietal subarachnoid hemorrhage is seen with minimal associated hemorrhage along the tentorium. Mild diffuse right cerebral sulcal effacement with minimal leftward midline shift measuring 2.5 mm. #Dural sinus thrombosis CTA head (1/11/21): Increased density within the superior sagittal sinus, inferior sagittal sinus, and transverse sinuses on noncontrasted images with no flow seen on postcontrast sequences consistent with venous sinus thrombosis #Left sided weakness 2/2 above #Recent jaw alignment procedure
948280	1/15/2021	TX	46	F	12/30/2020	1/8/2021	I have Factor V Leiden, tested positive for Covid on Nov 9, 2020. I received my Covid vaccine on Dec 29, 2020. On Jan 8, 2021 my upper right arm had a red area that was swollen, hot and painful. It continued to spread down my upper are to my forearm. On Jan 12, 2021 I spoke with nurse to see if anyone had reported blood clots as a reaction to the vaccine. Nurse did research this and stated he did not see any cases. After discussion with nurse, we agreed that I would get my PCP to order a venous doppler to rule out clots so we could make an informed decision to receive the 2nd dose vaccine. On Jan 14, 2021 the doppler showed superficial clots.
946743	1/15/2021	TN	62	F	1/12/2021	1/12/2021	She said she received her First Covid vaccine on 12/22/2020. She said on 1/4/2021 she worked that evening and started having severe pain in calf of her left leg no redness ,no heat, just hurt to work 1/8/2021 She had surgery on her left leg. 2nd Covid Vaccine received on 1/12/2021 She said she had PT on her right leg with severe pain in her left calf She said she did not have any therapy on her left leg. Two ? three hours later she developed chills, temp 100.1 took temp again later is was 99. She had ultrasound that showed a large blood clot She said the PA told her the blood clot could be from receiving the Covid vaccine

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946141	1/14/2021	IN	83	F	1/14/2021	1/14/2021	Moderna COVID-19 Vaccine At 2 PM I went blind in my left eye. Went to emergency room at Hospital Was told I have Blood clot in my eye causing the blindness and Ophthalmologist says it will probably be permanent
944735	1/14/2021	WI	44	F	12/30/2020	1/1/2021	Per patient report: On 1/1/2021 she started to have a fever, HA, ear pain, neck pain (back of neck), and muscle aches in upper back. This continued through the weekend. On Wednesday, 1/6/2021, she saw a provider for ear pain, chest pain (radiating to right arm). She was not prescribed/given treatment regimen. On Thursday, 1/7/2021, night, she started to have vomiting diarrhea, and chest pain. On Friday, 1/8/2021, she went in to be seen for chest pain and r/o PE. States she has a history of PE and had a CT performed, no clots found. EE states does not have vomiting and diarrhea from 1/13/2021 for the first time since the start of this symptoms. Continues to have GI issues: decreased appetite and upset stomach. Also states she feels very fatigued.

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944289	1/14/2021	NJ	22	F	1/6/2021	1/9/2021	<p>she was diagnosed with bilateral deep vein thrombosis (DVT) and pulmonary embolism (PE); she was diagnosed with bilateral deep vein thrombosis (DVT) and pulmonary embolism (PE); This is a spontaneous report from a contactable nurse (patient). A 22-year-old female patient received 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EK9231), via an unspecified route of administration in left arm on 06Jan2021 13:45 at single dose for COVID-19 immunisation. Medical history included allergy to all fish, and clots. The patient was not pregnant. There were no concomitant medications. The patient previously received 1st dose of BNT162B2 (lot number: EH9899) in left arm on 16Dec2020 13:45 for COVID-19 immunisation and experienced left sided lower back pain on 20Dec2020. No other vaccine received in four weeks. It was reported that the patient had the first covid vaccine on 16Dec2020 and on 20Dec2020 started with left sided lower back pain and then received the second on 06Jan2021 and then on 09Jan2021 11:00 her legs became blue and swollen and she was diagnosed with bilateral deep vein thrombosis (DVT) and pulmonary embolism (PE). The patient otherwise healthy and had never had covid. Other than the clots, she had no other health issues. The patient underwent lab tests and procedures which included nasal swab: negative on 09Jan2021. Events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, and life threatening illness (immediate risk of death from the event), hospitalized for 2 days (in Jan2021). Adverse event treatment: heparin drip and xarelto at home. Recovered with lasting effects on an unspecified date of Jan2020. This case was reported as serious, serious criteria was life threatening, caused/prolonged hospitalization.; Sender's Comments: The underlying risk factors/predisposing condition of thrombotic diathesis have been assessed to have played a contributory role toward the events.</p>

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941217	1/13/2021			U			My right leg from the knee down was purple and they thought I have a blood clot; My right leg from the knee down was purple and they thought I have a blood clot; This is a spontaneous report from a non-contactable consumer (patient). A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. Three days after vaccination the patient felt very sick and he/she was so bad that he/she thought he/she might die with outcome of recovered after one week. The patient reported also that on unknown date his/her right leg from the knee down was purple and they thought he/she have a blood clot, due to which the patient was hospitalized for 14 days. The patient ended in the hospital because his/her right leg from the knee down was purple and they thought he/she have a blood clot but they did an ultrasound that was not the case but they put he/she on antibiotic. The patient was still taking them but his/her leg has got better. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.
942005	1/13/2021	CA	50	F	1/4/2021	1/10/2021	swelling in neck and down chest blood clots enlarged lymph nodes
936556	1/12/2021	IN	23	F	1/9/2021	1/10/2021	Fever, tyneol lowered it. Cant break 99.0°. Cough. Fatigue. Joint pain in legs. Migraine. Tightness in right leg, very painful. Possible blood clot? Testing in process.
938147	1/12/2021	NH	37	F	12/30/2020	1/3/2021	I am not completely convinced that this is related to the vaccine but thought I should report it just in case. I thought I had a spider bite on my left foot, and then I thought it was shingles and then cellulitis. I was then diagnosed with a blood clot today. I have never had blood clots before.
938186	1/12/2021	MI	32	F	12/28/2020	1/12/2021	Heavy period with more bleeding. And cramping and multiple clots

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934028	1/11/2021	UT	32	F	12/28/2020	12/31/2020	Patient received her covid vaccine on 12/28/2020 in her left arm. Three days after vaccination she had pain and swelling in her right arm. She was seen by a health care provider on 12/31/2020 and an ultrasound showed extensive deep venous thrombosis in the left arm. She was started on a blood thinner (eliquis). She had blood tests done on 1/1/20 and this showed leukocytosis. She was found to have acute myeloid leukemia and admitted to our service for treatment. We do not have blood tests prior to 1/1/20 so it is unclear when her leukemia started. Her deep venous thrombosis could be related to her acute leukemia but I decided to report it due to the proximity to the time of her vaccine. Her arm pain and swelling improved after administration of the blood thinner. She is currently being treated for her leukemia.
933441	1/11/2021	CT	40	F	1/7/2021	1/8/2021	Skin rashes (itchy) and breathing shallow and arm sore. I got prednisone, benadryl, tylenol, clotimazole/hydrocortisone cream, albuterol breathing treatments. Getting better after day 3.
934745	1/11/2021	IA	79	F	1/9/2021	1/10/2021	Resident had seizure like activity followed by a vagel response with large bowel movement. Resident then began to show signs of blood clot to left lower extremity. No pedal pulse, area on leg warm to touch. Left lower leg now cold to touch, stiff, purple and white in color. No other signs of modeling, body warm to touch, no fever noted. Respirations and pulse increased with low oxygen levels. Resident not responding to stimuli.

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934912	1/11/2021	FL	28	F	12/24/2020	1/4/2021	DVT; have pain in same site where DVT is; This is a spontaneous report from a contactable consumer. A 28-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK9291), via an unspecified route of administration in left deltoid on 24Dec2020 10:00 at first single dose for COVID-19 immunization. Medical history was none. There were no concomitant medications. Caller was calling to report a possible adverse reaction to the Pfizer Covid-19 vaccine. The patient was currently at hospital, she was admitted for deep vein thrombosis (DVT) of left iliac vein, the patient had no past history as to why this would happen, that she is only 28 years old. Received the vaccine on 24Dec2020, the following day she did have pain in same site where DVT was. Took ibuprofen for the pain. The patient was admitted yesterday 04Jan2020 for the DVT, they were currently treating her with Lovenox injections and prescribing dose for discharge is Eliquis. CT scans and three shots of Lovenox for it, doing a doppler of bilateral legs and echocardiogram (echo) of her heart to make sure there is nothing else. The AEs require a visit to emergency room. The patient was asking if she can still get the 2nd dose based off the adverse event she experienced. Outcome of DVT was not recovered, of pain was unknown.
935738	1/11/2021	CA	56	F	12/18/2020	12/18/2020	After 7hrs of the vaccine I was feeling very tired I had muscle ache almost a week later I went to the ER because I had a lot of pain on my legs mainly on my right one I thought I had a blood clot but in the ER they told me it was just a reaction the the vaccine.
936435	1/11/2021	TX	33	M	12/19/2020	12/28/2020	Had a blood draw in left arm 12/24/2020. Eventually led to superficial venous thrombosis of left basilic vein confirmed by duplex us and ct angiogram w/ contrast. Indentured vein led to seek diagnosis and treatment



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932091	1/10/2021	FL	50	M	12/16/2020	1/5/2021	Started severe belly pain and went to Emergency room and diagnosed with mesenteric vein thrombosis after the CT scan of the abdomen, treated with heparin drip, antibiotic and discharged with anticoagulant pills(Eliquis). I am not sure that it is because of the vaccine my doctors are also not sure about it, but I am sure that I am a healthy person without any health issues . I am working as registered nurse, our unit is for covid-19 patient's since march 2020 and I had covid -19 on August month and recovered after 3 weeks.
927684	1/8/2021	IN	47	F	12/23/2020	12/25/2020	excessive sleeping; Extreme fatigue; temp 100; sore throat; loss of balance; Muscle weakness; This is a spontaneous report from a contactable nurse (patient). A 47-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EL1284), via an unspecified route of administration in the left arm on 23Dec2020 12:00 at a single dose for COVID-19 immunization. The patient's medical history included COVID-diagnosis from Mar2020 that resulted in blood clots and pneumonia both on 2020, and allergies to shellfish, eggs, peanuts. The patient was not pregnant. Concomitant medications included acyclovir [aciclovir], levothyroxine sodium (SYNTHROID), apixaban (ELIQUIS), escitalopram oxalate (LEXAPRO), and bupropion hydrochloride (WELLBUTRIN). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 25Dec2020 06:00, the patient experienced extreme fatigue, temperature of 100, sore throat, loss of balance, muscle weakness, and excessive sleeping. The events resulted in doctor or other healthcare professional office/clinic visit. The patient underwent other lab tests and procedures which included COVID test nasal swab was negative on 28Dec2020. Outcome of the events was not recovered. The events were considered non-serious by the reporter.

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930155	1/8/2021	UT	39	F	1/4/2021	1/4/2021	Employee reports 1/4 he had a sore arm, later that night HA, fever, chills. 1/5 1600 headaches progressed to migraine with extreme fatigue. 1/6 evening he went to ED due to symptoms and history of blood clots in the brain. CT was done in the ED. It showed signs of COVID in the CT chest. COVID test negative. 1/7 AM SOB and cough started. HA continues but manageable, dizziness and a crawling feeling under skin. 1/8 AM tightness in chest, crawling under skin increased, HA, dizziness and slight bodyaches.
930753	1/8/2021	MA	60	M	1/6/2021	1/7/2021	I woke up at approximately 4:00 am with an extremely dry mouth. I went into the bathroom and took a drink of water. I returned to bed. I noticed that my breathing was becoming more rapid. I had trouble catching my breath. I sat up on the side of the bed. My heart was pounding and quick. My breathing was difficult. I woke up my wife. After about 5 minutes my symptoms improved. She took my pulse which was now at 62ppm. I laid back down in a reclined position. My symptoms of difficulty breathing and elevated heart rate quickly returned. My pulse was now up to 98 ppm. I sat up again. My symptoms gradually improved. Being unsure of what was going on my wife called 911. The ambulance arrived in about 8 minutes. I was about 60% better. Vitals were improving other than my blood pressure which was 180/100 Being unsure of what was happening, I was transported to Hospital. I had a chest x-ray, a chest CT scan with contrast to rule out a blood clot, blood work including tests to rule out MI x2. All test were negative. By about 6:30 am I was feeling at least 80% better. My breathing I felt had returned to normal. My pulse was down into the 50"s which is my normal range.

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925652	1/7/2021			U	12/30/2020		Back of my right leg has a quarter size oblong shape lump it's little bit red but not warm to the touch; Back of my right leg has a quarter size oblong shape lump it's little bit red but not warm to the touch; Back of my right leg has a quarter size oblong shape lump it's little bit red but not warm to the touch, it may be a blood clot; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received single dose of BNT162B2 (Solution for injection, batch/lot number and exp date not reported), via an unspecified route of administration on 30Dec2020 18:30 SE for immunization. The patient's medical history and concomitant medications were not reported. Patient received the Pfizer Vaccine the day of reporting: 30Dec2020 at about 06:30 (tonight). Patient felt fine and still felt fine but when was going to rub some lotion on the back of right leg, has a quarter size oblong shaped lump (onset date not reported) which was little bit red but not warm to the touch. Patient didn't do anything to make it happen. Patient doesn't know if it may be a blood clot which was patient's question. "The blood clot something may be concerned about." Patient asked "Is this a blood clot, it could go to my heart and I could die tomorrow? So I am going to call my family doctor but thank you." The outcome of the events was unknown. Information about lot/batch number has been requested.

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925358	1/7/2021	PA	57	M	12/28/2020	1/2/2021	Developed left lower leg discomfort on day 5 post-vaccination with dose 1 of Moderna COVID-19 vaccine. Developed worsening pain, swelling and mild erythema of the left lower leg distal to the knee over the next 48 hours. Seen on 1/05/2021, and STAT venous duplex ultrasound ordered, which revealed a prominent deep vein thrombosis partially occlusive, partially nonocclusive extending from the left femoral vein distally. Started on anticoagulation with apixiban. No signs/symptoms of pulmonary embolus. No precipitating event that would raise risk of acute DVT (He does not have any open areas of his skin concerning for infection in the leg. No recent injury to the leg. No recent surgeries or period of immobility. No prior personal history of DVT, provoked or unprovoked. He does not smoke. He does drink alcohol in small amounts, to moderate amounts on occasion. No history of alcohol misuse or abuse.). He has chronic HIV infection, well controlled. He does have a family history of DVT (his mother had 1 provoked and 1 non-provoked DVT).
925429	1/7/2021	KS	59	M	12/18/2020	12/21/2020	Left Chest Pain that was sharp for about 5 minutes. Blood pressure initially was 196/96. Blood pressure came down, and I completed a full day of seeing patients. I then reported in the evening to the ER for testing. No Heart Attack or Blood Clot was diagnosed. So, this was musculoskeletal pain at the left costochondral region.

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925634	1/7/2021			U			<p>DVT; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender received BNT162B2, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The nurse asked if there is any DVT cases reported following the administration of Pfizer-BioNTech COVID-19 Vaccine. E-transmitting duplicate AE caller already reported a DVT case post vaccination. Caller also asked "Why is there's a statement indicating that individuals with a history of bleeding disorder or taking anti-coagulant should contact their vaccination provider? How did they prove 95 % efficacy? Why aren't antibodies produced after the 1st dose of Covid-19 vaccine?" The outcome of the event DVT was unknown. Information on Lot/batch number has been requested.; Sender's Comments: Very limited information was provided for this individual patient, such as pre-existing medical history, suspect administration details, clinical course and relevant supportive lab data for the reported Deep vein thrombosis (DVT). Pending further details, the Company would handle this reported DVT related to the administration of BNT162B2, COVID-19 immunization, for reporting purpose. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.</p>

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925644	1/7/2021	NY	85	F	12/23/2020	12/26/2020	Confirmed DVT in the left leg; COVID test (PCR swab): positive on 26Dec2020; COVID test (PCR swab): positive on 26Dec2020; This is a spontaneous report from a contactable other healthcare professional. An 85-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# ELO140, expiration date: Mar2021), via an unspecified route of administration in arm (deltoid; unknown side) on 23Dec2020 at single dose for Covid-19 immunisation. Medical history included type 2 diabetes mellitus from 2017 and ongoing, high blood pressure from 2017 and ongoing, atrial fibrillation (A-Fib) from 2019 and ongoing. The patient's concomitant medications were not reported. The patient was administered first dose of the COVID vaccine on 23Dec2020 and then was swabbed for COVID on 26Dec2020, and then on 28Dec2020 her PCR swab was positive for COVID. She was asymptomatic until she started complaining of leg pain. She ordered an ultrasound for the patient on 30Dec2020, and it confirmed a deep vein thrombosis (DVT) in left leg. The patient was being treated with anticoagulant apixaban (ELIQUIS) currently. Caller stated that this could be that it (DVT) is from COVID, but her real question was, could it be from the vaccine? In Pfizer's information packet for patients, there is section on what to tell your provider prior to getting vaccinated. One of the things on there is if you have a bleeding disorder or are on an anticoagulant. There is no explanation as to why it was in the packet of information. Caller has looked everywhere and can not figure out why that is on the FAQ/packet information. The patient was due for the second dose on 13Jan2020, but she was worried and hesitant to approve it. The patient underwent lab tests and procedures which included COVID test (PCR swab): positive on 26Dec2020, ultrasound of the left leg: confirmed DVT on 30Dec2020. The outcome of events was not recovered.; Sender's Comments: There is not a reasonable possibility that event "COVID test (PCR swab): positive" is related to BNT162B2 vaccine. The event occurred 3 days after vaccination, when vaccine was not expected to achieve the effect. The event DVT of legs is not considered related to BNT162B2 vaccine. The patient had underlying diabetes and cardiovascular disorders, which are considered as risk factors for DVT. The impact of this report on the benefit/risk profile of the Pfizer product is

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926361	1/7/2021	VA	36	F	1/2/2021	1/5/2021	<p>evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> <p>I have intense burning sensation in my left buttock cheek and thigh but no rash. I went to my gynecologist , first thinking I may have a yeast infection but she did not see a rash and couldn't diagnose me. She told me that my pain was probably neurological. She took my blood and sent it to a lab for possible yeast infection and STDs. She prescribed me Clotrimazole and Betamethasone Diporopionate 1%. I went to my PCP on Wednesday because the burning intensified and I thought that I may have shingles. I have a stuffy nose and my sense of smell isn't very good right now. My PCP gave me a Covid test and told me that she can not test me for shingles because I do not have a rash. She did prescribed me Gabapentin 100mg . I am awaiting Covid test and Lab results</p>

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925640	1/7/2021	NJ	60	M	12/20/2020	12/27/2020	DVT left calf; This is a spontaneous report from a contactable Physician (patient). A 60-year-old male patient started to receive the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Intramuscular on 20Dec2020 08:00 at single dose on right arm for COVID-19 immunization. Medical history included Gastric reflux. The patient had no known allergies. The patient had no covid prior vaccination. The patient had no covid tested post vaccination. Concomitant medications included omeprazole (PRILOSEC) and ergocalciferol (VIT D). The patient had not received other vaccine in four weeks. The patient experienced deep vein thrombosis (DVT) left calf on 27Dec2020 09:00 which resulted emergency room visit. Treatment received for the event included Xarelto. The outcome of the event was not resolved. Information on the lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.



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924184	1/6/2021	NE	35	F	12/28/2020	12/28/2020	DESCRIPTION THAT FOLLOWS IS FROM PATIENT: Monday 12-28 evening I begun to get chills and body aches, the next morning when waking up I felt like a truck hit me. Starting Tuesday morning, for three days, I got calf/feet cramps that were non-stop. I did call my doctor and got lab work done on 12-31. This lab work showed some kidney values that were off. Starting Sunday my legs and feet swelled up. I had a routine MS appointment on Monday and they stated since there is no data for folks with MS and the vaccine that they cannot rule out the vaccine is playing a role in some of this along with the IVIG. I did follow up with my primary care doctor on Tuesday and they re did lab work as well as did a ultrasound to rule out blood clots. She did state she felt like it was the perfect storm between the COVID vaccine and then the Immunoglobins that I am on. She suggested I download the app for CDC and report those items as well. The doctors are still suggesting I get the 2nd shot just have to do some things prior to the second shot.
922331	1/6/2021	RI	44	F	12/28/2020	12/28/2020	Initial swelling and soreness right after injection. Swelling and pain continued for the next few days, Motrin 800mg and Benadryl 25mg at bedtime were taken. Swelling and pain persisted. Area became hard, red, itchy and raised over the holiday. Swelling, redness and itchiness became worse over the weeknd into Monday. I was unable to lift my arm, bring it behind my back or reach. It was very painful and hot. I then contacted employee health. They did not feel it was infected but was the delayed reaction to the moderna vaccine. I did not feel comfortable with this and I then contacted my physician who looked at it and felt it was in fact cellulitis, I was sent for a ultrasound to rule out a blood clot and labs and an IV infusion of Rocephin as well as oral antibiotics. I received my first infusion yesterday. The swelling has improved greatly, however the redness has spread beyond the marked area on my arm and I will be receiving another dose of IV Rocephin today. My labs showed my CRP was elevated and my ALT/AST were elevated as well.
923031	1/6/2021	LA	31	F	12/30/2020	12/31/2020	Worsening arm pain after injection that eventually resulted in my being diagnosed with a blood clot in the arm that I received the injection on

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924035	1/6/2021	TX	28	F	12/28/2020	12/30/2020	So I got the vaccine Monday night after work. Tuesday and Wednesday I ran a super high fever, body aches, lymphnode swelling on that side. No big deal . Well Thursday morning I woke up with a rash on both of my legs and my legs swollen like tree trunks. It?s a petechial rash. I called the pharmacist told to take Benadryl and Zyrtec since Friday. So I went to the doctors last night since I still have this rash and it hasn?t gotten any better with Benadryl and Zyrtec. I got blood work done today. And I have to get an arterial and venous Doppler done on Wednesday next week. They are concerned I may have blood clots since my legs are so swollen with a petechial rash. They are also giving me steroid taper.
924162	1/6/2021	NE	35	F	12/28/2020	12/28/2020	AS REPORTED BY PATIENT: Monday 12-28 evening I begun to get chills and body aches, the next morning when waking up I felt like a truck hit me. Starting Tuesday morning, for three days, I got calf/feet cramps that were non-stop. I did call my doctor and got lab work done on 12-31. This lab work showed some kidney values that were off. Starting Sunday my legs and feet swelled up. I had a routine MS appointment on Monday and they stated since there is no data for folks with MS and the vaccine that they cannot rule out the vaccine is playing a role in some of this along with the IVIG. I did follow up with my primary care doctor on Tuesday and they re did lab work as well as did a ultrasound to rule out blood clots. She did state she felt like it was the perfect storm between the COVID vaccine and then the Immunoglobins that I am on. She suggested I download the app for CDC and report those items as well. The doctors are still suggesting I get the 2nd shot just have to do some things prior to the second shot.

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921228	1/5/2021	VA	77	M	12/24/2020	12/24/2020	vomited; nausea/ felt sick to his stomach; felt woozy; didn't feel well; right deltoid soreness; This is a spontaneous report from a contactable physician (patient). A 77-years-old male patient received the first dose of BNT162B2 (Lot: EH9899), via an unspecified route of administration in deltoid right, on 24Dec2020 11:30 at single dose for COVID -19 immunization. Medical history included pulmonary embolism half a dozen years ago. He has had no problems with Deep Vein Thrombosis or pulmonary emboli since then, since half a dozen years. He has had a battery of lab tests 2 months ago, his blood glucose was high, it was 106 mg. The potassium was ok. He has had no issues with vaccines in the past. He had an antibody test last Jul2020 because he had bacterial lower urinary tract prostate infection. Concomitant medication included rivaroxaban (XARELTO) at 10 mg a day and cefalexin sodium (CEPHALEXIN) at 500 mg three times a day, well approximately 3, sometimes he forget a dose. The physician reported possible side effects of Covid vaccine. The physician received the vaccine on 24Dec2020 at 11:30 in the late morning and felt fine. He woke up on 25Dec2020 and at 2:30AM he was sick to his stomach and vomited and didn't feel well the rest of the day. Since then he had been okay, he had occasional nausea and vomiting. He clarified that on 24Dec2020, in the late evening, his appetite which was usual, was robust. Then on 25Dec2020 at 2:30 in the morning he vomited, and had no trouble since then. From what he read, nausea and vomiting are observed following the injection. On 24Dec2020 just before bed, he had a light supper, his appetite was robust, then unexpectedly he woke up sick to his stomach and went back to bed on 25Dec2020. He clarified that he had not vomited since the one episode on 25Dec2020. He also added that he has not been nauseous since then. Caller also added that he felt a little woozy on Holiday 25Dec2020, it only lasted up until the evening of 25Dec2020. He had the 1 episode vomiting on 25Dec2020 and felt woozy until late evening of 25Dec2020. His right deltoid where he received the vaccine was a little bit sore on 24Dec2020, and he was still having a little bit of soreness, it is slight, not very tender, he is unable to do usual morning exercises with out noticing the discomfort, the exercise he is doing is chin ups, the soreness is not intense and it never was.

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							The lab test in 2020 included Height: under 5 feet 5 inches. Weight: about 165lbs or 167lbs. He had no positive test for COVID prior to the vaccine. All the tests were negative. The 1st one was nasopharyngeal, and all the next ones after were nasal swabs. He thought they are all reverse transcriptase tests. The last time he had a COVID test they did a nasal swab, it was this morning, and before that was last Monday or Tuesday, but he thought more so Monday. He had one PCR test. The outcome of the events vomited, nausea and felt woozy was recovered on 25Dec2020. The outcome of the event right deltoid soreness was recovering. The outcome of the other event was unknown. The 2nd dose for Covid vaccine was schedule for 14Jan2021.
920728	1/5/2021	NE	37	M	1/4/2021	1/4/2021	DEVELOPED CONTINUOUS CHEST PAIN WHEN BREATHING IN. WAS SENT TO THE EMERGENCY ROOM. WAS SEEN IN ER AND DISCHARGED AFTER OBSERVATION PERIOD. ER PROGRESS NOTE: Patient is a 37 y.o. male who arrived by Home presented to the emergency department for Chest pain. Patient states that approximately 15 this morning he received a Covid vaccine and approximately 1 hour later he started to have chest pain. Patient describing chest pain as sharp, left-sided, nonradiating, nonexertional, only occurring with taking a big deep breath, has never had similar symptoms before, not improving with home baclofen, currently a 3-4 out of 10, not occurring at rest only with deep breath. Patient states that he became concerned that it was a side effect of the vaccine and came to ED for further evaluation. Patient just denies any associated shortness of breath, nausea or vomiting. Patient states he has history of bipolar, takes no mental and has been taking as prescribed. Patient states he is otherwise healthy. Patient works at a healthcare facility, has a weekly Covid antibody test which is was been negative, denies any other associated symptoms today. Patient is a daily smoker, no history of blood clots, no recent travel or surgeries. Patient denies any headache, change in vision, nausea, vomiting, neck pain, back pain, fever, chills, shortness of breath, abdominal pain, flank pain, change in urination, diarrhea, constipation, rashes, lightheadedness, dizziness, or any other associated symptoms.

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918807	1/4/2021	AK	49	M	12/31/2020	1/2/2021	Patient got his Covid vaccine this past Thursday, 2 days ago. He experienced typical side effects of a sore left shoulder and some fatigue but was feeling well until this afternoon around 1:55 PM when he noticed throbbing of his left hand. He looked down and noticed that there was a purple discoloration to his middle finger and distal palmar aspect of his hand. He felt like there was maybe some swelling as well and that he might have been having an allergic reaction so called the emergency department for further advice and came in for evaluation. By the time I arrived to the emergency department the patient's left hand was no longer swollen and there was only a small purple discoloration to the palmar proximal middle finger. I was concerned that the patient developed a small blood clot that was resolved upon evaluation.
919376	1/4/2021	MT	19	F	12/30/2020	1/2/2021	Patient received Moderna vaccine, Wednesday 12/30. On Saturday 1/3/2021 patient felt pressure/tightness in lower extremity. When patient touched area, a noticeable ball was felt under the skin, tender to the touch and warm. Patient went into urgent care on Monday 1/4/2021 with a confirmed dx of a superficial blood clot. Unknown etiology of whether this is from current birth control or the COVID19 Moderna vaccine.
919000	1/4/2021	OH	49	F	12/23/2020	12/23/2020	I had itching and redness and knots that formed in my left leg. The knots were at the site of a varicose vein. I sought tx at an ER on 12/26 to ensure it was not a blood clot. I followed up with my family dr on 1/4/2021 (When her office reopened) and was diagnosed with Superficial Thrombophlebitis. The knots remain in my leg. The redness has mostly gone away. My PCP felt as I recently had covid, the vaccine likely flared up the inflammation in my body and caused this condition.

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917210	1/2/2021	UT	30	F	12/21/2020	12/27/2020	30YO F ICU nurse obesity (BMI 35) COVID 19 on Dec 2 symptoms, Dec 3 tested positive for COVID-19. never hospitalized, outpatient only. 12/12 completed isolation 12/21 received vaccine 12/7 developed Fever chills diarrhea SOB cough Urgent care visit. RLL consolidation on CXR given doxycycline 100 mg po bid worse, fever 40 targetoid lesions to LE (started before doxy) WBC 22K tachycardic tachypneic admitted requiring 2-4L oxygen CT angio without clot, diffuse ground glass and RML dense infiltrate DDimer 7.8 LDH 599 CRP 41 procal 0.67 ferritin 500 Viral respiratory PCR negative Sputum cx with oral flora (pending) COVID ag testing neg COVID PCR 1/3 targets positive (called as indeterminate).
916795	1/1/2021	MI	43	F	12/29/2020	12/30/2020	Soreness at injection site 3 hours post injection. 30 hours post injection, pt experiences a huge blood clot from vagina, about the circumference of a clementine. was not old blood, looked like frank blood. over the next 30 hours, pt experiences more clots, much smaller, about the size of a pea. pt has a headache and chills throughout. 48+ hours, experiencing what feels like menstrual cramps. no blood clots 72 hours post injection
911899	12/29/2020	CA	27	F	12/24/2020	12/24/2020	Pt came in for vaccination for COVID-19 at 4:03 . She received Moderna vaccine at 4:15. She experienced palpitation, worsening chills, headache, and presyncope. No loss of consciousness. Denies chest pain, shortness of breath but feels heavy to push air in and pulse OX 100%, No angioedema, No rash, No pruritus, No throat swelling, denies hoarse voice, or difficulty breathing. She traveled to MD on 12/14/20 to receive antibiotics. She was treated with Erythromycin dose for 6 days from MD. The patient was +COVID19 on 12/11/20 with fever, scratchy throat, congestion, cough, and SOB and was seen in urgent care on 12/13/20 where was DX + for COVID19. She was quarantine for 10 days when she was returned to work on 12/22/20. Her Chest X-ray was negative on 12/13/20. She was negative for nausea, vomiting, diarrhea. She denies any recent vaginal bleeding, or abdominal pain. Denies any history of cardiac disease, or history of arrhythmias. Denies any history of prolonged immobility, or history of clots.

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912138	12/29/2020	CA	32	F	12/28/2020	12/28/2020	She arrived at 12:30 and was vaccinated shortly after while waiting 15 for observation within the 1st 10 min she C/O tingling of her throat and lower lips, felt palpitation. No chills, No headache, + palpitations, and No presyncope. Tells me that she did not experience any loss of consciousness. Never had any chest pain, shortness of breath, or angioedema, rash, pruritus, throat swelling, hoarse voice, or difficulty breathing. The patient has had no recent illnesses, fevers, chills, nausea, vomiting, diarrhea, or flu-like illnesses. She has had no cough, rhinorrhea, or congestion. She denies any recent vaginal bleeding, or abdominal pain. Denies any history of cardiac disease, or history of arrhythmias. Denies any history of prolonged immobility, recent travels, or history of clots. In ED:32 year old female with PMHx as listed in HPI presents with concern for allergic reaction to mod chair and a COVID-19 vaccine, felt tingling in the back of her throat and lower lip, no swelling, wheezing, shortness of breath, throat tightening, rash, nausea vomit or dizziness. Vitals reviewed found to be within normal limit. Physical exam as per above, no signs of mucosal or oral swelling, no hives or rash and no wheezing on exam. Given above findings, low suspicion for allergic reaction this time but plan to observe patient in the ED for any delayed reaction.

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912388	12/29/2020	CO	29	F	12/21/2020	12/21/2020	Low-grade fever and chills (99.5 Fahrenheit); Low-grade fever and chills (99.5 Fahrenheit); headache; This is a spontaneous report from a contactable nurse (patient). A 29-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not provide), intramuscularly on right arm at 09:30 AM on 21Dec2020 at single dose for COVID-19 immunization. Medical history included deep vein thrombosis (DVT), covid-19 prior vaccination. Concomitant medication included escitalopram oxalate (LEXAPRO), rivaroxaban (XARELTO), atenolol, multivitamins. The patient experienced severe headache at 18:00 on 21Dec2020. Low-grade fever and chills (99.5 Fahrenheit) Q (every) 90 mins from 22:00 21Dec2020 till 04:00 22Dec2020. The events were assessed as non-serious. Since the vaccination, the patient had not been tested for COVID-19. The outcome of event headache was recovered in Dec2020, the outcome of events chills and low grade fever was recovered at 04:00 on 22Dec2020. Information on the Lot/Batch number has been requested.



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912225	12/29/2020	NC	42	F	12/19/2020	12/1/2020	BNT162B2 was given to the patient subcutaneously instead of intramuscular; upset; crying; This is a spontaneous report from a contactable nurse via medical information team. A 42-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via subcutaneous on 19Dec2020 at single dose for COVID-19 immunization. Medical history included deep vein thrombosis (DVT) from 3 years ago and unknown if ongoing. Concomitant medication included acetylsalicylic acid (ASPIRIN (E.C.) for DVT and multivitamins. The patient stated "BNT162B2 was given to me subcutaneously instead of intramuscular (IM)." She stated she works at (Name withheld) and it was administered by an employee and her hospital employee health will not talk to her and she was being brushed off. The patient asked what's needed to do moving forward. She stated she does not know the efficacy for subcutaneous administration. After providing information in attached document the patient asked what should her next steps be since the hospital will not answer do anything about this incorrect administration. BNT162B2 was administered her incorrectly. The patient was little upset and was crying about it in Dec2020. The outcome of the events was unknown. Information on the lot number/batch number has been requested.

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912165	12/29/2020	CA	36	F	12/28/2020	12/28/2020	<p>She arrive at 3:43 and she was nervous before the vaccination for COVID19 ( Morena) because has had anaphylactic reactions to Flonase. She was feeling well up to 15 min post vaccination when she felt she is going to pass out w/o loosing consciousness. She felt weak and feeling fainted when we transferred her to the stretcher. Her BP was 163/106 P=112, Pulse Ox 100% at 16:09. She was resting, received O2 lit per min, she was feeling chest tightness when she used her inhaler Albuterol 2 puffs X2 within 5 min. She was feeling weak and stating "I am going to pass out." Her repeat BP=152/110, P=94 with pulse Ox 100% at 16:12 repeat at 16:30 BP=139/100, P=99 pulse OX 100% She then C/O chills later. Paramedics were called and transferred in to ED. She takes AMLODIPINE 5 MG DAILY FOR HTN. She has family HX of HTN. Negative for headache, + palpitations, + presyncope, + shortness of breath, slight difficulty brathing. She did not experience any loss of consciousness. Never had any chest pain, angioedema, rash, pruritus, throat swelling, hoarse voice. The patient has had no recent illnesses, fevers, chills, nausea, vomiting, diarrhea, or flu-like illnesses. She has had no cough, rhinorrhea, or congestion. She denies any recent vaginal bleeding, or abdominal pain. Denies any history of cardiac disease, or history of arrhythmias. Denies any history of prolonged immobility, recent travels, or history of clots. In ED: 36 year old female presents with dizziness and presyncopal like symptoms approximately 15 minutes after receiving the Medina vaccine at this hospital the patient who is mildly tachycardic mildly hypertensive but otherwise normal and stable vital signs and is overall nontoxic appearing. Of note the patient's oxygen saturation was 97% while I was in the room and not the 2% that is documented here. EKG notable for a rate of 87 normal axis normal sinus rhythm T-wave inversion in V1 otherwise no evidence of Brugada interval abnormality or evidence of electrolyte abnormality that would require further workup at this time. Patient counseled to follow up with her primary care. Patient given EpiPen given her EpiPen has expired. Patient requested to go back to work I feel this is fair given patient will be on campus and can return to the emergency department should she develop any further symptoms. Patient states her symptoms have completely resolved and she has normal vital signs</p>

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currently heart rate in the 80s blood pressure 138 systolic  
feeling well and requesting to be discharged.

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910641	12/28/2020	MD	54	F	12/18/2020	12/18/2020	Weakness and tingling down left arm; Weakness and tingling down left arm; Lightheaded; PVC's every 3 beats; emotional too and just very tired; Can not read the vaccination card as she does not have her glasses; Palpitations; Fatigue; Slept a lot; Thready pulse and vertigo; Thready pulse and vertigo; Soreness in left arm at the injection site and down the left arm; Soreness in left arm at the injection site and down the left arm; This is a spontaneous report from a contactable nurse (patient). A 54-year-old female patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, reason for no lot number of COVID Vaccine: Can not read the vaccination card as she does not have her glasses, Expiry Date unknown), via an unspecified route of administration in the left arm on 18Dec2020 at single dose for 'Work with COVID patients'. Medical history included none. There were no concomitant medications. The patient experienced weakness and tingling down left arm (hospitalization) on 22Dec2020, lightheaded (hospitalization) on 22Dec2020, PVC's every 3 beats (hospitalization) on 22Dec2020, soreness in left arm at the injection site and down the left arm on 18Dec2020, thready pulse and vertigo on 19Dec2020, fatigue on 20Dec2020, slept a lot on 19Dec2020, palpitations on 21Dec2020. Details as follows: Caller says she received the vaccine, she is a nurse. She got the vaccine on Friday, 18Dec2020. She had soreness in her arm and at the injection site on Friday but that was it. On Saturday (19Dec2020) she noticed a thready pulse, but went on with her day with only a little arm pain. Sunday (20Dec2020) she was fatigued and the thready pulse continued. She slept a lot on Saturday (19Dec2020) and Sunday (20Dec2020). Yesterday (21Dec2020) she felt a little better, but had palpitations here and there. This morning (22Dec2020) she went into work, was very lightheaded, had tingling down her left arm, and had palpitations. So she hooked herself up to a monitor. Her pulse ox was between 97-99%. Her heart rate would be in the 90s and then drop to 48, so she went down to the ED. She has had a CT, and she is throwing PVC's every 3 beats. She has not been admitted as they are still waiting for results. She is still in the ED. They did a CT to see if there was a possible clot. On 18Dec2020 she received the vaccine around 2 PM. She had soreness at the injections site and down the left arm, which went

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away by Sunday (20Dec2020). She now (22Dec2020) has weakness and tingling down the left arm. It was never red or anything at the injection site. Saturday, 19Dec2020, she had thready pulse and Vertigo which lasted until Sunday 20Dec2020. She would be laying in bed and try to flip to the other side and having vertigo. When the fatigue started on Sunday (20Dec2020) she did not feel like herself. She was very emotional too and just very tired. Since she went to the ED she has had a CT scan, one with contrast and one without. She had a chest X-ray, and she is on a cardiac monitor. Results are pending. She has Trigeminy PVCs. She says she never goes to the hospital. But she is not admitted yet (pending clarification). Can not read the vaccination card as she does not have her glasses. Unable to read off the NDC, lot, and expiration date. History: Has been on the same vitamins for two years with nothing new. Blood pressure: Normal base line is 130s/80s maybe lower. Heart rate: Currently within her normal limits of 80s-90s. Depending on what happens, it was asked if she should get the second dose. The patient underwent other lab tests and procedures which included blood pressure measurement: 163/76 on 22Dec2020, chest x-ray: unknown result on 22Dec2020 (Result: Pending), computerised tomogram (CT scan): unknown result on 22Dec2020 (Result: Pending), heart rate: 80s-90s on 22Dec2020, Pulse oximetry: 97-99 % on 22Dec2020, cardiac monitor: results are pending on 22Dec2020. The outcome of events weakness and tingling down left arm, pvc's every 3 beats, lightheaded, palpitations and fatigue was not recovered. The outcome of the event soreness in left arm at the injection site and down the left arm was recovered on 20Dec2020. The outcome of the events thready pulse and vertigo was recovered on 20Dec2020. The outcome of the event slept a lot was recovered on 20Dec2020. The outcome of other events was unknown. Information on the lot/Batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject vaccine cannot be excluded for the reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once

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additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

908959	12/24/2020	CA	42	F	12/23/2020	12/23/2020	Observed for 15 minutes after vaccine. About 30 minutes later in my car, felt sharp shooting pains in left neck. About 8 hours after receiving first dose, started coughing up blood, bright red, with streaks and clots. No cough, fever. Seen in ER with chest xray and ct scan with contrast. No resolve. On second day after receiving vaccine? Continue to experience bright red sputum. No resolve.
908846	12/24/2020	MO	49	F	12/24/2020	12/24/2020	Very mild, but unexpected nose bloody nose from left nostril. Only noted when blowing nose. With 1 clot.
905649	12/21/2020	NH	37	F	12/16/2020	12/16/2020	The evening of 12/16 my headache begin at the next day fever of 103 stayed for 7 hrs took administered Tylenol exp chills, body aches, and rash on face around the eye spread to right side of nose, side went to hand area lasted from 12/17 to 12/21.The headache started effecting my neck contacted my PCP on 12/19. I went to ER on 12/19 ran tests CT scan check for clots negative, lumbar puncture and chest X-ray was fine and dint exp respiratory problems. I missed 3 days of from work 12/9 to 12/21.
904983	12/21/2020	LA	58	F	12/18/2020	12/18/2020	Friday night same night of vaccine. Arm started aching and hurting. After my shower, my whole arm was in pain. Pain then moved all the way to my back. I took two tylenol, and it calmed it down. At 3 am, it started hurting really bad, I had to take a lortab - a stronger pain med at 5am that morning. Around 10am, my whole back started hurting, and that evening, it still was hurting. I ended up taking 3 lortab that day. The pain went to my neck. On Sunday, I ended up taking two lortab . All together, I took 5 lortab to ease pain from this vaccine. I was scared that I was getting another blood clot from the feeling of the pain. I am still just sore. NOTE: I am on blood thinner