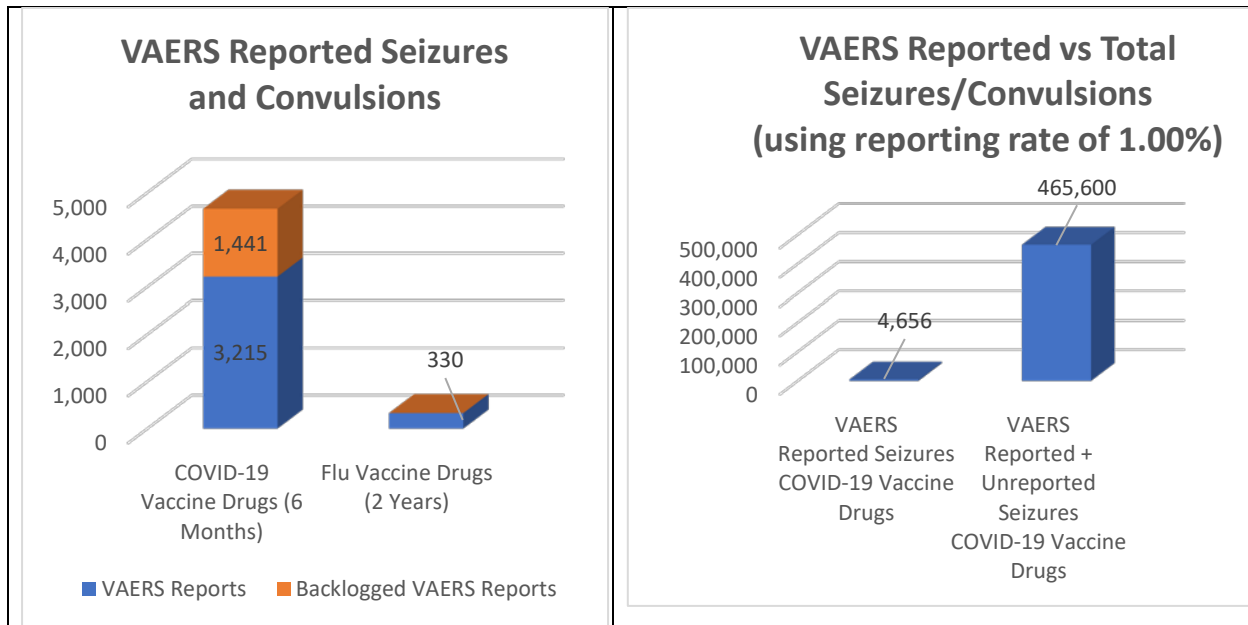


COVID-19 Vaccine Drug Reactions: Seizures and Convulsions

Preliminary Notes – Reactions Listings Start on Page 2 Below



1. Seizure and Convulsions 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#ReportingRate

3. The cases listed below were pulled from the VAERS raw data files with a query that looked for seizures and convulsions, *but not for tremors*. As you read through the cases below, it is possible that there will be an occasional erroneous case not related to seizures and convulsions. The exact query is as follows:
(symptom_text like "*seizure*" or symptom_text like "*grand mal*" or symptom_text like "*petit mal*" or symptom_text like "*convulse*" or symptom_text like "*convulsion*")

Seizures and Convulsions: COVID-19 Vaccine Drugs

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
1373295	6/4/2021	IN	78	F	5/20/2021	5/21/2021	Nausea; getting more and more sick, it is getting worse as the day goes; stomach problems; This spontaneous case was reported by a consumer and describes the occurrence of NAUSEA (Nausea), ILLNESS (getting more and more sick, it is getting worse as the day goes) and ABDOMINAL DISCOMFORT (stomach problems) in a 78-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 003C2HA) for COVID-19 vaccination. The patient's past medical history included Back surgery (2 back surgeries) since an unknown date. Concurrent medical conditions included Hypertension, Epilepsy, Spinal cord disorder (Spinal problem) and Seizures. On 20-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-May-2021, the patient experienced NAUSEA (Nausea) (seriousness criterion medically significant), ILLNESS (getting more and more sick, it is getting worse as the day goes) (seriousness criterion medically significant) and ABDOMINAL DISCOMFORT (stomach problems) (seriousness criterion medically significant). At the time of the report, NAUSEA (Nausea), ILLNESS (getting more and more sick, it is getting worse as the day goes) and ABDOMINAL DISCOMFORT (stomach problems) 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 medication included unspecified seizure medication, blood pressure patch and pain medicine. No treatment products were reported. Patient had her first dose on 20 May 2021 in her right dominant arm. On 21 May 2021, patient experienced nausea, getting more sick and worse as the day goes stomach problems. Patient called her family doctor but doctor was left for the day. Patient wanted to know what to do about her side effects. Patient provided her doctor's contact information and permission to contact her doctor. The patient had her first dose in her doctor's office. No treatment medications were reported.

<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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1374545	6/4/2021	MO					
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			35	M			
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					6/4/2021		
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						6/4/2021	
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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: Non-Significant follow up appended; 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.

Immediately following injection patient passed out and was diaphoretic with a low BP of 56/35. Became responsive but speech garbled and then experienced seizure (posturing and clonic movement) that lasted 3 seconds. Called 911, became responsive before EMS arrived on scene and refused ambulance.

<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>
1373209	6/4/2021	IL	21	F	3/17/2021	3/17/2021	Loss of consciousness; Seizure; This case was received via FDA VAERS on 25-May-2021 and was forwarded to Moderna on 25-May-2021. This regulatory authority case was reported by an other health professional and describes the occurrence of LOSS OF CONSCIOUSNESS (Loss of consciousness) and SEIZURE (Seizure) in a 21-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 040a21a) for COVID-19 vaccination. No Medical History information was reported. On 17-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Loss of consciousness) (seriousness criterion medically significant) and SEIZURE (Seizure) (seriousness criterion medically significant). At the time of the report, LOSS OF CONSCIOUSNESS (Loss of consciousness) and SEIZURE (Seizure) 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. The patient lost consciousness seconds after vaccine. This was followed by seizure activity for 20 seconds. Blood pressure and heart rate were measured by emergency medical service, however results were not provided. Concomitant product use was not provided by the reporter. Treatment information was not provided. Very limited information regarding these events has been provided at this time. No further information is expected.; Sender's Comments: Very limited information regarding these events has been provided at this time. 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>
1373462	6/4/2021	PA	71	M	3/4/2021	3/4/2021	Pain made sleeping extremely difficult; significant pain in muscle between right shoulder and base of skull/severe pain in muscle between right shoulder and base of skull; significant pain in muscle between right shoulder and base of skull; sleepy; This is a spontaneous report from a contactable Other HCP. A 71-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot number: EN6203), via an unspecified route of administration in left arm on 04Mar2021 at 10:45 as a single dose for COVID-19 immunization. The patient's medical history included idiopathic grand mal epilepsy. The patient's concomitant medication included phenobarbital, primidone, phenytoin and atorvastatin. The patient did not receive any other vaccine in four weeks. The patient was not diagnosed with COVID prior vaccination. The patient had no known allergies. . On 04Mar2021 at 16:00 (Thursday), the patient experienced sleepy. On 05Mar2021 at evening (Friday), the patient experienced significant pain in muscle between left shoulder and base of skull and on 06Mar2021 (Saturday evening) experienced severe pain in muscle between right shoulder and base of skull and pain made sleeping extremely difficult. The patient received Motrin 800mg somewhat alleviated with pain. The patient did not undergo COVID test post vaccination. The outcome of the event was not resolved. No follow up attempts are possible. No further information was 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>
1373858	6/4/2021	CA		F	2/20/2021	2/25/2021	like an affected brain function; intense chills/ severe chills so bad that she thought that she was going to have a convulsion.; intense chills/ severe chills so bad that she thought that she was going to have a convulsion.; symptoms like those for the flu/flu like symptoms; redness in her eyes; problems focusing her vision; pain in the eyes and very hard pain on the eft side of her skull that went down to the neck.; very hard pain on the eft side of her skull that went down to the neck.; pain in the eyes and very hard pain on the eft side of her skull that went down to the neck.; not thinking properly/her thinking processand her logic were affected; the muscular tone of the tongue was affected affecting her speech and swallowing; the muscular tone of the tongue was affected affecting her speech and swallowing; the muscular tone of the tongue was affected affecting her speech and swallowing; cry; This is a spontaneous report from a contactable consumer (Patient). A 78-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on 20Feb2021 (lot number: not reported) as second dose, single for COVID-19 Immunization. Patient had received first dose of vaccine Pfizer BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 30Jan2021 (at the age of 78-years-old) for COVID-19 Immunization and she was feeling fine. The patient medical history and concomitant medications were not reported. On 25Feb2021, 5 days after the administration of the second dose of the vaccine, patient experienced symptoms related with her eyes, her nervous system and symptoms like those for the flu, Ophthalmological symptoms like redness in her eyes, problems focusing her vision, pain in the eyes and very hard pain on the left side of her skull that went down to the neck and Neurological symptoms like an affected brain function, not thinking properly, the muscular tone of the tongue was affected affecting her speech and swallowing, these symptoms always on the left side of her head. The patient reported that the flu like symptoms were intense chills, so much that she could not get warmed even when she used very warm material, she took her body temperature and she found it to be normal, then she experienced severe chills so bad that she thought that she was going to have a convulsion, then she started to feel afraid and she started to cry, noticing

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							that her thinking process and her logic were affected. Patient visited multiple specialists like Neurologists, Ophthalmologists, and Physicians for the events. The patient underwent lab tests and procedures which included body temperature: normal on an unspecified date in Feb2021. The outcome of the events was reported as recovered on 23May2021. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.
1374113	6/4/2021	CA	46	F	6/3/2021	6/3/2021	Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Seizure-Severe, Systemic: Shakiness-Severe, Systemic: Tingling (specify: facial area, extremities)-Medium, Systemic: Weakness-Medium, Additional Details: <5 min post dose patient noted feeling short of breath, numbness, dizzy, sweaty, shaky and then lost consciousness. I was able to catch her head so she didnt hit a hard surface. Patient was unresponsive for 10 seconds. She started to seize and her eyes rolled to the back of her head. After she regained consciousness she was moved into the pharmacy and laid down. Pt was given a cool towel and water.1st BP (112/70 & HR74), 2nd BP 15min later (110/70 & HR 84). After 45 min pt left with family member
1374361	6/4/2021	NE	12	F	6/3/2021	6/4/2021	Patient awoke the morning after her 1st COVID vaccination. Reported she slept well. Her arm was sore from COVID shot. She was up for approximately 20 min and had brushed her teeth and did her hair. She was going to get dressed for the day and states she got a sudden pounding headache and felt nauseous. She was on her way out to the kitchen to tell us she didn't feel good when she blacked out. She face planted, hitting her forehead on the hardwood floor witnessed by both parents. She was out for approximately 30 seconds. Her blood pressure was 90/60, HR 120, O2 on rm air was 98%. She has no previous history of syncope. After spell heart rate ran in the 100-110s for about 30 min and then normalized around 88-95. Was tired and sleepy for 2 hours after. (No post ictal sx to suggest seizure) Patient also received Tdap and meningococcal vaccine in other arm at the time of 1st Covid vaccination. The night of her COVID shot patient had normal appetite and activity level.

<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>
1374438	6/4/2021	IL	19	M	6/3/2021	6/4/2021	generalized seizure
1374451	6/4/2021		63	F	3/27/2021	3/27/2021	R56.9 - Unspecified convulsions
1374522	6/4/2021	MO	35	M	6/4/2021	6/4/2021	Following injection patient passed out, was diaphoretic and had low BP of 56/35. Became responsive then speech became garbled and went into seizure (posturing and clonic movement) for approximately 3 seconds. Called 911. Became responsive before EMS arrived and refused ambulance to the hospital.
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.
1372600	6/3/2021	CA	16	M	5/18/2021	6/1/2021	Tonic Clonic seizure

<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>
1372152	6/3/2021	WI	46	F	6/3/2021	6/3/2021	The patient received the first dose of the Moderna Covid-19 vaccine. The patient was administered the vaccine in the immunization booth. The PQCF was reviewed by the administering pharmacist and the patient marked no for all questions including Question 5 concerning seizure disorders. The patient remained in the immunization booth due to the immobility of the patient. The immobility of the patient was not related to the following event. The patient's mother within 5 minutes of the vaccine being administered called that the patient was having a seizure. Code White was called to the pharmacy to support the pharmacy staff in the needs of the patient. The patient was monitored and associates were stationed near the patient as she remained seated during and after the seizure. The patient was monitored closely. The patient's mother stated after the seizure that the patient has seizures regularly and was "due for one" meaning a seizure. The patient was continuously monitored for 20-25 minutes at which point she attempted to walk under the supervision of the pharmacy manager. The patient was able to walk under her own power and it was determined at this point she was able to leave the pharmacy area. Follow up with the patient will occur later in the evening and the next day to ensure the patient is doing well.
1372097	6/3/2021	TX	39	F	6/2/2021	6/2/2021	We received an email today, 6/3/2021, from patients supervisor stating that approximately 30-45 minutes after we left the vaccine clinic, that the patient had a seizure or seizures. She does have a history of epilepsy. She was unconscious and had to be taken by ambulance to the hospital. She has recovered now and is resting at home. She was advised not to take her 2nd dose.
1372059	6/3/2021	MO	61	F	6/2/2021	6/3/2021	Pain from shoulder to elbow in left arm. Seizure next morning

<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>
1371949	6/3/2021	OR	33	M	5/27/2021	5/27/2021	After the individual received his vaccine he went to the medical monitoring area with two additional members of his party. At approximately 1412 the individuals friends alerted me that he needs help. I walked approximately 40 feet to find a 33 year old male patient that was unconscious and seizing. The seizure lasted about 20-30 seconds with the patient waking up confused. I instructed someone from my team to call 911 and request an ambulance. Another team member and myself assisted the patient to a wheelchair and moved him to our treatment area approximately 50 feet away. The patient was somewhat confused, hot & sweaty and fatigued. I took a basic set of vital signs and got: BP 90/70 Pulse 56 Respirations 22 LOC x 4 No CBG The ambulance arrived within 10 minuets and another round of vitals were taken. The patients blood pressure and pulse were still low. A CBG of 120 was achieved. The patient was still hot / sweaty and fatigued. The patient lied down on a cot and soon started feeling better. He stopped sweating and his BP / Pulse started rising to within normal limits. The two paramedics on site conducted a 12 lead ECG and didn't notice any abnormalities. Due to this incident being the first of its kind for the patient and without being able to find a definitive known cause it was recommended that the patient be transported to the local hospital for further evaluation. The patient declined and stated that he would have his friends take him if he starting feeling really bad. It was strongly advised that he be transported via medics to the hospital but in the end the patient refused.
1371929	6/3/2021	AZ	49	M	5/12/2021	5/20/2021	seizure (one time)
1372929	6/3/2021	CA	25	F	6/3/2021	6/3/2021	25 year old female with prior history of syncope was at public vaccine clinic when she syncopated 9 minutes s/p receiving her 1-time IM dose of J&J COVID-19 vaccine in her L deltoid. When she syncopated, she fell forward while sitting in a chair and hit her head on concrete. She suffered a 1cm superficial laceration on her L frontal scalp. There was a brief moment of generalized seizure-like activity that lasted for about 10 seconds. After this, she woke up and was able to sit up. Patient appeared anxious. She was alert and oriented x 3 once she was up with a GCS of 15.

<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>
1371361	6/3/2021	MD	59	F	6/3/2021	6/3/2021	PT STARTED TO FEEL DIZZY, WHEN LAID BACK SHE STARTED TO HAVE SEIZURE LIKE ACTIVITY. LEGS AND ARMS SHAKING, VERY STIFF, GARGLING NOISE FROM MOUTH, SWEATY, PALE, AND WASNT RESPONSIVE. 911 WAS CALLED AND DR. CAME IN ROOM TO ASSIST UNTIL EMS ARRIVED. SEIZURE LIKE ACTIVITY LASTED AROUND A MINUTE AND A HALF. ONCE PT CAME TO SHE WAS STILL UNABLE TO RESPOND TO ME FOR ANOTHER MINUTE AND THEN WHEN SHE COULD RESPOND SHE DIDNT HAVE ANY RECOLLECTION OF WHAT HAD HAPPENED. PTS VITALS WERE MONITORED AND GLUCOSE WAS ALSO CHECKED, ALL WERE NORMAL. EMS ARRIVED AND TRANSPORTED PT TO NEAREST ER.

<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>
1370312	6/3/2021	FL	62	F	4/15/2021	4/15/2021	have not received second dose; terrible feeling/ feeling off; No strength; No strength to walk; lethargic; had vomited; lost control of bowels; tingling all over my body; Stroke; completely lost consciousness; Seizure; barely move her arm; lightheaded; sick to my stomach/ Stomach issues; arm was painful; interrupted her sleep; vaccination was given directly into the infected area; headache; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of CEREBROVASCULAR ACCIDENT (Stroke), LOSS OF CONSCIOUSNESS (completely lost consciousness) and SEIZURE (Seizure) in a 62-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 Spider bite. On 15-Apr-2021 at 7:00 AM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Apr-2021, the patient experienced PAIN IN EXTREMITY (arm was painful), INSOMNIA (interrupted her sleep), DIZZINESS (lightheaded), GASTROINTESTINAL DISORDER (sick to my stomach/ Stomach issues), PRODUCT ADMINISTERED AT INAPPROPRIATE SITE (vaccination was given directly into the infected area) and HEADACHE (headache). On 16-Apr-2021, the patient experienced MONOPARESIS (barely move her arm). On 17-Apr-2021, the patient experienced CEREBROVASCULAR ACCIDENT (Stroke) (seriousness criterion medically significant), LOSS OF CONSCIOUSNESS (completely lost consciousness) (seriousness criterion medically significant), SEIZURE (Seizure) (seriousness criterion medically significant), PARAESTHESIA (tingling all over my body) and ANAL INCONTINENCE (lost control of bowels). On an unknown date, the patient experienced PRODUCT DOSE OMISSION ISSUE (have not received second dose), FEELING ABNORMAL (terrible feeling/ feeling off), ASTHENIA (No strength), GAIT DISTURBANCE (No strength to walk), LETHARGY (lethargic) and VOMITING (had vomited). On 15-Apr-2021, PRODUCT ADMINISTERED AT INAPPROPRIATE SITE (vaccination was given directly into the infected area) had resolved. On 16-Apr-2021, INSOMNIA (interrupted her sleep) had resolved. At the time of the report,

<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>
							<p>CEREBROVASCULAR ACCIDENT (Stroke), LOSS OF CONSCIOUSNESS (completely lost consciousness), SEIZURE (Seizure), DIZZINESS (lightheaded), FEELING ABNORMAL (terrible feeling/ feeling off), GASTROINTESTINAL DISORDER (sick to my stomach/ Stomach issues), ASTHENIA (No strength), PARAESTHESIA (tingling all over my body), GAIT DISTURBANCE (No strength to walk), ANAL INCONTINENCE (lost control of bowels), LETHARGY (lethargic), HEADACHE (headache) and VOMITING (had vomited) outcome was unknown, PRODUCT DOSE OMISSION ISSUE (have not received second dose) had resolved and PAIN IN EXTREMITY (arm was painful) and MONOPARESIS (barely move her arm) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Computerised tomogram: inconclusive (Inconclusive) inconclusive. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. The patient's left arm was already itchy and swollen from a spider bite. Pharmacist injected arm where the spider bite was located, even though she noted the spider bite. During the night her arm was painful and interrupted her sleep. The next day, she could barely move her arm and it was very painful. The patient was transported to hospital emergency room. IVs and CT scan for over two weeks followed were performed. 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. Most recent FOLLOW-UP information incorporated above includes: On 27-May-2021: Patient demographics, new serious events ,new non serious events added. event outcome of painful arm(unknown to not recovered), and arm discomfort(unknown to not recovered) were changed.; 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>

<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>
1370324	6/3/2021			U			<p>Seizure; Vomiting; Muscle aches; Chills; Pain in my arm from shot; 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 SEIZURE (Seizure) 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. 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, the patient experienced SEIZURE (Seizure) (seriousness criterion medically significant), VOMITING (Vomiting), MYALGIA (Muscle aches), CHILLS (Chills) and VACCINATION SITE PAIN (Pain in my arm from shot). At the time of the report, SEIZURE (Seizure), VOMITING (Vomiting), MYALGIA (Muscle aches), CHILLS (Chills) and VACCINATION SITE PAIN (Pain in my arm from shot) outcome was unknown. Not Provided The case pertains to one patient from chatbot. No concomitant medications were reported. The patient had these symptoms after second dose. Treatment information was not provided. 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. Reporter did not allow further contact; 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.</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>
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>

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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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.

<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>
1370586	6/3/2021	MD	32	F	5/13/2021	5/19/2021	<p>Nightly sleep seizures/spastic seizure lasting 5 minutes of uncontrollable myoclonus only of the left leg; Temporary, passing paralysis; spastic seizure lasting 5 minutes of uncontrollable myoclonus only of the left leg; longer aphasia (inability to speak); severe migraines; This is a spontaneous report from a contactable consumer. This 32-year-old female consumer reported that she received 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot Ew0179) on 13May2021 at 02:45 PM into left arm for COVID-19 immunisation. Medical history included Hypermobility Ehlers-danlos syndrome, non-epileptic seizures, migraines, mild traumatic brain injury, intractable pain, severe food allergies. Known allergies: Wheat, gluten, eggs, soy, estrogens. Historical vaccine included 1st dose of BNT162B2 (lot Ew0171) on 22Apr2021 at 02:45 PM into left arm for COVID-19 immunisation. Concomitant drugs included Morphine, hydrocodone bitartrate, paracetamol (NORCO), diazepam (VALIUM), Propranolol, Hydroxyzine. The patient had a non-epileptic seizure disorder that was well controlled. After the second dose she began to have nightly sleep seizures, severe migraines, but am writing because of a spastic seizure lasting 5 minutes of uncontrollable myoclonus only of the left leg, with longer aphasia (inability to speak) and temporary, passing paralysis. The symptoms passed in an hour but an epileptic patient could have died. Event onset time was 19May2021 06:30 PM. No treatment was received. The outcome of the event was resolving.</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>
1370620	6/3/2021	CT	65	F	2/16/2021	2/21/2021	seizure; This is a spontaneous report from a contactable consumer (patient). A 65-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in arm right on 16Feb2021 14:00 at the age of 65-years-old (Batch/Lot Number: EN6201) as 1ST DOSE, SINGLE for covid-19 immunisation. Medical history included Stage 4 cancer from an unknown date, known allergies: Sulfa, Emcin. Concomitant medications included osimertinib mesilate (TAGRISSO); levothyroxine sodium (SYNTHROID) and paracetamol (TYLENOL) 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. The patient was not Pregnant at time of Vaccination. 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 stated 10 days after vaccine (as reported) she had a seizure on 21Feb2021 19:30. She was not saying it was related to vaccine but she had heard other people have had this happen and she should report it. The patient was hospitalized for seizure for 3 days. The event resulted in emergency room/department or urgent care. The patient underwent lab tests and procedures which included Brain EEG (electroencephalogram), Brain MRI (magnetic resonance imaging) with unknown results on an unspecified date. Therapeutic measures were taken as a result of seizure. The outcome of the event was resolved in 2021.

<u>VAERS_ID</u>	<u>RECVDATE</u>	<u>STATE</u>	<u>AGE_YRS</u>	<u>SEX</u>	<u>VAX_DATE</u>	<u>ONSET_DATE</u>	<u>SYMPTOM_TEXT</u>
1370821	6/3/2021	IL	17	F	5/24/2021	5/24/2021	Inappropriate age at vaccine administration; Fever; Chills; bodyache; Seizure; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (Seizure) in a 17-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 24-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) (Intramuscular) 1 dosage form. On 24-May-2021, the patient experienced SEIZURE (Seizure) (seriousness criterion medically significant), PYREXIA (Fever), CHILLS (Chills) and MYALGIA (bodyache). On an unknown date, the patient experienced PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (Inappropriate age at vaccine administration). At the time of the report, SEIZURE (Seizure), PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (Inappropriate age at vaccine administration), PYREXIA (Fever), CHILLS (Chills) and MYALGIA (bodyache) outcome was unknown. Not Provided No concomitant medications were provided by the reporter. 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 Seizure, Pyrexia, Chills, and Myalgia, a causal relationship cannot be excluded. This report also refers to a case of product administered to patient of inappropriate age for mRNA-1273, lot # unknown, with no associated AEs.; 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 Seizure, Pyrexia, Chills, and Myalgia, a causal relationship cannot be excluded. This report also refers to a case of product administered to patient of inappropriate age for mRNA-1273, lot # unknown, with no associated AEs.
1371104	6/3/2021	CA	33	M	6/2/2021	6/2/2021	Systemic: Seizure-Severe
1371893	6/3/2021	WA	18	M	5/6/2021	5/7/2021	Partial seizure in face

<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>
1371236	6/3/2021	VT	35	F	6/1/2021	6/2/2021	I was dizzy, weak and nauseous. It felt as if I was going to vomit and then I went unconscious. My husband saw that I had collapsed back into the bed I was leaning against, with my eyes rolled back and I was making a gurgling sound. He attempted to get my attention several ways by loud yelling of my name and lightly hitting my cheek. I was unconscious for a few minutes and when I regained consciousness I had had broken into a heavy, soaking sweat. He described it as looking as if i had a seizure. I have no history of seizures and have never had one prior to this event and vaccine.
1371822	6/3/2021	AL	18	M	6/3/2021	6/3/2021	Approximately 5 minutes after receiving the vaccine, the patient passed out and his eyes rolled back (possible seizure activity). This activity lasted for approximately 1 minute. Patient also felt dizzy, sweaty, nauseous, and became pale. Patient was given a cold ice pack to lower his body temperature. Patient was also given crackers for nausea, and a bag just incase he had to vomit. Patient's mother was also here to tend to the patient. The mother also gave him clear fluids (sprite) to help with the nausea. After approximately 10 minutes, the patient was able to stand without feeling dizzy. He left the store with his mother to be watched closely (His mother is a nurse.) They also refused emergency medical services.
1371375	6/3/2021	OK	47	F	1/1/2021	2/1/2021	migraine headaches, severe joint pain in hips and seizure activity

<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>
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.
1371490	6/3/2021	AL	47	M	5/17/2021	5/17/2021	Flu symptoms immediately. 1 week +1 day post injection, severe body aches, fever, 1 week + 2 days seizure requiring hospitalization, ICU and vent for 4 days.
1371559	6/3/2021	VA	55	F	6/3/2021	6/3/2021	Pt received Moderna Covid-19 vaccine (second in series) at 1011, BP before vaccination 109/58, P/77. BP 20 minutes after vaccine was 93/57, P/60. At the end of pt's tx, 1035, pt stated she was cramping and then became unresponsive with some seizure like activity, upper body twitching. O2 applied, NS given, pt became responsive, then had another seizure like episode, then again became responsive. BP 115/80, P/88 at this time. NP was on site. Due to the fact that the pt had the Covid vaccine and did not have a seizure history, NP ordered for EMS to be called (1038). Upon their arrival (1042) pt was A&O X 4, BP 150/88, P/65, T/ 97.0. Report given, care was transferred to EMS, belongings sent with pt. Pt requested to be taken to hospital.
1371650	6/3/2021		40	F	1/23/2021	2/9/2021	Had a Seizure 2 wks after vaccine. No family or previous history of seizures. Had to be taken to emergency room by ambulance.

<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>
1371684	6/3/2021	MA	24	M	6/2/2021	6/2/2021	PATIENT WASN'T FEELING WELL AFTER VACCINE (WAS A LITTLE NERVOUS) AND ASKED FOR SOME WATER. PATIENT SAT DOWN IN WAITING AREA WHILE I WENT TO GET HIM A DRINK. WHEN I CAME BACK PATIENT WAS RIGID AND LOCK JAWED AND NOT BREATHING. WHEN WE GOT PATIENT TO FLOOR HE WAS RESPONSIVE TO A STERNUM RUB AND HAD A PULSE. AT THIS TIME HE STARTED TO PRODUCE SNORE LIKE NOISES, CONVULSED FOR LESS THAN A MINUTE THEN CAME BACK TO. EMT'S CAME AND CLEARED PATIENT. PATIENT STATED HE HAS A VASOVAGAL REFLEX HOWEVER HAS NOT HAD AN INCIDENT IN MANY YEARS. IT IS UNKNOWN IF THIS IS WHAT PATIENT EXPERIENCED OR A REACTION TO THE VACCINE.
1371888	6/3/2021	PA	24	F	1/31/2021	1/31/2021	So at around 9pm the evening of my shot, I started feeling feverish so I went to the other room to get my temperature and while I was waiting for my temperature to be recorded, I started to feel lightheaded and I called out for help. I woke up on the floor, I woke up to my roommate and boyfriend standing over me. They were on the phone with 9-1-1. I was out for about a minute and unresponsive. According to them, my arm was flailing and seizure-ish. I went to the ER, I was taken by EMS services. They gave me fluids and ran bloodwork and monitored me. They sent me home, I did have another episode of what I think was an episode of memory loss/passed out. I just remembered waking up in a room alone. I was at the ER for about 4-5 hours. They gave me IV fluids and I don't remember what else, some sort of supplement. It was magnesium oxide they gave me. When I left the ER I was really exhausted, and feverish and gross and I was pretty sick for the remaining two days. I didn't sleep well that night, I had a fever the following day and into the second day upon returning home as well.
1371230	6/3/2021	VA	20	F	6/1/2021	6/1/2021	PATIENT HAD SYNCOPE REACTION TO RECEIVING SHOT AND APPEARED TO HAVE A SEIZURE THAT LASTED A FEW SECONDS. PATIENT CAME TO AND WAS CONSCIOUS AND COHERENT.

<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>
1371782	6/3/2021	VA	28	M	6/3/2021	6/3/2021	28 year old male presented for initial dose of Pfizer-BioNtech at 1100 AM on 6/3/21. Pre-assessment form was filled out and reviewed with nursing student administering the vaccine. The client stated no known allergies to medications, food, venom, or environmental elements. He also stated no allergic reactions to previous vaccines. The client also stated that he had no known health issues. After administration the patient stated he was dizzy and then immediately became unresponsive, diaphoretic, eyes rolled back, and head hyperextended. Family was present and we asked if he had any seizure history and his family declined. At this time the patient and family informed us that after vaccines in the past he does faint but didn't inform staff before this vaccine was administered. The patient remained unresponsive for 45 seconds. Then his feet were elevated and he asked to lay down. At 11:11 AM his HR was 60 and O2 was 97% on pulse oximetry. He felt hot and was still diaphoretic and felt very fatigued. Once he started feeling better we sat him back up and his HR was 89 and O2 was 99%. We gave him 2 bottles of water and crackers. He remained in our care for 45 minutes. He then waited an additional 30 minutes in the post vaccine area. His family stated they were going to drive him home and get some food. The patient is expected to return June 24, 2021 for his second dose of the Pfizer vaccine. We provided additional discharge instructions
1368714	6/2/2021		71	F	2/27/2021	3/3/2021	R56.9 - Unspecified convulsions

<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>
1366905	6/2/2021			U			Seizure episode; 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 SEIZURE (Seizure episode) 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) (unknown route) 1 dosage form. On an unknown date, the patient experienced SEIZURE (Seizure episode) (seriousness criterion medically significant). At the time of the report, SEIZURE (Seizure episode) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. No treatment information was provided. No relevant concomitant medications were reported. 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.
1368395	6/2/2021	TN	18	F	6/2/2021	6/2/2021	Patient received the first dose Moderna she was a little scared but she was ok. She got her shot and was told to stay around for 15 minutes, she starting walking with her mom, when she told her mom she felt dizzy, then she passed out unto her mom's arms, her mom put her on the floor, did not heart her head. Mom helped her to get up and came back to the pharmacy, sat her down again. We called 911 for help, patient asked for water, while her mom went to get her some water, pharmacist was watching her when she had a short convulsion for about 2 to 3 seconds, she stretched her body to the back. When 911 came, she had already recovered her color, her vitals where ok, she was breathing normal. Patient refused to get on the ambulance, signed her release and left. Emergency personel advised her to follow up with her doctor.

<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>
1368403	6/2/2021	NY	23	U	6/1/2021	6/1/2021	patient was shaking with seizure-like movements, never lost consciousness, felt light-headed and dizzy, gave a cold compress then patient became ill, 911 was called, patient was evaluated and refused transport, this all happened over a 30 minute period
1368422	6/2/2021	NY	17	F	4/3/2021	4/29/2021	passing out episodes, seizures, hospitalized
1368497	6/2/2021	OK	65	F	3/15/2021	3/19/2021	She started having delusions and hallucinations, body tremors like epileptic seizure, she was falling down and using the bathroom on herself, her walk was a shuffled gate, she didn't remember almost 3 months in hospital, coma for 5 days and had a mini stroke. Her psych doctor thought maybe the vaccine could have triggered this type of reaction. She gained consciousness and was sent to a rehab nursing home where she's learning to walk to feed herself and getting stronger now that she's home. There's a long road to recovery.
1368591	6/2/2021	MO	16	F	6/1/2021	6/1/2021	Pt had loss of consciousness x 2 immediately after injection. , shaking of extremities described. Lasting appx 1 min each. return to baseline after . Differential was seizure vs. more likely vagal syncope
1368691	6/2/2021	SC	27	F	1/16/2021	1/22/2021	I woke up on Jan. 22nd and felt off. I developed a bad headache throughout the day and was sensitive to touch. I didn't sleep well that night and threw up in the middle of the night. I was very tired. I slept for most of the day Jan. 23rd and my parents stopped by that evening and noticed I wasn't feeling well. I had a fever and an altered mental status. My dad took me to the ER and I was admitted to the hospital that night. I had an EEG that showed I was having subclinical seizures and a spinal tap concluded that I had aseptic meningitis (which the doctors think is what caused the seizure). I regained my mental status Jan. 25th after being put on seizure medicine. The doctors thought the meningitis was most likely viral and I had an exhaustive infectious disease workup done which came back negative. The only thing that stood out was an abnormal ANA test. I was released from the hospital the evening of Jan 27th.
1368696	6/2/2021		24	F	4/2/2021	5/14/2021	Unspecified convulsions

<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>
1368246	6/2/2021	MO	62	M	5/26/2021	5/26/2021	He got his vaccine, within 15 minutes he was staring, and was offered something to drink and some graham crackers and his wife said and the nurse came over to see what was going on, and said that he had an absent seizure, he was not responding to anything. His oxygen was 93, his BP dropped. The nurse was watching his eyes to see if there was any reaction, but there was not. They kept talking to him until he responded and he had no idea of what happened. He has not had any more seizures. He has never had any seizures in the past. He came out of it and they did not take him to the ER. He is fine now. He currently has cellulitis around his eye.
1368708	6/2/2021		66	F	3/11/2021	3/24/2021	R56.9 - Unspecified convulsions
1368230	6/2/2021		97	F	2/2/2021	4/22/2021	seizures, brain tumors, other tumors not previously evident prior to Covid 19 vaccine.
1368719	6/2/2021		73	F	3/2/2021	3/25/2021	R56.9 - Unspecified convulsions N17.9 - Acute kidney failure, unspecified R56.9 - Seizure (CMS/HCC)
1368728	6/2/2021		55	M	4/8/2021	4/30/2021	R56.9 - Unspecified convulsions.
1368732	6/2/2021	WA	40	F	5/29/2021	5/31/2021	On 5/31/21, patient's husband described that the patient fainted and experienced seizure-like activity. She reported nausea and dizziness before and after the episode. It took approximately 2 minutes for her to regain consciousness and she didn't have any recollection of what had happened. On 6/1/21, patient's daughter contacted nurse triage after she experienced forgetfulness and word-finding trouble, performed a FAST exam, and patient was admitted. Work-up pending.
1368806	6/2/2021	CA	15	M	5/14/2021	5/29/2021	Unprovoked first-time seizure. Teen was sitting outside a restaurant waiting while watching phone, listening to music 15 days after first Pfizer COVID vaccine (no issues at time of vaccination). Parents witnessed his neck and eyes roll up and left before having a two short generalized tonic-clonic seizures. Taken to nearest ED by paramedics.

<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>
1366901	6/2/2021	NV	53	M	4/21/2021	5/22/2021	heart attack; grand mal seizure episodes "for the first time in over 2 years", he didn't remember the episode; he was freezing and was cold; throwing up profusely; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of MYOCARDIAL INFARCTION (heart attack) and GENERALISED TONIC-CLONIC SEIZURE (grand mal seizure episodes "for the first time in over 2 years", he didn't remember the episode) in a 53-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 036C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history provided by the reporter. Concomitant products included LACOSAMIDE (VIMPAT) for Seizure. On 21-Apr-2021 at 3:30 PM, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .5 milliliter. On 22-May-2021, the patient experienced MYOCARDIAL INFARCTION (heart attack) (seriousness criteria hospitalization, disability, medically significant, life threatening and intervention required), GENERALISED TONIC-CLONIC SEIZURE (grand mal seizure episodes "for the first time in over 2 years", he didn't remember the episode) (seriousness criteria hospitalization, disability, medically significant, life threatening and intervention required), NASOPHARYNGITIS (he was freezing and was cold) and VOMITING (throwing up profusely). The patient was hospitalized on 22-May-2021 due to GENERALISED TONIC-CLONIC SEIZURE and MYOCARDIAL INFARCTION. At the time of the report, MYOCARDIAL INFARCTION (heart attack), GENERALISED TONIC-CLONIC SEIZURE (grand mal seizure episodes "for the last time in over 2 years", he didn't remember the episode), NASOPHARYNGITIS (he was freezing and was cold) and VOMITING (throwing up profusely) outcome was unknown. Patient was admitted to hospital on 22-may-2021.patient lips were purple and had no pulse for 12 minutes, but was resuscitated.The hospital took out patient's breathing tube at on 23May2021, and hospital staff stated he will remain there for a while. 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. Vomiting is consistent with the known safety profile of

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

the product.; Sender's Comments: 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. Vomiting is consistent with the known safety profile of the product.

<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>
1366868	6/2/2021	MD	19	M	5/7/2021	5/7/2021	<p>Dizziness/ dizzy; Weakness/ very weak; Seizures; Fainted; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SEIZURE (Seizures), SYNCOPE (Fainted), DIZZINESS (Dizziness/ dizzy) and ASTHENIA (Weakness/ very weak) in a 19-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 07-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 07-May-2021, the patient experienced SEIZURE (Seizures) (seriousness criteria hospitalization and medically significant) and SYNCOPE (Fainted) (seriousness criteria hospitalization and medically significant). On 16-May-2021, the patient experienced DIZZINESS (Dizziness/ dizzy) (seriousness criterion hospitalization) and ASTHENIA (Weakness/ very weak) (seriousness criterion hospitalization). The patient was hospitalized on 07-May-2021 due to SEIZURE and SYNCOPE, then on 16-May-2021 due to ASTHENIA and DIZZINESS. The patient was treated with PARACETAMOL (TYLENOL) at an unspecified dose and frequency. At the time of the report, SEIZURE (Seizures) and SYNCOPE (Fainted) outcome was unknown and DIZZINESS (Dizziness/ dizzy) and ASTHENIA (Weakness/ very weak) had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. Description: During the day of the injection, at 5 to 10 minutes, the patient fainted and had seizures that required hospitalization. Also, on 16 May 2021 the patient required hospitalization again because of the dizziness and weakness. The patient was still dizzy and was very weak. The patient had a consult with a neurologist and who told that the symptoms were probably because of the vaccine. Other treatment information included unspecified pill for dizziness at the hospital. 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</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>
							cannot be excluded.
1369958	6/2/2021	HI	47	F	5/7/2021	5/7/2021	PT CAME FOR 1ST COVID VACCINE DOSE ON 5/7/21. DEVELOPED PAIN / NERVE TINGLING AND HAD SEIZURE LIKE ACTIVITY THAT NIGHT. LEFT SIDE WAS NUMB AND COULD NOT HEAR FROM LEFT EAR. RINGING IN EAR, EYE TWITCHING. ARTHRITIC-LIKE PAIN IN LEFT HANDS (NEVER ON RIGHT SIDE). HAS NOT BEEN TO ER BUT STILL AS EFFECTS ON 5/27/21. NEVER ANY PROBLEMS W OTHER VACCINES
1368702	6/2/2021		67	M	3/2/2021	5/5/2021	New onset seizure Unspecified convulsions Acute kidney failure, unspecified
1367888	6/2/2021	CA	22	F	6/1/2021	6/1/2021	Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient received first dose of vaccine with her mother. Prior to administration, patient mentioned she was anxious receiving shots having a history of fainting. Immediately after administration, patient stated that she was relieved. About 2 minutes later, patient's mother called for the pharmacist for help claiming patient was having convulsions and was unconscious. Paramedics were called. Patient regained consciousness after 20 secs with nausea & no recollection of loss of consciousness.

<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>
1366910	6/2/2021	WA		F	5/1/2021	5/22/2021	Passed out; Seizure; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) and SEIZURE (Seizure) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 004C21A) for COVID-19 vaccination. Concomitant products included COLECALCIFEROL (VITAMIN D [COLECALCIFEROL]) for an unknown indication. On 01-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-May-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant) and SEIZURE (Seizure) (seriousness criterion medically significant). On 22-May-2021, LOSS OF CONSCIOUSNESS (Passed out) and SEIZURE (Seizure) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No treatment information was provided. 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>
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.

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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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

<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>
1367153	6/2/2021	PA	74	M	3/31/2021	4/20/2021	<p>Unable to use left arm or hand; Seizure; Lost vision in left eye; This is a spontaneous report from a contactable consumer (patient wife). A 74-years-old male patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in Arm Right on 31Mar2021 10:00 (Batch/Lot Number: ER8730) (at 74 year old) as 2ND DOSE, SINGLE DOSE for covid-19 immunisation. Medical history included slight stroke from 2012, seizure disorder from 1972 and ongoing (She says her husband did have a seizure disorder since his car accident in 1972, but he hadn't had a seizure in years), road traffic accident from 1972 (Caller says her husband had a car accident in 1972 and had some injuries from that), injury from 1972 (Caller says her husband had a car accident in 1972 and had some injuries from that). The patient's concomitant medications were not reported. Historical Vaccine included first dose (LOT: EN6199) of BNT162B2 (Pfizer COVID-19 vaccine) for COVID-19 immunization on 10Mar2021 10:00AM in his right arm at 74-year-old experienced tiredness and arm soreness. The patient experienced seizure on 20Apr2021 with outcome of recovered in 2021, lost vision in left eye on 20Apr2021 with outcome of recovered on 21Apr2021, unable to use left arm or hand on 20Apr2021 with outcome of recovered on 21Apr2021. The events caused Emergency Room Visit, and were serious due to hospitalization since 20Apr2021 to May2021 for 19 days. The patient underwent lab tests and procedures which included magnetic resonance imaging and scan brain: no evidence of a stroke said it was a seizure on 20Apr2021. The consumer reported that her husband ended up going to the ER and spending 2.5 weeks in hospital after the second dose. She says it started out like a stroke, he lost vision in his left eye temporarily then couldn't use his left arm, couldn't raise it or use his hand or wiggle his fingers. She says that ended up being temporary too. She says he then took a seizure before the ambulance got there, so when he got to the hospital they assumed it was stroke and a seizure and he ended up in intensive care unit. She says as days went on and they did MRIs and brain scans, stuff like that, they found no evidence of a stroke said it was a seizure that caused it, and that next day he got his vision back after he was there overnight in the intensive care unit, and could use his arm, raise his arm, and hold things with his left hand. She says it was</p>

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1367193	6/2/2021		12	M	5/15/2021	5/1/2021	<p>20Apr, 20 days later, that this occurred and he was admitted to the hospital. The patient was home now after spending 2.5 weeks in the hospital. She says he is home and doing ok, he is back to how he was. She says that they did give him a seizure medicine.</p> <p>seizure; This is a spontaneous report from a contactable physician. A 12-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 15May2021 (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 seizure in May2021 with outcome of recovered. 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.</p>

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1367530	6/2/2021			U			SEIZURE LIKE ACTIVITY; SYNCOPE; CHEST PAIN; HYPOTENSION; DIZZINESS/LIGHTHEADEDNESS; VOMITING; PALLOR; DIAPHORESIS; TACHYCARDIA; ANXIETY-RELATED EVENTS; NAUSEA; This spontaneous report was received from multiple patients. No past medical history or concurrent conditions were reported. The patients 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. On an unspecified date, the patients experienced seizure like activity, syncope, chest pain, hypotension, dizziness/lightheadedness, vomiting, pallor, diaphoresis, tachycardia, anxiety-related events, and nausea. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the anxiety-related events, syncope, chest pain, hypotension, dizziness/lightheadedness, nausea, vomiting, pallor, diaphoresis and tachycardia was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210553168-covid-19 vaccine ad26.cov2.s-syncope and seizure like activity. 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).
1367749	6/2/2021	AZ	13	F	5/21/2021	6/1/2021	Full body seizure, loss of consciousness. Stopped breathing. Was transported to the hospital by ambulance. Outcome is pending follow up with neurologist.
1367785	6/2/2021	TX	13	F	6/1/2021	6/1/2021	Passed out. Seizure without shaking muscles contracted and fists clenched. Dizziness. Tingle in arms.

<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>
1367827	6/2/2021	PA	54	M	6/1/2021	6/1/2021	At 12-00pm the pharmacist gave patient a J & J Covid Vaccine. He asked him to sit down for 15 minutes. At approximately 12-10PM Patient yelled for assistance. At the time the pharmacist ran over to the chair. Patient said that he was going to pass out. His eyes rolled back and it seemed like a seizure, at that point he began to pass out. The pharmacist assisted him to the floor. He was unresponsive on the floor for 10 seconds. After 10 seconds he regained consciousness. He said he felt fine. We called the ambulance. They came 15 minutes later. The pharmacist did his vitals pulse: 60 respirations:16 blood pressure 115/70. At that time the ambulance came and assisted him to the hospital.

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1368271	6/2/2021		30	F	3/30/2021	4/2/2021	On April 15th, the otherwise healthy 30 year old daughter of my cousin passed away in a hospital from a massive stroke and seizures related to encephalitis of unknown cause. She recovered easily from Covid19 back in November of 2020, along with several of her close friends and family members with no lingering effects. On March 30th, she was given a single dose of the Moderna vaccine along with her teaching colleagues at a local high school. She initially complained of mild nausea and vomiting but quickly developed a severe headache prompting her to visit the local ER where she received treatment for a migraine. She returned to the ER at least one more time after no relief from the headache. By April 3rd, Saturday, she no longer recognized her sister nor knew what a mask was for. Her family rushed her again to the same ER and she was subsequently transferred the following day to a Hospital. Due to dangerously high intracranial pressure, she suffered a stroke with paralysis of her left side and a seizure. Multiple lesions were noted on her brain via MRI. A shunt was inserted to relieve the pressure, she was intubated and placed into a deep coma from which she would never awaken. Despite these medical interventions and pharmacological interventions, the pressure did not subside. A craniotomy was performed the following Saturday as a last ditch effort to relieve the unrelenting pressure in her brain. The craniotomy was able to reduce the pressure but it was too late. There was no longer any brain activity and my cousin's daughter was removed from life support after they were able to say their goodbyes. The medical examiner will be examining her brain to attempt to find a cause but that report may take 6 months.
1367857	6/2/2021	GA	17	M	6/1/2021	6/1/2021	Systemic: Fainting / Unresponsive-Severe, Systemic: patient had a seizure about 5 mins following administration-Severe, Systemic: Seizure-Severe, Additional Details: ems was called and patient was evaluated and pt was cleared with normal vitals and alert from ems parent refused to go to er i tried calling to follow up with patient and now answer on best contact number
1367896	6/2/2021		76	F	4/2/2021	5/17/2021	I63.9 - Cerebral infarction, unspecified N17.9 - Acute kidney failure, unspecified E87.1 - Hypo-osmolality and hyponatremia R56.9 - Unspecified convulsions

<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>
1367959	6/2/2021	TX	33	F	6/1/2021	6/1/2021	APPROXIMATELY 10 MINUTES OR SO AFTER RECEIVING SECOND DOSE OF MODERNA, PT EXPERIENCED A SEIZURE. PT'S MOTHER WAS NEXT TO THE PATIENT. THE PATIENT REMAINED SEATED IN HER CHAIR THROUGHOUT THE DURATION OF THE SEIZURE. MOTHER STATED THAT THE PATIENT HAS A HISTORY OF SEIZURES AND IS ON MEDICATION FOR THEM. SHE HAD ALREADY HAD MORNING DOSE AND STILL NEEDED EVENING DOSE. MOTHER DECLINED EMS SERVICES AND TOOK THE PATIENT HOME AFTER A 30 MINUTE OBSERVATION PERIOD AT THE PHARMACY. THE PATIENT WAS CONSCIOUS AND MOVING A FEW MINUTES AFTER THE SEIZURE OCCURRED.
1367966	6/2/2021	IN	44	F	5/31/2021	5/31/2021	Severe chills, looked like I was having seizures, extreme body aches, fever up to 101.7. Symptoms started within 10 hours of shot. Lasted 24 hours. Extremely lethargic, weak.
1367982	6/2/2021	ME	51	F	1/19/2021	1/22/2021	I had a metal taste in my mouth. I did not feel well. I was nauseous. When I came home, I was running a fever. I had a sore arm and my legs hurt. I did not feel good the next few days. Then I had a seizure on that Thursday or Friday. My husband called the ambulance and I went to the emergency room. I've had on and off seizures ever since.
1367995	6/2/2021	CA	20	F	6/1/2021	6/1/2021	Systemic: Fainting / Unresponsive-Mild, Systemic: Shakiness-Mild, Additional Details: Patient appeared to have short (<1min) seizure approximately 5 minutes after having COVID vaccine administered. She woke up, eventually alert and oriented. EMS was called and responded to call. She refused ER visit stating she was feeling fine, just a little shook up.
1368080	6/2/2021	WA	16	M	5/22/2021	5/24/2021	Two days later my grandson fainted, had a seizure and was taken to the ER. At the ER a CT scan of the head was performed. Also while getting an IV, my grandson also had a seizure. I do not have his CT scan results at this time. My grandson is also prepping for a surgery coming in June.

<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>
1368126	6/2/2021	NC	24	F	6/2/2021	6/2/2021	Pt had received her first vaccine and was in the observation area. She was seen to have slumped in her chair, preceding a syncopal episode. The patient remained in her chair during the episode. Pt informed us after the syncopal episode that she had felt as if she fell asleep. She has no medical history of seizures or syncope in the past. She did have limb movement during the period of syncope. The episode seemed to last no more than 15 seconds. The patient quickly woke and began speaking to us. She was clammy and sweaty, vitals were completely normal as taken by the RNs. She was observed in the private area for > 15 minutes, given drink and crackers, tolerated well. She ambulated well and had her fiancé pick her up. She will follow up with her PCP this week. vitals: BP: 120/80, P 72, O2 98%
1368148	6/2/2021		59	M	3/30/2021	5/16/2021	I63.9 - CVA (cerebral vascular accident) I63.9 - Acute ischemic stroke R29.810 - Facial weakness R56.9 - Unspecified convulsions
1368170	6/2/2021	WA	57	F	5/11/2021	5/12/2021	Convulsions, twitching at 1:00am . Strong adrenal in rush. Got out of bed and worked, moved around rapidly. I've had mild twitching, muscle contractions, numb nerves in arms and hands ever since. It is mild though. Seems to come and go in waves, along with intense fatigue. June 1, 2021 first day I did not have intense fatigue. Just found out I was supposed to receive a CDC text or reaction monitoring form; I did not.
1367836	6/2/2021	VA	19	F	6/2/2021	6/2/2021	Seizure activity noted within 30 minutes of vaccination. Pt known to have functional neurologic disorder and pseudoseizures daily (sometimes back-to-back). Pt alert and orientedx4. Pt dizzy and states she did not eat lunch today. Provided with water and granola bar. Second seizure noted 20 minutes later. Pt stayed for observation for additinal 40 minutes following second seizure. Client refused transportation to hospital and clients brother came to pick her up.
1365910	6/1/2021		16	M	5/31/2021	5/31/2021	Patient fainted and had convulsions for 5-10 seconds. He came to and was just fine.

<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>
1365237	6/1/2021	LA	40	M	6/1/2021	6/1/2021	Patient received his Janssen Covid-19 immunization. The patient arrived at 11:00am on 6/1/21 and completed his pre-screening questions and temperature check. The patient then completed his "Patient Questionnaire and Consent Form." The patient was administered his Janssen Covid-19 vaccine around 11:05am. About 2 minutes after administration, the patient appeared pale and sliding out of his chair. The pharmacy technician responded and held the patient under his arms. The patient convulsed and then became unconscious. We called 911, checked the patient for breathing and responsiveness. The patient didn't stop breathing and became conscious about 1 minute after losing consciousness. We placed the patient on the floor and placed cold compresses under his neck and on his wrists. EMTs arrived and evaluated the patient and made sure the patient was stable. EMTs offered to take the patient to the hospital but the patient declined.
1365519	6/1/2021		38	M	5/1/2021	5/26/2021	5 minutes after receiving the J&J vaccine, I went lights out. As I was sitting in the monitoring area, I was completely fine and then a wave came crushing down on me and I was out for about 5 minutes. The nurses said it looked like I was having a seizure. The EMTs called it a syncope event. I am a member of the military and have been pumped full of vaccines. I get my annual flu shot every year. I have survived 6 rounds of Anthrax vaccines and every other vaccine the military has pumped into me. This is the First Time I have ever REACTED this way. It was CRAZY!

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1364300	6/1/2021		11	M	5/17/2021	5/17/2021	11-year-old male patient received BNT162B2; 11-year-old male patient received BNT162B2; My son had a seizure 4 hours after receiving his first dose of the Pfizer vaccine.; This is a spontaneous report from a non-contactable consumer (patient's father). An 11-year-old male patient (reporter's son) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number unknown), on 17May2021 03:00 PM (at the age of 11-year-old) as 1st dose, single for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered was reported as other. The patient's medical history and concomitant medications were not reported. The patient was not diagnosed with COVID-19 prior to vaccination. Patient's father stated that his son had a seizure 4 hours after receiving his first dose of the Pfizer vaccine (onset date also reported as 17May2021 20:30). The event resulted in emergency room/department or urgent care visit. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was resolved for "seizure" and unknown for the other events. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

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1364318	6/1/2021	UT		U			3 days after the second shot, 2 seizures within 1 hour, hospital for help for 3 days; This is a spontaneous report from a contactable consumer(patient). A patient of unspecified age and gender received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number and Expiration date was unknown), via an unspecified route of administration, on an unknown date, as SINGLE DOSE for COVID-19 immunisation. Patient medical history and concomitant medications were not provided. The patient previously received first dose of BNT162B2 (PFIZ-ER-BIONTECH COVID-19 VACCINE, Batch/Lot number and Expiration date was unknown), via an unspecified route of administration, on an unknown date as SINGLE DOSE for COVID-19 immunisation. After 1 week of first dose of vaccination patient had experienced two strokes on both sides of the brain. On an unknown date, after 3days of second dose of vaccination, patient had two seizures within 1hour and was hospitalized for help for 3 days. The patient truly believed it was not a good thing, and patient suffered a lot. The outcome of the event was unknown.

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1364320	6/1/2021			M	5/26/2021	5/26/2021	absent seizure; This is a spontaneous report from a non-contactable consumer reported for her husband. A male patient of an unspecified age received bnt162b2 (BNT162B2, PFIZER-BONTECH, COVID-19 Vaccine, Solution for injection, Lot number and expiration date: Not reported), via an unspecified route of administration on 26May2021, as (Batch/Lot number was not reported) as 2ND DOSE, SINGLE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced absent seizure on 26May2021. It was reported that, the caller states her husband received his second dose of the Pfizer COVID-19 vaccine today, 26May2021. and during the 15 mins wait time from after receiving the vaccine he had what she states the nurses there are calling and absent seizure. The caller states his eyes were awake but he was not responding, as she was getting ready to bring him to the ER, he became responsive so they did not go to the ER. She is wondering if there has been reports of this and what she should do next. A review of the Pfizer COVID-19 vaccine did not find information regarding seizures. The seriousness criteria of the event was reported as serious (medically significant) by the reporter. The outcome of the event was recovering. No follow-up attempts are possible. No further information is expected.

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1364808	6/1/2021	PA	32	F	5/5/2021	5/20/2021	She got her vaccine, she went home and seemed to have slept a lot with both vaccines. She also had lack of appetite and did not want to come down to the table to eat, just wanted to sleep. If her mother could get her down to eat, she would take 2 bites of food and go back to bed, which mother feels the vaccine may have lowered her threshold for seizures. About 15 days after the vaccine she came to her door and she was banging in the hallway and was hollering help me. Her mother felt that she was having a seizure which she has not had any in about 2 1/2 years, and she was into one that her mother stopped with the cannabis oil. They have been controlled with the cannabis oil for the last 2 1/2 years but she was having multiple daily seizures prior to the cannabis oil. Her mother went downstairs and got her cannabis capsules and the MCT oil which she gave sublingually and she started to subside from the screaming and then moaned for 30 minutes. She then started to have involuntary neck movements and her head would swing back as she is walking, and she has been tapping her head on items and on her mother, which her mother thinks she is trying to tell her that something is wrong. She was not doing this prior to the 2nd vaccine. Her days and nights also seemed to be out of sorts since the vaccine as well. She is very limited in communication and does not speak much, but has so more since she started the cannabis oils.
1364876	6/1/2021	OK	31	F	4/22/2021	5/27/2021	DVT right leg, er visit, medication, still get my treatment Seizure

<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>
1365069	6/1/2021	MI	41	F	5/3/2021	5/29/2021	<p>Patient presents with ? SUICIDAL pt intoxicated and tried to hang herself on the shower curtain rod. boyfriend called 911. pt states this was a suicide attempt HPI: This is a 41y.o. female with significant past medical history of polysubstance abuse that presented to the hospital with chief complaint of suicide attempt. The patient apparently tried to hang herself on the shower curtain rod after reportedly drinking 1 liter of Captain Morgan's rum. She was found on the ground by her boyfriend whom reports she was 'blue in the face.' On examination she is resting in bed in no acute distress. She denies any fever, chills, chest pain/pressure, palpitations, shortness of breath, abdominal pain, nausea, vomiting, diarrhea, constipation, or urinary complaints. She denies any illicit drug use or ingestion of toxins. In the ED, patient mildly hypertensive, afebrile, stable SPO2 99% on room air. CBC, BMP, coags, UA unremarkable. Ethanol level 410. UDS negative. COVID positive. CT head and CTA neck unremarkable for injury. Admitted for further evaluation and management with psychiatry consultation. Suicide precautions implemented in ED. Pt seen and examined only by the attending physician. NP only responsible for chart review in an effort to limit exposure given the current pandemic and patient's COVID positive status. ROS: Constitutional: Denies fatigue, fever or chills. Eyes: Denies change in visual acuity, diplopia or pain. HENT: Denies nasal congestion, sore throat or tinnitus. Respiratory: Denies cough, difficulty in breathing or shortness of breath. Cardiovascular: Denies chest pain, palpitations or edema. GI: Denies abdominal pain, nausea, vomiting, constipation or diarrhea. GU: Denies dysuria, urinary frequency or hematuria. Musculoskeletal: Denies back pain, atrophy, spasticity or joint pain. Hematologic: Denies anemia, bleeding, or bruising. Integument: Denies rash or lesions. Neurologic: Denies headache, focal weakness, seizure or stroke. Endocrine: Denies temperature intolerance, polyuria, or polydipsia. Psychiatric: Denies irritability, +depression +anxiety. +suicide attempt</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>
1365072	6/1/2021	TN	36	F	6/1/2021	6/1/2021	Patient has a history of seizures. Patient received 2nd dose of Moderna Covid 19 vaccination. They did ok with the first vaccine. Approximately 5 minutes after receiving the vaccine the patient had a blank stare, which the caregiver noted and informed staff that patient was having a seizure. Within 30 seconds the patient was jerking, had clenched fists, and was not coherent. The caregiver was able to keep the patient in the chair and keep her from hitting her head. After jerking motions stopped the caregiver was able to contact the person responsible for medical decisions for patient and mother decided that she need to be taken to the hospital. EMS arrived and took patient to the hospital within 15 minutes after seizure. Patient was alert and oriented when EMS arrived.

<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>
1365105	6/1/2021	WI	50	F	3/27/2021	3/30/2021	<p>Patient is a 50 year old female with history significant for autism, developmental disability, hypertension, seizures, frequent falls, Tourette syndrome, s/p CVA. She presented 3/31/2021, through the Emergency Department from home with following an unwitnessed fall. She was found by her mother this evening on the floor at the bottom of a flight of stairs. She was last seen by her mother sometime in the morning. Patient not capable of providing history as verbalizations are limited at baseline to occasional single word expressions of needs. Patient was noted in the ED to have multiple bruises to her head, arms and legs in various stages of healing. Patient lives with her mother who is also her legal guardian. Mother was poor historian in the ED and was unable to help determine how long patient was on the floor. Patient's mother verbalized to ED provider that she is not able to supervise the patient at all times due to her own medical needs. ED provider noted that upon leaving the ED the patient's mother stated to staff that they should put the patient out of her misery. County Crisis Center was contacted by ED staff and a referral was made to Adult Protective Services. Patient does not answer review of systems questions when asked. Admit date: 3/30/2021 Discharge date: 4/5/2021 Primary diagnoses: Principal Problem: Severe sepsis, unknown origin, without end organ failure o Resolving, no fever o Vancomycin stopped. o Wbc improving, fever resolved o Blood cultures still negative o After 4days of IV antibiotics she was transitioned to oral augmentin when Dcing flagyl. o PCP to follow fever curve, white count... CT chest abdomen and pelvis negative at admission Blood cultures have remained negative</p> <p>Active Problems: Benign essential HTN Developmental disability Residual autistic disorder Fall o Most recent fall 03/30/2021, unwitnessed, possibly down unknown number of stairs o Followed by Neurology, for frequent falls, EEG on 01/18/2021 abnormal with focal epileptic seizures suspected, she has been started on Lamictal taper o Continue Lamictal as prior to admission Rhabdomyolysis o Due to Unwitnessed fall and immobile on floor for unknown number of hours on 03/30/2021 o CPK trending down. Kidney function has remained normal with ongoing IV infusion Hyponatremia Elevated troponin I level Cardiology, Dr. consulted from the ED, elevated</p>

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							troponin suspected to be secondary to rhabdomyolysis o Troponin 1.58 upon arrival, peaked at 1.88 and declining is subsequently o EKG demonstrates sinus tachycardia with 1st degree AV block and RBBB, rate 101, QTc 487 Echo was normal at 60% ejection fraction Closed anterior dislocation of right glenohumeral joint was reduced in the emergency department which will explain the large bruise over her right shoulder right shoulder active and passive range of motion intact Hypomagnesemia
1366337	6/1/2021	CA	21	M	6/1/2021	6/1/2021	Patient had a seizure about 40 seconds after receiving the COVID19 (Pfizer) vaccine. He urinated, and became cyanotic, not breathing and faint pulse. CPR as initiated and 911 called. Patient regained consciousness after 30 compressions and was taken to the hospital after ambulance arrived.
1365215	6/1/2021	VA	18	M	6/1/2021	6/1/2021	about 5 minutes after patient received shot , he came to pharmacy counter to say he felt light headed, as I (the pharmacist) headed out to have him sit down, dropped to a sitting position on the floor, I was able to get him up to a chair and was fanning him and we got him some water. he the passed out and his head lobbed backwards, I got behind him so he did not hit his head and he went into a mini seizure which only lasted about 5 seconds and then he came out of, he was in sweats and we called 911. He declined to go to hospital and his mom came and picked him up

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1363782	6/1/2021			U		4/1/2021	Intensive convulsion; unable to turn torso; severe back pain; musculoskeletal injury; muscle tear of some sort; This spontaneous report received from a patient. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included patient never had any conditions or issues, nor any record of chronic pain or back pain. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, batch number :Unknown and expiry: Unknown) 1 total , administered on APR-2021 for prophylactic vaccination. The Batch no was not reported and has been requested, No concomitant medications were reported. On APR-2021, the Patient experienced intensive convulsion, unable to turn torso, severe back pain and discharge with musculoskeletal injury. On APR-2021, the Patient experienced muscle tear of some sort. Laboratory data included: Scan (NR: not provided) No internal Issues. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from intensive convulsion, severe back pain, unable to turn torso, musculoskeletal injury, and muscle tear of some sort. This report was serious (Other Medically Important Condition).; Sender's Comments: V0-20210549341- covid-19 vaccine ad26.cov2.s-Intensive Convulsion-This 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.
1365495	6/1/2021	MO	16	F	6/1/2021	6/1/2021	Patient appear to have seizure just after receiving the vaccination. After apparent seizure or loss of consciousness patient appear weak and had a hard time answering questions. 911 was called and patient transported for medical care.

<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>
1365477	6/1/2021	TX	29	F	6/1/2021	6/1/2021	Patient was getting their 2nd covid immunization. They marked that they once had fainted from a previous immunization and had needle anxiety. I asked her if she had fainted anytime recently or during the first covid vaccine and she said no. Gave her the vaccine and let her remain in the chair. She then had gotten a little dizzie for a moment, and then told us she had just fainted. We called store management code white. We got her history, some soda, and ice pack. She didn't fall out of the chair but thought it would help her feel better. She stated she hadn't eaten much today and just got done working out at the gym and had low blood sugar. We checked her pulse Ox and heart rate and everything was within normal limits. We had her remain to she felt comfortable to leave. She didn't have any HX of seizures and and no signs of allergic reaction. Staff Said when she was here first time she had immunization anxiety and hung out for 40ish minutes but didn't faint first time.
1365425	6/1/2021	TX	23	F	5/1/2021	5/31/2021	First time seizure
1365424	6/1/2021	UT	41	F	5/27/2021	5/30/2021	Client present to the clinic today through telehealth and states that she got the Covid vaccine last week and since then has been having seizures just like she did when she had Covid. On Senday she had 5 seizures, and yesterday she had 2. This morning she had 1 seizure. She denies any fevers or sore throat but does have malaise with general body aches. She does take topiramate 100mg at bedtime every night.
1365402	6/1/2021	WA	24	M	6/1/2021	6/1/2021	Patient received vaccine and after a few minutes patient had seizure.
1365398	6/1/2021	KY	18	M	6/1/2021	6/1/2021	Pt received 1st Moderna covid vaccine at approx 10:25am with no apparent issue. He was sitting outside pharmacy in observation area playing on cell phone and approximately 10 minutes after receiving vaccine fell in the floor, hitting his head. EMTs were called immediately as a precaution. He was conscious when pharmacist reached his side. He reported remembering a buzzing in his ears and then woke up in floor. Pt reported no hx of seizures or fainting. He remained in floor for several minutes, reporting his head hurt, but was able to tell his name, location, and date with no issue.

<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>
1365290	6/1/2021	CA	16	F	5/25/2021	5/25/2021	My daughter had a mild seizure 5 minutes or less after receiving her first vaccine. She fell out of her chair, her eyes fluttered and rolled in the back of her head, her teeth were clicking and chattering and her body was shaking mildly. She lost consciousness for approximately 2 minutes. At 8:33 pm she felt a second seizure begin, her step father grabbed her before she could fall and again, her eyes fluttered and rolled in back of her head, her teeth were clicking and chattering and her whole body was shaking. The second episode lasted approximately 2 minutes as well, with her losing consciousness again. She was taken to the emergency room and stayed overnight for observation.
1365287	6/1/2021	WA	42	M	4/16/2021	4/16/2021	Seizure immediately following injection
1365122	6/1/2021	MI	19	M	4/7/2021	5/31/2021	HPI This is a 19-year-old male that presents for complaint of witnessed seizure-like activity. He arrives by EMS. Patient is currently awake alert and oriented x3. Today, he was out on the golf course with friends. It was a normal day and he returned home. When he got home, he was complaining of a headache to his mother. She gave him Motrin. Mother then heard a noise from the other room and found the patient on the floor unresponsive, displaying tonic-clonic activity, and eye rolling into the back of the head. This lasted for 4-5 minutes per mother. EMS arrived on scene he was postictal. Patient is never had this happen before. He denies any illicit substance, alcohol or medication use. Review of Systems Constitutional: Negative for chills, fatigue and fever. HENT: Negative for facial swelling and trouble swallowing. Respiratory: Negative for cough, shortness of breath and wheezing. Cardiovascular: Negative for chest pain and palpitations. Gastrointestinal: Negative for abdominal pain, diarrhea, nausea and vomiting. Genitourinary: Negative for dysuria and frequency. Musculoskeletal: Negative for back pain and neck pain. Skin: Negative for rash and wound. Neurological: Positive for seizures and syncope. Negative for weakness, light-headedness and headaches. Psychiatric/Behavioral: Negative for confusion. The patient is not nervous/anxious.

<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>
1365956	6/1/2021	AL	75	F	3/18/2021	3/18/2021	Fatigue, sleepy, headache, Body jerks(like convulsions) nausea, rash
1363779	6/1/2021	MA	60	M		4/1/2021	<p>FAINTING SPELL; PASSED OUT; This spontaneous report received from a consumer (wife) concerned a 60 year old male of unspecified race and ethnicity. The patient's height, and weight were not reported. The patient's concurrent conditions included Crohn's disease (diagnosed years ago), bee stings allergy, non smoker, non alcohol user, and marijuana abuse. The patient did not have primary care provider (PCP) and had not been to the doctor for 35 years. 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 01-APR-2021 to right arm for prophylactic vaccination. No concomitant medications were reported. Five or ten minute after vaccination patient's eyes rolled back and he passed out at the vaccine centre. Reporter was not sure if he fainted or had a seizure. He came back for a bit but then started having the fainting spell again. The patient taken by the ambulance to the hospital. In hospital, did a few tests which included blood pressure, blood sugar, electrocardiogram (EKG) but everything came back fine. He had not eaten before getting the vaccine. Healthcare professional (HCP) could not find any reason for his symptom. He had not eaten before getting the vaccine but it was nothing unusual. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fainting spell, and passed out on 01-APR-2021. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210546973-covid-19 vaccine ad26.cov2.s-Fainting spell, passed out. 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
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;</p> <p>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>

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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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,

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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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

<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>
1363716	6/1/2021	WA	44	M	2/12/2021	2/12/2021	Seizure; Condition aggravated; This case was received via FDA VAERS (Reference number: 1036286) on 18-May-2021 and was forwarded to Moderna on 18-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of SEIZURE (Seizure) in a 44-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 028L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included seizure. On 12-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-Feb-2021, the patient experienced SEIZURE (Seizure) (seriousness criterion medically significant) and CONDITION AGGRAVATED (Condition aggravated). At the time of the report, SEIZURE (Seizure) and CONDITION AGGRAVATED (Condition aggravated) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. no known allergies has been reported. the concomitant medications not reported. the patient has the medical history of seizures. Company Comment: Very limited information regarding the events has been provided at this time. Further information is not expected.; Sender's Comments: Very limited information regarding the events has been provided at this time. Further information is not expected.
1365695	6/1/2021	CA	91	M	2/25/2021	3/1/2021	After the first dose my father got what the eye doctor thought was pink eye. After treating him it didn't clear up. It was later diagnosed as herpes of the eye and he became blind in one eye. Shortly afterwards I read an article from researchers who stated they had found fragments of the herpes virus in the vaccine. After the second vaccine he was fine one day and 2 days later started having seizures. He was hospitalized for the seizures. His personality totally changed. He no longer recognized my sister. He also became hostile which is not the person he was. He was released from the hospital and brought to a new facility. Then the lights went out. he just stared off into space. A day later he was dead.

<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>
1365686	6/1/2021	AZ	20	M	6/1/2021	6/1/2021	Pt received his first dose of the Moderna Covid-19 vaccine. Immediately following the injection the pt began convulsing. Convulsions lasted for less than 30 seconds. Upon completion of convulsions pt was awake and alert. He stated he was thirsty. Before we could provide water to pt, the pt began vomiting. Pt was placed on his side and paramedics were called. Pt remained in a laying position until emt's arrived. Pt was examined and released. Pt was encouraged to follow up with his pcip.
1365531	6/1/2021	IL	45	M	5/24/2021	5/24/2021	MOTHER REPORTED HE HAD ADDITIONAL SEIZURES, VOMITING, EXTREME FATIGUE, STIFF ARM, SLURRED SPEECH, COULDN'T WALK WELL. MOSTLY AFFECTED RIGHT SIDE.
1363838	6/1/2021	FL		U		5/12/2021	SEVERE ITCHING/SCRATCHING ALL OVER; BRUISING; This spontaneous report received from a health care professional concerned a 22 year old of unspecified sex. The patient's height, and weight were not reported. The patient's concurrent conditions included autistic, non verbal, seizures, and obesity. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 205A21A expiry: 23/JUN/2021) dose was not reported, administered on 10-MAY-2021 for prophylactic vaccination. No concomitant medications were reported. On 12-MAY-2021, the subject experienced severe itching/scratching all over. On 12-MAY-2021, the subject experienced bruising. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from severe itching/scratching all over, and bruising. This report was 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>
1363995	6/1/2021	FL	30	M	5/12/2021	5/12/2021	<p>blurry vision five minutes after the shot; seizures on the same day; This spontaneous case was reported by a consumer and describes the occurrence of VISION BLURRED (blurry vision five minutes after the shot) and SEIZURE (seizures on the same day) in a 30-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 027C21A) for COVID-19 vaccination. The patient's past medical history included COVID-19 (had covid-19 twice before receiving the vaccine once in APR-2021) in April 2021. Concurrent medical conditions included Epilepsy. Concomitant products included LEVETIRACETAM (KEPPRA [LEVETIRACETAM]), LAMOTRIGINE, LOPERAMIDE HYDROCHLORIDE (LOMOTIL [LOPERAMIDE HYDROCHLORIDE]), ATORVASTATIN, LORAZEPAM (ATIVAN), ONDANSETRON (ZOFRAN [ONDANSETRON]) and CLONAZEPAM (KLONOPIN) for an unknown indication. On 12-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-May-2021, the patient experienced VISION BLURRED (blurry vision five minutes after the shot) (seriousness criterion hospitalization). 12-May-2021, the patient experienced SEIZURE (seizures on the same day) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 12-May-2021 to 19-May-2021 due to SEIZURE and VISION BLURRED. At the time of the report, VISION BLURRED (blurry vision five minutes after the shot) outcome was unknown and SEIZURE (seizures on the same day) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In April 2021, Computerised tomogram: unknown (Inconclusive) unknown. In April 2021, Lumbar puncture: unknown (Inconclusive) spinal tap from CNS fluid to make sure there was no cox in his brain. In April 2021, Magnetic resonance imaging: unknown (Inconclusive) unknown. mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was withdrawn on an unknown date. The patient had epilepsy as pre-existing condition and he was on unspecified medication for that. The patient has seizures on the same day of vaccination and was transferred to hospital. Patient had magnetic resonance scan (MRI) and patient had seizures over there for which he was moved to sister hospital where they did scan under</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>
							anesthesia. Before discharging patient from hospital they took spinal tap from central nervous system (CNS) fluid to make sure there was no Cyclooxygenase (COX) in his brain. Patient's physician told to not receive the second dose of Moderna vaccine. No treatment information was reported. Company 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 case was linked to US-MODERNATX, INC.-MOD-2021-154269 (E2B Linked Report). Most recent FOLLOW-UP information incorporated above includes: On 25-May-2021: Additional information was received and events, hospitalization details and laboratory data 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 US-MODERNATX, INC.-MOD-2021-154269:Crosslinked case of reporter friend case
1362369	5/31/2021	OR	21	F	5/11/2021	5/12/2021	I woke up around 2 in the morning with body aches, chills, and nausea. I started having muscle seizures that made me unable to talk, but I was still somewhat aware of things going on around me. I went to the ER where they observed my pulse and oxygen levels. I was also completed a full blood panel and an EKG was administered. woke up around 2 am with body ached, chills nausea i started havieng mucle seizurs, where I couldn't talk .I went to the ER week to get better
1362082	5/31/2021	AZ	14	F	5/29/2021	5/30/2021	Seizure
1362096	5/31/2021	TX	34	F	5/28/2021	5/28/2021	Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Additional Details: Pt was unresponsive approximately 5 mins after recieving COVID vax. Pt was sitting next to husband and husband called for help. Upon viewing the pt, pt appeared unconscious and possibly seizing. EMS (911) was called and in the mean time Rph attended to pt. By the time EMS arrived pt was starting to respond and gradually aware of environment and self . Pt was reccommended to visit hospital for further check up, but pt and husband declined. said shes doing fine and much better and husband agreed.

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1362098	5/31/2021	MI	19	F	5/30/2021	5/30/2021	Systemic: Seizure-Mild, Additional Details: Called patient and it seems that she had another seizure episode in the ambulance. She's doing okay.
1362104	5/31/2021	CT	29	M	5/30/2021	5/30/2021	Systemic: Chills-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Seizure-Medium, Additional Details: Patient stated that he smoked marijuana earlier in the day. Patient fell over onto the floor after administration. Woke up less than 30 seconds after falling over
1362123	5/31/2021	MI	19	F	5/30/2021	5/30/2021	Systemic: Seizure-Mild, Additional Details: Spoke to mother and she said her daughter had another seizure episode. She's doing okay now.
1362141	5/31/2021	AZ	33	U	5/29/2021	5/29/2021	Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Additional Details: Patient felt normal after the injection and for the remainder of the day. She woke up in the middle of the night to use the restroom and fainted in the bathroom. She then returned to bed where she felt like she "blackout for a short period". Her husband reported that she was shaking uncontrollably and her eyes were darting back and forth (this lasted about 10 sec). She was encouraged to be examined by a physician for any further issues. She stated that she is currently feeling ok.

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1362270	5/31/2021	IL	67	M	4/13/2021	5/15/2021	On Saturday, May 15, while sitting with his wife, "froze" for a short period of time, approximately 1-2 minutes. His wife did not know what was wrong and urged him to go to the hospital. His son brought him to the hospital, he presented with elevated blood pressure, a slightly asymmetric smile, and black tongue. He was admitted to the hospital and multiple tests (brain scans, electrocardiogram, etc.) were run to try to diagnose what had occurred. On the afternoon of Sunday, May 16, in the midst of being discharged from the hospital, pt had another "episode" which was later categorized by physicians as being a partial complex seizure, where he "froze" and became unresponsive for approximately 1 minute. During the event, he was wearing a heart monitor, which showed no unusual heart activity, but his blood oxygen level dropped during the event. On Sunday, May 16, pt had a second partial complex seizure (third seizure over the 2-day period). This seizure was timed at being approximately one minute in duration. Following the seizures on 5/16, patient was given Ativan and also a 1500mg loading dose of Keppra. On Monday, May 17, patient had a EEG administered, which indicated that there was no unusual activity occurring in the brain during the test. He was advised to continuing taking Keppra at 750mg/day. Pt does not have a family history of epilepsy, never played contact sports, and has not suffered brain injuries such as a concussion.
1362317	5/31/2021	TX	51	M	5/18/2021	5/22/2021	Sense of Deja Vu, could smell burnt rubber, and sense of impending doom. Started on Saturday 22 and increased in frequency throughout the week. Each episode lasted about 15 seconds. Went to the Clinic on 5/28 who then sent him to the emergency room where they treated him for prefrontal cortex seizures. He was released from the hospital with a referral to a neurologist.

<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>
1362496	5/31/2021	VT	20	M	5/31/2021	5/31/2021	I administered the vaccine and asked patient to move to the waiting area for his 15 minute observation period. He moved out to the chair and sat down about 2 minutes later his abdomen started to move back and forth a few times and then he started to have what appeared to be a seizure. It was very short (20 seconds), he remained in the chair. His mom and I moved him to the floor with his help. He then mentioned that he forgot to take his seizure medication last night and was feeling very nervous about the vaccine.
1362551	5/31/2021	CA	45	F	5/31/2021	5/31/2021	Patient experiences 2 seizures in the span of 10 minutes.
1362680	5/31/2021	WA	52	M	5/27/2021	5/27/2021	Received the vaccine and then sat in waiting area with no immediate issues. After about 10 minutes started to feel flushed and a couple seconds later blacked out. When coming around, felt disoriented and nurse was asking me questions as I was still sitting in chair. My wife reported that I was having a seizure and stiff against the wall with eyes rolled back and unresponsive for about a minute. My right arm was cramping, BP 220/180 and pulse 44. The clinic staff laid me on the floor and call an ambulance that took me to the ER for observation and testing.
1362301	5/31/2021	ME	29	F	5/31/2021	5/31/2021	minutes after vaccine patient fainted. when i went over to check on her she had a very mild seizure like rxn. then cam to and said "where am I". we administered cold pack to fore head, checked pulse. she came around a bit more and we gave her cold water. then a glucose tablet. color started to come back into her face. gave her peanut butter crackers and a banana. she stayed for about 1 hr. called her sister to come get her.

<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>
1361498	5/30/2021	TX	34	F	5/28/2021	5/28/2021	Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Additional Details: Pt was unresponsive appr 5 mins after receiving COVID Vax. Pt was sitting next to husband and husband called for help. Upon galncing at the pt, pt appeared unconscious and shaking, possibly seizing. EMS (911) was called and in the mean time RPH attended to pt. By the time EMS arrived pt was starting to respond and gradually aware of environment and self. Pt was recommended visit ER for further check up, but pt and husband declined, she stated she is doing fine and much better and husband agreed

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1361600	5/30/2021	GA	89	F	1/12/2021	1/12/2021	To whom it may concern, Nov. 9, 2020: I was taken to hospital to diagnose why I was sleeping (up to 20hours a day) and so drained. I was diagnosed with Covid-19, Pneumonia and was hospitalized for a week and half. I was not on respiratory equipment during this time. Jan. 12, 2021: Received First Moderna COVID-19 Vaccine Shot 1:15 p.m. At 10 p.m. I started, uncontrollable, none stop, and full body shaking (not shiver but shaking) that lasted over an hour. I called my son and 911 who sent an ambulance. My son said he thought I looked like I was having a seizure. The EMT said the only way I could find out what was happening would be to go to the hospital which I chose not to because I did not want to be re-exposed to Covid-19. The EMT suggested I take Benadryl. After the initial hour and taking a Benadryl my shaking subsided. I slept almost around the clock for 3 days. Feb. 9, 2021: Received Second Moderna COVID-19 Vaccine Shot 1:30 p.m. At 7 p.m. I was fine and talked to my son on phone. By 7:30 PM I had started shaking as described above. I called my son to the house and he gave me a Benadryl again. He held my head and shoulders during this shaking episode to keep my shaking from hurting my neck. After an hour or so the shaking again subsided. During the time the shaking was waning my son took a video of my shaking, in which I was shaking just not violently. Again, I slept 3 days. We have concluded these episodes are related to the Moderna COVID-19 Vaccine Shot. April 5, 2021: Appointment with Dr. During my doctor's appointment I told the doctor of my experiences and showed him the video. The doctor said he hadn't heard of this reaction. I asked him about the advisability of taking a booster shot. The doctor said we would have to wait and see. May 23, 2021 My questions are: Have you heard of this reaction before? If so, can you supply me with the information you have about it? If a booster is recommended, should I take it or how can I evaluate the risks either way? HOW WILL I BE ABLE TO FOLLOW THRU WITH THIS?
1361695	5/30/2021	RI	14	M	5/29/2021	5/29/2021	Systemic: Fainting / Unresponsive-Severe, Additional Details: Patient has long history of fainting whenever getting vaccines. No history of seizures, per mom.

<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>
1361767	5/30/2021	SC	60	F	5/27/2021	5/28/2021	approximately 26 hours after immunization, patient had first of 3 seizures lasting 15-25 seconds. patient normally has not had seizure for 34 days (since taking doxycycline). Husband and wife reported to pharmacy 5/30 approximately 3 pm.
1361782	5/30/2021	IN	24	M	5/28/2021	5/28/2021	05/28/21 around 22:30 waves of convulsions including uncontrolled shacking of the hands and upper body followed by chills and high body temperature. This lasted for until about 03:00 05/29/21. 05/29/21 consisted of mainly being in a bedridden state of fatigue, sleeping, loss of appetite, swollen and inflamed lymph glands particularly under the armpit of the injection site arm, soreness and pain in the injection site arm, headache, aches and pains throughout the entire body, and the inability to walk or stand for long periods of time. 05/30/21 lymph glands are still inflamed and swollen (particularly as stated above under the armpit of the arm that got the injection), head stills persists, along with some fatigue, and loss of appetite.
1361920	5/30/2021	WI	34	F	4/14/2021	4/19/2021	Migraines (aura, sensitivity to light and sound, confusion, extreme tiredness, nausea) resembling seizures every two weeks starting April 19th. 5 days after first dose.
1362021	5/30/2021	AZ	32	F	5/12/2021	5/15/2021	Had 2 grand mal seizures 2 days after getting vaccine. Have had brain fogginess, right side numbness and pain in face, arm and leg, increased anxiety.
1361475	5/30/2021	AZ	24	F	5/29/2021	5/29/2021	Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe
1361884	5/30/2021	WA	19	M	5/29/2021	5/29/2021	Pt was sitting in observation chair after his vaccination--a little slumped over and twitching as if he were having a seizure. He did not respond to me calling his name. Pt gained consciousness and was a little frightened, not understanding the situation or remembering where he was at. He felt a little better after some water. About 4 minutes later, he said he was losing his vision and seeing flashes of light. He was told to lie on the floor with his feet up. Within a few minutes, he said he was feeling a lot more like normal.

<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>
1361387	5/29/2021	CA	40	F	5/29/2021	5/29/2021	Onset of severe nausea followed by difficulty breathing, uncontrollable incessant dry heaving and coughing, spasms, full body shaking, full body tremors, inability to speak, seizure like reaction, dizziness, tingling in tongue,

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1359912	5/29/2021	FL	66	F	1/25/2021	1/26/2021	<p>Sepsis; Pyrexia; This regulatory authority case was reported by an other health care professional and describes the occurrence of SEPSIS (Sepsis) in a 66-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 030L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Vaccination: Flu (seizure like activity). Past adverse reactions to the above products included Seizure with Flu. Concurrent medical conditions included Sulfonamide allergy (sulfa (Bactrim) facial swelling), Allergy (environmental allergies), Factor V Leiden mutation (TSVT) and Asthma. Concomitant products included METOPROLOL, WARFARIN and FLUTICASONE PROPIONATE (FLONASE ALLERGY RELIEF) 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 26-Jan-2021, the patient experienced SEPSIS (Sepsis) (seriousness criterion medically significant) and PYREXIA (Pyrexia). The patient was treated with PARACETAMOL (TYLENOL) ongoing since an unknown date for Fever, at an unspecified dose and frequency. At the time of the report, SEPSIS (Sepsis) and PYREXIA (Pyrexia) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Feb-2021, Blood test: 1750 (Inconclusive) 1750. On 08-Feb-2021, White blood cell count: 2.4 (Inconclusive) 2.4. On 14-Feb-2021, Blood test: 26200 (Inconclusive) 26200. On 14-Feb-2021, White blood cell count: 5.82 (Inconclusive) 5.82. 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 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>

<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>
1359913	5/29/2021	MO	49	M	3/2/2021	3/2/2021	Seizure like phenomena; Breath sounds abnormal; Dizziness; Dyskinesia; Eyelid function disorder; Fall; Hyperhidrosis; Hypopnoea; Hypotonia; Muscle twitching; Pallor; Presyncope; Restless legs syndrome; Tremor; This case was received via FDA VAERS on 18-May-2021 and was forwarded to Moderna on 18-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of SEIZURE LIKE PHENOMENA (Seizure like phenomena) in a 49-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Vagal reaction (patient stated he has experienced vagal responses to injections in the past). On 02-Mar-2021 at 5:46 PM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Mar-2021, the patient experienced SEIZURE LIKE PHENOMENA (Seizure like phenomena) (seriousness criterion medically significant). 02-Mar-2021, the patient experienced BREATH SOUNDS ABNORMAL (Breath sounds abnormal), DIZZINESS (Dizziness), DYSKINESIA (Dyskinesia), EYELID FUNCTION DISORDER (Eyelid function disorder), FALL (Fall), HYPERHIDROSIS (Hyperhidrosis), HYPOPNOEA (Hypopnoea), HYPOTONIA (Hypotonia), MUSCLE TWITCHING (Muscle twitching), PALLOR (Pallor), PRESYNCOPE (Presyncope), RESTLESS LEGS SYNDROME (Restless legs syndrome) and TREMOR (Tremor). At the time of the report, SEIZURE LIKE PHENOMENA (Seizure like phenomena), BREATH SOUNDS ABNORMAL (Breath sounds abnormal), DIZZINESS (Dizziness), DYSKINESIA (Dyskinesia), EYELID FUNCTION DISORDER (Eyelid function disorder), FALL (Fall), HYPERHIDROSIS (Hyperhidrosis), HYPOPNOEA (Hypopnoea), HYPOTONIA (Hypotonia), MUSCLE TWITCHING (Muscle twitching), PALLOR (Pallor), PRESYNCOPE (Presyncope), RESTLESS LEGS SYNDROME (Restless legs syndrome) and TREMOR (Tremor) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Mar-2021, Blood pressure measurement: 120/72 (normal) 120/72 mmHg. On 02-Mar-2021, Heart rate: 64 (normal)

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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64 beats per minute. On 02-Mar-2021, Oxygen saturation: 99 (normal) 99%. On 02-Mar-2021, Respiratory rate: 20 (normal) 20 breaths per minute. 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 were provided. The patient remained in the vaccination chair for 5 minutes after injection and he reported feeling well and moved to the observation chair without any problems [~10ft]. After being in the observation chair the patient stood up and took 4-5 steps toward the wall and sat down on the floor. The patient stated he felt dizzy and then became limp and slumped to the right side, his eyes remained open with dilation of pupil fixed at 2mm with no blinking noted. The patient's breathing pattern became shallow and snoring sounds were noted. The patient did not respond when spoken to nor did he respond to soft shaking of the shoulders. The patient began to demonstrate large jerky body movements similar to seizure activity. The seizure like activity continued for 3-4 minutes before the patient was able to become aware of surroundings and answer orientation questions. The patient was diaphoretic, pale, shaking of hands and arms, restlessness of lower limbs with frequent repositioning/twitching of legs. EMS (emergency medical services) arrived to find the patient regaining stability. The patient reported to EMS that he is familiar with this type of response and declined to be taken anywhere. Treatment medications were not reported. Based on current available information and the temporal association between product use and the start date of the event a causal relationship cannot be excluded. The Company believes the event of Restless leg syndrome is not supported in the source documents and should be delete.; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the event a causal relationship cannot be excluded. The Company believes the event of Restless leg syndrome is not supported in the source documents and should be delete.

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1359914	5/29/2021		61	F	3/6/2021	3/6/2021	Seizure; Dyspnoea; Nausea; Paraesthesia; Somnolence; This case was received via FDA VAERS on 18-May-2021 and was forwarded to Moderna on 18-May-2021. This regulatory authority case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of SEIZURE (Seizure) in a 61-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 003A21A) for COVID-19 immunization. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Seizure. On 06-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Mar-2021, the patient experienced SEIZURE (Seizure) (seriousness criterion medically significant), DYSPNOEA (Dyspnoea), NAUSEA (Nausea), PARAESTHESIA (Paraesthesia) and SOMNOLENCE (Somnolence). At the time of the report, SEIZURE (Seizure), DYSPNOEA (Dyspnoea), NAUSEA (Nausea), PARAESTHESIA (Paraesthesia) and SOMNOLENCE (Somnolence) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood pressure measurement: 100/60 mmHg (Inconclusive) decreased. On an unknown date, Heart rate: 76 (normal) normal. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient is taking unknown medicines for the seizures.; 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>
1359984	5/29/2021	FL	20	F	4/29/2021	5/8/2021	<p>autoimmune encephalitis; epileptic seizures; Epileptic seizure; Lost 10 pounds; Vomiting; Nausea; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of AUTOIMMUNE ENCEPHALOPATHY (autoimmune encephalitis), EPILEPSY (Epileptic seizure) and EPILEPSY (epileptic seizures) in a 20-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 COVID-19 in July 2020. Concomitant products included ORAL CONTRACEPTIVE NOS for Birth control. On 29-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 08-May-2021, the patient experienced EPILEPSY (Epileptic seizure) (seriousness criteria hospitalization, medically significant and life threatening). On 10-May-2021, the patient experienced EPILEPSY (epileptic seizures) (seriousness criteria hospitalization, medically significant and life threatening). On an unknown date, the patient experienced AUTOIMMUNE ENCEPHALOPATHY (autoimmune encephalitis) (seriousness criteria hospitalization and medically significant), WEIGHT DECREASED (Lost 10 pounds), VOMITING (Vomiting) and NAUSEA (Nausea). The patient was hospitalized from 08-May-2021 to 09-May-2021 due to EPILEPSY, and then on 10-May-2021 due to EPILEPSY. At the time of the report, AUTOIMMUNE ENCEPHALOPATHY (autoimmune encephalitis), EPILEPSY (Epileptic seizure) and EPILEPSY (epileptic seizures) outcome was unknown and WEIGHT DECREASED (Lost 10 pounds), VOMITING (Vomiting) and NAUSEA (Nausea) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In October 2020, SARS-CoV-2 antibody test: positive (Positive) positive. On 09-May-2021, Magnetic resonance imaging: unknown (Inconclusive) unknown. Concomitant medication included unspecified thyroid medication. The patient recovered on 06 May2021. Afterwards, a few days later the patient was hospitalized on 08 May2021 for what was described</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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as an epileptic seizure. They proceeded to leave the hospital on 09 May2021 needing an MRI within the next two weeks. The patient was re-hospitalized at 9:00AM on 10May2021 for another epileptic seizure. They are currently examining her for an autoimmune encephalitis. The patient proceeded to recover and was tested for antibodies in October to which it was determined they did have antibodies. On an unknown date, and electroencephalogram was performed (results not provided). Action taken with mRNA-1273 in response to the drug was not applicable as the patient received both planned doses. Based on the current available information and temporal association between the use of the product and the start date of the event/s, 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/s, 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>
1360445	5/29/2021		18	F	4/20/2021	4/1/2021	Problems with her heart; Shortness of breath; Pain the chest; Low blood pressure; Passed out; Started shaking "like a seizure"; Started shaking "like a seizure"; Dizziness; Tiredness; Stomach pain; Chills; Fever; Sweats; Nausea; Vomiting/throwing up; Inflammation in the chest, muscle or maybe heart inflammation; Inflammation in the chest, muscle or maybe heart inflammation; Inflammation in the chest, muscle or maybe heart inflammation; Pain in the heart; Not feeling well; Had a severe allergic reaction; Headache; Weak; This is a spontaneous report from a contactable consumer (patient's mother). An 18-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EW0169; Expiration date was not reported) on the left arm on 20Apr2021 as a 1st dose, single dose, with route of administration unspecified, for COVID-19 immunization. The patient had no relevant medical history and concomitant medications. On 20Apr2021, the patient had passed out; started shaking "like a seizure"; dizziness; tiredness; stomach pain; chills; fever; sweats; vomiting/throwing up; and nausea. The patient was brought to urgent care/emergency room (ER) due to the reported events. On 21Apr2021, the patient had shortness of breath; pain in the chest; and low blood pressure. On 22Apr2021, the patient had problems with her heart. The patient was brought to urgent care/emergency room (ER) due to the reported events, and for cardiac work up. On an unspecified date in 2021, the patient was not feeling well; had a severe allergic reaction; headache; and was weak. In Apr2021, the patient had "inflammation in the chest, muscle or maybe heart inflammation". The patient received treatment for the events, pain in the chest and "inflammation in the chest, muscle or maybe heart inflammation" (double dose of naproxen. The patient's laboratory tests included normal blood pressure on 22Apr2021; chest x-ray on 21Apr2021 (results were not provided); echo sonogram on 22Apr2021 (results were not provided); electrocardiogram (EKG) was normal on 21Apr2021, 22Apr2021 and 23Apr2021. The outcome of the events was not recovered for tiredness; was recovered on an unspecified date in 2021 for chills, sweats, vomiting/throwing up; was recovering for pain in the chest; and was unknown for all the other events. The

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1360362	5/29/2021	CT	58	F	3/3/2021	3/3/2021	<p>patient's primary care provider was writing a doctor's note recommending that she not receive the second dose based on her reaction to the first dose, and the PCP recommended that the mother call Pfizer as well.</p> <p>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.</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>
1361266	5/29/2021	CA	22	M	5/29/2021	5/29/2021	Patient fainted shortly after receiving the vaccine. He was instructed to go have a seat in our observation area and wait for 15 minutes and I believe he fainted before he even sat down. As I approached him he was already conscious again and i had him stay put just to make sure he was ok before getting back into the chair. He was given water and he was closely monitored until his 15 minutes was up. A family member came to take him home just to be safe. While he was waiting he said it wasn't a seizure and he probably fainted because of his fear of needles. He mentioned it has happened multiple times before whenever he gets tattoos. None of this was indicated when he filled out his vaccine consent form.
1361238	5/29/2021	CA	44	F	5/28/2021	5/28/2021	After 5 min Injection, they started to feel dizzy and short of breath later to have a type of seizure and would not react and became unconscious. Then became conscious later but threw up as well after they woke up. The next day after the injection woke up around 7:15 am and felt dizzy once again and later sat down and fell to the ground and became unconscious.
1361144	5/29/2021	IN	17	F	4/6/2021	4/7/2021	FACIAL NUMBING AFTER FIRST DOSE, SEIZURE 20 DAYS AFTER SECOND DOSE WHICH WAS ADMINISTERED 5/4/2021

<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>
1360482	5/29/2021	MI	47	M	5/1/2021	5/13/2021	getting lightheaded and dizzy all the time; Seizure; This is a spontaneous report from a contactable consumer (patient) and a consumer (patient's ex-wife/ roommate) A 47-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER2613 and expiration date not provided), via an unspecified route of administration, on 01May2021 (at the age of 47-year-old), at single dose, for COVID-19 immunization. Medical history included blood cholesterol, high blood pressure, ongoing seizures from 1991; patient was being hit in the head with a steel baseball bat 13 times, and had a lot of brain damage; and ongoing sleep. Prior Vaccinations (within 4 weeks) provided as no. Concomitant medications included ongoing topiramate (TROKENDI XR) for seizure, ongoing allopurinol (ELAVIL) for sleep, and medication for cholesterol and one for high blood pressure. Patient had been on topiramate a couple of months. They were working with him to get him better than he was because he was having a lot of the little ones. He got the pill packs. He tried the little compartment things and they weren't working. Roommate suggested they try the pill packs to make it easier. There was the time on the packs. The patient experienced seizures on 13May2021; getting lightheaded and dizzy all the time on unknown date. Patient's second dose was scheduled 22May2021. Due to symptoms that he experienced he was afraid to take second dose. Patient had petite mal seizure last night on 13May2021, he got ahold of the doctor and got an appointment with his family doctor. They don't know about the seizure yet. Patient was feeling ok until he got the shot. Now, he was back to getting lightheaded and dizzy all the time. Patient got social security and had a hard time remembering his phone number. Patient's ex-wife clarified that patient called the doctor and got an appointment. He had upcoming appointment. The doctor wanted him to go to the emergency room. She had known him since 2005. When he had a mild seizure the ER doesn't do anything for him. They just leave him in the bed and wait until he comes to his senses. She just told patient to go in his room and lay down and offered him paracetamol (TYLENOL) and all that stuff. She couldn't move him when he was having one of the worse seizures because he turns into a board. She tried to get him aware. They didn't last long. Patient had grand-mal

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seizures since the age of 18 after being hit in the head with a steel baseball bat 13 times. He had a lot of brain damage. The brain can't fix itself. She was the only one that knows how to handle him. Patient's ex-wife listed at the doctor office because patient had a hard time explaining things and stutters a lot, he can't answer right away. The seizure patient had yesterday was a petite mal seizure. It wasn't a full blown grand mal seizure. He had three different phases of seizures. He had the staring one where he was looking out in space. Then he had the next one that happened in the car. He sat down and put his head back to relax. She thought he was taking a break, but it was a seizure. She touches him to focus and get him back. At night was when he has the worst ones where he loses control of his bladder, foams at the mouth, and turns into a board. He can't bend. He has only had 3 of those in the time she had known him. The other ones he had quite often. The quicker he comes out of it the less headache he has after it. If they let it run its course he has a bad headache and nausea. She tries to open his eyes because he comes out better. One time when he had grand mal seizure she couldn't get him rolled over and had to get help. Even though it was saliva and he was foaming at the mouth she was afraid he would choke on it. He had one starring seizure shortly before the COVID vaccine. He had them a lot. If they take blood or run scan it won't show patient had a seizure. For a little while patient and his roommate weren't together. If he did have seizure during that time he got himself out of it. He has only had 3 bad ones since 2005. Patient told his doctor that he thought it was related to the COVID shot. Patient's ex-wife didn't believe that was what caused the seizure (She thought if it was related it would have happened within 20 minutes of getting the vaccine). She thought he just had one. It played in his mind that he had the shot. Patient's brain stopped growing when he was 18 due to damage. The outcome of the events was unknown.; Sender's Comments: Based on known drug safety profile, there is reasonable possibility of causal association between the events Seizures, Dizziness and the suspect BNT162B2.

<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>
1360119	5/29/2021	NY	24	F	5/29/2021	5/29/2021	A 24 y.o female fainted and appeared to have a seizure. She loss consciousness and had muscle contractions. The seizure was approximately 2 minutes. Patient did not hit her head or injury any part of her body. She was gradually dismounted from the chair and placed on the floor. 1st B/P reading was 70/40, then 108/63. Patient after waking up was alert and oriented X3. Once EMS arrived she was assessed and encouraged to go to the hospital for follow up. Patient and father refused to go to the hospital. They verbalized "She has an important exam for school". Patient stated she will follow up after her exam.
1360472	5/29/2021	CA		F	5/13/2021		passed out; not breathing; shaking; not awake; not coherent; not feeling good; arm was aching a little bit/her arm was hurting and her arm was achy; This is a spontaneous report from a contactable consumer (patient) and patient's mother. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 13May2021 20:30 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Patient got to work on 14May2021 at 08:00 and the manager let her go home because her arm was hurting and her arm was achy, and she was not feeling good, but she was feeling fine when she got home. At 11:00 AM, she came home and went into the house and came back outside. The patient's mom said that they were on the front porch and her daughter passed out and looked like she was having a seizure kind of thing (shaking really bad), she was not awake, not coherent and not breathing. They got her into the house once she came to, they cooled her off and let her sleep for about 45 minutes. Patient said that she felt like she went to sleep and what she remembered next she felt like she was waking up. She said that she slept and nowshe feels fine. Outcome of events was recovered. Information about Lot/Batch number 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>
1361057	5/29/2021	WA	56	F	5/27/2021	5/28/2021	I received my 2nd Covid 19 shot at clinic. I began to get sick that night. But by 4:00 am I woke up with seizures, freezing cold, nausea, fatigue, fever of 101.3, pain throughout my body. I had slightly labored breathing and took Elderberry juice. My nose was stuffy. I have a slight wheezy cough. Slightly labored breathing, not severe. I took ibuprofen 500 mg yesterday for the sore shoulder. This morning at I took Bayer's low-dose chewable tablets 350 mg. I really couldn't eat much from nausea, but I ate applesauce, broth, juices, and water. Later that day, as suggested by my doctor I took Tylenol PM. I am feeling 50% better the next day. High 102.5 Temperature went away in 48 hours.

<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>
1360494	5/29/2021	WA	37	F	5/12/2021	5/12/2021	Seizure; Major weakness (cannot walk or stand unsupported, cannot lift objects more than a pound or two); Major weakness (cannot walk or stand unsupported, cannot lift objects more than a pound or two); Major weakness (cannot walk or stand unsupported, cannot lift objects more than a pound or two); Minor weakness (wobbly legs); Minor to moderate stabby headache; Abdominal cramps; Joint pain (especially left wrist which has buckled under pain a few times and right pelvis area); Muscle pain (is decreasing, but flares up, especially in legs); Dizzines; Severe fatigue; Sore arm from injection; Minor fever; 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 the left arm on 12May2021 02:45 PM (batch/lot number: EW0712) as 1st dose, single for COVID-19 immunization. Medical history included Tourette's syndrome, tarsal tunnel (right foot), hyperreflexia, and known allergies to lavender. Concomitant medication included multivitamins; minerals (DAILY MULTIVITAMIN) taken for an unspecified indication, start and stop date were not reported. The patient previously took hydrocodone, acetaminophen (VICODIN) and experienced allergies. Facility where the most recent COVID-19 vaccine was administered was pharmacy or drug store. 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 seizure on 12May2021 03:05-03:45 PM, then on 15May2021 02:55-03:25 AM; major weakness (cannot walk or stand unsupported, cannot lift objects more than a pound or two) on 12May2021 03:05 PM; minor weakness (wobbly legs) on 12May2021 02:50 PM (this weakness increased); dizzines on 12May2021 02:45 PM to evening 14May2021; severe fatigue, has been increasing since shot, having to spend longer and longer in bed, nap a lot, very tired on 12May2021 02:45 PM; sore arm from injection around 12May2021 (reported as 02:40 PM; pending clarification) to morning of 14May2021; minor fever (estimate 99-100 degrees max) on the night of the 12May2021, broke around 02:00 AM on 13May2021,

<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>
							<p>night of 14May2021, broke around 2:45 AM on 15May2021, afternoon of 15May2021, broke around 06:00 PM; minor to moderate stabby headache on 12May2021 02:50 PM, intermittent, managed by paracetamol (TYLENOL); abdominal cramps on 12May2021 02:45 PM; joint pain (especially left wrist which has buckled under pain a few times and right pelvis area) on 12May2021 02:45 PM; and muscle pain (was decreasing, but flares up, especially in legs) on 12May2021 02:45 PM. No treatment was received for the events, except for the event headache which included treatment of paracetamol. The outcome was recovered on 14May2021 for the events dizziness and sore arm from injection; and not recovered for the rest of the events. No follow-up attempts are possible. No further information is expected.</p>
1360518	5/29/2021	NY	24	F	5/29/2021	5/29/2021	<p>A 24 y.o female fainted and appeared to have a seizure. She loss consciousness and had muscle contractions. The seizure was approximately 2 minutes. Patient did not hit her head or injury any part of her body. She was gradually dismounted from the chair and placed on the floor. 1st B/P reading was 70/40, then 108/63. Patient after waking up was alert and oriented X3. Once EMS arrived she was assessed and encouraged to go to the hospital for follow up. Patient and father refused to go to the hospital. They verbalized "She has an important exam for school". Patient stated she will follow up after her exam.</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>
1360538	5/29/2021	MA	60	M	2/18/2021	2/18/2021	Covid 19 PCR swab positive; Covid 19 PCR swab positive; dose 1 on 18Dec2020, dose 2 on 18Feb2021; dose 1 on 18Dec2020, dose 2 on 18Feb2021; This is a spontaneous report from contactable nurse and a consumer. The reporter reported similar events for different patients. This is 7th of the 11 reports. A 60-year-old male patient received BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 intramuscularly administered in right deltoid on 18Dec2020 (Batch/Lot Number: EH9899) as single dose, dose 2 intramuscularly administered in right deltoid on 18Feb2021 (Batch/Lot Number: EK9231) as single dose, for COVID-19 immunisation. Medical history included type 2 diabetes mellitus, blood cholesterol increased, mitral valve prolapse, seizure; from an unknown date and unknown if ongoing. Concomitant medication(s) included metformin (METFORMIN) taken for type 2 diabetes mellitus, start and stop date were not reported; atorvastatin calcium (ATORVASTATIN CALCIUM) taken for blood cholesterol increased, start and stop date were not reported; zonisamide (ZONISAMIDE) taken for seizure, start and stop date were not reported; losartan (LOSARTAN) taken for an unspecified indication, start and stop date were not reported; fenofibrate (FENOFIBRATE) taken for an unspecified indication, start and stop date were not reported. The patient had not been treated with immunomodulating or immunosuppressing medications or received any other vaccines around the time of COVID-19 vaccination. No other vaccine within 4 weeks. The patient had a positive Covid 19 PCR swab test on 30Mar2021. It's unknown if the patient had SARS-CoV2 antibodies at diagnosis. 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. Supplemental oxygen or mechanical ventilation was not required. These was no new or worsened symptoms/signs during the COVID-19 illness. He had respiratory symptoms including nasal congestion and sore throat, and neurological symptoms including loss of taste and smell since 27Mar2021. No other symptoms. No pre-existing diseases worsened during the SARS-CoV2 infection. The event did not require the initiation of new medication or other treatment or procedure. The event COVID-19 was resolved on an unspecified date. Product Quality

<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>
							Investigational report conclusion: The complaint for lack of effect of the PFIZER-BIONTECH COVID-19 VACCINE INJECTABLE lot EH9899 was investigated. The investigation included reviewing manufacturing and packaging batch records, deviation investigations, and an analysis of complaint history for the reported lot. The final scope was determined to be the reported finished goods lot EH9899, fill lot EH9783, and the formulated drug product lot EH9782. A complaint sample was not returned. No related quality issues were identified during the investigation. There is no impact on product quality. No root cause or CAPA were identified as the complaint was not confirmed. All release testing performed prior to the release of the reported batch was within specifications.; Sender's Comments: Based on known drug safety profile, there is reasonable possibility of causal association between the events Drug ineffective, COVID-19, Off label use, Inappropriate schedule of vaccine administered and the suspect drug BNT162B2.,Linked Report(s) : US-PFIZER INC-2021389615 Same reporter/ drug/ event, different patient
1360742	5/29/2021	NY	31	F	5/28/2021	5/28/2021	Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Additional Details: Looked over at chair patient was passed out, thought she was having a seizure. Had technician call 911. It took a minute for patient to come to. She felt hot, and kept feeling like she was going to pass out. Ambulance/Fire came and she signed off, they stated that she just passed out, that it is common. Patient left feeling ok and on her own.

<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>
1360863	5/29/2021	MA	22	M	5/28/2021	5/28/2021	AFTER PATIENT RECEIVED THE VACCINATION, HE SAT DOWN IN THE WAITING AREA. AFTER APPROXIMATELY 1 MINUTE THERE WAS A NOISE AND I NOTICED THAT HE WAS SLUMPED TO THE RIGHT SIDE AND STARTED TO CONVULSE. I RAN OUT TO THE PATIENT AND ENSURED THAT HE DID NOT FALL AND HELD HIM IN PLACE UNTIL HE STARTED TO COME TO. AFTER ABOUT 30 SECONDS THE PATIENT STARTED TO BECOME AWARE AND COULD HEAR ME TALKING BUT WAS STATING HE COULD NOT SEE. AFTER ABOUT 30 SECONDS HIS SIGHT RETURNED. DURING THE TIME THAT I WAS FIRST WITH THE PATIENT, THE STORE MANAGER CALLED 911 AND THE EMS WAS ON SITE AFTER APPROXIMATELY 5 MINUTES. I HAD THE CUSTOMER SIT DOWN AND GAVE HIM WATER UNTIL THE PARAMEDIC ARRIVED. THEY TOOK A HISTORY OF THE PATIENT AND AFTER A FEW MINUTES TOOK HIM BY AMBULANCE TO THE LOCAL HOSPITAL FOR ADDITIONAL OBSERVATION.
1360938	5/29/2021	FL	59	F	3/28/2021	3/28/2021	9 hours after the vaccination, I woke with seizure like sub-0 chills where I where I felt like I was lying in the snow without clothes on. Very hard shaking. Put on flannel pj's and wool socks, but could not get warm. The violent shaking lasted about 3 hours. Along with what felt like 12 migraines at the same time. My forehead was very hot, but that could have been from my hand being so cold. My thermometer battery was dead. The next morning, and for almost a week, I felt very lethargic as if I were watching myself from outside my body, hard to drive and focus, head felt like a giant bruise and I was incredibly tired. The tiredness has never gone away and I feel weaker every day here two (2) months later.
1361020	5/29/2021	MA	14	F	5/28/2021	5/28/2021	Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension-Medium, Systemic: Shakiness-Medium, Additional Details: pt passed out immediately after vaccination briefly, when she regained consciousness she convulsed for about 2 seconds, heart rate at 58, with weak pulse, called 911, pt taken to er as a precaution

<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>
1358387	5/28/2021	IN	48	F	5/28/2021	5/28/2021	<p>The patient let us know that she had had a seizure after the first COVID shot and that she has them after every vaccine. This has happened since she was a little girl. The patient was visibly nervous before the vaccine was administered. During her observation time following the vaccine administration, she let provider know that she could feel her left arm tightening up. Provider provided the patient with an ice pack for her neck to try to calm her down. The patient asked for us to not call a rapid response yet and that "I'm trying to calm myself down." observed the patient's left hand starting to grasp and the patient became tearful so asked the patient if she was okay. The patient stated she was okay. Provider asked her to let her know if she felt like she was going to have a seizure. About a minute later, the patient let provider know she felt one coming. Provider called the RRT as the clinic Team Lead, let the patient know she was going to recline her in the chair she had been vaccinated in. Seconds after the chair was reclined, the patient's eyes started to roll back in her head and her eyelids started to flutter. Within about 10 seconds, the patient was jerking up and down in the chair. The clinic staff ensured the patient was safe until the arrival of the RRT. As the RRT arrived, the patient's seizure ended. The patient became alert to talk to the team that arrived to the clinic. She refused being seen by the ED. The clinic staff agreed to monitor her vitals until she felt comfortable to leave. After around 30 minutes after the seizure, the patient was in good spirits and stated she would like to stand and see how she felt. The patient stood up and walked around for a moment before saying she was ready to leave. Provider checked the patient out, and she left the clinic.</p>

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1359717	5/28/2021	CO	32	M	4/23/2021	4/24/2021	Pfizer-BioNTech COVID-19 Vaccine EUA: one day after vaccination patient brought in by ambulance to emergency department (ED) for generalized tonic-clonic seizures. Patient experienced first seizure and treated, evaluated, and released from ED at another facility. Patient experienced another seizure at home and brought to this facility. Patient experienced a third seizure in the ED, antiepileptic medication was initiated, patient was admitted then discharged the next day stable on antiepileptic medication and follow-up in place. On subsequent follow-up visit with primary care patient reported no seizures but back pain. Found to have a thoracic compression fracture from seizures prior to hospital admission. On neurology follow-up continues to be seizure-free and compliant with antiepileptic medication. Diagnosed with focal epilepsy and will continue to be followed by outpatient neurology.
1359541	5/28/2021	TX	16	M	5/28/2021	5/28/2021	About 10 mins after shot, fainted with eyes rolling back in head, convulsions for a few seconds. Patient helped to lay on floor. Showed confusion for a few seconds and then came to. EMTs checked vitals and blood sugar levels and said things were normal. Visited urgent care facility a few hours later where physician said episode was likely vasovagal syncope.
1359298	5/28/2021	CO	25	M	5/28/2021	5/28/2021	After 2 minutes of vaccination, patient passed out and had an absent seizure. However, it lasted about 1 to 2 minutes, he was able to wake up by himself.

<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>
1359275	5/28/2021	CA	28	M	5/27/2021	5/27/2021	After administration, the patient sat in a chair for observation. 2-3 minutes after administration patient had a loss of consciousness, falling out of his chair onto the carpeted floor. Patient observed having seizure-like contractions of his upper extremities and slight arching of his back while having this loss of consciousness. LOC lasted less than 10 seconds. Patient was placed on his side, and when he regained consciousness could answer all questions appropriately and without delay. Patient was placed in a wheel chair and taken to a private observation area where vital signs could be attained. Patient again had a LOC while being wheeled in the wheel chair to the private observation area. Patient was placed on a gurney, supine. Vital signs taken and patient was found to have a heart rate in the 40s and a blood pressure of 90/66. Patient was ashen and diaphoretic. Patient was observed for 30 minutes in the private observation area where his condition improved to normal before leaving the facility.
1359272	5/28/2021	CA	39	M	5/18/2021	5/28/2021	PER PT - FAINTED, PER RPH SEEMS LIKE A SMALL SEIZURE FOR 3-5 MINUTES. CLIENT DID NOT RESPOND BUT WAS BREATHING THE WHOLE TIME - UNRESPONSIVE ON THE COUCH LAYING DOWN. RPH CONTINUE TO MONITOR BREATHING AND AFTER A FEW MINUTES THE PATIENT GAIN CONSCIOUSNESS. THE PATIENT BECAME FULLY AWARE OF LOCATION AND WHAT HAPPENED. STAFF CALLED 911 BUT WHEN THEY ARRIVED PATIENT REFUSED HELP.
1358746	5/28/2021	NJ	16	F	5/27/2021	5/27/2021	4-to-5-minute after administering the vaccine, pt start having a very short episode of seizure. It didn't last for more than 1 to 2 seconds. It was very quick that most of us didn't see it. Then pt laid down the pt down for few minutes. She felt fine and her mom took her home.
1358596	5/28/2021	NY	35	M	5/26/2021	5/27/2021	Patient suffered a seizure one day after receiving vaccine in prison.
1358560	5/28/2021		73	F	3/13/2021	3/16/2021	Patient was admitted with a breakthrough seizure episode. Although patient had history of seizures, admitting provider had concerns that breakthrough seizure may have occurred due to vaccine inflammatory response.

<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>
1359848	5/28/2021		39	U	4/23/2021	4/23/2021	Mild seizure type activity.
1357674	5/28/2021		62	F	5/20/2021	5/20/2021	Patient presented to vaccine clinic for second covid vaccine. Following first dose, patient had mild side effects in the observation area after the first dose of the covid, where she was observed in our reaction room area more closely, for feeling foggy and "just not right", however patient was fine to be able to be sent home. Patient was encouraged to contact physician to verify they should receive second covid vaccine. When patient was in observation area, after receiving her second covid vaccine shot, she told the observation nurse that she had a headache. The nurse immediately took her to our reaction room area and was closely observed. Patient was talking and acting fine. Within minutes, she started to have a seizure. Documentation in patient's chart regarding incident. Patient then transferred via ambulance to ED. Per EMS patient had 5-6 seizures requiring 4mg Ativan IM. Patient reports she has seizures, is seen by Neurology and takes Keppra and Depakote. On further documentation review, patient was seen by Neurology and was felt to not have seizures. She was also seen by psychiatry who noted that patient most likely has psychogenic nonepileptic seizure-like activity. Patient observed in the ED without further symptoms or episodes. Discharged to home.
1356535	5/28/2021	MA	37	F	4/10/2021	4/18/2021	Simple partial seizures started almost 8 days after 1st Moderna shot, and have continued ever since. I have grand-mal, and never simple partial. I'm taking antiseizure medicine, which was increased, but they continue. A low grade fever of 99.0, the highest was 99.4, for two weeks. Rashes, red, itchy and raised, on my wrists started after 2nd shot, alternating on and off. One time on my neck and onto face. Then a rash on my right upper arm, had stopped about 5 days ago. but today a new one on my wrist started. Pain in my arms on and off, and new pain started today in my left arm , before the rash started.

<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>
1357030	5/28/2021	NY		M		5/21/2021	SEIZURE (PASSED OUT); WEAK; This spontaneous report received from a consumer 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: Unknown) dose was not reported, administered on 21-MAY-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 21-May-2021, the patient got the vaccine and passed out, patient had 2 seizures. patient had not eaten much during day so patient might have been weak. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the seizure (passed out) and weak was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: covid-19 vaccine ad26.cov2.s-seizure (passed out). 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>
1357181	5/28/2021			F	1/29/2021	2/2/2021	has a feeling that she described as an "internal seizure" that is not noticeable to the eye but that she feels in the brain and head; tachycardia; without strength in her legs and arms; headache; anxiety; 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; lot/batch number unknown), via an unspecified route of administration on 29Jan2021 as 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 (PFIZER-BIONTECH COVID-19 VACCINE) on 08Jan2021 for COVID-19 immunization. On 02Feb2021 (four days later), the patient experienced without strength in her legs and arms in addition to experiencing a headache. She was diagnosed with anxiety and prescribed with Prozac, after a few days of treatment she was studied and got good results. She has managed to regain strength in her arms and legs exercising but still had a headache. During the evenings (unspecified date), she experienced tachycardia and had a feeling that she described as an "internal seizure" that was not noticeable to the eye but that she felt in the brain and head. Therapeutic measures were taken as a result of without strength in her legs and arms, headache, and anxiety. The outcome of the events without strength in her legs and arms and anxiety was recovering; the outcome of the event headache was not recovered; and the outcome of the other events was unknown. Information about lot/batch number cannot be obtained. Additional 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>
1357231	5/28/2021	AL		F			<p>seizure-like effects; tried to speak but her brain could not process it; difficulty in speaking; having slurred speech/more episodes with her tongue and slurred speech episodes; This is a spontaneous report from a contactable nurse (reported for herself). A 65-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on an unspecified date (lot number: not known) at 1st dose, single for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Caller is a 65-year-old retired nurse who took the 1st dose of the Pfizer COVID Vaccine. She experienced seizure-like effects after vaccination, in which she had difficulty in speaking, almost having slurred speech. She mentioned that she tried to speak but her brain could not process it. During the first onset, the medications prescribed to her seemed to not work, she had more episodes with her tongue and slurred speech episodes. She went from taking her medications once a day to now twice day, attributing to her regained ability to speak. She was recommended not to get the 2nd dose. She will be having an MRI and MRA and will follow up for 4 months. She is asking if this has been reported and if she should go get her 2nd dose. The outcome of all events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on chronological connection to the vaccine a causal relationship between reported events 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 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>
1357256	5/28/2021	IN	53	M	5/1/2021	5/1/2021	Seizures back to back to back/cause him to have more seizures; Wetting himself; This is a spontaneous report from a contactable consumer (patient's father). A 53-year-old male patient received bnt162b2 (BNT162B2 reported as PFIZER COVID-19 VACCINE), dose 2 via an unspecified route of administration on 01May2021 (Lot Number: EW0161; Expiration Date: 31Jul2021) as 2nd dose, single for covid-19 immunization (keep him alive and healthy). Medical history included ongoing sugar (diabetes) that was diagnosed with sugar 15 years ago (2005), heavy (overweight) been heavy for years. (biggest at 250 and is down to 236-238 now. It was stated that he lost weight before the shot and they do not know why), ongoing seizure all his life (he has had seizures all life), cholesterol (blood cholesterol abnormal), son that is special needs and high functioning and on vagus nerve apparatus. The patient received the first dose bnt162b2 (BNT162B2 reported as PFIZER COVID-19 VACCINE) via unknown site on 10Apr2021 (Lot number: EW0158) for Covid-19 immunization. Concomitant medication included unspecified medications for seizures and has a VMS (unspecified). The reporter stated that has a son that is special needs and high functioning. The father stated that he has had seizures all life, so he wanted to know if the shot cause him to have more seizures. The father mentioned that he is having seizures back to back to back and wetting himself. The father does not think this has anything to do with the shot, but his mom does. The reporter mentioned that the patient's mom looked online and saw something that stated it causes seizures. The reporter inquired if there were any reports of having seizures for special needs or anybody. He added that the patient had four seizures back to back in his sleep on May2021. The reported further stated that he has an apparatus that was put in his chest that slows the vagus nerve to seizure activity which he has had it since 2004. It was mentioned that that two weeks ago (May2021) when he was with his mom and last night that the seizures started in his sleep. He also was wetting himself which started two weeks ago (May2021) when he was with his mom. The reporter mentioned that he has blood work every 90 days (unknown date) for seizure medications and cholesterol but does not wish to provide (unknown). The father mentioned that the treatment included the patient taking

<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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his medication for his seizures as for the wets himself, he got cleaned up and puts fresh clothes on. The outcome of the event convulsions aggravated was recovered on May2021 while the outcome of the other event was recovered on 12May2021.; Sender's Comments: Based on available information the reported seizures and urinary incontinence are unrelated to bnt162b2. These are due to the patient's underlying seizure disorder. Case will be reassessed if additional information is received.

<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>
1357293	5/28/2021	NC	57	F	5/1/2021	5/4/2021	<p>passing out/sort of out of body-ish awareness; Patient had never had a seizure, but it felt more like that than a faint; Felt heavy in upper arms/chest; Felt heavy in upper arms/chest; feeling uncoordinated walking through house; felt out of body; felt pain in knees/pain in right knee; joints seizing/cracking really hard; abrasions on both of knees; Moderate damage to L mcl; Must have fallen; stinging spot in the back of head; This is a spontaneous report from a contactable consumer (patient). A 57-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EW0171) via an unspecified route of administration, administered in arm left on 01May2021 09:00 (at the age of 57-year-old) as single dose for COVID-19 immunization. Medical history included leukemia from 1998, breast cancer from 2001. No Known allergies. Concomitant medications were not reported. The patient previously received first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0164) on 10Apr2021 08:00 AM (at the age of 56-year-old) in left arm for Covid-19 immunization, then experienced adrenal disorder and epinephrine increased. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not receive any other medications within 2 weeks of vaccination. Patient woke up Tues, 04May2021 08:00 AM. Felt heavy in upper arms/chest. Started feeling uncoordinated walking through house. Didn't remember actually passing out but felt out of body and felt pain in knees, and joints seizing/cracking really hard. sort of aware something was happening, but sort of out of body-ish awareness. Came back to awareness. abrasions on both of knees, moderate damage to L mcl. pain in right knee. must have fallen but no awareness of that - came to laying on back. Patient had never had a seizure, but it felt more like that than a faint. Also noticed a stinging spot in the back of head that seemed to travel up the back of skull for several days. Treatment was not received for the adverse event. Reporter assessed events were non-serious. 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 event "passing out/sort of out of body-ish awareness" was recovered in May2021, of other events was unknown.</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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<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>
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

<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>
							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.
1357325	5/28/2021	MA		F	1/14/2021	3/30/2021	nasal PCR positive; nasal PCR positive; This is a spontaneous report received from a contactable Nurse and a contactable physician. This is the 5th of the 11 reports. A 28-year-old female patient received first dose and second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 24Dec2020 and 14Jan2021 separately, both at single dose for COVID-19 immunization. Medical history included ongoing seizures. Concomitant medication included ongoing lamotrigine (LAMICTAL) for seizure disorder. The patient had not been treated with immunomodulating or immunosuppressing medications or received any other vaccines around the time of COVID-19 vaccination. The patient had nasal PCR positive on both 30Mar2021 and 02Apr2021. The patient did not have SARS-CoV2 antibodies at diagnosis. The outcome of the events was resolved in 2021. Information on the 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 events of COVID-19 test positive and vaccination failure due to temporal relationship. Case will be re-assessed upon the additional information provided.,Linked Report(s) : US-PFIZER INC-2021389615 Same reporter/ drug/event, different patient

<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>
1357335	5/28/2021	PA	38	F	2/26/2021	3/3/2021	her blood level was 3.2 March 3rd, she was in the ICU; This is a spontaneous report from a contactable consumer (Patient's mother). A 38-year-old female patient received first dose of BNT162B2 (BNT162B2) via an unspecified route of administration, administered in Arm Right on 26Feb2021 (Batch/Lot Number: EN6205; Expiration Date: 30Jun2021) as 1ST DOSE, SINGLE for covid-19 immunization. Medical history included sickle cell disease from an unknown date, bone marrow transplant from 1993, stroke from an unknown date (when she was two and a half years old), paralysis (paralyzed on her left side by a stroke when she was two and a half years old), seizure and blood transfusion both from unknown dates. Concomitant medications included lamotrigine (LAMICTAL ODT) and pregabalin (LYRICA) both taken for seizure, start and stop dates were not reported. The patient experienced her blood level was 3.2 march 3rd, she was in the icu on 03Mar2021 and was hospitalized from 03Mar2021 to 13Mar2021. She says her daughter was admitted to the hospital during February and was discharged February 19th, and that day she got a blood transfusion, they gave her 3 units of blood for a sickle cell complication. Reporter says her daughter got the first dose of the Pfizer COVID-19 vaccine February 26th, and was supposed to get her second dose in March, but she she went back to the hospital because she had a bad crisis, her blood level was 3.2 March 3rd, she was in the ICU. She wants recommendation about getting her 2nd dose. Reporter stated, We don't feel comfortable that she doesn't have the 2nd dose. We just want to have the 2nd dose and be safe. She received her Pfizer covid vaccine on 26Feb2021 expiry 30Jun2021. Patient had a bone marrow transplant at age of 10; she's received so many blood transfusions, she has so many antibodies. She had a bone marrow transplant in 1993 when she was 10 years old, that was 28 years ago. Patient's age clarified to 38, and caller says her daughter is not a baby, they would like to know what should they do, should they go ahead and have her get the second dose of the Pfizer COVID-19 vaccine. Reporter says her daughter is paralyzed on one side from a stroke she had when she was a kid. Clarifies that her daughter had been discharged from the hospital before she got the vaccine, she was discharged February 19th, then got her first

<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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dose February 26th. She says on March 3rd her daughter was back in the hospital in the ICU for four days, then was in the hospital from March 3rd to the 13th. She says she received 3 more blood transfusions or 3 units of blood. She says because of that, she has not done her second dose. Reporter says her daughter takes Lamictal on a regular basis, and Lyrica, she has been taking it more than 20 years for seizures, but her seizures stopped and went away completely, so the medication is controlling it, it is not often she has them, she takes those two meds for seizures. She says something about her daughter taking Psyllium seeds, no further details provided about this. She says her daughter gets the flu shot every year and does ok. No further details provided about unspecified flu shots. Reporter added her daughter has sickle cell, sometimes she sees her doctor every 3 months and when her blood level is low she gets transfusions, and when it doesn't get caught that it is getting low she ends up in the hospital and they do transfusions anyway. She says in the beginning she did a bone marrow transplant when she was 10 years old, and then later her left side was paralyzed when she was two and a half. She says her daughter lives a very normal life until her blood is low, which happens a lot of times when she has her period, then that one goes out, and then she goes back to herself, with her sickle cell. The patient underwent lab tests and procedures which included blood count: 3.2 on 03Mar2021. Outcome of the event was unknown. Follow up attempts are completed. 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>
1357336	5/28/2021	UT	68	M	3/18/2021	3/20/2021	Grand mal seizure; Neurological problems; could not talk; he knew the answer but he could not verbalize the answer; Massive migraines; anxious he starts stuttering; anxious he starts stuttering; This is a spontaneous report from a contactable consumer. A 68-year-old male consumer received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Batch/Lot number: EN6204, Expiry date: 30Jun2021) via an unspecified route of administration on left arm on 18Mar2021 14:40 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient never had seizures until after taking the COVID vaccine. There was no History of all previous immunization with the Pfizer vaccine considered as suspect. The patient was not administered with any other additional vaccines but was taking vaccinations for the flu, pneumonia, and everything his whole life and has never had reaction to any one of them. The patient had not received any prior vaccinations within 4 weeks. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Batch/Lot number: EM9809, Expiry date: 30Jun2021) via an unspecified route of administration into the left arm on 25Feb2021 as single dose for COVID-19 immunisation. On 20Mar2021, the patient stated that the problem was that he started developing neurological problems where he could not talk for about two days after he got the second shot. He stated his wife did not notice the symptoms and the work he does 99% of the time, he does not have to talk to anyone. But the problem was, the last day he worked which was over two weeks ago, he almost jeopardized two major accounts because he did not realize what he was saying. He spent a week in the intensive care unit (ICU) and had lost over two weeks of work well actually closer to three weeks. The patient was barely getting back to the point of feeling normal and he could not tell about all of the neurologists he had talked to but it had been at least four and he had to go see his personal neurologist now. He Stated that he had to be put on medication and was in the intensive care unit for over a week and the reason was is because he had to be put on medication to stop the seizures. He stated he has to take medication for the rest of his life and also had a hospital stay in the intensive care unit and

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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this continued until he went to the intensive care unit and was transported by ambulance on Tuesday 04May2021. He could not talk when someone asked him a question, he knew the answer, he could sit there and hear someone but he could not verbalize the answer, this stopped and was taking medication that stopped it. But on 04May2021, he had a grand mal seizure and his wife called 911 and he was taken to the hospital and then transferred to the ICU for a week. The event Grand mal seizure resulted in hospitalization and was in hospital from 4May2021 to 11May2021. He stated he had to be put on medication to stop the seizures. He had some more grand mal seizures in the hospital. He stated that he was taken to Hospital where he was in the emergency room from 9 o'clock to 2:30 in the morning and then was transferred to Hospital where he was admitted to the intensive care unit. He does not have these anymore but he was not sure exactly when his last one was but he was in the hospital. On 20Mar2021, he also has had massive migraines a couple of times a day (two times a day) and then he got to the point that if he got anxious he started stuttering. He stated the symptoms started about two days after the second shot, so suspect product was the second dose. The patient took the COVID 19 shot because they said he needed to. The events resulted in Emergency Room visit and Physician Office. There was no relevant laboratory tests reported. The treatment included that he confirmed that he was given medication in the hospital for his symptoms and was taking medication at home. The outcome of the events Neurological problems, could not talk was unknown. The event Grand mal seizure was recovered on an unspecified date in May 2021, While other events Massive migraines, anxious he starts stuttering was not recovered/Not resolved. Information on Lot/Batch number was available. Additional 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>
1357358	5/28/2021	AR	39	F	12/31/2020	1/21/2021	<p>pancytopenia; viral sepsis; fever/ running high fever; stomach upset; arm pain; headache; more tired; never felt quite right/ feeling generally unwell; elevated inflammatory markers like Ddimer; This is a spontaneous report from a contactable nurse(patient). This 39-year-old female patient (not pregnant) received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK9231) at single dose on 31Dec2021 10:00 via an unknown route in right arm for Covid-19 immunization. Medical history included SLE and seizures. Prior to vaccination, the patient was diagnosed with COVID-19. Past drug history included tramadol hydrochloride (ULTRAM). 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 included levetiracetam (KEPPRA), aciclovir (ACYCLOVIR), azathioprine (IMURAN), cefixime (FLEXERIL), methenamine mandelate, methionine (G), hydroxychloroquine sulfate (PLAQUENIL). After immunization on 21Apr2021 16:00, patient had the stated reactions of fever, stomach upset, arm pain, and headache for 2-3days. But then she seemed to stay more tired and never felt quite right. 2 days before her second dose she started running high fever and feeling generally unwell. Covid and flu test were negative. Urgent care ran a CBC and it showed pancytopenia. She was sent to the hospital and admitted for 9 days with what appeared to be viral sepsis, elevated inflammatory markers like Ddimer, and pancytopenia of unknown origin. It took almost 7 weeks to get back to some kind of normal functioning. Patient ran fevers for 18 days. The doctors did not feel like the viruses, lupus, or medications alone could explain the illness that she had and worried that the vaccine was a catalyst to all the rest of the events. She showed positive IGG immunity but now she did not. IGM/IGG on an unknown date was negative. The adverse event result in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Outcome of the events was resolving. The report was assessed as serious with seriousness criteria of historization and lie-threatening. Follow-up attempts are needed. Further information is expected.</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>
1357445	5/28/2021	PA	59	F	3/21/2021		SEIZURE; SLURRED SPEECH; LEG PAIN; HEADACHE; SORE ARM; FEEL WEIRD (NOT HERSELF); This spontaneous report received from a patient concerned a 59 year old white and not Hispanic or Latino female. The patient's height, and weight were not reported. The patient's concurrent conditions included hypothyroid. The patient did not do drugs. 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, 1 total, administered on 20-MAR-2021 to right arm for prophylactic vaccination. No concomitant medications were reported. On 21-MAR-2021, the patient experienced sore arm the next day after receiving vaccine. On 22-MAR-2021, The patient had headache the following week that did not go away for about 5-7 days and nothing was relieving the pain. On 24-MAR-2021, the patient experienced leg pain and thought it was arthritis but she had never had leg pain like that before and her legs were really hurting. On 04-APR-2021, Sunday the patient was still feeling it. The next day woke up fine but still had leg pain and decided to take a hot bath and she really started to feel weird (not herself) and she was talking to the delivery woman and she was slurring her words (she did not do drugs) and was a healthy person. The patient laid down and her fiancé wanted to take her to the hospital. The patient's mom came over and she wanted to show her a new fridge and called it a fire place. 911 were called and the patient was taken to the hospital and admitted with seizure for 5 days. The patient had the seizure 15 days after the JnJ vaccine on 05-APR-2021, in the afternoon. The patient underwent 2 Magnetic resonance imaging (MRI) and a bunch of tests, computed tomography scan (CAT scan), electroencephalogram (EEG). No MD could claim this was from the JnJ vaccine. It was reported that the patient never had a seizure before in her life. A colleague told the patient that she read an article that said that she could have seizures and she was hypothyroid and thought that it a contraindication to the vaccine. The patient was admitted for 5 days and all tests came back normal. The patient was having speech issues but they were improving. The patient's mobility was fine and eye function was fine. The patient missed a lot of work. The patient had follow up with neuro in a month and would

<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>
							see another neuro and pen medicine and it was an ongoing situation. This was to make sure that everything was okay. Laboratory data (dates unspecified) included: CAT scan (NR: not provided) Normal, EEG (NR: not provided) Normal, and MRI (NR: not provided) Normal. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from seizure, leg pain, and headache on 2021, and sore arm, was recovering from slurred speech, and the outcome of feel weird (not herself) was not reported. This report was serious (Hospitalization Caused/Prolonged).; Sender's Comments: V0-20210552079-covid-19 vaccine ad26.cov2.s -Seizure- This 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.
1357640	5/28/2021	NV	26	F	5/27/2021	5/27/2021	Systemic: Nausea-Mild, Systemic: Seizure-Mild, Systemic: Vomiting-Mild, Additional Details: After Janssen vaccine shot given to patient.Patient lowered her face and body to our blood machine monitor and appear to experienced partial seizure with mild symptoms. Called 911. Patient was assessed her side effects and she told them that she had history of epilepsy and haven't had an episode for at least a year. Provide water to her and also garbage bin next to her due to Patient being nausea. Paramedics arrived about 3 minutes after they were called.
1358553	5/28/2021	AZ	41	F	4/27/2021	4/27/2021	04/27/2021-Headache,Fever, Chills, N/V Diarrhea. 4/29/2021- Hospital ED: Witnessed seizure while in ED. Fever, Chills Headache.

<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>
1358145	5/28/2021	PA	26	F	5/20/2021	5/20/2021	<p>Immediate numbness following injection. Later that evening ~7:00 p.m. joints and muscles in left arm/shoulder curled and seized-up. Tingling pins and needles with loss of sensation and dexterity. At bed time May 20th - continued pain, stiffness and swelling accompanied by high fever, chills, excessive sweating, and muscle convulsions. Intense ringing in ears. Next morning (May 21st) I had to miss work. Continued fever, chills, loss of appetite, mild nausea, nerve spasms and locked joints throughout entire body. I felt as though my body was poisoned. The weekend consisted of major fatigue and falling asleep during the day intermittently. Numb arms, weakened grip - could barely make a fist, and had a loss of coordination. Brain fog, delayed thoughts and physical responses. CONTINUED MUSCLE WEAKNESS AND NERVE SPASMS. I contacted doctor for help since my PCP's office was not open until Monday. I began taking Magnesium and B vitamins. I was drinking 1.5 gallons of water daily and still feeling thirsty. Called Doctor on the 24th to report involuntary muscle spasms in neck shoulders and lower back, joint stiffness, numbness, slowed circulation (pins and needles), and a vertigo-like falling sensation at bedtime. Cannot get to sleep comfortably without the spasms and my head rolling. He recommended Benadryl and Tylenol which I began taking which helped the numbness but not the shakiness and nerve spasms. He also offered a muscle relaxer, but I was concerned about waking up and driving to work in the early mornings so I declined since having trouble waking up with all the fatigue. It didn't matter anyway because since then I have missed work due to the sudden weakness, head fog, indigestion, and nerve tremors. Wednesday, I needed assistance going up and down stairs because my limbs felt limp like rubber bands. My joints are unusually cracking while my breathing is more labored. My resting heart rate was elevated and I could feel it beating harder than normal. Thursday, I drove myself to the E.R. because I feel as if I have aged 30 years in under a week. Their blood tests, EKG, and x-rays found nothing abnormal and I received fluids through an IV. However my nervous system feels absolutely shot. THIS IS NOT NORMAL. I WAS INCREDIBLY HEALTHY BEFORE THE SHOT. I WAS NOT INFORMED OF THESE RISKS. I LIVE A CLEAN, ACTIVE LIFESTYLE WITH REGULAR</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>
1357237	5/28/2021	MN	57	M	5/11/2021	5/11/2021	<p>DIET AND EXERCISE. I HAVE NEVER NOT BEEN ABLE TO ARTICULATE MY BODY MOVEMENTS FLUIDLY AND PRECISELY. my doctor suspected I previously had an asymptomatic case of Covid, and that I had an allergic reaction directly related to the vaccine that attacked my nervous system. I FEEL SO MISERABLE AND WRONG. I worry about my quality of life from here on out even though I'm told these symptoms will pass. Today, over a week post my first shot, I have loss of sensation in my arms, tingling in my extremities and base of skull, neck, and lower back (worse at night and when resting). My nerves are still randomly firing and I feel shaky. My body feels as if it has slowed down its automatic functions.</p> <p>body aches; chills; headache; dizziness; goes from being cold and hot; passing out a few times; shaking similar to seizure/eyes kind of glazed; This is a spontaneous report from a contactable consumer (patient's wife) reported that a 57-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19, lot number: EW0182), via an unspecified route of administration, administered in arm left on 11May2021 08:00 (at the age of 57-years-old) as 2nd dose, single dose for covid-19 immunisation. The vaccine was administered at the Pharmacy/drugstore. The patient medical history included covid before, he had a bad case of it from Nov2020. The patient previously received BNT162B2 (PFIZER-BIONTECH COVID-19, lot number was not reported) on 20Apr2021 (at the age of 57-years-old) as 1st dose, single dose for covid-19 immunisation, and experienced all of the same symptoms (body aches, chills, goes from being cold and hot, headache and dizziness) but he did not pass out. The patient always gets the flu vaccine. The patient's concomitant medications were not reported. On 11May2021 15:15, the patient experienced passing out a few times, eyes kind of glazed, and shaking similar to seizure; and at 19:00, the patient body pain, chills, headache, dizziness and goes from being cold and hot. The outcome of the events was unknown.</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>
1358381	5/28/2021	MA	22	M	5/28/2021	5/28/2021	Patient seemed to be having a seizure within minutes of vaccine. Head tilted back, arms started shaking in patients lap, Patient was unresponsive and seemed to stop breathing momentarily. Patient seemed to recover within 5 minutes and was able to answer paramedic questions once they arrived. Declined further treatment or to go to hospital
1358299	5/28/2021	NJ	32	F	5/27/2021	5/27/2021	Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Systemic: Seizure-Mild, Systemic: Vomiting-Mild, Additional Details: PATIENT STARTED FELLING DIZZY SOON AFTER THE VACCINE. KEPT LOOSING CONSIIOUSNESS. STARTED THROWING UP SOON AFTER.
1358298	5/28/2021	VA	16	M	5/26/2021	5/27/2021	My son had a mild seizure that lasted 1 - 2 minutes. He has never had a seizure before. He then vomited a few minutes after the seizure.
1358197	5/28/2021	MI	45	M	5/28/2021		Approximately 5 minutes after administering the vaccine, he was waiting in his car with a friend, He became unresponsive and appeared to have lost consciousness. Upon arrival to the vehicle he looked to be having a seizure. Did not respond to verbal commands but did respond to sternal rub. EMS called. BP 118/58 and pulse 60. He was diaphoretic and pale. EMS arrived and during their interview he had another more intense and longer seizure. Transported to the Emergency Room.
1357649	5/28/2021	TX	20	M	5/21/2021	5/21/2021	Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Seizure-Medium, Systemic: Vomiting-Severe
1358155	5/28/2021	ID	22	F	2/4/2021	3/2/2021	WITHIN 28 DAYS OF MY LAST VACCINATION I STARTED HAVING EPISODES OF PASSING OUT AND HAVING SEIZURES. I HAVE HAD SEIZURES NOW EVERY DAY SINCE THE BEGINNING OF MARCH. NOTHING HAS CHANGED IN MY LIFE BESIDES GETTING THIS VACCINATION.

<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>
1357666	5/28/2021	TX	20	M	5/17/2021	5/17/2021	Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Additional Details: While sitting on the chair, patient fainted and started to have seizure for 1-2 second then recovered completely by himself. Called 911 but patient did not want to have any medical attention. After that, patient sit for more than 30 minutes before going home.
1358138	5/28/2021	IA	13	F	5/28/2021	5/28/2021	RN reported that patient became flaccid after her vaccination, then became rigid, crossed her legs, and lightly slammed her head back against the wall. He reports that she fainted but had some seizure-type activity, but minimalized. She was monitored by both RN and myself. She was lowered to the floor to lay on the floor, was fanned, and her BP and pulse were monitored by RN. She was accompanied by her mother, and her mother declined having EMS contacted. Once patient regained consciousness, she was alert, laughed and talked to us, and regained a sitting position. We then gave her cold water to drink, and she was able to get up into a chair. After sitting for several minutes, she was able to walk out of the room and into one of our monitoring cubicles for an extended monitoring timeframe. We kept her here for 30 minutes for further observation, then left accompanied by her mother. Due to RN's report of the seizure-type activity, mom is going to contact patient's pediatrician to see if further treatment is needed.
1358056	5/28/2021		47	M	4/17/2021	4/18/2021	Seizure, resolved
1358015	5/28/2021	CA	18	M	4/26/2021	4/26/2021	Adverse event reported by patient's mother. Patient with severe autism disorder and partial complex epilepsy disorder. Patient had a breakthrough seizure about 3 hours after first moderna vaccination. Seizure lasted approximately 3 minutes per mother, who is his caretaker. Patient recovered to baseline after the seizure. Unknown if any medications were given. Mother did not have the patient evaluated in a clinic or ER after the event. Adverse event was not known until patient presented for the second vaccination, at which point, second vaccination was delayed.
1357895	5/28/2021	NC	54	M	5/27/2021	5/28/2021	SEIZURE MEMORY LOSS IN COHERENT

<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>
1357775	5/28/2021	TX	18	F	5/27/2021	5/27/2021	patient states she had a seizure
1358513	5/28/2021	NY	17	F	5/18/2021	5/19/2021	She had been bleeding since May 2. We took her to Hospital Pediatric ER on Thursday, the ambulance took her in because she had a seizure on Wednesday (the Ambulance - they stabilized her that day and took her vitals and was sure she was okay - they knew we had an appt to go in the next day at 10:00 am for tests (previously scheduled); Thursday morning she had another seizure - we gave her seizure meds and she came out that - she ate breakfast after and then took her regular meds and the next thing we know ,50 minutes later, her head drop forward and her arms go completely limp and there was no response. She was breathing but she was out. I called the ambulance. And they took her in to ER. What they put in the paperwork was that she had a seizure and they wrote that she had had syncope episode - it took 20 minutes to come out of it. Which she has never had anything like that. We were in the ER for 7 hours. Was admitted to Hospital -from 24th -28th.
1358173	5/28/2021	OR	42	F	5/26/2021	5/26/2021	Pt reports probable seizure during sleep on night of 5/26/21-woke up in morning in "wet bed" due to urinary incontinence, one of the signs that she has had a seizure. States seizures usually only occur about once a year and can't remember when last seizure was but probably over a year ago. Also had right foot pain, possibly due to trying to get out of bed during night, no other sx.

<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>
1357196	5/28/2021	OR	25	F	5/12/2021	5/12/2021	Lose consciousness and faint as well as began to have a seizure; Lose consciousness and faint as well as began to have a seizure; Lose consciousness and faint as well as began to have a seizure; Vitals were not great, faint pulse, dilated pupils; Vitals were not great, faint pulse, dilated pupils; Vitals were not great, faint pulse, dilated pupils; This is a spontaneous report from a contactable consumer (patient). A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration, administered in right arm on 12May2021 09:45 (Batch/Lot Number: EW0182) (at the age of 25 years old) as 1st dose, single for COVID-19 immunization. The patient was not pregnant at the time of vaccination. The patient medical history included COVID-19. Concomitant medication included lithium taken for an unspecified indication, start and stop date were not reported. The patient previously took amoxicillin and had allergies. Facility where the most recent COVID-19 vaccine was administered was in Pharmacy or Drug Store. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 12May2021 10:00, the patient experienced lose consciousness and faint as well as began to have a seizure, vitals were not great, faint pulse and dilated pupils. After vaccine administration, patient began to lose consciousness and faint as well as began to have a seizure. EMT's were called vitals were not great, faint pulse and dilated pupils. The adverse event result in Emergency room/department or urgent care. Treatment received for the adverse event included ambulance ride, EMT's (as reported). The patient was recovering with lasting effects. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was recovered with sequelae on unspecified date.
1355247	5/27/2021	DC	27	M	5/27/2021	5/27/2021	Employee have a history of a seizure disorder received vaccine 1030 seizure started at 1047

<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>
1354695	5/27/2021	OH	19	M	5/27/2021	5/27/2021	Patient passed out within 45 seconds of vaccine, convulsed for 5 secs while unconscious. woke up with in a minute, vomited after 3 minutes. He was able to say his name and address. BP 116/69 Pulse 68. patient said that this has happened before after an unknown booster at age 17. Only ate french fries earlier today. Was able to stand after 5 minutes. Put cool paper towel on neck, ate fruit bar and drank water before leaving
1354774	5/27/2021	MA	26	M	5/27/2021	5/27/2021	9:05am pt had just received 1st dose Pfizer vaccine and lost consciousness at the table with seizure like activity. Pt was lowered to floor with assistance of several staff members. Pt very diaphoretic with decrease in skin color. Didn't hit head. Pt mother called per pt request and states him having no hx of seizures and NKA. BP 94/60 and HR 84. 9:20 am pt assisted to stretcher with heavy assist. 9:24am A&O when EMS unit arrived to transport pt to hospital for further evaluation and care.
1354900	5/27/2021	CT	22	M	5/13/2021	5/15/2021	patient with hx of epilepsy controlled, no seizures since 2018 on Depakote and lamictal, after second dose of Moderna vaccine two days later has had 7 seizures in one week. No other obvious seizure trigger.
1354915	5/27/2021		25	M	5/27/2021	5/27/2021	Seizure
1355109	5/27/2021	MI	25	F	5/5/2021	5/6/2021	High heart rate, fainting, convulsing or seizure, vomiting
1356081	5/27/2021		27	F	5/19/2021	5/23/2021	Loss of consciousness, seizure and urinary incontinence during seizure

<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>
1355174	5/27/2021	CA	51	M	5/7/2021	5/20/2021	<p>On 5/20/21 the patient was at home with his mother when he had acute nausea, light-headedness, and abdominal pain. He presented to the ED by ambulance. Excerpt from ED notes of MD follows: "Initial ED interventions: iv fluids, low dose iv ativan, iv toradol, iv zofran. ED course: patient arrives very anxious, writhing on bed, difficult to redirect. With chronic tonicities, not seizing. Mother arrives, and he recognizes her, seems to be consoled somewhat by her presence, but she is unable to direct him, and describes his behavior as irregular, and events acute this evening at her home. Patient rests, and then HR decrease to 50s on monitor and patient found to be pulseless - I immediately start chest compressions, and achieve ROSC after PEA arrest with administration of EPI/compressions. Patient intubated per procedure note without complication. L femoral central attained per procedure note without complication. CPR performed over ED course intermittently (always PEA arrest) with ROSC achieved with administration of EPI, EPI drip started in addition to sedation meds, and iv fluids. No obvious STEMI on ECG to administer lytics, with suspicion of dissection and AAA prominent. I am able to stabilize and accompany patient to CT suite, where I recognize B/L massive PE immediately. I discuss with Dr. of Cardiology, who agrees with administration of alteplase. I discuss risks with mother who consents verbally. Patient without response to alteplase, and with continued pattern of PEA arrest following bradycardia. I discuss etiology of presentation with mother, and that patient is with very poor prognosis of survival, and likely poorer prognosis of neurological status, and patient is made comfort care, and fentanyl drip increased, patient is taken off of ventilation and drips. Pronounced deceased at 22:00. MDM: Initial concern for but not limited to appendicitis, AAA, diverticulitis, renal stones, pyelonephritis, musculoskeletal pain, pancreatitis, toxic ingestion, ACS, obstruction, perforation, sepsis (2/2 PNA, UTI, meningitis, intra-abdominal infection), AAA, dissection, PE - as ED course progresses, differential narrows and consider more likely PEA arrest secondary to ACS, PE, dissection, AAA, necrotic pancreatitis, tension PNX (less likely). Considered but do not suspect seizures, stroke. Imaging studies reviewed - CXR with ETT in place, no acute pathology. CTA chest/A/P remarkable for massive</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>
							proximal B/L PE. Labs reviewed. ECGs without STEMI, with sinus tach initially, LBBB after initial ROSC, and then AFib in RVR on subsequent ECG. Per above, patient suffered massive B/L PE, with subsequent cardiac arrest, despite heroic efforts including thrombolysis. Death called at 22:00. Diagnosis: massive B/L PEs, PEA arrest. Disposition: deceased.~~
1354558	5/27/2021	PA	35	M	3/29/2021	4/1/2021	seizure at 3:30 in the morning. Partner discovered seizure activity awoken from sleeping. Last seizure activity was 2 years prior to event. No change in medications prior to immunization.

<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>
1355310	5/27/2021	SC	45	F	5/17/2021	5/17/2021	This is a 45-year-old female with past medical history of multiple sclerosis, hypothyroidism, pseudoseizures, conversion disorder, who presents to the emergency department from COVID-19 vaccination clinic after having a reported allergic reaction and seizure-like activity. She presents by EMS who reports that she was given intramuscular epinephrine as well as IV Benadryl for her symptoms. EMS reports that they saw generalized convulsive activity while the patient was alert and oriented, he reports this as "pseudoseizure-like activity". She was receiving her second dose of the COVID-19 vaccination today, she reports that she immediately thereafter got a rash to her torso and became short of breath. She was feeling well prior to the vaccination. She denies any other recent acute illnesses including fevers, chills, nausea, vomiting, diarrhea, chest pain. She says that she is currently undergoing a relapse of her multiple sclerosis and has been wheelchair-bound for 1 month. This is a 45-year-old female with past medical history of multiple sclerosis, hypothyroidism, pseudoseizures, conversion disorder, who presents to the emergency department from COVID-19 vaccination clinic after having a reported allergic reaction and seizure-like activity. She presents by EMS who reports that she was given intramuscular epinephrine as well as IV Benadryl for her symptoms. EMS reports that they saw generalized convulsive activity while the patient was alert and oriented, he reports this as "pseudoseizure-like activity". She was receiving her second dose of the COVID-19 vaccination today, she reports that she immediately thereafter got a rash to her torso and became short of breath. She was feeling well prior to the vaccination. She denies any other recent acute illnesses including fevers, chills, nausea, vomiting, diarrhea, chest pain. She says that she is currently undergoing a relapse of her multiple sclerosis and has been wheelchair-bound for 1 month.
1355373	5/27/2021	MA	13	M	5/15/2021	5/17/2021	Patient had a syncopal episode with complete LOC and question of seizure activity. Was found to be tachycardic, BP within normal range.

<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>
1355390	5/27/2021	IL	15	F	5/26/2021	5/26/2021	Pt came in to pharmacy with her mom for her 1st dose Pfizer vaccine appointment at 2pm on 5/26/21. We checked her in and (pharmacist) gave her shot with her mom present at 2 10pm and she was fine with no issues. Within 2 minutes in of her observation period, she started fainting and having seizure like for about 10 seconds, and regained conscious and said she felt dizzy and then blacked out. She was pale and sweating and asked for water. Our shift lead happened to be closed by her chair where she was sitting so she prevented pt from falling down from the chair and called pharmacist for help from inside the pharmacy. Pharmacist rushed to the patient and asked shift lead to call 911. Pt was consious, but lethargic, she could breath normally, no sign of obstruction airway. Pharmacist lift her legs up to opposite chair and started to take BP. Paramedic arrived within minutes and took her vitals which was normal. Mom agreed for paramedic took her out in stretcher to hospital for check up.
1355527	5/27/2021	OR	40	F	5/27/2021	5/27/2021	After receiving vaccination, patient was reported to have fainted, with a potential seizure, and fallen over resulting in injury to head and laceration to forehead. Pharmacist was notified in which patient was immediately placed in laying position with elevation to her head and support to neck. Patient reported nausea, confusion, attempted to vomit without success. Patient was able to report name when prompted. 911 was called, fire service and ambulatory service arrived for further assessment. Patient was deemed safe without necessity of going to emergency room.
1356063	5/27/2021	WI	31	F	5/27/2021	5/27/2021	immediately had a seizure within a few minutes after the injection (~5mins). seizure lasted approximately 1 minute and was witnessed by the patient's long-term partner.
1355166	5/27/2021	VA	31	F	5/26/2021	5/26/2021	Systemic: Patient fainted 2 times due to feeling dizzy and on one occasion for 5-8 seconds was shaking like a mini seizure. EMS came and cleared her, she refused the trip to hospital-Medium, Systemic: Seizure-Mild, Additional Details: As described above

<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>
1354165	5/27/2021	NY	21	F	5/26/2021	5/26/2021	Patient apparently passed out while waiting after receiving vaccine. She was sitting in a chair and fell over to her right side. She appears to have had a petit mal seizure. Her pupils were very dilated and it took her several minutes to become fully responsive, although she was unresponsive for just a short period of time. She is a student and the EMS staff who responded to the 911 call reports that she is well known to them, as she has a history of "pseudo-seizures". Patient's BP was 138/84 and SPO2 was 98%. Pt was transported to ED around noon, and was back to the clinic by 1:15 to collect her eyeglasses that had been left where she was sitting.

<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>
1353070	5/27/2021	FL	33	F	4/13/2021	5/11/2021	<p>Body went on involuntary convulsion; Felt like her brain was swollen; Feeling dizzy; Disoriented; Arm hurting very bad; Pouring out cold sweat; Extremely cold; Teeth chattering/Shivering; Body was shaking; Symptoms were worse; Fever with temperature of 104; Severe head pain; Severe muscle aches; This spontaneous case was reported by a patient and describes the occurrence of SEIZURE (Body went on involuntary convulsion) and BRAIN OEDEMA (Felt like her brain was swollen) in a 33-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 046B21A and 007B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 13-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-May-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 11-May-2021, the patient experienced SEIZURE (Body went on involuntary convulsion) (seriousness criterion medically significant), BRAIN OEDEMA (Felt like her brain was swollen) (seriousness criterion medically significant), DIZZINESS (Feeling dizzy), DISORIENTATION (Disoriented), PAIN IN EXTREMITY (Arm hurting very bad), COLD SWEAT (Pouring out cold sweat), FEELING COLD (Extremely cold), CHILLS (Teeth chattering/Shivering), TREMOR (Body was shaking), CONDITION AGGRAVATED (Symptoms were worse), PYREXIA (Fever with temperature of 104), HEADACHE (Severe head pain) and MYALGIA (Severe muscle aches). At the time of the report, SEIZURE (Body went on involuntary convulsion), BRAIN OEDEMA (Felt like her brain was swollen), DIZZINESS (Feeling dizzy), DISORIENTATION (Disoriented), PAIN IN EXTREMITY (Arm hurting very bad), COLD SWEAT (Pouring out cold sweat), FEELING COLD (Extremely cold), CHILLS (Teeth chattering/Shivering), TREMOR (Body was shaking), CONDITION AGGRAVATED (Symptoms were worse), PYREXIA (Fever with temperature of 104), HEADACHE (Severe head pain) and MYALGIA (Severe muscle aches) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Body temperature: 104 (High) fever. Reporter called on 12-May-2021 to</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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report feeling dizzy, disoriented, her arm hurting very bad, severe muscle ache, shivering, pouring out cold sweat, she was extremely cold, had fever with temperature of 104, her body went on involuntary convulsion, her teeth chattering, her body was shaking, she had severe head pain and she felt like her brain was swollen. The symptoms started 11-May-2021 after she received her second Moderna COVID-19 vaccine on 11-May-2021 around 9am in the morning. Symptoms were worse around 10 pm evening. She took Tylenol but it did not help. She said the symptoms were still ongoing, but it was fading. She received the second vaccine in her left upper arm with vaccine lot 046B21A. She received the first vaccine on 13April 2021 in her left upper arm with vaccine lot 007B21A. She did not have a doctor. Treatment medication included: Tylenol. 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.

<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>
1353115	5/27/2021	IN	28	M	3/24/2021	4/24/2021	I passed out and then I hit my head on floor and chin; Hit my head on floor and chin; I hurt my neck and put neck braces on me in hospital; My wife jumped up and came to me and put me up on floor and heard gargling noise; I have 2 provoked seizures from Moderna shot; Doctors found every thing normal in result except sinus; I woke up with slight headache; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (I passed out and then I hit my head on floor and chin), HEAD INJURY (Hit my head on floor and chin), NECK INJURY (I hurt my neck and put neck braces on me in hospital), GASTROINTESTINAL SOUNDS ABNORMAL (My wife jumped up and came to me and put me up on floor and heard gargling noise) and SEIZURE (I have 2 provoked seizures from Moderna shot) in a 28-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 043B21A and 040A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 24-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Apr-2021 at 5:30 PM, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 24-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (I passed out and then I hit my head on floor and chin) (seriousness criteria hospitalization and medically significant), HEAD INJURY (Hit my head on floor and chin) (seriousness criterion hospitalization), NECK INJURY (I hurt my neck and put neck braces on me in hospital) (seriousness criterion hospitalization), GASTROINTESTINAL SOUNDS ABNORMAL (My wife jumped up and came to me and put me up on floor and heard gargling noise) (seriousness criterion hospitalization) and HEADACHE (I woke up with slight headache). On an unknown date, the patient experienced SEIZURE (I have 2 provoked seizures from Moderna shot) (seriousness criterion medically significant) and SINUS DISORDER (Doctors found every thing normal in result except sinus). The patient was hospitalized on 24-Apr-2021 due to GASTROINTESTINAL SOUNDS ABNORMAL, HEAD INJURY, LOSS OF CONSCIOUSNESS and NECK

<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>
							INJURY. At the time of the report, LOSS OF CONSCIOUSNESS (I passed out and then I hit my head on floor and chin), HEAD INJURY (Hit my head on floor and chin), NECK INJURY (I hurt my neck and put neck braces on me in hospital), GASTROINTESTINAL SOUNDS ABNORMAL (My wife jumped up and came to me and put me up on floor and heard gargling noise), SEIZURE (I have 2 provoked seizures from Moderna shot), SINUS DISORDER (Doctors found every thing normal in result except sinus) and HEADACHE (I woke up with slight headache) outcome was unknown. Concomitant medication use was not reported. It was reported that the patient was not taking any medication on regular basis. The patient reported that they did bunch of tests like CAT scan, EEG test, they monitor my heart for 30 days. Results were not reported. For treatment the patient reported they gave him IV and seizure medication which he was not taking right now. 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.
1353295	5/27/2021	TX	36	M	2/24/2021	2/24/2021	Sinus; Shoulder pain; This is a spontaneous report from a contactable consumer (Patient). A 36-year-old male patient received BNT162B2, dose 1 via unknown route in left arm on 24Feb2021 at 10:00 AM (at the age of 36 years old) at single dose for covid-19 immunization. The patient medical history included seizure disorder and had known allergies: penicillin. Concomitant medications were not reported. Patient had other unspecified medications in two weeks. There was no other vaccine in four weeks. The patient experienced sinus and shoulder pain on 24Feb2021 at 03:00 PM. AEs was not resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care. No Covid prior vaccination and no Covid tested post vaccination. No treatment for the AEs. The outcome of events was not recovered. No follow-up attempts are possible. No further information is expected. The information about lot number and expiration date cannot 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>
1353527	5/27/2021	NY	69	F	4/19/2021	4/20/2021	<p>Arm was swollen and sore; Arm was swollen and sore; Felt under the weather/Did not feel well; Fever; Felt achy; Headache; This is a spontaneous report from a contactable nurse (patient). A 69-year-old female patient received bnt162b2, via an unspecified route of administration, administered in Arm Left on 19Apr2021 11:00 (Lot Number: ER8731) as 1st dose, single for covid-19 immunisation. Medical history included Chronic pain, covid-19 from Jan2021, Aneurysm on an artery to her spleen, Multiple back and hip surgeries, 8 Surgeries, Cholesterol, Osteoporosis, Nerve pain, pain, Multiple failed fusions. Concomitant medications included atorvastatin taken for cholesterol; colecalciferol (VITAMIN D) taken for osteoporosis; gabapentin taken for Nerve pain; marijuana taken for pain; calcium. The patient previous received the Trumemba meningococcal vaccine in 2017 for immunization and experienced Seizures; Meningococcal vaccine for immunization and experienced felt under the weather; Pneumococcal vaccine for immunization. She did not feel well after vaccine. She stated her temperature never got above 99 after the first dose. Arm was swollen and sore, felt under the weather, fever, felt achy, headache; they were occurred maybe 20 to 21 hours after vaccine (20Apr2021). Her arm was swollen and sore. She felt under the adds that this was for about 5 days, her temperature was 99 and that was as high as it got. She felt achy and her arm was sore. She had a headache. She added that this went into the second day and she started feeling worse. She had COVID in January, which is probably why she reacted to the first shot. She stated that is what she has heard. She started to feel better until she got the second shot. The causality as yes. She received a chest xray at the end of Feb2021 and she just saw pulmonologist and has to go back for a pulmonary function test. She confirmed this was from before the vaccine and to follow up after she has had Covid. The patient reported the events as serious as medically significant. The outcome of the events was recovering.; Sender's Comments: Based on the available information, a possible contribution of the drug to the events Arm was swollen and sore, Felt under the weather/Did not feel well, Fever, Felt achy and Headache cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer</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>
							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.
1353751	5/27/2021	NH	58	F	5/10/2021	5/10/2021	Developed high fever night of obtaining 2nd vaccine that got as high as 103. Swollen lymph nodes and glands lasted for 2 days. Three days later, tremors feeling possible seizure but did not have one. Additionally stated to have muscle spasms, weakness and muscle contractures mainly right side extremities and lower back and pelvis area started. The muscle spasms have continued to occur just not every day any more. I had muscle spasms in my leg last night so would not say all symptoms have resolved yet.
1354666	5/27/2021	OH	19	F	4/13/2021	5/15/2021	Patient started having seizure like activity and weakness in her arms and legs; the patient was brought by EMS to the ER and admitted for testing. She had tics that were occurring of her head and neck area. After she was released with no abnormalities noted to be causing her symptoms, she was referred to a Functional Movement Disorder specialist at a clinic, who diagnosed her with Functional Movement Disorder. Her symptoms resolved completely about a week after her hospitalization.

<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>
1353772	5/27/2021	TX	20	F	4/16/2021	5/14/2021	<p>Epileptic seizure; Twitching of the legs/Twitching of the arms/Her body would not stop twitching; Muscle spasm; Fever at 104 degrees Fahrenheit; This spontaneous case was reported by a consumer and describes the occurrence of EPILEPSY (Epileptic seizure), MUSCLE TWITCHING (Twitching of the legs/Twitching of the arms/Her body would not stop twitching), MUSCLE SPASMS (Muscle spasm) and PYREXIA (Fever at 104 degrees Fahrenheit) in a 20-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 008C21A and 008C21A) for COVID-19 vaccination. No medical history was reported. On 16-Apr-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 14-May-2021, the patient experienced EPILEPSY (Epileptic seizure) (seriousness criterion medically significant), MUSCLE TWITCHING (Twitching of the legs/Twitching of the arms/Her body would not stop twitching) (seriousness criterion medically significant), MUSCLE SPASMS (Muscle spasm) (seriousness criterion medically significant) and PYREXIA (Fever at 104 degrees Fahrenheit) (seriousness criterion medically significant). At the time of the report, EPILEPSY (Epileptic seizure), MUSCLE TWITCHING (Twitching of the legs/Twitching of the arms/Her body would not stop twitching), MUSCLE SPASMS (Muscle spasm) and PYREXIA (Fever at 104 degrees Fahrenheit) outcome was unknown. Patient received her second dose of the Moderna COVID-19 vaccine yesterday on 14MAY2021 at 10:30 AM. Patient experienced epileptic seizure, twitching of the arms, twitching of the legs, muscle spasm, and fever at 104 degrees Fahrenheit after receiving the second dose of the vaccine. She was sent to hospital twice yesterday. She came home last night from the hospital, went to sleep, and then she woke up around 4am screaming for his wife. Her body would not stop twitching and she kept punching herself with her arm. She went to the hospital again so they can calm her symptoms down. The emergency room doctors prescribed her medications for her shakiness and twitchiness. Her symptoms have been going on for 28 hours. The caller mentioned that the emergency room</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>
							doctors did not know what to do with patient but to prescribe her medications to treat her symptoms. Patient was a healthy young girl until she got the second dose of the vaccine. Patient received the first dose of the Moderna COVID-19 vaccine on 16APR2021 and she experienced only experienced arm soreness for a couple days. No treatment information provided. No concomitant medication 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. This case was linked to MOD-2021-132361 (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.
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.

<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>
1354191	5/27/2021	OR	48	M	5/27/2021	5/27/2021	Patient felt faint within 2 minutes of vaccination. His vision went dark. When I walked back into the room he was pale and sweating, but responding to questions from the person he arrived with. His arm twitched a few times and his head rolled to the side for a few seconds. Then he regained consciousness, but momentarily looked confused. The patient has a history of seizures, but has not suffered from one in 10 years. After that, the patient remained alert, but continued to sweat and felt light headed for most of standard wait time post vaccination. After the 15 minute wait period the patient felt more normal and left.
1354207	5/27/2021	MO	12	M	5/27/2021	5/27/2021	PT was sitting with guardian and started to have seizure like activity for him which consists of audible and visual auras and Right arm twitching. This lasted about 1 min. Once we got him into a dark room he started having slurred speech and Left sided weakness that lasted about a min. He was A&OX1. Pt had a right sided slant in his eyes. His pupils were dilated to a 9 and were equal and non reactive. he became sluggish and kept starring off to the right side. This lasted about 2 mins and 45 sec. His pupils returned to 6 and were equal and reactive and he became less lethargic. He started to complain of a head ache. At 1302 he stated that he stated tapping his face and trying to speak. He began to have a right sided glance again and his pupils dilated to an 9 again and we equal and non reactive. he did not respond to his name. This lasted for almost 2 mins. He then stated he was foggy and his pupils returned back to a 6 and were equal and reactive. He was struggling to find sounds in the room. His Vital signs were initial B/p 138/98 resp 22 HR-78. at 1320 his B/P was 128/68 Resp 20 HR 80. Pt was transported by EMS for medical evaluation by his neurologist.

<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>
1354352	5/27/2021	NJ	17	F	5/26/2021	5/26/2021	Patient upon seated for the 15 minutes post-vaccination fainted. When she was coming through, she started shaking as if she was having a seizure. When I reached the patient, she was shaking and then came through and stopped shaking. Patient was still pale, sweating, and didn't feel okay. 911 was already called once the patient was shaking. As I am checking in on the patient, the mom discloses that she has fainted at least twice before and when she comes through she shakes but it is not seizures. However, during the screening process, patient and mom stated the patient never had any problems when getting vaccinated. I got her BP checked and it was 102/61 and HR of 92. We had the patient sit still and drink water. When EMS arrived within 5-10 mins, they took her vitals and it was 112/70s and HR of 84 with 98% O2 sat. Patient and mom decided to be taken to the ED to make sure she is okay.
1354479	5/27/2021	SC	44	F	5/27/2021	5/27/2021	Patient had 2 seizures about 5 minutes after receiving her first Covid vaccine. Spouse was with her and did not think seizure was due to vaccine, but that she has a history of seizures if over anxious or becoming overheated. They did not want me to call 911 and seizures resolved.

<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>
1354500	5/27/2021	NC	16	F	5/4/2021	5/23/2021	The afternoon of May 4th, (the patient) had a headache at the back of her head. She took an Ibuprofen and went to bed. Over the course of the next 3 weeks, the headache would return, but was alieved with Ibuprofen. On the evening of May 23rd, 2021 (the patient) came to me and said she had a twitching in her neck. I looked, but did not see anything that was concerning. It was just a twitch. On the evening of May 24th, (the patient) went to dinner with her father. On the way to dinner, they were having a regular conversation when (the patient) began to stutter really bad. Her father pulled the car over and looked at her. He noticed her head was shaking uncontrollably and she could not talk. He immediately took her to the emergency room. When I arrived, it looked like she was having a seizure. (The patient) has never had any kind of speech problem, so she has never stuttered. the drs told us that they did not have a neurology dept, so we took her to another hospital. After numerous tests, we were told to take her home and it was probably something like stress and she should see mental health

<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>
1353533	5/27/2021	UT	17	F	3/26/2021	3/26/2021	1-20 minute bouts where tics appear "seizure-like," repetitive; many persistent involuntary tics including coprolalia and violent motor tics; had one minor chronic tic before vaccination/many persistent involuntary tics including coprolalia and violent motor tics/Noticed increase in severity and frequency; many persistent involuntary tics including coprolalia and violent motor tics; Tics often include hitting oneself and banging head against things/violent; significant distress; persistent headache; chronic fatigue/sleepiness; lightheadedness; decrease in appetite; feeling of pressure in certain locations inside the head; intermittent earaches in both ears; persistent feeling of brain being "on fire," and "like a parasite has invaded the brain."; chronic fatigue/sleepiness; This is a spontaneous report from a contactable consumer (patient). A 17-year-old female non-pregnant patient received bnt162b2 (PFIZER BIONTECH COVID-19 MRNA VACCINE) via an unspecified route of administration, administered in Arm Right on 26Mar2021 as first single dose and on 16Apr2021 as second single dose (Batch/Lot number was not reported) for covid-19 immunization. Facility where the most recent COVID-19 vaccine was administered: Other. Medical history included asthma, allergy to nuts, penicillin and ongoing chronic tic. No other vaccines within 4 weeks prior to the COVID vaccine. No covid prior vaccination. Concomitant medications included duloxetine; atomoxetine; hydroxyzine; loratadine. The patient previously took amoxicillin and experienced allergies. The patient experienced neurological symptoms included many persistent involuntary tics including coprolalia and violent motor tics. Smaller tics can be suppressed for minimal amounts of time before uncontrolled, violent/loud tics occur in rapid succession. Tics often include hitting oneself and banging head against things. The patient had one minor chronic tic before vaccination. Initial onset occurred nine days after vaccination from 04Apr2021. Noticed increase in severity and frequency approximately nine days after second dose of Pfizer vaccine. Symptoms cause significant distress. Additional symptoms included: persistent headache (from date of first vaccine to present); chronic fatigue/sleepiness; light-headedness; decrease in appetite; feeling of pressure in certain locations inside the head not related to the skull or skin;

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

intermittent earaches in both ears; persistent feeling of brain being "on fire" and "like a parasite had invaded the brain, start date was 26Mar2021; and "1- 20 minute bouts where tics appear "seizure-like," repetitive, violent, and controlling". The patient underwent lab tests and procedures which included Spit test: negative (other) on 26Mar2021 and Apr2021, Covid test: negative on 26Mar2021 and on Apr2021. The events resulted in: Doctor or other healthcare professional office/clinic visit. No treatment received; the patient was not recovered. Information on lot/batch number has been request.

<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>
1353771	5/27/2021	FL	30	M	5/12/2021	5/12/2021	seizure; completely blurry vision; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SEIZURE (seizure) and VISION BLURRED (completely blurry vision) in a 30-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included COVID-19 from 16-Mar-2021 to 25-Apr-2021 and COVID-19 from 28-Dec-2020 to 16-Feb-2021. Concurrent medical conditions included Drug allergy (Allergy to NSAIDS), Penicillin allergy, Drug allergy (Allergy to Tramadol), Drug allergy (Allergy to Wellbutrin) and Allergy to antibiotic (Allergy to cephalexin antibiotics). On 12-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-May-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced VISION BLURRED (completely blurry vision) (seriousness criterion hospitalization). On 13-May-2021, the patient experienced SEIZURE (seizure) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 12-May-2021 due to SEIZURE and VISION BLURRED. At the time of the report, SEIZURE (seizure) had not resolved and VISION BLURRED (completely blurry vision) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The patient experienced 3 episodes of seizure on 13-May-2021 and another 2 episodes of seizure on 14-May-2021. The patient stated that the doctor advised him not to receive the second vaccination dose. The patient was hospitalized right after the events. At the time of reporting, the patient was still in the hospital. Additional treatment details were not provided. Concomitant medication information was not provided. Company comment: Very little information has been 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. Further information has been requested.; Sender's Comments: Very little information has been 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

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

be excluded. 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>
1353478	5/27/2021	NY	69	F	5/10/2021	5/10/2021	chills; Fever; Achy; had a hard time sleeping; did not feel well; headache; Arm was sore; This is a spontaneous report from a contactable nurse reported for herself. This 69-year-old female patient received the 2nd dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0171) via an unspecified route of administration in the left arm on 10May2021 at 16:00 for COVID-19 immunization. Medical history included chronic pain from multiple back and hip surgeries, 8 surgeries in 10 years, it seemed like it was every January; Covid in January. Concomitant medications included atorvastatin for cholesterol for about 2, maybe 3 years; ergocalciferol (VIT D) for osteoporosis for 5 years; gabapentin for a couple of months for nerve pain; medical marijuana since she had multiple failed fusions and 8 surgeries in 10 years, calcium. The patient had no other vaccinations within four weeks prior to the first administration date of the suspect vaccines. The patient previously received the 1st dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8731) via an unspecified route of administration (injection in the left arm) on 19Apr2021 for COVID-19 immunization, experiencing Arm was swollen and sore, felt achy, headache and fever. The patient previously received Trumemba meningococcal vaccine about 2017 and had seizures. The patient had an aneurysm on an artery to her spleen and had to have surgery. Since it was on her spleen it affect her immune response. She had to get a bunch of vaccines, that was one of them. The other was pneumococcal and other ones. She just had like under the weather feeling but not horrible from the meningococcal vaccine. After the second vaccine, the patient experienced arm was sore, headache, fever, chills, achy. Around 8 o'clock on 10May2021, her arm was getting sore and she was getting a headache. This was a quicker response than the first vaccine. She had a hard time sleeping. When she got up this morning, she knew she had a fever. She took it first thing and it was 100.4. She got up and had something to drink and then it took her about an hour and a half to get something to eat. Her temperature went up to 101 a couple of hours after that. She waited two hours and caved and took tylenol. The patient reported that that one dose helped her not to feel so chilled, achy and feverish. The patient stated that the CDC Website and the paperwork on the vaccine does

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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not say if it was okay to take Tylenol afterwards. Event websites said to contact healthcare provider but she did that and she cannot get through. She ended up taking 600, 2 regular strength - the patient stopped the sentence and stated she actually took 650 mg of Tylenol and then her temperature came down to 99 and she felt better. The patient stated said she had to do this. She felt too sick. She hoped that it was okay. She called her local health department and they transferred her to the vaccine line. It was automated and she could not get a person to ask if she could take Tylenol. The patient added she still had a sore arm there, but at this point, knock on wood, it was not as bad as it was the first time. She tended to sleep on her right side more. It was sore. It was not like horrible. It was not like she can't use it, because she can. The worse thing was that she was achy and under the weather with a low grade fever which she heard people get but none of her friends have. None of them had Covid. She waited over 3 months for the vaccine because her husband's doctor, a doctor she did not see, said do not get it too soon because people get more of a reaction if they got it too soon. He said wait three months, so they waited 3 and a half months. About chills and achy, the patient did not feel as cold right now so she knew the Tylenol helped. She was starting to get warm and was wearing a few sweaters. She expected something and she will be grateful if this was as bad as it got. She did not take a lot of Tylenol because she did not like to take too much of anything so she tried not to take anything again until later if needed. The patient stated there was no question that the second set of symptoms were caused by the vaccine. The patient added that the second set of symptoms were also not life threatening and confirmed as not serious. The patient confirmed as left arm was sore, the arm where she received injection. She guessed everything she had experienced was actually medically significant because of the fact that Pfizer wanted people to report things like this. The patient stated she had her vaccine card but was not sure why she might need it, going forward it might be important to have for various things. The patient received a chest x-ray at the end of February, and she just saw pulmonologist and had to go back for a pulmonary function test. The patient confirmed this was from before the vaccine and to follow up after she had had Covid, it

<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>
							was a formality. It was not from the vaccine, it was from the virus. The event did not required a visit to Physician office or Emergency Room after the vaccines. The patient was nervous to get bnt162b2, but was happy to make it through the first one. Now, she was on day 2 of the second one and as long as she can take Tylenol to help with the symptoms she will be okay she things. She did not think she was getting worse. These kinds of things come in waves. The patient added that she would not have been able to talk to call handler three hours ago because of the fever and achy and dizzy and everything. Outcome of the events was unknown.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021533417 same patient/drug, different dose/event
1351354	5/26/2021	CT	50	F	5/26/2021	5/26/2021	triggered seizures, headache, muscle pain
1350736	5/26/2021	AR	45	M	5/24/2021	5/24/2021	A little more than 5 minutes after receiving shot had a seizure. Told me his wife he didn't feel right and hands were very sweaty cold his eyes rolled back in head. Lost his color loss control of bodily functions(urine). Throwing up hard. EMT were called vitals were alright. Once we were home vomiting subsided and he slept hard.

<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>
1350802	5/26/2021	NM	18	M	5/26/2021	5/26/2021	18 year old otherwise healthy male, with mild asthma, and history of vasovagal syncope with prior vaccinations, IV's and any type of injection on multiple occasions. He has no history of prior seizures or seizure disorder. He received his vaccine at about 9 AM and walked to our 15 minute observation area. Within 5 minutes of sitting down, he stated he was not feeling well, became unresponsive, and had a series of 3 very brief, witnessed tonic clonic seizure activity, each lasting 5 seconds or less, with only a few seconds between. Following this he was minimally responsive, still sitting up, eyes opened, and only mumbled in response to questions. He was pale, confused, mildly diaphoretic, BP was 119/99 pulse was 61, O2 sat was 96% and resp rate was approximately 20. He was NOT incontinent of stool or urine. He was fully conscious and oriented to person place time and situation within 5 minutes. He soon regained his color and vitals continued to be stable. He does have a history of "low blood pressure" per his report. He was feeling well, but because of the history witnessed seizure activity the decision was made to transport to hospital. He was transported by Ambulance Service to Hospital. Prior to vaccination today was feeling well. He was accompanied by his girlfriend. Diagnosis per supervising MD, was Post vaso-vagal syncope seizure activity. Or seizure activity related to vaso-vagal syncope.
1350837	5/26/2021	SC	67	M	2/24/2021	2/26/2021	Grand mal seizure 2 days following vaccine. Patient was hospitalized.
1351135	5/26/2021	NV	35	F	5/24/2021	5/26/2021	Witnessed seizure, no history of any medical problems

<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>
1351193	5/26/2021	FL	39	M	5/26/2021	5/26/2021	Patient was in observation waiting his 15 minutes when he stated he started felling dizzy. He then went into a syncopal episode and started having seizure like movements. The nurses onsite assisted the patient to the floor to prevent any injuries. After about 5 minutes the patient came to. As EMT was being called the nurse assessed the patient blood pressure and other vitals which read as the flowing BP 176/86 , RR 19 , HR 83. The EMT team arrived on site around 2:15 and assessed the patient. The EMT's did a 12 lead on the patient and noticed some elevation in his heart rhythm and told the patient that he recommends he go to the hospital the patient refused and went home instead.
1352727	5/26/2021		33	M	5/1/2021	5/24/2021	Seizure with loss of consciousness, but without passing out, lasting shorter than 2 minutes with no prior history of seizures. Other present symptoms included: aura including heightened fear, visual and auditory abnormalities, loss of awareness, loss of muscle control in face and neck, staring episode, breathing difficulties/gurgling, and loss of bladder control. All symptoms subsided upon regaining consciousness/awareness.
1351335	5/26/2021	FL	54	M	4/22/2021	4/23/2021	Patient experienced HA on way home from receiviong vaccine. HA persisted on 4-23-21 throughout morning and into early afternoon. Patient became catatonic at home, family called 911 and pateint was rushed to hospital via ambulance in hypertensive crisis and seizure activity. Patient diagnosed with brain bleeds in two sepearate areas of brain. Original commentary by neurosurgeon was this was unrelated to Moderna vaccine, current neurologist thinks it could have been related. Patient was in hospital for several days then released on 4-28-21. Patient is healing, going to therapy and compliant with all neurology follow ups. Patient still not released to return to work or to driving as of 5-26-21.
1350567	5/26/2021	NY	16	F	5/19/2021	5/19/2021	Patient went stiff/possible seizure 5 minutes after getting the vaccine. She came back after approx. 30 seconds. EMS was immediately called and her blood pressure and pulse were both taken prior to EMS arrival. Blood pressure was 91/51 with a pulse of 48. PER EMS, the patients blood sugar was low.

<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>
1351379	5/26/2021	TX	49	F	3/4/2021	5/20/2021	On 5/20/21 I suffered from a CVST stroke with low platelets and a seizure
1351456	5/26/2021	VA	24	M	5/26/2021	5/26/2021	patient fainted immediately after for about 1 second, his head dropped but then he woke back up. right after the dose he began breathing quickly, so i instructed him to take his mask off and lay back if he needed. i grabbed him a water and took his blood pressure/hr. EMS was called, patient denied care. HIS BP WAS 104/73 AT 12:53 PM AND HIS hr WAS 72 BPM. I did notice some mild seizure like physical symptoms as he woke up - arms and shoulders jerked a little for a few seconds. he said that the same, but worse, reaction happened after his first dose.
1351520	5/26/2021	AZ	28	F	5/3/2021	5/4/2021	Pt began feeling bad with chest pain and fatigue, SOB after the vaccine. Per spouse woke up in the middle of the night and tried to get out of bed but fainted and possibly had a seizure, had foam coming out of her mouth. Was transported to the ER and released.
1351622	5/26/2021	SD	37	F	2/1/2021	4/25/2021	Sudden onset of seizure activity while at a student volleyball game on 4/25- I have no seizure history with myself or anyone in my family.
1351639	5/26/2021		25	F	5/26/2021	5/26/2021	Pt reported SOB and generalized pruritis. SOB continued to worsen. Wheezes were noted BLL. Pt also began to produce stridorous sounds. 50mg Benadryl given IM at 1351. Pt also took 2 puffs of albuterol inhaler. Admitted to hospital recently for intubation for her seizures. Felt better after medication administration. Pt requested to go home, advised to go to ED if symptoms returned.
1351663	5/26/2021	NJ	16	M	5/26/2021	5/26/2021	Patient had the vaccine and then he fainted after the needle removed. He passed out and then he had seizure after. He brought to the Emergency room and was released.

<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>
1352354	5/26/2021	NJ	15	F	5/25/2021	5/26/2021	Driving her to school this morning, she had a grand mal seizure for a little more than a minute...a couple hours until back to communicating. She's recovering perfectly as usual. She has them occasionally (every few months) but normally driven by her menstrual cycle which is not coming up and made this uncommon. I just wanted to report it so you have the information. It could be in the birth defect category below, but I'm not a doctor so not sure and selected none of the above.
1351309	5/26/2021	FL	49	F	5/26/2021	5/26/2021	Seizure, sweating, not coherent

<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>
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

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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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

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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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

<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>
1348843	5/26/2021	KY	22	F	5/8/2021	5/14/2021	<p>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.</p> <p>Seizure like shaking and jerking in my sleep since week after COVID vaccine, symptoms: shaking and jerking and difficulty breathing and can?t wake up</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>
1349022	5/26/2021	MN	68	F		3/1/2021	FALL/SHE FELL OVER AGAIN; UPON DISCHARGE WENT HOME WITH WALKER/SENT HER HOME WITH A WALKER; HAVING TROUBLE WITH HER DAILY LIFE; RED POLKADOTS ON HANDS; DRY SKIN; SOMETHING IN THROAT/RASPY THROAT; LEGS COLLAPSED; HER LEGS TURNED TO RUBBER; SAT DOWN HARD ON HER RIGHT ASS; HIT HEAD ON THE PAVEMENT; IT HURT; GOT UP DURING THE NIGHT; This spontaneous report received from a patient concerned a 68 year old other race female. The patient's height, and weight were not reported. The patient's past medical history included has broken 3 bones in the top of the foot, stroke, and shattered her shoulders and arm, and concurrent conditions included seizure, hydrochlorothiazide allergy, and penicillin allergy. The patient taking blood pressure pills and pills for seizures (unspecified). The patient received Covid-19 (suspension for injection, route of admin not reported, batch number: 1808978, expiry: UNKNOWN) 1 total dose, administered on 24-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 24-MAR-2021, the patient hurts. Then the patient went home; and went to store for picked up some groceries. On the way back to car the patient's legs turned to rubber and she sat down. Her legs collapsed and sat on ass hit head on the pavement. On 25-MAR-2021 the patient got up during the night and same things happened again and she fell over again and spent the night on the floor and admitted to hospital (dates unspecified) for 4 days and the patient received blood thinner shots (unspecified) in her stomach. The patient discharged from hospital (dates unspecified) with walker. On an unspecified dates the patient had all kinds of tests and all came back normal. On an unknown date the patient having trouble with her daily life. The patient had a physical therapy and occupational therapy for a month. On 30-MAR-2021, the patient experienced dry skin and something in throat/raspy throat. On an unknown date the patient had red polkadots on hands. The action taken with covid-19 vaccine was not applicable. On an unknown date the patient was recovered from fall/she fell over again, and not recovered from dry skin, and something in throat/raspy throat and the outcome for and the outcome of red polkadots on hands, her legs turned to rubber, sat down hard on her right ass, legs collapsed, hit head on

<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>
1349034	5/26/2021	MN	65	M	5/21/2021		<p>the pavement, got up during the night, it hurt, upon discharge went home with walker/sent her home with a walker and having trouble with her daily life was not reported This report was serious (Hospitalization Caused / Prolonged). FALL/SHE FELL OVER AGAIN. 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>VOMITING; This spontaneous report received from a patient concerned a 65 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included seizure. 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 20-MAY-2021 for prophylactic vaccination. The batch number was not reported and has been requested. Concomitant medications included levetiracetam for seizures. On 21-MAY-2021, the subject experienced vomiting. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of vomiting 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>
1349125	5/26/2021	OH	47	F	5/14/2021	5/14/2021	one episode of seizure attack while sleeping; low grade fever of 100F; injection arm soreness; tiredness; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (one episode of seizure attack while sleeping) in a 47-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 027C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Epilepsy. Concomitant products included PHENOBARBITAL (PHENOBARBITONE COX) and LEVETIRACETAM for Seizure, ZONISAMIDE and PARACETAMOL (TYLENOL) for an unknown indication. On 14-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 14-May-2021, the patient experienced VACCINATION SITE PAIN (injection arm soreness) and FATIGUE (tiredness). On 15-May-2021, the patient experienced PYREXIA (low grade fever of 100F). On 17-May-2021, the patient experienced SEIZURE (one episode of seizure attack while sleeping) (seriousness criterion medically significant). At the time of the report, SEIZURE (one episode of seizure attack while sleeping), VACCINATION SITE PAIN (injection arm soreness), FATIGUE (tiredness) and PYREXIA (low grade fever of 100F) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Body temperature: 100 °F (High) 100 °F. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The treatment information included 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.; 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>
1349127	5/26/2021	KY	22	F	3/19/2021	4/4/2021	found dead; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (found dead) in a 22-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 032m20a) for COVID-19 vaccination. Concurrent medical conditions included Traumatic brain injury, Movement disorder, Seizures (since she was a baby at 11 months old) and Speech loss. Concomitant products included CLONAZEPAM, OXCARBAZEPINE (TRILEPTAL) and GABAPENTIN for an unknown indication. On 19-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on 04-Apr-2021 The patient died on 04-Apr-2021. The cause of death was not reported. An autopsy was not performed. Reporter stated that death certificate said the cause of death was natural causes. She did have her yearly physical exam after her first dose with her physician prior to her death and no other health issues were noted at the time of the exam. 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: Natural causes

<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>
1349421	5/26/2021		65	F	3/19/2021	3/19/2021	seizure like activity; it was very frightening for her; slurred speech and could not talk; more she started to talk the more slurred her speech got; slurred speech and could not talk; more she started to talk the more slurred her speech got; her tongue started feeling funny; On 19Mar2021 I had weakness in left arm radiating up to left side of neck on left side; went back to get the second one and they wouldn't give it to her; told to seek medical advice; he seizure activity occurred and it was like she had not taken her medicine.; This is a spontaneous report from a contactable consumer. This 65-year-old non-pregnant female patient (not pregnant at the time of vaccination) received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; formulation: Solution for injection, Lot Number: EN6205, Expiry date: Unknown) via unspecified route of administration in left arm on 19Mar2021 at 13:15 (at age of 65-year-old) as a single dose for COVID-19 immunisation. Patient's Medical History (including any illness at time of vaccination; Provide other relevant medical history including but not limited to these conditions: diagnosed allergies, compromised immune status, respiratory illness, genetic /chromosomal abnormalities, endocrine abnormalities (including diabetes) and obesity); history of partial seizures and migraine headaches since 1996. Facility where the most recent COVID-19 vaccine was administered was Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Any other medications the patient received within 2 weeks of vaccination: Yes (Topomax). Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient was not tested for COVID-19. The patient had known allergies (but not specified). The patient not received other vaccine in 4 weeks. Concomitant medication include Topomax 50 mg one tablet twice daily for partial seizures and migraine headaches (Batch number: 20EG075 and expiry date Mar2022). No further details provided. No other vaccines given the same day or 4 weeks prior. No problems with vaccines in past. On 19Mar2021, at 13:15, the patient experienced seizure like activity, patient was very frightened, slurred speech and could not talk, more she started to talk the more slurred her speech got, her tongue started feeling funny, weakness in left arm radiating up to left side of neck on left side. The patient

VAERS_ID RECVD DATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

took her medication that morning and it was like she hadn't taken it. The patient went back to get the second one and they wouldn't give it to her and said to seek medical advice. After vaccination, immediately after the injection she felt the medication radiating in the arm and going up the left side of the neck and then her tongue started feeling funny. On 19Mar2021, the patient had weakness in left arm radiating up to left side of neck on left side, and slurred speech and could not speak immediately after getting Pfizer Covid 19 vaccine. She told nurse and they had waited another 15 min, and when it was over she felt like she had woke up refreshed and awake but it bothered me. The patient took medication to help and after getting the Pfizer Covid 19 vaccine 1st dose my medicine did not seem to be working on 19Mar2021 and continue to date. The patient received the first dose of the Covid vaccine and it appears to have given her seizure like activity and had explained all of that on the application. It was very frightening for her. Her doctor sent her for MRI/MRA testing and she does not know why she went into this as soon as she was given the Covid vaccine. She does take an anticonvulsant for partial seizures as well as migraine headaches and takes that everyday. Took her medicine that morning and it was just like she hadn't taken it. When she takes the anticonvulsant she doesn't have a problem, but after given the Covid vaccine immediately afterwards the seizure activity occurred and it was like she had not taken her medicine. Does not know what to do, she went back to get the second one and they wouldn't give it to her and advised her to get medical advice and then she would have to wait 30 minutes instead of the 15 minutes since having that reaction. The patient wanted to know if she should get second dose. That day she was observed and told to wait 30 minutes instead of the 15minutes until everything subsided. Immediately afterwards she had slurred speech and could not talk and was told if she was not okay they would send her to the emergency room. Had the seizure immediately afterwards before she could get to the waiting area. Went to see the neurologist yesterday and they want to see her back in 4 months. Does not provide manufacture and states she has been on Topamax for years and has had this condition since 1996. Also mentions on bottle she saw a S/N and GTIN, but does not provide any further details. The patient had

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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gotten the results from the MRI/MRI and had the testing done on 30Apr2021. Again mentioned that immediately after the injection she could feel the medication radiating in her arm and going up the left side of her neck and then her tongue started feeling funny. The more she started to talk the more slurred her speech got. Caller stated she has already completed a vaccine adverse event application online on 09Apr2021 and provides reference: DFB2A40A-8C82-4220-B77E-F0A0F1C1F89E. The Outcome of the event weakness in left arm radiating up to left side of neck on left side was unknown and went back to get the second one and they wouldn't give it to her; told to seek medical advice was not recovered, feel the medication radiating in the arm and going up the left side of the neck and then her tongue started feeling funny/took her medication that morning and it was like she hadn't taken it, slurred speech and could not talk; more she started to talk the more slurred her speech got, it was very frightening for her and seizure like activity was recovering. Follow up needed, further information has been requested.; Sender's Comments: Based on the information currently available, a possible contributory role of the suspect vaccine BNT162B2 in triggering the onset of Seizures , dysarthria, Aphasia and other event cannot be excluded. But also consider medical history of partial seizure. however, the reported event of fear is consider as a consequence of seizure that patient experienced and not related to the suspect vaccine. 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.

<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>
1349441	5/26/2021	FL	54	F	3/31/2021	4/1/2021	'seizes'/seizure; This is a spontaneous report from a contactable consumer (patient). A 54-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), on 31Mar2021 at 13:00 (at the age of 54-years-old) as 1st dose, single (Batch/Lot Number: ER8732), via an unspecified route of administration, administered in arm left for COVID-19 immunisation. Medical history included coconut allergy from an unknown date and unknown if ongoing. Concomitant medications included topiramate and triamterene, both taken for an unspecified indication, start and stop dates were not reported. Between 31Mar2021 and 21Apr2021 (reported as Apr2021), the patient had a total of 10 'seizes'/seizure. Before, he had 2 to 4 'seizes' within a three months' time. The patient received the second dose of BNT162B2 on 21Apr2021 at 13:00 (Batch/Lot Number: EW0151), via an unspecified route of administration, administered in arm left for COVID-19 immunisation. There was no treatment received for the event. The outcome of the event was unknown. Information about lot/ batch number has been requested.
1350634	5/26/2021	MI	16	F	5/17/2021	5/17/2021	Patient sat about 2 minutes after getting vaccine and started to walk away to sit in our designated area. She immediately turned around to sit down again. She then proceeded to start falling to her right and passed out. I was able to catch her and then she started shaking as if having a seizure. This lasted about 5 seconds. She stopped and then it happened again for about 5 seconds. When she came to, she tried to walk away again and had to return to sitting. Then she vomited twice. Upon checking her blood pressure after about 30 minutes, it was 97/66. She sat for a total of about an hour before feeling good enough to leave. She was nauseous for the remainder of the day and the next day as well.

<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>
1349563	5/26/2021	SC	70	F	2/19/2021	4/2/2021	<p>She keeps losing more and more weight; Petite mal seizures/frequency of seizures increased; Grand mal convulsion/ One clonic tonic or grand mal seizure; This is a spontaneous report from a contactable Nurse (patient). A 70-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 administered in Arm Left on 19Feb2021 08:45 (Lot Number: EN6198) as 2ND DOSE, SINGLE for covid-19 immunisation. Medical history included epilepsy (diagnosed since age 6), guillain-barre syndrome (she cannot get the flu vaccine anymore because of her history of with Guillain-Barre Syndrome), she had COVID-19 in AUG2020 and has been having increased seizures since then as well, Seizures. She was positive on her COVID test, she forgets what was that it said when it came back, it didn't say positive, it said something else, she went back and forth after that first COVID test. She says it said detected, it didn't say anything else. She says after that she came home and self quarantined for 14 days, then went back for piece of mind to get a negative test, but they said positive, so then she quarantined 21 days that time. She says she went back and they tested her with the gold test which takes longer to her understanding to study that, and that came back negative. She says after 21 days she built up enough antibodies for it to be negative. She clarifies that she had COVID and COVID testing done before getting the doses of the Pfizer COVID-19 vaccine, before she got her her vaccinations. She had no other vaccinations on the dates she got her Pfizer COVID-19 vaccine doses or in the four weeks prior. She uses Lysol wipes and Clorox to clean her house and her door knobs. She says she uses hand sanitizer and wears 1-2 masks. She says in 1990 she had an airborne virus that put her in intensive care for 21 days and she was paralyzed, so she is thankful to be alive, and that she is no longer paralyzed. She says this came along, and it brought back a lot of horrible memories. Caller says she had to live with something, and her mask, and a lot of handwashing. Call handler attempted to clarify this statement with the caller. Concomitant medications included clobazam (Manufacturer: Microlabs. NDC: 4271-315-01, EXP: 09Aug2021) 10mg tablets, two twice a day taken for seizure; levetiracetam (LEVETIRACETAM 1A FARMA) 500mg, four tablets in the morning and four at night,</p>

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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taken for seizure. The patient previously received first dose of bnt162b2 administered in Arm Left on 22Jan2021 08:45AM (Lot Number: EL3249) for covid-19 immunisation . The patient would like to know if the COVID-19 infection increases seizure activity. She has a history of epilepsy and has received both dose of her vaccine. She states that she petite mal seizures and has One clonic tonic or grand mal seizure on 2APR2021 at 12:35AM. She also reports that she keeps losing more and more weight and does not know why. She states that in JUL2020 she was 196 pounds and today she weighs 177 pounds. About frequency of seizures increased, the patient says that her seizures had been pretty well been controlled, for 6 months. She says that there were a couple times she had months seizure free, but now can't get through the day without multiple seizures. She says they are petit mal, but she is also having grand mal seizures. She clarifies that her seizures increased last July, after she got out of rehab, they got worse during the month of August. She confirms that she was diagnosed with COVID-19 in August 2020. She clarifies her seizures increased before she got the doses of the vaccine this year. She says she had convulsions on 2Apr2021, a grand mal seizure, at 12:35 in the morning. She was just wondering if there was any connection between COVID-19 and increased seizure activity. She says her neurologist and she are both hitting their heads on the floor and trying to think of what combination of meds could stop her seizures and convulsions to get her down to where she is not having multiple petit mal every day. She says she used to see her neurologist every 2-3 months, now she sees him every month. She says every 2-3 months he changes her medication. She says he has her on two drugs now, and he increased them both, they are hoping to get answers, if her seizures have not calmed down and gone away he is going to take her off Keppra. She is taking the Keppra generic, named Levetiracetam, she takes 500mg, four tablets in the morning and four at night. She says the other anti seizure medication is Clobazam, she takes two pills a day. She says each time he puts her on a different drug it is another chemical change to her body and another expense to be constantly changing drugs. She says her neurologist might change her medications again when she goes back May 20th for her follow up. She says there

<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>
1350622	5/26/2021	KS	12	M	5/25/2021	5/26/2021	could be drug interactions and stuff that her neurologist might not be aware of, she is not having a fun time. She says her neurologist tried to put her on two different drugs to good take care of the problem, one was Keppra and her insurance denied that one so he said let's try this one and put it thru her insurance for authorization and it was accepted but they said they don't carry it and get her private pharmacist. The outcome of Petite mal seizures and Grand mal seizure was not recovered, of other event was unknown. Seizure for 20 seconds and then post ictal for 10-15 minutes, by time got to the ED back at baseline

<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>
1349629	5/26/2021			F			<p>seizure; patient missed second dose appointment due to hospitalization; This is a spontaneous report from a non-contactable consumer (patient) from a Pfizer-sponsored program. A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on an unspecified date as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced seizure on an unspecified date, which required hospitalization. It was also reported that the patient missed second dose appointment due to hospitalization on an unspecified date. The patient reported that she received first dose before the hospitalization. The clinical outcome of seizure and patient missed second dose appointment due to hospitalization was unknown. The reporter (patient) assessed the causality between the event and BNT162B2 as unrelated (reported as: nothing to do with seizure). The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: Based on an implied chronological connection to the vaccine, a causal relationship between event seizure and BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA 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.</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>
1350285	5/26/2021	IN	27	M	5/24/2021	5/25/2021	The same day as the injection I experienced severe pain a few hours after in my bicep rather than my shoulder where I experienced pain during the 1st vaccine dose. I also experienced the common fatigue. However, at 12:13a.m on May 25th, I was woken from sleeping to what can only be described as either the most severe case of the shakes that have ever been experienced, or convulsions. I was unable to move, speak, and could hardly breathe. The effects of this lasted well over an hour and a half. It was only after what I was experiencing stopped, that I suddenly became burning hot, but did not have a fever. 98.7° was what was read at the time I started to feel hot. Since then I have experienced severe joint and knuckle pain on my left hand, still bicep soreness, pain in my left forearm, again joint and knuckle pain in my left hand, and headaches.
1350299	5/26/2021	OH	26	M	5/25/2021	5/25/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hyperventilation-Severe, Systemic: Seizure-Severe
1350358	5/26/2021	NY	14	F	5/23/2021	5/23/2021	Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Severe, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Systemic: Weakness-Severe, Additional Details: within minute of injection patient passed out, parent and witness said patient had seizure like shaking (I did not personally witness this), became extremely pale and non-responsive for few minutes. Before shot given Mom informed me patient normally faints and has extreme anxiety and aversion to needles.

<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>
1350383	5/26/2021	MI	76	M	3/16/2021	5/11/2021	This is a 76y.o. male significant past medical history of HTN, MI, dyslipidemia, and ESRD on hemodialysis that presented to the hospital with chief complaint of fall. He states he fell out of his recliner chair yesterday and landed on his left side. He admits to striking his head but denies any LOC. He reports he did miss hemodialysis on Monday secondary to episodic diarrhea. He is seen today resting in no acute distress. Endorsing overall he is feeling well. Denies any fever, chills, chest pain, shortness of breath, abdominal pain, nausea, vomiting, diarrhea, or changes in motor strength. In the ED, patient hypertensive, afebrile, stable SPO2 on room air. CT head, C Spine and radiographs negative for acute process. CXR concerning for pneumonia. He was started on antibiotic therapy and admitted to observation for further evaluation and management with nephrology consultation. ROS: Constitutional: Denies fatigue, fever or chills. Eyes: Denies change in visual acuity, diplopia or pain. HENT: Denies nasal congestion, sore throat or tinnitus. Respiratory: Denies cough, difficulty in breathing or shortness of breath. Cardiovascular: Denies chest pain, palpitations or edema. GI: Denies abdominal pain, nausea, vomiting, constipation or diarrhea. GU: Denies dysuria, urinary frequency or hematuria. Musculoskeletal: Denies back pain, atrophy, spasticity or joint pain. Hematologic: Denies anemia, bleeding or bruising. Integument: Denies rash, lesions, or history of cancer. Neurologic: Denies headache, focal weakness, seizure or stroke. Endocrine: Denies temperature intolerance, polyuria or polydipsia. Lymphatic: Denies tender, abnormal, swollen glands. Psychiatric: Denies irritability, depression or anxiety.

<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>
1350414	5/26/2021	PA	14	M	5/25/2021	5/25/2021	Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe, Systemic: Vomiting-Severe, Additional Details: AFTER SHOT ADMINISTERED,PATIENT WAS WALKING TO WAITING AREA FOR OBSERVATION, WE FAINTED AND HAD 2 SEIZURES ABOUT 40 SECONDS LONG. NO PULS OR BREATHING. GAVE 10 CHEST COMPRESSIONS AND 2 BREATHS. EMERGENCY WORKER SHOPPING IN STORE HELPED ROLL TO RESCUE POSITION AFER FEEELING PULSE IN THE WRIST. HE SPIT UP A SMALL AMOUNT OF SPIT. HE SHORTLY CAME AORUND IN ABOUT ANOTHER MINUTE. NO EPINEPHRINE WAS ADMINISTERED.
1351328	5/26/2021	VT	16	F	5/26/2021	5/26/2021	Patient experienced seizure activity after receiving 2nd dose of pfizer vaccine. Sx started approximately 5 mins after receiving injection. fell and hit head. B/L upper extremity contractures noted that did not resolve and was associated with extreme pain and muscle rigidity.

<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>
1349507	5/26/2021	SC	61	M	4/16/2021	4/18/2021	<p>Bad cold; Coughing, from a dry cough at first to a very wet cough; Coughing, from a dry cough at first to a very wet cough; Very large thick solid segments of gelled mucous coming out of my sinuses; could not think as tightly as usual on 19Apr2021; Sinuses became burning; Bad headaches; Unusually tired; This is a spontaneous report from a contactable consumer (patient). A 61-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) dose 2 via an unspecified route of administration, administered in arm left on 16Apr2021 17:00 (Lot Number: Lot EW0151) as 2nd dose, single for covid-19 immunisation. Medical history included Mild seizure disorder and Hay fever. No known allergies. Concomitant medications received within 2 weeks of vaccination included carbamazepine; oxcarbazepine; diphenhydramine hydrochloride (BENADRYL). The patient Did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously received first dose of BNT162B2 in arm left on 20Mar2021 05:00 PM (Lot number: ER8727). Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, patient has not been tested for COVID-19. No other vaccine in four weeks. The patient felt fine following the 2nd shot, for 48 hours on 18Apr2021, but unusually tired so he knew it must had been the shot. The next day on 19Apr2021 his sinuses became burning and he assumed it was hay fever because he had experienced some symptoms of that for the previous two weeks. But the next day on 20Apr2021, Tuesday, it was worst, like a bad cold (which all of this "reaction" may had been), but then the next 3 days he could barely get out of bed and that's unusual because he run every day and nothing stops him, including a cold. he had bad headaches on 19Apr2021 for 5 days or so and symptoms included coughing, from a dry cough at first that Wednesday to a very wet cough and very large thick solid segments of gelled mucous coming out of his sinuses, something he had never seen before. After almost two weeks he felt better but was still coughing, and now three weeks later he was still really tired, could not think as tightly as usual on 19Apr2021. His doctor's office told him not to come in, just to take pain reliever and cough syrup, which he was doing anyway. Test was neg. The adverse event result in doctor or other healthcare professional office/clinic visit. No covid prior</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>
							vaccination. The patient underwent lab tests included covid test (Nasal Swab): negative on 24Apr2021. The outcome of events could not think as tightly as usual on 19Apr2021, sinuses became burning, bad cold, bad headaches and very large thick solid segments of gelled mucous coming out of my sinuses was recovered and other events was not recovered. No follow-up attempts are needed. No further information is expected.
1351261	5/26/2021	WA	44	M	5/19/2021	5/20/2021	Could not control movements from waist up. Having spasms of muscles from waist to head. Could move legs and feet purposely. No seizure activity. BP 116/70, HR 72 Reg, R 18 Skin cold and clammy. Laid him down, elevated feet, covered with blankets. Unable to obtain O2 sat with pulse oximeter. He could not communicate orally. Only by blinking. Event started at 2:30 am about 13 hours after vaccine. Symptoms slowly resolved over 2 hours until he was able to rest. Administered (2) 325 mg Tylenol at 4:30 am. Able to communicate orally, squeeze both hands, awake, alert and oriented. All symptoms subsided. O2 sat 99. Next day only extremely sore muscles from waist up

<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>
1345826	5/25/2021	CT	64	F	4/7/2021		<p>feels like had seizure; delirious; head swelled up like a pumpkin/face, neck, hand swelling; Bloating; migraine headache in half of head; injection site hot, hard, pink, swollen bigger than a deck of cards; brain fog; GI system feels like 100 bottles of hot sauce; GI system felt like 100 bottles of hot sauce; No appetite; shortness of breath; fast heartbeat; injection site hot, hard, pink, swollen bigger than a deck of cards; injection site hot, hard, pink, swollen bigger than a deck of cards; injection site very red; nausea; fatigue; face, upper chest, and arms turned pinkish; fever; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (feels like had seizure) and DELIRIUM (delirious) in a 64-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 07-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 07-May-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 SEIZURE (feels like had seizure) (seriousness criterion medically significant), DELIRIUM (delirious) (seriousness criterion medically significant), SWELLING (head swelled up like a pumpkin/face, neck, hand swelling), ABDOMINAL DISTENSION (Bloating), MIGRAINE (migraine headache in half of head), VACCINATION SITE WARMTH (injection site hot, hard, pink, swollen bigger than a deck of cards), FEELING ABNORMAL (brain fog), ABDOMINAL DISCOMFORT (GI system feels like 100 bottles of hot sauce), FUNCTIONAL GASTROINTESTINAL DISORDER (GI system felt like 100 bottles of hot sauce), DECREASED APPETITE (No appetite), DYSPNOEA (shortness of breath), HEART RATE INCREASED (fast heartbeat), VACCINATION SITE INDURATION (injection site hot, hard, pink, swollen bigger than a deck of cards), VACCINATION SITE SWELLING (injection site hot, hard, pink, swollen bigger than a deck of cards), VACCINATION SITE ERYTHEMA (injection site very red), NAUSEA (nausea), FATIGUE (fatigue), RASH (face, upper chest, and arms turned pinkish) and PYREXIA (fever). At the time of the report, SEIZURE</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>
							(feels like had seizure), DELIRIUM (delirious), SWELLING (head swelled up like a pumpkin/face, neck, hand swelling), ABDOMINAL DISTENSION (Bloating), MIGRAINE (migraine headache in half of head), VACCINATION SITE WARMTH (injection site hot, hard, pink, swollen bigger than a deck of cards), FEELING ABNORMAL (brain fog), ABDOMINAL DISCOMFORT (GI system feels like 100 bottles of hot sauce), FUNCTIONAL GASTROINTESTINAL DISORDER (GI system felt like 100 bottles of hot sauce), DECREASED APPETITE (No appetite), DYSPNOEA (shortness of breath), HEART RATE INCREASED (fast heartbeat), VACCINATION SITE INDURATION (injection site hot, hard, pink, swollen bigger than a deck of cards), VACCINATION SITE SWELLING (injection site hot, hard, pink, swollen bigger than a deck of cards), VACCINATION SITE ERYTHEMA (injection site very red), NAUSEA (nausea), FATIGUE (fatigue), RASH (face, upper chest, and arms turned pinkish) and PYREXIA (fever) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Heart rate: increased (High) increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not given. Action taken was not applicable as patient completed both the doses. 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, 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, Further information has been requested.
1348476	5/25/2021	MO	59	F	5/13/2021	5/13/2021	PATIENT WITH HISTORY OF SEIZURES WENT INTO A SEIZURE ABOUT 5 MINUTES AFTER ADMINISTRATION. PATIENT ALSO HAD SEIZURE WITH 1ST DOSE.
1347896	5/25/2021	MO	30	F	5/21/2021	5/21/2021	Seizure and loss of consciousness, resulting in emergency room visit

<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>
1347825	5/25/2021	OR	45	F	4/27/2021	5/19/2021	Seizure
1347797	5/25/2021	OR	15	F	5/23/2021	5/23/2021	Seizure at the time of vaccination. Mother in the car and recorded. Known history of seizures and they will follow up with an epileptologist. They are comfortable going home as this happened after the nasal swab as well and they suspected this would happen today. No further information needed today.

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1347736	5/25/2021	WA	74	M	5/21/2021	5/21/2021	CONTACT NOTE: Patient and spouse on campus today for scheduled covid vaccine. Spouse is also caregiver. 1442- this RN responded to alert from Front desk identifying the patient and the report of his wife whom had brought him to the lobby for help as he had had a "Focal seizure". Unknown baseline moving forward- evident patient totally dependent, unknown speech baseline. Right hand and bilateral legs contacted. This RN donning PPE as per above walked onto lobby scene with Wife controlling patient's home wheelchair of which he was secured into with a gait belt. Per wife "He had his covid shot about 3 hours ago, he has a history of seizures" Patient unresponsive to name or sternal rub, radial pulse present, thready, even chest rise, eyes open, equal bilateral pupils. This RN wheeled patient to hallway also responding to the FD message, Team Nurses involved in patient's care. This RN attempting to illicit response, some grimace to sternal rub. 1443 74/40 BP HR: 56 SPO2 87% RA- eyes open and reactive to light. Oxygen 4L applied. 1444- Patient responsive to sternal rub, follows commands to blink when he hears his name consistent with the assessment command "blink if you can hear me". 90/57 HR: 80 SPO2 100% 4 L NC 1450- able to grip with left hand, right hand contracted and with pulse oximetry applied. Respirations continue even and unlabored, saturations satisfactory, no verbal response, blinks at will, appears to be gaining lucidity. Decreased to 2L NC, moving head freely. 1500 86/56 78hr 1 L NC 99% with good non-verbal response, pupils contracting bilaterally equally in harmony, remains non-verbal. Able to grip and release RN fingers, move head freely, blink at command. Patient transferred to Gurney and transported. OF Note: EMS on standby for all of assessment from ~1445 forward. SBAR provided with known history, presentation, and known Dx on file. Wife/Caregiver to go with patient via ambulance, patient wheelchair stored, name on chair. All personal belongings : yellow cap, black bag, given to wife. Wife informed staff will follow up post discharge, understands to notify via call to staff of discharge from Hospital Facility: Hospital. OUTPATIENT MEDS: DRUG LIST As of May 21, 2021 This object does not handle Complex Pharmacy Orders. ----- ASPIRIN 81MG CHEW TAB GALANTAMINE HYDROBROMIDE 8MG TAB HYDROPHILIC (EQV

<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>
							AQUAPHOR) TOP OINT METOPROLOL TARTRATE 25MG TAB MULTIVITS W/MINERALS TAB/CAP (NO VIT K) OMEPRAZOLE 20MG EC CAP SERTRALINE HCL 100MG TAB TAMSULOSIN HCL 0.4MG CAP
1347659	5/25/2021	OK	40	F	3/2/2021	3/9/2021	One week after 1st covid vaccine pt. c/o itching and rash on right lower jaw, worse at night, helped with OTC cortisone cream. After 2nd covid vaccine, itching and rash got worse, spread across face and to back of neck. Rash "comes and goes", is worse at night and pt. gets short term relief w/the cortisone cream. Takes Depakote for a seizure condition and has contact allergies to plants and animals; is otherwise healthy. Has not sought care from her PCP because of cost. Advised on other OTC measures and if not improved, to see her PCP for eval. She feels it is not a serious condition but wanted to report it.
1347580	5/25/2021	NY	21	F	5/25/2021	5/25/2021	On 05/25/21 at 03:23PM patient received the Janssen Vaccine Covid-19 and 10 minutes post administration she had 2 anxiety induced seizure (pseudo-seizures). The first seizure lasted about 2 minutes, followed by a second seizure that lasted approximately 30 seconds. The patient stated she's gotten anxiety induced seizures in the past, but never after a shot administration. She was fine for 10 minutes, then said she felt a seizure onset. We lowered her and placed her flat on the ground. Her heart rate was around 100bpm and blood pressure 140/90. The paramedics came to the scene and took patient to Hospital to get checked out.
1347473	5/25/2021	FL	67	M	3/12/2021	3/13/2021	I experienced a seizure. A family member told me I was "out" for 1 or 2 minutes, got very stiff, breathed very heavy then seemed as though I stopped breathing, involuntarily urinated. When I came to, my speech was slurred for a few minutes and my blood pressure was very low. The EMT's arrived, took my blood pressure, reported it was 85 / 58. After a few minutes, drinking some fluids, I began to feel more normal. I declined to go with the EMT's. That afternoon, I was extremely tired and slept most of the afternoon.

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1346998	5/25/2021	VA	17	M	4/21/2021	4/21/2021	Patient fainted 10 minutes post-vaccination and reportedly had shaking/seizure-like activity. Patient felt cold and dizzy and requested transport to ER. Transported to medical center by EMS.
1346813	5/25/2021	VA	47	F	4/16/2021	4/16/2021	Patient was described as having a "Grand mal" seizure within 15 minutes of vaccination. Patient was observed, refused transport to ER, and was released to home when she felt better.
1346739	5/25/2021	FL	26	F	5/24/2021	5/24/2021	Client underwent seizure activity 10 minutes subsequent to vaccine administration. Nursing staff was available to keep client safe and to assess for airway, breathing and circulation; supplemental oxygen and rescue inhaler (provided by client's caregiver) was administered. EMS was dispatched and client was safely transported to a local hospital emergency department.
1346613	5/25/2021	AL	17	F	5/25/2021	5/25/2021	PATEINT RECEIVED INJECTION AND ABOUT 6 MIN LATER SHE FAINTED AND HAD A 5 SEC SEIZURE. WOKE UP ON HER OWN
1345409	5/25/2021	NJ	75	F	5/5/2021	5/12/2021	Convulsions, unable to walk, Uncontrolled.
1346649	5/25/2021	NJ	15	F	5/24/2021	5/24/2021	Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Mild
1343707	5/24/2021		15	M	5/21/2021	5/21/2021	Approximately 1 minute after receiving vaccine, patient experienced what appeared to be a generalized tonic-clonic seizure, lasting 4-4.5 minutes. The patient regained consciousness and was awake, alert and oriented x3. Patient and father refused transport by EMS to ED for evaluation. The patient's father reported prior history of seizures after needlestick.
1343284	5/24/2021	NY	28	M	5/24/2021	5/24/2021	Pt received IM vaccination and was told to wait up front in store. Noticed patient seizing in his chair less than 5 minutes after the shot. He was lowered to the floor and placed on his side. Total seizure was about 30 seconds. Pt came around and had no previous history of seizures.
1343206	5/24/2021	FL	36	F	5/21/2021	5/21/2021	Pt was given vaccine and shortly after experienced seizure activity, EMS was called and pt. was transported to ER.

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1343550	5/24/2021	AR	39	F	5/24/2021	5/24/2021	Patient's husband said patient passed out and had a seizure around 30 minutes after vaccine. When I arrived at patient she was sitting up conscious. Ambulance arrived and she was turned over to their care.
1342590	5/24/2021	RI	21	M	5/20/2021	5/1/2021	Very high fever, 108, leading to passing out, convulsion then vomiting

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1342964	5/24/2021	KY	15	M	5/15/2021	5/23/2021	At approximately 6 PM on 05/23/2021, family was sitting down for dinner when all of a sudden she noticed that he was turning his head to the left and appeared to be falling out of his chair. Mom states that eyes were darting back and forth at this time. He was not responding to her shouting his name and his left arm was curled in towards his body with the rest of his body remaining stiff. This lasted approximately 1 minute, followed by a time of confusion and drowsiness. Approximately 1 minute later mom states that patient's eyes rolled back to his head and he had full body movement consistent with tonic-clonic seizures. Family were able to lay him onto the ground during this time. Mom denies any color change, apnea, or loss of bowel or bladder. States he did have one episode of emesis following the event, and 2 episodes of emesis in the ambulance on the way to ED. Patient has no previous history of seizures or seizure-like activity. No new ingestions. Has not been sick recently and denies any new sick contacts. There has been no head trauma. Per Mom, patient's dad has a history of "partial seizures" but never required any medication for them. At arrival to the ED he continued to be drowsy and not at his normal baseline. Continue to hold his left wrist up toward his body in a contracted manner and tended to have repetitive speech. Briefly, ER course significant for a CT head and evaluation by pediatric neurology. CT head was unremarkable for acute intracranial process. A CBC, CMP, and coags were also obtained due to patient's continued contracture positioning and the possibility of a stroke. CMP was unremarkable with a sodium of 139, potassium of 3.7, chloride of 107, bicarb 25, BUN of 12 and creatinine of 0.64. CBC was also unremarkable with WBC of 10.72, hemoglobin of 14.8, hematocrit of 44.4 and platelets of 370. There was 81.77% neutrophils after evaluation by neurology it was felt that the patient remained postictal and recommended that he be admitted on continuous EEG and possible MRI in the a.m.
1343058	5/24/2021	MO	33	M	4/15/2021	5/16/2021	High and low swings to my blood sugar levels. Low blood sugars to the point of seizure requiring emergency attention .

<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>
1343184	5/24/2021	IN	23	M	5/22/2021	5/22/2021	Passed out in observation room approx. 5 minutes after the dose, had a mild seizure and tore up my left ear on the carpet. History of passing out in hospital settings, possible vasovagal syncope, no history of seizures. recovered on hallway bed with granola bars and sprite. Approx. 9:30 pm temperature jumped within a couple of hours to around 101, after going to bed was half-awake-half-asleep until 7 am with vivid dreams/internal dialog.
1343575	5/24/2021	IA	17	M	5/18/2021	5/18/2021	Patient reported they couldnt stand the sight of blood and had fainted during draws before. Father was present in the vaccine office as well. Immediately fooling the administration of the vaccine patients eyes glazed over and he fainted. A few seconds later he began to have a spastic seizure that was short in nature, followed by a voiding of his bladder before he regained consciousness. Patient was given water, glucose tablets, and instructed to lay on the floor of the room with his feet elevated while a member of the staff stayed with him to treat and watch him. Followed up with patient and doctor soon after to learn this was the only time it has happened, patient fully recovered.
1343249	5/24/2021	TX	41	M	5/22/2021	5/22/2021	~15-30 mins post vaccine dose, patient developed seizure and transferred to outside hospital emergency room via ambulance. Unknown if patient admitted.
1343672	5/24/2021	CO	20	M	5/24/2021	5/24/2021	Pt received his vaccine and returned to the waiting room. Within 5 minutes he slumped to the floor, he lost consciousness and had a brief seizure lasting less than 30 seconds There was a sheriff deputy in the waiting area that asked him his name, year, president and where he was. He was able to answer all questions, but was still shaking. We called 911 and EMTs were here within 2 minutes and took over. After assessing him and taking his vitals they decided to transport him to Hospital.
1344175	5/24/2021	MI	57	M	3/1/2021	5/23/2021	tested covid positive by PCR on 5/23/2021, may have pneumonia, mild, unclear if covid or bacterial cause. Patient presented with a seizure after binge drinking, relapsed alcoholism

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1343730	5/24/2021	OH	16	F	5/24/2021	5/24/2021	Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Medium, Systemic: Seizure-Medium, Systemic: Shakiness-Medium, Additional Details: Patient had seizure with 1st vaccine, pediatrician informed mother to have patient lay down if it happens again. Patient said she felt out of it (at 11am) after administration of this vaccine so we helped her lay down on the floor with her head propped up. Gave her water and turned on the fan to try and make her more comfortable. Patient decided to try sitting up slowly after 10-15 minutes, then after another 10 minutes she was able to stand and felt back to normal and left the store 11:30am.
1343737	5/24/2021	OR	32	F	5/19/2021	5/22/2021	New onset generalized seizure, arrhythmia. Patient was sent to ED where labs and imaging were normal. She is now back at baseline and will be seeing a neurologist.
1343751	5/24/2021	OR	36	M	5/15/2021	5/16/2021	Diaphoresis started same day following COVID vaccine 05-15-2021. On 05-16-2021, patient lost consciousness and had a seizure. Taken to ED for evaluation.
1343871	5/24/2021	TX	15	F	5/22/2021	5/22/2021	Pt received vaccine and was standing outside of immunization room with her parents waiting for her brother to receive vaccine. She felt dizzy and fainted. She hit her head and collapsed. She was seizing/shaking on the floor. She was conscious with no visible bleeding. She was able to say her name and DOB correctly. Mother reported no history of epilepsy or seizure. Called emergency services and pt was taken to Clinic for further evaluation. A 1.5cm laceration was noted behind her left ear. Pt received 2 staples in the lacerated area.
1343913	5/24/2021	KY	17	F	5/24/2021	5/24/2021	Possible seizure; EMS removed patient within 15 minutes of beginning of adverse event
1344047	5/24/2021	MA	66	F	5/19/2021	5/19/2021	Patient developed generalized tonic clonic seizure several hours after Pfizer vaccine.
1344049	5/24/2021	TX	47	M	5/24/2021	5/24/2021	Patient had become extremely paleness, sweating, coldness of the hands, light headed, dizziness, weakness, shaky like trembling sign of minor seizures.

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1344902	5/24/2021	MI	23	M	5/24/2021	5/24/2021	Patient had reported previously losing consciousness after vaccination a few years prior. About one or two minutes after receiving the vaccine the patient lost consciousness and experienced mild convulsions lasting in total about 10 seconds. His mother was present and explained this was the same reaction he had experienced several years earlier with a previous vaccine. The patient regained consciousness and reported that he felt dizzy, but otherwise okay. He appeared clammy and asked for some water. I gave him a bottle of water, which he drank slowly. He reported to us feeling the same as he had after the previous vaccine reaction. As patient was conscious and speaking clearly, I watched him and asked him to wait until he felt comfortable to stand. At one point he asked to sit on the floor, but was eventually able to sit on the chair again, then move to another chair in our waiting area about 20 minutes post-vaccination. I asked him to wait for a total of 30 minutes or longer if he felt anything unusual. At 6:39 approached me and said her son was feeling normal and they would be leaving.
1344876	5/24/2021	SC	18	F	5/24/2021	5/24/2021	Patient frequently faints following vaccinations. About 2-3 minutes after receiving vaccination, patient fainted while sitting in a chair. Once patient began to come to, she convulsed. Pharmacist and nearby customers helped lay her on the ground. Patient came to and was given water and a glucose tablet. EMS was called at the start of the incident. Patient remained lying down until she felt ok to sit up. EMS checked her blood pressure, which was normal and she was ok to go home.
1344402	5/24/2021	NM	39	M	5/24/2021	5/24/2021	Patient had a seizure immediately following vaccine administration. EMS services were called to pharmacy.
1343618	5/24/2021	FL	28	F	5/18/2021	5/21/2021	Lips, finger nails, and toe nails turned blue/purple. Body convulsions caused by feverish chills, fever of 102.4. Unresponsive moments.
1341688	5/23/2021	NY	12	F	5/17/2021	5/23/2021	First time seizure 6 days post vaccination GTC w/ post ictal state. Unknown duration of seizure. Back to baseline in ER
1342319	5/23/2021		29	M	5/23/2021	5/23/2021	Pt had focal seizure. Evaluated by EMS- Transported to Emergency room/department or urgent care

<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>
1341624	5/23/2021	FL	15	M	5/22/2021	5/22/2021	Systemic: Dizziness / Lightheadness-Severe, Systemic: Seizure-Mild, Additional Details: patient suddenly fell down, had a slight seizure last around 5 sec and regains concious. He feels fine but pharmacy still called 911 and was escort to receive emergery/urgent services.
1341674	5/23/2021	FL	42	M	5/17/2021	5/17/2021	Could not get air into lungs, made sugar get out of control, had a seizure and turned purple, passing out , ambulance had to come get me from vehicle and take me to emergency room in the hospital, kept me there for about 6 hours then released me to go home, went to my Doctor next day and he immediately sent me to hospital. I was checked for Blood Cloth due to the signs being there along with other tests I am home however I still do not feel well.
1341840	5/23/2021	FL	27	M	5/23/2021	5/23/2021	After injection, patient jolted and eyes fluttered. He seemed to be having a seizure like reaction. He then slumped to side and head hit side of wall since we had chair with side rails positioned against wall. He lost conscious for maybe 30 seconds and then eyes opened. I asked if he was OK and the first thing he asked for was water. He said he felt light headed and dizzy. I had my intern who was working grab him water from the deli and had him sit and rest. He started sweating and asked for paper towels. I grabbed him a couple of towels so he can wipe his face. I continued to check on him while doing my work. He seemed fine after that. After 30 minutes, I checked his blood pressure. It read 100/63. I continued to monitor him and he left after that. He did have friend with him the entire time who helped him.
1342166	5/23/2021	FL	82	F	4/8/2021	4/9/2021	stroke-like symptoms; left side extreme weakness; gran mal seizure with loss of cognitive function; gran mal seizure with cognitive awareness; loss of depth perception and dizziness. Treatment: increase in lamotrogine from 200mg/150mg to 200mg/200mg
1341935	5/23/2021	IL	14	F	5/23/2021	5/23/2021	pt fainted/had seizure 50 to 10 minutes after covid vaccine. pt did not fall, dad held her.head and eyes rolled back, shaking and stiff for 2 seconds per dad. pt alert, breathing, and movement looked normal when I saw pt . pt mom called 911 and pt was taken to hospital . no history of fainting or seizures per dad

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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. :(

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1341822	5/23/2021	WA	25	F	5/22/2021	5/22/2021	About 30 seconds after the vaccine was administered the patient collapsed in her chair and began to seize. Prior to the collapse she had asked to sit for a moment and said that she was feeling strange. I stabilized her in the chair until the seizure finished, it lasted about 30 seconds. I then helped her to the floor and had her sit against the wall. She was pale and confused but conscious. She complained of head and neck pain, as well as oral pain. She denied seizures in the past, but states that she may have previously had "seizure-like activity". I asked my technician, to call 911. Once emergency services was on the way I kept her in the immunization room with the door propped open and got her an apple juice. Then I stayed with her until EMS arrived. EMS determined that she was stable and stayed with her until family arrived to take her home

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1340314	5/22/2021	AZ		F	4/11/2021	4/13/2021	joint and muscle pain; Exhaustion; earlier and increased menstrual symptoms; earlier and increased menstrual symptoms; brain fog; shortness of breath on exertion; sleep disturbances; joint and muscle pain; This is a spontaneous report received from a contactable consumer (patient). A 33-year-old female patient (not pregnant at the time of vaccination) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Right on 11Apr2021 12:00 (Lot Number: EW0162) as single dose for COVID-19 immunisation. Medical history included wolff-parkinson-white syndrome (WPW), Atrioventricular nodal reentry tachycardia (AVNRT), anaemia, arrhythmia, psoriasis, Psoriatic arthritis, Ankylosis spondylitis, Premenstrual dysphoric disorder (PMDD), endometriosis, tinnitus, hip impingement, Raynaud's syndrome, Irritable bowel syndrome (IBS), depression, anxiety, celiac, unspecified seizure disorder and allergy to gluten. The patient received other medications within 2 weeks of vaccination. The patient previously received vancomycin, cardizem and experienced drug allergy. The patient experienced exhaustion, earlier and increased menstrual symptoms, brain fog, shortness of breath on exertion, sleep disturbances, joint and muscle pain on 13Apr2021 14:30. It started 2 days post vaccination, and has continues for 12 days, so far. It waxes and wanes. 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 treatment for events. The outcome of events was not recovered. No follow-up attempts are needed. No further information is expected.

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1340165	5/22/2021	NY	58	F	3/21/2021	3/21/2021	myoclonic seizure; Dizziness; fever; This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCLONIC EPILEPSY (myoclonic seizure), DIZZINESS (Dizziness) and PYREXIA (fever) in a 58-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included COVID-19 in January 2021. Concurrent medical conditions included Migraine headache. On 21-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Mar-2021, the patient experienced MYOCLONIC EPILEPSY (myoclonic seizure) (seriousness criteria hospitalization and medically significant), DIZZINESS (Dizziness) (seriousness criterion hospitalization) and PYREXIA (fever) (seriousness criterion hospitalization). The patient was hospitalized on 21-Mar-2021 due to DIZZINESS, MYOCLONIC EPILEPSY and PYREXIA. At the time of the report, MYOCLONIC EPILEPSY (myoclonic seizure), DIZZINESS (Dizziness) and PYREXIA (fever) 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. Treatment medications were not reported. Concomitant medications were not reported. 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.
1341086	5/22/2021	WA	12	F	5/22/2021	5/22/2021	AFTER RECIEVING VACCINE FIRST DOES PT HAD A SEIZURE AND VOMMITED. DOES HAVE HISTORY OF SEIZURES.

<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>
1340382	5/22/2021	MA	16	M	5/7/2021	5/8/2021	Not sure if seizure; body muscles started shaking; Pain in lower spine on back; Pain in lower spine on back; This is a spontaneous report from a contactable consumer (patient). A 16-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration (at the age of 16-years-old), administered in Arm Right on 07May2021 13:00 (Batch/Lot Number: Unknown) as 2nd dose, single for COVID-19 immunization. Medical history included type 1 diabetic, allergies to severe peanut, "tree but", shellfish. Concomitant medication included insulin lispro (HUMALOG) taken for an unspecified indication, start and stop date were not reported. The patient previously received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration (at the age of 16-years-old), administered in right arm on 16Apr2021 13:00 (Batch/Lot Number: Unknown) as 1st dose, single for COVID-19 immunization. The patient experienced Pain in lower spine on back and body muscles started shaking uncontrollably, not sure if seizure on 08May2021 02:00. No treatment received for the events. The outcome of the events was recovered. The event seizure was considered as serious (medically significant). Facility where the most recent COVID-19 vaccine was administered was 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. Information about lot/batch number is requested.
1340410	5/22/2021			U			Had a seizure after getting their vaccine; This is a spontaneous report from a non-contactable other HCP. A patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), UNKNOWN, SINGLE for covid-19 immunisation. The patient had a seizure getting vaccine. The patient reportedly had a known seizure problem. Outcome of the event was unknown. Information on the lot/batch number has been requested.

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1340429	5/22/2021		27	F	4/17/2021		Breakthrough seizures; This is a spontaneous report from a non-contactable consumer (patient). A 27-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration administered in right arm on 17Apr2021 (at the age of 27-year-old) (Batch/Lot number was not reported) as 1ST DOSE, SINGLE for COVID-19 immunisation. The patient was not pregnant at the time of the vaccination. Medical history included epilepsy. The patient had known allergies to Ceclor. Concomitant medications included levetiracetam (KEPPRA); lacosamide (VIMPAT); and sertraline hydrochloride (ZOLOFT). On an unspecified date, the patient experienced breakthrough seizures. The patient stated that she was on a medicine to control epilepsy and the night after getting the shot, she experienced a breakthrough seizure. There was no treatment received from the event. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

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1340439	5/22/2021	MT	24	F	5/5/2021	5/5/2021	still didn't feel good; slight fever it was 102; throwing up; anaphylactic allergies, and swell up like her throat, neck and face swelled a little bit; Cold and flu symptoms; Cold and flu symptoms; her arm was really killing her; This is a spontaneous report from a contactable consumer (patient). A 24-year-old female patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration on 05May2021 (Lot Number: EW0167) as single dose for covid-19 immunisation. Medical history included weird blood pressure (kind of have weird blood pressure, it goes up and down pretty frequently, no treatment), endometriosis, seizure. Concomitant medications included lamotrigine (LAMOTRIGINE) taken for seizure; quetiapine. The patient had an adverse reaction to the first of the two vaccine shot and wanted to know if she can get the second. She had pretty bad cold and flu symptoms and did have anaphylactic allergies, and swell up like her throat, neck and face swelled a little bit on 06May2021. It wasn't enough to go to the emergency room. She took Benadryl and kind of monitored but she thought her doctor would have called it like a pre-anaphylactic sort of reaction. The patient was having the reactions on yesterday (06May2021), still didn't feel good today (07May2021). She started to swell up she took Benadryl and Tylenol because she had slight fever it was 102 (06May2021). So, Tylenol 400 mg (took 2 pills), took 600 mg of Ibuprofen and the Benadryl 200 (200 but not entirely sure). She tried not to take medication unless have to, the moment she started throwing up she took the Benadryl only took that once, her arm was really killing her so she did take the Ibuprofen twice yesterday (06May2021) and twice Wednesday (05May2021). The fever came back yesterday (06May2021). Tylenol, probably the same twice on Wednesday, twice on Thursday, the patient hadn't had to take any today (07May2021). The outcome of events was not recovered.

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1341185	5/22/2021	CA	14	M	5/22/2021	5/22/2021	<p>Situation: 14yo male came in for first dose Pfizer vaccine. Within 5 mins after receiving vaccine, patient had a seizure for approximately 1 minute. During seizure, patient was incontinent of urine. RN was able to get to patient's side before he fell. Background: Patient did not alert vaccinator or RNs that he had a history of seizure. Mom informed staff after the event that he had a febrile seizure when he was a young child. She did not disclose what age he was at the time of the previous seizure. Assessment: RN observed patient in an active seizure for 1 minute in which his body contracted out and his eyes rolled back. She was at his side to prevent him from falling. He was placed on a gurney and moved to room 6 for closer observation for 30 mins. Pfizer vaccine administered on 5/22/21 at 12:52PM 1255 vitals ? 121/64(83), 97.3F 1257 vitals ? 122/75(90) 1311 vitals ? 116/76, HR 68, 100% O2 1318 vitals ? 112/75, HR 68, 100% O2 1325 vitals ? 111/61, HR 68, 99% O2 Recommendation: MD on call, was called and notified of the event. Her recommendation was for the patient to go to the ED for evaluation and labs. RN called the ED to notify them of the patients intended arrival. The mom agreed to take the patient to ED for further evaluation. The patient was taken out via wheelchair.</p>

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1340497	5/22/2021	NJ	63	F	5/2/2021	5/2/2021	seizures; Vomiting; This is a spontaneous report from a contactable consumer (patient). A 63-year-old female patient received BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), second dose via an unspecified route of administration, administered in left arm at the age of 63-year-old on 02May2021 (Lot Number: EWQ0171) as single dose for covid-19 immunisation. Medical history reported as no. There was no known allergies. Concomitant medication included telmisartan (MICARDIS) from 2021 (received within 2 weeks of vaccination). The patient previously took first dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in right arm on 11Apr2021 (Lot Number: ER8729) as single dose for covid-19 immunisation. The patient experienced vomiting and 3 episodes of severe seizures after 9 hours of last vaccine dose on 02May2021. The patient was taken to the hospital emergency room and ICU for treatment. The patient reported the case as non-serious. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The was not pregnancy at time of vaccination. Prior to vaccination, the patient wasn't diagnosed with COVID-19. Since the vaccination, the patient had been tested for COVID-19. The patient underwent lab tests and procedures which included covid test(Blood test): negative on 03May2021. Therapeutic measures were taken as a result of the events. The outcome of the events was recovered in May2021.

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1340500	5/22/2021	CT	55	F	3/2/2021	3/3/2021	<p>She aspirated and she was dead within week on respirator; she aspirated and she had pulmonary problem to begin with; 3 convulsions within 24 hours of having her first Pfizer / three grand mal compulsive seizures; This is a spontaneous report from a contactable physician. A 55-years-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 02Mar2021 (Batch/Lot number was not reported, vaccinated at the age of 55 years old) as single dose for covid-19 immunisation. Medical history included epilepsy, myocardial metabolism disorder. She has a myocardial metabolism disorder, very specific one and it is A467T mutation in the polymerase gamma gene and that is because of her epilepsy. It was because of that it's a progressive disease get involved with many part of the body that is all so causes seizure. Concomitant medications included clobazam; lamotrigine; escitalopram; amitriptyline; calcium folinate (LEUCOVORINE); lorazepam; mesalazine; butalbital, caffeine, paracetamol (FIORICET); vitamin b2 [riboflavin] (VITAMIN B2 [RIBOFLAVIN]); ubidecarenone (COQ10 [UBIDECARENONE]); l-carnitine [levocarnitine]; vitamin b complex (B COMPLEX [VITAMIN B COMPLEX]); vitamin a [retinol]; vitamin c [ascorbic acid], all taken for an unspecified indication, start and stop date were not reported. The patient previously took sulphur, nepatop, dilantin [phenytoin], prednisone, and lidocaine and all experienced hypersensitivity. The patient had received 3 convulsions within 24 hours of having her first Pfizer and she had epilepsy like she has been suffering from years and she aspirated and she was dead within week on respirator. She had three grand mal compulsive seizures and because of the seizures; she aspirated and she had pulmonary problem to begin with. She was put on a respirator and she was on respirator from the day she was admitted and she probably died within about two days. when the vaccination was, precise 24 hours later she had three grand mal compulsive seizures and because of the seizures she aspirated and she had pulmonary problem to begin with. She had 3 convulsive seizures that stayed for about 10 minutes and she had not, she normally would have the focal seizure just in her left arm. She has not had it big seizure in probably 20 years. The physician stated that don't know what killed</p>

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							her was not seizure when she wasn't he hospital she was intubated and she was alive. What killed her was she was aspirated and they could not get her off the respirator and she did not have COVID. When she was admitted to the hospital they did a lot of blood test. Before that, her cortisone level usually runs about 200, with metabolize of 700, and her lamotrigine level runs about between 4 and 8.5 of all other routine her Full blood count (CBC) routine is quite normal. It was not reported if an autopsy was performed. Outcome of events Grand mal seizure and Pulmonary disorder was unknown. Information on batch number has been requested.; Sender's Comments: Based on the available information and known product profile, the causal relationship between the reported seizures along with the consequent aspirations which lead to death and the use of BNT162B2 cannot be fully excluded. However, it is noted that the patient has multiple comorbidities which confound the reported drug event pairs. 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: She aspirated and she was dead within week on respirator
1340667	5/22/2021	FL	14	M	5/14/2021	5/20/2021	Seizure. He was stiff, shaking uncontrollably, gasping for air. Seizure lasted 2-3 minutes. Rescue was called to the house. Had to be taken to ER. ER conducted CBC test. Results came back normal. Was prescribed as needed Valium suppository bc this was his first seizure ever
1340795	5/22/2021	MD	15	F	5/22/2021	5/22/2021	Pt. fell to floor from chair, dizziness, possible seizure activity 12 Lead, started IV, 0 meds. Vital signs: 89/40 Pulse:60 89/41 Pulse :55 89/42 Pulse:56 Recorded by RN. Pt. transported to hospital via ambulance at 11:32 A.M. with mother.

<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>
1340831	5/22/2021	MO	65	F	2/16/2021	3/9/2021	stroke like systems including seizure, memory loss. Transported to emergency room at hospital via ambulance . Following test performed; cat scan, IGG scan, and MRI with kontras . No exact cause for the seizure was determined at this time.
1341067	5/22/2021	MI	15	F	5/22/2021	5/22/2021	Patient began to feel light headed and asked her mom for water. Patient then fell to the side and hit her head as she fell to the floor, then had a seizure lasting 30 sec. patient was Alert and oriented x4 when we got to her. Patient stated she felt like she was falling asleep and dreaming then remembers everyone standing over her. Patient has small bump on upper left of head. Patient was taken to medical center for treatment and observation.

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1340164	5/22/2021	TN	30	F	1/19/2021	1/19/2021	Seizure; Syncope; Diarrhoea; Chills; Vomiting; This case VAERS (Reference number: 0989940) 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 and describes the occurrence of SEIZURE (Seizure) and SYNCOPES (Syncope) 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 Epilepsy. Concurrent medical conditions included Drug allergy (sulfa). Concomitant products included LAMOTRIGINE, PHENYTOIN SODIUM (DILANTIN D.A.) and LEVONORGESTREL (MIRENA) 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 19-Jan-2021, the patient experienced SEIZURE (Seizure) (seriousness criterion medically significant), SYNCOPES (Syncope) (seriousness criterion medically significant), DIARRHOEA (Diarrhoea), CHILLS (Chills) and VOMITING (Vomiting). At the time of the report, SEIZURE (Seizure), SYNCOPES (Syncope), DIARRHOEA (Diarrhoea), CHILLS (Chills) and VOMITING (Vomiting) 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. Patient experienced profuse vomiting and diarrhea, syncope, chills, seizures. Emergency room visit received 3 bags of lactated ringers, 12 mg of IV zofran, 12.5 mg of IV Phenergan. Full blood work and 2 computerized tomogram (CT) scans but results were not provided. Based on the current available information and temporal association between the use of the product and the start date of the events of chills, vomiting, and diarrhea, a causal relationship cannot be excluded. Causality for the events of seizure and syncope are probably related to the patient's medical history.; 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 of chills, vomiting, and diarrhea, a causal relationship cannot be excluded. Causality for the events of seizure and syncope are probably related to the

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1340486	5/22/2021	IN		M			<p>patient's medical history.</p> <p>His son having back to back seizure; His son having back to back seizure; This is a spontaneous report from a contactable consumer (patient's father). A male patient of an unspecified age received 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number: Unknown), via an unspecified route of administration on an unspecified date as 2ND DOSE, SINGLE for covid-19 immunisation. Medical history included seizure (son already had a history of seizure). The patient's concomitant medications were not reported. On an unspecified date patient received 1st dose of BNT162B2 for covid-19 immunisation. On an unspecified date reporter son having back to back seizure after getting the second shot of Pfizer Covid Vaccine. Patient got VNS prior to getting shot. Son already had a history of seizure. The caller is asking does this medicine cause more seizure. The outcome of the event was unknown. Information on the lot/batch number has been requested.</p>
1337252	5/21/2021	MD	79	F	2/9/2021	2/18/2021	presented to the ER at on 2/18/21 with seizures and was found to positive for COVID in the ER, was admitted and placed on the ventilator from 2/18/21 to 2/19/21
1337315	5/21/2021		31	M	5/4/2021	5/4/2021	Had a seizure.
1336768	5/21/2021	PA	14	F	5/20/2021	5/20/2021	Patient stated she was not feeling well after her first dose of pfizer covid vaccine. Patient had seizure like activity and was unconscious for a about 15-30 seconds. an ambulance was called vitals were taken. patient and patent family declined transport to medical facility.
1337430	5/21/2021	MI	14	M	5/21/2021	5/21/2021	Within 30 secs to 1 minute following vaccination patient started to seize. He came out of the seizure quickly (approx 20-30 sec). EMS was called and on site in minutes. Patient was breathing on his own but breathing was rapid. He lost color in his face/lips. When EMS arrived they noted that he was hypotensive and bradycardic. He began to regain color while EMS was on site. They opted to take him in for further evaluation. No history of seizures.

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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.
1337440	5/21/2021	VA	17	M	5/21/2021	5/21/2021	Patient fainted approximately 5 minutes after receiving his second Pfizer vaccine. He was observed to have tonic-clonic jerking but this was not seizure nor does the patient have a history of seizures. His mother reported fainting previously during stressful situations. Ice pack was given and BP was taken at 11:20 and was 100/65 and pulse was 101. When EMS arrived, patient's BP was 134/80 and pulse was 83. Patient reported stomach pains post-fainting. EMS cleared patient to leave and he signed off that he did not want to go to the hospital.
1338359	5/21/2021	CA	18	F	5/9/2021	5/21/2021	Grandmother explained on 5/21/21 that pt had rare sickness called Panda disease that can lead to seizures, twitching, and tics. States pt had to go to ER in the evening after due to severe seizure onset, vomiting, and increased swelling in injection site.
1338373	5/21/2021	CA	28	M	5/15/2021	5/15/2021	13 Hours After Dose: Chills set in, which caused back spasming and back muscle seizing in addition to shaking for approximately 20 minutes (it may have been convulsions). Also had a fever, nausea, dizziness, and injection site pain. 24-70 hours later: Fatigue and a headache 70 hours later: Woke up with major chest pains and went to ER. Testing eventually determined it to be myocarditis. Hospital stay was approximately 54 hours.

<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>
1336870	5/21/2021	WA	85	M	1/20/2021	2/3/2021	Patient presented to the ER on 2/3/2021 with a seizure 2 weeks after his Pfizer vaccination, and was found to have striking inflammatory lesions on MRI that we presume are related to inflammatory CAA. We placed him on steroids and his edema has resolved. He feels back to his baseline. We're uncertain to what degree the induction of an inflammatory response by the vaccine might have precipitated this event (of course it did not precipitate his CAA) but to be on the safe side, we stated that he should not get his second COVID vaccination.
1336848	5/21/2021	AZ	27	F	3/29/2021	4/2/2021	On 04-02-2021, woke up feeling dizzy and out of it also has loss of consciousness. I went to the movies with my sister and had a seizure some time while at the movies. I went to the hospital and at the hospital I had a second convulsion seizure at the hospital which lasted 10 minutes and something that I had low blood count. They kept me at the hospital for 2-3 days. I also had migraines and taking anti convulsion medication. They performed MRI, EEG's, CT scans and all my exams came back within normal limits. I am not epileptic. I believe I am now stable and taking my medicine as prescribed, I am still out of work and I have not had a seizure since being at the hospital.
1337481	5/21/2021	TN	89	F	5/19/2021	5/21/2021	Resident had been experiencing cognitive decline over approximately the last month. Resident was treated for UTI on 4/29/21, labs were obtained on 5/3/21 and were unremarkable. Resident had seizure like episode at approximately 0830, resident was DNR Comfort Measures and resident's family did not want resident sent to hospital. Resident expired at 0920 on 5/21/21.
1337820	5/21/2021	TN	15	F	5/18/2021	5/18/2021	Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Medium
1338376	5/21/2021	IN	15	M	5/21/2021	5/21/2021	About 3 min after giving vaccine, pt was seen potentially having a seizure. Unconscious for about 5 seconds. Came to. Hot, sweating, dizzy. Dizziness continued for approximately 45 minutes.

<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>
1338614	5/21/2021	CA	42	M	4/17/2021	4/17/2021	<p>Within 3-5 minutes developed dizziness, tingling in feet and hands, elevated blood pressure, mild nausea. Within an hour started having trouble with focusing his vision. Was given IV fluids at hospital in ER 5 hours after the injection, while leaving the hospital developed a slight limp on right leg. Felt feverish when he got home, took Tylenol when he got home. Noted extreme fatigue. The next morning was lethargic, dizzy and right side of face felt heavy, around 11 am. Called for a telemedicine visit around 12:30p. Became weak and unable to use right side of body, upper and lower extremities and right side of face was drooping, visible to wife. Wife had support of right side of body to move around. Went to urgent care around 2p. During urgent care evaluation, his vision became more impaired and speech became unclear, had to really focus to speak. Transferred to ER. Lost ability to write name, couldn't respond when asked for SSN. Admitted as a "stroke 4". Had CT scan, CT angiogram, MRI, blood labs, cognitive tests, neurologic tests. Neurology consult. Had lost sensation to heat and pressure. All imaging and labs were normal. After MRI, had convulsions. Wasn't dx'd as a seizure. Neck felt tight afterwards. Admitted to hospital x 1 week. Had a burning, red, rash on hands, feet. No bumps, hives, but just a "splotchy" red discoloration on surface of skin that would burn and itch, often flaring at night. Rx'd ativan. Checked for autoimmune disease, Bell's palsy, followed by neurologists, repeat MRI normal. Started to improve, discharged after one week with no clear diagnosis. Discharged to rehab facility. Patient preferred to transfer care to outpatient rehab service closer to home with more social support. Repeat hospitalized 3 weeks later, less extreme, went back to ER, stroke eval neg. Developed more aphasia. Called back to ER for further evaluation of C-spine due to mild abnormality on first scan. On further evaluation not thought to be connected to symptoms. EEG report pending. +Right hemiplegia, aphasia persists. +Rash, itching, burning persist.</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>
1338625	5/21/2021	NM	32	F	5/20/2021	5/21/2021	Outcome: unexpected/unexplained death Had first dose Moderna Vaccine 3/31/21. She described body aches and mild fever ? ?like I had COVID again for a day? ? lasting about 36 hours, and then felt fine. Had dose # 2 Moderna vaccine about 6:50 PM at Community vaccination site. She was driver, received left deltoid injection from Doctor. During observation period reported no symptoms, was happy and talkative with family and staff. Family reports later that evening she did not feel well ? ?just not hungry? and wanting to lie down. Slept well, then woke up feeling better except for left arm achiness at injection site. Did not report redness, rash, or any difficulty breathing. Was talkative, walking around, took a shower, and was planning to drive to the grocery store later that day. Mid morning ? maybe beginning about 11 AM, family said she went in and out of bathroom several times. She told them she had vomited three times and was feeling shaky. Her oral temperature was 101.3. About 1:30 PM, she was in her room and called out for her mother. When family went into the room, she was shaking ?like she was having a seizure? and then her eyes rolled back and she fell to her side and stopped breathing. Family called 911 and started CPR. CPR was continued by EMT?s once they arrived, but they were not able to resuscitate her.
1337473	5/21/2021	GA	76	M	5/7/2021	5/20/2021	SEIZURE
1337531	5/21/2021		14	F	5/14/2021	5/14/2021	Patient had syncopal episode with seizure. Diaphoretic and hives noted after regaining consciousness.
1337947	5/21/2021	FL	21	M	5/21/2021	5/21/2021	PATIENT FELL TO THE FLOOR AND HAD A SEIZURE WHICH LASTED ABOUT 45 SECONDS. THIS WAS FOLLOWED BY VOMITING.
1333584	5/20/2021	NY	15	M	5/19/2021	5/19/2021	Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: possibly seizure related. patient fainted and hit head on wall upon fall. came to and went in and out a couple times. stable until EMS arrival

<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>
1332774	5/20/2021	NY		M			<p>3 days after the shot he had a grand mal seizure lasting 3 minutes; This is a spontaneous report from a contactable consumer (patient's mother). 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: Not Provided) as single dose for covid-19 immunisation. Medical history included seizure and epilepsy. The patient's concomitant medications were not reported. An adverse reaction happened with her disabled son and she can't complete the report now because she has to go to the doctors. She wants to know if she could call back. He lives upstate in a residential home, one of the first places to give vaccines and she called them several times to say they needed to report it. He has epilepsy and 3 days after the shot he had a grand mal seizure lasting 3 minutes, he has not had a seizure that long in over 2 years. He has not had a seizure since then. She stated it was the pfizer covid 19 vaccine. She spoke with his neurologist and he said it probably triggered it. If he was to get vaccinated again like if he needed a booster. This happened on the second dose. She told them that it was considered an adverse event. If he ever needed to go for a booster since he has epilepsy she would go to his doctor and make sure his medication was at a higher level so maybe he would not have a seizure the second time. No further information provided. People with seizures should know this could give you a seizure. He usually has 30 second seizures, last year he had 2 seizures in the whole year both 30 seconds. The event outcome was unknown. Information on the lot/ batch number has been 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>
1332860	5/20/2021	CT		F	4/12/2021	5/12/2021	<p>has had 4 very brief episodes of syncope in the past 4 days/ dizzy and passed out; Test: On monitor for 24hr w/ no, Result: Arrhythmia; After each episode, she consistently describes dark and blurred vision for 15 min; arm twitching; then dizzy and passed out; she felt scorching hot for a few minutes; This is a spontaneous report from a contactable physician. A female patient of an unspecified age received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, lot number: EP6955 and expiration date were unknown), via an unspecified route of administration in arm right on 12Apr2021 as single dose for COVID-19 immunisation. Medical history included anxiety , depression from an unknown date and unknown if ongoing. Concomitant medication included escitalopram oxalate (LEXAPRO) taken for anxiety, depression from an unspecified date. Previously the patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, lot number: EP6955 and expiration date: 30Jun2021), via an unspecified route of administration in arm right on 22Mar2021 as single dose for COVID-19 immunisation. It was reported that the patient who will be 20 years has had 4 very brief episodes of syncope in the past 4 days and spent 8 hours in ER Friday. Blood work, ECG, Echo, and MRI without contrast were normal. Doctors are baffled. Reporter enquired about the vaccine-related seizures 1 month after the second dose and asked for email address for a medical monitor supporting the vaccine trial. It was reported that the patient is perfectly healthy She does not drink or use any illicit drugs. She takes BCP to regulate her period and one month ago she started 5 mg/day Lexapro for test anxiety and COVID-induced depression. On Wed 12May2021 10 am while at work, she felt scorching hot for a few minutes, then dizzy and passed out; witnessed by 2 work colleagues. She will ask her colleagues tomorrow how long she was unconscious. On Thurs 13May2021 while at work she felt dizzy briefly but did not pass out. On Fri 14May2021 shortly after lunch while working in her cubicle, she woke up with computer keyboard imprint on her face. Unwitnessed, no warning whatsoever. Sat pm after dinner while in backseat of car, she felt dizzy and within a minute or so she had brief LOC lasting less than 1</p>

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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minute. Sun 16May2021 after breakfast while bathing, she passed out. Unwitnessed. Her phone was nearby so she was able to call me. After each episode, she consistently describes dark and blurred vision for 15 min. Then she feels fine. No obvious seizure activity although last night her boyfriend said her right arm was twitching. No incontinence. Seen by her PMD on Thurs 13May2021 and we spent 8 hours at the ER Friday 14May2021: PE, orthostatics, CBC, Chem 18, pregnancy test, U/A, ECG, ECHO and MRI of brain without contrast was normal. No Neuro or cardiology consult (yet). Today her doctor is recommending she be admitted for observation, consults and further testing. The patient has not received any other vaccinations prior 4 weeks and has no history of allergies. All tests done at the hospital came back normal. Daughter is currently in the hospital being discharged today 17May2021. She will wear a Holter monitor for 2 weeks to record any further events. Cardiology and neurology both conclude the adverse events were not cardio or neurological origin. Physician does not think it was seizures. She did not intend to report seizures-it was syncope. She does not have any further adverse events or history to report at this time beyond what she already reported. The patient underwent lab tests and procedures which included blood test: normal, blood thyroid stimulating hormone: normal, electrocardiogram: normal, electroencephalogram: normal, investigation: normal, investigation: arrhythmia, investigation: normal, physical examination: normal, pregnancy test: normal, urine analysis: normal on 13May2021, echocardiogram: normal, electrocardiogram: normal, full blood count: normal, investigation: normal, magnetic resonance imaging normal: normal on 14May2021. The outcome of the events was unknown.; Sender's Comments: As there is limited information in the case provided, the causal association between the events syncope, arrhythmia, dizziness, feeling hot, vision blurred, muscle twitching and the 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

<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>
							to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
1332869	5/20/2021	FL	58	F	4/20/2021	4/23/2021	High Fever, 106+, convulsions, trouble breathing, pneumonia, I've never been so ill in my life. I nearly died.
1332879	5/20/2021	FL	14	F	5/19/2021	5/19/2021	Client experienced a seizure reaction shortly after vaccine injection (2 mins.) for few seconds (5). Mother verbalized she always has that reaction after she shot. VS BP 95/66, P 90, O2Sat 100%. VS 114/73, P 90, O2Sat 100%. After 30 mins. of observation resident stated, "I am feeling great." Mom declined the need to go to the hospital. In stable condition, resident was send home.
1332979	5/20/2021	FL	30	M	5/12/2021	5/12/2021	Eye blurry ness, epileptic seizures

<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>
1333218	5/20/2021	PA	71	M	2/24/2021	3/19/2021	ED, Discharged , 3/13/2021 (4 hours), Hospital ED, MD Last attending o Treatment team Shortness of breath +1 more Clinical impression Chest Pain o Shortness of Breath o Dizziness Chief complaint, Patient presents with o Chest Pain, o Shortness of Breath o Dizziness. History of Present Illness , Patient is a 71 yr.. male with Hx of stage IIICM Metastatic Adenocarcinoma of the sigmoid Colon, Coronary disease, Hypertension, Dyslipidemia, Chronic Renal insufficiency, presenting to the ED with chest pain. Patient notes that he woke up this morning with pain in the right side of the chest with some associated shortness of breath. Notes symptoms. Additional information for Item 18: Notes symptoms are worse when he is up trying to exert himself and gets incredibly short of breath and fatigued. States he tried to do some workout in the garage but was unable. Denies chest pain worsening with exertion, but has been fairly constant since it began. Reports it is a dull ache. Pain is dissimilar from his previous heart attack. States he has had a mild cough, but no significant production. Denies any fevers, chills. No abnormal nausea or vomiting other than typical chemo induced side effects. Given continued issues, decided to come in for further evaluation. Review of Systems; Constitutional: Positive for fatigue. Negative for appetite change, chills, diaphoresis and fever. HENT: Negative for sore throat. Eyes: Negative for visual disturbance. Respiratory: Positive for cough and shortness of breath. Negative for choking and chest tightness. Cardiovascular: Positive for chest pain. Negative for palpitations and leg swelling. Gastrointestinal: Positive for nausea and vomiting. Negative for abdominal pain and diarrhea. Genitourinary: Negative for dysuria. Musculoskeletal: Negative for back pain and neck pain. Skin: Negative for rash. Neurological: Positive for light-headedness. Negative for seizures, syncope, numbness and headaches. ED to Hosp-Admission, Discharged, 4/5/2021 - 4/25/2021 (20 days) Hospital, MD, Last attending Treatment team Sepsis, due to unspecified organism, unspecified whether acute organ dysfunction present. Principal problem Discharge Summary, DO (Physician), Inpatient Discharge Summary; BRIEF OVERVIEW; MD, Discharge Provider: DO, Primary Care Physician at Discharge: MD, Admission Date: 4/5/2021, Discharge Date: 4/25/2021. Discharge Diagnosis; Medical Problems ;Hospital

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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Problems; POA, (Principal) Sepsis, due to unspecified organism, unspecified whether acute organ dysfunction present, Yes, Essential hypertension Yes, Chemotherapy-induced peripheral neuropathy, Yes. Overview Signed 5/10/2019 2:03 PM by MD, Pins and needles and numbness in tips of finger and toes, Lung metastasis Yes. Hypoxia Yes. COVID-19 Unknown, Acute respiratory failure with hypoxia Yes, Palliative care encounter Not Applicable, Declining functional status No. DETAILS OF HOSPITAL STAY; Presenting Problem/History of Present Illness/Reason for Admission, Sepsis, due to unspecified organism, unspecified whether acute organ dysfunction present. Acute hypoxemic respiratory failure due to COVID-19, Respiratory failure. Sigmoid perforation with abscess. Hospital Course; 71-year-old male prolonged admission for acute hypoxic respiratory failure secondary to COVID-19. No history of colorectal adenocarcinoma with lung mets. Prior resection of bowel, prior chemotherapy. Required management in the ICU due to worsening respiratory failure over the time that he has been admitted to Hospital (20 days). He had remained on BiPAP therapy throughout that time, received appropriate corticosteroids, and antiviral therapies. Approximately 1-1/2 weeks ago he began to develop mild left lower quadrant abdominal pain. In the last 48 hours this is significantly worsened. CT abdomen and pelvis was obtained on Friday, which displayed pneumoperitoneum, sigmoid abscess with sigmoid perforation. There is a prior anastomotic site distal to this. Given his overall complexity he was to be medically managed to avoid the need for OR and intubation. He did well through the initial 24 hours of IV antibiotics, fluids and bowel rest. This afternoon he became increasingly dyspneic, required implementing nonrebreather mask, and subsequently developed severe rigors, tachycardia. I obtained a stat follow-up CT scan which shows similar findings of free air within the abdomen. Given signs of impending sepsis, BiPAP therapy was initiated, bolus IV fluids were given. Blood gas, blood counts, lactic acid are pending. He is receiving empiric Zosyn. I discussed this with general surgery, whom is well-known to the patient. In agreement the patient likely needs surgical intervention. However given his overall complexity and in light of the fact that this area surrounds the ureter, and

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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we do not have urology coverage. It was felt he was most appropriate to be managed in Hospital. Case was discussed with Dr. at Hospital, patient will be transferred there via air transit. At this time his blood pressure appears stable, he is tachycardia, is currently on BiPAP which will be transitioned to CPAP for transport. He has received several doses of Dilaudid, for improved pain control. No further advancement of airway was performed prior to discharge. Case was discussed with family at length, all risks and benefits of transfer were discussed with wife and patient. It is recommended to involve pulmonary critical care services including surgical ICU care as if requiring surgery he is high likelihood for prolonged vent needs. Operative Procedures Performed: Treatments: See above; Procedures: Na Consults: pulmonary/intensive care and general surgery. Pertinent Test Results: CT abdomen pelvis with contrast [3279871876] (Abnormal) Resulted: 04/25/21 1811. Order Status: Completed Updated: 04/25/21 1812. Narrative: PROCEDURE INFORMATION: Exam: CT Abdomen And Pelvis With Contrast, Exam date and time: 4/25/2021 17:36, Age: 71 years old, Clinical indication: Abdominal pain; Additional info: Sepsis, bowel perf. HX of Covid19 +, malignant colon with lung metastasis. Bowel perf. TECHNIQUE: Imaging protocol: Computed tomography of the abdomen and pelvis with 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. Contrast material: 350 OMNI; Contrast volume: 80 ml; Contrast route: INTRAVENOUS (IV); COMPARISON: CT ABDOMEN PELVIS W CONTRAST 4/23/2021 16:46, FINDINGS: Tubes, catheters and devices: Catheter terminates in the right atrium in satisfactory position. Lungs: Moderate airspace opacities throughout the lung bases are similar to prior and consistent with Multilobar pneumonia consistent with the history. Liver: No hepatic masses. Gallbladder and bile ducts: Cholelithiasis. Pancreas: No ductal dilation. No masses. Spleen: No splenomegaly or focal lesions. Adrenal glands: No mass. Kidneys and ureters: 10 mm benign left renal cyst, no follow-up necessary. No renal masses or Hydronephrosis bilaterally. Stomach and bowel: Redemonstration of

perforated proximal sigmoid diverticulitis. Small pneumoperitoneum is stable. Predominantly gas containing, 25 x 28 mm collection adjacent to the inflamed sigmoid colon similar to prior; a fistulous tract extends toward the midline containing gas and fluid, with suspected fistula to adjacent loops of small bowel. Moderate to severe descending and sigmoid diverticular burden. Minor right diverticular burden. No small bowel obstruction. A somewhat clumped appearance of small bowel in the right lower quadrant near the colon enteric fistula. Appendix: No evidence of appendicitis. Intraperitoneal space: Mesenteric edema around the small bowel, slightly increased, however no new mesenteric collection. There is no extravasation of enteric contrast into the collection adjacent to the sigmoid colon. Vasculature: Mild aortoiliac atherosclerosis. Lymph nodes: No significantly enlarged lymph nodes. Urinary bladder: Unremarkable as visualized. Reproductive: Unremarkable as visualized. Bones/joints: Degenerative changes in the spine. Multilevel disc space narrowing. Multilevel central canal and neuroforaminal stenosis in the lumbar spine. No acute fracture or subluxation. Soft tissues: Small fat-containing right inguinal hernia. Small fat-containing left inguinal hernia. Large ventral abdominal hernia containing gas, which has replaced the previous contents of fat and bowel loops. Volume increased compared to prior. IMPRESSION: 1. Redemonstration of perforated proximal sigmoid diverticulitis. Small pneumoperitoneum is stable. 2. Similar perisigmoid collection; colon enteric fistula, probably at least subacute in duration. The perisigmoid collection is prominently gaseous and there is no frank abscess. 3. Suspected mild enteritis the small bowel loops or loops associated with the fistula. No obstruction. 4. Additional findings as described are similar to recent prior imaging. COMMENTS: Any incidental renal lesion less than 1 cm or classified as too small to characterize, or any incidental cystic renal lesion characterized as simple-appearing, is likely benign. No follow-up imaging is recommended for these lesions per consensus recommendations based on imaging criteria. THIS DOCUMENT HAS BEEN ELECTRONICALLY SIGNED BY MD, CT abdomen pelvis with contrast (Abnormal) Resulted: 04/23/21 1804, Order Status: Completed Updated: 04/23/21 1804, Addenda: THIS

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

REPORT CONTAINS FINDINGS THAT MAY BE CRITICAL TO PATIENT CARE. The findings were verbally communicated via telephone conference with RN at 6:03 PM EDT on 4/23/2021. The findings were acknowledged and understood. THIS DOCUMENT HAS BEEN ELECTRONICALLY SIGNED BY MD Signed: 04/23/21 1804 by, MD. Narrative: PROCEDURE INFORMATION: Exam: CT Abdomen And Pelvis With Contrast, Exam date and time: 4/23/2021 4:42 PM, Age: 71 years old Clinical indication: Abdominal pain; Localized; Left; Additional info: HX of colon cancer. Worsening left sided abdominal pain. HX of colon cancer. Worsening left sided abdominal pain. TECHNIQUE: Imaging protocol: Computed tomography of the abdomen and pelvis with 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. Contrast material: OMNIPAQUE 350; Contrast volume: 80 ml; Contrast route: INTRAVENOUS (IV); Other contrast: Oral, omnipaque 12mg premixed solution, 500mL pt unable to drink 1000mL; COMPARISON: 1. CT ABDOMEN PELVIS W CONTRAST 2/12/2021 11:06 AM, 2. CT ABDOMEN PELVIS W CONTRAST 11/13/2020 11:42:26 AM, 3. CT ABDOMEN PELVIS W CONTRAST 8/24/2020 10:14:40 AM, FINDINGS: Lungs: Bilateral lower lung consolidation. Liver: No mass. Gallbladder and bile ducts: Cholelithiasis, no biliary ductal dilatation. Pancreas: Normal. No ductal dilation. Spleen: Normal. No splenomegaly. Adrenal glands: Normal. No mass. Kidneys and ureters: Normal. No hydronephrosis. Stomach and bowel: Collection of fluid and gas adjacent to the proximal sigmoid colon where there are multiple diverticuli, extraluminal gas arises from a proximal sigmoid perforation which is proximal to the sigmoid anastomosis. No bowel obstruction, no wall thickening at the anastomosis. Appendix: No evidence of appendicitis. Intraperitoneal space: Pneumoperitoneum. Small collection of fluid and gas in the left pelvis and left lower abdomen, maximum short axis diameter approximately 2 cm, arising from the proximal sigmoid colon. Vasculature: No abdominal aortic aneurysm. Lymph nodes: No significant adenopathy. Urinary bladder: Unremarkable

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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as visualized. Reproductive: Unremarkable as visualized. Bones/joints: No acute findings. Soft tissues: Ventral hernia containing bowel without entrapment. IMPRESSION: Perforated diverticulitis, small pericolic abscess; the sigmoid perforation is proximal to the sigmoid anastomosis. Physical Exam at Discharge; Heart Rate: (!) 131, Resp: (!) 42, BP: (!) 168/92 Temperature: 37.1 °C (98.7 °F) Weight: 107 kg (236 lb. 12.4 oz.), General appearance: alert, appears stated age, cooperative, severe distress and morbidly obese, Head: Normocephalic, without obvious abnormality, atraumatic, Neck: supple, symmetrical, trachea midline and thyroid not enlarged, symmetric, no tenderness/mass/nodules. Lungs: retractions and diminished breath sounds Heart: tachycardia, RR. Abdomen: Distended significantly tender in the left lower quadrant with guarding throughout. Extremities: Trace pretibial, Skin: Skin color, texture, turgor normal. No rashes or lesions or Ecchymosis areas throughout upper extremities. Neurologic: Alert and oriented X 3, no focal deficit. Discharge Instructions; Condition at Discharge, Discharge Condition: critical. Admission, Discharged 4/25/2021 - 5/1/2021 (6 days) Hospital, MD, Last attending Treatment team Respiratory failure, acute. Principal problem, Discharge Summary MD (Resident) Cosigned by: MD at 5/18/2021 1:24 PM; Final Summary for Deceased Patient, BRIEF OVERVIEW; Admitting Provider: MD; Discharge Provider: MD Primary Care Physician at Discharge: MD Admission Date: 4/25/2021, Discharge Date: 5/1/2021, Final Diagnosis, Principal Problem: Respiratory failure, acute. Active Problems: Malignant neoplasm of sigmoid colon. Sepsis, due to unspecified organism, unspecified whether acute organ dysfunction present COVID-19. Perforated viscus. DETAILS OF HOSPITAL STAY Presenting Problem/History of Present Illness/Reason for Admission Respiratory failure, acute, Hospital Course; Patient is a 71 yr.. male with history of metastatic colorectal adenocarcinoma with lung metastases, prior bowel resection and chemotherapy. The patient initially tested positive for Covid in early March. His symptoms at that time are mild and resolved. He was later vaccinated and that month. He started having severe symptoms again on 4/3 for which he presented to Hospital. Since that time, he has received full course of Remdesivir and steroids.

<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>
							<p>He had a CT scan performed on 4/23 which revealed pneumoperitoneum secondary to presumed perforated sigmoid diverticulitis with focal sigmoid abscess. Patient was weaned down to minimal nasal cannula settings but somewhat suddenly earlier on 4/25 patient had increased work of breathing, became tachycardia, and had rigors. Hospital ordered repeat CT scan which showed similar findings in the abdomen. Patient had been maintained on Zosyn. Repeat labs were sent which were largely unremarkable. Given concerns for worsening sepsis and potential need for surgery, he was subsequently transferred Hospital. On admission to hospital, he had a normal lactic acid and no leukocytosis. He did not have evidence of peritonitis. The decision was made to treat his diverticulitis conservatively. However, early on 4/26 the patient started to develop a lactic acidosis. An extensive discussion was had with the patient and his wife regarding surgery and the possibility the patient may never be able to separate from the vent given his worsening Covid pneumonia. The patient elected to undergo an exploratory laparotomy with with segmental resection of distal descending and loop transverse colostomy. However, as the days progressed the patient had worsening respiratory status that required deep sedation, paralytics and proning all of which were unsuccessful in maintaining his oxygen saturation greater than 88%. His wife, knowing that he would not want to have a prolonged course on the ventilator, elected for transition to palliative extubating with comfort care on 4/30 and the patient expired roughly 10 minutes after extubation.</p>
1333227	5/20/2021	OK	16	F	5/19/2021	5/19/2021	<p>The patient had a Vasovagal response. She had a 15 second seizure ,blood pressure dropped, was flush, tired and nauseated. She has no memory of 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>
1333283	5/20/2021		17	F	5/19/2021	5/19/2021	While waiting for 15 mins monitoring after getting Pfizer covid vaccine, she fainted and fell off the chair. She fell on the ground and hit her head. Nurse and pharmacy staff rushed to her aid. She appeared to have convulsions for about a couple seconds but regained consciousness right away. We checked vital signs : low blood pressure but high heart rate, oxygen level was good. We placed ice pack on her head where said was hurting. She and her mother refused to call 911. She felt better, however we recommended her mom to take her to urgent care for further evaluations
1333317	5/20/2021	MA	76	M	5/1/2021	5/14/2021	Approximately 2 weeks after receiving vaccination, patient developed confusion and lethargy. He presented to the hospital where he was found to be febrile. Alteration mental status continued to worsen, and then had a generalized seizure. Patient was empirically treated for possible meningoencephalitis but diagnosis is not confirmed.
1333319	5/20/2021	MA	15	F	5/19/2021	5/19/2021	Patient received vaccine and while walking around the store began to feel lightheaded/dizzy and fainted. Her parent caught her and brought her to the ground where she began to have a seizure. Paramedics were called and took over care of the patient. She was conscious and breathing after her seizure
1333323	5/20/2021	IA	23	M	5/14/2021	5/14/2021	Patient received the Janssen vaccine. Less than 1 minute after receiving the vaccine, passed out and had seizure like activity for 10 sec. When he fell, his hit the right side of his head. When he came to, he knew where he was. Ambulance was called, he refused to go to the hospital. BP was 138/78 and pulse was in the 60's. Leading up to passing out, reported that he felt warm, then passed out. After waking up and coming to, he was feeling better.
1333326	5/20/2021	NE	25	F	1/20/2021	4/1/2021	Pt has experienced seizure events and amnesia. She is continuing to undergo extensive evaluations. Events started around April 22, 2021.

<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>
1333687	5/20/2021	TX	33	M	5/19/2021	5/19/2021	Patient told me before I gave him a shot, he sometimes faints. Patient leaned back in the chair just in case he faints. I gave him the shot then after a few minutes, he said he was going to prop his leg up on the chair. After a few minutes later, he told he was going to lay on the floor just in case he faints. Patient had a seizure for less than 1 minute. Afterwards, the patient told me he sometimes get seizures especially after vaccination, when he bumps his elbow, or once when he got his ear cleaned. He had test in the past to determine root cause but doctor do not know why he had seizure. He said he did not want his girl friend to come in because he didnt want her to freak out just in case he had a seizure. I observed patient for full 30 minutes to make sure he was well to leave and his girl friend took him home. I did not know about his seizure history and he did not indicate it on the vaccine form.
1334697	5/20/2021	NM	14	M	5/20/2021	5/20/2021	As per father the pt had 3 convulsions, became very disoriented. Upon my arrival he was extremely pale and somewhat disoriented. His heart rate was 47 as per the pulse ox and he had no palpable radial pulse. His initial blood pressure was 101/60. During our interaction his pulse increased to 60 and became palpable at the radial. His pulse was irregular. His color improved as did his mentation. Pt was transported to hospital
1333754	5/20/2021	GA	34	F	4/24/2021	4/24/2021	After 2nd dose of Pfizer at 8:30 pm on April 24 2021 I developed seizures Taken to hospital via ambulance given Ativan to stop seizures, kept in hospital for 5 days
1334004	5/20/2021	WI	34	F	4/6/2021	5/11/2021	Experienced seizure event on 5/11/2021 ER reports non-verbal upon admission, altered mental status, urine screen positive marijuana & benzodiazepines. Tested positive for Covid-19 5/11/2021 Hospitalized 5/11/2021-5/18/2021. D/C diagnosis: Acute metabolic encephalopathy Active issues: hypolemia, Seizure (HCC) , Covide infection, AKI (Acute kidney injury), elevated troponin, elevated LFTs. Hospital Attending Hospitalist MD Consults: Doctor of teleneurology

<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>
1334070	5/20/2021	NY	50	M	5/20/2021	5/20/2021	Patient had syncopal episode after vaccination. Had been recently traveling (flew from Spain with minimal food and sleep in last 24 hours). Patient has history of syncope in the past with Botox injection. Patient regained consciousness spontaneously. No seizure activity or head injury. Symptoms resolved and patient discharged
1334145	5/20/2021	NC	22	M	5/18/2021	5/18/2021	Within 60-90 seconds after receiving J&J vaccine, patient became lightheaded, sat down, then subsequently passed out. Then had 2-3 jerking motions similar to seizure activity. Was lowered to the floor and called a CODE ASSIST. patient was not registered at the time, but was in a hospital. No previous reaction to injections. Patient taken to ED for workup. Patient diaphoretic and bradycardic at 36. given IV fluids and performed EKG. was later discharged from ED
1334208	5/20/2021	IL	18	M	5/20/2021	5/20/2021	Patient is 18 year old male who received his first dose of Pfizer COVID 19 vaccine. graduate intern, administered the dose and within the first minute, patient tensed up and passed out. He appeared to look like he had a seizure. Patient was passed out for less than a minute. When he came to, he said he fell asleep. He said he felt warm. We checked his Blood pressure and it 94/62 and pulse was 54. We called 911 and laid patient on a mat. He was given gatorade and a warm wash cloth. Paramedics arrived and rechecked BP. It was 110/66 and pulse was 66. They evaluated him and told him to have someone drive him home. Patient has not history of seizures and no history of adverse reaction to vaccine. He did receive a tetanus booster on 5/17/21. Only other medical history is asthma. He uses albuterol prn but has not had to use it for > 4 years.
1333517	5/20/2021	CA	24	F	4/22/2021	4/22/2021	Systemic: Seizure-Severe, Additional Details: pt had seizure 12 hours after the vaccine was administered and was hospitalized

<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>
1334594	5/20/2021	IL	15	M	5/19/2021	5/19/2021	After receiving vaccine, we were told to sit and wait 10 minutes before leaving. About 7 minutes into waiting, my son said he was thirsty and not feeling that good. we started to walk to get a water and he totally blacked out and exhibited mild like seizure activity. After he "came too", he complained of blurry vision and still didn't feel good as we waited for ambulance. Once ambulance came he was feeling a little better. Vitals all checked out good and were declined going to hospital. He doesn't remember anything that happened in Pharmacy, except that he thought he was going to die.
1333577	5/20/2021	IL	12	F	5/18/2021	5/18/2021	Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Mild, Systemic: Vomiting-Mild, Additional Details: Patient passed out within 30 seconds of receiving the Pfizer COVID vaccine. She was out for about 15-20 seconds, during which time she had a couple spasms. After that, she woke up, was aware that she had passed out, then threw up once. She waited with her mom for 30 minutes after that, but felt fine during that period.

<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>
1334892	5/20/2021	AL		F	1/26/2021	4/15/2021	encephalopathy; seizures; This spontaneous case was reported by a consumer and describes the occurrence of ENCEPHALOPATHY (encephalopathy) and SEIZURE (seizures) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 036C01A and 006M20A) for COVID-19 vaccination. The patient's past medical history included Systemic lupus erythematosus since an unknown date. 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 15-Apr-2021, the patient experienced SEIZURE (seizures) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced ENCEPHALOPATHY (encephalopathy) (seriousness criteria hospitalization and medically significant). At the time of the report, ENCEPHALOPATHY (encephalopathy) and SEIZURE (seizures) outcome was unknown. Treatment information not provided. Concomitant medications were 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.
1334899	5/20/2021	NC	72	M	1/1/2021	4/21/2021	Grand mal seizure; encephalopathy

<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>
1334945	5/20/2021	CA	16	F	4/30/2021	4/30/2021	Fainted; Didn't know if it was a convulsion or a seizure; Shaking; was very anxious; This is a spontaneous report from two contactable pharmacists. A 16-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0167, expiry date: Aug2021), via an unspecified route of administration, administered in the left deltoid, on 30Apr2021 15:30, as 1st dose, single, for COVID-19 immunisation, at a pharmacy/drug store. There were no medical history and concomitant medications. On 30Apr2021 15:30, the patient received the first dose of the COVID-19 vaccine and was very anxious. She wanted her mom to be present. On the same day, 30Apr2021 15:35, five minutes later, the patient was shaking, and she fainted. The reporter did not know if she was having a convulsion or a seizure. A few minutes later, the patient was sitting and becoming more alert. The patient was given water and one dose of Benadryl. The patient's vital signs were checked (unknown result). The reporter talked to the patient's mother and contacted the patient's pediatrician. The events resulted to emergency room and physician's office visits. Later in the evening, the reporter followed up with the mother and she confirmed that the patient was doing well and better. The mother asked the reporter if the patient should get the second dose of the COVID-19 vaccine. The outcome of the events fainted, shaking, "didn't know if it was a convulsion or a seizure" and "was very anxious" was recovering. The reporter assessed the events fainted, shaking, "didn't know if it was a convulsion or a seizure" as serious (medically significant). The reporter considered that BNT162B2 has a causal effect to the adverse events. Follow-up (18May2021: New information received from a contactable pharmacist includes: reporter information, lab data, suspect drug details (vaccination site and vaccination time), event details (onset time provided, outcome updated to recovering, causality and seriousness assessment provided). Follow up attempts are completed. No further information is expected.; Sender's Comments: Based on the available information, and on a reportedly closed temporal association, the company assessed that a reasonable possibility could not be excluded that the reported events (fainted; didn't know if it was a convulsion or a seizure) were related to the suspect product BNT162b2 (PFIZER-BIONTECH

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

COVID-19 VACCINE). 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.

<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>
1335965	5/20/2021	MI	64	F	1/17/2021	2/1/2021	felt achy; does not have the energy; sore inside my mouth; sound can hurt my ears; base of my left thumb hurts underneath the thumb where the thumb attaches to the hand; left hand cramp and tightness; Couldn't talk; could barely open her eyes / not be able to open her eyes; fell to the floor; food can taste extra, extra intense; ALT 71 (normal 7-52); sodium 131 (normal 136-144); MCH 34.20 (normal 26-34); MCV 100.30 (normal 80-98); i have a hard time seeing my computer screen; Headache; back pain; neck pain; shoulder pain; short term memory loss/memory problems; skin hurts; flustered; my body temperature, I can be freezing one minute and so hot; brain fog; can't find the words; I feel like I have ADD but on steroids; worked really hard to keep focus; not feeling well; itchy scalp that would be due to the Shingles; Muscle cramps; Muscle tightness; hard to walk; intense anxiety; big emotions, big anger, really really intense; big emotions, big anger, really really intense; exhausted/ fatigue; shingles; like the flu; staring into space; myoclonic jerks; hard time sleeping; stomach gas and bloating; stomach gas and bloating; This is a spontaneous report from a contactable consumer, the patient. A 64-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot: EJ1686), via an unspecified route of administration in the left arm on 17Jan2021 (at the age of 64-years-old) as a single dose for COVID-19 immunization. Medical history included ongoing preglaucoma diagnosed 3-4 years ago, ongoing anxiety and depression her whole life, bronchitis at age 5, sinus infections, ongoing sinus allergy "stuff" and allergies (now the patient managed the allergies and did not get sinus infections), "vaginitis" over 10 years ago and just essentially being dry, menopause a long time ago, both big toes have some fungus for probably 3 years (toenails look ugly, discolored and thick), ongoing arthritis and bone spurs to C5 and C6 to the area of the neck for which the patient did physical therapy (PT) for about 2 years, low on b-12 when she had shingles last time in 2016, "because I dont want to get Covid" (prophylaxis therapy), nearsighted and wore bifocals. Concomitant medications included bupropion for anxiety and depression for 5 years or longer, loratadine for allergies, COLECALCIFEROL (VITAMIN D3) for depression for 10 (maybe 20) years or more, vitamin b complex (SUPER B

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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COMPLEX) from 2016 and ongoing for "low on B-12", cyanocobalamin (VITAMIN B-12) from 2016 for low B12, latanoprost for preglaucoma, clonazepam from 2012 and ongoing for anxiety, ESTROGENS CONJUGATED (PREMARIN) vaginal cream for "vaginitis" and just essentially being dry, ascorbic acid (VITAMIN C) for "because I dont want to get Covid" and an unspecified complete multivitamin for women 50 and older from 2020 "so I wouldn't get Covid". The patient previously got the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot: EK5730) in the left arm on 30Dec2020 (at the age of 64-years-old) for COVID-19 immunization. Around the middle of Feb2021, the patient had a hard time sleeping. She still napped during the day most days. Also around middle of Feb2021, the patient noticed muscle jerks, which came and went. It had gotten worse. The doctor said these were myoclonic jerks. The worst was on 28Mar2021. In the middle of the night, the patient called her on call doctor and asked if it might be a seizure. The physician said it was not a seizure. The weekend of 06Mar2021, the patient started to not feel well. She did not sleep well that Friday or Saturday night. She could not access her memory (short term memory loss) as of 07Mar2021, was flustered and it was clear that something was off as the day progressed. On 07Mar2021, the patient felt her skin hurt, like when you had a fever and the skin hurts. This came and went. Around 07Mar2021, the patient felt intense anxiety which branched out into other intense emotional reactions (big emotions, big anger). On an unspecified date, the patient had a sore inside the mouth. Around 07Mar2021, the patient felt freezing one minute and so hot the next. On 07Mar2021 at 03:00, the patient experienced a bad headache. It was like her neck and her back and her shoulders had intense pain, cramping pain and she had to soak in Epsom salt. The severe headache happened twice, lasted about 2-3 days, moved from the right side of the head, or top of the head. She stayed home from work on 08Mar2021 and 09Mar2021. The patient was exhausted and felt achy, like the flu. She had an appointment with the doctor on 15Mar2021. She was not feeling well at this point. The patient developed shingles (one spot on the right-hand side on back of head) sometime after 15Mar2021 and was diagnosed on 22Mar2021. The patient had an itchy scalp due to the

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

shingles and claimed shingles caused memory issues and brain fog, since 07Mar2021, (it seemed like she got "COVID brain"). The patient was prescribed Valacyclovir 1 mg oral tablet every 8 hours, 30 tablets, for the shingles on 22Mar2021. The open spot on the scalp crusted over by 01Apr2021 when the patient saw the physician again. The patient stated that shingles has lasting effects: brain fog, can't find the words, short-term memory problems have been coming and going since 07Mar2021, felt liked she has attention deficit disorder (ADD) on steroids, worked really hard to keep focus. This has worsened, maybe manifested more so in the last 3-4 weeks or so. Sometimes when she got anxious, her prefrontal cortex did not function well. After being diagnosed with shingles, the patient began to take propranolol 40 mg in Mar2021 as needed (patient takes 1/8 or part of 1/8 of a tablet, just biting off a tiny piece). Initially when she had shingles, she had "some finger in the light socket, fight or flight internally"; the propranolol helped with this. She took it very regularly in Mar2021 and had taken once a week at most the last 2-3 weeks. The patient also took "Brain Goo" as of 22Mar2021 which caused the stinkiest gas in the universe, and the patient was bloated, (reported as from Feb2021) depending on what she ate, and because of that, the following week, the patient took an anti-gas pill, simethicone. She had muscle cramps (in the left upper thigh on the inside of the leg and outside of the leg) and tightness, in Mar2021, that made it hard to walk. The other area that tended to cramp up and cause problems were the arches, mostly the left arch. She reported it was probably 24Apr2021, she came downstairs in the afternoon or early evening and had such an intense cramp like a Charlie Horse and fell to the floor. Muscle cramps come and go, they shift around, it's in the left arch. It's not intensely sharp like it was that day. Right now, her left arch has a knot. The patient began taking tizanidine around 08Apr2021 at 4mg 1 tablet 3 times a day for muscle cramps and tightness, which can get painful, and tizanidine helps relax that. The patient experienced fatigue due to which the patient cannot go to the grocery store by herself very easily as she gets wiped out. The patient had to hang on to the cart because she does not have the energy. She described fatigue and stamina as she had energy for a while and then she crashed. She reported she had to

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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carry protein with her because she can literally crash. She reported her left leg gave out and she had to grab onto the counter and she almost went to the floor. On 24Apr2021, the patient couldn't talk and could barely open her eyes. It felt like her body was shutting down. She couldn't get herself up off the couch to go to the bedroom. This had not happened again. She told her physician about it who was sending her to a neurologist. On 02May2021, her left hand knotted up- had a cramped muscle and tightness. The base of her thumb hurt (underneath the thumb where the thumb attaches to the hand). The patient felt that sound can hurt her ears, which came and went. The patient had a hard time seeing the computer screen, which started between 01Apr2021- 08Apr2021. The patient mentioned this to the physician. She was nearsighted and wore bifocals and will take her glasses off to see the screen better). Food tasted extra intense as of 15Apr2021. On 06May2021, the patient was exhausted after being on the phone so long yesterday. On 06May2021, the patient reported staring off into space "like she could die and it wouldn't matter" and it felt like her brain was cramped up (like her brain was going to shut down). Caller reported that she has been staring off into space steadily, and it was kind of scary. Caller reported that the staring off into space has not occurred again like the first time where she felt like her brain was cramped. Caller reported that she feels like the staring off into space was connected in the same part of her brain that caused her to not be able to talk or open her eyes on the night of 24Apr2021. The patient reported that the staring off into space had continued on and off but not to that degree of intensity. She reported that the first time she stared off into space, she felt like she couldn't interrupt or stop staring off into space. Caller reported that she doesn't know how she stopped staring off into space the first time, but now when she stared off into space she can move her eyes. Caller reported that it felt like she had a cramp in her brain because she couldn't move her eyes. The staring into space was now better otherwise she would have gone to the emergency room. The patient underwent laboratory tests which included on 01Apr2021 which included: ALT 71 (normal 7-52), sodium 131 (normal 136-144), MCH 34.20 (normal 26-34), MCV 100.30 (normal 80-98), and on 02Apr2021, sodium 144, SARS-CoV-2

<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>
							IgG Ab Antibody Test: reactive (detected value reactive, range non-reactive). The clinical outcome of staring into space, couldn't talk, "could barely open her eyes / not be able to open her eyes" was resolved on an unspecified date; herpes zoster and itchy scalp that would be due to the Shingles, sore inside my mouth was resolved on Mar2021; hard time sleeping, myoclonic jerks, not feeling well, "short term memory loss/memory problems", skin hurts, intense anxiety, "big emotions, big anger, really really intense", "my body temperature, I can be freezing one minute and so hot", headache, back pain, neck pain, shoulder pain, exhausted/fatigue, brain fog, "I feel like I have ADD but on steroids", worked really hard to keep focus, muscle tightness, "base of my left thumb hurts underneath the thumb where the thumb attaches to the hand", left hand cramp and tightness, i have a hard time seeing my computer screen, food can taste extra, extra intense, was not resolved; flustered, felt achy, like the flu, can't find the words, hard to walk, fell to the floor, does not have the energy, sound can hurt my ears, ALT 71 (normal 7-52), sodium 131 (normal 136-144), MCH 34.20 (normal 26-34), MCV 100.30 (normal 80-98) was unknown; stomach gas and bloating, muscle cramps was resolving. Follow-up attempts are needed. further information is expected
1335977	5/20/2021	WA	13	F	5/20/2021	5/20/2021	Patient wa receiving their first Pfizer COVID vaccine. Student was well hydrated and had eaten a meal prior to vaccination. After administering vaccine, patient lost consciousness, slumped to her left side, and had seizure-like body jerk movements. She then regained consciousness, then lost consciousness again immediately after and proceeded to have whole body jerking movements. She then started sliding to the floor from her seat. Patient was lowered to ground with help from another RN. Vitals were taken, BP 102/82, HR 48 and RR 20. Dr. assessed patient and 911 was called for further assessment. Patient was not transported in ambulance and left clinic with parent recovered.

<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>
1332516	5/20/2021	MD	18	M	4/20/2021	5/5/2021	not going to receive 2nd dose; tonic-clonic seizure/intense seizure; This spontaneous case was reported by a consumer and describes the occurrence of GENERALISED TONIC-CLONIC SEIZURE (tonic-clonic seizure/intense seizure) in an 18-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 025B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Seizure (1st time he had seizure when he took Benadryl 10 month ago when he was 17 year old).). Concurrent medical conditions included Autism. Concomitant products included LORATADINE (CLARITINE) for an unknown indication. On 20-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-May-2021, the patient experienced GENERALISED TONIC-CLONIC SEIZURE (tonic-clonic seizure/intense seizure) (seriousness criterion medically significant). On an unknown date, the patient experienced INCOMPLETE COURSE OF VACCINATION (not going to receive 2nd dose). At the time of the report, GENERALISED TONIC-CLONIC SEIZURE (tonic-clonic seizure/intense seizure) outcome was unknown and INCOMPLETE COURSE OF VACCINATION (not going to receive 2nd dose) had resolved. No treatment details provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No treatment medication information was provided. The patient was on testing at the time of report. Company comment: Very limited information regarding this event has been provided at this time. Further information has been requested. Causal relationship cannot be excluded for the event of Generalised tonic-clonic seizure. Company causality for Incomplete course of vaccination was assessed as not applicable.; Sender's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested. Causal relationship cannot be excluded for the event of Generalised tonic-clonic seizure. Company causality for Incomplete course of vaccination was assessed as not applicable.
1334556	5/20/2021	MS	16	F	5/5/2021	5/7/2021	Grand mal seizure

<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>
1332724	5/20/2021	TX	73	M	4/14/2021	4/4/2021	Seizure; This is a spontaneous report from a contactable consumer (patient). A 73-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), on 17Mar2021 (Batch/Lot Number: EN6206) as 1ST DOSE, SINGLE and then on 14Apr2021 (Batch/Lot Number: ER8733) as 2ND DOSE, SINGLE; both dose administered via an unspecified route in the right arm for COVID-19 immunisation. The patient had no prior vaccinations within 4 weeks. Medical history included pain and inflammation and has a little problem hearing. The patient had no other medical history and no family medical history. Concomitant medication included ongoing etodolac taken for pain and inflammation. The patient was in good health and everything. He got the first shot on 17Mar2021, and 17 days later, he had a seizure on 04Apr2021. He has never had seizures in his whole life. He had the second vaccine on 14Apr2021 and had a second seizure 17 days later on 01May2021. Patient had both seizure in the afternoon. The patient further reported that he was taking a medicine that was supposed to keep him from having another seizure. It was Lev, and he can't read the rest. It looks like pmr, then acetam. He started taking that when he had the first seizure. The patient also mentioned that they did a brain magnetic resonance imaging (MRI) and bloodwork. He doesn't remember the exact date. The patient was taken to the emergency room by an ambulance. He was hospitalized both times. He doesn't remember how long he was in the hospital the first time. The second time he was there for 5 to 6 hours. They cut him loose pretty quick. The patient was first hospitalized from 04Apr2021 to an unknown date and then hospitalized again on 01May2021 for seizure. Therapeutic measures were taken as a result of seizure. The outcome of the event was unknown.

<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>
1332428	5/20/2021	MA	31	F		4/7/2021	SKIN LESIONS THAT LOOK LIKE BLISTER; HIVES; FEVER; NAUSEA; HEADACHE; CONVULSIONS; BURNING SENSATION IN SPINAL COLUMN AND NECK; SWEATING; This spontaneous report received from a patient concerned a 31 year old female. 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, batch number: Unknown expiry: UNKNOWN) dose was not reported, administered on 07-APR-2021 in Left Deltoid for prophylactic vaccination. The batch number was not reported and has been requested. On 07-APR-2021, the patient experienced adverse effects of fever, chills, nausea, burning sensation in spinal column and neck, convulsions, sweating and headache after receiving the JANSSEN COVID-19 VACCINE. On an unspecified date, the patient experienced skin lesions that look like blisters appeared on her arms, legs, feet, ankles, thigh, neck and face and also experienced hives which has been ongoing since then. The patient has not taken any medications for these adverse effects, but she takes sertraline as concomitant medication. On 13-May-2021, the patient stated that she visited the HCP who advised her to get OTC Zyrtec and prescribed a steroid cream which she is yet to pick from the pharmacy The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from convulsions, burning sensation in spinal column and neck, sweating, fever, nausea, and headache on 09-APR-2021, and had not recovered from hives, and skin lesions that look like blister. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210532543-COVID-19 VACCINE AD26.COVID-19 S-Convulsions- 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.

<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>
1332367	5/20/2021	GA	62	M	5/10/2021		SEIZURES; PAIN IN JOINTS; VISION BLURRY; This spontaneous report received from a patient concerned a 62 year old male. The patient's height, and weight were not reported. The patient's past medical history included he had been healthy individual all his life. The patient's concurrent conditions included patient was non-alcohol user, and non-smoker. The patient had no history of comorbidities. The patient had no known allergies and 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: 11-MAY-2021) 1 total dose was administered at left arm on 10-MAY-2021 (reported as Monday) for prophylactic vaccination. No concomitant medications were reported. On 10-MAY-2021, the patient experienced blurry vision (vision blurry) which had happen all of sudden. On 12-MAY-2021, (reported as Wednesday) after taking JNJ vaccine he was taken to the emergency room because he had developed seizures (seizure), the patient experienced pain in joints (pain in the joints) which had happen all of sudden and was hospitalized. The patient was treated with Levetiracetam 500 mg for seizure. He was hospitalized for a day. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from seizures, and had not recovered from pain in joints, and vision blurry. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210529765-COVID-19 VACCINE AD26.COV2.S-Seizures. 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: 20210529765-COVID-19 VACCINE AD26.COV2.S-Pain in joints. This event(s) is labeled per RSI and is therefore considered potentially related.

<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>
1332357	5/20/2021	MO		F			<p>CONVULSIONS/SEIZURES; HYPERTHYROIDISM; DRUG INTERACTION; FLUCTUATING HEART RATE; NUMBNESS DOWN FACE; NUMBNESS AND TINGLING IN ARM; ABNORMAL VISION; SKIPPED DOSES; 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 covid-19 infection, and concurrent conditions included neurological issues related to covid, and seizures. On 19-MAR-2021, 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 once total, administered for prophylactic vaccination. The patient received Topiramate (capsule, hard, oral, batch number was not reported) 100 mg, 1 time every 1 day, from OCT-2020, 100 mg, 1 time every 1 day, from 08-MAY-2021, and 200 mg, frequency, and therapy dates were not reported for neurological issues related to covid. The batch number was not reported and has been requested. Concomitant medications included thyroid. On an unspecified date in 2021, the patient experienced hyperthyroidism, and was hospitalized (date unspecified) and experienced convulsions/seizures, numbness down face, abnormal vision, fluctuating heart rate, numbness and tingling in arm and had skipped doses (coded as drug dose omission). Patient went to the hospital where she had stopped Topamax for 6 days to check whether electroencephalogram (EEG) would show up, and thyroid function test (NR: not provided) high (hyperthyroid). levels had dropped. The hospital ultimately could not found anything. But she went back to a different hospital for more neurological testing and was taken off of Topamax again. She had another thyroid test and her levels had dropped. On, 07-May-2021, the patient was discharged and started taking it again from the night of 08-May-2021. The numbness had came back. She saw online that Topamax and Armour Thyroid should not be combined. She mentioned that at some point her dose was increased to 200 mg a day and she had experienced more seizures. On an unspecified date in 2021, the patient experienced drug interaction The action taken with covid-19 vaccine ad26.cov2.s was not applicable; and action taken with Topiramate was not reported. The patient recovered from hyperthyroidism,</p>

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

had not recovered from numbness down face, and abnormal vision, convulsions/seizures, fluctuating heart rate and numbness drug interaction and tingling in arm was not reported. This report was serious (Hospitalization Caused / Prolonged). This report was associated with a product quality complaint 90000179114.; Sender's Comments: V0. 20210522141-COVID-19 VACCINE AD26.COV2.S -Convulsions/Seizures, Hyperthyroidism, Drug interaction. 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). 20210522141-TOPOMAX-Convulsions/Seizures. This event(s) is labeled per RSI and is therefore considered potentially related. 20210522141-TOPOMAX-Hyperthyroidism, Drug interaction. 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>
1332561	5/20/2021	NY	33	F	2/8/2021	2/9/2021	Fever up to 101; chills; body aches; fatigue; This is a spontaneous report from a contactable consumer (patient herself). A 33-year-old non-pregnant female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, formulation: solution for injection Batch/Lot Number: EL9264), via an unspecified route of administration, administered in Arm Left on 08Feb2021 10:45 as 2nd dose single for covid-19 immunisation. Patient previously received BNT162B2 for Covid-19 immunization (lot number=EL3247, administration time=01:00 PM, vaccine location=Left arm, dose number=1)Medical history included thyroid cancer from 2018 and unknown if ongoing and seizure and allergies to medications, food, or other products was reported as none. Concomitant medication included levothyroxine sodium (SYNTHROID) and levetiracetam (KEPPRA). The patient was not diagnosed with COVID-19 before vaccination and it is unknown if the patient diagnose with COVID-19 after the vaccination. On 09Feb2021 at 07:00, the patient experienced fever up to 101, chills, body aches and fatigue. The patient underwent lab tests and procedures which included body temperature: on 09Feb2021 Fever up to 101. Therapeutic measures were taken as a result of the events with advil and tylenol. The outcome of the event were recovering. Follow-up (12May2021): Follow-up attempts completed. No further information 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>
1329500	5/19/2021	TX		F	2/1/2021	2/1/2021	full blown seizure and had several since then; little mini twitches on her face; This is a spontaneous report received from a contactable consumer reporting for his mother in law. An 89 years old female patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date in Feb2021, for COVID-19 immunisation. Medical history included pacemaker ongoing from 2015 and open heart surgery several years ago. The patient was very strong and lucid and could remember everything from the past. This lady was small. Until recently, she never took meds. Concomitant medications included alprazolam (XANAX) taken occasionally at 0.25 mg and maybe omeprazole (PROTONIX) for cholesterol. 2 to 3 days after the first vaccination, on an unspecified date in Feb2021, the patient started having little mini twitches on her face. They thought nothing of it. On the fifth day (in late Feb2021 or early Mar2021) she had a full blown seizure and had several since then and was hospitalized for like 20 days the first time. The reporter thought the patient had a total of about 4 or 5 seizures. When she experienced another seizure, they took her back and she was in the hospital for about 5 or 6 days, then released her. She had been back twice since then. The last time, they took her late at night and was out in the morning. That last time, she was not admitted. She was hospitalized at least 4 times, maybe a week or two apart, each time, all at the same hospital. They could not find out what was wrong with her. They put her on anti-seizure medication. They had tried several (the reporter thought more than 2). It was really a lot worse. It was really bad on her. The medications they had been giving her had really thrown her for a loop. They now believe she was way over medicated and sitting at home. They suggested for her to see a neurosurgeon who won't see her until the end of May. She had been having seizures and never had before. Seizures required ER visit. Events outcome was unknown. The hospital said they would give the second dose but they never did. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021501795 same drug/patient, different vaccine dose/AE

<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>
1330262	5/19/2021		70	M	2/10/2021	2/10/2021	Following her covid vaccine patient presented to the observation area where she reported a headache. Within minutes she was in and out of consciousness with seizure like activity. Vital signs were stable, however her O2 sat was at 86%. Patient was transferred to the ED & admitted to the hospital. Admitted to the hospital. Patient with history of migraines and seizures. Evaluated inpatient for possible vaccine reaction vs. seizure vs. psychogenic seizures vs. AMS related to metabolic encephalopathy vs. B1 deficiency.
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 irreversibile brain injury. Decision made with family to withdraw care

<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>
1329663	5/19/2021			F			SEIZURES; PARALYSIS ON ONE SIDE OF BODY; This spontaneous report received from a consumer via social media via a company representative concerned a female of unspecified age (teenager), 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) 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 seizures, and paralysis on one side of body, and on an unspecified date, she was hospitalized. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the seizures and paralysis on one side of body was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210530732-covid-19 vaccine ad26.cov2.s-seizures and paralysis on one side of body. 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).

<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>
1329594	5/19/2021	MI		M	4/22/2021	4/22/2021	unwell feeling; unable to move an inch; it had inflamed every cell in my body; ears, teeth, gums, hair, and especially brain; AS patient. First shot began electric shocks in lower back. Second vaccine after 24 hours gave me blinding siezures in my entire left back muscle. Saw stars blacked out. Laid on wooden floor for 5 hou; Saw stars blacked out; Inappropriate schedule of vaccine administered; Inappropriate schedule of vaccine administered; This is a spontaneous report from a contactable consumer (patient himself). A 67-year-old male consumer received the second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number unknown) via an unspecified route of administration in left arm on 22Apr2021 13:30 at single dose for COVID-19 immunisation. First dose of BNT162b2 was administered via an unspecified route of administration in left arm on 02Mar2021 13:30. Relevant medical history included hepatitis C, and ankylosing spondylitis. The patient had allergy to levothyroxine sodium (SYNTHROID). Concomitant medications were not reported. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine. Second vaccine after 24 hours gave him blinding seizures in his entire left back muscle. Saw stars blacked out (as reported). Laid on wooden floor for 5 hours unable to move an inch without triggering seizure. 20 hours later he was able to get to bed. Have had overwhelming unwell feeling every single day since. Doctor suggested one Valium twice a day and 2 at bed. Seizures have stopped. The biggest problem is it had inflamed every cell in his body: ears, teeth, gums, hair, and especially brain (as reported). The patient had a concussion 8 years ago and this is triggering swollen brain synapse genius, followed by overwhelming guilt/anxiety/depression/anger (as reported). He got these daily attacks on his entire cellular being (as reported). His wife is freaked out because she had to hear the patient scream at the top of his lungs (even in his sleep if turning wrong) and they don't know how to turn off these full body cellular attacks (as reported). The patient have seen 4 top doctors and they basically have no answers. Onset date for all events was 23Apr2021, unwell feeling, unable to move an inch and inflammation to every cell in his body started at 12:00. All events were life-threatening and emergency room visit was required. Seizure resolved on an unspecified date,

<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>
							while the other events were not resolved. Outcome for inappropriate schedule of vaccine administered and off label use was unknown. The patient was not diagnosed with COVID-19 prior to vaccination, while he was tested for COVID-19 since the vaccination: nasal swab was negative on 10May2021. Information on lot/ batch number has been requested.
1330314	5/19/2021	CA	15	F	5/19/2021	5/19/2021	Pt had syncope x 1 postvaccination followed by seizure x 2. Pt recovered spontaneously after 3-5 seconds. No labored breathing. Alert and oriented x 3. Pt brought to ER.

<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>
1329504	5/19/2021		29	M	4/19/2021	4/25/2021	Numerous grand mal seizures, never before experienced,, including 2 instances of status epilepticus. Have had epilepsy since 2012 and current medication levels are in normal range.; Numerous grand mal seizures, never before experienced,, including 2 instances of status epilepticus. Have had epilepsy since 2012 and current medication levels are in normal range.; This is a spontaneous report from a contactable consumer reporting for self. A 29-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration, administered in right arm on 19Apr2021 at 13:30 (Batch/Lot number was not reported) as single dose (at the age of 29 years old) for COVID-19 immunization. There was no other vaccination received in the 4 weeks prior. Medical history included epilepsy since 2012, autism spectrum disorder, respiratory illness in Nov2019 (not caused by the flu but with COVID-like symptoms), high blood cell count (previous treatment). There were no known allergies. Concomitant medication(s) included lamotrigine (LAMICTAL) and escitalopram oxalate (LEXAPRO), both taken for epilepsy, start and stop date were not reported. On 25Apr2021 at 20:30, the patient experienced numerous grand mal seizures, never before experienced, including 2 instances of status epilepticus. The patient has had epilepsy since 2012 and current medication levels were in normal range. There was no treatment received for the adverse event. The events resulted in a Doctor or other healthcare professional office/clinic visit. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events grand mal seizures and status epilepticus was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

<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>
1330585	5/19/2021		12	F	5/19/2021	5/19/2021	An incomplete Vaers report was previously submitted for this patient. Please reference Report. Please disregard previous report. Adverse Event At 10:10am, patient was sitting with her mother when she started to convulse while sitting upright in a chair and vomited as well. This episode lasted for about 15seconds. Past medical Hx Patient reported one syncope episode after receiving a shot in the past, blood was drawn. No Hx of seizure disorder Treatment Patient was given crackers, juice, water EMS called at 10:31am for patient to have further evaluation. Patient was in stable condition prior to transport to ER A translator used, parent consent was provided.
1329467	5/19/2021	CA	48	F	4/23/2021	4/27/2021	had multiple seizures over a few day; This is a spontaneous report from a contactable (patient) via COVID-19 Vaccine Adverse Event Reporting System (COVAES). A non-pregnant 48-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 on 23Apr2021 at 10:45 AM (Lot Number: Ewo172), at the age of 48 years, as a single dose for COVID-19 immunisation. 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 prior history of epilepsy, petit mal seizures. None for the last 20 years. The patient did not receive any other medication within 2 weeks of vaccination Past drug events included penicillin [benzylpenicillin], ampicillin, amoxicillin, clindamycin, vancomycin. The patient reported that on 27Apr2021 at 08:30, four days after vaccine she had multiple seizures over a few days. No treatment was given for the event. The clinical outcome of the event was recovered. She reported "I am now seizure free again". It was also reported that since the vaccination, the patient had not been tested for COVID-19.

<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>
1329444	5/19/2021	MN	44	F	4/16/2021	5/2/2021	developed Bell's Palsy on the right side of my face; This is a spontaneous report from a contactable consumer (patient) This 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) (Batch/Lot Number: EW0164), dose 1, via an unspecified route of administration in the left arm on 16Apr2021 at 14:00 (at the age of 44-years-old) as 1ST DOSE, SINGLE for covid-19 immunisation. Medical history included seizure from an unknown date and unknown if ongoing (Seizure disorder-7 years no seizure, 5 years no medication) and penicillin allergy from an unknown date and unknown if ongoing. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included vitamin d [vitamin d nos] (VITAMIN D [VITAMIN D NOS]) taken for an unspecified indication, start and stop date were not reported. The patient previously took erythromycin [erythromycin estolate] and experienced hypersensitivity. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 02May2021 at 14:00, the patient developed Bell's palsy on the right said of her face. The event resulted in an emergency room/department or urgent care visit. The patient underwent lab tests and procedures which included sars-cov-2 test (nasal swab) (03May2021): pending results. Therapeutic measures taken included unspecified steroids and unspecified anti-viral medications. Clinical outcome of the event developed Bell's palsy was not resolved.

<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>
1329285	5/19/2021	CO	84	F	1/21/2021	1/1/2021	she seems to have a cold with a runny nose; full of phlegm; Adds now she seems to have a cold with a runny nose; feeling tired/she is tired; extreme chills and freezing; she cut her lip in two places from her teeth chattering; Uncontrollable shaking/worst part was the chills, almost like a seizure'; she had extreme chills and freezing for 3 hours starting when she went to bed.; She started to feel nausea later on Monday; stiff neck on the right side of the back of her neck the day after the vaccine; headachy; Adds hers were like a fast flu; she was so sick she had to get back in bed yesterday; This is a spontaneous report from a contactable consumer (Patient). A 84-year-old female patient re-ceived first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for Injection, Batch/Lot Number: EL3247; Expiration Date: unknown), via an unspecified route of administration, administered in arm left on 21Jan2021 16:00 (at the age of 84-year-old) at a 1st dose, single for COVID-19 immuniza-tion. Medical history included thyroid disorder. No medical history (including any illness at time of vac-cination) was reported. None of the patient family medical history was reported. The patient did not receive any other vaccines prior to the COVID vaccine within 4 weeks. Concomitant medication includ-ed levothyroxine sodium (SYNTHROID) at a dose of 0.88 mg 1x/day (.088 mg; take once daily by mouth) via oral route of administration taken for thyroid disorder. Consumer states she received the Pfizer COVID 19 vaccine 21Jan2021 at 1600PM in the left arm. The effects didn't come until Tuesday night when she went to bed. The patient experienced worst part was the chills, almost like a seizure, headachy, she was so sick she had to get back in bed yesterday, hers were like a fast flu on an unspeci-fied date in Jan2021, she seemed to have a stiff neck on the right side of the back of her neck the day after the vaccine on 21Jan2021, she started to feel nausea later on Monday on 25Jan2021 and she had extreme chills and freezing for 3 hours starting when she went to bed on 26Jan2021. Adds she took two Advil, put on sweats and took a heating pad into bed then she was able to fall asleep. She cut her lip in two places from her teeth chattering and uncontrollable shaking Tuesday night on 26Jan2021. When she put the heavy clothes on and took that Advil the chills stopped, and she slept for four hours. she is tired on 27Jan2021, she seems to

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

have a cold with a runny nose and full of phlegm on 28Jan2021. The patient received Advil as a treatment medication to the events extreme chills and freezing. The events were reported as non-serious. Outcome of the events she seems to have a cold with a runny nose, full of phlegm was not recovered; headachy, adds hers were like a fast flu, she seems to have a cold with a runny nose, worst part was the chills, almost like a seizure, she was so sick she had to get back in bed yesterday was unknown; she started to feel nausea later Monday, she cut her lip in two places from her teeth chattering, feeling tired/she is tired was recovering; stiff neck on the right side of the back of her neck the day after the vaccine was recovered on 25Jan2021, and re-maining other events extreme chills and freezing, she had extreme chills and freezing for 3 hours start-ing when she went to bed, uncontrollable shaking recovered on 26Jan2021. She was asking about getting the second dose considering her chills, Mentioned she talked to a few people who had the chills and were tired after the second dose but they were not as bad and every-thing was over in a day or so. Caller declined to report on anyone she knows who had chills and was tired after the vaccine. Adds she is scheduled to receive the next dose of the vaccine 10Feb2021. Adds it scares her a little bit because of the extreme chills. Follow-up attempts are completed. 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>
1329115	5/19/2021			U			SEIZURE; SEVERE MUSCLE ACHES; 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 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 seizure and transported to hospital. CT scan performed -no problems. Patient experienced sever muscle ache. Laboratory data (dates unspecified) included: CT scan (NR: not provided) No Problem. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the seizure and severe muscle aches was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0;20210530480- covid-19 vaccine ad26.cov2.s-Seizure. This 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.

<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>
1329584	5/19/2021	VA		F			I had a seizure with no prior history; This is a spontaneous report from a Pfizer-sponsored program, received from a contactable consumer (patient). A female patient of unspecified age and unknown if pregnant received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not reported), on unspecified date as 2nd dose, single for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not reported), on unspecified date as 1st dose, single and she experienced headache and fatigue. It was reported that patient had a severe reaction to second dose of COVID vaccine. She had seizure with no prior history. She was concerned about getting a booster shot. Also want to know what ingredient in vaccine caused this. Proposed response was reported as speak from the attached documents regarding ingredients. It was asked if she was allergic to any ingredient of the vaccine. Without knowing if she was allergic to a specific ingredient it would be difficult to say what caused her reaction. Referred to health care professional (HCP). The outcome of the event was unknown. Information on the lot/batch number 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>
1330351	5/19/2021	IL	22	F	5/19/2021	5/19/2021	Patient reported before the vaccine was administered that she had a history of fainting upon receiving vaccines in the past. As predicted, she fainted within seconds of administering the Janssen vaccine. While unconscious, patient had a few mild head/neck twitches which then progressed to 2-3 full body twitches/spasms before regaining consciousness. Total time unconscious with less than 1 minute. Once fully awake and alert, patient informed me that she had a history of a seizure once before. We gently laid her on the floor and I took her vitals. Vitals were low with BP 90/49, HR 49, and O2 90%. She continued to lay on the floor for approximately 10 minutes before checking her vitals again. At that time, vitals were better with HR 60 and O2 99; I was unable to retake her BP at that time, but patient claimed that it usually was on the low side. She called her mother who agreed to come stay with her to keep watch for more events at her home. A family friend was also called to come pick her up and drive her home. Before leaving, I strongly advised patient to see a doctor to check everything out. Patient just moved here and claims to not have a primary at either location.
1330418	5/19/2021		12	F	5/19/2021	5/19/2021	Patient reported history of syncope episode with another vaccine in the past. Patient has history of seizure disorder. At 10:10am, patient was sitting with her mother when she started to convulse sitting up right in a chair. She also vomited while convulsing for about 15seconds. Full consciousness regained.
1330717	5/19/2021	OK	23	M	5/18/2021	5/18/2021	Pateint was given vaccine on 5/18/2021, soon after her injection, she passed out in the lobby. Code Blue was called. After medical team arrived, her HR= 48; BP= 89/56; O2= 100% on 3L and she responded to verbal commands. Hx of needle phobia. Not sure whether her Syncope was secondary to Vasovagal vs. J&J Vaccine vs. Seizures, therefore, we called EMS to take her for further evaluation.
1330860	5/19/2021	NY	61	M	12/16/2020	5/11/2021	Autoimmune encephalitis with generalized tonic/clonic seizure.

<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>
1330866	5/19/2021	IL	16	F	4/26/2021	5/10/2021	<p>is a 16-year-old female patient admitted with tachycardia. Starting 1-1/2 weeks ago, mom notes that she has had episodes where she feels her heart racing. It began 1-1/2 weeks ago with her crying and her watch that her heart rate was 208. They went to the ED, where she was given some fluids and her heart rate improved so she was sent home. She had had prior episodes of mild tachycardia up to the 140s in the past but which has always improved with fluids. Mom states that she used to have a lot of trouble maintaining her hydration and would not drink a lot of water. Since the last 1-1/2 weeks, she has been having these episodes 1-2 times a day that last about 1 to 2 minutes with a max of 5 minutes. When it comes on, she feels dizzy and lightheaded, and after the episode she feels a big rush of blood to her head. She also has some associated shortness of breath. She denies having any episodes of chest pain at all. She has never passed out, she has never felt like she was going to pass out, she has never felt like she was out of balance. She denies any nausea or vomiting during episodes. She denies any headaches during the episodes. She does have history of migraines, but has not had one in the last couple weeks. Her prior resting heart rate was in the 80s per her watch, and lately it has been in the 110s to 120s while awake in 80s while asleep. Along with the episodes, she also feels some pulsating sensation in her abdomen. She does not have any abdominal pain. Today, her heart rate was again in the 200s, but it was worse than before because it lasted about 30 minutes total. Lately they have been using an app that continuously monitors her heart rate. Since these episodes started, she has cut down on her caffeine intake and she has increased her water intake. Does not feel that this helped. She has never had syncope in the past and has never had seizures in the past. Patient was started on carvedilol which has helped control heart rate and was encouraged to drink fluids. Per primary care team, her current episode of tachycardia was not due to the vaccine.</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>
1331213	5/19/2021	AL	73	F	4/28/2021	4/29/2021	Patient's daughter called today wanting to report an adverse event that she believed was related to mother's covid vaccine. Patient received first vaccine 3/27 and on 4/4 had to go to the ER with severe dizziness. This incident was not reported to the pharmacy until today. Patient received 2nd dose on 4/28. On 4/29, the ambulance was called by patient's husband because the patient had passed out. When she got to the ER, they determined that the patient had a seizure and she was admitted to the ICU. The patient does not have any history of seizures. She is still currently in the hospital but was moved to a regular room on 5/10 or 5/11 (daughter did not know the exact date). She is still having effects such as cannot feed herself and daughter said that communication is VERY limited.
1331314	5/19/2021		15	M	5/19/2021	5/19/2021	patient felt dizzy right after the shot and had a seizure about 2 minutes later
1331455	5/19/2021	AL	48	F	4/21/2021	5/17/2021	On Monday, 05/17/2021 at approximately 3:30am, I had a seizure at home. According to my husband and daughter, it lasted a few minutes. When I came to, I remember being disoriented, dizzy, nauseous, sweating and headache in the back of my head. I was taken to the Hospital.
1331525	5/19/2021	CA	16	F	5/19/2021	5/19/2021	PT HAD A SEIZURE APPROX. 30 MINS AFTER RECEIVING THE COVID VACCINE, PT FAINTED, STIFFENED UP, AND BEGAN TO CONVULSE. PT WAS PLACED ON COTT IN THE RECOVERY POSITION, 911 WAS CALLED AND VS OBTAINED. P74, R22, BP118/80, O2SAT 98% ON RA. SEIZURE LASTED APPROX 10 SECONDS, AMBULANCE ARRIVED WITHIN 10 MINS, AND TOOK OVER PT'S CARE. PT'S COLOR REMAINED PINK THROUGHOUT, AND SHE WAS SLEEPY BUT ABLE TO ANSWER QUESTIONS APPROPRIATELY. VS: P83, R24,BP116/80, POX99% ON RA. PT TAKEN IN AMBULANCE TO HOSPITAL FOR FURTHER EVALUATION

<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>
1331797	5/19/2021	IL	18	F	5/19/2021	5/19/2021	Patient experienced sharp ear pain, tunnel vision, numbness of the hands and face, muscle tensing and shaking, and mild seizure like behavior (she was unresponsive for 5 seconds and then came back to responsiveness) starting 2 hours after her vaccine. She was taken by ambulance to the ER.
1332027	5/19/2021	TX	50	F	5/19/2021	5/19/2021	After leaving pharmacy, patient experienced a seizure while riding as a passenger in a vehicle. Patient was hospitalized and diagnosed with a "Brain Bleed" according to mother.
1331230	5/19/2021	MD	12	F	5/19/2021	5/19/2021	Pale diaphoretic, syncope witnessed loc Possible seizure Transported by ambulance with mother at 11:45am BP 67/30 P 46 14 99% at 12:00am BP 84/62 P 58 12 100%
1330371	5/19/2021	MI	59	F	5/13/2021	5/13/2021	Convulsions, Seizures
1330936	5/19/2021		13	M	5/19/2021	5/19/2021	Patient had convulsive seizure, became unresponsive and was cyanotic, sternal rub, patient opened eyes. Heart rate was thready. Patient felt nauseous. Patient was disoriented for 1min and quickly regained orientation. Patient was given water, patient laid on the floor. Discharged to ER Past Medical Hx Hx of seizure at age 4
1328283	5/18/2021	TX	20	M	5/18/2021	5/18/2021	Syncope with what appeared as a short seizure. Patient placed flat on floor and at that time he asked "Where am I"? Respiration good, pulse good, no discoloration, no swelling , and not cold or clammy. While tending to patient a tech-in-training called 911. First responders arrived approximately 5 or 10 minutes later and followed up with the patient. He states he has never had a reaction to a flu vaccine but does not like to see the shot being given. He said that he could feel the medicine going into his muscle and it made him feel weird and doesn't remember anything after that until he asked "Where am I"? He stayed another 10 minutes and said he felt fine. His brother drove him home.

<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>
1328059	5/18/2021	TX	12	M	5/18/2021	5/18/2021	Patient appear to have a mild seizure (faint, stiffness on the arm that got the vaccine injection, eye rolled) about less than 5 seconds. Patient became fully awake as being put to laying down on the floor. Patient was able to answer to all questions was asked. Patient stated that he was nervous and scared of getting the vaccine. Patient's mother stated that he had fainting history of seeing cut or bleeding. The event occur 30 seconds after received that vaccine.
1327800	5/18/2021		93	M	3/26/2021	5/13/2021	weakness, falls, delusions, seizure
1327778	5/18/2021	UT	13	F	5/18/2021	5/18/2021	Patient came to the pharmacy to receive 1st dose of the Pfizer covid vaccine. About 5 minutes later patient felt unwell. According to her mom she passed out for about 5 seconds then jerked up and passed out again for a few seconds and woke up. Mom was unsure but thought it looked like a mini seizure. Both pharmacist was informed and checked on patient. Patient was hot and sweating but breathing was fine. Patient was coherent and could talk. Patient was given water. Blood pressure check was 102/69. Patient remained sitting with head over legs as that made her feel better. EMT arrived at the scene and took patient away on a stretcher for further observation.
1327525	5/18/2021	MA	82	F	2/6/2021		She received her first dose on 2/6/21 around 11:30 a.m. On 2/7/21 she was a bit tired and her arm was a little sore. Sometime after the afternoon of 2/7/21 and the morning of 2/8/21 she was found unconscious and unresponsive on the floor. As her dinner from the evening of 2/7/21 was still on the table unfinished and she was fully dressed we assume that whatever caused her to end up on the floor unconscious happened on 2/7/21. She was taken to the emergency room and it was determined that she was not going to survive. She never regained consciousness and was having seizures all the way to the hospital in the back of the ambulance. She was made comfortable and passed on 2/11/21.
1327491	5/18/2021	CA	23	F	4/10/2021	4/11/2021	Pt presented to ER early the following am, with seizures. Pt reports having a small reactions immediately after vaccine administration. Pt reports muscle stiffness, eyes rolling back, shaking, diaphoretic. Pt also reports having a second episode of syncope when she arrived home.

<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>
1327444	5/18/2021		86	M	4/3/2021	5/13/2021	seizure, encephalopathy, death
1327151	5/18/2021	IL	15	M	5/18/2021	5/18/2021	Pt was given vaccine and began telling his brother he felt lightheaded. Pt's brother began to inform his mother. Pt then slumped in chair and began to fall to the floor. Mother tried to brace pt's fall. Pt still hit the floor and lightly hit his head. LPN's stated pt had a 5 second episode of convulsions that appeared to be a seizure. Pt did lose LOC for about 15 seconds and came to. Pt did not realize what had happened. Pt was placed on a cot. Pt stated he felt warm and lightheaded. Pt's VS were taken at 1640 - BP 136/70, HR 61, RR 18, 99% O2. EMS were called and in route. Pt began feeling better. Another set of VS were taken at 1645 - BP 127/76, HR 80, RR 16, 99% O2. Pt had ice packs placed on his neck and forehead. Pt sat up on cot after another 5 minutes and another set of VS were taken at 1650 - BP 123/82, HR 89, RR 16, 99% O2. Pt stated he was feeling better but still had a minor headache. EMS arrived and advised pt to be checked out. Mother agreed to take her son to the hospital herself not via EMS. Refusal form was signed by mother from EMS. Pt, mother, and brother left to go get checked out.
1328500	5/18/2021		23	F	5/18/2021	5/18/2021	patient passed out on floor and appeared to have seizure like symptom. Felt faint , dizzy, and flushed. called 911. Medical team arrived and patient proceeded to get nauseated and throw up.
1326754	5/18/2021	TX	23	F	5/18/2021	5/18/2021	Patient received the Pfizer covid-19 vaccine and during the 15 minute observation time began having a seizure. EMS was called and picked patient up and took them to the ER patient came to and was conscious before leaving the store with ems.

<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>
1327150	5/18/2021	CA	14	M	5/18/2021	5/18/2021	After receiving vaccine in the left deltoid, patient fell face down on to the floor. Patient was noted with what appeared to be two seizures lasting 10-15 seconds in duration. Patient received immediate attention, contacting EMS and recording vital signs. Blood pressure noted at 105/64, heart rate 55, O2 saturation noted at 99%. EMS arrived and provided immediate attention. Parental guardian (Mother) refused transportation to the emergency room. Mother was provided patient education in the risk of refusing medical care. Mother signed AMA form and stated she would take patient to the hospital.
1326686	5/18/2021	CA	21	M	5/17/2021	5/17/2021	Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Medium, Systemic: Seizure-Mild, Systemic: Shakiness-Medium, Additional Details: Patient was immediately nauseous after vaccination, but that resolved quickly. Minutes after sitting down for the observation period, patient seemed to jerk and looked like he was seizing. He did not have trouble breathing. He was lucid after going in and out of consciousness for a minute or so. He was hypotensive and pale, but after water and some candy, patient was feeling much better. After the 30min observation period, his blood pressure was up and he was able to walk without trouble.
1326654	5/18/2021	PR	15	M	5/17/2021	5/17/2021	Systemic: Seizure-Mild, Additional Details: AFTER 5 MINUTES OF ADMINISTRATION VACCINE PATIENT BEGAN A SEIZURE OF LESS 1 MINUTE MOTHER DESCRIBED TONIC SEIZURE PATIENT NOT HAD PAST HISTORY OF SEIZURE
1326616	5/18/2021	NY	20	M	5/17/2021	5/17/2021	Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Seizure-Medium
1326558	5/18/2021	CA	14	M	5/18/2021	5/18/2021	Vasovagal syncope with mild convulsion for 5 seconds.

<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>
1326229	5/18/2021	MN	58	F	4/19/2021	4/19/2021	I supposedly had a seizure/diagnosis was Convulsions; I began vomiting non-stop.; dry heaving; This is spontaneous report from a contactable consumer. A 58-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Lot Number: EW0164) via an unspecified route of administration in left arm on 19Apr2021 12:15 as 1st single dose (at the age of 58-years-old) for COVID-19 immunization. The patient was not pregnant at the time of vaccination. Patient medical history was not reported. The concomitant medication included escitalopram at a dose of 10 mg. Facility where the most recent COVID-19 vaccine was administered was reported as Other. 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. Patient has not been diagnosed with COVID-19 since the vaccination. At about the 13 minute mark post-vaccination and while waiting in the facility, on 19Apr2021 at 00:30 (as reported) patient supposedly had a seizure. She was sitting and feeling fine and then came into the medical tent. The military medic/personnel insisted she had a seizure. After she came to, she began vomiting non-stop. They put her in an ambulance and she continued vomiting/dry heaving at that point on the way to the hospital and at the hospital. She was given anti-nausea medication in the ambulance and again in the emergency room. The diagnosis at (withheld) was convulsions, unspecified type. The adverse event resulted in a visit to Emergency room/department or urgent care. The treatment given for the adverse events included Lab tests, CT Head without Contrast, Zofran. The outcome of the events was recovered. Information on Lot/Batch number was available. Additional 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>
1326151	5/18/2021	PA	58	M	1/8/2021	4/1/2021	foaming from the mouth/foaming at the mouth; blood sugar dropping; He would not wake up and was unresponsive; seizures; swelling on brain; Pneumonia aspirating; so cold he could not work or anything; This is a spontaneous report from a contactable consumer reporting on behalf of her fiancé. A 58-years-old male patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on 08Jan2021 (Batch/Lot Number: EL3248) as SINGLE DOSE for covid-19 immunization at the age of 58 years old. Medical history included sugar /diabetic, blood pressure. None vaccines administered on same date with the Pfizer vaccine considered as suspect. No other vaccinations within four weeks prior to the first administration date of the suspect vaccine. Family Medical History Relevant to AEs was none. Concomitant medication(s) included metformin hcl for Diabetes, he has been on for a long time; pregabalin for his back and leg because he had 2 pinched nerves or something and he has to get it repaired with injections. He has not gotten injections because of what he has been going through right now. It is 25 mg and he has been on this for a little while; lisinopril for cholesterol and is a blood pressure and heart pill; vitamin d [vitamin d nos] (VITAMIN D [VITAMIN D NOS]) for his vitamin D was low; diclofenac sodium (DICLOFENAC NA) for inflammation, he has been on this for as long as she knows; potassium chloride (POTASSIUM [POTASSIUM CHLORIDE]) for his potassium is low, She has been giving this to him. Whenever he gets blood work, sometimes they say his potassium is low so she gives it to him everyday; amlodipine besylate for blood pressure and heart; sertraline hcl for a mood pill, he has been on a long time; Metoprolol succinate for blood pressure and heart, He has been on for a long time. The patient previously received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration on 28Dec2020 (Batch/Lot Number: EJ1682) as SINGLE DOSE for covid-19 immunisation. The patient experienced foaming from the mouth/foaming at the mouth, blood sugar dropping, he would not wake up and was unresponsive, seizures, swelling on brain, pneumonia aspirating, so cold he could not work or anything in Apr2021. Reported as: He had the Pfizer shot, but he is currently hospitalized, he had an experience of foaming from the mouth, 3 months after the

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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vaccine. He is on a trach/ requires trach and feeding tube. He is also on dialysis to clean the toxins in his blood. Caller stated she is calling on behalf of her fiancé. He can not talk to anyone at the moment. The reason she is calling is because he had his vaccine 08Jan2021. Caller states but the thing is that nobody knows what symptoms anybody is going to have. It has been what, 3 months, but his sugar dropped to 40 one day, and 30 one day. He was foaming at the mouth and had seizures. Aspirated, pneumonia: caller states that her fiancé aspirated and had pneumonia in his right lung and has been in the hospital ever since. Foaming at the mouth: He is on a trach and feeding tube, dialysis in his neck, and caller is trying to figure out what is going on. Caller adds that he was foaming at the mouth. Blood sugar dropping, so cold he could not work or anything: caller states this happened Tuesday 2 weeks ago. She has been working and going there to see him. This is the first time she has trying to think and get answers herself. Caller adds that she tested his blood sugar and must have touched it with her own finger because it said 197. The paramedic said no it was 40. Caller states the paramedic gave her fiancé IV stuff that shot it up and brought it up to 290, which was good. They wanted him to eat peanut butter and jelly and he said no and fought with them. The sugar was still not going up, and sugar was out of sorts. He took a few bites and it was okay. He asked for soup because he was so cold he could not work or anything. Caller becomes tearful and adds that her fiancé's mom passed 6 months ago and they were talking. He got 20 units of lantus, normally he takes 50. They went to bed and caller adds she guesses because her nerves were shot or something she called off of work that night. She got up to go to the bathroom and let the dogs out and went to check on him. She did not have the light on and when she turned the light on she saw her fiancé foaming at the mouth. He would not wake up and was unresponsive. Paramedics came and gave him a shot and IV to put sugar back in. They asked which hospital she would like him to go to and they said they could not take him to that hospital so they took him to another place. Seizures: They then put a breathing tube into him. The doctor said she was sorry but she knocked the man's tooth out. Then, they had to switch him to the mother hospital because they had to put probes on his

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

head to monitor his seizures because he had seizures. He had swelling on the brain, pneumonia, and was aspirating. Caller adds she is not sure if she touched the strip with her finger and that was the false reason, and his blood sugar was only 40. caller confirmed that the blood sugar increased to 290 following the paramedics giving her fiance sugar. Caller adds she does not know how to work that stupid thing. He never showed her how to do it. If he had showed her, she would know what to do. She said it said 197 but the paramedics told her it was 40. She has to learn how to do this. Patient requires trach, feeding tube, and dialysis: Caller was asked to clarify dates and she states that this was Wednesday, the next day. He has not foamed from the mouth since then, and they are not sure if he is doing seizures or not. They asked and the hospital said they are not sure because they do not have probes on him. Now, he is on a trach and feeding tube. They are also giving him some type of dialysis through his neck to get rid of toxins in the blood and filtering it back to him. Caller clarifies date of hospitalization as 15Apr2021 she would think, but she does not even know. Caller thinks it has been two or three weeks. First, he went to the place she mentioned and then he was transferred to the other and that is where he has been since. Indication: he worked up on 4 a lot which he is the maintenance where he works. They wanted him to get the Pfizer because not too many people wanted to go up there. He figured he would take it and with his blood pressure and sugar it would help. He was up there fixing things and stuff like that, or at least that is what she was told by someone else. Caller verifies that the low blood sugars, foaming at the mouth, and being unresponsive were what hospitalized the patient. She does not know dates, she thinks it was around 15Apr2021, and he is still in the hospital. Investigations: caller states that she knows he went back, she does not know when, and that since it is May now, he must have gone back a few months ago for lab work. It was in the morning, he went before work, and they did all kinds of stuff and to see where his A1C was. Caller adds that it was 11. Whatever else they are checking him for now she is not sure. Reporter details: caller states that she is a health care professional right no. She adds she is in housekeeping and in the health field and that she hears a lot of things, just because she does not say

<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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them. caller does not clarify statement regarding hearing a lot of things. Her head is going all sorts of ways. Caller adds she is batting her head against the wall. She is trying to put her head around everything happening. This is the only thing different. Everybody's body is different. No AEs required a visit to Physician office. but leading to Emergency Room, She states that it is the MIC Unit, and then clarifies as MICU. The outcome of the events was unknown. No follow-up attempts are needed. No further information is expected.

<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>
1325850	5/18/2021	WA		U	5/5/2021		CELLULITIS; HIGH BLOOD PRESSURE; ABSCESS IN ARM; HEADACHE; SEPSIS; PAIN; REDNESS IN ARM; FEVER; This spontaneous report received from a 49 year old patient of unspecified sex and ethnic origin. The patient's height and weight were not reported. The patient's past medical history included seizure disorder but had not experienced since 1998. 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 04-MAY-2021 13:00 on right arm for prophylactic vaccination. No concomitant medications were reported. On 05-MAY-2021, the patient experienced redness in arm and fever. On 06-MAY-2021, the patient experienced pain. Laboratory data included: Pain scale (NR: not provided) Level 8-10. On 07-MAY-2021, the patient experienced sepsis, headache, abscess in arm. On the same date, the patient reported initially low fever and later high fever, body temperature was (NR: not provided) 101.9 (unit not reported). On unspecified date MAY-2021 the patient went to emergency room for fever. Patient went to physician where took blood work .On 10-MAY-2021, patient's White blood cell count was high 18.53 (unit not reported) and the patient experienced cellulitis, was treated with liquid Augmentin and blood pressure was high 159/108 (unit not reported), Heart rate was high 147 (unit not reported). On an unspecified date in MAY-2021, second attempt White blood cell count was high 14.63. diagnosed as sepsis and treated with dose of antibiotic unasyn. Currently on unspecified date in MAY-2021 patient had fever of 101.4 (unit not reported). Patient had to be cautious of fevers due to a seizure disorder. On 12-MAY-2021 patient went to ortho surgeon and went back to hospital to treat arm abscess drained.100 cc was removed and still draining puss. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from fever, pain, redness in arm, cellulitis, high blood pressure, headache, sepsis and abscess This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210521005-covid-19 vaccine ad26.cov2.s-Sepsis, cellulitis and abscess in arm. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has 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>
							scientific plausibility. There is no information on any other factors potentially associated with the event(s).
1325415	5/18/2021		36	F	5/13/2021	5/13/2021	Pt had syncopal episode with possible convulsion (passed out for about a minute, face turned purple, and had contractions of the arms and hands with sweating) about 10-15 minutes post injection. 911 called. Checked EKG, vitals, BG and was advised to go the ER but she refused for further evaluation.
1326954	5/18/2021	KS	15	F	5/17/2021	5/17/2021	Patient started feeling dizzy/faint right after administration, she was sweating and felt hot to the touch, then she convulsed and shot up out of her chair for a few seconds before sitting back down. As she sat back down she vomited and then seemed to get better after. 911 was called and she was better by the time they arrived and blood pressure and vitals where all good.
1326856	5/18/2021	CA	23	F	5/17/2021	5/17/2021	When patient filled out the form she stated that she tended to have seizures with immunizations. About 3 minutes after the Covid immunization she did have a light seizure.
1323428	5/17/2021	MA	15	M	5/15/2021	5/15/2021	Vaccine given to patient and had a reaction to the vaccine. Patient appeared to have a vaso-vagal reaction color drained from his face and broke out in a sweat and then became unresponsive, then woke up. Moved to stretcher and vital signs monitored, heart rate to 40, appeared to have a seizure and post ictal. Mom present, instructed to call pediatrician and ask about second dose administration. Patient given OJ and banana, monitored for over an hour, color and VS improved, discharged with Mom.
1325260	5/17/2021	SC	35	M	5/17/2021	5/17/2021	Patient experienced a seizure about 5 minutes after receiving the vaccine. No history of seizure activity ever.

<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>
1322551	5/17/2021			F			<p>SEIZURES; POTASSIUM LEVEL DROPPED; SUGAR LEVELS DROPPED; WHITE BLOOD CELL COUNT DECREASED; NUMBNESS; SWOLLEN LYMPH NODES IN NECK; FELT LIKE DYING; TEMPERATURE WENT UP; UNABLE TO GET UP; This spontaneous report received from a patient via a company representative concerned a female of unspecified age received via social 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, Expiry Date: UNKNOWN) dose was not reported, 1 total, administered on 16-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 unspecified date of 2021, the patient's temperature went up and White blood cell count decreased to 1800. The patient's sugar level was dropped although the patient was not having any sugar problems. The patient also experienced swollen lymph nodes in neck, seizures, and numbness. The patient's potassium level was dropped to 3.0. The patient was unable to get up off couch. The patient was hospitalized for 1 day. The patient also felt like dying. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the temperature went up, White blood cell count decreased, sugar levels dropped, swollen lymph nodes in neck, seizures, numbness, potassium level dropped, unable to get up and felt like dying was not reported. This report was serious (Hospitalization Caused / Prolonged).;</p> <p>Sender's Comments: V0: 20210516164-COVID-19 VACCINE AD26.COV2.S-Seizures, Potassium level dropped, Sugar levels dropped, White blood cell count decreased, Numbness, Swollen lymph nodes in neck, Felt like dyeing, Temperature went up, Unable to get up . 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>
1322614	5/17/2021	ME	18	F	5/15/2021	5/15/2021	After injection pt felt light headed. Syncopal episode with seizure activity, was placed on floor and pt regained consciousness within 30 seconds. Patient was given water and sx resolved.
1322854	5/17/2021	PA	17	F	5/16/2021	5/16/2021	Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: syncope/seizure like activity-Medium, Systemic: Hypotension-Medium, Additional Details: Patient experienced a syncope/fainting/hypotensive event immediately post vaccination that had characteristics of possible seizure activity. Patient regained consciousness after a few minutes and seemed disoriented but stable (still hypotensive). Transported to reading hospital (tower health) emergency room for evaluation
1322991	5/17/2021	GA	62	M	5/11/2021	5/12/2021	Seizure
1323095	5/17/2021		33	M	5/17/2021	5/17/2021	Post vaccination seizure and loss of consciousness
1323138	5/17/2021	MA	31	F	4/7/2021	4/9/2021	FIRST 24-48 HOURS; FEVER, CHILLS, CONVULSIONS, NAUSEA, HEADACHE, BURNING SENSATION IN NECK & SPINAL COLUMN, FATIGUE. FROM 4/9/2021-PRESENT; SPORADIC BODYWIDE SKIN HIVES THAT ARE RED, BUMPY AND ITCHY- SPORADIC BLISTER LIKE SKIN LESIONS ON ANKLES, LEGS AND ARMS.
1323329	5/17/2021	NC	34	F	1/5/2021	4/25/2021	-received vaccine while pregnant: normal pregnancy except for vision loss Feb 2nd -baby born on due date, no complications, healthy weight (6 lbs 15.8 oz) and baby is healthy SYMPTOMS 3 months post-vaccine, over a 3 week period beginning 4/25/21: -tingling and "crawling sensation" in arms, legs, left side of head, left ear - extreme headache, fatigue, jerking/convulsions, extreme muscle weakness -ER visit 5/9/21: CT, EKG, labs all normal -fever up to 102F, increased pulse -loss of appetite -numbness in extremities -nerve pain -breast pain -chills and night sweats -pronounced weakness - tongue ulcer -cognitive issues such as brain fog, confusion

<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>
1323410	5/17/2021	MA	12	M	5/13/2021	5/13/2021	From ED Note: 12 year old male with PMH of asthma on flovent, food allergies with epi-pen (has not required this) and pre-syncope/syncope who presents with concern for loss of consciousness and possible seizure-like activity following a COVID vaccine. Mom notes that he was in his usual state of health when he presented to COVID clinic to get his first vaccine. He got the Pfizer vaccine, seconds after getting in his left arm, mom noted that he looked very "wide eyed" and distraught. She notes that he slumped forward and had lost consciousness for approximately 5 seconds. She noticed shaking movements in his right arm and bilateral lower legs. She notes that his left arm was against her and therefore cannot comment on it. She notes that his eyes were closed. No tongue biting and no incontinence. No secondary trauma. She notes that when these 5 seconds were over he then had a period for about 30 minutes where he looked pale and was breathing heavy but was alert and answering questions. She notes that he has had presyncopal episodes and episodes of feeling faint when getting flu shots in the past. However, this time she noted that he had shaking which made her nervous for possible seizure activity. Patient denies any chest pain or headache prior to the symptoms. She came via ambulance for further evaluation. On arrival, he reports that he feels 90% back to his baseline. He notes that he does not feel quite ready to run around yet however denies any pains or discomforts, headache, weakness, numbness, or tingling. He had eaten a full breakfast prior to getting the shot. He had a normal night sleep and a normal day yesterday per mom. Medical History: as above Surgical history: none Family History: Reviewed and no pertinent related family hx pertaining to this visit Social History: Lives with family Allergies: food allergies Medications: flovent, epi-pen Immunizations: Up to date Medical Decision Making 12 year old male with PMH of asthma on flovent, food allergies with epi-pen (has not required this) and pre-syncope/syncope who presents with concern for loss of consciousness and possible seizure-like activity following a COVID vaccine. On arrival, he was alert, well-appearing, in no acute distress. His vital signs were normal for age on room air. His physical exam was very reassuring as above with a normal neurologic and cardiac evaluation. Differential includes vasovagal/syncope in the setting of a known

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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stressful trigger vs seizure given report of shaking in his extremities. We feel the latter is significantly less likely given the timeline of the events. Has no known seizure activity nor any triggers per history (fever, trauma, etc.). He also has a normal neurologic assessment. At this time we will defer neurology consults given low concern for seizure. It is possible that this represents a side effect of the vaccine however we also feel that this is less likely given the fact that his symptoms have been seconds after receiving the vaccine. Nonetheless we reported the symptoms to the pharmacist who recorded it in the database. We attained an EKG showing a known incomplete right bundle branch block (unchanged from 2013) and a slightly prolonged QTC of 477 (previously 451). I encourage patient to stay well-hydrated, well rested in the setting of his suspected syncopal episode this morning. I also suggested that for further vaccinations, that he lay down on the table and drink/eat well prior. We provided strict return to ED criteria in the setting of worsening symptoms. All questions were answered at the time of discharge. Mom verbalized her understanding and agreement of the plan. He was discharged in a stable condition with mom at side.

**After patient was discharged, cardiology called the follow-up team due to the prolonged QTC to ensure that we were aware. I contacted the patient's PCP to do a follow-up EKG in 1 month's time.

<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>
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>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>

<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>
							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.
1323792	5/17/2021	TX	14	F	5/17/2021	5/17/2021	PATIENT HAD BEEN ON CHAIR MONITORING FOR 14 MINUTES WHEN SHE FAINTED. NOT CERTAIN IF SHE HAD A SEIZURE. HOSPITAL WAS CALLED TO THE SCENE AND SHE WAS TRANSFERRED TO HOSPITAL FOR OBSERVATION. PHARMACIST SPOKE TO PATIENT'S MOM THIRTY MINUTES LATER AND SHE WAS ENROUTE. MOM STATED SHE WAS DOING OKAY.
1324043	5/17/2021		36	F	5/5/2021	5/5/2021	Employee had a seizure about an hour post vaccination. EMS was called and employee was transported to ER.
1324109	5/17/2021	GA	14	F	5/13/2021	5/13/2021	Vasovagal Syncope @ 10:05 14 year old female. No breakfast or fluids in am before vaccination. EMT called BP 104/68 oxygen 99% HR 78 . BS 85. 10:14 seizure like behavior eyes roll back in head both arms constrict. BP 100/60 IV fluids started 100ml saline. 10:30 BP 104/70. (Per mother history of syncope four years ago after receiving an allergy shot.) alert and oriented x4 at 10:40. released to mother .

<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>
1324141	5/17/2021	MN	12	M	5/17/2021	5/17/2021	Patient received the vaccination. Approximately 20 seconds after receiving the dose patient said "I'm going to faint". Patient appeared to faint but also appeared to be having a seizure. The patients legs appeared to go rigid and he make movements with his arms. He appeared very pale. The patient "came to" within approximately a minute? Patients mother and I were able to lay Patient down on the floor. I asked his mother if she would like us to call 911 and she said yes. Prior to the incident, I discussed Patients past history of seizures with his mother. She said he had seizures when he was younger and had been on medication, but he was no longer on any medication and had been seizure free for approximately 5 years.
1324171	5/17/2021	CA	27	M	5/17/2021	5/17/2021	Patient felt nausea and could not breath so he stood up and took a breath. When he stood up he lost consciousness and fell. Patient hit his fore head and started having a seizure. The seizure lasted about 1-2 minutes before he regained consciousness. Patient was taken away by the EMS
1324250	5/17/2021	FL	42	M	4/6/2021	4/18/2021	Taken to ER with Grand mal seizures & possible stroke; admitted to hospital with seizures
1324256	5/17/2021	WA	24	M	5/17/2021	5/17/2021	LIGHT HEADEDNESS, THEN SEIZURE FOR ABOUT 10 SECONDS. WE CAUGHT PATIENT AND LIED HIM ON THE FLOOR AND TURNED PATIENT ON A SIDE, ARM WAS SWELLING AND TURNED ORANGE. PATIENT WAS CONCIOUS, EMT ARRIVED AND TOOK HIM TO THE HOSPITAL.

<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>
1324568	5/17/2021	WA	17	M	5/17/2021	5/17/2021	PATIENT FAINTED FEW MINUTES AFTER RECEIVING THE VACCINE. HE LOOKED LIKE HE WAS HAVING A SEIZURE. IT LASTER FOR A BOUT 15-17 IN MY ESTIMATE. HE WAS ALERT AFTER AND ANSWERING QUESTIONS ABOUT HIS NAME, DOB AND WHERE HE WAS. TOOK HIS BLOOD PRESSURE TWICE-5 MIN APART AND IT WAS LOW. 113/58 AND THEN 102/50 TO MY RECOLLECTION. PARAMEDICS WERE CALLED IMMEDIETLY AND PATIENT HAD HIGHER BLOOD PRESSURE WHEN THEY WALKED IN. IT WAS "NORMAL". PATIENT TOLD US HE HAS A HISTORY OF VASOVAGAL SYNCOPE AND HE FAINTED BEFORE WHEN HIS BLOOD WAS DRAWN. HE SAID THAT IT SEEMED LIKE A SEIZURE BEFORE BUT CHECKED WITH NEUROLOGIST AND WAS NEVER DIAGNOSED WITH EPILEPSY. PT LEFT IN A STABLE CONDITION
1324773	5/17/2021	NM	37	M	5/17/2021	5/17/2021	Pharmacist gave a Johnson + Johnson shot to the patient. After the shot the patient got up and sat down in a "Post-Vaccination waiting area" chair. A few minute later the patient got up and walked towards the pharmacy asking for water, as he was walking to the pharmacist the patient fainted, fell to the ground and bumped his head on the counter. Patient woke up a several second later confused and laid on the floor. Code white and 911 was called. Another pharmacist grabbed an ice pack and a bottle of water for the patient. Patient said he went to the dentist office recently and received a shot in the mouth and something similar happened as well. The patient did not disclose this information to the immunizing pharmacist. Patient told us to cancel the 911 call and asked to leave, the pharmacist recommended he stay a while longer so we can monitor him. Patient said he had no history of diabetes or seizures. Patient forehead was slightly red.

<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>
1323330	5/17/2021	CA	13	F	5/14/2021	5/14/2021	10 minutes after her first dose she had been sitting in a chair & developed diaphoresis, warm skin, loss of vision,& low blood pressure. Pt was initially not responsive, when transferred to a wheel chair to take her to a gurney, left arm & left leg jerk twice. Took her to lay down and check her blood pressure. En route, in the wheel chair within about 5 to 10 seconds, she became responsive and said she could not see. Her vision returned to normal within a minute. Her initial blood pressure was 97/64 with O2 Sat 100% on room air. Her skin temp was 95.5, and her HR was 95. She continued to be responsive with excellent oxygenation and When the EMTs arrived she had a blood sugar of 90 and improving blood pressure with a regular rate and rhythm. Her diaphoresis resolved, and she continued to improve, tolerating water. Had similar reaction last year to flu shot, no hx of seizures
1322138	5/16/2021	OR	15	F	5/16/2021	5/16/2021	Patient had what appeared to be absence seizures (facial twitching, unresponsive but moving eyes, fist clenching) for 30 seconds. This occurred 10 minutes post injection. Patient did not fall out of chair as her grandmother was right next to her. 911 was called, patient recovered immediately after and had no other incidence. patient taken to hospital.
1322457	5/16/2021	OK	14	M	5/16/2021	5/16/2021	About 5 min after receiving shot, his head went to the side, lost consciousness. His legs, arms, hands went stiff and he started shaking. His eyes rolled back in his head, textbook seizure. Lasted a little less than a minute. When came to he said he couldn't see anything. After about 30 seconds he could start to see. He turned pale, felt like he was going to throw up. But never did. A few minutes later he started to get a little color back in his face. He is tired but was better.
1321744	5/16/2021	TX	15	M	5/15/2021	5/15/2021	Syncope and alleged seizure as reported by mother and bystanders (Pharmacist did not witness 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>
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.
1322150	5/16/2021	MI	15	F	5/16/2021	5/16/2021	Patient received injection and sat down in the waiting area with her Mom. Less than 5 minutes after the injection she fainted and appeared to have a small seizure , her mother shouted at her and shook her and she became conscious and vomited. 911 was called , they evaluated the patient and she went to the hospital.
1321585	5/16/2021	TX	13	M	5/15/2021	5/15/2021	Systemic: Seizure-Mild, Additional Details: Mother stated that he had the same reaccation after getting the flu shot but did not tell us prior to injection. Called 911 (parents called MD) pt was assessed by the fire department and EMS and was cleared to leave. parents did not want the patient transported to the hospital, they plan to follow up with the MD
1321944	5/16/2021	TX	13	M	5/16/2021	5/16/2021	Syncope, seizure lasting less than 5 min, vomiting
1321951	5/16/2021	IL	16	F	5/16/2021	5/16/2021	Patient has a seizure history. Mother stated they have had numerous vaccines in the past without a problem though. Patient was waiting the period of time afterwards. Mother then stated she was having a reaction. Mother stated she is a nurse and said she believed the patient was having a seizure. Mother later was not sure if patient had fainted also since she was nervous about receiving the shot in the first place. After paramedics arrived, they took her glucose and was 77. Paramedics let mom then take patient home to get food.

<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>
1321992	5/16/2021	TX	16	M	5/16/2021	5/16/2021	<p>Patient was given Pfizer Vaccine on 5/16/21 at 11:00-11:10am. I read through the patient medical history through the handheld and noticed there was "yes" on seizure history. I ask the mother what happened and she told me it was from the first incident with the Pfizer vaccine. At the time of the first incident the mother stated that patient fainted and convulsed upon regaining consciousness. Patient has had no history of seizures prior to then or had any big injuries that could trigger it. Patient's mother states physicians think it's triggered by anxiety and not a true seizure, so MRI or tests was not needed. Doctor recommended patient to come back if it happens again. With the information provided I used professional judgement and was on high alert with the patient. After administering the vaccine to the patient, I monitored patient's vitals carefully. Patient was stable and I walked with him to his seat near the wall and left him with his family. About a few minutes later the mother told me to come to her aid. Patient had a 1 time continuous seizure for about 30 seconds-1minute. After regaining consciousness the patient said he did not remember getting the vaccine. Patient's mother was very concerned and under control and did not overreact to the situation. Also, I promptly relayed to (pharmacist) to call 911 and he called a member of management. While pharmacist was on the phone with 911 the patient regained consciousness. I monitored patient's vitals while I waited for a member of store management. Store management took a little bit longer to respond (5-10 minutes) but arrived to document the whole incident. About 30 minutes after the incident patient's vitals were stable and the ambulance was not needed and the family took him to the hospital to get monitored. Patient rode the electric wheelchair was escorted out by store management to the car.</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>
1322012	5/16/2021	PA	21	F	4/18/2021	4/25/2021	Has intractable epilepsy, she usually has 5-6 seizures per day that are generally brief myoclonic-astatic type of seizures. The day after received her second dose of COVID19 vaccine she had an increase in seizure frequency. By 4/25/2021, she started to develop fevers and new type of seizure with more body twitching and stiffening of her arms. She was admitted to Hospital in on 4/27/2021 with fever, status epilepticus, found to have an aspiration pneumonia. She required antiepileptic medication dose adjustment with addition of Valproic acid to her drug regimen, but this caused excessive sedation. She was discharged from hospital on 5/14/2021. Status epilepticus did resolve and she was more alert by the end of hospitalization.
1322025	5/16/2021	MO	56	F	2/14/2021	3/23/2021	Seizure occurred. Never had a seizure before. Hospitalized . Started on Lamictal. Neurologist felt seizure was direct relation to Covid Vaccine
1322062	5/16/2021	KY	57	F	4/9/2021	4/10/2021	The day following vaccination, I felt oxygen deprived and nauseous. After going to bed at 12 am, I awoke at 1:30 with hammer like pains in the right thigh, right head, and bottom of right foot. Later I awoke again at 5:30 am with a seizure like jerk. The next day I had stinging pain in my right side and the bottom of the right foot. My heart raced and skipped beats and felt like it was flopping. The oxygen deprived feeling continued for 5 days. The hammer like pains subsided. I continued to feel nauseous and exhausted for 2 weeks after vaccination. The third week I was just very tired. It was such a terrible experience, I didn't think I would live through it.
1321241	5/15/2021	AZ	18	F	5/14/2021	5/15/2021	My daughter did not sleep all night, had fever & chills. Got up early in am & fainted on tile floor in kitchen. She was easily aroused after fainting. Helped her to a chair Then she had a seizure. It was very short lasting, then she vomited. She was very weak for 2 hrs. after that & she continued to slowly consume water & crackers. After getting her to bed she slept for one hour. Still too weak to go to bathroom alone. Improvement shown after 5 hrs of rest & fluids/some food.

<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>
1320170	5/15/2021		19	M			seizure like movements; passed out; dizzy; nausea; This is a spontaneous report from a non-contactable healthcare professional (HCP). A 19-year-old male patient received BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date (age at vaccination: 19 years old) (Batch/Lot Number: ew0167) as single dose for COVID-19 immunisation. The patient's medical history and 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 experienced dizzy, nausea, passed out, seizure like movements on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.
1320092	5/15/2021	CA	51	F	4/14/2021	4/15/2021	This is a spontaneous report from a contactable consumer, the patient. A 51-year-old non-pregnant female patient reported that she received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Batch/lot number: EWO151) via an unspecified route in the left arm on 14Apr2021 at 11:30 (at the age of 51-years-old) as a single dose for COVID-19 immunization. Medical history included diabetes mellitus. 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. Concomitant medications the patient received within 2 weeks of vaccination included insulin and metformin. On 15Apr2021 at 06:00 (reported as 18 hours later), the patient had a "gran map seizure" and had to be taken to the hospital via ambulance. The event resulted in visit to emergency room/department or urgent care. The patient was not treated for "gran map seizure". The clinical outcome of "gran map seizure" was unknown. Since the vaccination, the patient has not been tested for COVID-19.

<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>
1320096	5/15/2021	FL	68	F	2/24/2021	2/24/2021	loosing urine; mind would 'go off' for a couple of seconds and she would just urinate.; seizure; she would just urinate.; This is a spontaneous report received from a contactable consumer (patient). A 68-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for Injection, Lot number and Expiration date were not reported), via an unspecified route of administration, administered in Arm Left on 24Feb2021 10:00 (at age of 68 years old) as single dose for COVID-19 immunisation. The patient medical history was not reported. Concomitant medication included omeprazole (PROTONIX). No Prior Vaccinations (within 4 weeks). No AE(s) following prior vaccinations. No Additional Vaccines Administered on Same Date of the Pfizer Suspect. The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for Injection, Lot number and Expiration date were not reported), via an unspecified route of administration, administered in Arm Left on 03Feb2021 (at 68 years old) as single dose for COVID-19 immunisation. Caller stated she received Pfizer's COVID vaccine and shortly afterwards (on 24Feb2021), her mind would 'go off' for a couple of seconds and she would just urinate. She stated, "I never had this issue before. It happened one day, then 2 days later, then 2 days later. My mind would just go off for a second and I would just stand there and urinate. And it went on for 10 days every other day. Now it just happened. I just unloaded yesterday (29Apr2021). It all just started happening after the 2nd vaccine. It may be related or may not. The urologist said that's strange and they said there's nothing they can do about it. I will be seeing the neurologist on 07Jun2021." Caller calling about the Pfizer COVID vaccine. She states that 2 days after getting the second shot every now and then her mind would go off, like a mini seizure and then she would loose her urine. She states that she has never had this issue before. It has been going on for almost over a month now, but it has been going down a little less, but it's still happening. She is going to a neurologist, but the neurologist can't see her until June. She is wondering has anyone else had an issue with this? She states she has been to a urologist, but they say they can't do anything for her and that she needs to see a neurologist. She states that it is very strange. She does state that it is

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

becoming less and less, and it is like every 4 days now. She states she did have a 6 day stretch where she didn't have any incidence of the mini seizure or loosing her urine. She states she has never had anything happen to her like this, not even close. It happens out of the blue, and she doesn't even feel the sensation to urinate. She states she could be talking to someone, or in a store talking to someone and her mind goes out for just a second and then she just pees. She states that she is aware of what is going on. Caller states that she doesn't know what a mini seizure is like and does not know how to describe this event. However, it is usually when she is talking to someone, her mind might go off for a second then she just pees. She states it's weird. She states that it is usually when she is out, and that it doesn't happen at home. She states that she doesn't have the sensation of having to go to the bathroom she just goes. She says it's weird, nothing like this has ever happened before. She doesn't have a problem with fizzing out for a couple seconds. Caller states she doesn't want to use mini-seizure because then that marks her of having epilepsy. She also states that her doctor told her not to describe it as a seizure because they are not sure what it is yet. She wants to use the term fizz out for a min. Fizzing out for a minute: She clarified and states that the last two times this happened she did not fizz out, but she still just peed out of nowhere, without even having a sensation of having to pee. The last time she fizzed out was 10Apr2021. She doesn't know what to do and she is hoping that it gets figured out. She went four days without anything happening and then she was waiting in line and it just happened. She states she just urinated but doesn't recall fizzing out. She states it is not every day but every four days now, the urine. She states that it happened after the second vaccine. Dates for loosing urine was 04Mar2021. Physician Office visit for all events (went to the doctor after this happened. She states that the events might of happened before the second vaccine, she is not sure, but she started righting it down shortly after receiving the second vaccine). The outcome of the event loosing urine was not recovered, for other events was unknown. information on the lot/batch number has been requested.

<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>
1320099	5/15/2021		54	M		4/20/2021	convulsions; Fever (up to 103 F degrees); chills; confusion; dizziness for first 48 hours; body aches for 96 hours.; This is a spontaneous report from a non-contactable consumer who reported for himself. A 54-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EW0172), via an unspecified route of administration, in Arm Left on 20Apr2021 at 13:30 (at 54 years) at single dose for covid-19 immunisation . Medical history included known allergies penicillin. Previously, on 29Mar2021, patient took the first dose of the vaccine (lot Number: EQ0150) administered in Arm Left for covid-19 immunisation. The patient's concomitant medications were not reported. Patient had no COVID prior vaccination and was not covid tested post vaccination. On an unspecified date in 2021 patient experienced fever (up to 103 F degrees), chills, convulsions, confusion, dizziness for first 48 hours, body aches for 96 hours. No treatment given. Patient recovered from all the events on an unknown date in 2021. No follow-up attempts are possible. 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>
1320090	5/15/2021	MN	60	M	4/27/2021	4/27/2021	<p>This is a spontaneous report from a contactable consumer, the patient. A 60-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 27Apr2021 (at the age of 60-years-old) as a single dose for COVID-19 immunization. Medical history included ongoing tremors and prostate issue. The patient had no known allergies. The patient was not diagnosed with COVID-19 prior to vaccination. Concomitant medications included clonazepam, tamsulosin, oxybutynin. The patient did not receive any other vaccinations within 4 weeks of the vaccine. On 27Apr2021 (the first day), the patient was a little tired. On 28Apr2021 (the second day), the patient experienced joint pain, felt very tired and weak. By 19:00-20:00, the patient realized he was going to have a tremor attack, but quickly turned into what would be called a seizure. The patient lost motor skills, speaking and breathing issues accrued. The symptoms where coming and going. With the help of his wife, the patient managed to take one 0.5 mg clonazepam. The situation lasted for around an hour, after which the patient went to bed. The next morning, 29Apr2021, the patient still had a lot of joint and muscle pain. As soon as he tried to start some minor work around the house, the tremors started again, but this time the patient took clonazepam and rested in bed all day. Today, 30Apr2021, the patient was tired from the situation and will be resting also. Since the vaccination, the patient was not tested for COVID-19. The clinical outcome of seizure, " tremor attack / tremors started again", joint pain, tired, weak, lost motor skills, speaking and breathing issues accrued and muscle pain was resolving. Information about lot/batch number 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>
1320177	5/15/2021	MN		M	4/30/2021	4/30/2021	seizure; faint; feeling dizzy; drained again; his lips lost their color; difficulty hearing; nauseous; sweating profusely; This is a spontaneous report from a contactable pharmacist. An adolescent male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot Number: Er8736), intramuscular, administered in Arm Left on 30Apr2021 20:30 as 1st dose, single for COVID-19 immunization. Medical history, none known. 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 reported no previous adverse events with prior vaccinations, specifically dizziness or fainting. After the shot he went to the bathroom, returned fairly quickly & reported feeling dizzy and quickly took a seat and thought he might faint. Soon thereafter he seemed to have a seizure. His eyes remained open but rolled back, he stayed upright but was unresponsive. They removed his mask & his mother & they kept talking to him. It ended after about 10 seconds & he asked how long he had been out. His color was momentarily better, but drained again & his lips lost their color. They asked if he had any difficulty breathing and he did not. He reported that he had difficulty hearing (like he had headphones on) & was sweating profusely. His mother kept encouraging him to take deep breaths, they got him some water & asked if he had a history of hypoglycemia- he did not. They asked if they could get him a candy bar& they asked for a granola bar which they acquired. He was too nauseous to eat it & asked. The events started on 30Apr2021 20:30. No treatment was given. The outcome of the events was recovered.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the seizure and the other 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 including EEG and head CT/MRI, 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

<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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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.

<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>
1320178	5/15/2021	MO	66	F	4/14/2021	4/23/2021	pre-syncopal and syncopal episodes; pre-syncopal and syncopal episodes; seizure; This is a spontaneous report from a contactable consumer. A 66-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: ER8731), via an unspecified route of administration, administered in right arm on 14Apr2021, at 10:00 (Batch/Lot Number: ER8731) as single dose for covid-19 immunization. Medical history included hypertension, breast cancer, penicillin allergy, allergy to sulfa, and osteoporosis from unspecified dates. Concomitant medications included metoprolol tartrate (MANUFACTURER UNKNOWN) taken for an unspecified indication, start and stop date were not reported; losartan (MANUFACTURER UNKNOWN) taken for an unspecified indication, start and stop date were not reported; folic acid (MANUFACTURER UNKNOWN) taken for an unspecified indication, start and stop date were not reported; exemestane (MANUFACTURER UNKNOWN) taken for an unspecified indication, start and stop date were not reported. The patient experienced pre-syncopal and syncopal episodes and seizure on 23Apr2021, which were serious as they involved hospitalization. The patient was hospitalized for 2 days for the events. The patient underwent lab tests and procedures which included blood test: negative on 22Apr2021, Covid-19 test: negative on an unspecified date, since the vaccination, scan: no lesions on an unspecified date. Details were as follows: a week and a half after the vaccine, patient started having pre-syncopal and syncopal episodes, increasing in frequency. After two days, patient went to the emergency room, where she had a seizure and was admitted to the hospital. Scans showed no lesions. Patient was put on Keppra, and no more seizures. Therapeutic measures were taken as a result of the events; treatment received for the adverse events included benzodiazepine, Keppra, and intravenous fluids. 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>
1320255	5/15/2021	MI		M			had two seizures on the same day; epilepsy; This is a spontaneous report received from a non-contactable consumer reported for a 20-year-old male patient 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. The medical history and concomitant medications were not reported. The patient had epilepsy. He had two seizures this week on the same day and he had not had a seizure in 1.5 years. The outcome of the events was unknown. Information on the lot/batch has been requested.
1320379	5/15/2021	IL		M			had 2 seizures; This is a spontaneous report from a contactable consumer (parent). A 16-year-old male patient received bnt162b2 (lot/batch number unknown) via an unspecified route of administration on an unknown date at 2nd dose, single for COVID-19 immunization. Medical history and concomitant medication were not reported. The patient previously received bnt162b2 (lot/batch number unknown) via an unspecified route of administration on an unknown date at 1st dose, single for COVID-19 immunization. The patient had 2 seizures after receiving his 2nd dose of the Pfizer vaccine. The seizures occurred approximately 15 hours after the vaccine was given. He has no underlying seizure condition. The event was reported as serious for Life-threatening. The outcome of event was unknown. Information on the Lot/Batch number has been requested.
1321240	5/15/2021	CO	18	M	5/15/2021	5/15/2021	Patient received the vaccine and while sitting down within one minute he fainted and fell on the floor. He remained on the floor until paramedics arrived. Paramedics took his vitals and observed him for a period of time. They said it was fine for him to leave with someone else to drive him. While waiting for family to arrive the patient began to have a seizure. Paramedics returned and this time they took the patient for further care.

<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>
1321355	5/15/2021	NE	13	F	5/15/2021	5/15/2021	Patient was sitting with her mother in front of the pharmacy for the 15 min waiting period after vaccination, and mom alerted us to "something going on here." I (pharmacist) went over to the patient and she appeared to be having a seizure, hands clenched, eyes rolled back in head, and she shook a small amount for a short period of time, though mom believes she just passed out. Mom and I protected head and held her in place, it was over within a few seconds. A Nurse Practitioner was in the clinic next door and we alerted her. Together, we laid her down, asked her questions, took pulse with pulse oximeter and blood pressure. All seemed within normal range. We called 911 due to appearance of seizure. Rescue squad came and evaluated her.
1321078	5/15/2021	ME	18	F	5/15/2021	5/15/2021	After injection, patient felt light headed. Syncopal episode with some seizure activity. Was placed on floor of vaccinator's area with feet elevated with return of consciousness within 30 seconds. She was escorted Medical Lead's area for observation. Was given water and observed for an hour. Vital signs were stable(102/80., pulse 72) , light headedness resolved and taken to vehicle in a wheelchair. Was not the driver.
1320056	5/15/2021	WV	35	M	4/28/2021	4/29/2021	Grand Mal seizure; Heart palpitations; This is a spontaneous report from a contactable consumer (patient). A 35-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via unspecified route of administration in left arm on 28Apr2021 at 14:00 (lot number: EW0158) at single dose for COVID-19 immunization. The relevant medical history included epilepsy, childhood leukemia and COVID-19 (Prior to vaccination, the patient was diagnosed with COVID-19), all from unspecified date. Concomitant medications included lamotrigine (LAMICTAL ODT). The patient experienced Grand Mal seizure and heart palpitations on 29Apr2021 at 18:00. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was recovering.

<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>
1320082	5/15/2021	FL	40	F	4/23/2021	4/1/2021	difficulty walking; difficulty with speech / slurred speech; fingers are going numb holding the phone; feels like she is coming down with a respiratory illness; nausea; vomiting; cough; sweating; headache; body pain, achy and uncomfortable; body pain, achy and uncomfortable; overall feeling badly; cognition was not there; Problems with breathing; aspirating; sleepiness; fatigue; stomach pain; her nerve response is strong/affected; swelling in hands and feet; had arm soreness; This is a spontaneous report from a contactable consumer (patient). A 40-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EW0162), via an unspecified route of administration in the left arm, on 23Apr2021 at 15:00 (at the age of 40-years-old) as a single dose for COVID-19 immunisation. Medical history included ongoing neuropathy (few years ago, at least since 2015 or 2016), seizures or epilepsy (had focal/absence seizures since a kid; not on any seizure medication, do have a neurologist), hard time with her vision, cancer from an unspecified date to an unspecified date (cancer as a teenager but has been cancer-free for a very long time), and glaucoma. The patient had a family history of cancer and heart problem. Concomitant medications included latanoprost (MANUFACTURER UNKNOWN) taken for glaucoma from Apr2021 and ongoing and gabapentin (MANUFACTURER UNKNOWN) taken for neuropathy from an unspecified start date and ongoing. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: ER8730), intramuscularly in the left arm, on 02Apr2021 for COVID-19 immunisation and experienced not very many side effects with first dose, not enough to be a problem; influenza vaccine (MANUFACTURER UNKNOWN) in 2021 (maybe) for immunisation; and polio vaccine (MANUFACTURER UNKNOWN) as a child for immunisation and experienced severe pain in her legs and she had trouble walking because of pain. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced difficulty walking and difficulty with speech / slurred speech on 23Apr2021, which required hospitalization from Apr2021 to 26Apr2021. The patient also experienced body pain, achy and uncomfortable, overall feeling badly, cognition

VAERS_ID RECVD DATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

was not there, and problems with breathing on 23Apr2021; sweating and headache on 26Apr2021; vomiting and cough on 27Apr2021; feels like she is coming down with a respiratory illness and nausea on 28Apr2021; sleepiness, fatigue, stomach pain, her nerve response is strong/affected, swelling in hands and feet, aspirating, and had arm soreness in Apr2021; and fingers are going numb holding the phone on 29Apr2021. The clinical course was reported as follows: The patient stated that she works in healthcare support and she is a first responder; she identifies as a person with a disability (unspecified). She stated that she did not have very many side effects with first dose, not enough to be a problem. By dinnertime, closer to 18:00-19:00 on 23Apr2021, she started experiencing difficulty walking and with her speech. She was concerned about having a stroke but that she is active and generally healthy. This was unusual for her and she started feeling pain through her body and overall feeling like crap. She did not expect the neurological stuff. By the end of the night on 23Apr2021, she realized she was not feeling good and went to the hospital either that night on 23Apr2021 or early the next day on 24Apr2021 and was admitted to the hospital. The patient stated that her cognition was not there, and her speech was kind of slurry, she felt like everything was slowing, and did not feel like herself. She could not get up unassisted, could not get up out of the bed, chair, or go to bathroom, and still requires the use of a walker and bedside commode, but now with the walker and assistance caller can make it to the bathroom. She also had problems with breathing, but she had a negative COVID-19 PCR test in Apr2021 both arriving to and leaving from the hospital; she did not believe them to be COVID-19 symptoms. At the hospital they did an x-ray or computerized tomography (CT) scan and a magnetic resonance imaging (MRI) on her brain in Apr2021 with unknown results. They gave her 3 or 4 intravenous (IV) unspecified medications and she had her complete blood count (CBC) labs done in Apr2021 with unknown results. There was an issue with her lungs, and she is currently waiting for her doctor to read report to see if there is an issue there. The patient stated that she never experienced anything like this after a vaccine. She cannot even get up and move around it is pretty serious. Caller states that at first when she had the symptoms,

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

she thought she was going to wait it out, maybe her immune system is overresponding, give it a chance to resolve. She reported that she could not stand up, legs were shaking and that she had pain that was from her breasts down; felt like a ton of bricks. The patient stated that she is cognitively alert now, speaking normal. There are times it goes in waves where she feels like she can walk with walker but then a few hours later that is not the case. On Tuesday, 27Apr2021 night, the patient had a light dinner but then she was vomiting. Caller states that the pain was throughout her body and felt like someone lighting firecrackers. The patient initially stated 28Apr2021 was when the cough started, but later clarified she first noticed it on 27Apr2021, but at that time she was vomiting and thought it was due to that. However, the next day 28Apr2021, she still had this cough and that the cough was getting worse. She felt like she has a respiratory issue and has been coughing. She was not able to stay awake, even without taking any medications. She does take medications regularly but did not take the medications those days and not having medications would not cause sleepiness. She thought the doctor gave her sedative, but they did not. She states she had fatigue to the point where she was dead asleep, and nurse would come in to take vitals or do whatever and she would wake up suddenly with someone in front of her. She was sitting up with the nurse trying to read the discharge instructions and she fell asleep sitting up. She also complained of stomach pain. The patient had not been to work and not been having to use her brain and talking like she would for 8+ hours a day. She stated that the cough hurts, it feels like somebody is lighting firecrackers in her body. It also feels like this when she sneezes; the nerve response is strong. She reported that it is not a constant hacking cough, not really a dry cough; the cough is in-between productive and dry cough and cough is a bit better now and worse towards the evening. She still has swelling in her feet and hands. It looks like it has gone down a bit. She has a history of neuropathy and that her fingers are going numb holding the phone now. She got the shot in her left arm and those fingers are going numb. She was so tired and feels like did not get enough sleep. The fatigue had a slight improvement. She is more awake than when she was in the hospital. However, it depends as the day goes on, she is wiped

<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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out and has to go lay down. She stated that her nerve response is affected, and she had a difficult time with the neuro exam in Apr2021 with unknown results in the hospital. She was having an issue with her arms. She can't say anything about whether it affected her vision because she already has a hard time with her vision. She stated that she was throwing up pretty bad; the pain was really severe through her whole body while vomiting. After the vomiting stopped, the coughing got worse and she was coughing a little bit before the vomiting, but during the vomiting it was to the point she felt like she was drowning. She reported that she was vomiting through her nose and aspirating. After her MRI she started to get a really bad headache. Then when the nurse was coming to read the discharge information, she started to get sweats. She is not menopausal so she cannot blame the sweating on menopause, as reported. The patient also had arm soreness, but does not care about that long as it does not leave any scars. This was not a big deal for her at all. This started shortly after getting the vaccine. She waited for the observation time and no sensation out of the normal, then later towards the night started feeling like having really bad mensural cramps, like an achy feeling where have to go lie down. Then her lower half started to get worse. Her arms were affected and difficult time with the neuro testing. The patient stated she is now on the road to recovery. The clinical outcome of difficulty walking, difficulty with speech / slurred speech, body pain, achy and uncomfortable, nausea, sleepiness, fatigue, and stomach pain was recovering and of overall feeling badly, cognition was not there, problems with breathing, sweating, headache, vomiting, cough, feels like she is coming down with a respiratory illness, her nerve response is strong/affected, swelling in hands and feet, aspirating, had arm soreness, and fingers are going numb holding the phone 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>
1320024	5/15/2021	OR	22	F	4/28/2021	4/28/2021	seizures; This is a spontaneous report from a contactable consumer (patient). A 22-year-old female patient received the first dose of BNT162B2 (BNT162B2) via an unspecified route on left arm 1st dose, single for COVID-19 immunization on 28Apr2021 01:00 at 22-year-old. Medical history included cerebral palsy. There were no concomitant medications. The patient experienced multiple side effects throughout the day followed by seizures on 28Apr2021 17:00, reported as serious due to disability with outcome of recovering. Doctor or other healthcare professional office/clinic visited, emergency room/department or urgent care visited, reported as disability or permanent damage. The patient was treated by diphenhydramine hydrochloride (BENADRYL). Information on Lot/Batch number has been requested.
1319845	5/15/2021			U			seizure; Rash on Both legs; Headaches; Fever; Fatigue; Nausea; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (seizure) 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. No relevant medical history 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, the patient experienced SEIZURE (seizure) (seriousness criterion medically significant), RASH (Rash on Both legs), HEADACHE (Headaches), PYREXIA (Fever), FATIGUE (Fatigue) and NAUSEA (Nausea). At the time of the report, SEIZURE (seizure), RASH (Rash on Both legs), HEADACHE (Headaches), PYREXIA (Fever), FATIGUE (Fatigue) and NAUSEA (Nausea) outcome was unknown. 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.

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
1319772	5/15/2021	CO	40	F	4/6/2021		<p>Cerebral venous sinus thrombosis; Pulmonary embolism; PLATELET COUNT DECREASED; Activated partial thromboplastin time shortened; Rash erythematous; Dizziness; Headache; ALANINE AMINOTRANSFERASE INCREASED; ANGIOGRAM PULMONARY ABNORMAL; ASPARTATE AMINOTRANSFERASE INCREASED; BLOOD ALKALINE PHOSPHATASE DECREASED; BLOOD ELECTROLYTES NORMAL; HAPTOGLOBIN NORMAL; THROMBIN TIME PROLONGED; ULTRASOUND SCAN NORMAL; VENOGRAM ABNORMAL; This spontaneous report received from a patient, concerned a 40-year-old. This case was described in a literature article, reference: outcomes of bivalirudin therapy for thrombotic thrombocytopenia and cerebral venous sinus thrombosis after vaccination: The patient's height, and weight were not reported. The patient's concurrent conditions included tonsil exudate, seasonal allergies, strain of cervical portion of right trapezius muscle, and migraine headaches. There was no history of thrombosis, clotting disorders, inflammatory bowel disease, collagen vascular disorders or cancers. The patient was not pregnant at the time of reporting, was not using estrogen-containing medications or tobacco and had no recent surgical history. On 01-APR-2021, the patient received covid-19 vaccine (suspension for injection, intramuscular, batch number: 042A21A, and expiry: UNKNOWN) dose was not reported, once total administered on left arm for prophylactic vaccination. Concomitant medications included cyanocobalamin, menatetrenone, and paracetamol. On post-vaccination day 5, 06-APR-2021, the patient developed a headache, sinus pressure, myalgias and sore throat with tonsillar exudate. On day 8, she presented to urgent care and was prescribed amoxicillin/clavulanate potassium, a methyl-prednisolone taper and methocarbamol. No laboratory evaluation was performed. She continued to have worsening headaches (different to her normal headaches), especially with movement, associated photophobia and intermittent dizziness prompting her presentation at the Emergency Department on post-vaccination day 12, 13-APR-2021. She denied fever, weakness, numbness, vision changes, speech difficulty, gait instability, seizure. Her initial vital signs were within normal limits, except blood pressure was 141/96 mmHg. Physical examination revealed small areas of petechiae</p>

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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on her chest and right cheek of the face and mild tonsillar exudate without cervical lymphadenopathy. A detailed neurological examination was normal, and she had no leg swelling or pain. She was admitted to the hospital for further testing and management. The patient was found to have thrombocytopenia, an elevated D-dimer, normal fibrinogen, and mild elevation of the serum transaminases. Laboratory data on 13-APR-2021 included: alanine aminotransferase was 87 U/L, aspartate aminotransferase was 65 U/L, blood alkaline phosphatase was 25 U/L, other blood electrolytes were normal, haptoglobin was 208 mg/dL, partial thromboplastin time prolonged was 26.4 sec, platelet count was $20 \times 10^9/L$, and thrombin time was 14.9 sec, D-dimer was 27,150 to 47,570 FEU. Peripheral smear did not reveal schistocytes or other evidence of hemolysis. The patient's nasopharyngeal swab tested negative for SARS-CoV-2 RNA by reverse-transcriptase-polymerase-chain-reaction assay. An initial heparin induced thrombocytopenia antibody test, HIT IGG PF4, (HemosIL LIA assay) was negative. A confirmatory HIT PF4 ELISA resulted positive. While the patient did show a transient drop in hemoglobin (nadir of 12.3 g/dL on 15-APR-2021), there was no clinical evidence of bleeding. Mild transaminitis was present on time of admission; investigation for causes such as autoimmune hepatitis did not reveal an etiology. A CT angiogram of the chest showed a mild burden of acute pulmonary embolism with subsegmental filling defects in the right lower lobe. No right heart strain or lung infarct. A CT venography of the head/brain showed occlusive dural venous sinus thrombosis involving the left transverse and sigmoid sinuses extending into the left internal jugular vein. There is no associated infarct. There was possible additional nonocclusive thrombus in the right internal jugular vein. A lower extremity ultrasound was negative for DVT. A right upper quadrant ultrasound confirmed no portal vein thrombosis. The patient was treated with bivalirudin, a direct thrombin inhibitor with a short half-life. Infusion was started at 0.15 mg/kg/hr with titration parameters to target a PTT goal of 50-80 seconds. Additional pharmacologic interventions to aid in platelet recovery included intravenous globulin 1 g/kg/day for 12 days and prednisone 1 mg/kg daily. The patient demonstrated steady improvement until discharge on hospital day 6

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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and continued to show improvement. Platelet count was $115 \times 10^9/L$ (at discharge on hospital day 6/post-vaccination day 18) and was $182 \times 10^9/L$ (during outpatient follow-up on post-vaccination day 21). The patient did not demonstrate any sequelae of thrombosis. The patient was recovering well from the events of cerebral venous sinus thrombosis, pulmonary embolism, low platelet count, activated partial thromboplastin time shortened, dizziness, and rash erythematous, and vision changes was not reported. The event of headache resolved on an unspecified date. This report was serious (Hospitalization Caused / Prolonged). This case, from the same reporter is linked. Additional information was received from traditional media and the literature via a company representative on 07-MAY-2021. The following information was updated and incorporated into the case narrative: Literature citation, author details, company representative added as reporter, patient race, medical history, platelet count, clinical progression, lab data, corrective treatment, and outcome.; Sender's Comments: V2: Follow up from literature provided clinical details; company assessment remains the same. This case initially obtained concerns a 40-year-old White female who was hospitalized for cerebral venous sinus thrombosis, pulmonary embolism (PE) and thrombocytopenia 12 days after receiving covid-19 vaccine. Medical history included migraine headaches. There was no history of thrombosis, clotting disorders, inflammatory bowel disease, collagen vascular disorders or cancers. She was not pregnant, was not using estrogen-containing medications or tobacco, & had no recent surgical history. Concomitant medications included cyanocobalamin, menatetrenone, & paracetamol. Post-vaccination day 5 (PVD5), she developed a headache, sinus pressure, myalgias & sore throat with tonsillar exudate. PVD8, she went to urgent care & was prescribed amoxicillin/clavulanate, methylprednisolone taper & methocarbamol. PVD12, headaches worsened, prompting Emergency Department visit. She was hospitalized for further testing and management. Labs showed: Platelets (PLT) $20k/uL$, peripheral smear without schistocytes or hemolysis, d-dimer 47K, normal fibrinogen, negative Covid-19 PCR swab, positive HIT PF4 ELISA. CT of brain showed occlusive dural venous sinus thrombosis involving left

<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>
1319640	5/15/2021	FL	45	M	5/8/2021	5/14/2021	<p>transverse & sigmoid sinuses extending into left internal jugular vein. CTA showed PE in right lobe. Ultrasound did not show deep vein thrombosis of lower extremity or portal vein. Treatment included bivalirudin, IVIG, & prednisone. Patient improved and was discharged on PVD18 with PLT 115; PLT 182 on PVD21. She was recovering without sequelae of thrombosis. 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.</p> <p>On 5/13/2021 patient developed a cough in the evening. Patient woke up not feeling well on 5/14/2021, and also had nausea and vomiting. Patient was driving a vehicle when he had a seizure. No prior history of seizures. Drifted off the road, no significant damage to vehicle. Patient post-ictal following seizure, seizure activity was witnessed by bystanders. CT brain showed small subdural hematoma. A CTA chest performed due to hypoxemia and tachycardia at Hospital showed Multifocal groundglass type nodular infiltrates throughout the right lung involving the upper lobe, middle lobe, and lower lobe, minimal left lower lobe patchy infiltrate, as well as patient's known thymoma. These multifocal groundglass infiltrates were not previously mentioned on a CT chest performed on 4/10/2021. Patient was transferred to this facility for evaluation by neurosurgery. Patient was mildly tachycardic, hypoxemic to 88% on room air, and tachypneic. Patient reported decreased sense of taste & smell for 1 month, which he attributed to his losartan use. A covid/flu/rsv PCR on 4/10/2021 was negative, and a viral respiratory pathogen panel with covid PCR was negative on 5/14/2021, as was an antigen & NAAT for COVID on 5/14/2021. Patient was treated with antibiotics and admitted for further management.</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>
1320051	5/15/2021	TN	20	M	4/21/2021	4/23/2021	I got out of my truck and collapsed; I had a grand mal seizure, seizing for 5 plus minutes; Slammed my head repeatedly on the concrete during the seizure leaving my head bleeding and cuts all over me.; Slammed my head repeatedly on the concrete during the seizure leaving my head bleeding and cuts all over me.; I leaned forward slamming on the gas colliding with another vehicle.; I don't remember starting my vehicle; This is a spontaneous report from a contactable consumer (patient). A 20-year-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EP7533), via an unspecified route of administration at the age of 20-year-old at arm left on 21Apr2021 22:30 at single dose for COVID-19 immunization. Medical history included epilepsy, haven't had a seizure until now for 2 years. Prior to vaccination, the patient wasn't diagnosed with COVID-19. Concomitant medications included Men's Multivitamin GNC and fish oil received within 2 weeks of vaccination. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The was leaving he apartment complex to go to school after work around 7am 23Apr2021, the patient didn't remember starting he vehicle, but he leaned forward slamming on the gas colliding with another vehicle. he got out of his truck and collapsed, he had a grand mal seizure, seizing for 5 plus minutes, having to go to the emergency room, he slammed his head repeatedly on the concrete during the seizure leaving his head bleeding and cuts all over he. He was now unable to drive for 6 months and need to get an MRI an EEG and be put on medication. Adverse events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization. The patient was hospitalized for one day for events. Facility where the most recent COVID-19 vaccine was administered in workplace clinic. Since the vaccination, the patient hasn't been tested for COVID-19. The patient was received treatment for all events. The outcome of events was unknown. Follow-up attempts are needed. 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>
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>

VAERS_ID RECVD DATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

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.

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

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)

<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>
1317036	5/14/2021	MD	21	M	5/14/2021	5/14/2021	Patient was given Janssen COVID-19 immunization via intramuscular route in the deltoid region of the left arm. Patient was fine following the vaccination and was instructed to sit for 15 minutes to be monitored. Approximately 5 minutes after patient was sitting, his body suddenly went straight and his eyes were open. He started to seizure for about 5 seconds and hit his head against the counter. He regained consciousness afterwards and was in distress. After calling EMS, they checked for his blood pressure, Pulse Ox, and blood sugar levels, which they considered stable. They asked the patient if he felt fine at that time, which he said yes. They told him to wait at the pharmacy until his Dad came to pick up him.
1316754	5/14/2021	GA	57	M	3/25/2021	3/25/2021	Person suffer a stroke and started having seizures and continuously having Seizures
1316576	5/14/2021	IN	57	F	3/6/2021	3/10/2021	Seizure on 3.10.2021. Treated in ER on 3.10.2021. Bit tongue and experience insentience. Prescribe Keppra XR 500 mg Tablet. Take twice a day.
1316515	5/14/2021	KS	34	F	5/13/2021	5/13/2021	Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Severe, Systemic: Seizure-Severe, Systemic: Vomiting-Severe, Additional Details: patient had a seizure when she was 12 after taking hep b vaccine (22 years ago). Patient had no reaction from COVAX dose 1.
1317190	5/14/2021	CO	38	M	5/13/2021	5/13/2021	Patient began feeling lightheaded and faint while sitting down approximately five minutes after the vaccination administration. Within 2 minutes of this the patient began having a seizure that lasted for approximately 30 seconds. Patient slid to the floor and become unresponsive. An Epi-pen was administered and shortly after patient stabilized and regained consciousness. Within 2 minutes he was able to answer questions and was oriented to place and time. Within 10 minutes the paramedics were on scene and patient was stable and talking to them. They recorded a blood pressure of 130/90 at this time. They took him to the local hospital from here.

<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>
1316163	5/14/2021	CA	17	M	4/28/2021	4/28/2021	Seizure; Felt dizzy; Eye sight was blurry; Shake and jerk; Shake and jerk; Skin turned pale; Heart rate was high; Nauseous; This is a spontaneous report from a contactable consumer. A 17-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in left arm on 28Apr2021 16:00 as unknown, single for covid-19 immunisation. The patient medical history was not reported. Concomitant medications included fish oil; magnesium [magnesium citrate]; vitamin d [vitamin d nos]; probiotic [bifidobacterium lactis]; vitamin b complex (VITAMIN B). The consumer stated, approximately 20 minutes after receiving the vaccine (28Apr2021 16:15) the patient felt dizzy, eyesight was blurry, and he began to shake and jerk. It resembled a seizure. His skin turned pale, heart rate was high, and he felt nauseous. It took him approximately 5-10 minutes to feel "normal" again. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The adverse event result in emergency room/department or urgent care. There is no treatment for AE. 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 resolving. Information about Batch/Lot no. has been requested.
1317535	5/14/2021	MI	18	M	5/13/2021	5/13/2021	Patient has history of vasovagal syncope / seizure and told us in advance. When he was administered the vaccine, he passed out for just a short period of time and had a minor seizure (approx. 5 seconds).

<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>
1316173	5/14/2021	TX	66	F	3/2/2021	4/24/2021	fever blisters; ear ache; stress; 2nd dose of the Pfizer Covid vaccine on 02Mar2021 and on 24Apr2021 she went to the emergency room with Bell's Palsy; This is a spontaneous report from a contactable consumer (patient) via a Pfizer-sponsored program. A currently 67-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in the left arm on 02Mar2021 16:00 (also reported as 16:30) (Batch/Lot Number: Unknown) as 2nd dose, single dose (at the age of 66-years-old) for COVID-19 immunisation. Medical history included bell's palsy from 07Jan2015; and an unspecified risk factor. The patient had no concomitant medications. The patient did not have any prior vaccinations within 4 weeks. The patient did not have family medical history that was relevant to adverse events and no relevant tests were done. The patient previously took shingles vaccine (Merck) that started with the letter 'Z' and had Bell's Palsy in Jan2015 which was exactly 6 weeks after she got a shingles vaccine; tetanus vaccines 10 years ago as a booster and experienced severe swelling on her arm, swelling in her body; Quadravalent flu vaccine and never had a reaction to the flu vaccines; and the first dose of BNT162B2 (reported as 'Pfizer COVID') for COVID-19 immunisation on 02Feb2021 in the left arm. On 24Apr2021, the patient experienced bell's palsy. On unspecified dates, the patient experienced fever blisters, ear ache and stress. The events were reported as follows: Her HCP should have the information on the shingles vaccine she got in 2015. When she had bell's palsy the 1st time in 2015, she had to go to the hospital for a day and a half to rule out everything and the best they found was that she had herpes simplex based on the blood work done at that time and it was what her HCP believed it was at that time because it showed she had some kind of virus but neither time she had bell's palsy did she have seizure or other symptoms other than the ear ache she had this time. The patient got the second dose of the vaccine on 02Mar2021 and on 24Apr2021 she went to the emergency room with Bell's palsy. She can talk better when she holds her mouth. She was out of town when she noticed the symptoms of bell's palsy the night before on 24Apr2021 and when she got home she then went to the emergency room on 25Apr2021; she could tell

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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something was happening again and it was noticeable and she had an ear ache the day before and her face was drooping. The HCPs swear there was no correlation between the vaccine and bell's palsy but she found this very coincidental. The patient stated that she would rather get bell's palsy again than get covid. For treatment, the only thing she has done was to call the HCP to schedule the follow-up visit as directed by the emergency room (ER) HCP; she went to the ER to rule out stroke and they did rule out stroke; states the only other thing she can think of is that she had quite a bit of stress because they put down her dog on Sunday and other than that she had an ear ache at her granddaughter's track meet on the day before on 24Apr2021 and the emergency room visit was on 25Apr2021. She has had recurrent fever blisters and her HCP has given her a prescription for Valcyclovir and she takes that at the onset of fever blisters and where she gets the fever blisters is constantly on the previous side where she had bell's palsy and was in the same spot on her left side of her lip. States the Valcyclovir she has was one gram tablets and she takes one when she has a fever blister and one 12 hours later; states she has two prescriptions for the Valcyclovir and they are in orange pharmacy bottles with no lot numbers, expiry dates and NDC numbers and the other prescription for Valcyclovir is also 1 gram and she takes it three times per day now after this outbreak. The patient required a visit to the ER or medical doctor office. The outcome of the 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>
1316347	5/14/2021	CA		M		4/1/2021	STROKE; PASSED OUT; DIZZINESS; DID NOT FEEL WELL; HEARTBURN; HEADACHE ON THE FRONT LEFT SIDE; RECURRENT SEIZURE; 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, unknown, batch number: 1805029, expiry: UNKNOWN) dose was not reported once a total on left deltoid, administered on 28-MAR-2021 11:00 for prophylactic vaccination. No concomitant medications were reported. On 30-MAR-2021 patient went to the hospital because patient did not feel well and was given seasick pills. Two days later patient was still not feeling well and went to hospital, where the doctor said that patient having a Stroke, and patient in the middle of a Stroke. The doctor administered intravenous to patient .The patient was hospitalized for 3-4 days then transferred to Hospital (where patient is insured) and was hospitalized for 4-5 day. On an unspecified date in 2021, the patient had recurrent Seizure .Three days in a row and then one day rest and then it came back again, basically for the month came different times. Patient said his eyes would roll back to his head. On unspecified date in 2021, patient had dizziness and passed out and went to hospital where they said they should have never released patient. Patient was hospitalized for 2 days and did work up. Then hospital took patient back and they didn't do what hospital did. Patient mentioned feeling better at hospital with the treatment they provided him but when hospital cared for patient, they did not use the same. Patient also mentioned that he was sent to rehab to learn how to walk. Patient had experienced heartburns but they did not give him medication for heartburn. Patient was upset and got his friend to buy Antacid for him and he took it with relief. Patient used a walker/cane to get around and was perfectly fine before. On unspecified date in 2021 patient experienced headache on the front left side of the head (like someone is stepping). The action taken with COVID-19 VACCINE AD26.COV2.S was not applicable. The outcome of the headache on the front left side, dizziness, recurrent seizure, heartburn, stroke, passed out and did not feel well was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically

<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>
							Important Condition).; Sender's Comments: V0: 20210507602-COVID-19 VACCINE AD26.COV2.S-stroke, recurrent seizure, passed out, dizziness. 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). 20210507602-COVID-19 VACCINE AD26.COV2.S-did not feel well. This event(s) is labeled per RSI and is therefore considered potentially related.
1318590	5/14/2021	PA	55	F	5/6/2021	5/7/2021	Seizure, involuntary muscle spasms, fatigue, nasal congestion, eye swelling and feeling out of it
1316836	5/14/2021	NC	39	M	4/6/2021	4/16/2021	Had difficulty seeing clearly. All the colors on the packages in the grocery store shelf were running together. This occurred for about three minutes, then completely locked up. Fell backwards and began having a seizure. No history of seizures prior to this. Difficulty breathing, completely locked up. Appears to be a tonic clonic seizure.
1319226	5/14/2021		38	F	5/14/2021	5/14/2021	At approximately 1505 this 38 yo white female displayed seizure type activity while sitting in the observation station at the mobile vaccine clinic. Staff safely lowered her from chair to side lying position. Seizure activity observed for less than one minute, drooling noted. Post-ictal for approximately 5 min AEB delay in response to questions, following directions and formulating complete sentences. Neuro: PERRLA, hand grips equal, lower extremity strength strong and equal bilat. EMS services arrived, took charge, assessed and put pt on transport gurney but she declined transport. EMS staff stated familiarity with pt and seizure history. She remained in observation for 30 min longer VSS with BP 120/82, R 20, P 90.
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..

<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>
1318915	5/14/2021	FL	40	F	4/16/2021	4/18/2021	Pt experienced a breakthrough seizure requiring hospitalization (pt had been seizure free for 20 years). Also experienced vertigo. Pt did not have any fever or other systemic side effects, only a sore arm after receiving the shot till the seizure occurred. Pt also reports no alcohol consummation or change in diet.
1317251	5/14/2021		92	M	2/19/2021	3/5/2021	Acute kidney failure, unspecified SEIZURES
1318043	5/14/2021	WA	16	F	5/12/2021	5/12/2021	received vaccine and stood up. During walking out of room, fainted and potentially had seizure as she fell. Head hit the ground. Stayed awake, alert after she fell. Generally knew who, what, when, where and that she just had vaccine. EMS called who arrived and transported to ER for evaluation.
1317986	5/14/2021	CA	13	M	5/13/2021	5/13/2021	Patient received the vaccine and was completely fine immediately following. We walked around the store, conversed, and 10-12 minutes after injection he had syncope and generalized tonic clonic seizure for minutes. We were transported 911 to Hospital ED where he had normal labs, normal brain MRI, and consultation with Peds Neuro. He was post-ictal for 30+ minutes to follow the incident. He has secondary trauma to his R temporal and occipital bones and likely a mild concussion resulting from the fall.
1317768	5/14/2021		36	M	5/14/2021	5/14/2021	Fainted Spasms like seizure (20 seconds)
1317762	5/14/2021		82	F	2/15/2021	3/7/2021	J18.9 - Pneumonia, unspecified organism D69.6 - Thrombocytopenia, unspecified R56.9 - Unspecified convulsions

<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>
1317710	5/14/2021	SC	85	F	5/13/2021	5/14/2021	Presented to hospital with AMS with possible seizure activity. Daughter at bedside to assist with HPI, given patient's AMS. Daughter reports that she went over to see her mom at approximately 930 this morning and found her alert and oriented x3 with complaints of nausea, congestion and cough s/p her second COVID-19 vaccination, which she received yesterday. Daughter reports that at approximately noon, her mom had an episode of emesis, with her arms clenching up and shaking for approximately a minute, for which she called EMS. Daughter reports that her mom has been lethargic with AMS s/p episode. Daughter reports her mother has never had seizure activity before, but she has had several previous TIAs. She denies any recent injury, fall or medication changes. Patient lethargic with AMS noted, unable to follow simple commands, does tell me her first name with several prompts. PATIENT REMAINS HOSPITALIZED AT THE TIME OF THIS REPORT.
1318941	5/14/2021	FL	71	F	3/17/2021	4/1/2021	On 4/1/2021 Patient had at least one seizure at home and upon arriving at the ER/hospital had a severe seizure. She was admitted to the hospital for treatment and was in the intensive care unit for about 9 days. She was given seizure medicine along with other fluids to keep her hydrated and fed. Multiple EEGs were taken to track the electrical activity within her brain - which even with high doses of medication was very active. A spinal tap was done to test for infection and no viruses were found. An MRI was completed to identify what part of the brain was being impacted. The area of the brain that was impacted was the side and the images showed it was very inflamed. She has since been moved to a physical therapy facility to try to help her improve. At this time, she still needs assistance for all activities and would not be able to return home due to the level of care she needs. Her current diagnosis is autoimmune encephalitis. She has never had seizures before and this one began about two weeks after receiving her first dose of the COVID-19 shot. She has been unable to receive her second shot due to being in the hospital and physical therapy facility. Due to the timing of the seizure event, we are very concerned with her receiving her second shot as well.

<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>
1313024	5/13/2021	NJ	50	M	3/29/2021	4/22/2021	seizure; Stroke like event; This is a spontaneous report received from a contactable consumer (Patient) reporting for himself. A 50-year-old male patient received first dose of BNT162B2 (BNT162B2) via an unspecified route of administration on 29Mar2021 01:00 (Batch/Lot Number: EP6955) as SINGLE DOSE for covid-19 immunization. Medical history included rheumatoid arthritis from an unknown date. The patient's concomitant medications were not reported. The patient experienced seizure and stroke like event on 22Apr2021 at 11:00. The patient was hospitalized for seizure and stroke like event for 5 days. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 22Apr2021. Outcome of the events was unknown. Information on Lot/Batch number was available. Additional information has been requested.
1314964	5/13/2021	KS	23	M	5/13/2021	5/13/2021	Shortly after receiving the vaccine patient felt light headed and removed mask. He then passed out falling forward in chair and hitting his head he then went into convulsions. Quickly came to and was able to walk out with EMS.

<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>
1315885	5/13/2021	IL	31	M	10/14/2020		<p>grand mal seizure; vision changes; Feelings of pressure at the back of his neck radiating to right side of his head; This spontaneous case was reported by a physician (subsequently medically confirmed) and describes the occurrence of GENERALISED TONIC-CLONIC SEIZURE (grand mal seizure) in an adult 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 ADALIMUMAB (HUMIRA) solution for injection for Crohn's disease. Concurrent medical conditions included Crohn's disease (moderate to severe). On 14-Oct-2020, the patient started ADALIMUMAB (HUMIRA) (Subcutaneous) dosage form. 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 GENERALISED TONIC-CLONIC SEIZURE (grand mal seizure) (seriousness criterion hospitalization), VISUAL IMPAIRMENT (vision changes) and NECK PAIN (Feelings of pressure at the back of his neck radiating to right side of his head). At the time of the report, GENERALISED TONIC-CLONIC SEIZURE (grand mal seizure) had resolved and VISUAL IMPAIRMENT (vision changes) and NECK PAIN (Feelings of pressure at the back of his neck radiating to right side of his head) 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. The patient had a seizure three days after his first Moderna Covid vaccine and was hospitalized. CT scan was negative. The reporter's causality for co-suspect drug, adalimumab, was not provided. Concomitant product use was not provided. No treatment information was provided. This case concerns an adult male, with PMH of Crohn's disease, hospitalized with a serious unexpected event of generalized tonic-clonic seizure (grand mal seizure), and nonserious unexpected visual impairment and neck pain. Event onset with unknown latency after first dose mRNA-1273. 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</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>
							Comments: This case concerns an adult male, with PMH of Crohn's disease, hospitalized with a serious unexpected event of generalized tonic-clonic seizure (grand mal seizure), and nonserious unexpected visual impairment and neck pain. Event onset with unknown latency after first dose mRNA-1273. 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.
1315401	5/13/2021	GA	58	M	2/9/2021	2/19/2021	I suffered relatively severe reaction to the 2nd Moderna dose: Very sore arm for 4 or 5 days, several hours of chills 14 hours after the injection, and swollen lymph nodes, including an egg-sized lump under the left arm that persisted for a week. However, the significant event was a seizure 10 days after the injection. This was a first seizure with no prior history or obvious cause. Seizure began while I was asleep. Wife heard odd noises, couldn't wake me and called 911. I woke up in an ER hours later. Neurologist said the MRI was clear, but EEG showed unusual activity in the left temporal lobe. Prescribed Keppra (ongoing) and speculated that the seizure might be related to aging. He thought the timing of the event 10 days after the CoViD vaccine was coincidental. However, I am reporting it out of an abundance of caution.

<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>
1315154	5/13/2021	IL	16	M	5/4/2021	5/5/2021	Patient is a 16-year-old male patient admitted with seizure like activity. One day prior to admission patient received his second COVID vaccine, Pfizer brand. On the day of admission Patient woke at 0200 with pain in the left side of the chest, mid-axillary per patient's description it was cramp-like pain and he was able to go back to sleep. At 0500 he got up to use the restroom and went into the kitchen. He told his mom he didn't feel well and fell forward making a gurgling sound, arms rigid, was unresponsive, and this lasted 1.5minutes according to mom. Mom called EMS and when he awoke he stated he was nauseous. After EMS arrived it was 2-3 minutes and he did not feel well again, he stood up and head fell back, eyes open, he was shaking, and making a gurgling noise again, this episode lasted 30 seconds. Upon awaking he was disorientated for a few minutes then back to baseline, he was nauseous again and very tired. He came to the ED where EKG (pending), CBC (normal), PT/PTT/INR (slight elevation), CMP (normal), TSH (normal), Ethanol (None), Troponin (normal), Head CT (normal), and chest xray (normal) were done. He received a NS bolus was given. He was admitted to the pediatric hospitalist for further evaluation and management. This is where he had a 24hour Video EEG with normal EEG he was discharged home.
1315010	5/13/2021	CA	62	M	4/28/2021	4/30/2021	Acute encephalitis with seizure-like symptoms
1314774	5/13/2021	MN	17	F	4/30/2021	4/30/2021	school nurse filled out incident report per their policies. Incident highlights: "Pt got her mom's attention and started to slump down, Mom and volunteer? Were able to assist her to the floor. No injuries during the episode, did not hit her head. She has twitching of her extremities which appeared to be a seizure. Mom stated there was no seizure history. EMS was called. Pt was alert when EMS arrived, they assessed her and it was determined that she should get an evaluation but EMS gave the option to transport themselves for follow up as she appeared stable." unable to contact mother, no additional information available.

<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>
1314744	5/13/2021	KS	19	M	5/13/2021	5/13/2021	pt fainted approx 2 minutes after vaccination while sitting in waiting area. 911 was called. Pt was placed supine and was unconscious for approx 60 seconds with involuntary movements of arms and upper body consistent to passing out (not seizure like in intensity). confused, clammy/nauseas upon awakening, remained supine for 2-3 minutes. upon sitting up pt became dizzy and laid down again. paramedics arrived began assessment. BP, EKG, BG all normal. pt reports not having eaten today, also reports congenital heart defect that was corrected surgically while an infant. Mother arrived and decision was made in conjunction with paramedics to take pt to hospital for further eval based on his symptoms of lightheadedness/nausea continuing.

<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>
1314722	5/13/2021	CA	50	F	4/7/2021	4/7/2021	<p>Within 5 minutes from receiving my J&J vaccine, I went to sit down and I started feeling very hot in my body. My heart started to race, had chest discomfort and had trouble breathing, my trachea closed up, had blurry vision and pain in my chest. I felt like I could not breathe and when the nurse came over to ask me I could not speak to her, I went into a shock and I was placed on the floor and I could not hear anything nor could open my eyes, from my hips down to my feet I could not feel anything, my legs went completely numb and I had a syncope. What I was told from the nurse that I was given an Epi-pen to help with my reaction. When I came back my body was having convulsions, felt my head spinning, had pain in my chest that so very intense and the nurse got me up and took me to a nearby ambulance and the EMT staff placed like a heart monitor because my heart was racing super fast. I also felt heaviness in my chest and inside the ambulance I was given two injections on my left arm and when I slowly started coming back, I was already at the hospital. I was at the hospital from 2pm to 4:30pm more less being monitored. At the hospital x-ray of the chest was performed as well as lab work and I was discharged home. When I got home, I still did not feel good, I felt heaviness to my chest, still have trouble breathing and get chills during the night. I also could not stand up and have a nerve sensation to my body and the chest pain to my left side is still very present. I have blurry vision, dizziness, headaches, and my heart-beat continues to race very fast. I get headaches, have abdominal pain and I peed blood few times then that's when I was able to pee, my abdominal pain was painful like having a baby. On Friday 04-08-2021, I again went to the hospital because I had fallen to the floor on my kitchen floor and my daughter took me to the hospital. I let the nurse staff know that I still have continued chest pain and pressure, difficulty breathing and headaches, dizziness and they monitored and gave me three pills as medication. I was discharged home about 5pm with a referral to see a neurologist due to my chest pain, blurry vision, dizziness and fever which I had these past three weeks. I do not know why I felt all these symptoms after my J&J vaccine.</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>
1314511	5/13/2021	WI	76	M	2/15/2021	3/8/2021	had severe headaches that started a week after his 2nd covid shot., he was seen by NP on 2/25/21, was instructed to take ibuprofen short term, labs were drawn and were normal. On 3/8/21 suffered tonic clonic seizures, was unresponsive and taken to ER by EMS. remained unresponsive following the seizures and was placed on hospice care and died on 3/12/21.
1314307	5/13/2021	NH	48	M	5/5/2021	5/5/2021	Patient said he had a seizure at home in his sleep. He said he wetted his pants and his wife told him he had a seizure. He sought medical attention after and his doctor changed his seizure medications. He is now asked by his doctor not to drive for 2 months
1314306	5/13/2021	MI	16	F	5/12/2021	5/12/2021	The patient felt tired and describes her eyes going dark, then passed out a few minutes after vaccination. She was vaccinated and then left the immunization room to sit down for a 15 minute waiting period. When she went to sit down, she collapsed on the floor. Her mother assisted her into a chair. She continued to be incoherent and have her eyes rolling back into her head for a few minutes. We used a cool cloth on her forehead and the back of her neck. The parents requested that we call 911. EMS arrived shortly and evaluated her. Heart rate, blood pressure, pulse ox, blood sugar and chest sounds were all within normal range. The patient stated that her arm felt heavy and "funny". She then stated that her tongue felt funny. EMS evaluated her tongue and said it looked normal. To err on the side of caution, she was taken to the hospital to determine whether or not she was having a delayed onset anaphylactic reaction. This patient has no history of seizures.
1314299	5/13/2021	NY	32	M	5/12/2021	5/13/2021	Febrile seizure

<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>
1314258	5/13/2021	CT	20	F	5/13/2021	5/13/2021	Patient had a seizure and vomited. The seizure lasted a couple of minutes. She fell from the chair that she was sitting in when she got the vaccine. A gentleman that came with her picked her up and sat her on a chair. He was holding her from there on. We called code Blue on the intercom and called the ambulance. Once she came back from seizure she was fully conscious and aware of her surrounding. She knew her name, address, where she is, etc. The ambulance took her away to Hospital. (She did mention to the ambulance that she had a seizure about a month ago because she took medicine and alcohol that she was not suppose to.)
1314205	5/13/2021	IL	36	M	4/26/2021	4/27/2021	I got the shot around 3:15PM on Monday 4/26/21. Woke up Tuesday 4/27/21 with a minor headache and just felt out of sorts. Around noon that day I had a seizure at work and was rushed to the ER. While at the hospital waiting for a room to open up, I had another seizure. This one was much worse than the first. They had to intubate me and I spent 5 nights in the ICU. Another 3 on the Neurology floor for observation. The seizures caused Rhabdomyolysis which caused damage to my kidneys and significant muscle loss/damage. I wasn't able to walk at all for 3 days. After that I started to be able to get up out of bed and move around a little more each day.

<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>
1313067	5/13/2021	VA	18	F	4/1/2021	4/2/2021	seizure; This is a Spontaneous report from a contactable other healthcare professional (HCP). An 18-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 01Apr2021 at single dose for COVID-19 immunisation. Medical history included Bipolar disorder, Depression, Attention deficit hyperactivity disorder (ADHD) and sleep (disorder). Concomitant medication included cariprazine hydrochloride (VRAYLAR) orally from 18Mar2021 to 02Apr2021 at 1.5 mg, daily for Bipolar disorder; escitalopram oxalate (LEXAPRO) at 10 mg for Depression; amfetamine sulfate (EVEKEO) 2 times a day for ADHD; bupropion hydrochloride (WELLBUTRIN) and mirtazapine (REMERON) for sleep (disorder). It was reported patient experienced seizure on 02Apr2021 after using concomitantly Vraylar, Lexapro, Evekeo, Wellbutrin and Remeron, experienced seizure after using concomitantly Lexapro and Wellbutrin. The initial report from the United States was received via Company representative originating from a nurse on 15Apr2021, regarding an 18-year-old female patient who experienced seizure, drug interaction, and labelled drug-drug interaction medication error following the administration of cariprazine hydrochloride, amfetamine sulfate, escitalopram oxalate, mirtazapine, Pfizer Covid-19 and bupropion hydrochloride. Company received the report on 16Apr2021. Reportedly, the patient began cariprazine hydrochloride 1.5mg daily orally for Bipolar disorder on 18Mar2021, had the Covid-19 vaccine on 01Apr2021, and had a seizure on 02Apr2021. The patient had no history of seizures. The reporter did not believe the seizure was caused by the cariprazine hydrochloride (causality for seizure was also reported as unlikely). The patient was taken to the emergency room but not admitted, treatment and outcome unknown other than the emergency room staff advised the patient to "discontinue everything". The reporter assessed the relationship between cariprazine hydrochloride and the event of seizure as unlikely. Laboratory tests were not reported. The patient experienced the seizure one day after Covid 19 vaccine. Considering the short onset latency, the vaccine was also considered co-suspect. The case in confounded by patient's use of co-suspect medications that could have lowered the seizure threshold. The following important missing medical information will be

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

helpful for further case evaluation: medical history, indications and therapy dates for all suspects, action taken, lab results (drug blood levels), investigations, treatment, outcome. Treatment information was not provided. At the time of the report, the outcome of seizure was reported as unknown. This case was considered serious due to the following seriousness criterion: medically significant. Information on batch number has been request.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation. Contributory role of concomitant medications should also be considered. 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.

<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>
1313012	5/13/2021	NY		F	3/30/2021	4/1/2021	seizures; fever of 103-104F; This is a spontaneous report from a contactable consumer. A 25-year-old female patient (reporter's daughter) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 30Mar2021 14:00 (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. On 01Apr2021, the patient started with fever and seizures. She was admitted to the hospital from Tuesday, 06Apr2021 to Saturday, 10Apr2021. During this time, she was seen by all the specialists, had CT scans, MRI, encephalograms, blood tests, and they have not been able to explain what happened to her. On 19Apr2021, she was seen by a neurologist and he explained that physically everything was fine in her body and brain, it's not epilepsy, this was probably the effect of the vaccine. To this day, patient continued with a fever of 103-104F, she takes acetaminophen 500 mg every 6 hours and ice packs were applied to her stomach and forehead. Reporter had a 1-minute video when patient got the seizures and can send it. Outcome of seizure was unknown, of fever was not recovered. Information on the batch/lot number has been requested.
1312669	5/13/2021	WA	36	F	5/12/2021	5/12/2021	About 10 minutes after receiving the 0.5 ml dose of the Jansen vaccine while the patient was waiting in observation, she had a brief (~10 second) LOC followed by a mini seizure. Patient was being observed by 2 EMTs and 3 nurses. Patient recovered quickly, had a strong pulse, steady breathing, and was aware and responsive.
1314107	5/13/2021	UT	26	M	5/12/2021	5/13/2021	102° F fever, chills, aches, nocturnal Grand Mal Seizure

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1315876	5/13/2021	IN	42	M	4/5/2021	5/4/2021	<p>doesn't remember anything; muscle spasms in back and legs; very tired; very sore; fever; grand mal seizures; sweating and being soak and wet; This spontaneous case was reported by a patient (subsequently medically confirmed) and describes the occurrence of GENERALISED TONIC-CLONIC SEIZURE (grand mal seizures) in a 42-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 037B21A and 006B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Epilepsy (The patient has a history of grand mal, petit mal and stress seizures. Patient stated that he has at least one minor seizure once a month and the last seizure he had with this great intensity was about 3 to 4 months ago.) and Drug allergy (aspirin). Concomitant products included MIDAZOLAM for Seizure, CLOBAZAM (ONFI), ESLICARBAZEPINE ACETATE (APTOM) and TOPIRAMATE (TOPAMAX) for an unknown indication. On 05-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-May-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 04-May-2021, the patient experienced GENERALISED TONIC-CLONIC SEIZURE (grand mal seizures) (seriousness criterion medically significant). 04-May-2021, the patient experienced HYPERHIDROSIS (sweating and being soak and wet) and PYREXIA (fever). On 05-May-2021, the patient experienced MEMORY IMPAIRMENT (doesn't remember anything), MUSCLE SPASMS (muscle spasms in back and legs), FATIGUE (very tired) and MYALGIA (very sore). On 05-May-2021, GENERALISED TONIC-CLONIC SEIZURE (grand mal seizures) had resolved. At the time of the report, HYPERHIDROSIS (sweating and being soak and wet), MEMORY IMPAIRMENT (doesn't remember anything), MUSCLE SPASMS (muscle spasms in back and legs), FATIGUE (very tired), MYALGIA (very sore) and PYREXIA (fever) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-May-2021, Blood test: unknown (Inconclusive) Result not provided. It was reported that the patient took midazolam and swiped his magnet across his vagus nerve stimulator (VNS) for</p>

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							treatment. Action taken with mRNA-1273 in response to the event was Not Applicable. It was reported that the patient was asymptomatic after first dose and experienced symptoms on 04May2021 at midnight after second dose of vaccine. 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. The medical history of epilepsy was assessed as strong cofounder.; 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. The medical history of epilepsy was assessed as strong cofounder.
1309961	5/12/2021	AZ	18	F	5/1/2021	5/1/2021	Systemic: Seizure-Medium
1311433	5/12/2021		80	F	3/27/2021	5/8/2021	CVA (cerebral vascular accident) Unspecified convulsions
1311200	5/12/2021		67	M	3/2/2021	5/5/2021	R56.9 - New onset seizure (CMS/HCC) R56.9 - Unspecified convulsions N17.9 - Acute kidney failure, unspecified
1310949	5/12/2021	VA	43	F	1/28/2021	5/2/2021	On May 2nd started with symptoms of food poison, went to urgent care, gave her hydration and sent her home. On May 7th was taking to the hospital, look very weak and was confused, couldn't answer basic questions. They kept her in the hospital. On May 8th she had an apparent seizure and was not until May 11 that she came out of it, being able to recognize people (though very weak). In the meantime her two kidneys stopped working. She continues to have seizures despite of the hospital giving her anti seizure medications. You could talk to the hospital more about the medical details.
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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1310863	5/12/2021		56	M	3/24/2021	3/25/2021	Patient came to vaccine site on 4/23/21 to get second COVID Moderna vaccine. He reported a stroke a day after his previous 1st dose Moderna on 3/24/21. He was hospitalized with stroke and seizures. He has a history of uncontrolled diabetes, high cholesterol, and triglycerides. He smokes and has a history of cirrhosis. Dr. spoke with the pt and approved the second dose administration. No reactions documented following the vaccine.
1310826	5/12/2021	NY	34	F	3/13/2021	4/5/2021	23 days after the second does the the Pfizer\BioNTech vaccine, I experienced a nocturnal seizure. I was 21 weeks and four days pregnant with my first child (estimated delivery date of August 12, 2021). I was diagnosed with high blood pressure and prescribed labetalol at 100 mg twice a day 4 days before the adverse event. It was my first time being put on blood pressure medication. During the seizure, I fell out of bed hitting my head, face, shoulder, hip and ankle on the right side of my body. 911 was called and I was brought to the ER and eventually transferred to Hospital on the labor and delivery floor. They ran a series of labs and tests which resulted in a three day stay. They determined that I have gestational diabetes and epilepsy which they believe had been dormant until the seizure.

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1310811	5/12/2021	NC	72	M	4/5/2021	4/7/2021	Wife reports that patient started declining on 4/5/21 after his second covid immunization. He started to have intermittent fevers, shortness of breath and labored breathing. Wife reported he would "get sweaty and hot " and therefore she would give him tylenol. He saw his pcp 2 days later on 4/7/21 for these symptoms. In addition she noticed him to present with decline in his cognition and hemibody weakness and swelling. His pcp was also concerned about diastolic dysfunction. He received an outpatient ECHO. He was placed on lasix and referred to cardiology. On 4/19 He saw cardiology who ordered EKG and reviewed his echo. Felt that his afib was likely contributing to his shortness of breath. His echo and recent blood work revealed preserved EF. He had occasional scattered wheezes on exam and therefore inhaler and cxr was ordered. On 4/22 he presented to the Emergency room for breakthrough seizure. Breakthrough seizure lasted longer than usual (20 minutes), so ED performed a CT head, which showed an age indeterminant lacunar infarct in the anterior limb of the internal capsule. (new from MRI 2 months earlier!)
1309980	5/12/2021	TX	27	M	5/8/2021	5/8/2021	Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Additional Details: Patient fainted and had seizures like symptoms along with cramps. Patient fainted for less than a minute. Was breathing and talking soon afterwards. 911 was called.

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1309750	5/12/2021			U	4/29/2021		<p>BODY CONVULSIONS FROM CHILLS; BODY ACHES; TEARY EYES; RAPID BREATHING; STUFFY NOSE; CHILLS AND CHATTERING TEETH; PRESSURE HEADACHE; FEVER WITH CHILLS; SORE MUSCLE; 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 administration was not reported, batch number: unknown) dose was not reported, 1 total, administered on 29-APR-2021 at around 11:00 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 29-APR-2021, the patient experienced body convulsions from chills, body aches, teary eyes, rapid breathing, stuffy nose, pressure headache, chills and chattering teeth, fever with chills and sore muscle. On 29-APR-2021 at around 15:00, treatment medications included: paracetamol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from body convulsions from chills, body aches, teary eyes, rapid breathing, stuffy nose, chills and chattering teeth, and sore muscle, and was recovering from fever with chills, and pressure headache. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210460597-covid-19 vaccine ad26.cov2.s- body convulsions from chills. 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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1309586	5/12/2021			F	4/1/2021	4/27/2021	<p>my arm hurt; I was hallucinating; my body was convulsing/having a literal seizure; uncomfortable; thirsty and craved water; tired; couldn't get up; felt freezing because I was so cold; teeth were chattering extremely fast; my teeth were chattering extremely fast like I had hypothermia; became very hot; shaking involuntary; This is a spontaneous report from non-contactable consumer (patient). An adult female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), dose 2 via an unspecified route of administration, administered in left arm on Apr2021 (Batch/Lot Number: EW0110) as second dose, single for COVID-19 immunisation. The patient's medical history was not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included metformin; spironolactone; ethinylestradiol, ferrous fumarate, norethisterone acetate (JUNEL FE); all taken for an unspecified indication, start and stop date were not reported, received within 2 weeks of vaccination. Patient historically took the first dose of BNT162B2 (lot number: EW0150) on the left arm on Apr2021 for COVID-19 Immunization. On 27Apr2021, patient went to bed at like 1200 and her arm hurt but she didn't take any medication. Then, patient like woke at about 1:47 and was shaking involuntary, everything was so uncomfortable and she was hallucinating trying to connect all her limbs - like she grew extra arms and legs and she had like her hands had mini hands and a friend that she hadn't seen in a while (who was not there) was holding her head up. She was very thirsty and craved water so bad but she was so tired and shaking that she couldn't get up. After about 30 minutes, she got up and her body was convulsing while standing and her room which is typically warm felt freezing because she was so cold and her teeth were chattering extremely fast like she had hypothermia. She got water, took some ibuprofen and she got back in her bed. she texted a friend at 2 something in the morning because she thought she was having a literal seizure like she couldn't control her body at all. Then, her body eventually stopped shaking on Apr2021 and she was just above sleep level for another hour or two and then became very hot. Since the vaccination, the patient has not been tested for COVID-19. The patient underwent lab tests and procedures which included covid-19: negative on Apr2021. The</p>

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							outcome of the event 'having a literal seizure' and 'shaking involuntary' was recovered on Apr2021, while for the other events, it was unknown. No follow-up attempts are possible. No further information is expected.
1309580	5/12/2021	NJ	50	M	4/19/2021	4/22/2021	Brain inflammation; Stroke like event/seizure; Stroke like event/seizure; This is a spontaneous report from a contactable consumer (patient). A 50-year-old male patient received bnt162b2 (Pfizer-BioNTech Covid-19 Vaccine), via an unspecified route of administration, administered in left arm on 19Apr2021 16:00 (Lot Number: ER8731) 2ND DOSE, single for COVID-19 immunization. Medical history included rheumatoid arthritis from an unknown date and unknown if ongoing. 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 previously received 1st dose of bnt162b2 (Pfizer-BioNTech Covid-19 Vaccine, lot number: EP6955) on 29Mar2021 01:00 PM in the left arm for COVID-19 immunization and experienced stroke like event/seizure. The patient had stroke like event/seizure following first and second injections. The patient also had brain inflammation. Events onset date reported as 22Apr2021 11:00. The events were reported as serious due to hospitalization in Apr2021 for 5 days. Events resulted in doctor or other healthcare professional office/clinic visit and a visit to emergency room/department or urgent care. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient been tested for COVID-19 since the vaccination. Outcome of events was unknown. The patient underwent lab tests and procedures which included Nasal Swab: negative on 22Apr2021. No treatment received for the events. Further information has been requested.
1310246	5/12/2021		53	M	3/12/2021	3/17/2021	Hypo-osmolality and hyponatremia Acute kidney failure, unspecified Unspecified convulsions Hyponatremia

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1309374	5/12/2021		27	M	5/11/2021	5/11/2021	Patient has history of passing out when getting blood drawn. As patient was standing to get vaccination card filled out, he told associate to call RPH that he wasn't feeling well. I ran out to give my attention and patient was sweating and looked dizzy. His eyes started to shut while he was standing and as I was holding his arm and back to support him he started to fall to the ground. Patient gently went to the ground, I pushed him over to one side and he was out for about 3 seconds and woke back up. Patient was very hot and sweaty. He wanted to move to a more private area so I made an area with a privacy panel available to him. Patient stated to me that he has no history of seizure, but suffers from mild anxiety. Myself or one of the associates was with him for approximately 45 minutes just to make sure he was ok. His blood pressure was taken (twice) and water was given. His BP readings were normal. Patient was on his way. Moderna series completed.
1307307	5/11/2021	TX	17	M	5/7/2021	5/7/2021	Pt received vaccine to R arm and within 3mins collapsed and hit back of hit head. Pt had seizure like activity for 1-2mins. Afterwards, pt was weak and confused. Pt taken to ER where he was given IVF and medication for nausea. Pt had neg head CT and CXR. Pt was discharged about 4hours later.

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1306327	5/11/2021	LA	83	U	3/8/2021	4/8/2021	<p>suspected TIA or stroke vs seizure disorder; Suspected TIA or stroke vs seizure disorder; Suspected TIA or stroke vs seizure disorder; Encephalitis; This spontaneous case was reported by a pharmacist (subsequently medically confirmed) and describes the occurrence of TRANSIENT ISCHAEMIC ATTACK (suspected TIA or stroke vs seizure disorder), CEREBROVASCULAR ACCIDENT (Suspected TIA or stroke vs seizure disorder), SEIZURE (Suspected TIA or stroke vs seizure disorder) and ENCEPHALITIS (Encephalitis) in an 83-year-old patient of an unknown gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 08-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 08-Apr-2021, the patient experienced TRANSIENT ISCHAEMIC ATTACK (suspected TIA or stroke vs seizure disorder) (seriousness criteria hospitalization and medically significant), CEREBROVASCULAR ACCIDENT (Suspected TIA or stroke vs seizure disorder) (seriousness criteria hospitalization and medically significant), SEIZURE (Suspected TIA or stroke vs seizure disorder) (seriousness criteria hospitalization and medically significant) and ENCEPHALITIS (Encephalitis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 08-Apr-2021 to 19-Apr-2021 due to CEREBROVASCULAR ACCIDENT, ENCEPHALITIS, SEIZURE and TRANSIENT ISCHAEMIC ATTACK. On 19-Apr-2021, TRANSIENT ISCHAEMIC ATTACK (suspected TIA or stroke vs seizure disorder), CEREBROVASCULAR ACCIDENT (Suspected TIA or stroke vs seizure disorder), SEIZURE (Suspected TIA or stroke vs seizure disorder) and ENCEPHALITIS (Encephalitis) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. The action taken with mRNA-1273 in response to the event was not applicable. The patient received IVIG x5 doses and prednisone, along with seizure meds for treatment. Temporary pacemaker placed 13-Apr-2021 (HR=32). The patient was improved</p>

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							post-treatment and was discharged on 19-Apr-2021. 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.
1306553	5/11/2021	NY	46	M	5/10/2021	5/10/2021	Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Hypotension-Medium, Systemic: Nausea-Medium, Systemic: Seizure-Medium
1306586	5/11/2021	FL	60	M	5/10/2021	5/10/2021	Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Nausea-Medium, Systemic: Seizure-Mild, Systemic: Shakiness-Medium, Systemic: Vomiting-Mild
1306601	5/11/2021	CA	33	M	5/10/2021	5/10/2021	Systemic: Chills-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Medium, Systemic: Seizure-Severe
1306667	5/11/2021	ME	59	M	5/3/2021	5/3/2021	He got his vaccine, was in the store at the meat counter and then had a visual effect as people were looking at him funny, and things went from black/white to black/gray/white and passed out (told he had a seizure and on film at the grocery store), then woke up in the back of the ambulance on the way to the hospital. In the hospital he was given an injection to slow his heart rate down, said that he drank a pot of coffee and then had another 16 oz coffee after that. He was not admitted, treated in the ER, fed him and was discharged home and then walked about 1/2 mile to his truck at the supermarket, and finished his shopping. He has been a little tired since then, has been taking it easy and not pushing himself too hard and not working too many hours.
1306718	5/11/2021	NY	66	M	3/18/2021	3/25/2021	Hemodialysis; dizziness and seizure secondary to uremia 1 week after vaccination
1306735	5/11/2021	LA	52	F	5/4/2021	5/5/2021	CHILLS, FEVER, DIARRHEA, SEIZURES (3 TIMES LASTING 10-15 MINUTES)

<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>
1306809	5/11/2021	LA	51	F	4/29/2021	5/3/2021	Client reports, "I got my vaccine on the 29th, and on the 3rd I found myself on the floor under my counter with a big bruise on my face. I had blood on my pillow in the other room where I may have bitten my lip, but I don't remember anything about what happened. I'm worried I may have had a seizure, and I've never had seizures." Client denies any event preceding this one, and is unsure of duration of event. Purple and yellow hematoma noted to client's orbit of right eye and to right cheek. Client denies ongoing signs or symptoms, at this time.
1306814	5/11/2021	NY	67	M	3/8/2021	3/18/2021	Hypoxia readmission 1 hour after discharge from initial admission for seizure, hyperglycemia, and trach procedure
1307295	5/11/2021	OK	31	M	5/11/2021	5/11/2021	immediately after vaccination, patient lost consciousness, had a period of muscular jerks similar to seizure, for about 30 seconds. After that, could respond (had no memory) but was generally not lucid for another 90 seconds. At that point, the patient could respond, wanted to lie down, started sweating profusely, and after about 5-10 minutes was generally recovered. Patient stated that they have had previous issues while giving blood.
1307340	5/11/2021	NC	18	M	5/11/2021	5/11/2021	Site: Pain at Injection Site-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Headache-Medium, Systemic: Hypotension-Medium, Systemic: Numbness (specify: facial area, extremities)-Medium, Systemic: Seizure-Severe, Systemic: Tachycardia-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium, Systemic: Weakness-Medium, Additional Details: Patient was given COVID vaccine and moved to another chair to be observed. Upon sitting in other chair, he almost immediately went stiff, began convulsing, and then went unconscious. Patient came to, 911 was called, and patient was transported to ER.
1307352	5/11/2021	NY	24	F	5/10/2021	5/10/2021	Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Mild, Systemic: Seizure-Mild, Additional Details: patient fell over and passed out a few minutes after administration, possible seizure occurred. EMT services were called and patient declined to go with them.

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1307790	5/11/2021	OK	68	M	3/24/2021	3/26/2021	He got first Pfizer COVID shot March 3 with no problem. He got second COVID shot March 24, sore arm at the time, but then early AM March 25 and also early AM March 26 he had what was suspected to be seizure (both times). EEG, MRI are negative, but prolactin level is up, and the episodes were consistent with seizure. He is now on Keppra, not having any more episodes.
1307843	5/11/2021	AL	36	M	4/26/2021	4/27/2021	Witnessed seizure in a restaurant while working . Was sent to Hospital in via ambulance.
1306939	5/11/2021	AL	33	F	5/11/2021	5/11/2021	The Patient received the vaccine at 8:33am. She was sitting in the waiting area after her dose and started to have a seizure at or around 8:45am. She fell from her chair. The pharmacist on duty immediately responded and assisted as much as possible. No drug interference was administered. The patient seized for about 3 minutes and then came to. She waited for EMS to arrive but they took longer than she wanted to wait and she left the store at 9:05 am.
1307856	5/11/2021		72	F	2/25/2021	3/8/2021	R56.9 - Seizure

<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>
1305733	5/11/2021	OH	47	M	4/22/2021	4/23/2021	generalized convulsion/second seizure witnessed by medical staff; elevated CSF protein to 79, CSF Glucose 73; elevated CSF protein to 79, CSF Glucose 73; severe headache; confused; This is a spontaneous report from a contactable physician. A 47-years-old male patient received the first dose of BNT162B2 (PFIZER COVID 19 VACCINE), intramuscular on 22Apr2021 09:30 (Batch/Lot number was not reported) at age of 47 years as single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. Patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, patient had been tested for COVID-19. On Friday 23Apr2021, patient woke up with severe headache, per wife was confused. Then had a generalized convulsion. Presented to the ED, had a second seizure witnessed by medical staff. Workup with MRI, CTA and LP were notable for an elevated CSF protein to 79, CSF Glucose 73, otherwise no structural abnormality was identified. Patient was clinically improving after being treated with seizure medications as of 26Apr2021. The adverse event result in Emergency room/department or urgent care, hospitalization. Covid 19 pcr nasal swab on 24Apr2021 was negative. Outcome of events was unknown. Follow-up needed. Information about batch/lot number has been requested.; Sender's Comments: Considering a plausible temporal relationship , a possible contributory role of suspect product BNT162B2 to the reported event seizures, CSF glucose increased, CSF protein increased, headache, confusional state 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.
1308079	5/11/2021		66	F	3/11/2021	3/24/2021	Unspecified convulsions
1308248	5/11/2021	MA	25	M	5/11/2021	5/11/2021	AFTER ADMINISTRATION PATIENT IMMEDIATELY LOSS COUNCIOUS AND BEGAN TO CONVULSE

<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>
1308905	5/11/2021	FL	44	F	4/24/2021	4/25/2021	Within less than 36 hours after receiving the 1st dose pf the Pfizer Vaccine, I suffered a Grand Mal Seizure . I was treated in the ER and followed up with my Neurologist. Dr. prescribed high dose of anti-seizure medication to take prior to Vaccine #2 on 5/16/2021
1307042	5/11/2021		69	M	4/7/2021	4/19/2021	Pneumonia, unspecified organism Thrombocytopenia, unspecified Trigeminal neuralgia Unspecified convulsions
1305782	5/11/2021	NY	50	F	4/22/2021	4/26/2021	Shakes that feel like a seizure; Shakes that feel like a seizure; Choking; Side effects are minimal unless she got sun on her; sunlight made her sick; Nauseous; Light headed; Weak; Sweaty but chills; Sweaty but chills; Brain fog got really bad; This is a spontaneous report from a contactable consumer(patient). The 50-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 22Apr2021 16:00 (Lot Number: ER8736) as first dose, single for covid-19 immunization. Medical history included Polycystic ovarian syndrome(PCOS), Neuropathy, disabled, asthma, allergies, beat kidney cancer, autoimmune deficiency, anemic, gastric bypass. Concomitant medications included hydrocodone 10-325, escitalopram oxalate (LEXAPRO) 20mg, omeprazole 20mg. The patient had known allergies: tramadol, melamine, gabapentin. The patient stated sunlight made her sick. Side effects are minimal unless she got sun on her. Even through window. She got nauseous, shakes that feel like a seizure, light headed, weak, choking, sweaty but chills. Brain fog got really bad. She had brain fog from it but to the point she forgot she was headed to the bathroom after sunlight touched her. She had been able to handle indirect sunlight until today. Now she can't have any sunlight touch her without a reaction. Direct or Indirect. Nothing helped. Just sundown. Once the sun went down, the side effects calmed down. Events occurred on 26Apr2021 14:30 with outcome of recovering. There was no treatment received. Since the vaccination, the patient had not been tested for COVID-19.Case was assessed as non-serious by reporter.

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1305672	5/11/2021	MA	17	F	4/25/2021		<p>The patient had a first time seizure a few minutes after having the vaccine; This is a spontaneous report from a contactable physician. A 17-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) (Batch/Lot number: unknown), dose 1, intramuscularly on 25Apr2021 at 12:00 PM (at the age of 17-years-old) as a single dose for covid-19 immunisation. The patient's medical history was reported as none. Concomitant medications were not reported. The patient had no known allergies. The patient did not receive any other vaccines within four weeks prior to the vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. No other medication was received within 2 weeks of the vaccination. On an unspecified date, the patient had a first time seizure a few minutes after having the vaccine. No therapeutic measures were taken as a result of the event. The event seizure did result in an emergency room/department or urgent care visit. Clinical outcome of the event first time seizure a few minutes after having the vaccine was resolved. It was also reported that since the vaccination, the patient had not been tested for COVID-19. Follow up attempts needed. Further information is expected.; 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 seizure 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 including EEG and Head CT/MRI, 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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1305024	5/11/2021	FL	63	M	4/20/2021	4/20/2021	<p>it was convulsive shaking; I started shaking so bad/I was shaking out of my skin/shaking lasted for 15-20 minutes; chill bumps; I could not stand up; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (it was convulsive shaking) in a 63-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 007821A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 20-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 20-Apr-2021, the patient experienced SEIZURE (it was convulsive shaking) (seriousness criterion medically significant), TREMOR (I started shaking so bad/I was shaking out of my skin/shaking lasted for 15-20 minutes), PILOERECTION (chill bumps) and DYSSTASIA (I could not stand up). On 20-Apr-2021, SEIZURE (it was convulsive shaking), TREMOR (I started shaking so bad/I was shaking out of my skin/shaking lasted for 15-20 minutes), PILOERECTION (chill bumps) and DYSSTASIA (I could not stand up) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. It was reported that, patient was scared to take the 2nd vaccine. Patient almost fell back. 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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1306197	5/11/2021	NY	58	F	4/24/2021	4/24/2021	Twelve hours after the second shot, I had convulsions; About 5 hours after the second shot, my lips started to swell; I had a pain that started in my left armpit, shot down to my inner elbow, and caused my whole arm to get rigid; I had a pain that started in my left armpit, shot down to my inner elbow, and caused my whole arm to get rigid; Then my body would jerk and I groaned; Then my body would jerk and I groaned; This is a spontaneous report from a contactable consumer (patient). A 58-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0169) at left arm on 24Apr2021 09:45 AM at second dose, single for COVID-19 immunisation. Medical history included chronic rhinitis and Lyme disease. Patient previously received Morphine, cefzil and grass. Patient previously received the first dose of BNT162B2 on 03Apr2021 09:45 AM (lot number: EP7533) on Left arm for Covid-19 Immunization. Concomitant medication included loratadine, astaxanthin (BIOASTIN), spirulina spp. the patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. About 5 hours after the second shot (also reported as 24Apr2021 22:00), her lips started to swell. she took her allergy medicine and she felt better. Twelve hours after the second shot, she had convulsions. she had a pain that started in her left armpit, shot down to her inner elbow, and caused her whole arm to get rigid. Then her body would jerk and she groaned. It stopped and started in intervals, with calm in between. It was unknown prior to vaccination, if the patient diagnosed with COVID-19. Not tested for COVID-19. Outcome of the events was recovering. Follow-up information requested.
1302027	5/10/2021	NJ	26	F	5/9/2021	5/9/2021	Systemic: Fainting / Unresponsive-Medium, Systemic: Nausea-Medium, Systemic: Seizure-Mild, Additional Details: Patient received vaccine. After about 5-10 minutes the patient stated she was very nauseous. I went to grab a trash can for her and within the 20 seconds or so it took to grab she had what seemed like a single muscle spasm or convulsion then she slid out of her chair onto the floor. She was breathing and coherent right away however she did not remember getting on the floor. Called 911 and EMS came out and took her vitals. She stated she felt fine afterward and did not go with them.

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1302281	5/10/2021	FL	34	M	5/10/2021	5/10/2021	34 y/o male with no known medical history, who presents with seizure like activity lasting 2-3 seconds post vaccination. Patient states that this is his second vaccination in the two-dose series. Patient denies previous reaction with the first vaccination. Patient states that he fears needles. Patient was witnessed with upper arm stiffening, convulsions and syncope lasting 2-3 seconds. RNs lowered patient to the ground with legs elevated. Patient regained consciousness within seconds. Patient was not post ictal. Patient denies headache, sore throat, difficulty breathing or itch. Patient vitals (151/79 BP, 98% O2, 74 HR, 14 Resp, Glucose 125, EKG NSR). Fire rescue was called. Patient was placed in wheelchair and taken to private area where he was further assessed by the Paramedics, NP and RN. Patient was noted to be diaphoretic. Water provided and patient placed in Trendelenburg position. Fire rescue arrived. Patient refused to be transported to the ER, although it was advised by the NP. Fire rescue did not have the patient sign out AMA. AMA form provided and signed, witnessed by the NP. Patient aware of risk involved with no seeking further medical evaluation, such as worsening adverse reaction, subsequent seizures, cardiac event, MVA and/or death. Patient verbalized understanding. Patient ambulated to his car without difficulty.
1302173	5/10/2021	GA	18	F	5/8/2021	5/8/2021	Pt passed out for few minutes, had seizures like symptoms
1302104	5/10/2021	IN	27	F	5/7/2021	5/8/2021	Fever of 103, Chills, Body convulsions, shaking,vomiting, chest pain on left side, stiffness on left side of body, weakness of the body, unable to stand long period of times, on going night sweats, migraine.

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1302527	5/10/2021	VA	17	F	5/10/2021	5/10/2021	Patient presented for second dose of Pfizer COVID vaccine. Per mom, patient had anxiety attack after first dose last approximately 45-60 minutes. Patient transferred from vaccine clinic to private room with stretcher prior to vaccine administration. Post vaccine administration, patient exhibiting typical symptoms of panic attack per mom (seizure-like activity, unable to respond to verbal stimuli, sternal rub or fingernail pressure). EMS arrived at 0925. Patient regained consciousness after EMS arrived, back to baseline at 0940. Patient and mother declined EMS transfer to ED for further evaluation. Patient and mother informed to seek medical attention immediately for any worsening/concerning symptoms. Patient discharged via wheelchair with mother.
1302031	5/10/2021	GA	46	M	5/7/2021	5/7/2021	Systemic: Hypertension-Medium, Systemic: Seizure-Medium, Additional Details: Pt had seizure like activity / HTN crisis 3 min after injection. Hx of heart problems and phobia of needles. Pt lost airway and then consciousness, Pt was assisted to floor. EMS was called. After airway positioning and sternal simulation pt regained consciousness. Pt was handed off to NP care and then later to EMS after being evaluated. Wife stated they did not go to hospital and later went to dinner, when she picked up vaccine cards.
1302506	5/10/2021	KY	37	M	1/19/2021	5/7/2021	Seizure like activity without any personal or family history. All vitals and tests were normal when taken by EMT and RN at the hospital.
1302026	5/10/2021	NJ	26	F	5/9/2021	5/9/2021	Systemic: Fainting / Unresponsive-Medium, Systemic: Nausea-Medium, Systemic: Seizure-Mild, Additional Details: Patient received vaccine. After about 5-10 minutes the patient stated she was very nauseous. I went to grab a trash can for her and within the 20 seconds or so it took to grab she had what seemed like a single muscle spasm or convulsion then she slid out of her chair onto the floor. She was breathing and coherent right away however she did not remember getting on the floor. Called 911 and EMS came out and took her vitals. She stated she felt fine afterward and did not go with them.
1302001	5/10/2021	MA	17	M	5/9/2021	5/9/2021	Systemic: Seizure-Mild, Systemic: Shakiness-Mild

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1301968	5/10/2021	MA	72	M			LOW INTERNATIONAL NORMALISED RATIO (INR); This spontaneous report received from a patient concerned a 72 year old male. The patient's weight was 240 pounds, and height was 72 inches. The patient's past medical history included strokes at 42 and 44 years of age, and grande mal seizure at age 44 with stroke, and concurrent conditions included primary antiphospholipid antibody syndrome, blood thinners for 30 years, non-smoker, social alcohol drinker, artificial aortic valve after first stroke at age 42, and pacemaker, and other pre-existing medical conditions included the patient did not have any history of drug abuse or illicit drug use. the patient's father and brother had primary antiphospholipid antibody syndrome (pps) both was deceased and his nephew recently discovered that he also have had primary antiphospholipid antibody syndrome (pps). the patient's father died at age 60 and his brother died at age 73 from primary antiphospholipid antibody syndrome (pps). The patient experienced drug allergy when treated with phenytoin. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805031 expiry: UNKNOWN) dose was not reported, administered on 11-MAR-2021 for prophylactic vaccination. Concomitant medications included warfarin sodium. On 2021, the subject experienced low international normalised ratio (inr). Laboratory data included: INR (NR: not provided) 3.4, 2.0. On 03-MAY-2021, Laboratory data included: INR (NR: not provided) 2.5. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from low international normalised ratio (inr). This report was non-serious.; Sender's Comments: V0: Medical assessment comments not required as per the standard procedure as the case is assessed as non-serious.
1301656	5/10/2021	IL	21	F	5/4/2021	5/4/2021	fainting, eyewitness reported seizure (patient also had scrapped left shoulder)

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1302071	5/10/2021	TX	27	M	5/6/2021	5/6/2021	During the 15 Observation Patient passed out and fell out of the chair. Patient was unresponsive for approx 30 seconds. He had seizure. Patient be came alert and responsive confused for about 2 minutes. After becoming more alert. Patient stated he has had this happen before when we was giving blood. Patient had not eaten anything before coming to get vaccine as well. 911 was called. BP was 160/80, pulse 60, O2 sat 97% . Patient refused to go the hospital. Stated he felt fine now. I observed him for another hour before letting him leave our facility.
1303570	5/10/2021	OR	36	F	5/10/2021	5/10/2021	Approximately 1 hour post vaccination, patient began having seizure like activity with repetitive movements and could not speak. Was breathing normally and making repetitive sounds.
1302188	5/10/2021		38	F	5/7/2021	5/7/2021	During 15 minute observation period, patinet fell from chair to carpeted floor with seizure lasting 4 mintues, airway maintained, EMS activated. Patient continues to have intermitent seizures till EMS arrived. Left with EMS. Chart review shows no arrival to a ED so unknown to patient outcome. Hx of mutiple ED and hospital admissions due to seizures. Patient notes states not always taking medications due to her work.
1303919	5/10/2021	HI	74	M	4/6/2021	4/9/2021	Progressively worse headaches culminating in seizure, unconsciousness, and subdural hematoma requiring helicoptering to the ER and brain surgery to drain the hematoma.
1302664	5/10/2021	DC	34	M	5/10/2021	5/10/2021	Patient experienced light headedness, dizziness and passed out for about 2-3 seconds. Minor convulsions during unconsciousness.
1303545	5/10/2021	VA	59	U	4/21/2021	4/22/2021	2 seizures within 24 hours of second dose.

<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>
1303515	5/10/2021	UT	16	M	5/8/2021	5/8/2021	Mom contacted our clinic today reporting that patient received the COVID vaccine at the Pharmacy. Mom reports about 2-3 minutes after the vaccine was given, patient 'had a seizure'. Mom reports loss of consciousness, twitching/jerking, pale skin, nausea. These s/s lasted less than 1 minute. They were at the pharmacy when the episode occurred. When he was alert and awake after the episode, he was acting normal and continues to act normal.
1303487	5/10/2021	KS	23	M	5/10/2021	5/10/2021	Patient received vaccination. Walked to observation area and fell to the floor. Remembers feeling anxious and warm and also reports history of high blood pressure and anxiety. Patient alert and orientated in EMS room on exam. Reports not eating. Blood pressure 130/90, O2 97% and pulse 65. No history of seizures. Possibly hit his head. Pupils equal and reactive. Refused an ice pack and refused any further medical care including EMS. Will follow up with primary care provider. Water and snack provided.
1303350	5/10/2021		73	F	3/2/2021	3/25/2021	This 73 year old female received the Covid shot on 3/2/21 and went to the ED and admitted on 3/25/21 with the following diagnoses listed below. R56.9 - Seizure R56.9 - Unspecified convulsions N17.9 - Acute kidney failure, unspecified
1303311	5/10/2021		71	F	2/27/2021	3/3/2021	This 71 year old female received the Covid shot on 2/27/21 and went to the ED on 3/3/21 and was admitted on 3/4/21 with the following diagnoses listed below. R56.9 - Unspecified convulsions

<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>
1302965	5/10/2021	MN	26	M	5/9/2021	5/9/2021	- a 26 yo male, received a Janssen vaccine at approximately 1:30pm on 5/9/21 - Prior to administration, I asked patient if he had any issue with vaccines prior and he stated no. His consent form did not indicate medication allergies or a history or reactions. - Less than 5 minutes after administration, the patients friend, who also received a vaccine, stated that he was having a seizure - I instructed her (pharmacy technician) to call 911. - I observed the patient laying on his side by the wall in the pharmacy waiting area; he was conscious with eyes open. I did not observe him seizing. He did have a red spot on his forehead where his head hit the wall. He was also sweating. His friend stated that he seized for less than 5 seconds. - I gave the patient a frozen water bottle for his head and a room temperature water bottle. - The patient stated he did not want to pay for an ambulance which I relayed to her. - The EMT did arrive anyway and checked on the patient. - The patient and his friend left the store together, without EMT support or transfer. - The EMT team did not communicate with me prior to leaving the store.
1302862	5/10/2021	MD	57	M	5/7/2021	5/7/2021	Systemic: Seizure-Mild, Additional Details: Patient experienced seizure within 20 minutes of administration that did not last for more than 5 minutes. Patient was able to sit back in chair to await ambulance.
1302766	5/10/2021	SC	19	M	5/10/2021	5/10/2021	Starting within two minutes of receiving Janssen vaccine patient became pale in color, clammy, and started exhibiting seizure like activity (jerking). Patient fell out of his chair and onto the floor. Patient does not remember incident, stated he only remembers looking at his phone then becoming alert again to people surrounding him. Patient was assessed by pharmacist immediately and EMS was called at 9:35 am. Vitals were taken by pharmacist at 9:37 am. Patient was re-assessed upon arrival of EMS.
1304160	5/10/2021		50	M	4/15/2021	4/29/2021	CEREBROVASCULAR ACCIDENT R56.9 - Seizure (CMS/HCC)
1300787	5/9/2021	WA	24	M	5/8/2021	5/8/2021	Systemic: Flushed / Sweating-Mild, Systemic: Headache-Mild, Systemic: Seizure-Mild

<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>
1301329	5/9/2021	FL	33	F	5/9/2021	5/9/2021	Patient was given her shot, she got up and sat down in the nearest observation chair, then immediately said she was dizzy and thought she was going to pass out. I went to her and she repeated that she was about to pass out. When her head started to roll back I was able to hold her by her shoulders. Her eyes rolled back and her head dropped back and she started convulsing. She lost consciousness for about 10 seconds. When she came to she didn't know what was happening. She was very sweaty by this time. I asked if she had a history of seizures or had ever fainted before and she answered no. EMS was called. I checked her BP and it was 84/41. The patient tried to stand to assist with finding her husband in the store but I told her she had to sit until EMS arrive. We offered her water and orange juice and she asked for both. When the husband got there we asked him if she has a history of fainting or seizures and he said this has happened multiple times, mostly as a result of seeing blood. He said she hasn't had seizures but she has had tremors when this has happened. I checked her BP again and it was 116/88. She was feeling a lot better. EMS arrived and she was stable by that point. They recommended that she go to the hospital, but patient opted not to go.
1301283	5/9/2021	CA	25	F	4/12/2021	4/21/2021	poor oral intake . Seizures. on admission she was found to have lactic acidosis. Transaminase elevation and thrombocytopenia and Cr of 1.2
1300915	5/9/2021	TX	71	F	4/1/2021	4/1/2021	Six hours after receiving the vaccine shot my teeth started chattering with such intensity I could hardly speak, and my arms started to shake as if I were having a mild seizure. I could hardly zip up my jacket, due to the intense shaking. I immediately rushed to the local ER. My temperature had jumped to 103 degrees.
1300778	5/9/2021	CA	24	M	5/8/2021	5/8/2021	Site: Redness at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Seizure-Severe, Additional Details: pt did not have reddness or pain at site, but fainted and had a seizure

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1300769	5/9/2021	PA	21	M	5/8/2021	5/8/2021	Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Hypotension-Medium, Systemic: Nausea-Medium, Systemic: Seizure-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium, Systemic: Visual Changes/Disturbances-Medium, Additional Details: Patient had a history of seizures from 2012-2015 but is no longer on medication of any sort. About 5-7 min after vaccine was given he had seizure like activity. He had cold sweats, low blood pressure, and was very pale. He complained of dizziness, nausea, tingling in hands, and blurred vision. 911 was called and he left with EMT
1300763	5/9/2021	NJ	17	M	5/8/2021	5/8/2021	Site: Pain at Injection Site-Mild, Additional Details: Patient was waiting after the his first covid shot and he was talking with his parents, they had a conversation for 5 minutes and then the patient fainted, fell down, had seizure for few seconds and then woke up in few seconds. Patient was sweating, feeling hot. He was breathing normal. Face was red. 911 was called. Patient had no issues with needles. HR was 104. Patient felt better after 10-15 mins and left with his parents. No hospitalization needed.
1300756	5/9/2021	TX	16	M	5/8/2021	5/8/2021	Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Medium
1300772	5/9/2021	TN	41	M	5/8/2021	5/8/2021	Systemic: Fainting / Unresponsive-Mild, Additional Details: Fainted. Responded after about 10 seconds. Has history of fainting / abscent seizures. Pulse and blood pressure normal immediately after incident occurred.
1299807	5/8/2021	IA	32	F	4/28/2021	5/1/2021	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

<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>
1299172	5/8/2021	MN	16	M	4/23/2021	4/23/2021	seizure; passed out; light headed; fell out of chair and hit floor; making a gurgling/growling sound; his right arm was contracted and tight; his right arm was contracted and tight; This is a spontaneous report from a contactable consumer, the parent. A 16-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot: ER8736), via an unspecified route of administration in the left arm on 23Apr2021 at 09:30 (at the age of 16-years-old) as a single dose for COVID-19 immunization. Medical history included Ehlers-Danlos syndrome. The patient had no known allergies. The patient was not diagnosed with COVID-19 prior to the vaccination. Concomitant medications were none. The patient did not receive any other vaccinations within 4 weeks of the vaccine. On 23Apr2021 at 09:45 (reported as 13 minutes after the vaccine), the patient said he was lightheaded and then fell out of the chair and hit the floor. He started making a gurgling/growling sound. After the nurses flipped him over, they noted that his right arm was contracted and tight. They were unable to determine if he had passed out or had a seizure. He had no seizure history. He regained consciousness after about 45 seconds to a minute. The patient was not treated for the events. Since the vaccination, the patient was not tested for COVID-19. The clinical outcome of passed out was resolved on 23Apr2021, while of seizure, lightheaded, fell out of chair and hit floor, making a gurgling/growling sound, his right arm was contracted and tight was resolving.

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1299269	5/8/2021	NJ	89	F	4/6/2021	4/1/2021	severe allergic reaction; Swollen lymph nodes; unable to move her left side of her body; muscle and joint pain; muscle and joint pain; total numbness of her body; severe migraine; Headache / head pain; Injection site redness; Injection site swelling; arm was hurting a lot; This is a spontaneous report from a contactable consumer. An 89-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot unknown, first dose) solution for injection intramuscular in the left arm on 06Apr2021 at 13:30 (at the age of 89-years-old) as a single dose for COVID-19 vaccination. Medical history included seizures from 1970, serious migraines (would guess this was diagnosed about the same time as the seizures) from 1970, broken leg and ankle (diagnosed 4-5 years ago, she can't walk), severe arthritis (this was diagnosed about 5 years ago), Blood pressure high, and uses a walker and a wheelchair (prior to getting the vaccine). There were no concomitant medications. On 07Apr2021, the patient experienced severe allergic reaction, swollen lymph nodes, unable to move her left side of her body, muscle and joint pain, total numbness of her body, severe migraine, headache, injection site redness, and injection site swelling. In Apr2021, the patient experienced arm was hurting a lot. The patient went to the emergency room because she couldn't move the left side of her body, had a really bad migraine, and her head started hurting, but she didn't stay in the hospital. Treatment for the event migraine included acetaminophen (TYLENOL) but that was not doing anything. Shots of prednisone was offered for migraine but the patient refused. The outcome of the events allergic reaction, swollen lymph nodes, muscle and joint pain, total numbness of her body, severe migraine, headache, injection site redness, and arm was hurting was unknown. The outcome of the events unable to move her left side of her body and injection site swelling was recovering. Information about lot/batch number 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>
1299301	5/8/2021	OK	16	F	3/17/2021	3/27/2021	worst seizure; This is a spontaneous report from a non-contactable consumer (patient parent). A 16-year-old female 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 17Mar2021 10:30 at single dose for covid-19 immunisation. The patient's medical history included catamenial epilepsy has been taking 1000 mg Keppra twice daily to help control seizures. The shortest duration between seizures was approximately 1 month, and that was before her epilepsy diagnosis and starting on the Keppra. Additionally, patient's medical history included ADHD. The patient was not pregnant at time of vaccination. The patient's concomitant medications included levetiracetam (KEPPRA) for catamenial epilepsy at 1000 mg, 2x/day, amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), and unspecified medication. On 27Mar2021 08:30, the patient experienced her worst seizure ever. Also reported as suffered a cluster of seizures which is atypical for her. Last night the reporter read an article about some women starting their periods after years of not having it soon after receiving the Covid vaccine, so I looked back at my daughter's seizure record and noticed a potential link. Treatment included increased her Keppra dosage to 1250 mg. The event caused the patient for physician office visit. The outcome of the event was unknown. No follow-up attempts are possible. No further information is expected.

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1299307	5/8/2021	OK	16	F	3/31/2021	3/31/2021	worst seizure; First Pfizer Covid Shot on 17Mar2021# Second Pfizer Covid Shot on 31Mar2021; This is a spontaneous report from a non-contactable consumer (parent of patient). This report is for the second dose. A 16-year-old non-pregnant female patient received BNT162B2(PFIZER BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in left arm on 31Mar2021 (Batch/Lot Number: ER8727) as single dose for COVID-19 immunisation. Relevant medical history includes catamenial epilepsy and attention deficit hyperactivity disorder (ADHD). Patient had no other vaccines in 4 weeks. Patient had no known allergies. Patient had not had COVID prior to vaccination. Concomitant medications included levetiracetam (KEPPRA) taken at 1000 mg twice daily to help control seizures, start and stop date were not reported and amphetamine aspartate, amphetamine sulfate, dexamphetamine saccharate, dexamphetamine sulfate (ADDERALL) taken for an unspecified indication, start and stop date were not reported. Patient historically took first dose of Pfizer BNT162B2 (Lot number EN6206) on the left arm at age 16 years on 17Mar2021 at 10:30AM for COVID-19 immunisation and experienced worst seizures. Reporter's daughter has been diagnosed with catamenial epilepsy, and has been taking 1000 mg KEPPRA twice daily to help control seizures. The shortest duration between seizures was approximately 1 month, and that was before her epilepsy diagnosis and starting on the KEPPRA. She has recently suffered a cluster of seizures which is atypical for her. Last night, reporter read an article about some women starting their periods after years of not having it soon after receiving the COVID vaccine, so reporter looked back at her daughter's seizure record and noticed a potential link. Patient had her first Pfizer COVID Shot on 17Mar2021, and she experienced her worst seizure ever on 27Mar2021 (10 days after COVID vaccine). On 31Mar2021, patient had her second Pfizer COVID Shot and she experienced her second worst seizure ever on 10Apr2021 (again 10 days after the second COVID vaccine. Again, her daughter has never had seizures occur in such a short duration, with the minimum time between seizures being one month. The adverse reaction resulted in doctor or other healthcare professional office/clinic visit. Patient was

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1299308	5/8/2021	TN	33	M	4/21/2021	4/21/2021	<p>treated for the event which is increase in KEPPRA dose to 1250 mg. Patient had not been tested with COVID-19 post vaccination. Vaccination facility was at a public health department. The outcome was unknown. No follow up attempts are possible. No further information is expected.</p> <p>I had a seizure and I am not common to having seizure; This is a spontaneous report from a contactable consumer (patient). A 33-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at the age of 33-year-old, dose 2 via an unspecified route of administration, administered in left arm on 21Apr2021 (Lot Number: ER8735) as single dose for COVID-19 immunisation. The patient had no medical history. Concomitant medication included bisoprolol 10 mg. The patient was previously vaccinated with the first dose of BNT162B2 on 31Mar2021 at the age of 33-year-old for COVID-19 immunisation. The patient stated that he had a seizure on 21Apr2021, and he was not common to having seizure. No treatment was received for the event. The outcome of the event 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>
1299329	5/8/2021	PA	26	M	4/29/2021	4/30/2021	seizure; Body soreness; Inability to sleep/stay asleep; Loss of memory/confusion; Loss of memory/confusion; This is a spontaneous report from a contactable consumer. A 26-yearsold male patient received his second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), on 29Apr2021 13:00 (Lot Number: EW0161) via an unspecified route of administration, administered in Arm Right as single dose for covid-19 immunization (Age at vaccination: 26 years). Medical history included High blood pressure. Concomitant medication included marijuana. The patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in right arm (lot number: EW0150) on 08Apr2021, 10:00AM for covid-19 immunization (Age at vaccination: 25 years). The patient experienced seizure, body soreness, inability to sleep/stay asleep (initial insomnia), loss of memory/confusion on 30Apr2021 07:00. The events were assessed as life-threatening by the reporter. The patient was not diagnosed with COVID-19 prior vaccination and the patient has not been tested with COVID-19 since the vaccination. Outcome of the events was not recovered. No follow-up attempts are needed. No further information is expected.

<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>
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

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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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.

1300533 5/8/2021

37 M

4/17/2021

4/28/2021

My prescribed medication therapeutic levels were stable. After receiving Pfizer BioN Tech vaccination on April 17, 2021, it triggered me a seizure (convulsion) on April 28, 2021. Why is Pfizer vaccination causing convulsions?

1299429 5/8/2021 FL

53 M

5/5/2021

5/5/2021

Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Seizure-Severe, Systemic: Shakiness-Severe, Additional Details: He came with his caretaker (sister) and was told side effects after vaccine administration. I also advised to remain seated for 15 minutes. The patient is special needs and got up anyways. I had pharmacy door open to watch patient while sister was in front of him watching him for reactions. I saw him through door standing against the wall. I ran to help him sit back down and he collapsed and hit his head on the floor . Sister said he has seizures. Called 911

<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>
1299123	5/8/2021	FL	47	F	4/12/2021	4/12/2021	had seizures; she fell; she was sleeping a lot; fever; fatigue; This is a spontaneous report from a contactable consumer (patient) received via Medical Information Team. A 47-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 12Apr2021 at 12:00 (Lot Number: ER2613) (at the age of 47-year-old) as single dose for COVID-19 immunisation. Medical history included ongoing ulcerative colitis. The patient's concomitant medications were not reported. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot Number: EN6208) for COVID-19 immunization. The patient experienced fever and fatigue (on 12Apr2021) but then got better. On Monday 19Apr2021 she was sleeping a lot, she fell and then had seizures. The patient was taken to the emergency room and a CT scan was performed; she was there for 5-6 hours. The patient confirmed that she was not admitted to the hospital. The patient outcome of fever and fatigue was recovering, the outcome of the other events was unknown.
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

<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>
1299947	5/8/2021	WA	20	M	4/29/2021	4/29/2021	Within 1 hour of the vaccination, patient developed headache (lasted 2-3 days), and 1 week of nausea, intermittent vomiting, extreme fatigue, generalized weakness. He had decreased oral intake for solids and liquids, up to 5-6 total episodes of emesis over the last week. He was seen in urgent care 5/5 and treated with Zofran. He had decreased urine output the next two days (~15 hours without voiding). And was seen in ED 5/7 and transferred to ICU for management of severe hyponatremia, though never developed seizures or neurologic abnormalities.
1299950	5/8/2021	NC	31	F	5/8/2021	5/8/2021	The patient received the Janssen Johnson & Johnson vaccine from a certified immunizing technician. She was asked to wait 15 minutes after receiving the vaccine before leaving the pharmacy and remained seated in the post vaccination waiting area chair. She began feeling dizzy and lightheaded. She was caught by her family members and the pharmacist on duty before she fell. She briefly had a mild seizure and lost consciousness for a minute. When she regained consciousness she stated that she felt nauseous and was seeing double. 911 was called. EMTs arrived and checked her alertness and how she was feeling. The EMTs then took her off in a stretcher to the hospital out of an abundance of caution due to brief loss of consciousness.
1300235	5/8/2021	NY	16	M	5/4/2021	5/5/2021	Child woke up at 3 am with severe nausea. Within minutes he complained about not being able to breathe. His lips turned blue and he was about to pass out. As I was able to keep him awake, I am not sure whether he would have had a febrile seizure (it very much looked like it) or just fainted. The fever spike was too fast, and his body couldn't handle it. His extreme nausea persisted for four hours (but he didn't vomit). He was completely debilitated. Fever spiked to 103 but stabilized at 102 for the following 24 hrs.
1300374	5/8/2021		75	F	3/26/2021	4/9/2021	This 75 year old female received the Pfizer Covid shot on 3/29/21 and went to the ED on 4/9/21 and was admitted on 4/9/21 with the following diagnoses listed below. I63.9 - Acute CVA (cerebrovascular accident) R56.9 - Unspecified convulsions

<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>
1299349	5/8/2021			U	2/26/2021		<p>I had a seizure and I have never had a seizure in all my life; It was like my lungs are about to collapse and especially my left lung; Difficulty in breathing; Dizziness; Have been bothered with my hand; Have been terrible ever since I had my shot; My first symptom was like in my head, it was like sinus pressure; My first symptom was like in my head, it was like sinus pressure; This is a spontaneous report from a contactable consumer. A 65-year-old patient of an unspecified gender received first dose of bnt162b2 (PFIZER COVID-19 VACCINE, Solution for injection), via an unspecified route of administration on 26Feb2021 as single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient reported, had been having difficulty in breathing, dizziness, bothered with hand and have been terrible ever since had the shot, had never felt like this before. These symptoms started like about two weeks after taking the first one and first symptom was like in my head, it was like sinus pressure and everything but now, it has gone. And it just kept going on for about two weeks. Then on March the 11th, the patient went to doctor and told him about how the feeling was, and they gave a shot, a steroid shot (Unspecified Medication) as he was having difficulty breathing, like lungs are about to collapse and especially left lung and then, was okay for a day or so and two days after. The patient had a seizure and never had a seizure in all life of 65 years. The patient had to go to the hospital. The patient does not feel well. The outcome of events was unknown. Information on the lot/batch number has been 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>
1299087	5/8/2021	KY	34	F	4/15/2021	4/15/2021	After 15 minutes of sitting I passed out; slight seizure; headache; diarrhea; severe lethargy; arm soreness; This is a spontaneous report from a contactable consumer. A 34-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EW0164), via an unspecified route of administration, administered in Arm Right, at the age of 34 years, on 15Apr2021 12:45 at a SINGLE DOSE for covid-19 immunisation. Medical history included basedow's disease, gastrooesophageal reflux disease and allergy to metals from an unknown date and unknown if ongoing. Concomitant medications included methimazole (METHIMAZOLE) taken for an unspecified indication, start and stop date were not reported. The patient previously took hydrocodone and experienced drug hypersensitivity and gluten and experienced food allergy. The patient stated, "After 15 minutes of sitting I passed out and had a slight seizure, then passed out and seized a second time. I had headache and diarrhea for two days following with severe lethargy and arm soreness" on 15Apr2021 01:00 PM. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 19Apr2021. No treatment was received for the events. The outcome of the events was recovered on an unspecified date.

<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>
1299086	5/8/2021	PA	19	F	4/20/2021	4/20/2021	nausea; passed out; seizure; enlarged heart; hurt knee; sore mouth; This is a spontaneous report from a contactable other HCP (patient). A 19-year-old female non-pregnant patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EP7534) via an unspecified route of administration, in the left arm on 20Apr2021 at 11:00 (at the age of 19-years-old) as a single dose for COVID-19 immunisation. Medical history was none. The patient's concomitant medications were not reported. The patient has no history of COVID-19 prior to vaccination. The patient had received other vaccines within 4 weeks prior to the COVID-19 vaccine: 2nd dose of Human papilloma virus (HPV) vaccine on 06Apr2021 in the right arm. On 20Apr2021 22:30, the patient experienced passed out, seizure, hurt knee, sore mouth, enlarged heart, and nausea. The patient reported, "I was fine all day until around 10:30 pm I went into my mothers room and she was asking me how my arm feels I told her it was fine and right after saying that she said I passed out in front of her and then I began to have a seizure for about 50 seconds and then I woke up. After waking up from the event I had a hurt knee and sore mouth as well as an enlarged heart. I have no history of seizures in the past so it was definitely scary." The patient underwent lab tests and procedures which included SARS-COV-2 test: negative on 20Apr2021. Therapeutic measures taken included anti seizure meds, fentanyl, and paracetamol (TYLENOL). The patient recovered with sequelae from the events, passed out, seizure, hurt knee, sore mouth, and enlarged heart. Outcome of nausea was unknown.; Sender's Comments: A contributory role of BNT162B2 to the reported events cannot be fully excluded based on close temporal relationship and lack of alternate explanation at this time. However, the information provided is very limited and does not allow for a complete medical assessment. 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

<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>
1298899	5/8/2021	NV	61	F	4/26/2021	4/27/2021	<p>Investigators, as appropriate.</p> <p>aura seizure; aura seizure; fatigue; headache; heart palpitations; aphasia; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (aura seizure) in a 61-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 008C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included MARIJUANA for an unknown indication. On 26-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Apr-2021, the patient experienced PALPITATIONS (heart palpitations), APHASIA (aphasia), FATIGUE (fatigue) and HEADACHE (headache). On 30-Apr-2021, the patient experienced SEIZURE (aura seizure) (seriousness criterion medically significant) and AURA (aura seizure). At the time of the report, SEIZURE (aura seizure), PALPITATIONS (heart palpitations), APHASIA (aphasia), AURA (aura seizure), FATIGUE (fatigue) and HEADACHE (headache) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No medical history was provided by the reporter. Treatment included Aspirin for headache. 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, the previous history of previous injury, is 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. However, the previous history of previous injury, is a confounder.</p>

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1298876	5/8/2021	CA	74	F	4/29/2021		<p>DIZZINESS; PAIN AT THE INJECTION SITE; STOMACH ACHES; This spontaneous report received from a consumer concerned a 74 year old female. The patient's height, and weight were not reported. The patient's past medical history included brain cancer, and concurrent conditions included seizures, dementia/Alzheimer, and vertigo. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 205A21A, and expiry: UNKNOWN) dose was not reported, administered on 29-APR-2021 15:00 for prophylactic vaccination. Concomitant medications included levetiracetam for seizures. On 29-APR-2021, the subject experienced stomach aches. On 29-APR-2021, the subject experienced pain at the injection site. On 06-MAY-2021, the subject experienced dizziness. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from stomach aches on 29-APR-2021, and pain at the injection site on 30-APR-2021, and had not recovered from dizziness. This report was non-serious.</p>

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1298811	5/8/2021	IN	54	F	4/29/2021		SEIZURE; RED PETECHIAE ON ABDOMEN; FEVER OF 103; This spontaneous report received from a patient concerned a 54 year old female. The patient's height, and weight were not reported. The patient's past medical history included stroke from patent foramen ovale (PFO), and concurrent conditions included lupus, epilepsy, menopause, and patent foramen ovale. 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 29-APR-2021 at 17:00PM, for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 29-APR-2021, within an hour after vaccination, the patient experienced seizure and about five hours later the patient experienced red petechiae on abdomen and fever of 103 F. The patient consulted doctor and started taking 10 mg of prednisone. The patient's seizures were still spiking; they were trying to control the seizures with Lorazepam. The patient was expecting that prednisone will help. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from seizure, and the outcome of red petechiae on abdomen and fever of 103 was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210503252-COVID-19 VACCINE AD26.COV2.S-SEIZURE. 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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1299146	5/8/2021	MO	32	F	1/19/2021	2/1/2021	Seizures; Memory issues; Epilepsy; This is a spontaneous report from a contactable nurse (patient). A 32-year-old non-pregnant (including at the time of the vaccination) female patient received the 2nd dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration administered on arm left on 19Jan2021 (Batch/Lot number was not reported) as SINGLE DOSE for COVID-19 immunization at the physician's office. Medical history included depression and anxiety. Concomitant medication included venlafaxine hydrochloride (EFFEXOR) taken for an unspecified indication and therapy dates. She had no COVID-19 prior to vaccination. The patient received the first dose of PFIZER-BIONTECH COVID-19 VACCINE on 29Dec2020 01:30 PM (Batch/Lot number was not reported) on the right arm as COVID-19 immunization. Then, received the 2nd dose on 19Jan2021. The patient was then diagnosed with epilepsy in Feb2021 a month after getting 2nd dose. On 08Mar2021 10:30, the patient had seizure and memory issues. The patient was brought to the emergency room/department or urgent care due to the events. Then was admitted in the hospital on 08Mar2021. The patient had nasopharyngeal swab on 05Mar2021 and showed negative. The patient received an unspecified treatment for the events but not yet recovered. Information on the lot/batch number has been requested.; 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 Epilepsy.,seizures, memory impairment. 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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1299171	5/8/2021	WA	18	F	4/20/2021	4/20/2021	vomited; nauseous; visibly distressed; hyperventilating; began seizing/visibly having tonic clonic seizure; HR 116/HR 114; HR 56; RR 30; BP of 141/46; This is a spontaneous report from a contactable nurse. An 18-year-old female patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number: EW0170), intramuscular, administered in the right arm on 20Apr2021 at 12:45 as a single dose for COVID-19 immunization. Medical history included anxiety from an unknown date and unknown if ongoing. Concomitant medications included fluoxetine hydrochloride (PROZAC) taken for an unspecified indication, start and stop date were not reported. The patient did not have COVID prior to the vaccination. The patient did not receive other vaccines in four weeks. The patient had not been tested for COVID post vaccination. On 20Apr2021 at 12:45, the patient and her father moved into the waiting area with vehicle. According to the patient's dad, the patient began seizing in the car one minute after the vaccine administration. The dad called out to waiting area monitor. At 12:57 the patient was visibly having tonic clonic seizure and was administered with EpiPen in the right Leg. 911 was called. The patient stopped seizing and was awake and confused. She then became AOx4 (oriented to four spheres; time/place/person/situation). The patient visibly distressed and hyperventilating. At 12:59 the patient had tonic clonic movements and seizure again. The seizure lasted less than 15 seconds. The patient then became AOx4 again, distressed, and became nauseous. Heart rate (HR) was 56 and SpO2 was 98%. At 13:00 the patient vomited while sitting up. The patient was still distressed and hyperventilating with respiratory rate (RR) of 30. The patient's post vomiting HR was 116 and SpO2 was 97%. The patient moved to a stretcher and moved to the shade. At 13:06 firefighters arrived and the patient had an HR of 114, BP of 141/46, SpO2 of 97%, RR 24 and AOx4. At 13:12 the ambulance arrived and the patient was taken to (Place). The events resulted in a visit to the Emergency room/department or urgent care. The outcome of the events was unknown.; Sender's Comments: Based on the available information, and on close temporal association, a reasonable possibility cannot be excluded that the suspect drug BNT162B2 (Pfizer-BioNTech COVID-19 vaccine) contributed to the occurrence of the serious event

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							Generalised tonic-clonic seizure. 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.
1296710	5/7/2021	NC	32	F	5/7/2021	5/7/2021	Pt was given the vaccine. Within less than 5 minutes, she said she was feeling light-headed and proceeded to pass out. She fell to the floor, and I went out to assist her. She was able to keep her head from hitting the floor, and I supported her head as she regained consciousness. She tried to sit up but lost consciousness again and appeared to convulse (arms and legs drawn up). She regained consciousness again, and was completely lucid. We called 911 and EMT arrived and continued their usual procedures including checking blood pressure, heart rate, and blood glucose. Her BP was 130/80 laying, and 80/60 sitting. Her pulse was 50. Her blood sugar was 56 before consuming glucose and 71 after. She was given water as well. She declined a ride to the hospital but did have a friend give her a ride home.
1294575	5/7/2021	OH	40	M	5/6/2021	5/6/2021	Had a severe colonic seizure and stopped breathing. He said he felt funny after the shot, like he was light-headed and dizzy. Then out of nowhere I heard him moan and saw he was foaming at the mouth and violently convulsing and turning blue. I did cpr and the paramedics arrived and took him to the hospital. We are following up with a neurologist tomorrow.

<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>
1294726	5/7/2021	TN	67	F	3/2/2021		<p>seizure; Feel woozy; felt even weaker; jittery feeling; shaky; doesn't feel well; It has left her with a stutter; This is a spontaneous report received from contactable consumer (patient). A 67-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EN6198), dose 1 via an unspecified route of administration on 02Mar2021 (at the age of 67years) as single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported that she got her first shot on 02Mar2021 and the second shot 25Mar2021. She took the first shot and she wanted to say a day or so after that she got up and did some things around the house and she went to the cloth store. She clarified that she went to the fabric store and came out she had a jittery feeling. Then she began to feel woozy and stated she may need to eat. She drove up to by (withheld) and there was a cookout restaurant in the same vicinity as (withheld). When she went to turn into the lot, she was "shaky" and pulled into the parking space. She added that the best thing is for her to go home. She didn't want to take the interstate and went to the back way just in case something happened. She went home and it was approximately 10 miles away. When she got home, she felt even weaker. Her husband was outside because he fishes and was working on his boat. She told him that she doesn't feel well and was shaky. He told her to go in the house and he would come in. She went in through the basement and when she got to the step her foot wouldn't come up, so she crawled up the steps. When her husband came in, she went into a seizure and had no control. She could hear her husband speaking but couldn't speak so he called. They told him to give her four 81 mg of aspirin. So, he gave her some aspirin. She could hear them when they came in to get her, but she couldn't respond. They took her to the hospital. At the hospital they did two CAT scans and another unspecified test. The patient added that she was concerned because she is a very active person, and this is not her normal talk. Before the shot she did a lot of sewing and that's her business. But a few days after the shot she began to have a lot of seizures and went to the hospital. And when she came home it continued. Before she left the hospital, she had not spoken to anyone. When her husband came in, she couldn't get her words</p>

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1294737	5/7/2021	WA	43	M	4/20/2021	4/20/2021	<p>out. It has left her with a stutter, and she decided to go to speech therapy. She went in and a few days it seemed like it had helped. The patient further stated that she is not getting back to normal and needs a walker or cane and she's 68 and healthy. The outcome of events was unknown. Information on lot/batch number was available. Additional information has been requested.</p> <p>syncopal episode; mild seizure activity; This is a spontaneous report from a contactable healthcare professional. A 43-year-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ew0161) at the age of 43-years-old, intramuscular in left arm on 20Apr2021 at 11:00 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were reported as none. He has no COVID prior to vaccination and denied being allergic to anything. There was no other vaccine in four weeks and no other medications in two weeks. The patient received his first dose of COVID-19 vaccine in a workplace clinic on 20Apr2021 and experienced syncopal episode with mild seizure activity at 11:15, within the 15-minute period post vaccination (as reported). No treatment was given in response to the events. It was unknown if the patient was tested for COVID post vaccination. The outcome of the events was unknown.; Sender's Comments: A contributory role of BNT162B2 to the reported events cannot be fully excluded based on close temporal relationship and lack of alternate explanation at this time. However, the information provided is very limited and does not allow for a complete medical assessment. 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.</p>
1295377	5/7/2021	TX	63	F	3/18/2021	3/25/2021	seizure, 3/25/21

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1295876	5/7/2021		20	M	5/5/2021	5/5/2021	Patient displayed syncope and observed contracting arms (those who witness expressed seizure like activity lasting less than one minute). Patient was pale and diaphoretic with a glazed over look. Vitals were taken and patient was transported to hospital for evaluation.
1295948	5/7/2021		33	M	4/1/2021	4/1/2021	Patient received vaccine in a drive up clinic and was waiting in his car during the 15 minute observation time. 10 minutes after the vaccine, he became lightheaded and alerted for medical attention. When we arrived at his car he was having tonic clonic seizure like activity which lasted about 20 seconds. Patient was reclined in his car seat, VS taken and stable. Oriented x4 but described feeling light headed, tingling in left arm and lips, and diaphoresis. EMS arrived and assumed care. Extended observation showed improving vital signs, and resolution of described symptoms. Patient was released from EMS care and was transported to the ER by a friend for further eval.

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1296184	5/7/2021	MI	45	M	5/6/2021	5/6/2021	Before receiving the vaccination the patient mentioned he had a fear of needles. Patient was asked if he ever fainted after getting a vaccination or injection and patient reported no. The vaccine was administered to the patient and patient appeared to be fine for the next few minutes after getting vaccinated. Patient was told he could take a seat in the waiting area and wait until his 15-minutes were up and he could go. Patient was seated in the waiting area for about a minute but then got up to walk down one of the isles. When walking down the isle patient fainted and collapsed. This occurred approximately 10 minutes or so after he received the vaccine. Patient was helped to a chair and once seated appeared to shake/convulse (almost like a seizure) for approximately 5-10 seconds before snapping out of it and regaining consciousness. Afterwards he was alert and talking but didn't remember fainting. 911 was called and he was checked out by paramedics. After observing him for 15 minutes or so and determining his heartrate and blood pressure were normal and he appeared to be ok, the paramedics told him they can take him to the hospital to be evaluated further, or he was free to leave on his own without going to the hospital. The patient said he felt fine and declined being taken to the hospital. After another 10-15 minutes the patient left under his own power. Patient mentioned he would possibly be calling his physician and alerting them to the episode.

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1297326	5/7/2021		68	F	3/6/2021	3/7/2021	~~Encephalopathy with worsening aspiration (already chronic aspirator) starting one day after second COVID." 68YF with baseline cerebral palsy and seizure disorder, mostly nonverbal at baseline, who presents on 3/30/21 to the hospital with several weeks of decreased alertness and decreased oral intake. Caregiver did report temporality associated with completion of COVID-19 vaccine. She was found to be hypoxic with evidence of aspiration pneumonia and with hypernatremia suggestive of poor PO intake. An EEG was performed that did not show any definite seizure activity. She was kept on telemetry while in the hospital which also captured several pausea, one up to 7 seconds long likely also contributing to her encephalopathy secondary to poor perfusion. She was evaluated by speech who did not feel that she was safe for any type of modified diet and would require tube feedings should this wish to be pursued. In addition, there was also evidence of acute blood loss anemia with suspected GI bleed. Palliative care was consulted. Her son and caregiver were contacted and wished to avoid PEG tube placement or further aggressive work-up. She was felt to qualify for hospice and hospice services at her prior group home were arranged. She was started on oral morphine while here in the hospital to help with air hunger, discomfort, and anxiety. In addition to oral morphine, she was discharged with liquid Augmentin to complete antibiotic course for aspiration pneumonia. On 4/5/21 (the day of discharge) Pt appeared less anxious than she had been. She is nonverbal at baseline but was awake and alert and reaching for the hand of any staff in the room. Discharge to group home on hospice.
1295415	5/7/2021	IN	64	F	4/12/2021	4/13/2021	on 5/01/2021 member was with family and reported having a seizure which she does not remember having, stated she was drinking a Coke and spilled some and the next thing she remembers is being taken to hospital in ambulance, stated had Pfizer first covid shot on 4-12-2021. Stated started getting sick after this shot ?not felt well, didn?t feel like myself, achy, out in left field, had fever the following day after injection, loss of appetite and sense of taste, in a fog and not feeling well,?

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1296012	5/7/2021	NE	51	M	5/6/2021	5/6/2021	Arrived to emergency department via ambulance from nursing home with complaints of "looking like he was about to have a seizure". Patient became unresponsive and a code was called. ACLS performed but the patient did not recover from cardiac arrest.
1295080	5/7/2021	WV	16	F	5/5/2021	5/5/2021	Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Systemic: Seizure-Mild, Additional Details: Parents were with patient. says it happens every time she gets shots or blood work. possible NES and/or hypotension. says its happened in docs office before and they're testing her for pots and her sister has non epileptic seizures. She was fine after about 15 minutes. gave her a cold packet to put on the back of her neck and just monitored her for further symptoms.
1292984	5/6/2021	NC	17	M	5/5/2021	5/5/2021	Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Medium, Systemic: Seizure-Severe, Systemic: Vomiting-Medium, Additional Details: Patient began to seize/faint in chair within 5 minutes post-vaccination. Paramedics were called as I stabilized patient on floor. Consciousness regained within 60 seconds, patient confused/unaware of what had occurred. Patient flush, lightheaded, vomiting. Paramedics arrived and confirmed patient was stable and safe to leave scene without further intervention.
1294185	5/6/2021	CA	16	M	5/6/2021	5/6/2021	5 Minutes post vaccination, pt experienced seizure like symptoms. Speech was slurred and patient went into a fetal position and was flailing his arms. He returned to the chair and we placed him on the floor while waiting for 911. The paramedics check him out and with advice from the mother he was not taken to the hospital. He was escorted to his parents car and driven home.

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1294131	5/6/2021	VA	42	F	3/24/2021	3/28/2021	3/31 stroke like symptoms ED with admission for testing 4/20 stroke like symptoms ED with admission for testing 4/27 seizure 4/28 seizure during MRV confirmed no stroke 5/2 15 seizures ED visit to stop seizure activity 5/3 19 seizures, admission for LP and EEG study 5/4 4 seizures discharged, tests inconclusive 5/5 2 seizures 5/6 2 seizures All are accompanied by severe headache, blurred vision, confusion
1294102	5/6/2021	LA	84	F	4/23/2021	4/24/2021	symptoms started evening of vaccine dose. Felt fine in am. found on floor by family brought to hosp by EMS, seizure disorder; didn't have the strength to get to bed due to fatigue, which is history. Also abd pain and diarrhea and myalgias. Mottled reticular rash diagnosis identified: Abdominal pain; Acidemia; Acute kidney injury; Lactic acidosis; Mottled skin; NSTEMI (non-ST elevated myocardial infarction); Right hip pain; Tachypnea; Weakness

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1294087	5/6/2021	WI	40	M	4/30/2021	5/1/2021	Seizure; Spike Body temperature; Swollen Lip; Headache; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (Seizure) in a 40-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 30-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-May-2021, the patient experienced SEIZURE (Seizure) (seriousness criterion medically significant), BODY TEMPERATURE INCREASED (Spike Body temperature), LIP SWELLING (Swollen Lip) and HEADACHE (Headache). At the time of the report, SEIZURE (Seizure), BODY TEMPERATURE INCREASED (Spike Body temperature), LIP SWELLING (Swollen Lip) and HEADACHE (Headache) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-May-2021, Body temperature: inconclusive (Inconclusive) temperature is not coming down, it is not going up, but it is also not coming down. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment medication included paracetamol. 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.

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1294080	5/6/2021	TX	50	F	3/23/2021	3/23/2021	blackout that happened a few times and it was described as sitting on the couch and patient was not there; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (blackout that happened a few times and it was described as sitting on the couch and patient was not there) in a 50-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 040A21A and 200GC21A) for COVID-19 vaccination. The patient's past medical history included Stress (first blackout started and patient believed it was due to stress) in 2017 and Seizure (seizure in sleep) in January 2020. Concomitant products included LEVETIRACETAM for Seizure. On 23-Mar-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-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (blackout that happened a few times and it was described as sitting on the couch and patient was not there) (seriousness criterion medically significant). At the time of the report, LOSS OF CONSCIOUSNESS (blackout that happened a few times and it was described as sitting on the couch and patient was not there) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. 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. This case was linked to MOD-2021-095441 (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.

<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>
1294065	5/6/2021			F		3/17/2021	MUCH OF THE FLUID LEAKED OUT OF ARM; INCORRECT ADMINISTRATION; INCOMPLETE ADMINISTRATION; This spontaneous report received from a health care professional via a company representative concerned a 53 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included mast cell activation syndrome, fibromyalgia, gastroparesis, and seizures. 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 17-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 17-MAR-2021, the subject experienced much of the fluid leaked out of arm. On 17-MAR-2021, the subject experienced incorrect administration. On 17-MAR-2021, the subject experienced incomplete administration. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the much of the fluid leaked out of arm, incorrect administration and incomplete administration was not reported. This report was non-serious.
1293663	5/6/2021	CA	54	M	5/6/2021	5/6/2021	Patient within 5 minutes after receiving injection was being monitored and began to slump forward in the chair. The patient quickly became completely unconscious and was helped to the floor. The patient was presenting with seizure like symptoms, foaming at the mouth and loss of body functions. Patient remained unconscious for 1 minute or less before regaining consciousness. He was able to speak immediately after. Patient had a rapid heart rate and was sweating. Patients blood pressure was elevated as well. Patients blood sugar was tested and was 146. 911 was called immediately at time of emergency and when they arrived they help that patient sit up. They took the patient to the emergency room since he did not immediately regain all functions and this vitals remained elevated.
1293374	5/6/2021	SC	63	F	4/17/2021	4/17/2021	Patient stated that she went home after vaccination and after about 2 hours she got red in the face head was spinning, and was walking sideways. She suffered a seizure and was hospitalized for 1 week.

<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>
1294337	5/6/2021	CA	18	M	4/30/2021	5/1/2021	Multiple seizures that were not common with epilepsy. This occurred for a couple of days after the vaccine.

<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>
1293024	5/6/2021	AZ	74	U	4/7/2021	4/8/2021	<p>Patient is a 74 y/o female with PMH significant for meningitis at age 2 resulting in developmental delay (non-verbal at baseline and seizure disorder) who presented for poor oral intake, dysphagia, and inability walk due to increased lower extremity weakness that has been occurring since April 9th. The patient is typically ambulatory but needs significant assistance with ADLs. She is able to feed herself (tends to eat baby food). Eventually, the patient was admitted for sepsis 2/2 UTI and now with concerns for remote stroke with persistent dysphagia and acute encephalopathy. Since April 9th, the family has noted that the patient has had difficulty swallowing baby food and seems to be uncomfortable; she is able to make a couple of audible sounds or gestures that suggest pain and that is why they brought her. The family also reports that the patient received her second dose of the Pfizer-BioNTech COVID-19 vaccine on 04/07/2021. On 04/08/2021, the patient had one staring episode, but then returned to baseline. She was at baseline during breakfast on the morning on 04/09/2021, but around lunchtime, she had another staring spell and was unable to swallow food as well as unable to walk, stand, or move her lower extremities. The patient has limited language at baseline but also has not been able to say the few words she used to communicate with her family, only moaning and grunting since that time. Since 04/09, she has not been able to consume any solid foods, only eating a very small amount of smashed/liquified fruit and drinking Pedialyte. Sister has been massaging her legs regularly in hopes of re-establishing movement but saw nothing until yesterday (05/05/2021) when the patient moved toes bilaterally and briefly lifted her right leg. Neurology Consult on 05/05/2021: The patient had mildly bradycardiac and hypertensive (170s/80s). Labs reviewed and showed mildly elevated WBC (i.e., 12.9 K/MM3) and urinalysis was consistent with UTI. Imaging was reviewed and consistent with chronic CVA, likely occurring on 04/09/2021 while the patient was in hypercoagulable post-COVID vaccine state. Neurology recommends CT angio head and neck, TTE w/ bubble, A1c, fasting lipid panel, DVT prophylaxis via lovenox 40mg SC daily, D-dimer levels, EKG, PT/OT?Speech therapy evals, BP control via lisinopril 10mg daily w/ goal of < 140/90, and ASA 81mg daily</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>
1292009	5/6/2021	NC	47	M	5/4/2021	5/4/2021	Patient experienced a seizure episode immediately after I administered his COVID-19 vaccine. I administered the vaccine at 10:22 AM and a few seconds later Patient started to shake and toss his head back. I immediately called 911/paramedics after his wife and I helped him to lay to his side. His seizure episode lasted about 2 or 3 minutes. He quickly regained consciousness and became fully responsive before the paramedics arrived.
1292020	5/6/2021	UT	20	M	5/5/2021	5/5/2021	PATIENT OBSERVED TO HAVE POSSIBLE SEIZURE ACTIVITY IN CHAIR. PATIENT BROUGHT TO THE FLOOR AND LASTED ABOUT 1 MINUTE. PATIENT HAD CONTRACTED ARMS, HUNCHED OVER, PALE, DIAPHORETIC, AND VERBALLY UNRESPONSIVE. 911 DISPATCHED AND ARRIVED WITHIN FEW MINUTES. PATIENT DID NOT RECALL EVENT ONCE VITALS STABILIZED AND WAS TRANSPORTED TO NEAREST HOSPITAL.
1292006	5/6/2021		39	M	5/5/2021	5/5/2021	Rigors, Fever, Convulsions.
1291922	5/6/2021	CA	22	M	5/5/2021	5/5/2021	Systemic: Seizure-Mild, Additional Details: lasted seconds

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1291617	5/6/2021	CO	60	F	4/6/2021	4/6/2021	wanted to die because it was soo painful; a little headache; serious pain; convulsing for almost an hour; cramps all over my body\ spasming; muscle weakness; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (convulsing for almost an hour) in a 60-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 Lupus erythematosus, Rheumatoid arthritis, Fibromyalgia and Spinal fusion. Concomitant products included METHOTREXATE, ETANERCEPT (ENBREL), HYDROXYCHLOROQUINE SULFATE (PLAQUENIL S) and IBUPROFEN (ADVIL 12 HOUR) for an unknown indication. On 06-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Apr-2021, the patient experienced SEIZURE (convulsing for almost an hour) (seriousness criterion medically significant), MUSCLE SPASMS (cramps all over my body\ spasming), MUSCULAR WEAKNESS (muscle weakness) and PAIN (serious pain). On an unknown date, the patient experienced CONDITION AGGRAVATED (wanted to die because it was soo painful) and HEADACHE (a little headache). At the time of the report, SEIZURE (convulsing for almost an hour), MUSCLE SPASMS (cramps all over my body\ spasming), MUSCULAR WEAKNESS (muscle weakness), CONDITION AGGRAVATED (wanted to die because it was soo painful), HEADACHE (a little headache) and PAIN (serious pain) 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. 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.

<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>
1291612	5/6/2021	OH	38	M	4/26/2021	4/26/2021	thinks it was a potential seizure; vasovagal effect from the needle; Patient fell off the bench onto the floor and became rigid and stiff and exhibited some rigid movement; Patient fell off the bench onto the floor and became rigid and stiff and exhibited some rigid movement; This spontaneous case was reported by a pharmacist (subsequently medically confirmed) and describes the occurrence of SEIZURE (thinks it was a potential seizure) and PRESYNCOPE (vasovagal effect from the needle) in a 38-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 007C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 26-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Apr-2021, the patient experienced SEIZURE (thinks it was a potential seizure) (seriousness criterion medically significant), PRESYNCOPE (vasovagal effect from the needle) (seriousness criterion medically significant), MUSCULOSKELETAL STIFFNESS (Patient fell off the bench onto the floor and became rigid and stiff and exhibited some rigid movement) and FALL (Patient fell off the bench onto the floor and became rigid and stiff and exhibited some rigid movement). At the time of the report, SEIZURE (thinks it was a potential seizure), PRESYNCOPE (vasovagal effect from the needle), MUSCULOSKELETAL STIFFNESS (Patient fell off the bench onto the floor and became rigid and stiff and exhibited some rigid movement) and FALL (Patient fell off the bench onto the floor and became rigid and stiff and exhibited some rigid movement) was resolving. 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 medications taken by the patient were not provided. The reporter reported that patient never had any allergic reactions to vaccines or medications before and had no past medical histories for vasovagal reactions. After receiving the vaccine, the patient waited in the pharmacy for 15 minutes - 20 minutes. The patient fell off the bench onto the floor and became rigid and stiff and exhibited some rigid movement. The patient was out of it for 15-30 seconds.

<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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The reporter stated that she called 911. The patient came to, his eyes were huge, but he was aware to self and surroundings. The emergency team came, took the patient's vitals which were stable and stated the patient likely experienced a vasovagal effect from the needle. However, the reporter thinks it was a potential seizure; more than a vasovagal response. Emergency team offered no treatment. The emergency team had encouraged the patient to follow up with a doctor but the patient did not want to make a big scene. Emergency team offered no treatment for the patient. 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.

<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>
1291606	5/6/2021	MI	45	F	3/29/2021	4/1/2021	convulsing; Hallucinating; Fever of 104 degrees; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (convulsing) in a 45-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 023M20A and 025B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 29-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) (unknown route) dosage was changed to 1 dosage form. In April 2021, the patient experienced SEIZURE (convulsing) (seriousness criterion medically significant), HALLUCINATION (Hallucinating) and PYREXIA (Fever of 104 degrees). At the time of the report, SEIZURE (convulsing), HALLUCINATION (Hallucinating) and PYREXIA (Fever of 104 degrees) outcome was unknown. Concomitant product use was not provided by the reporter. Treatment medication included Paracetamol. Action taken with mRNA-1273 in response to the events was not applicable. 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. Fever is consistent with event safety profile.; 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. Fever is consistent with event safety profile.

<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>
1291537	5/6/2021		53	F	5/4/2021	5/4/2021	The patient is a 53yo F with history of asthma, non-epileptic seizures who on 5/4/21 received the 1st Pfizer vaccine of her vaccination series. Immediately afterward, she developed full-body shaking and SOB. She was immediately sent to the ER where she was found to have stridor but without angioedema, hypoxia, urticaria, vomiting, hypotension, or other signs of anaphylaxis. During her stay in the ER, I oversaw her care and her symptoms completely resolved after IM Epi, benadryl, famotidine, albuterol/ipratropium, steroids, and magnesium. After an observation period in the ED, she had no recurrence of symptoms and was ultimately discharged.
1291442	5/6/2021	CA	57	F	4/21/2021	4/29/2021	16 hours later chills, fever, nausea and extreme tiredness. Lasted for 24 hours. A week and one day later had an unexplainable seizure of two to three minutes and afterwards being unconscious for 25 minutes. Cat scan and MRI all normal.

<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>
1293227	5/6/2021	NM	26	F	4/20/2021	4/28/2021	26 year old nonverbal with known refractory intractable epilepsy, spastic quadriparesis cerebral palsy, developmental delay, presented to ED with the concerns of seizures by the mom. Patient was recently seen in the urgent care for UTIs. Her current AED include: Clobazam 5 mg BID, Oxcarbazepine 600 mg BID and Lorazepam 1mg qhs. Patient is being followed by Dr. in the epilepsy clinic. Patient is being admitted to neurology service due to concern for new type of seizure witnessed at home characterized by smiling and staring. Similar events captured during the evening of 4/30 are without electrographic correlate. In the setting of bowel regimen that was held due to endoscopy and worsened bowel gas pattern seen on KUB at time of admission. these new events were initially have EEG correlated abundant bursts and runs of high amplitude 5-6 Hz theta with occasional bifrontal sharp waves; multiple pushbutton events (predominantly smiling and staring) without definitive epileptiform discharge or seizure. She was initially loaded with Keppra 600 mg (20mg/kg) in the ER, and after the concerns of the EEG we Loaded with lacosamide 60mg with scheduled lacosamide 30mg BID liquid and increased Clobazam to 10mg while continuing Oxcarbazepine 600 mg BID and home Lorazepam 1 mg qhs. on 5/2/2021 no more EEG concerns of dischrages. will be discharged home and cont to follow with Dr on 5/4/2021
1291958	5/6/2021	VA	18	F	5/1/2021	5/1/2021	About 10-15 hours after injection - Came down with headache, fever, body aches, fatigue, and night sweats. Recovered fully 24 hours after injection. May 5th, 2021 ~7:30 am (4 days post-vaccination) I stood up from a seated position and then collapsed moments later and had, what my brother described as, a seizure which was followed by confusion, nausea, and fatigue.

<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>
1288950	5/5/2021	CA	20	F	5/4/2021	5/4/2021	Systemic: Seizure-Severe, Additional Details: Pharmacist was informed that she was uncomfortable with needles and blood, but had not had a severe reaction to any vaccine previously. RPh checked if she had fainted before and told her to sit for 15 minutes then will check on her and if she is lightheaded or dizzy extend to 30 minutes. RPh administered Janssen shot to patient and asked if she was okay. She confirmed then patient got up. Patient moved to another chair & started seizing. RPh and mother took care until well enough to get up.
1291314	5/5/2021			U			seizure; This is a spontaneous report from a non-contactable consumer. A patient (the consumer's cousin) 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 a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced seizure and hospitalized over a week on an unspecified date. The outcome of event, seizure was unknown. No follow-up attempts are possible; information on the lot/batch number cannot be obtained.

<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>
1291309	5/5/2021			F	3/25/2021	3/1/2021	<p>felt a little woozy/ woozy and dizzy; I began violently shaking/ tremble; I couldn't lift my foot up I had to crawl up the steps; convulsions/ seizure like shaking it is terrifying; couldn't talk; she can't walk; palsy; not being able to function like I did/ am unable to be a minister now; stuttering; This is a spontaneous report from a non-contactable consumer (patient). A 68-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on 02Mar2021 (Batch/Lot number was not reported) as single dose (dose 1) and then via an unspecified route of administration on 25Mar2021 (Batch/Lot number was not reported) as single dose (dose 2) for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient took the first shot on 02Mar2021, a few days, maybe on 2nd day or day or so after she took the shot, she went to the store and I felt a little woozy. She thought maybe she needed something to eat, but when she went to restaurant, she began to tremble and needed to get home. The patient drove slowly, when she got home, her husband was outside and she got out of the car and told him she was woozy and dizzy. She went in side and when she got to steps, she couldn't lift her foot up and had to crawl up the steps. She began violently shaking, she sat in a chair, it got worse. Her husband called the number, because she couldn't talk, like convulsions, just shaking, when Emergency people came, they took her to the hospital and she was there for 2 days. They did 2 computerized tomography (CT) scans, Magnetic resonance imaging (MRI) couldn't detect anything, but she continued with shaking and trembling. They weren't doing anything to find out what it was. One doctor said one thing the other said they didn't see anything, they sent me home. The patient was in hospital for 2 days, may have been 3 days, on 3rd day she went home (as reported). The patient went to the doctor and he sent her for other tests, but no one can determine or figure out what was going on. She didn't stutter, she was speaking normal, she was a minister. She was unable to be a minister now. She was well and doing well, then after that she can't walk, some times in bed at night, she go into shaking all over like she has palsy. She had to use a cane to walk. Some days she was feeling fine. She was still using a cane to walk and was stuttering, did not</p>

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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have her normal walk, she was afraid that she will fall. She was really trembly and shaky. Some days she can be fine, but then it comes right back. The patient stated that before she took the shot, she was fine. She is now 68 years old, she owns her own business sowing, active, walks and had no issues at all. Now, she was not able to go down stairs to sowing area and do anything. She had to use the buggy at the grocery store, because she can't walk and at night, some nights, she has a bell, her husband had to hold her from seizure like shaking it was terrifying. She had her second dose on 25Mar2021, the next day, she experienced worsening effects, she never had this shaking and not being able to function like she did before. She was concerned lthat she was having seizure and palsy, because she had never been like this. It didn't start until after the first shot was bad and after the second one, it intensified even more. The patient stated that ever since the shot, her life had changed, she had never been in this position before. She can't think of anything else, checked her medications, never had any problems. She had been to the doctor, they can't detect anything else that could have caused her to get in this condition. Nothing like this. The patient stuttering, having to think of what she has to say, she had never ever had anything like this. She wanted to reach out because it was life changing and she was afraid and have never experienced anything like this at all. It has taken away any opportunity to get a job or anything. The outcome of the events was not recovered. Information about the Lot/batch number 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>
1290768	5/5/2021	TX	21	M	3/30/2021	4/27/2021	Grand mal seizure; "extreme sluggishness; "swollen eyes, they were basically swollen shut; dark and red coloration around his eyes/his eyes were red; difficulty breathing; sore arm; fatigue; he had a high fever just by touching him, he was extremely warm to the touch.; This spontaneous case was reported by an other caregiver (subsequently medically confirmed) and describes the occurrence of GENERALISED TONIC-CLONIC SEIZURE (Grand mal seizure) in a 21-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002C21A and 020B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included ADD. On 30-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Apr-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 SLUGGISHNESS ("extreme sluggishness), EYE SWELLING ("swollen eyes, they were basically swollen shut), OCULAR HYPERAEMIA (dark and red coloration around his eyes/his eyes were red), DYSPNOEA (difficulty breathing), PAIN IN EXTREMITY (sore arm), FATIGUE (fatigue) and PYREXIA (he had a high fever just by touching him, he was extremely warm to the touch.). On 28-Apr-2021, the patient experienced GENERALISED TONIC-CLONIC SEIZURE (Grand mal seizure) (seriousness criteria hospitalization, medically significant and intervention required). The patient was hospitalized from 28-Apr-2021 to 28-Apr-2021 due to GENERALISED TONIC-CLONIC SEIZURE. On 28-Apr-2021, GENERALISED TONIC-CLONIC SEIZURE (Grand mal seizure) had resolved. At the time of the report, SLUGGISHNESS ("extreme sluggishness), EYE SWELLING ("swollen eyes, they were basically swollen shut), OCULAR HYPERAEMIA (dark and red coloration around his eyes/his eyes were red), DYSPNOEA (difficulty breathing), PAIN IN EXTREMITY (sore arm), FATIGUE (fatigue) and PYREXIA (he had a high fever just by touching him, he was extremely warm to the touch.) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood test: (Inconclusive) No results were provided. On an unknown date, Chest X-ray:

<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>
							(Inconclusive) No results were provided. On an unknown date, Computerised tomogram: (Inconclusive) No results were provided. On an unknown date, Urine analysis normal: (Inconclusive) No results were provided. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medication were reported. Treatment included Advil for fever, Maxipime, Keppra for seizure prevention and normal saline. Action taken with mRNA-1273 in response to the event 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-2021-098517, MODERNATX, INC.-MOD-2021-097451 (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. MODERNATX, INC.-MOD-2021-098517:Case for dose 1 MODERNATX, INC.-MOD-2021-097451:Cross linked case
1290719	5/5/2021	CA	64	F	3/12/2021	3/12/2021	I started to get Migraines the day of the shot. I was nauseous and I did have seizure which only happens twice a year. My seizures are not always triggered by migraine. I have a history of hives and I get reactions to bites. I decided to get the Johnson & Johnson because it seemed to be a better option. Ten days after the vaccine I had a Migraine that was so bad I had to go to the doctor. When I got there my blood pressure was high. I was given some migraine medicine, but it did not help. The migraine was there for four weeks after the shot. I still got a numbing headache after the shot until five weeks after the shot.
1290197	5/5/2021	PA	73	F	4/10/2021	4/11/2021	Cardiac arrest, seizures 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>
1290193	5/5/2021	NH	30	M	5/5/2021	5/5/2021	A few minutes after vaccine was administered, patient moved to the waiting room and we heard a bang from the waiting area. We looked over to see patient slumped over and seizing. My technician called 911 and I put a cool compress on his neck and he started to come to. The seizure stopped but the patient was still feeling lousy. I had him lay down with his knees elevated until the EMT's arrived
1289980	5/5/2021	CT	17	F	4/29/2021	5/2/2021	non-epileptic seizures onset 3 days after 2nd dose. 5-6 hours in the ER, trying to figure out if it was epilepsy, then 48 hours of observation once valium was given to calm the muscle spasms down. 5-5-2021 patient still has seizures less frequently, but they still occur. patient did not have these prior to 2nd dose of vaccine.
1289506	5/5/2021	MI	18	F	5/5/2021	5/5/2021	Patient was waiting the 15 minutes after her vaccination and lost consciousness. She began to shake slightly which concerned me and we called 911. She came to within a minute and was aware of her surroundings. She stated she felt ok but her head hurt from hitting the floor. We gave her an ice pack for her head. After about 5 minutes she got back in the chair and was here until EMS arrived. While they were there questioning her she lost consciousness again two separate times and displayed potential seizure activity again. They put her on the stretcher and took her to the hospital. She reported she has not had seizures in the past but has fainted from a vaccination in the past but was younger and received 3 immunizations.
1289195	5/5/2021	OH	42	M	5/4/2021	5/5/2021	Seizure

<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>
1291322	5/5/2021	WI	40	M	4/14/2021	4/14/2021	Had seizures and ended up in emergency room; Had seizures and ended up in emergency room; scar in left arm/scar in his left arm before he had a seizure; 'he could feel a bump, it was like a bump in there. So, it was between his armpit his heart where he felt the bubble; This is a spontaneous report from a contactable consumer (parent). A 40-year-old male patient received the second dose of BNT162B2 (lot number and expiry date were not reported), via an unspecified route of administration, administered in left arm on 14Apr2021 (at the age of 40-year-old) as single dose indicated to prevent from Corona virus (Covid-19 Immunization). Medical history included seizures and gout. The patient's concomitant medications included unspecified medication for seizures. The patient previously received the first dose of BNT162B2 (lot number: ER8730) on 24Mar2021 for Covid-19 Immunization. The patient got the second Pfizer shot later this month, left the office, 45 minutes later (on 14Apr2021) he had seizures and ended up in emergency room. He has had small seizures but they are not back to back, of and on throughout the years and now we are saying that maybe COVID Vaccine shot is what provoked him to, what made him had seizures. Reporter stated, even though he has had seizures in the past like it could be 2, 3 years apart for one. But the shot it caused him to have another seizure, but he is not going to continue to have seizures, as he is on medication (unspecified medication) right now. But the medication is on, if they take him off it, he could have multiple seizures constantly (name of medication not clarified further). Also on 14Apr2021, the patient also had a scar in left arm, it is another symptom he had. He had the scar in his left arm before he had a seizure, he said over here between his heart and his arm felt like a (incomplete sentence), now they don't know if he had a one scar or what it says but he says that 'he could feel a bump, it was like a bump in there. So, it was between his armpit his heart where he felt the bubble' (not clarified further). The patient underwent laboratory test which included: blood work, a urine sample and they did a CAT scan to see knowing the problem in his brain, all on 14Apr2021 with unknown result. The day of the test was on the 14th, it would have been on a Wednesday. It was the same day that he got the second shot. So, he had these test done on 14Apr (14Apr2021). Reporter confirmed of getting the test

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1288956	5/5/2021	CA	20	F	5/4/2021	5/4/2021	<p>results on Thursday, so did not have the details. Therapeutic measures were taken as a result of seizures which included Levetiracetam 500 mg tablet, he takes one tablet twice a day, so he takes two tablets a day. This was ordered by his doctor in emergency room. The outcome of the events was unknown. Information on the lot/batch number has been requested.</p> <p>Systemic: Seizure-Severe, Additional Details: Patient seized for 1-2 minutes after being given vaccine. Pharmacist had patient sit/lay down for 30 minutes and mother took care of patient until she recovered. Pharmacist checked in every 10 minutes. Patient was offered but did not request any ambulance or further medical assistance.</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>
1291311	5/5/2021	OH	16	F	4/2/2021	4/17/2021	<p>This is a spontaneous report from a contactable consumer (patient's father) via Medical Information team. A 16-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration, administered in the right arm on 02Apr2021 at 10:15 (batch/lot number and expiration date were unknown) as a single dose for COVID-19 immunization. The vaccination facility type was reported as a "drive thru COVID-19 vaccine clinic." The patient's parents thought it was best for the patient to take the Pfizer COVID-19 vaccine, since she was eligible to get it so she would be protected. Relevant medical history included acne on the face from an unknown date and unknown if ongoing. Concomitant medication included isotretinoin taken for acne on the face, which she took for almost 3 months from an unspecified start date to 19Apr2021. The patient had no history of previous immunization with the Pfizer vaccine, since this was her first dose. There were no additional vaccines administered on the same date of the Pfizer suspect vaccine. The patient had no prior vaccinations (within 4 weeks) and had no adverse events (AEs) following prior vaccinations. The patient had no family medical history relevant to the AEs. On 17Apr2021 at about 16:15 in the afternoon, the patient experienced seizure. It was further reported that the patient had a side effect after receiving the Pfizer COVID-19 vaccine; the patient had a seizure 15 days after receiving the vaccine. The reporter was asking if seizure had been reported with the vaccine. The reporter had no idea for sure if it was the vaccine, but he wanted to let Pfizer know. The reporter was hoping the patient would be okay and it won't happen again. The patient would see her physician at the time of the report on 21Apr2021 in a few hours. They would listen to the doctor at the appointment, and they had an appointment with the neurologist to see if she should get the second dose on Friday. They didn't know yet. The reporter didn't have the vaccination card with him. The patient had no conditions other than this event. The patient went to the emergency room for the event on an unspecified from which she had blood tests, urine tests, and a computerized axial tomography (CAT) scan of her brain and they said they couldn't find anything wrong at that time. They needed to follow up with the hospital in the</p>

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1288886	5/5/2021	FL	37	M	5/4/2021	5/4/2021	area to see a neurologist, which they would be doing the following day. They told them to follow up with the neurology department at their Hospital and told them until they find out more information; the patient could do what she needed to do, but she couldn't drive a car. The reporter asked if Pfizer has had any reports of this and wondered if there had been other reports of seizures. The outcome of the event was unknown. Information on the batch/lot number has been requested.
1288875	5/5/2021	NY	33	F	3/11/2021	3/19/2021	Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Headache-Mild, Systemic: Seizure-Mild, Systemic: Shakiness-Medium, Additional Details: About 5 minutes after the shot, the patient lost consciousness, fell face forward on the ground. Face appeared grey, was unresponsive, but was making grunting sounds. His body appeared to be shaking lightly, possible seizure, was not responsive. Oral benadryl was not possible at this point. Turned patient on back/side in order to administer the epipen. Patient quickly became alert and responded. No injection site reaction. Paramedics arrived shortly to check vitals and transfer him
1288731	5/5/2021	MD	77	F	4/30/2021	4/30/2021	Found to be COVID-19 positive, altered mental status and symptomatic with O2 requirement. Treated with one 200mg dose of remdesivir and dexamethasone 6mg IV daily x 5 days. Oxygen delivered via nasal cannula and SO2 remained over 90% (and mostly over 95%) the entire admission. Acute encephalopathy and Seizure, possible, post-dialysis versus dialysis disequilibrium syndrome occurred during this admission and was the reason for time spent in the ICU (~24 hours).
							presented to local ED lethargic, disoriented and unable to provide clear history on evening of 5/1/21 with severe frontal headache and increasing lethargy throughout the day. Admitted to hospital with suspected subacute stroke. Overnight developed LT sided weakness and RT gaze. Transferred to another healthcare facility on 5/3/21 with suspected seizure / encephalitis.

<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>
1288455	5/5/2021	NJ	44	F	4/9/2021	4/10/2021	Seizure; This is a spontaneous report from a contactable consumer. A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration on 09Apr2021 (Batch/Lot number was not reported) as single dose for COVID-19 immunization. The patient had no medical history. The patient had 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) on an unspecified date. The patient experienced seizure on 10Apr2021. The patient had no other vaccine in four weeks. The patient was tested for COVID post vaccination. The patient underwent lab tests and procedures which included nasal swab: negative. Therapeutic measures (medication and follow-up treatment) were taken as a result of seizure. The outcome of the event was not recovered. The event was reported as serious-hospitalized, disability, life-threatening.

<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>
1288416	5/5/2021	PA	17	M	4/17/2021	4/17/2021	increased seizure activity/mini seizures; increased seizure activity/mini seizures; confusion and memory issues; confusion and memory issues; fatigue/tired; This is a spontaneous report from a contactable consumer. A 17-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 17Apr2021 09:00 (Lot Number: EW1064) as SINGLE DOSE (at age of 17 years old) for covid-19 immunisation. Medical history included epilepsy (interactable epilepsy) from an unknown date and unknown if ongoing. There were no concomitant medications. Historical vaccine information included BNT162B2 dose 1 on 25Mar2021 09:00, lot number as ER8733, in the left arm for COVID-19 immunisation(at age of 17 years old). On 17Apr2021, the patient experienced increased seizure activity, fatigue/tired, confusion and memory issues. After the 2nd shot, about 4-5 hours, he experienced increased seizure activity and it has progressed to today, today he is a little bit better but it has progressed to point he is having a lot of confusion and memory issues. He has several different types of seizures but he has what are called mini seizures, the blank stare, the confusion. Nothing has stopped completely, he isn't back to his baseline as far as his seizures. He always has seizures, daily so she is calling about the increased activity and when she says his baseline she means he has not returned back to his baseline activity, but he is doing better than yesterday. Saturday, Sunday, and Monday were horrible. Today he started to get back to his normal self. The events did not require a visit to the Emergency Room or Physician Office. Outcome of the increased seizure activity/mini seizures, confusion and memory issues were recovering. Outcome of fatigue/tired were not recovered.

<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>
1288407	5/5/2021	CO	59	M	3/31/2021	3/31/2021	<p>Extreme fatigue; brain fog; Passed out; Told possible seizure; Felt ill shortly after receiving shot; Threw up; This is a spontaneous report from a contactable consumer (the patient) and then from a contactable consumer (the patient's wife). A 59-year-old male patient received the first dose of BNT162B2 (lot number not provided), via an unspecified route of administration in the left arm on 31Mar2021 10:00 (at the age of 59-years-old) as a single dose for COVID-19 immunization. The patient had no medical history. The patient did not have any known allergies. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included: fish oil (OMEGA 3 FISH OIL). The patient did not receive any other vaccines within four weeks prior to the vaccination. On 31Mar2021, the patient felt ill shortly after receiving the shot. Told to sit down. Passed out. Awoke on the floor. Told possible seizure. Sat up. Threw up. Told to lie back down. Ambulance came and took him to the hospital. He spent 90 minutes in the Emergency Room. He was unable to work for a couple of days. He had extreme fatigue and brain fog. He was not back to relatively normal for at least 10 days. Treatment received was reported as yes: ran tests including 3 EKGs, on an unspecified date. The outcome of the events was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. Information on the lot/batch number has been requested.</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>
1288401	5/5/2021	MD	53	M	4/19/2021	4/19/2021	Seizure; No recollection of anything that happened between 2000 and 2100 hours; Very foggy, not thinking properly, repetitive in what he was saying; Very foggy, not thinking properly, repetitive in what he was saying; Very foggy, not thinking properly, repetitive in what he was saying; Not comprehending; He was very cold; Very tired; Very Sweaty; Headache; This is a spontaneous report from a contactable consumer (Patient's wife). A 53-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration on 19Apr2021 12:30 (Lot Number: EW0164) as SINGLE DOSE (at age of 53 years old) for covid-19 immunisation. Medical history included ongoing epilepsy diagnosed with this when he was 15 years old, seizure from an unknown date and unknown if ongoing (then at 2015 he had a seizure). Concomitant medications included levetiracetam (KEPPRA) 1250 mg, daily (250mg; 5 pills a day) taken for epilepsy from an unspecified start date and ongoing; carbamazepine (CARBAMAZEPINE) 1000 mg, daily (200mg; 5 pills a day) taken for an unspecified indication from an unspecified start date and ongoing. Family Medical History Relevant to events was none. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 19Apr2021, the patient experienced seizure, Very foggy, not thinking properly, repetitive in what he was saying, very distant, like he was looking at his wife but not seeing her or hearing her, Headache, He was very cold, Very tired, Not comprehending, Very Sweaty, No recollection of anything that happened between 2000 and 2100 hours. The patient received his vaccine yesterday 19Apr2021 at 1230. On 19Apr2021 by 1500 he was very foggy, not thinking properly, and repetitive in what he was saying. He was very distant, like he was looking at the consumer but not seeing her or hearing what she was saying. He was very cold, very tired, and not comprehending. Then at 2015 he had a seizure. She called the paramedics, her husband was very sweaty on 19Apr2021 and that point and had no recollection of anything that happened between 2000 and 2100 hours. Patient was not taken to the Emergency Room or admitted to the hospital. Her husband is completely aware and recovered now. Consumer reported on 19Apr2021 he had a headache that is persisting since the seizure. The consumer

<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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reported that her husband is epileptic, but he hasn't had a seizure in over 10 years and hasn't missed any doses of his medication. Patient was evaluated by the Paramedics that came to his home but was not taken to the Emergency Room. Relevant Tests were none. Outcome of Seizure was Recovered/Resolved with Sequel on 19Apr2021. Outcome of Very foggy, not thinking properly, repetitive in what he was saying, He was very cold, Very tired, Not comprehending, Very Sweaty was recovered on 19Apr2021. Outcome of headache was not recovered. Outcome of No recollection of anything that happened between 2000 and 2100 hours was unknown.

<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>
1288377	5/5/2021	TX	70	F	2/26/2021	3/1/2021	seizures; This is a spontaneous report from a contactable consumer (Patient's husband). A 70-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), at the age of 70-year-old via an unspecified route of administration, administered in Arm Left on 26Feb2021 (Lot Number: EN6203) as single dose, second dose of BNT162B2 via an unspecified route of administration, administered in Arm Left on 19Mar2021 (Lot Number: EN8727) as single dose both for covid-19 immunisation. Medical history included High blood pressure, atrial fibrillation. No family medical history. No prior vaccination within 4 weeks. Ongoing Concomitant medications included rivaroxaban (XARELTO); losartan taken for hypertension; hydrochlorothiazide taken for blood pressure abnormal, fluid imbalance; diltiazem hydrochloride (CARTIA XT) taken for atrial fibrillation; loratadine. After the first shot, about a week and a half later, she started having seizures in Mar2021. Since the second shot, it had gotten worse. The event resulted in Emergency Room visit. She was taken in twice. The first time, she was in the hospital for 4 days. This occurred last month, in Mar2021. After the second dose, she had been hospitalized, the end of March, almost April. They took her twice. The first time, they did a bunch of tests and were questioning seizure or a stroke. At the end, they thought it was a seizure. She then came home and had it worse. They put her on medication. The patient underwent lab tests and procedures which included tests: all were negative, computerised tomogram: unknown results, electroencephalogram: unknown results, magnetic resonance imaging: unknown results all in Mar2021. The events outcome was not recovered.

<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>
1288371	5/5/2021	PA	38	F	4/1/2021	4/2/2021	demyelination with brain inflammation; demyelination with brain inflammation; seizures; Fever; 2 seizures fever vomiting and demyelination with brain inflammation; This is a spontaneous report from a contactable consumer (patient). A 38-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route on left arm single dose for COVID-19 immunisation on 01Apr2021, 06:45 PM, at 38-year-old. Medical history included: diabetes and hypertension; known allergies: penicillin. No other vaccine in four weeks and no other medications in two weeks. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) for COVID-19 immunization on unknown date, 06:45 PM, at 38-year-old. On 02Apr2021, the patient had 2 seizures, fever, vomiting and demyelination with brain inflammation. Emergency room/department or urgent care visited and hospitalization for 10 days. Treatment included: plasma exchange, steroids, fluids and IV antibiotic. Lab data included: negative COVID test on 02Apr2021. Outcome of the events was resolving. Information about lot/batch number has been requested.
1288069	5/5/2021	CA	29	F	4/1/2021	4/1/2021	Pale/unresponsive approx. 1 min after receiving vaccine. Appeared to have a seizure. After about 5-7 min appeared to improve. Reported after event that she had hx of "vasvagsals". Transported to local hospital for further assessment.
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.

<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>
1291245	5/5/2021	NC	17	M	5/5/2021	5/5/2021	Passed out and had seizure lasting 45-60 seconds.
1285417	5/4/2021	VA	71	F	4/14/2021	4/24/2021	Arm was sore and difficult to move for 24 hours. 10 days after getting the shot my disabled young adult patient who is 29 years of age developed Herpes Zoster shingles as diagnosed by the hospital requiring anti viral meds valtrex, gabapentin and atarax for 7 days. She is non vocal with Phelan Mcdermid syndrome, Autism spectrum disorder, generalized seizures, developmentally delayed at 18 months, intellectual disorder. Prior to this her care givers were given Moderna vaccine and she experiences stroke symptoms and was admitted to hospital for 4 days her brain and ct scan were all negative and she was given physical therapy due to dragging her right leg and inability to move her arms. She does have coordination issues and weak muscles with the PMS. I am of the opinion the vaccines contributed to her symptoms. Please see the magazine article I researched. April 28, 2021. My daughter did not get the vaccine and I did not take the 2nd vaccine of pfizer due to this and alerted the infectious disease provider at the Medical Center along with my primary provider.

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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.
1286147	5/4/2021	NJ	31	M	5/4/2021	5/4/2021	Shortly after the administering the vaccine the person tensed up and became unresponsive. He appeared to be having a seizure. I was able to get the patient to the floor and he became responsive. He said he "was ok". We had contacted EMS. We had the patient lie flat until the EMT's arrived. He was very sweaty and tired but he insisted he was fine. He refused to go to the ER and he was able to get a ride home.
1286376	5/4/2021	OH	63	F	4/7/2021	4/18/2021	seizure

<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>
1286704	5/4/2021	IA	20	F	4/9/2021	4/9/2021	Shortly after receiving the Janssen vaccine, patient complained of shakiness and hot. Has history of migraines, Cerebral Palsy with brain injury at birth sustained. At 1 pm, BP=160/100, Pulse=71 and regular. Sp O2 reading 100% on room air. She was concentrating on not succumbing to seizure possibly and by 1:06 pm, her blood pressure is 140/80 and feeling better. Was stating she was feeling better and blood pressure was 140/80. Encouraged to drink 2 water. She was able to ambulate with friends after 30 minutes of recovery. Encouraged to drink fluids and rest.
1285946	5/4/2021	WI	58	F	3/24/2021	4/1/2021	Suffered several seizures in the weeks following the administration of first dose.
1287368	5/4/2021	OR	26	M	4/30/2021	5/4/2021	Seizure 3-4 days after injection. Patient currently admitted to hospital for observation.
1286810	5/4/2021	CA	24	M	4/24/2021	4/24/2021	AFTER THE PT RECEIVED THE VACCINE, HE CAME TO REGISTER TO SIGN FOR IT. THEN HE WAS TOLD TO SIT FOR 15 MINUTES TO MAKE SURE HE DOESNT HAVE ANY ALLERGIC OR ADVERSE REACTIONS. HE WAS LOOKING AROUND THE STORE WHEN HE ALL OF THE SUDDEN HAD SEIZURE AND FELL ON THE FLOOR. WE CALLED EMS RIGHT AWAY HOWEVER HE WOKE UP AND BOTH HIM AND HIS FRIEND TOLD US TO DISCONNECT WITH EMS. HIS FRIEND TOLD US THAT HE HAS EPILEPSY AND HE HAS EPISODES LIKE THIS TIME TO TIME. THE PT EXPERIENCED SOME CUTS ROUND HIS FORHEAD AND HIS (L)EYEBROW WHICH WE HELPED CLEAN UP WITH DISINFECTANT AND BANDAID. AFTER HE LEFT WITH HIS FREIND (WHO WAS THE DRIVER), WE FOLLOWED UP WITH HIM AND HIS FREIND AND THEY SAID HE IS DOING WELL.
1286876	5/4/2021	FL	53	F	1/4/2021	1/12/2021	On January 12 around 10:50 PM, patient began convulsing in her sleep similar to a seizure and lightly foaming at the mouth. By 11:20, police and emergency services had arrived and moved her into an ambulance for transport to a hospital. She stopped convulsing by about 11:20 but did not seem to become conscious until they arrived at the hospital around 11:50

<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>
1285671	5/4/2021	WV	16	M	4/16/2021	4/19/2021	Patient was given dose #1 at a vaccine community clinic on Friday. There were no reports of him being ill. Parents were present at the time of the vaccine. He went to school on Monday and had a seizure and was transported to hospital. He was placed on life support and was unresponsive. He began improving and was taken of life support on Wednesday and was discharged after a few days.
1285656	5/4/2021	OR	18	F	5/1/2021	5/1/2021	for 18 y.o. woman who experienced a 10-15 second seizure in observation area. No trauma. Found to have low CBG, history of anemia. No seizure disorder. Alert and talking while waiting for transport.
1285629	5/4/2021	CA	75	M	4/19/2021	4/23/2021	SEIZURE 4 DAYS POST VACCINE.
1285492	5/4/2021	CA	47	M	4/30/2021	4/30/2021	C/O SYNCOPE, SEIZURE ACTIVITY X 20 SECS, NAUSEA, NO HX PRIOR ALLERGIES, PROVIDED WATER AND SNACK, SX RESOLVED, NO TRANSPORT.
1285794	5/4/2021	NJ	71	F	4/5/2021	4/23/2021	Dural venous sinus thrombosis complicated by intracranial hemorrhage and seizure
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.
1285183	5/4/2021	MD	23	M	5/3/2021	5/3/2021	Systemic: Chills-Severe, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe

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1284804	5/4/2021	CA		F	3/26/2021	3/27/2021	Seizures; lost consciousnesses; vertigo; This is a spontaneous report received from a contactable consumer (patient). A 49-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 26Mar2021 (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 vertigo the following morning (27Mar2021) after the first dose. It was "positional vertigo" and not something that patient have on a regular basis but usually when it did happen, she went to the ear specialist and the Epley maneuver was done and resolves it. Patient have been having issues with vertigo since the first dose. She also developed a seizure, 11 days after the first dose. On 06Apr2021, she apparently had a seizure and have no history of seizures. Patient apparently lost consciousnesses and drove slowly and hit a pole. They had to break the window to get patient out of the car and she didn't remember any of it. It had to be less than an hour that I was out; from the time recorded on the incident report and patient waking up in the ER room and looking up at the clock in the room, it was under an hour. The outcome of event vertigo was recovered in 2021, the outcome of other events was unknown. Patient received the second dose on Friday, 16Apr2021. No follow-up attempts are possible, information about batch number cannot be obtained.

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1284735	5/4/2021	NY	64	F	3/4/2021	3/6/2021	<p>Angioedema; Shock; stridor; dry cough; Hoarse voice; Sneezing; Rhinorrhea; Dizzy; nausea; Hypotension; Weakness feeling; Generalized erythema; Generalized pruritus with skin rash; Generalized pruritus with skin rash; Diarrhoea; Vomiting; Throat closed in; the sides of the throat, down my neck , straight over my chest felt as if someone was squeezing me, chest felt heavy; Potential anaphylactic reaction; Difficulty breathing; severe brain fog; Severe chest pain hard to breath felt as if being smothered; difficult to sleep nights before as felt wired after the shot; bp slightly elevated 140/80; Became very groggy; eyes heavy, had about 3 sleep attacks; 3 sleep attacks; This is a spontaneous report from a contactable Health Care Professional (patient). A 64-year-old non-pregnant female patient received the first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, Lot Number: EN4206) at single dose, intramuscularly, in the left arm, on 05Mar2021 at 10:00 AM, for COVID-19 immunization. The patient also received hylan g-f 20 (SYNVISC), via an unspecified route of administration, in knee, on 04Mar2021, at single dose, for an unspecified indication. Relevant medical history included narcolepsy from an unspecified date, in 1973, cataplexy from an unspecified date, complex regional pain syndrome (CRPS) from an unspecified date, in 2003, osteoporosis from an unspecified date, gastroesophageal reflux disease (GERD) from an unspecified date, hypertension from an unspecified date and arthritis from an unspecified date, in 2003. Concomitant medications included methylphenidate hydrochloride (RITALIN), imipramine, baclofen, atenolol, rosuvastatin calcium (CRESTOR), ezetimibe (ZETIA), imipramine hydrochloride (TOFRANIL), montelukast sodium (SINGULAIR), acetylsalicylic acid (BABY ASPIRIN) and clonidine, all taken for an unspecified indication, start and stop date were not reported. The patient reported allergy for drugs like lisinopril, spiro lactone, ghb (gamma-Hydroxybutyric acid), epinephrine and all seizure type medications. The patient became very groggy, felt eyes heavy, had about 3 sleep attacks, on 06Mar2021, at 13:00. Also reported difficulty to sleep nights before as felt wired after the shot (insomnia) and bp was slightly elevated 140/80 on 07Mar2021. On 27Mar2021 at 13:00, throat closed in, felt the sides of the throat, down her neck, straight over her chest felt as if someone was</p>

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squeezing her, chest felt heavy (severe chest pain hard to breath, felt as if being smothered, throat closing in severe chest heaviness). Severe brain fog. Potential anaphylactic reaction and difficulty breathing were reported. On an unspecified date, the patient experienced angioedema, shock, stridor, dry cough, hoarse voice, sneezing, rhinorrhea, dizzy, nausea, hypotension, weakness, generalized erythema, generalized pruritus with skin rash, diarrhoea and vomiting. Decrease level of consciousness and loss of consciousness were not reported. The patient underwent lab tests and procedures which included oxygen saturation: normal on 06Mar2021 and blood pressure measurement: 140/80, slightly elevated, heart rate: 99, respiratory rate: 20 on 07Mar2021. The patient was not hospitalized and was not admitted to an Intensive care unit. The patient did not have COVID prior to vaccination and the patient did not test COVID post vaccination. The patient recovered from throat constriction, chest heaviness, potential anaphylactic reaction and difficulty breathing. Clinical outcome of angioedema, shock, chest pain, stridor, dry cough, hoarse voice, sneezing, rhinorrhea, dizzy, nausea, hypotension, weakness, generalized erythema, generalized pruritus, skin rash, diarrhoea and vomiting was unknown. Outcome of the other events was reported as recovering. Follow up attempts are completed. No further information is expected. Follow up (26Mar2021): New information received from a contactable Health Care Professional includes: adverse events added, clinical course and case seriousness updated from non-serious to serious. Follow-up (20Apr2021): New information received from a contactable Health Care Professional includes: medical history, concomitant medications details and additional adverse events added (Potential anaphylactic reaction and difficulty breathing added as additional adverse events). Follow-up attempts are completed. No further information is expected.; Sender's Comments: Based on known safety profile and/or temporal association, the contribution of the suspect drug to the onset of serious 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

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1285414	5/4/2021	MA					
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						4/26/2021	
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this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

Case had Covid-19 dx on 3/18/21. No SXS. Had Janssen vaccine administered on 4/7/21. Approx 2 wks later c/o fevers and a seizure on 4/26/2021. Was eval in medical facility then at another for seizure. Her fever was 102.7 about 1 hr prior to her seizure.

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1284735	5/4/2021	NY	64	F	3/4/2021	3/6/2021	<p>Angioedema; Shock; stridor; dry cough; Hoarse voice; Sneezing; Rhinorrhea; Dizzy; nausea; Hypotension; Weakness feeling; Generalized erythema; Generalized pruritus with skin rash; Generalized pruritus with skin rash; Diarrhoea; Vomiting; Throat closed in; the sides of the throat, down my neck , straight over my chest felt as if someone was squeezing me, chest felt heavy; Potential anaphylactic reaction; Difficulty breathing; severe brain fog; Severe chest pain hard to breath felt as if being smothered; difficult to sleep nights before as felt wired after the shot; bp slightly elevated 140/80; Became very groggy; eyes heavy, had about 3 sleep attacks; 3 sleep attacks; This is a spontaneous report from a contactable Health Care Professional (patient). A 64-year-old non-pregnant female patient received the first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, Lot Number: EN4206) at single dose, intramuscularly, in the left arm, on 05Mar2021 at 10:00 AM, for COVID-19 immunization. The patient also received hylan g-f 20 (SYNVISC), via an unspecified route of administration, in knee, on 04Mar2021, at single dose, for an unspecified indication. Relevant medical history included narcolepsy from an unspecified date, in 1973, cataplexy from an unspecified date, complex regional pain syndrome (CRPS) from an unspecified date, in 2003, osteoporosis from an unspecified date, gastroesophageal reflux disease (GERD) from an unspecified date, hypertension from an unspecified date and arthritis from an unspecified date, in 2003. Concomitant medications included methylphenidate hydrochloride (RITALIN), imipramine, baclofen, atenolol, rosuvastatin calcium (CRESTOR), ezetimibe (ZETIA), imipramine hydrochloride (TOFRANIL), montelukast sodium (SINGULAIR), acetylsalicylic acid (BABY ASPIRIN) and clonidine, all taken for an unspecified indication, start and stop date were not reported. The patient reported allergy for drugs like lisinopril, spiro lactone, ghb (gamma-Hydroxybutyric acid), epinephrine and all seizure type medications. The patient became very groggy, felt eyes heavy, had about 3 sleep attacks, on 06Mar2021, at 13:00. Also reported difficulty to sleep nights before as felt wired after the shot (insomnia) and bp was slightly elevated 140/80 on 07Mar2021. On 27Mar2021 at 13:00, throat closed in, felt the sides of the throat, down her neck, straight over her chest felt as if someone was</p>

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1284433	5/3/2021	CO
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4/5/2021

5/3/2021

this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

4-5-21 vomiting ,headache 4-6-21 spine pain , headache cont ,vomiting 4-7-21 spine pain , headache cont ,vomiting reaction to morphine and oxy (anaphalactic shock) x 2 er visits 4-8-21 spine pain , headache cont ,vomiting, seizures/ trimmers ,confussion/memory loss ,bladder incont. numb and teng in right side face and arm. facale swelling and drooping Er Visit 4-9-21 spine pain , headache cont ,vomiting, seizures/ trimmers ,confussion/memory loss ,bladder incont. numb and teng in right side face and arm. facale swelling and drooping 4-10-21 spine pain , headache cont ,vomiting, seizures/ trimmers ,confussion/memory loss ,bladder incont. numb and teng in right side face and arm. facale swelling and drooping ER 4-11-21- 4-14-21 spine pain , headache cont ,vomiting, seizures/ trimmers ,confussion/memory loss ,bladder incont. numb and teng in right side face and arm. facale swelling and drooping 4-14-21 spine pain , headache cont ,vomiting, seizures/ trimmers ,confussion/memory loss ,bladder incont. numb and teng in right side face and arm. facale swelling and drooping went to my PCP she sent me staright to hospital due to facial drooping and swelling in Face and convosiont/trimmeres. 4-22-21 spine pain , headache cont ,vomiting (min), seizures/ trimmers ,confussion/memory loss ,bladder i numb and teng in right side face and arm. facale swelling and drooping Fallow up with pcp waiting to see nerology for seizure activity 4-23-21-5-2-21 spine pain , headache cont ,vomiting, seizures/ trimmers ,confussion/memory loss . numb and teng in right side face and arm. facale swelling and drooping

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1281454	5/3/2021	NY	42	M	5/2/2021	5/3/2021	Pt had some pain in his right arm and fever after taking the vax. Next day he woke up, went to the wash room and then had a seizure. His father gave him a cold compress and provided him with water and extra seizure medicine. His father called the Neurologist. He was told to give him some Tylenol for his fever and extra seizure meds if needed and to FU w/ an office appt if he has another seizure. It had been more than a year since he has had a seizure but had one on 4/14/21 that was 3 days after taking the 1st Covid Vax.
1281657	5/3/2021		22	F	5/3/2021	5/3/2021	Dizziness and vasovagal episode. Hx of vasovagal and seizure x1. Patient went decorticated and immediately awoken after ammonia given.
1281869	5/3/2021	FL	43	F	5/3/2021	5/3/2021	two seizure episodes. patient was coherent before, between and after
1282311	5/3/2021	NY	33	M	4/5/2021	4/26/2021	Patient presented w/ loss of consciousness on 4/26. Initial workup negative. Pt then had a witnessed seizure requiring intubation for airway protection. After extubation on 4/29, patient was noted to have profound leg weakness out of proportion to brief intubation. Infectious and neurologic workup negative for transverse myelitis. Thought to be possibly auto-immune Guillain-Barre like peripheral neuropathy. Started on plasma exchange with immediate good response.
1282675	5/3/2021	NY	46	F	4/22/2021	4/23/2021	Seizure
1283764	5/3/2021	SC	38	F	5/3/2021	5/3/2021	Patient received dose in right arm with no complications. However, about 1-2 minutes after vaccination patient reported feeling lightheaded. As I was instructing her to remain seated, she passed out and was unresponsive. She appeared to be having a seizure immediately after that lasted about 1 minute. Once this episode passed, she became responsive and could talk. EMS arrived and took over.
1284447	5/3/2021	NC	52	F	4/2/2021	4/28/2021	Reduced immune system, potential. Strep throat infection required 4 antibiotics to resolve. Immediately followed by new onset seizures.

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1286893	5/3/2021	AS	31	F	4/10/2021	4/11/2021	At 22 hr mark, had a seizure and began vomiting. Vomiting continued throughout the day. No fever or other adverse symptoms besides the vomiting. Went to bed at 10pm with low grade fever (100). Had a complicated seizure at 10:56pm, incontinent, grossly disoriented and agitated, garbled language. Called 911. Then drove my daughter to local hospital, to ED, just prior to midnight. Discharged 4/12/21 (about 3 hrs at ED)
1281231	5/3/2021	MN	17	F	5/2/2021	5/2/2021	Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Seizure-Medium, Systemic: Vomiting-Mild
1280979	5/3/2021	CA	18	F	4/28/2021	4/28/2021	Pt had a seizure, vomited about 7 hours following vaccine
1279812	5/2/2021	NY	26	M	5/1/2021	5/1/2021	Systemic: Seizure-Severe, Additional Details: within 5 minutes after administration, he collapsed, lost consciousness and had a seizure which lasted 30-40 seconds. we protected his head and laid him flat on ground and called 9-1-1. he maintained breathing and pulse throughout. when EMTs arrived he walked out with them for further evaluation.
1280794	5/2/2021	VA	16	M	5/2/2021	5/2/2021	Patient came into the immunization room for his shot along with his mom. He did state he hated needles, but was in good spirits. He got the shot, I filled out his card, and directed him and his mom to sit in the waiting area for 15 mins in case of dizziness or a reaction. They were walking out of the room to the waiting area and he almost immediately fainted. He fell and possibly hit his head on the chair/ floor when he went down. (This was maybe 2 mins post-injection). He almost looked like he was going to have a seizure (arms were tensed up, his eyes were not focused, was starting to shake) but then he suddenly came-to. He seemed to be pretty coherent after he woke back up but 911 was called since he was bleeding

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1279809	5/2/2021	MD	29	M	5/1/2021	5/1/2021	Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Body Aches Generalized-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Seizure-Severe, Systemic: Shakiness-Severe, Systemic: Tachycardia-Severe, Systemic: Tingling (specify: facial area, extremities)-Severe, Systemic: Visual Changes/Disturbances-Medium, Systemic: Weakness-Severe
1279824	5/2/2021	MN	34	M	5/1/2021	5/1/2021	Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Additional Details: Patient received vaccine, went out to sit on chair in waiting area. Leaned over and passed out, pharmacist ran out to patient, bystander helped lower patient to ground, all the while the patient was breathing very heavily, sounded seizure like or that he was gasping for breath. Asked tech to call 911. While being lowered to ground patient regained consciousness. Mother came around the corner and stated patient has history of reacting this way to vaccines, neither pt nor mom told us this before.
1279904	5/2/2021		83	F	3/8/2021	4/8/2021	Pt admit 4/8/21 2' suspected TIA or stroke vs seizure disorder. Encephalitis (MRI+) post-Moderna COVID-19 Vaccine 2nd dose 3/8/21. Started on IVIG x5 doses and prednisone, along with seizure meds for tx. Temporary pacemaker placed 4/13 (HR=32). Pt with improved mentation post-tx and sx. Discharged home stable 4/19.
1280207	5/2/2021	NV	71	M	2/1/2021	4/7/2021	Awoke unable to breathe, severe weight in right lung. Called Clinic, advised to go to ER at Hospital. Chest CT showed multiple pulmonary embolli in both lungs-placed on Eliquis. 19 days later had severe nausea, vomiting, fainting. Clinic nurse again advised going to ER where cerebral hemorrhage was diagnosed. Patient life flighted to Hospital. Eliquis discontinued, Keppra started to prevent seizures. In ICU 4/26-28, released to home.

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1280277	5/2/2021	CA	16	F	5/2/2021	5/2/2021	Patient passed out with associated convulsions within 2 minutes of vaccine being administered. No previous Hx of this post vaccination but did occur once after donating blood. Patient was lowered to flat position on floor.
1280300	5/2/2021	PA	47	M	3/6/2021	3/20/2021	Developed petichiae on 3/20. Labs drawn 3/22 showed Platelets of 20,000. Started 150mg prednisone 3/29. Neurological symptoms that week. Seizure and brain bleed noted on 4/3. Intubated and transferred from local hospital to neuroscience hospital.
1280450	5/2/2021	CA	17	M	5/2/2021	5/2/2021	5 second seizure activity.
1280879	5/2/2021	HI	22	M	5/2/2021	5/2/2021	Patient was administered the Janssen COVID vaccine at 403 pm. I returned back to the pharmacy to prep his partner's vaccine and when I came back at 405 pm, he was loopy with his head swaying. He wasn't responding to verbal communication by his spouse and me nor through touch as I shook his shoulder. He then lost consciousness and so I lifted his head to check for breathing and pulse which he had. I asked my technician to call 911, and asked my other tech to help me transition him to the floor so we can raise his legs to provide blood flow to his head. Mid-transition, he had a seizure. We brought him completely to the floor and just as I was about to turn him to his side, he regained consciousness. Pupils were dilated, breathing normal, pulse elevated. He also was able to speak immediately and confirmed feeling "okay". I then had my technician remain outside with him laying on the ground as I returned back inside the pharmacy to call management and my technician was still on the phone with EMS. Paramedics and management arrived within 10 minutes upon which patient was then taken to the hospital. Wife followed and we rescheduled her vaccine.

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1280533	5/2/2021	FL	18	F	5/1/2021	5/1/2021	Pt explained on Covid-19 consent form that she has syncope when seeing a needle. She explained she has an intense fear of needles and has fainted in the past when getting vaccinations. She also explained that she has anxiety. She explained that when she faints it looks like a seizure but it is not. When pt was given shot she was responsive during the needle going in. She was in a seated position. We talked the entire time of administration. After putting the the bandage on her right arm she explained she felt sick(about 40 seconds after injection). She was still responsive for about two minutes then she fainted and her body shook about two times. My coworker and I got her on the ground, she was still responsive enough to ask for a cup of water. Which we gave her, she then went unresponsive for 20 seconds and spilled the water. After this we sat with her on the ground for another 5 minutes and she said she was fine. We helped her to a seated position. We then made her wait another 30 minutes in our waiting area. She assured us she was fine and reiterated that this has happened before in the past anytime a needle was involved. On 5/2/2021 she was contacted and she explained she looked a little pale throughout the day of vaccination, but feels fine now and just has a sore arm.
1280538	5/2/2021	MA	77	F			Burning back pain in the first lumbar dermatome distribution starting on 3/10. Drop attack on 3/17 leading to Hospital admission 3/17. Episodic acute confusional state leading to readmission to Hospital 3/24 A clinical diagnosis off absence seizure made prompting beginning Keppra with no further episodes of seizure The Neurologist as noted above
1280776	5/2/2021	NC	17	F	5/1/2021	5/2/2021	Woke up at 6:30 AM on May 2 with chills and moderate-severe headache, took 2 Ibuprofen at 7:00 AM. Took nap and then stood to speak to my mother, followed by a severe headache for a few seconds and then a seizure lasting less than 1 minute. Hospital released and recommended follow up with PCP for referral to neurologist. No further events as of May 2nd at 9:15 PM
1280571	5/2/2021		39	F	5/2/2021	5/2/2021	The patient was vaccinated and said that she feels dizzy, nervous. The patient sat on the chair ,passed out and had a seizure.

<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>
1279275	5/1/2021	NJ	80	F	4/6/2021		<p>arteries in my head on that side is narrowing, were narrowed.; seizure; it felt like somebody hit me on the head; I am sleeping a lot; violent headache; my body jerked; This is a spontaneous report from a contactable consumer (patient). An 80-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: ER8733), via an unspecified route of administration on 06Apr2021 (at the age of 80-years-old) as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient previously received the first dose of BNT162B2 on an unspecified date for COVID-19 immunisation. Consumer stated, "What happened when I came home exactly at 1:50, I had it exactly at 5:15. I thought somebody shot me in the head. I had the TV remote in my hand, and it felt like somebody hit me on the head and remote went flying across the room and on to the floor. That was the first time and a half hour later it happened again I had a teaspoon in my hand at the dinner table, my body jerked and that went across the room than it happened two more times. I had nothing in my hand. But I jerked in my body, body jerked and a violent headache for 6 days now. I have had MRI of the head and I have to see if my neurologist, but he cannot see me till the 30Apr2021." Lab work: Consumer stated, "I went and had the MRI." When asked for any other help, consumer stated, "No, but I still don't know. I still have to go to my neurologist and my artery doctor because they said my arteries in my head on that side is narrowing, were narrowed. So, I am in for a long holiday. I had to go to a lot of doctors to figure out what they are going to do, and I am sleeping a lot, there is something wrong. I just want Pfizer to know just something not right with that. If you want also my husband but he came with me and he had shot with me. He had headache for five days but nothing else just the headache for 5 days from the same LOT." On 21Apr2021, information due to 2nd shot of Pfizer was again reported. She had a reaction 4 hours after that shot, kind of like a seizure, she had a TV remote in my hand and out of nowhere it when flying out of my hand across the table and onto the floor, this result happened 4 times within two hours that same day. Have had headache for 16 days since. The patient underwent lab tests and procedures which included magnetic</p>

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

resonance imaging: unknown result on an unspecified date. The outcome of the 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>
1277171	5/1/2021	CO	56	F	4/8/2021	4/1/2021	seizures; soreness; extreme fatigue; injured; illness; This is a spontaneous report from a contactable consumer, the patient. This 56-year-old non-pregnant female patient the second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration in the right arm on 08Apr2021 13:30 (at the age of 56-year-old) as single dose for COVID-19 immunization. Medical history included seizure (not medicated), asthma, allergies, deprived of nightly decent sleep (from 24/7 low frequency torture by neighbor's ventilation system), and allergies: DILANTIN (phenytoin sodium), "1 other seizure drug" and sulfonamide drugs. The patient was receiving unspecified concomitant medication(s). The patient previously took the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN) via an unspecified route of administration in the right arm on 18Mar2021 13:30 (at the age of 56-year-old) as single dose for COVID-19 immunization. On 11Apr2021 00:30, the patient experienced seizure. On an unspecified date in Apr2021, she also experienced the soreness, extreme fatigue, injured and illness. The clinical course was described as follows: "I suffer from occasional seizures for which I am not medicated and I had one after midnight 2 days after the vaccination. Other symptoms were just soreness and extreme fatigue. I suspect this seizure is due to my lack of oxygen from my laying in bed the next day in this case but wanted to report it in case it matters. I normally suffer seizures very rarely and always in bed at 3 or 4 a.m. at times when I am sick or lacking sleep. This time I had my seizure in the bathroom and I am afraid I have no further information except that I likely only had one since I was missing from the bedroom for less than an hour as near as we can tell. I woke up on the floor injured and unaware of my surroundings. I have never had a seizure while awake before unless it was a second one. I have been deprived of nightly decent sleep by several neighbors for over 3 years now by a low frequency noise from a pot grow ventilation system that has caused me illness and was bad near the time of vaccination." No treatment was received for the adverse events. The clinical outcome of the seizure, soreness, extreme fatigue, injured and illness was resolving. The lot number for the vaccine, BNT162b2, was not provided and will be requested during follow-up.

<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>
1278666	5/1/2021	CA	62	F	4/13/2021	4/13/2021	felt low blood pressure; weak; confused; When fell hit self on head, lip, nose, and eye; When fell hit self on head; bruises on face; had burst lip; diarrhea; leg pain; fainted; seizure; felt hot; chills/shaking.; This is a spontaneous report from a contactable consumer (patient herself). This 62-year-old female patient (not pregnant) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot number not provided), via an unspecified route of administration in the left arm, on 13Apr2021 at 21:00 (at the age of 62-year-old) as single dose for COVID-19 immunisation. Historical vaccine includes the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot number EP6775 MS 389) administered via an unknown route in the left arm on 17Mar2021 (at 10:00 AM) for COVID-19 immunisation. No other vaccine was received in four weeks. Relevant medical history included gastritis and anxiety. Past drug history included allergy to mirtazapine (REMERON). Relevant concomitant medications included diazepam (VALIUM), vitamins and probiotics. On 13Apr2021 at 23:00 the patient had chills / shaking. On 14Apr2021 at 02:00 AM, she felt hot. She went to bathroom, felt low blood pressure, weak, and fainted. Woke up, felt disoriented, not know where she was, confused. When fell hit self on head, lip, nose, and eye. She suffered various bruises on face. May have had seizure, had burst lip and felt was biting. Then suffered diarrhea that day. She also experienced leg pain. She went to the doctor on 16Apr2021. On unknown date, blood work up was done and results were not provided. The patient was recovering from the events. Information on the lot/batch number 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>
1278540	5/1/2021	WI	18	M	4/12/2021	4/12/2021	Loss of consciousness; Seizure; Drowsiness, couldn't stay awake; Vomiting; This is a spontaneous report from a contactable consumer (patient). An 18-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 12Apr2021 (11:30) as a single dose, with route of administration unspecified, for COVID-19 immunization at the pharmacy/drug store. Medical history included peanut and penicillin allergy. The patient's concomitant medications were not reported. On 12Apr2021 (11:45), the patient had loss of consciousness; seizure; drowsiness/could not stay awake; and vomiting. The events had resulted in an emergency room/department for urgent care, and were assessed as serious (medically significant). The patient was hospitalized in Apr2021 due to loss of consciousness. The patient had received epinephrine (EPIPEN) as treatment for the reported events. The outcome of the events was recovered in Apr2021. The patient did not have COVID-19 prior to the vaccination, and had not been tested post-vaccination. Information on the lot/batch number has been requested.
1278441	5/1/2021	FL	58	M	4/7/2021	4/12/2021	Low fever beginning on 1:00AM Monday 12Apr; Experienced nausea Monday 12Apr evening and seizure; Experienced nausea Monday 12Apr evening and seizure; This is a spontaneous report from a contactable consumer. A 58-year-old male patient received first dose of BNT162B2 (BNT162B2) via an unspecified route of administration on 07Apr2021 (Batch/Lot Number: ENG201) as SINGLE DOSE for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced nausea Monday 12Apr evening and seizure and low fever beginning on 1:00am Monday 12Apr at 01:00. The patient was hospitalized for experienced nausea Monday 12Apr evening and seizure and for low fever beginning on 1:00am Monday 12Apr for 4 days. Therapeutic measures were taken as a result of low fever beginning on 1:00am Monday 12Apr. It was unknown if therapeutic measures were taken for the events Experienced nausea Monday 12Apr evening and seizure. The outcome of the 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>
1278349	5/1/2021	NY	45	M	4/24/2021	4/29/2021	Patient suffered a seizure and pulmonary edema four days after receiving second Pfizer shot. He was pronounced dead several hours later. Patient had no health issues and was 45 years old.
1278326	5/1/2021	NY	18	M	5/1/2021	5/1/2021	% minutes after the patient was vaccinated he c/o abdominal discomfort, he told his mother that he felt like he was falling. Patient the fell to the floor and had a seizure the lasted approximately 5-10 seconds. Pt awoke postictal.
1278206	5/1/2021	NY	17	F	5/1/2021	5/1/2021	~~Approximately 2 minutes after vaccination the 17 year old female had a "tonic seizure". Became unresponsive for about 2 minutes. Mother reports daughter has a history of fainting/seizure after blood draws ("she's afraid of needles")" Patient left with family ambulating.
1278200	5/1/2021		43	M	4/30/2021	4/30/2021	Received first Covid shot, immediately had aura of a seizure, then had seizure like activity

<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

<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>
							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.
1278080	5/1/2021	CA	32	M	5/1/2021	5/1/2021	pt mentioned prior reaction history of seizures but hasn't happened in a long time. Felt anxious when getting vaccine and motioned he thinks he might be having an anxiety attack before shaking. I was near patient when seizure started was able to guide him off chair slowly onto ground to try to protect head but head was slightly bumped on the ground; only lasted 2 to 5 seconds but pt felt fine after awakening and asked how long seizure went on for. Denied EMS services and after 30 minutes of rest with cold water and an ice pack patient felt better and left store.
1278050	5/1/2021	VA	24	M	5/1/2021	5/1/2021	After patient got vaccine a few minutes later he fainted while sitting in chair and fell to the floor. He came back quickly. He stated he started to feel hot before he fainted. He said he was now cold. Pt also said he was nauseated and felt clammy. WE eventually moved him to vaccination area to take blood pressure. While taking Blood pressure , he fainted again and was having seizure like symptoms(flailing arms, fit kicking and his head falling back) 911 was called.He came back quickly. He was monitored at scene by EMT. His blood glucose was 115 and initially they were only able to get systolic of 75. They removed him from pharmacy on stretcher and monitored him outside. His blood pressure was fine and they released him. He came back to the pharmacy and was fine

<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>
1276421	5/1/2021	WV		M		4/1/2021	SEIZURES; DID NOT SLEEP WELL; IRRITABILITY; ANGER; CRYING; BAD RASH ON HIS BOTTOM; This spontaneous report received from a consumer concerned a 32 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included quadriplegia, deafness, and seizures. 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-APR-2021 on left arm for prophylactic vaccination. Concomitant medications included unspecified seizures medications. On 06-Apr-2021, after receiving the vaccine the patient did not sleep well, since then extra seizures. The patient has had an inaudible seizure for several years. On 21-APR-2021, the patient slept through the night, irritability. The patient was totally different, angry, crying a lot, had rash, one on his bottom and bad one there. The patient took seizures medicine three times a day. The patient did not have any further information. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the did not sleep well, seizures, irritability, anger, crying and bad rash on his bottom was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 : - Covid-19 vaccine ad26.cov2.s-SEIZURES- 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

<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>
1276486	5/1/2021	CO		M		3/11/2021	<p>CONVULSING; ELEVATED BLOOD PRESSURE 190; FELT BAD; This spontaneous report received from a patient concerned a 61 year old male. The patient's height, and weight were not reported. The patient's concurrent condition included bee stings allergy, and concurrent conditions included occasionally drinks beer, and non-smoker. 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, 1 total dose administered on 11-MAR-2021 in left arm for prophylactic vaccination. No concomitant medications were reported. After vaccination on March 11th 2021 after 30 minutes later Blood Pressure went up (190) and then convulsion started ,so they called ambulance.They took to the emergency room. after that patient underwent lab test. they gave him (Alban) Intravenous. The patient was in the hospital for few hours and then it calm down. He felt pretty bad for few days after 4to 5 days he feel normal. Currently, patient was back to normal. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from elevated blood pressure 190, and convulsing on 11-MAR-2021, and felt bad on 16-MAR-2021. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:-COVID-19 VACCINE AD26.COV2.S-convulsion, blood pressure high. These event(s) are considered unassessable. The event(s) have compatible/suggestive temporal relationship, are unlabeled, and have unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>
1279137	5/1/2021		32	M	5/1/2021	5/1/2021	<p>2nd time submitting this because first submission said error; doing another report just in case. Patient got vaccine and said felt anxious then started having a seizure for 2-5 seconds pt said they had history of this prior but has been a while. I was near patient and able to slightly guide patient down but head did slightly hit floor. Patient woke up and said they were fine . Had patient stay an extra 30 minutes and gave ice pack and water and left the store after ensure they felt fine.</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>
1276753	5/1/2021	MA	54	F	3/23/2021	4/24/2021	Seizures; Sleep erratic; slept all day; Runny nose; excruciating pain, body was too much in pain; weakness; body ache; Fever 102F at night time; Nausea; Headache; Joint pain, pain in every joints; Muscles pain especially lower back; lethargic; Could not sleep; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (Seizures) 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 Seizures (History of seizures). Previously administered products included for an unreported indication: FLU VACCINE VII (Allergic reaction to flu vaccine, could not breath and in the ER room for 2 days and seizure activity.) in 2011. Concomitant products included LAMOTRIGINE (LAMICTAL) for Seizure. On 23-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-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 24-Apr-2021, the patient experienced LETHARGY (lethargic), INSOMNIA (Could not sleep), ARTHRALGIA (Joint pain, pain in every joints), MYALGIA (Muscles pain especially lower back), HEADACHE (Headache) and NAUSEA (Nausea). On 25-Apr-2021, the patient experienced SEIZURE (Seizures) (seriousness criterion medically significant), SLEEP DISORDER (Sleep erratic), SOMNOLENCE (slept all day), RHINORRHOEA (Runny nose), PAIN (excruciating pain, body was too much in pain), ASTHENIA (weakness), MYALGIA (body ache) and PYREXIA (Fever 102F at night time). On 26-Apr-2021, PYREXIA (Fever 102F at night time) had resolved. At the time of the report, SEIZURE (Seizures), SLEEP DISORDER (Sleep erratic), LETHARGY (lethargic), INSOMNIA (Could not sleep), SOMNOLENCE (slept all day), RHINORRHOEA (Runny nose), PAIN (excruciating pain, body was too much in pain), ASTHENIA (weakness), ARTHRALGIA (Joint pain, pain in every joints), MYALGIA (Muscles pain especially lower back), MYALGIA (body ache), HEADACHE (Headache) and NAUSEA (Nausea) outcome was unknown. Treatment included 1 tablet of Ibuprofen 200mg at approximately 3:00am 25Apr2021. Company comment: This case

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

concerns a 54 Y/O F with H/O influenza vaccine reaction, with serious unexpected event of seizure, and nonserious unexpected sleep disorder, insomnia, lethargy, somnolence, asthenia, pain, rhinorrhea, and expected pyrexia, headache, myalgia, arthralgia, nausea. Latency Day 1 after 2nd dose mRNA-1273. Event outcomes unknown. Based on current available information and temporal association between use of the product and start date of the event, a causal relationship cannot be excluded.; Sender's Comments: This case concerns a 54 Y/O F with H/O influenza vaccine reaction, with serious unexpected event of seizure, and nonserious unexpected sleep disorder, insomnia, lethargy, somnolence, asthenia, pain, rhinorrhea, and expected pyrexia, headache, myalgia, arthralgia, nausea. Latency Day 1 after 2nd dose mRNA-1273. Event outcomes unknown. Based on current available information and temporal association between use of the product and 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>
1278704	5/1/2021	CO	26	M	4/17/2021	4/17/2021	Seizure; crashed my car.; don't remember 45 minutes of my life; This is a spontaneous report from a Contactable Consumer (patient). A 26-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Right on 17Apr2021 13:15 (Batch/Lot Number: ER8735) as SINGLE DOSE for covid-19 immunisation at a vaccine facility, at 26 years old. Medical history included known allergies: Penicillin from an unknown date. No other vaccine in four weeks. Patient did not COVID prior vaccination and has not been tested for COVID post vaccination. Concomitant medication included bupropion; and venlafaxine hydrochloride (EFFEXOR) taken for an unspecified indication, start and stop date were not reported. Patient waited 15 minutes and felt normal. Patient stopped for gas and soda and then patient stated to be honest he woke up surprised with EMT, police and fire just telling him he started having a seizure and crashed his car on 17Apr2021 13:30. Patient stated "that's craziest laser I don't remember 45 minutes of my life (onset 17Apr2021). Thought I would be like 140. It was 3 pm which leave a large gap. This is really scary for me and my family". The events resulted in emergency room visit for seizure and crashed his car. The patient was hospitalized for seizure and for crashed his car for 1 day. Therapeutic measures were taken as a result of seizure and crashed my car (Some things to regulate my heart rhythm). Outcome of the events seizure and crashed his car was not recovered while unknown for don't remember 45 minutes of his life.

<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>
1277285	5/1/2021	TX	67	F	2/20/2021	2/20/2021	joint pain; muscle pain; Headache; This is a spontaneous report received from a contactable consumer (patient). A 67-year-old female patient received the first dose of BNT162B2, via an unspecified route of administration on 20Feb2021 09:30 at single dose for COVID-19 immunization. Medical history included degenerative arthritis, seizure disorder diagnosed when she was young, hip replacement from 2005 (the left hip was replaced in feb2005 and the right hip was in dec2005), and allergic to iodine dye. Concomitant medications were not reported. Patient previously took codeine and experienced allergy. Her husband and her both got the pneumonia and flu shot either late 2020 or early 2021, and they gave only half the pneumonia shot, they did not give full amount and said that they had to come back the same time next year to get the rest of it. On 20Feb2021, typical side effects happened later that day evening, it was a headache, then next day (21Feb2021) it was a headache and she did have joint and muscle pain, it all subsided. Outcome of the events was resolved. No follow-up attempts are needed; information about lot/batch number cannot 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>
1277363	5/1/2021	WI	23	F	4/13/2021	4/14/2021	unconscious; seizure; throwing up while unconscious; This is a spontaneous report from a contactable other healthcare professional (patient). A 23-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: Ew0169), dose 1 intramuscular, administered in Arm Right on 13Apr2021 14:45 (at the age of 23years) as single dose for Covid-19 immunization. The patient is not pregnant at the time of vaccination. There were no medical history and concomitant medications. 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 on 14Apr2021 (10:15 PM), the patient was unconscious for about 15 seconds, having a seizure for 5 seconds, and throwing up while unconscious. The adverse events resulted in Emergency room/department or urgent care. 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 recovering.; Sender's Comments: Based on known drug safety profile, there is reasonable possibility of causal association between the events loss of consciousness, seizure, vomiting and the suspect vaccine BNT162B2. 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.
1277435	5/1/2021	FL	55	F	4/30/2021	4/30/2021	Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypertension-Severe, Systemic: Seizure-Severe

<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>
1277501	5/1/2021	GA	25	M	4/30/2021	4/30/2021	Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fever-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Hyperventilation-Mild, Systemic: Shakiness-Mild, Systemic: Stroke-Mild, Systemic: Weakness-Mild, Additional Details: patient was nervous and was hesitant about needles just prior to vaccination. as soon as the vaccination was done, patient became tense and seizure like activity for ~10 seconds, then he became coherent and was sweating/ pale/ feverish. Gave the patient water, ice packs, and offered to call 911 once he was coherent. Patient refused and then called friend to take him home.
1277661	5/1/2021	NJ	69	M	3/10/2021	3/24/2021	focal seizure Having muliple focal seizures around 2 weeks after 2nd vaccine no treatment yet

<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>
1278688	5/1/2021	CO	16	M	4/16/2021	4/16/2021	About an hour later he was disoriented; headache; seizure; fever was over 103/temperature spiked so quickly; This is a spontaneous report from a contactable consumer. A 16-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration, administered in right arm on 16Apr2021 13:00 (Batch/Lot number was not reported) (at the age of 16-years-old) as a single dose for COVID-19 immunisation. Medical history included mental illness and autism from unspecified dates and unknown if ongoing. There were no concomitant medications. Patient previously took the first dose of BNT162B2, administered in right arm on Mar2021 (Lot number was unknown), at the age of 16 years old, for COVID-19 immunisation. There were no other vaccines in four weeks. Several hours after receiving the second dose of Pfizer Covid vaccine on 16Apr2021 20:00, the individual developed a headache and took ibuprofen (ADVIL) and water. About an hour later, he was disoriented and the parent (who was a nurse practitioner) asked him questions and he was having a hard time answering. Patient's fever was over 103 in the ambulance. He was tested for everything at the hospital and all was negative. It was determined to be an adverse reaction to the vaccine and what likely happened is his temperature spiked so quickly that he had a seizure. The events resulted in emergency room/department or urgent care. Treatment for other adverse events was unknown. There was no COVID prior vaccination and patient was not COVID tested post vaccination. The outcome of the events was recovering. Information about lot/batch 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>
1279191	5/1/2021	TX	20	M	4/14/2021	4/14/2021	<p>my teeth was opening and closing as if I was having a seizure; My body was involuntarily twitching; I was cold; shaking; shivering; headaches; 1st dose: 28Mar2021/2nd dose: 14Apr2021; 1st dose: 28Mar2021/2nd dose: 14Apr2021; This is a spontaneous report from a contactable consumer (patient). This 20-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number ER8731) on 14Apr2021 16:45 at single dose in right arm for COVID-19 immunisation. Medical history was none. Concomitant medication was not reported. The patient previously received first dose of BNT162B2 (lot number ER8733) on 28Mar2021 12:00 in right arm. The patient had no Known allergies. The patient had no COVID prior vaccination. The patient had no COVID tested post vaccination. The patient had not received other vaccine in four weeks. On 15Apr2021 04:00, his body was involuntarily twitching and his teeth was opening and closing as if he was having a seizure. He thought it was because he was cold so he put on 3 layers of clothes and 2 bundles of blankets and turned the heat up, but his body was still shaking and he was still cold. He tried to go back to sleep to see if that would fix it, but it did not until he went to work and around 7:30 a.m., the shivering stopped, but the headaches persisted and he had to ask to go home and he received an occurrence because he did not have a doctor's note. He clocked out at 8 and he went to sleep for an hour in the car in the parking lot because he was in no condition to drive home. Treatment received for the events included Acetaminophen and rest. The outcome of teeth was opening and closing as if I was having a seizure, body was involuntarily twitching, was cold, shaking, was resolving. The outcome of shivering was resolved. The outcome of headaches was not resolved.</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>
1279027	5/1/2021	NY		M			multiple seizures; sick; pain in his legs; This is a spontaneous report from a contactable consumer. A male patient (reporter's husband) of an unspecified age received the second 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. The patient's medical history and concomitant medications were not reported. The patient received the first dose of bnt162b2 on an unspecified date for COVID-19 immunization. The patient received the two shots of the COVID-19 vaccine and has been sick ever since the second dose was administered on an unspecified date. The patient also experienced multiple seizures in the evening on an unspecified date. He has also been suffering from pain in his legs which he did not encounter before the contact with the second dose of the vaccine. The outcome of the events was unknown. No follow-up attempts are needed; information about lot/batch number cannot 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>
1279008	5/1/2021	CA	48	F	3/26/2021	3/27/2021	Dizzy; Seizure; lost consciousnesses; don't remember any of it; apparently lost consciousnesses and drove slowly and hit a pole; "positional vertigo"; This is a spontaneous report from a contactable consumer (reporting for herself). A 48-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 26Mar2021 (Batch/Lot Number: EP8737) as single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. On 27Mar2021, the patient developed positional vertigo after the first dose. On 06Apr2021, the patient apparently had seizure with no history of seizures. The patient also had lost consciousness and drove slowly and hit a pole. They had to break the window to get the patient out of the car. The patient did not remember any of it. The patient stated that it was less than an hour that she was out; from the time recorded on the incident report and waking up in the emergency room (ER) and looking up at the clock in the room, it was under an hour. On an unspecified date, the patient experienced dizzy. The patient lab work and stuff done when she was in the ER after she had the seizure. The outcome of the 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>
1278949	5/1/2021	NY	45	F	4/5/2021	4/5/2021	it could have been a seizure; Unconscious/Collapsed/ diagnosed her as having a Syncopal Episode; Urinated on self/Wet her pants; Headaches; Feeling light headed; Felt her heart beat faster; Sore arm; This is a spontaneous report from a contactable nurse (patient mother). A 45-year-old female patient received bnt162b2 (BNT162B2, lot number EW0150 and expiration date was not provided), via an unspecified route of administration first dose on 05Apr2021 15:00 at single dose for covid-19 immunisation. The patient's medical history included ongoing Hypertension (Patient diagnosed in her late 30's), ongoing Hypothyroid (Patient diagnosed when she was around 20 years old), ongoing Allergies, ongoing Gastroesophageal reflux disease (The patient was exposed to a chemical in her 20's that caused this condition), ongoing Birth control, ongoing Allergic to eggs (States patient has never received the flu vaccine due to her egg allergy), and ongoing Allergic to shellfish. The patient's concomitant medications included ongoing levothyroxine at 150 ug, 1x/day for Hypothyroid, ongoing Hydrochlorothiazide at 12.5 mg, 1x/day for hypertension, ongoing omeprazole at 20 mg, 1x/day for gastroesophageal reflux disease, ongoing losartan at 100 mg, 1x/day for hypertension, ongoing norethisterone (SHAROBEL) for Birth control. On 06Apr2021 13:00, the reporter stated that her daughter fainted at work, lost her urine, and was unconscious and was taken to the Emergency Room. Primary Care Physician told her daughter she should have no problem getting the second vaccine. States that she was not certain if her daughter should get the second shot. It was scheduled for next week. Also, reported that after lunch reporter stated that her daughter fainted in her office at work. She had urinated on herself and was unconscious. Caller was concerned it could have been a seizure. Her daughter was taken to the Emergency Room and they diagnosed her as having a Syncopal Episode. On 06Apr2021, the patient had headaches that continue since these events. The reporter stated that her daughter's doctor told her daughter that the blood work and electrocardiogram done at the Emergency Room were normal. The Emergency Room and her daughter's doctor acted like her symptoms were not serious. The reporter looked at the Vaccine Adverse Event Reporting System website and it said that a syncopal episode is a reportable event. Says that her

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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daughter's doctors did not report this event. Says doctors need to have training on the importance of reporting events. The reporter called the Food and Drug Administration last week but she hasn't heard anything from them. States they told her it could take 5-7 business days. Says she called Pfizer today to see if there was any further information or guidance she could get as she is concerned about her daughter. She says her daughter has her own office so she was in there alone when she collapsed. Someone found her on the floor. The reporter was asking for guidance on administration of the second vaccine dose following a syncopal episode after the first. The patient received her first vaccine dose on 05Apr2021 15:00 and she was fine, she had a sore arm, but went to work the next day (06Apr2021) and after lunch she reported feeling light headed and felt her heart beat faster and went to get up and a colleague later found her on the floor and she had wet her pants. They took her to the ER around 1 pm the day after her vaccination and diagnosed her with a syncopal episode stating that they didn't think it was from the shot. The events syncope, urinary incontinence, seizure, and headache were considered as serious (medically significant) by the reporter. The events syncope, and urinary incontinence caused emergency room visit and physician office visit. The outcome of the events syncope, urinary incontinence was recovered on 06Apr2021. The outcome of the event Headache was not recovered. The outcome of the remaining events was unknown.; Sender's Comments: Based on the information currently available, a causal association between the reported events and bnt162b2 cannot be fully excluded. Case will be reassessed when 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 RAs, Ethics Committees, and investigators, as appropriate.

<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>
1278922	5/1/2021	DE	26	F	4/16/2021		breakthrough seizure and frequent seizures; This is a spontaneous report from a contactable consumer. A 26-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose via an unspecified route of administration, administered in Arm Left on 16Apr2021 13:00 (1:00PM) (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. The patient is not pregnant at the time of vaccination. Medical history included ongoing epilepsy and known allergies latex, bee stings from an unknown date and unknown if ongoing. No other vaccine in four weeks. The patient had no Covid prior vaccination and not Covid tested post vaccination. The patient was vaccinated at a facility. Concomitant medication included (reported as Other medications in two week): cenobamate (XCOPRI) and zonisamide (ZONISAMIDE); both taken for temporal lobe epilepsy, start and stop date were not reported. The patient previously took bnt162b2 for covid-19 immunisation first dose from 18Mar2021 at 01:00 PM in the left arm. The patient also previously took oxcarbazepine and experienced allergies (reported as Known allergies: Oxcarbazepine). It was reported that the patient has temporal lobe epilepsy well controlled on Xcopri(200mg) and zonisdamide(300mg) and experienced breakthrough seizure and frequent seizures during the last 14 hours (reported as 15Apr2021 at 08:00 PM [20:00]). Previously well controlled for the past 2-3 months, upon titration to current dose of zonisamide/xcopri. The outcome of the event was recovering. No treatment for the reported event. Information on the lot/batch number 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>
1278904	5/1/2021	WV	16	F	3/24/2021	3/25/2021	Seizure; This is a spontaneous report from a Pfizer sponsored program COVAX US Support from a contactable consumer (patient's grandmother). A 16-year-old female patient received bnt162b2 (Pfizer COVID vaccine), via an unspecified route of administration, administered in arm on 24Mar2021 (Batch/Lot number was not reported) as single dose for COVID-19 immunisation. Medical history included epilepsy from 2016 to an unknown date. There were no concomitant medications. The patient experienced seizure on 25Mar2021 03:00 with outcome of recovering. It was added that the patient did not have a seizure for 3 years and took her off after 2 years. She had not been on seizure medications for 4-5 years. She had been seizure free and had not been to her neurologist for 4-5 years. Epileptic but never had a seizure for the past 6 years. She is going back to the same doctor. She was diagnosed as being epileptic 5 years prior. Time the vaccination was given: 14:00-14:30. Her neurologist is informed not to get second dose. NO ER required. The patient went to the doctor. Last Friday, she had an EEG and results are unknown now. They have not had follow up appointment yet to get results. The patient underwent lab tests and procedures which included electroencephalogram: results are unknown on an unspecified date. Information on the lot/batch number 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>
1278836	5/1/2021	NC	83	F	2/24/2021	2/24/2021	lactic acid was high; dementia had suddenly progressed; spot where her lung was starting to collapse; potassium, Vitamin D and Vitamin B12 were low; potassium, Vitamin D and Vitamin B12 were low; potassium, Vitamin D and Vitamin B12 were low; stopped talking; Cellulitis in her arm/ cellulitis was further down her arm, around her wrist hand area (Her wrist was huge, hot, red, and her hand was swollen); it burned when she peed; blood in her urine; wanted to sleep/getting worse with sleeping; was shutting down; she was dehydrated because her urine was dark; urine was dark; began just feeling bad/having like a terrible time/having a hard time/really not feeling good; more confused; lethargic; had trouble her getting up/was having to do everything for her, feed her, bathe her; couldn't walk; lost her appetite; arm was sore; This is a spontaneous report from a contactable consumer (patient's daughter). An 83-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3247), via an unspecified route of administration, administered in the left arm, on 24Feb2021, as single dose, for COVID-19 immunisation. Medical history included mild asthma, dementia (moments like putting things in the wrong place and being forgetful) and was confused. There were no concomitant medications. Historical vaccine included the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231) received at age 83 years, on 03Feb2021, for COVID-19 immunisation. On 24Feb2021, after the second vaccinations, the patient's arm was sore. On 06Mar2021, the patient began just feeling bad, was having like a terrible time, having a hard time, was really not feeling good; was more confused; lethargic; had trouble getting her up, was having to do everything for her, feed her, bathe her; couldn't walk and lost her appetite. On 09Mar2021, the patient was shutting down. On the same day at 18:30, the patient had gone in the bathroom and said it burned when she peed. So, the patient was taken to urgent care so it would not get out of hand. At the urgent care, they said she has a UTI, there was blood in her urine so they gave her Cipro but they cultured her urine and it grew no bacteria but there was still blood in her urine and she was getting worse with sleeping and she didn't even get up to eat. The patient was also dehydrated and her urine was dark. The events dehydrated, urine was dark, it burned when she peed,

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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blood in her urine required emergency visit on 16Mar2021. The reporter thought the patient was going to die. On 16Mar2021, in the ER, they did blood work (unknown result), chest xray which showed she had a spot where her lung was starting to collapse (they said it was a tiny place, from not getting up and moving around, they said it would correct itself) and the patient's potassium, Vitamin D and Vitamin B12 were low. They did a CT scan of the head and chest to look for stroke or seizure and there was nothing. They blamed it on her dementia that had suddenly progressed. The patient was hospitalized from 16Mar2021 to 18Mar2021. On 12Mar2021, the patient experienced cellulitis in her arm. The reporter clarified that the cellulitis was further down her arm, around her wrist hand area. Her wrist was huge, hot, red, and her hand was swollen. On 24Mar2021, the patient followed up with the family doctor because the hospital wanted her to follow up with a GYN because they didn't feel it was urinary at all. When the reporter took the patient in to see the doctor, she couldn't walk in, she had to roll her in a wheelchair, she had stopped talking again. On 26Mar2021, the doctor sent the patient to the emergency room (unspecified reason) and they kept her. They said her lactic acid was high. She was admitted on 26Mar2021 and discharged on 29Mar2021. On 29Mar2021, the patient's potassium was 3.3 and her lactic acid level was back to 2. The patient was recovering from lactic acid was high; potassium, Vitamin D and Vitamin B12 were low; began just feeling bad/having like a terrible time/having a hard time/really not feeling good; more confused; lethargic; had trouble her getting up/was having to do everything for her, feed her, bathe her; couldn't walk; lost her appetite; was shutting down; stopped talking. The patient recovered from cellulitis in her arm/ cellulitis was further down her arm, around her wrist hand area (Her wrist was huge, hot, red, and her hand was swollen) in Mar2021; and arm was sore on 29Mar2021. The outcome of events spot where her lung was starting to collapse, dementia had suddenly progressed; she was dehydrated because her urine was dark; it burned when she peed; blood in her urine; and wanted to sleep/getting worse with sleeping 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>
1277804	5/1/2021	NY	26	M	4/29/2021	4/29/2021	Was observed for at least 15 minutes. Arrived at home and had a seizure, was rushed to the hospital. Mother claimed patient is in ICU.
1276470	5/1/2021	GA	19	F		4/9/2021	<p>NUMBNESS AND TINGLING IN ARM; IT STARTED IN HER LEFT PINKY AND RADIATED UP THE LEFT ARM. IT HURT FOR A FEW HOURS; BRAIN HURT; SHAKINESS; BODY PAIN; CHILLS; EXHAUSTION; SEIZURES; This spontaneous report received from a health care professional concerned a 19 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 was not reported, 1 total, administered on 09-APR-2021 on left deltoid for prophylactic vaccination. The batch number was not reported and it has been requested. No concomitant medications were reported. On 09-APR-2021, the patient experienced seizures, confusion, pale appearance and nausea after forty five minutes patient was okay. The patient was drove back home and slept for 7 hours then experienced exhaustion. The next morning on 10-APR-2021, the patient's brain hurt to work and experienced body pain, shakiness, chills. Ten days later on 19-APR-2021, the patient experienced numbness and tingling in left arm. It was started in left pinky finger and radiated up the left arm. It was hurt for a few hours (just 1 episode). health care professional has ordered tests but they had not been completed yet. The patient was seen by a pediatric neurologist on 22-APR-2021 for evaluation of seizures. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of seizures, exhaustion, chills, body pain, shakiness, brain hurt, numbness and tingling in arm, It started in her left pinky and radiated up the left arm, It hurt for a few hours was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210450038- JANSSEN COVID-19 VACCINE Ad26.COV2.S-Seizures. 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>

<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>
1274025	4/30/2021	PA	19	F	4/30/2021	4/30/2021	Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Shakiness-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Systemic: Tinnitus-Mild, Systemic: Visual Changes/Disturbances-Mild, Systemic: Weakness-Mild, Additional Details: 5 minutes after vaccine pt felt lightheaded and blurred vision. then passed out. patient advised to sit down then passed out again and started to shake head (seizure like symptoms) for a few seconds. patient was pale, confused and started sweating, fingers were cold to touch. Then her fingers started to get numb and tingly. she was having a hard time seeing colors and she started having ringing in ears. Ambulance was called and they took over.
1272941	4/30/2021	CA	16	F	4/26/2021	4/26/2021	Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: shakes-Mild, Systemic: Shakiness-Mild, Additional Details: pt fainted and had shakes/ convulsions for a few seconds. after 30 seconds pt awake and stated ok , after 30 min pt stated ok after 30 min observation. mom n dad brought to hospital dad called and said pt was ok . no unusual findings
1272982	4/30/2021	IL	17	F	4/29/2021	4/29/2021	Systemic: Dizziness / Lightheadness-Mild, Systemic: Seizure-Mild, Systemic: Shakiness-Mild
1273354	4/30/2021	GA	16	M	4/28/2021	4/29/2021	Absence Seizure Tonic Clonic Seizure
1273424	4/30/2021	LA	41	F	4/7/2021	4/7/2021	4pm severe peri orbital eye pain and severe headache 4:30p Severe ear pain with light sensitivity 9pm fever, severe chills,with excessive uncontrollable shakes that appeared to look like a convulsion, uncontrollable teeth chattering, hot flashes, diaphoretic , elevated blood pressure and teeth nerve pain, severe body aches and lasting muscle soreness
1273508	4/30/2021	WI	66	M	4/12/2021	4/12/2021	PATIENT HAD SEIZURE 9 HOURS AFTER GETTING THE VACCINE

<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>
1275522	4/30/2021	IL	27	F	3/7/2021	3/8/2021	I had a fever starting after the shot, and it increased nerve pain from my chronic condition escalating into a flare up where I was incapacitated and immobile due to pain. I started having seizures everyday for about 1 week after the injection, and then again on weeks 3-5 post injection. The pain flare lasted for over 5 weeks. I continue 7wks after the shot to have a fever, and still have not fully recovered from the complications of my flare up.
1273974	4/30/2021	IL	23	F	4/30/2021	4/30/2021	Patient fell to floor unconscious with seizure. Mucous was coming out of mouth. Patient was placed on side with cold gel packs place on neck and forehead. Patient regained consciousness in about 2 minutes. 911 was called. Dr. overheard page and came to assist. Patient refused ambulance when they arrived. Her boyfriend was going to take her to the ER to have the bump on head be looked at.
1274146	4/30/2021	VA	62	M	4/14/2021	4/16/2021	Seizure
1274242	4/30/2021	FL	36	M	4/10/2021	4/10/2021	The family reported he had a seizure 4 hours after immunization while driving motorcycle and while on bipolar medications. Ended up in hospital.
1274294	4/30/2021	NC	22	M	4/30/2021	4/30/2021	Patient fainted within 5 minutes after receiving the Janssen vaccine. He then appeared to be experiencing a seizure lasting no more than a minute. No history of fainting or seizure. EMS was called and arrived within about 10 minutes, and patient appeared to experience another seizure and he vomited. EMS then transported the patient to the hospital.

<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>
1274385	4/30/2021	CA	61	F	3/27/2021	3/31/2021	<p>~~Moderna COVID-19 Vaccine EUA" -- received 1st dose 3/27/2021 Received 1st Moderna vaccine in R arm on 3/27/21. Within first hour, she had a headache, R eye pain, and felt tired; symptoms subsided after she laid down. On 3/31 in early AM, felt sudden and more severe headache and same eye pain, and "electrical contractions down neck, back, and spine." Went to medical facility, then transferred to hospital, and transferred to another hospital via helicopter. 61-year-old female, generally very healthy, on no medications, here complaining of sudden onset right sided stabbing/electrical headache which began 30 minutes prior to arrival. She states she was standing at work when had sudden onset severe headache radiating into her right eye. Stating that it feels like my right eyeball is going to explode. She ranks the pain a 9 out of 10. She does have a history of migraine headaches which have never been evaluated with imaging or by neurology. They were normally frontal, and she has not had one in more than 2 years. She states that this headache is dramatically different than her prior migraines. Patient states associated with this sudden onset headache, she had bilateral neck pain, and substernal chest pain. Upon arrival to clinic, she points to her substernal region as the site of her chest pain. She denies associated shortness of breath, irregular heart rate/rhythm, presyncope. She does feel slightly weak. Of note, patient states she had a MODERNA COVID-19 vaccine on Saturday and subsequently had some right-sided shoulder pain. Her symptoms are on the same side. - 7:50 AM: BP 165/109 (R arm); pulse 86; no antihypertensives given, given a total of 100 mcg fentanyl over 1 hr - 9:04 AM: BP 150/92 (R arm); pulse 60; transferred to hospital and then to transfered to another hospital via helicopter for SAH 3/31/2021 ED - given nicardipine IV, dexamethasone IV, levetiracetam, and antiemetics. Nero noted that no associated trauma, LOC, or seizure with the HA, Neuro assessment - day 4 (plus possible re-rupture within last 24 hours) of good clinical grade HH2 low volume aSAH due to ruptured R ICA ANR 4/1/2021 - completed successful and uncomplicated RICA oblong aneurysm coiling (successful coil elimination & preservation adjacent PcommA infundibulum). Patient was admitted to critical care for post procedure care, monitoring, and management of sodium, blood pressure, and headache.</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>
							Levetiracetam discontinued since patient did not have any seizures. 4/7/2021 - discharged
1274611	4/30/2021	ME	85	F	4/29/2021	4/29/2021	Family reported patient had fatigue, temp of 100 F, nausea, vomiting, and a seizure within 24 hours
1274688	4/30/2021		59	F	4/21/2021	4/27/2021	Dizzy when ambulating to bathroom, fell, hit head, had subsequent seizure-like activity
1274798	4/30/2021	FL	25	M	4/30/2021	4/30/2021	PT appear to have a Focal Seizure and syncope ensue. PT hit his head but no abrasion. Pt awake and alert. Reported feeling tightness in chest and anxious before passing out. Rescue Team contacted ; PT refuse transfer. Vitals in all normal range; BP:120/70 HR:98 Spo2: 97-98. Pt monitor longer in observation by Nurse and Rescue Team REFUSE Transport vitals taken before leaving site. Vitals before leaving site: BP:122/77 HR:90 Spo2 97-99.Pt was able to be ambulatory and leave site
1274974	4/30/2021	WA	24	F	4/30/2021	4/30/2021	History of fainting, showed signs of fainting, then had multiple seizures, LOC, incontinence, hypotensive, normal HR. Taken by ambulance to hospital. Unknown results or whether admitted patient was admitted.
1275224	4/30/2021	VA	29	M	4/30/2021	4/30/2021	Patient passed out during 15 minute wait time and began to have a seizure after receiving the J&J vaccine. Seizure last about 5-10 seconds. Pt was turned to his side and remained in the same position until EMS arrived. He was conscious after the seizure and was responding and speaking full sentences. EMS was on the line until they arrived in person. Medical EMS personnel were called and responded. They advised pt had a history of seizures. Pt refused to go to the hospital with EMS. EMS cleared pt to continue regular activities. Event time approximately 3:00-3:20pm.
1273758	4/30/2021	IA	44	F	3/5/2021	3/7/2021	Seizures lasting for 10 days. The first 3 days experienced 1 per day. The next 4 days experienced multiple. Ended up at hospital. Treated there in neurology. The next three days experienced one per day. Then they stopped. And I felt completely back to normal. Resumed normal exercise and daily activities.

<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>
1271678	4/29/2021	MI	21	F	3/23/2021	4/5/2021	Hepatitis / Encephalopathy (seizures, ADEM, MISC/A) PRESENTING PROBLEM: Fever and chills [R50.9] Hepatitis [K75.9] Febrile illness, acute [R50.9] Acute nonintractable headache, unspecified headache type [R51.9] Seizure (HCC) [R56.9] MIS-C associated with COVID-19 (HCC) [M35.81] Active Issues Requiring Follow-up MIS-C/A - 2/2 COVID-19 infection vs idiosyncratic reaction to J&J vaccine -prednisone taper over 16 days as above -ID will be arranging follow up serial labs (CBC with diff, CMP, Ferritin level, CRP, LDH) -Bactrim prophylaxis while on steroids -Acyclovir 400 mg BID for prophylaxis (hx of recurrent HSV infection of eyelid) - duration to be clarified by ID at follow up -ASA 81 mg daily -TTE w/ normal coronaries. She will need cardiac MRI, to be arranged by adult congenital cardiology Generalized tonic-clonic seizures - witnessed and captured on EEG 4/9. No further events. Continue Keppra 1500 mg BID. outpatient f/u with neurology Abnormal MRI brain - diffuse T2 white matter hyperintensities - non-specific. She will need follow up MRI brain w/ and w/o contrast in 1 month and follow up with neurology clinic ADHD - given insomnia, Senthuri was recommended to avoid vyvanse for now. She will discuss with her outpatient prescriber Anxiety and depression - zoloft increased to 125 mg daily Insomnia - 2/2 trauma from critical illness. Improved with trazodone HS. Elevated EBV PCR - ID will continue to monitor. Nausea/vomiting - resolved. Likely 2/2 gastritis in setting of steroid use. PPI BID x 4 weeks DISCHARGE DISPOSITION: Home without services
1272475	4/29/2021	TX	71	F	4/13/2021	4/14/2021	Vomiting, unconsciencious, convulsions. Transported by ambulance to Hospital. Hospitalized for 5 days. CAT scan, EEG,
1272409	4/29/2021	AZ	30	M	4/29/2021	4/29/2021	Seizure.

<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>
1272277	4/29/2021	VA	45	F	2/5/2021	4/29/2021	Approximately 5-6 days after my second Pfizer vaccine dose, I began having paresthesias in patchy areas on the outside of my right ankle. Over the next 3-4 weeks, the paresthesias (burning, tingling, temperature sensation) progressed to the other leg and then ascended up the legs bilaterally to the upper thigh area. I consulted my neurologist and he ordered a MRI of the cervical and thoracic spine. The day after the MRI (4/15/21), I had two seizures in the morning after being seizure free for a year. I had significant fatigue and felt very poorly. A few hours later, I had a sudden onset of severe bilateral leg weakness. Because I could not walk, EMS was called. I went to Hospital where I was admitted for leg weakness. Additional imaging was performed. I was able to walk a few steps after receiving a dose of 1g solumedrol via IV that night. My symptoms improved over the next few days with IV steroid treatment. I was discharged on 4/19/21 and was advised to follow up with outpatient neurology. My neurologist initially diagnosed acute transverse myelitis and ordered physical therapy. I continued a steroid taper for 6 days after hospital discharge. Today (4/29/21), my symptoms have improved but continue to have adverse effects. I am able to walk but tire quickly and am very fatigued. I have been unable to work since hospital discharge.
1270027	4/29/2021	ME	55	M	4/6/2021	4/6/2021	Day of injection:fever over 100, body aches, fatigue Day 2-same as day 1 plus dizziness, extreme high blood pressure and a seizure Day 3&4-all symptoms continue except the seizure Day 5&6-fever broke, now just dizzy and blood pressure spikes Day 7-most symptoms subsided, but blood pressure still spikes slightly and tinnitus began and continues

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1269542	4/29/2021	NY	65	F	1/20/2021	1/1/2021	Spasms in left arm; Went to ER bc I thought it was a seizure; This is a spontaneous report from a contactable consumer. A 65-year-old non-pregnant female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) at the age of 65 years, via an unspecified route of administration, administered in Arm Left on 20Jan2021 (Batch/Lot Number: EL3247) as a single dose for covid-19 immunization. Medical history included cancer from an unknown date and unknown if ongoing. Concomitant medications included levetiracetam (KEPPRA); mesalamine; prednisone; and folic acid, all taken for an unspecified indication, start and stop date were not reported. In Jan2021, the patient experienced spasms in left arm and went to ER because she thought it was a seizure. The patient was hospitalized due to the events for 2 days. The patient underwent lab tests and procedures which included negative test for Covid-19 on 26Mar2021. The outcome of the events was recovered with sequelae
1269545	4/29/2021	ME	35	F	4/14/2021	4/14/2021	had 5 small seizures; felt very dizzy; This is a spontaneous report from a contactable consumer (patient). A 35-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in arm left on 14Apr2021 09:45 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included pre-diabetes and depression. Patient was not pregnant. The patient's concomitant medications were not reported. There were no other vaccine in four weeks. The patient previously took antibiotics and antidepressants and experienced allergies. 5 minutes after getting the vaccine, patient felt very dizzy. She had 5 small seizures on 14Apr2021 10:45 which resulted in emergency room/ urgent care. Treatment was received for the events. Outcome was recovering. Patient had covid prior to vaccination on an unspecified date and had not been tested post vaccination.

<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>
1269632	4/29/2021	NY	65	F	2/14/2021		<p>Spasms in left arm; ultimately leading to the left arm becoming completely numb after 2nd dose; went to emergency room because she thought it was a seizure; shortness of breath ever since 2nd dose; This is a spontaneous report from a contactable consumer (patient). A 65-year-old female patient received the second dose of BNT162B2 (PFIZER BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in arm left on 14Feb2021 (at the age of 65 years old) (Lot Number: EM9810) as single dose for COVID-19 immunisation. Medical history included cancer. The patient was not pregnant at the time of vaccination, had no known allergies and did not have COVID prior to vaccination. Concomitant medications included levetiracetam (KEPPRA), mesalamine, prednisone and folic acid; all taken for an unspecified indication, start and stop date were not reported. The patient had her first dose of BNT162B2 on 20Jan2021 for COVID-19 immunization and experienced spasms in left arm and seizure. No other vaccines were administered within four weeks. In 2021, patient experienced spasms in left arm, ultimately leading to the left arm becoming completely numb after second dose. Patient went to emergency room because she thought it was a seizure. This happened twice. She also had shortness of breath ever since second dose. The events resulted in hospitalization for two days from an unknown date in 2021. It was unknown if any treatment was given. The patient recovered with lasting effects The patient underwent COVID-19 test (nasal swab) with result of negative on 26Mar2021 (post vaccination). The outcome of the events was recovered with sequel. No follow-up attempts are needed. No further information is expected.</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>
1269670	4/29/2021	ID	58	F	4/1/2021	4/6/2021	Had 5 seizures with in 36 hours 5 days after the first vaccine./Other medical history: Seizures; Had 5 seizures with in 36 hours 5 days after the first vaccine./Other medical history: Seizures; This is a spontaneous report from a contactable consumer (patient). A 58-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot Number: ER8727), via an unspecified route of administration on 01Apr2021 13:30 (58-years-old) as single dose for COVID-19 immunization. Medical history included seizure. Patient is not pregnant. Patient had no COVID prior vaccination. Patient was not tested for COVID post vaccination. Concomitant medication included valproate semisodium (DEPAKOTE) for seizure. The patient previously took Paxil and experienced allergies. The patient had 5 seizures within 36 hours 5 days after the first vaccine (06Apr2021 11:45). They had to increase semisodium which has helped keep the seizures at bay. She have not had seizures in two years. Event resulted in Doctor or other healthcare professional office/clinic visit and Emergency room/departement or urgent care. Therapeutic measures were taken as a result of event (Increase in routine medicine). The outcome of the event was recovering.
1269756	4/29/2021	NJ		U			Seizures; allergic reactions; This is a spontaneous report from a contactable consumer (patient) via Pfizer sponsored program. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 and dose 1; both via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received both vaccines & both times had seizures & allergic reactions. The patient was medicated properly for the second dose and symptoms were severe. The outcome of events was unknown. Information about lot/batch number 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>
1269758	4/29/2021	VA	59	F	4/13/2021	4/14/2021	<p>Lost consciousness; dizzy like she was about to faint; twitching and shaking; eyes went to one side; she was about to faint; seizure; Diarrhea; chills; head hurting; eyes hurting; Muscle soreness; joint pain; Nausea; temperature of 99.3; This is a spontaneous report from a contactable consumer (daughter of patient) and another consumer. A 59-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 13Apr2021 16:21 (Lot Number: EW0164; Expiration Date: Aug2021) at vaccination age of 59 years old as single dose for covid-19 immunisation. Medical history included vertigo, antacid therapy. Concomitant medication included esomeprazole magnesium (NEXIUM 24HR) taken for antacid therapy from an unspecified start date and ongoing. No additional vaccines administered on same date of the Pfizer Suspect. The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot EP7533), on 23Mar2021 at 17:38 PM at age of 59 years old in the right arm as single dose for covid-19 immunisation and only had a little bit of muscle soreness on her right arm on 23Mar2021 after the first dose and it went away the day after (24Mar2021). The patient took Tetanus shot about two weeks before the first dose of the Pfizer COVID 19 vaccine. Then received the second dose on 13Apr2021 16:21PM in the left arm. After the second dose she had chills; her head was hurting; her eyes were hurting; she had muscle soreness; she had joint pain all yesterday 14Apr2021. Then this morning 15Apr2021, after taking a Tylenol and getting a shower she felt dizzy like she was about to faint. Her mother had vertigo but this was not like her usual vertigo. Her mother sat on the bed and started to have what looked like a seizure with twitching and shaking; then she lost consciousness. Her mother's eyes were open and they saw her mother's eyes twisted, went to one side, and she fell back on the bed. They called at 05:30 AM and the ambulance arrived quickly but by the time they arrived she had regained consciousness. They recommended she follow up with HCP. They called the doctor who advised her to rest, and make an appointment to see the doctor tomorrow. Reporter clarified her mother had the chills from 10:00 AM today (15Apr2021) and had them day with a lot of headache,</p>

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eyes hurting goes along with the headache, and she had a temperature of 99.3. The chills and temperature resolved last night then the eyes hurting ended this morning (15Apr2021) with the headache. All of the other symptoms resolved yesterday (14Apr2021). She also had nausea that started yesterday (14Apr2021) and she started to have diarrhea once today (15Apr2021) and felt like it had stopped. The nausea was coming and going from time to time. The events did not require a visit to emergency room or physician office. The outcome of events chills, muscle soreness, joint pain, temperature of 99.3 was recovered on 14Apr2021. The outcome of events Lost consciousness, head hurting, eyes hurting, felt dizzy, twitching and shaking, eyes went to one side, Diarrhea was recovered on 15Apr2021. The outcome of event seizure, she was about to faint was unknown. The outcome of event nausea was recovering.

<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>
1269764	4/29/2021	NY	39	F	3/25/2021	3/26/2021	Severe nausea; vomiting; loss of consciousness; seizures; This is a spontaneous report from a contactable other healthcare professional (patient). A 39-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8727 and expiration date not provided) via an unspecified route of administration, administered in left arm on 25Mar2021 as a single dose for COVID-19 immunisation. Medical history included Cancer hx, Supraventricular tachycardia (SVT), Sjogrens, Epilepsy, Chronic kidney disease (CKD), Hyperthyroidism, Short gut, Osteoarthritis, malnutrition, Bartter's Syndrome Type 3, Hashimoto's Disease, Allergies to Penicillin, Adhesive, Vicryl sutures and cobalt. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included hydroxychloroquine; doxycycline; and levothyroxine sodium (SYNTHROID) and more (unspecified). The patient previously took iron dextran, povidone-iodine (BETADINE), metronidazole (FLAGYL), lamotrigine (LAMICTAL) and doxepin and experienced Allergies. The patient also took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6205) in the left arm on 04Mar2021, 01:15 PM for COVID-19 Immunization. The patient did not receive any other vaccine in 4 weeks. On 26Mar2021 19:00, the patient experienced Severe nausea, vomiting, loss of consciousness, seizures. The events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care and Life threatening illness (immediate risk of death from the event). Treatment was given in response to the events which included IV antiemetics, IV hydration, IV Benadryl, Antiepileptics. The patient underwent COVID test post vaccination via nasal swab (rapid antigen test) on 01Apr2021 which was negative and via nasal swab (PCR) on 16Apr2021 which was negative. The outcome of the events was not recovered.; Sender's Comments: Based on the close temporal relationship, the association between the events nausea, vomiting, loss of consciousness, and seizures 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

<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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review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

seizures; dizziness; fatigue; passed away; This is a spontaneous report from a contactable Consumer. This Consumer reported for a 33-year-old male patient (friend) who deceased who received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number unknown), via an unspecified route of administration on an unknown date in Mar2021 at a single dose for COVID-19 immunization. The reporter wanted to know if there were any reports or information on patients having severe seizures or blood clotting, he was trying to find out for some information on similar adverse events that occurred with the Johnson & Johnson COVID vaccine, but from receiving the Pfizer-BioNTech COVID-19 vaccine the person that had the severe reaction went to the doctor and the doctor said it was highly unlikely from the vaccine. The reporter tried to look online for potential side effects, to help the family provide some type of (information about this). The reported stated the patient was very healthy, young 33 years old, never had a history of seizures, he had no past medical issues. He received second dose middle of march, he passed on 13Apr2021. On the third week after receiving second dose, he started experiencing dizziness and fatigue that later progress into seizures, he was admitted into the hospital, and was no longer under control. Doctors said was highly unlikely it was from the vaccine however every test came back negative; X-Rays, biopsies, everything negative. The patient deceased and outcome of the events was unknown. Information on the Lot/Batch number has been requested. ; Reported Cause(s) of Death: passed away

<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>
1272098	4/29/2021	CA	18	M	4/29/2021	4/29/2021	<p>Patient received Pfizer vaccine on left deltoid and immediately displayed seizure like activity while sitting down. Patient eyes rolled back and was briefly unresponsive for a few seconds. EMS was notified at this time. The patient was assisted and carried down to the matted floor and feet were elevated on a chair. Patient did become responsive and was alert and oriented but continued be dizzy. Patient did not have labored breathing or respiratory distress at this time. Patient's vital signs were taken at 14:50: 130/71, 80hr, 95% PsO2, 18rr The fire department arrived and transported patient to Hospital. Patient did have another seizure like activity and patient's heart rate dropped into the 40-50s. Peripheral IV on right hand was initiated and bolused. Patient's mother, was notified of event and patient's sister who was waiting outside was brought into facility. Patient's sister who is 14 years old was later picked up by mother.</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>
1270011	4/29/2021	NM	54	U	4/9/2021	4/9/2021	<p>feel weird, objects looked distorted,; could not sleep; felt hyperactive with her eyes popping out of her head; bone pain; muscle soreness; Headache; hallucinations; This spontaneous case was reported by a consumer and describes the occurrence of HALLUCINATION (hallucinations) in a 54-year-old patient of an unknown gender 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 was provided by the reporter. Concomitant products included GABAPENTIN for Peripheral neuropathy, CLONAZEPAM (CLONAZEPAM AUDEN) for Seizures, METOPROLOL, DROXIDOPA and MONTELUKAST SODIUM (SINGULAIR) for an unknown indication. On 09-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 09-Apr-2021, the patient experienced HALLUCINATION (hallucinations) (seriousness criterion medically significant) and HEADACHE (Headache). On an unknown date, the patient experienced FEELING ABNORMAL (feel weird, objects looked distorted,), SLEEP DISORDER (could not sleep), EUPHORIC MOOD (felt hyperactive with her eyes popping out of her head), BONE PAIN (bone pain) and MYALGIA (muscle soreness). On 11-Apr-2021, HALLUCINATION (hallucinations) had resolved. At the time of the report, FEELING ABNORMAL (feel weird, objects looked distorted,), SLEEP DISORDER (could not sleep), EUPHORIC MOOD (felt hyperactive with her eyes popping out of her head), BONE PAIN (bone pain), MYALGIA (muscle soreness) and HEADACHE (Headache) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Treatment given included Naproxen. 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. Headache and myalgia are consistent with the product safety profile.; 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. Headache and myalgia are consistent with</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>
							the product safety profile.
1271767	4/29/2021	RI	18	F	4/28/2021	4/28/2021	Seizure... 1/2 hour prior to incident patient was with friends in a classroom leisurely using PowerPoint. She reports she had pain in her teeth and her chest felt tight. She just didn't feel well. Closer to incident student felt dizzy, like she was "going to pass out". States she turned to someone to tell that person she was not feeling well "but I couldn't talk; the words would not come out". She felt herself sway and then knew she fell to the floor. She felt like she was lying still for a bit but she could hear people around her and she heard someone say "somebody start timing this" (as if they knew it was a seizure).
1270078	4/29/2021	NY	18	F	4/28/2021	4/28/2021	Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Medium, Systemic: Shakiness-Medium
1270151	4/29/2021	NY	27	M	4/28/2021	4/28/2021	Systemic: Seizure-Mild, Additional Details: before the shot, patient said he gets nervous and cautioned that he might get lightheaded. after the shot, he started having a seizure. full body contractions in a wave-like pattern from the bottom up. seizure lasted 20 seconds. we offered to call ambulance, but patient refused. he stayed in the store for 30 minutes, when he left he said he felt fine. no previous history of seizures.
1270608	4/29/2021	IL	89	M	4/24/2021	4/25/2021	Patient with unresponsive, catatonic state, concern for seizures, persisting encephalopathy. Awoke and improved 24 hours later after seizure medications started. Started on Keppra despite negative workup and was awake and alert out of post-ictal state over 24 hours from admission.

<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>
1270848	4/29/2021	NY	39	F	4/28/2021	4/29/2021	<p>Patient received vaccine at 2:15 pm at Public Health clinic. She waited the appropriate 15 minute observation period and was feeling well. She then came to PCP office for a routine medical exam and reported feeling well when she first came, although her blood pressure was slightly elevated but pulse was normal. She was taken to an exam room and left for approximately 5 minutes, at which time she presented to the nurses station reporting that she thought her tongue may be swelling. Nurse evaluated and got NP to evaluate immediately. Patient reported she could still breath normally and swallow but that she was still feeling the swelling increase. At this time NP left to get PCP while nurse elevated HOB as patient began to choke on her tongue. PCP ordered epinephrine, 1 mL administered immediately. 911 called. Patient reported she was starting to feel better, swelling began to decrease. She then started to feel shaky, was pale and diaphoretic. She lost consciousness for approximately 10 seconds and pulse was not palpable. Staff readied for CPR and AED brought to room but patient regained consciousness prior to any care being necessary. She began to speak in full, clear sentences and was alert and oriented. 2L o2 applied. She was speaking with staff normally for around 5 minutes while awaiting ambulance, began to feel hot and felt her heart racing. Her PCP advised her that this was a normal sensation brought on by epi. As EMS arrived, patient reported feeling intense chest pain radiating down left arm, intense headache, and tingling in her fingers. As she was being transported to stretcher, patient experienced a 1.5 minute seizure followed by an episode of vomiting. She then left the building via ambulance and was take to Hospital emergency department. There it appears that she received 2 more rounds of IM epinephrine, IV epi, CPR, and was intubated. She was transferred from there to ICU where she is currently admitted on ventilation under sedation and receiving cardiac testing due to continued hypoxia and tachycardia.</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>
1271138	4/29/2021	PA	51	F	1/12/2021	2/16/2021	Within 10 minutes of the shot I had a severe headache, numbness in my lips, feet and hands and was weak and unable to walk without fear of falling. These symptoms continues for an hour, and while still weak I returned to work. I awoke the next day with a fever, body aches and fatigue that lasted 3 days. I have had 3 more bouts of severe fatigue since the shot and on Monday 4/26/2021 I suffered a seizure but have no history nor symptomology of seizure activity, and was hospitalized for 2 days.
1271161	4/29/2021	NY	17	F	4/29/2021	4/29/2021	Recipient is a 17yo who presented for second dose of COVID-19 vaccine. She reported some anxiety related to receiving dose #2, and had some nausea after dose #1. She was alone as a driver of her own POV. Consent was obtained from the recipient and her custodial grandparent by phone, witnessed by doctor. She initially did well after the vaccine, but after approximately 5 minutes began to complain of feeling nauseated, lightheaded, and tingling extremities (hands and feet). She was noted to be hyperventilating, and was placed in a supine position but continued to feel some lightheadedness and difficulty breathing. Breath sounds were clear without wheezing noted, HR 70s with RRR. She was noted to have ongoing anxiety, nausea and symptoms progressed and although she remained normotensive to hypertensive (initial BP 128/74), she had repeated episodes of syncope. She was transferred to the ambulance and further vitals and EKG were obtained. She had some confusion after episodes of syncope and some seizure-like activity with syncope, with very brief episodes of LOC, with noted tachycardia with HR up to the 140s during episodes of syncope. BP ranged 129/86 to 140/84. IV access obtained and she was given NS and started on oxygen at 2 liters, but saturations remained in the 98-99% range. She was ultimately transferred to the local ER for further evaluation and management given ongoing symptoms, evaluated at hospital.
1271162	4/29/2021	IL	64	M	4/28/2021	4/29/2021	patient was found down on the ground. he was slow to respond but eventually came around. he had a syncopal event or seizure.

<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>
1271472	4/29/2021	WI	62	M	3/23/2021	4/21/2021	Patient admitted with left sided weakness on 4/21/21. First covid-19 vaccine (Moderna) received on 3/23/21. MRI/MRA shows acute infarcts of the right caudate body and striatum. H/o HTN, hep C with cirrhosis, COPD, tobacco abuse, alcohol use disorder, GTC seizure disorder. ECHO on 4/21/21 which was normal. Patient thought to be actively overusing alcohol at home. Patient was treated for stroke and discharged on medications to help with alcohol withdrawal symptoms (clonidine, gabapentin) as well as aspirin, plavix, and atorvastatin for new stroke. Thrombocytopenia noted (platelets 50K), however patient?s platelets have historically been low likely related to alcohol use. Per hospitalist discharge summary, low suspicion for vaccine induced thrombocytopenia. HIT Ab test ordered on 4/21/21, resulted negative. It seems to be coincidental that stroke occurred about a month after patient?s first covid-19 vaccine but reported to VAERS for completeness. Did not add covid-19 vaccine to patient?s allergy list. Patient received second covid-19 vaccine (Moderna) on 4/28/21.
1271051	4/29/2021	MD	69	F	3/21/2021	3/29/2021	3/23: upset stomach; diarrhea. 3/24: severe vomiting and diarrhea. so severe that transported to ER; provided fluids and anti nausea meds and discharged. DX--Viral Gastroenteritis; hyperglycemia. Later that evening experienced seizure and fell out of bed unconscious; suffered shoulder fracture. Transported to ER again, experienced 2nd seizure en route, and hospitalized/intubated in ICU.

<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>
1269772	4/29/2021	WI	43	M	4/23/2021	4/23/2021	Seizure; Cardiac arrest; Arrhythmia; Began convulsing and then tipped over; Began convulsing and then tipped over; 12 lead EKG without ischemic changes, arrhythmia; Febrile 38+; This is a spontaneous report from a contactable other HCP. A 43-years-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot Number: EW0169) via intramuscular route in arm left on 23Apr2021 at 12:45 as single dose for covid-19 immunisation. Historical Vaccine included first dose of bnt162b2 (Lot Number: EW0150) via intramuscular, administered in arm left on 02Apr2021at 14:15 for covid-19 immunisation. Medical history included obstructive sleep apnea, food allergy and intolerant of peanuts-causes sneezing and there were no concomitant medications. On 23Apr2021 at 18:30 the patient experienced a seizure resulting in cardiac arrest. Witnesses described patient began convulsing and then tipped over. AED applied with no shock advised. Unknown down time prior to initiation of CPR. Rhythm PEA upon arrival of EMS. 7 mins CPR before ROSC obtained. Initial Troponin 12. 12 lead EKG without ischemic changes, arrhythmia, etc. Transthoracic echo without regional wall abnormalities or significant findings. CT of head negative for acute intracranial process. No history of seizure, cardiac issues, drug use, etc. Intubated and sedated. Febrile 38+ on arrival requiring active cooling measures to maintain normothermia. The case classified as serious emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). On 23Apr2021, the patient underwent lab tests and procedures which included body temperature: 38+ on arrival requiring active cooling measures to maintain normothermia, computerised tomogram head: negative for acute intracranial process, echocardiogram: without regional wall abnormalities or significant findings, electrocardiogram: without ischemic changes, arrhythmia, investigation: pea, sars-cov-2 test: negative Nasal Swab and troponin: 12. Treatment received included multiple life support measures, treatment for seizures, etc. No covid prior vaccination. Patient had covid tested post vaccination. No other vaccine in four weeks. The outcome of the events was not recovered.; Sender's Comments: Based on strong temporal

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

association the causal association between the reported events seizure, cardiac arrest, arrhythmia, began convulsing and then tipped over, febrile 38+ and the usage of the vaccine are considered related. 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.

<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>
1270761	4/29/2021		20	F	3/11/2021	3/18/2021	<p>After first vaccine: History: Moderna COVID vaccine on 3/11/2021. Arm soreness over the first day or two but nothing else that really struck her. A few days after she started to notice axillary pain that progressed up her right neck and down to her right hand. She saw a physician who thought she was having nerve pain brought on by the vaccine. Around the 18th she started to feel a snapping pain in her wrist. Went to ED on the 20th because she started to have arm shaking, she was given ativan, her arm shaking stopped and they discharged her home. That evening her fingers felt clenched. On the 21st she woke up in the morning, went to urinate and dropped to the floor because her legs felt like jello and felt like they kept giving out. They initially thought the ativan was just making her feel out of it. They waited until the evening but then needed to go to the ED. The concern was GBS and transverse myelitis. They ate dinner and decided to drive to ED, on the drive she was kind of falling asleep periodically. Then she suddenly couldn't lift her water bottle. She started to be completely out of it, Mom says she wasn't responding. Pt says that she felt like she knew what was going on, felt a little out of body and wasn't quite responding. Mom couldn't get her out of the car, she was carried into the ED and at that point she started to recover a little bit more. About 10 minutes later she started to feel better. She was admitted because she was still having trouble walking. In the hospital she had a normal CT head and video EEG but she didn't have any events while on the monitor. Discharged home the following day with the diagnosis of functional neurologic disorder and instructions to establish care with an adult PCP. They advised considering CBT as well. Since discharge her legs feels tired, going up the stairs feels much harder than it should. She has not had any falls and no longer feels like she is going to fall. She follows with a therapist, has had dissociative episodes and panic attacks in the past. Assessment: 20 YOF with PMH of panic attack, POTS, IDA and benign heart murmur who developed weakness of b/l LE and altered consciousness approximately 10 days after her first dose of Moderna COVID vaccine. Also had an episode of unilateral arm shaking the day prior that resolved with ativan in the ED. At this point unclear if directly related to vaccination. Differential includes mild Guillain-Barre 2/2 previous infection or vaccination,</p>

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

stress reaction/anxiety, POTS complication, myasthenia gravis, tick bite, infection, heavy metal poisoning, B12 deficiency, seizure disorder, atypical migraine. Functional Neurologic Disorder diagnosed by neurology after overnight admission for video EEG which captured no events. CT head also WNL per neurology discharge summary. Neurologic exam today WNL. After Second Vaccine: History: She had her 2nd vaccine on 4/15 (6 days ago). Had vaccine in right arm again, she did have some arm pain again. She had coffee without breakfast in the morning. Had finished her first virtual class, went to the restroom during her second class, felt strangely in the restroom, went back to her room. She then passed out. Her fall was unwitnessed. She called to her roommate when she came to but her roommate hadn't heard the fall. She thinks she was only out for a few seconds but cannot be sure. Called her Mom who advised her to eat something so she ate an orange sitting on the floor. She got up to make herself breakfast and she passed out again. Again unwitnessed but patient thinks it was very fast. She crawled over to the couch, sat on the couch for for 15 minutes then felt fine for the rest of the day. She did not feel nauseous at all. She denies palpitations, difficulty breathing and chest pain. Today in office after orthostatics and blood draw she fainted again, only out for seconds. BP elevated immediately after the event but WNL minutes later. These syncopal episodes reminded her of her syncopal episodes with IDA and POTS. They do not feel like the episode after the first vaccine when she lost feeling in her legs and was very out of it. She feels like her arm pain from the first vaccine never fully resolved. After the arm pain worsened from the 2nd shot she tried a 3 day course of aleve to see if that helped things. At this point it is mostly just her right wrist that is painful. Overall feels more localized to wrist than prior. She has since stopped the aleve, last was last night. She has not noticed redness or swelling in wrist or arm. LMP was 4/2-4/6. She went almost a year without menses so stopped her OCP, but her menses have returned recently and she has restarted OCP. Assessment: Right arm pain persisted from the first vaccination but otherwise sx had resolved. She got 2nd vaccination on 4/15, only arm pain but yesterday had 2 brief syncopal events and one today in the office. Orthostatic BPs not completely convincing for orthostatic hypotension today.

<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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1266687	4/28/2021		46	U	4/4/2021	4/4/2021	Seizure.
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1269310	4/28/2021	SC	71	F	1/28/2021	1/28/2021	Dizzy; Blood pressure systolic high; headache; extremely tired; sore arm; This is a spontaneous report from a contactable consumer (Patient) via Medical Information Team. A 71-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: EL1284 Expiry date: 01Apr2021), via an unspecified route of administration, administered in right arm on 28Jan2021 around 03:30 PM (at the age of 71-years), as a single dose for COVID-19 immunisation. The patient got her COVID-19 Vaccine in her right arm because she had her lymph nodes removed on her left side due to left-sided breast cancer. Medical history included Seizure (She had a seizure at age 6, again at 12, both times she was told that seizures were because of a high fever. She said she was given phenobarbital at the time. She said her tests always showed something was abnormal. She said her next seizure was in her 40s and she had an MRI, and nothing was there. Patient was started on medicine and sent to a neurologist. Patient said she went through lots of medicines and either had a reaction, or the medicine did not control her seizures. In 1998 seizure at her doctor office, and the doctor had to do CPR on her, and then had an ambulance taken her to the emergency room. Patient had a vagal nerve stimulator implanted for seizure control in 1998 and she has a lead that goes to her head and neck, and a battery in her right shoulder). Stroke (In 12Feb2002 that was caused by hormone medicine & seizure medicine that interacted with each other at 52 years old and was hospitalized for 4 months, needing physical therapy, speech therapy, and a couple other types of therapy), Total hysterectomy (in Dec2001, she was started on a hormone pill after her total hysterectomy and hormone pill interacted with a seizure medicine she was taking at the same time, and caused her to have a major stroke on 12Feb2002), Diabetes (2009), TIA (2009), Left-sided breast cancer (From Dec2015 and will make a decision to continue with cancer medicine, anastrozole 1mg takes at supper. Mfg. Zydus Pharmacy NDC: 68382-209-06, GTIN: 00368382209061, SN: 30100085636501, Lot: M009071, Exp: 30Jun2022), Lymphadenectomy, patient had unspecified allergies in the past from medicines and ongoing triglycerides that are out of the ballpark. Patient got her regular flu shot in either Oct2020 or Nov2020.

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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The patient concomitant medications included Anastrozole, Jardiance, Vascepa and Prolia. Patient was taking Jardiance 10mg pill once in the morning at breakfast, for about 2 years, dispensed in a (Pharmacy Name Withheld) pharmacy bottle with no NDC, Lot, and Expiration Date, and the manufacturer is listed as Boehringer Ing on the prescription label. Patient was taking Vascepa 1gm capsule at dinner time daily, and after 3 months of taking Vascepa, her triglycerides are down to 190. She said she started Vascepa 1gram capsules about 1 to 1-1/2 years ago that was dispensed in a (Pharmacy Name Withheld) pharmacy bottle with no NDC, Lot and Expiration Date. She said the manufacturer is Amarin Pharma 1 as listed on the Vascepa 1gram prescription label. Patient couldn't take 2 Vascepa 1gram capsules because she was in too much pain. Patient was taking Prolia injection done twice a year from three years at her doctor office for osteoporosis. On 28Jan2021 (same day of vaccination), patient was immediately dizzy, sat down and the room was spinning, they checked BP and it was up to 180, unknown what was bottom number. They moved me to a separate room and continued to check my BP. Patient walked with a nurse to another chair, and the nurse checked back with her after 5 minutes, and she got even worse. The nurse checked her blood pressure on her right arm, and her top blood pressure number had jumped to 180. Later moved to a private room with a recliner where nurse continued to monitor her every few minutes. Nurse called an emergency room doctor around 3:30PM to see if she needed to be transferred to the hospital emergency room. The emergency room doctor told the nurse to continue monitoring her where she was, and as long as her blood pressure did not go any higher, or nothing else happened, she could go home. Patient blood pressure went down to 130 and she was released from the COVID-19 Vaccine waiting area at 5:30PM. Patient experienced a headache and was extremely tired and had a sore arm. Patient spoke to one of her doctors and they mentioned having the Moderna vaccine for her second dose and one of her doctors told her to take the second COVID-19 Vaccine dose, while another doctor told her not to get the second COVID-19 Vaccine dose. Patient asked if she should get her second vaccine dose if she experienced a reaction to the first also if her BP will go up again with the

<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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second vaccine dose because she was afraid it will do it again and asks whether she should take the Moderna instead. Patient asked if she still need to stay away from my new grandson, should wait 21 days after first dose, and should still wear a mask or she was protected. Patient stated that according to nurse, she was only the second person to have that kind of reaction. Patient informed nurse that she was diabetic, but she does not take insulin. She said her last Hemoglobin A1C was 6.4. Patient wanted to visit a cardiologist because she has a big family history of heart problems and though never had a heart attack, but she is always concerned because her triglycerides are out of the ballpark. She clarified that a normal triglyceride level is 150 and her triglycerides were staying over 300. Patient lab tests included blood pressure (180, later came down to 130), triglycerides (over 300) on 28Jan2021, cholesterol and Haemoglobin (6.4) on an unspecified date. The patient did not take any other vaccine on that same day, as well as four weeks prior vaccination. The patient had hoped to get the Moderna COVID-19 Vaccine. She said her primary care doctor told her to take the Moderna COVID-19 Vaccine, but she couldn't find anyone who she could register with. The outcome of the events dizziness and systolic blood pressure increased was recovered for and unknown for all other 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>
1269140	4/28/2021	OH		U	3/26/2021		SEIZURES LIKE SHAKING; DIFFICULTY BREATHING; FEELING FAINT/DIZZINESS; DIFFICULTY FEELING EXTREMITIES; NAUSEA; 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: 1802068, and expiry: unknown) dose was not reported, 1 total dose administered on 15-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 16-MAR-2021, Laboratory data included: Electrocardiogram (NR: not provided) not reported. Patient was hospitalized for 2 days after receiving the vaccine. Patient reported that, the reaction appeared approximately 16 hours after vaccination, patients had to seek from the emergency room and it was result of the vaccination based on bodily reactions On 26-MAR-2021, dizziness ,difficulty breathing/feeling faint, difficulty feeling extremities, seizures like shaking, experienced and nausea. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from seizures like shaking, difficulty breathing, feeling faint/dizziness, nausea, and difficulty feeling extremities. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210440664-COVID-19 VACCINE AD26.COV2.S-seizures like shaking, difficulty breathing, feeling faint/dizziness and difficulty feeling extremities. 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). 20210440664-COVID-19 VACCINE AD26.COV2.S- Nausea. This event(s) is labeled per Agency and is therefore considered potentially related.

<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>
1268689	4/28/2021	OK	18	F	4/25/2021	4/25/2021	18 yo female requests to have injection in supine position due to previous history of passing out with injections. Mom at pts side and sts pt first passed out at the age of 4 years old when she witnessed her father having blood drawn for a health screen. She also reportedly passed out after receiving a vaccine at Pharmacy in 2017. Due to her history of injection related syncopal episodes, pt is placed in a supine position on the cot as precaution. Approximately 30 seconds after receiving the injection, the pt was witnessed becoming unresponsive by this HCP. Pt was then witnessed having her eyes roll up and back followed by a few seconds of generalized seizure activity. HCP remains at pts side. The cot has a suspended cloth and is soft, therefore, pt is safe from harm on it. Seizure ends after seconds and pt awakens. She is initially confused but orients quickly. She remains AOX4 and has no complaints. Spoke with mom extensively about pts condition and presenting symptoms. VS- HR initially 52 but quickly improves to 77, BP 107/64, RR 16, sats 98%. Pt will follow up with pts pediatrician. Mother and pt do not want pt evaluated at the ER today and do not want an ambulance. VAERS info given.
1268125	4/28/2021	CT	84	M	2/10/2021	3/11/2021	Presented to ED following witnessed seizure in setting of COVID+ and BG <50. Given dextrose. COVID treated with dexamethasone and antithrombotic - aspirin 81 mg and intermediate dosing of enoxaparin. Hospital course complicated by UTI. Discharged back.
1267932	4/28/2021	MD	32	F	3/7/2021	3/7/2021	Day 1 (3/7/21): sever ice-pick like headache right back toward the left front of the head. Then sever flu-like symptoms including: fever, chills, fatigue, and body aches and pains. Flu symptoms lasted 3 days. Day 6 (3/12/21): severe head pain like an ice-pick in the back right radiated to the front left, heard a loud humming inside my head, it felt like my head was gyrating, AND my vision in my right eye became distorted and I couldn't move my legs I couldn't feel them - I thought I was having a seizure. After the Day6 event I have had persistent tremors, muscle twitches, weakness in legs, phantom sensations on my left side hand/arm or left leg, forgetfulness, memory problems, word retrieval problems, constant ringing in ears and nausea.

<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>
1267047	4/28/2021	NY	63	M	4/26/2021	4/26/2021	Pt stated that about 1.5 hours after receiving second dose began feeling burning in leg, headache, burning and numbness in first finger all unilaterally. He went to the hospital and was treated over the course of 2 days. He identified as having symptoms of stroke though hospital staff stated it was a seizure.
1266952	4/28/2021	AZ	18	M	4/26/2021	4/26/2021	Between 5 and 10 minutes after the immunization, patient sat down with his father and starting feeling ill with a headache. Head was shaking a bit and the patient vomited. He was given some water while the paramedics were on their way. Patient was coherent and talking fine sitting in the chair. He was asked if he gets seizures ever and he both him and his dad said no. Dad said he just doesn't like needles. No issues giving the shot at all. He didn't look and said he hardly felt it. Paramedics arrived, patient still had a bit of headache. He vomited a small amount before he left with his father.
1266906	4/28/2021	CT	30	F	4/28/2021	4/28/2021	at 4/28/21 patient was vaccinated w/ Jessen vaccine and soon became pale and observed to become flaccid and pass out. pt's HR was 50, sat 99% and BP 70/40. Pt soon observed with BLUE contracting and BLUE adducting followed by urine incontinence. Pt did not fall and was sitting in her chair the entire episode that lasted for approximately 40-60sec. Pt awake and continued to have hypotension, dizziness reported. EMS contacted and pt transferred to local ER for evaluation of suspected syncope and seizure s/p vaccination.
1266821	4/28/2021	MD	40	F	4/23/2021	4/24/2021	Pt was seen in Family Medicine on 4/23/2021. Was given her first Moderna vaccine that day. On-call doctor received phone call on 4/24/2021 that pt had expired. Death certificate states cause of death: seizure due to possible complication of COVID 19 vaccine. Conditions if any, leading to immediate cause: cerebellopontine angle tumor of brain
1269566	4/28/2021	OR	68	M	3/24/2021	3/31/2021	Facial pain or headache becomes more severe, drowsiness or confusion, swelling of the forehead or eyelids, vision problems including blurred and double vision, seizure, dry mouth nausea tiredness constipation, double vision Diplopia, one eye is affected, vertigo, speech or walking

<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>
1266725	4/28/2021	TX	75	F	4/28/2021	4/28/2021	Dizziness, confusion, spasm, possible seizures.
1267656	4/28/2021		48	U	3/26/2021	3/26/2021	Patient had a seizure.
1266470	4/28/2021	NV	80	F	4/2/2021	4/3/2021	At 1:30am on 4/2/21, my mother had fallen at home and was transported to the hospital. She was not injured from the fall however by 4/4/21, she was showing signs of end stage dementia. Her symptoms literally came on as if switching on a light. Through testing ruled out stroke, cancer, seizure as well as a lumbar puncture was negative for infection. She remains hospitalized and is transitioning to a specialized care facility that will provide 24/7 care.
1266433	4/28/2021		75	F	4/1/2021	4/23/2021	Patient presents on 4/21 with sudden onset of severe headache start about 4 days ago and has been persistent since. The pain is all over her head with no particular focal area. CT head: RIGHT PARIETAL CORTICAL INFARCT She had an echo on 4/21/2021 showed normal LV size and function with LVEF 55-60% with no regional wall motion abnormalities. Normal RV structure and function. 1+ AI. No PFO by color doppler. No valvular issues. No history of atrial fibrillation. Patient then had two episodes of seizure on telemetry unit on 4/23/2021 followed by post-ictal phase Patient was discharge 5/26/21 to home with neurology follow-up scheduled in 2-4 weeks. Patient will also receive a Holter for 2 weeks.
1266354	4/28/2021	IA	31	M	4/28/2021	4/28/2021	Patient received vaccine in clinic around 10:20am. Patient waited around the pharmacy for around 20 min and then left. Patient returned around 11-11:10 am with his mother in which we were notified that he was having a reaction. We brought the patient into the patient care room in which he was vomiting and patient's mother stated that he had a seizure. Patient was conscious but had some altered mental status. Patient denied any falls. 911 was called and EMS took patient to the hospital.
1266253	4/28/2021		25	M	4/1/2021	4/1/2021	Patient received 1st Moderna vaccine Reaction: Seizures Severity: High

<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>
1266127	4/28/2021	CO	28	F	4/6/2021	4/6/2021	Fatigue; Brain fog; Sweating a lot; Was ghost white; severe chills,freezing; Very very high fever; Nausea; Had a seizure; Blue lips; Fainted; Was out for like 30 minutes; Something white on the patient's mouth; Little lightheaded; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SEIZURE (Had a seizure), CYANOSIS (Blue lips), SYNCOPES (Fainted) and LOSS OF CONSCIOUSNESS (Was out for like 30 minutes) in a 28-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 06-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Apr-2021, the patient experienced SEIZURE (Had a seizure) (seriousness criteria medically significant and life threatening), CYANOSIS (Blue lips) (seriousness criterion life threatening), SYNCOPES (Fainted) (seriousness criterion medically significant), LOSS OF CONSCIOUSNESS (Was out for like 30 minutes) (seriousness criterion medically significant), ORAL DISCHARGE (Something white on the patient's mouth), DIZZINESS (Little lightheaded), HYPERHIDROSIS (Sweating a lot), PALLOR (Was ghost white), CHILLS (severe chills,freezing), PYREXIA (Very very high fever) and NAUSEA (Nausea). On an unknown date, the patient experienced FEELING ABNORMAL (Brain fog) and FATIGUE (Fatigue). On 06-Apr-2021, SEIZURE (Had a seizure), CYANOSIS (Blue lips), SYNCOPES (Fainted), LOSS OF CONSCIOUSNESS (Was out for like 30 minutes), ORAL DISCHARGE (Something white on the patient's mouth), HYPERHIDROSIS (Sweating a lot), PALLOR (Was ghost white), CHILLS (severe chills,freezing) and PYREXIA (Very very high fever) had resolved. At the time of the report, DIZZINESS (Little lightheaded), FEELING ABNORMAL (Brain fog), FATIGUE (Fatigue) and NAUSEA (Nausea) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The patient's concomitant medication included Adderol used for an unknown indication. The patient had received 1st dose of Moderna vaccine and was monitored

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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for 30 minutes at the facility where she got the vaccine , the patient went to her house and had little light headed and nausea, that evening she went to sleep and around 9 or 10 Hours after she had received the 1st dose of the Moderna vaccine she" fainted and had a seizure. She was out for like 30 minutes, she had blue lips, had something white on her mouth. The HCP told, that she should go to the hospital but it was really busy so they stabilized her at her house. The patient had never had seizures, it is a life threatening event. The patient is being seen by a neurologist and her primary care, and "they have just started with the CT scans and the studies(caller did not specify)" with pending results, so once the caller has all the test results she wouldlike to call back and give the most updated details on the patient's case. The patient had fatigue and brain fogs, but she did not have another seizure, Caller reported that "for now, we are dealing with the symptoms she had on the 06-Apr-2021. The patient had cancelled her 2nd dose appointment. The patient treatment medication included Advil on 06-Apr-2021. 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. chills, nausea, pyrexia and fatigue are consistent with the product safety profile.; 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. chills, nausea, pyrexia and fatigue are consistent with the product safety profile.

<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>
1266058	4/28/2021	MD	28	F	4/7/2021	4/7/2021	Low grade fever; seizure; Passed out; syncope/ fainted; Blood pressure drop; Sore arm; This is a spontaneous report from a contactable consumer (patient's parent). A 28-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not provided) at the age of 28-years-old, via an unspecified route of administration in left arm on 07Apr2021 at single dose for COVID-19 immunization. Medical history included autism, being nervous, passed out, and anxiety. Concomitant medications included sertraline hydrochloride (ZOLOFT), quetiapine fumarate (SEROQUEL), gabapentin, bupropion hydrochloride (WELLBUTRIN), and lorazepam (ATIVAN) for being nervous. The patient received the Pfizer vaccine last Wednesday (07Apr2021) and immediately after that, at about 1:30 (unspecified), she just started having a seizure. They thought that it was more of a major response she was just having, fighting and was nervous about it, but it was kind of a different situation. The reporter has seen the patient passed out before. She did some blood test on 07Apr2021 and her sugars were fine. The reporter's concern was that they didn't know whether she should get the second one. The reporter didn't believe she got a seizure but was not sure about it. It's just that what immediately happened after she got the shot was that she passed out and they called the ambulance. After she passed out, she went to the emergency room and they did blood work on her. The reporter just did not know if they were going to let her go for the second dose because they couldn't relay if it was a seizure or a bizarre response where she just syncope and fainted. They were just thinking it was a bizarre response as it was just blood pressure drop but they were just not sure where to go from here. The patient was told to rest and intravenous fluid and something through the blood were given. The patient also experienced sore arm from 07Apr2021 for 2 days and had a low-grade fever the following day (08Apr2021). The outcome of the event sore arm was recovered on 09Apr2021 and recovered on Apr2021 for all other events. Information about the lot/batch number 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>
1266053	4/28/2021	CT	37	F	4/9/2021	4/13/2021	she was an epileptic and she do take anti-seizure meds. She have had 3 seizures in the last 24 hours; This is a spontaneous report from a contactable consumer. A 37-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: ER 8731), via an unspecified route of administration, administered in Arm Left on 09Apr2021 15:15 as [SINGLE DOSE] for covid-19 immunisation (Age at vaccination: 37 years). Medical history included epilepsy. Concomitant medications included lamotrigine and hyoscine butylbromisde (COLOSPAN). On 13Apr2021, 13:00 the patient stated that she was an epileptic and she do take anti-seizure meds. She have had 3 seizures in the last 24 hours. The patient was not pregnant. The patient did not have covid prior vaccination and was not test post vaccination. The patient did not received any treatment for the event. Outcome of the event was not recovered.

<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>
1266044	4/28/2021	DC	30	F	4/12/2021	4/13/2021	lost consciousness for a brief period; doing something that looked like a small seizure; got tunnel vision; vasovagal response; feel faint, dizzy, and lightheaded; feel very weak; This is a spontaneous report from a contactable consumer (patient). A 30-year-old female consumer received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 12Apr2021 at 14:30 at single dose in left arm for COVID-19 immunisation at the age of 30-year-old. Lot number was EP7524. Medical history included periodontal surgery. Concomitant medications included spironolactone, adapalene, benzoyl peroxide (Epiduo Forte), azelaic acid (FINACEA), aciclovir, hydrocortisone (Xerese). The patient believed she experienced some kind of vasovagal response. On 13Apr2021 at 08:00, the patient got up from sleeping and went to the restroom, where she started to feel faint, dizzy, and lightheaded. The patient sat down and got tunnel vision and she started to feel very weak but regained her vision after sitting. The patient was helped back to bedroom but had to stop and sit in the floor where patient lost consciousness for a brief period, less than 10 seconds. Her partner said patient was doing something that looked like a small seizure. The patient had had this response before many times when giving blood and even after her periodontal surgery. The patient was recovering from the 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>
1266041	4/28/2021	MD	39	M	4/4/2021	4/11/2021	seizure one week after second vaccine; This is a spontaneous report from a contactable consumer (patient). A 39-year-old male consumer received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 04Apr2021 at 11:00 as single dose for COVID-19 immunisation at the age of 39-year-old. Medical history was unknown and concomitant medications included ibuprofen (ADVIL), mometasone furoate (FLONASE). Historical vaccine included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 14Mar2021 for COVID-19 immunisation at the age of 39-year-old. On 11Apr2021, the patient experienced seizure; the patient was treated for the event. On unknown date, the patient underwent Computerised tomogram, Electroencephalogram, Magnetic resonance imaging (results unknown). The patient was recovering 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. Information about lot/batch number 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>
1265995	4/28/2021	AZ		F	3/17/2021	3/18/2021	Seizure; lost control of her blaster as soon as she stood; dull headache; This is a spontaneous report from a contactable consumer (patient) reported that a 75-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: er2613), via an unspecified route of administration, administered in arm left on 17Mar2021 12:00 as a single dose for covid-19 immunisation. The patient had no other medical history. The patient had no known allergies. The patient had no covid-19 prior vaccination. The patient was not pregnant at the time of vaccination. The patient did not have any other vaccine in four weeks. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: En6202), administered in left arm on 24Feb2021 12:00 PM (at the age of 75-years-old) for covid-19 immunization. The patient did received other medications in two weeks. On 18Mar2021 02:00 AM, the patient experienced seizure, recovered from the desire about 30 minutes after stood up, lost control of her blaster as soon as she stood, and dull headache daily. The patient did not received any treatment for the events. The outcome of the 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>
1265907	4/28/2021	MO	67	M	3/30/2021	3/31/2021	severe grand mal seizures; he only has half of his memory; some of his levels were high last week in his bloodwork; This is a spontaneous report from a contactable consumer (patient's wife). A 67-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8730 and expiration date not provided) via an unspecified route of administration, administered in left arm on 30Mar2021 13:10 as a single dose for COVID-19 immunisation. Medical history included ongoing hypothyroid which he have had for 15 years. Concomitant medication included ongoing levothyroxine for hypothyroid which he had been taking for too long to remember, over 10 years. The patient took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6206) in the left arm on 08Mar2021 for COVID-19 immunization. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine. The reporter (patient's wife) called about the Pfizer vaccine for COVID 19. She called to report that her husband almost within 24 hours after receiving his second vaccine, he a had severe grand mal seizure and had to be hospitalized from 31Mar2021 to 02Apr2021. She confirmed that he have had severe grand mal seizures on 31Mar2021. She said that he did not regain consciousness afterwards and that this was within 24 hours after receiving the 2nd vaccination. When probed for end date, the reporter stated that they could not find anything wrong with him. She said he only has half of his memory on an unspecified date. There was a lasting memory effect. He is on seizure medications, he is not allowed to drive for 1 month because he had the seizure, he has a zoom call meeting with his doctor on 19Apr2021. She says not driving is a problem, he is trying to work from home. She said upper arm for shot location then consulted her husband in the background who said both shots were in his left arm. She said he takes low dose thyroid medication. She consulted her husband in the background for some information. After giving some information she says no he doesn't take anything else. He is never sick and he's never ever been hospitalized. This is his first time ever. She said her son says when the body gets into that condition, it enters fight-or-flight, he went into fight, 5 firefighters had to hold him so they could give him the calm-you-down medications in

<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>
							the ambulance. One was his son, he said that he had the power of 10 men. She said her husband doesn't remember any of it. She says he is very healthy. For investigation, she said, well everything turned out negative. She says he had a CT scan, MRI, EEG, bloodwork, urinalysis on an unspecified date in 2021 and they can't find anything wrong. She said that they just said everything was normal. She said some of his levels were high last week, on an unspecified date in 2021 in his bloodwork and his doctor wanted him to do bloodwork again in 3 weeks. She said several things were high. The events required a visit to emergency room. She said that the fire department took him. She did not visit the physician office until after he got out of the hospital where he saw his primary doctor. She said she wanted to include on the report that it scared the crap out of her. She said, she was holding his neck up and tilting his head up to make sure he was getting air. She wanted to let everyone know what happened. The outcome of the event Grand mal seizure was recovered with sequelae on an unspecified date while the outcome of the rest of the events was unknown.
1266739	4/28/2021	NJ	28	F	2/8/2021	4/23/2021	The day following the Moderna injection with severe headache and sensitivity to light which lasted for 3 days. then followed by low level confusion and forgetfulness, loosing words during conversation until 2/23/2021 when had grand mal seizure. I have a history of epilepsy since 13 yrs old and had been seizure free for 8+ years until 2/23/2021. Since that seizure with continued forgetfulness , foggy feeling in head, and eye fluttering. Seen by epilepsy specialist on 4/12 and was admitted to hospital for video EEG and MRI and found to have significant both focal and generalized seizure activity despite my usual anti-seizure medications that had been working for 14 years. My medications were changed and I was discharge home after 6 days.
1267034	4/28/2021	TX	48	F	4/22/2021	4/23/2021	Seizure occurred 24 hours after receiving the vaccine that latest about one minutes.

<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>
1264303	4/27/2021	AZ	42	F	2/24/2021	2/24/2021	My husband and I sat down at the same time to get the shot. I got the shot stood up waited for my husband to get his. We then went to the chairs to wait. Right as we sat down I started having to clear my throat. They gave me water and I couldn't swallow it. I started struggling to breath. They had me lay down and I was still having a hard time breathing. They took my oxygen and it was extremely low. I started having convulsions. They used an Epi pen on my right leg and then called 911. I started convulsing and couldn't breath or control my body. I lost consciousness right after the ambulance got there. Last thing I remember was somebody picking me up and putting me on the stretcher and then I woke up in the emergency room with them hooking me up to an EEG.
1262497	4/27/2021	HI	22	M	4/26/2021	4/26/2021	Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Additional Details: Less than 5 mins after injection, patient blacked out and fainted to the ground and hit his head in the process. patient experienced mild seizure/movement after fall and regained consciousness after about 10-15 seconds later after pharmacist rolled patient to his side. patient reported similar events after having his blood drawn. ambulance was called and EMT team came to check out patient. patient reportedly felt fine, but after advise from EMT, patient drove himself to ER to get checked out.
1262660	4/27/2021	IL	16	M	4/20/2021	4/20/2021	Pt had a seizure roughly 5 min after receiving the vaccine
1262969	4/27/2021		32	M	3/9/2021	3/9/2021	Collapsed, or lost conscious; Seizure like activity.

<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>
1263131	4/27/2021	NY	18	M	4/27/2021	4/27/2021	<p>Recipient received dose #2 vaccine today, and almost immediately had response with witnessed seizure-like activity, with posturing, tonic-clonic movement of his upper extremities, and eye movement with lateral nystagmus. Loss of consciousness was noted. Symptoms lasted approximately 15-30 seconds, and patient was placed in a reclined position. He regained consciousness quickly and became pale and diaphoretic. He was normally responsive and answered questions appropriately. Initial BP 74/32, HR 38, SpO2 98%. He drank some Gatorade and had improvement of symptoms gradually over 15-20 minutes. Repeat BP 100/58, HR 78. No past history of seizures. One prior syncopal event after pain response with sports injury. No prior difficulty with dose #1. After recovery, patient reported immediate pain with vaccine administration, then vision went blurry and he lost consciousness. Mother was driving the vehicle, and she witness symptoms as well as nursing staff in the vaccine pod. After recovery, options for further medical evaluation were discussed given complicated vasovagal response with seizure-like activity, mother called pediatrician to see if he could be seen, they recommended ER. Mother chose to drive by personal vehicle, rather than EMS transport. Symptoms were fully resolved and patient was transported to ER for further evaluation by personal vehicle.</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>
1263480	4/27/2021	MT	17	F	4/21/2021	4/22/2021	At 2am 4/22 patient started to feel sick and sent a text that I didn't read until 630 as I was asleep. She had severe muscle aches, hurt to move, hurt to breathe and felt like she was having a heart attack. She felt like she might pass out and had some blurred vision. At 630am, I saw her texts and immediately brought her 2 tylenol and a large glass of water. She went back to bed. She woke up around 10:45 and was feeling decent except for a headache but no fever or anything so we went to try on some Prom dresses. At the dress shop, she collapsed and had a seizure lasting around a minute. She lost her bladder and was completely confused and incoherent. She's never had a seizure before. I scooped her up, brought her to the ER where they ran every test and scan imagineable. Full blood work up and cultures, a chest xray, a CT scan of her brain and lungs. Her temp was high 103-104 and she had full body chills and a pounding headache. Her BP kept dropping and got as low as 81/36. They threw 2 bags of IV fluids into her and admitted her to the hospital. She had also developed a heart murmur. Over the course of the night, her BP stabilized but her temp continued to spike and come back down with Tylenol/Ibuprofen. She also had IV Tordahl for the headache. Her inflammatory markers were high at 15.3 which we were told should be less than 1. They reran labs in the morning but everything came back really low which they felt was a dilution effect from all the fluids so wanted us to follow up with her primary care on Monday. On Saturday night, her lymph nodes were swollen to the size of ping pong balls but have since slowly reduced in size although still there. Her labs were better from discharge and her white blood cell count was within range and her inflammatory marker was down to 1.7. Her blood sugar was a little low. She did pass out and have seizure like response to giving blood in the doctors office, lost bladder control again, shot pupils, etc. She is still stuttering over words, has some short term memory retention and has some motor function issues which they think is a result of the initial seizure and should resolve itself over time. Her liver function tests were totally normal in the hospital but are a high now so they will be checking her out again next week.

<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>
1262282	4/27/2021	FL	23	F	4/26/2021	4/26/2021	Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Systemic: Weakness-Medium, Additional Details: pt passed out after reporting not feeling well, 911 had been called, pt taken to hospital and released today, severe muscle twitching possible seizure like
1263702	4/27/2021		47	F	3/14/2021	3/14/2021	Seizure.
1262544	4/27/2021	MD	33	F	4/7/2021	4/7/2021	Within half an hour to 45 minutes I experienced an aura (episode prior to a seizure). I have been seizure free for 7 years; controlled via medication. Later that evening I had a fever, chills and severe body aches, along with extreme fatigue. This continued for 2 days. Felt better by the evening of Friday, April 9th. I missed 2 days of work due to the reactions.

<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>
1264386	4/27/2021	FL		M	4/5/2021		SEIZURE; VERY LOW BLOOD PRESSURE; ACHING BONE; FLU SYMPTOMS; DID NOT FEEL COMFORTABLE; NOT FEELING WELL; LEGS WERE SORE; GENERALIZED FATIGUE; This spontaneous report received from a physician concerned a 27 year male. The patient's height, and weight were not reported. The patient's concurrent conditions included generalized allergy to fish (but not to crustaceans or shellfish). 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, 1 total administered on 05-APR-2021 on right arm for prophylactic vaccination. No concomitant medications were reported. It was reported that the patient had the covid-19 vaccine ad26.cov2.s on 05-APR-2021, 6 minutes after, he was not feeling well and his father found him on the floor having seizure. Emergency unit was called. They found he had a very low blood pressure and did not feel comfortable releasing him so they took him to the hospital. Laboratory data included: Blood pressure (NR: not provided) very low. The patient was provided with intravenous line and did EKG (electrocardiogram). Laboratory data included: EKG (NR: not provided) not reported. He was discharged the same day. He did not had seizure since then. On 05-APR-2021, he experienced the flu symptoms, aching bone, generalized fatigue and legs were sore for 48 hours and then they were cleared. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from seizure, and very low blood pressure on 05-APR-2021, and aching bone, flu symptoms, not feeling well, legs were sore, and generalized fatigue on 07-APR-2021, and the outcome of did not feel comfortable was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210435573 -covid-19 vaccine ad26.cov2.s- Seizures. 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>
1264541	4/27/2021	CA	26	M	4/27/2021	4/27/2021	THE PATIENT STARTED SWEATING WITH SHAKES FOR A FEW MINUTES THEN STARTED FILLING COLD HE STATED IT FELT LIKE SEIZURE NOT SURE IF THAT'S WHAT HE HAD. HE STATED HIS CHEST FELT TIGHT. HIS EYE MAY HAVE ROLLED BACK NOT SURE AFTER A FEW MINUTES(5-10 MINUTES) HE STARTED FILLING BETTER WE CALLED 911 AND THEY CAME WITHIN 5-10 MINUTES HE WAS OBSERVED FOR A WHILE HE SAT ON THE CHAIR TILL BETTER AND WENT TO ER FOR FURTHER OBSERVATION
1264638	4/27/2021	MI	53	F	3/1/2021	3/25/2021	Had several myclonic seizures during the morning which ended in a grand mal seizure later in the morning of March 25th which resulted in my shoulder being shattered. This led to me having a reverse shoulder replacement.
1264661	4/27/2021	TX	20	M	4/26/2021	4/27/2021	Patient's mother called today and stated that he had a seizure this afternoon at 1:35 PM. She stated that she and her husband are both nurses. She happened to be off today and was home with her son. She stated that the seizure was like a Grand Mal seizure that lasted approximately 5 minutes. She stated that he has had a diabetic seizure before when his blood glucose levels were low. She stated his blood glucose was 71. She said this was different, he had no residual after effects. He was not incontinent of bowel or bladder and he woke up quickly afterwards. About an hour after the seizure he ate and only complained of a headache. She gave him ibuprofen 600 mg and he put an ice pack on his head. She said he is better. She stated that she is a nurse and this really scared her, since it was so different than any other seizure he has ever had. She was thankful she was home. She call his primary healthcare provider and she did not feel he needed to be seen.

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1264688	4/27/2021			F			<p>Whole body convulsing all day; Not doing well after her Moderna vaccine; Tongue began to spasm and hasn't quit/bad shape; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SEIZURE (Whole body convulsing all day) 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 (No recorded medical history). 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 SEIZURE (Whole body convulsing all day) (seriousness criterion medically significant), MALAISE (Not doing well after her Moderna vaccine) and MALAISE (Tongue began to spasm and hasn't quit/bad shape). At the time of the report, SEIZURE (Whole body convulsing all day), MALAISE (Not doing well after her Moderna vaccine) and MALAISE (Tongue began to spasm and hasn't quit/bad shape) had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Reporter did not allow further contact. Most recent FOLLOW-UP information incorporated above includes: On 12-Jan-2021: No specific follow-up information recorded. On 12-Jan-2021: No specific follow-up information recorded. On 12-Jan-2021: No specific follow-up information recorded. On 15-Jan-2021: No specific follow-up information recorded.; 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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1264840	4/27/2021	WI	28	F	4/27/2021	4/27/2021	PATIENT WAS PANICKING BEFORE GETTING THE VACCINE. WAS VERY NERVOUS AND AFTER GOT THE SHOT HAD LITTLE SEIZURES AND FAINTED FOR FEW SECONDS. REGAINED CONSCIOUSNESS WITHIN FEW SECONDS. WAS TALKING AFTERWARDS. DID NOT WANT TO LIE DOWN SO MADE HER KEEP HER HEAD BETWEEN THE LEGS FOR PROPER BLOOD FLOW. DID COLD COMPRESS FOR SOME TIME. PATIENT STARTED FEELING BETTER AFTERWARDS. PARAMEDICS HAD ARRIVED BY THAT TIME AND TOOK HER VITALS WHICH SEEMED GOOD PER PARAMEDICS. PATIENT SIGNED A WAIVER AND PARAMEDICS LEFT AFTERWARDS. WE GAVE PATIENT GATORADE TO DRINK AND HAVE ONE OF THE PHARMACY ASSOCIATES BE BY PATIENT'S SIDE. AFTER STAYING IN THE PHARMACY FOR ABOUT AN HOUR PATIENT LEFT ALONG WITH HER HUSBAND
1265409	4/27/2021	OH	44	M	4/11/2021	4/25/2021	Patient reports seizures on 4/25/2021 requiring 911 call, ambulance, and hospitalization stay. Patient mental status changed to violent and resulted in a dislocated shoulder when hospitalized. Patient has no history of seizures or violent behavior.
1263645	4/27/2021	MN	42	M	4/6/2021	4/14/2021	Headache from 4/14/21 to 4/24/21, tonic-clonic seizure on 4/24/21 admitted to hospital on 4/24/21

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1261544	4/27/2021			F		3/23/2021	seizure; 14 pound weight gain; This spontaneous case was reported by an other health care professional and describes the occurrence of SEIZURE (seizure) in a 43-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 Primary pulmonary hypertension. Concomitant products included MACITENTAN for Primary pulmonary hypertension, APIXABAN (ELIQUIS), EPOPROSTENOL SODIUM (FLOLAN) and SILDENAFIL CITRATE for an unknown indication. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, the patient experienced SEIZURE (seizure) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced WEIGHT INCREASED (14 pound weight gain). The patient was hospitalized from 23-Mar-2021 to 25-Mar-2021 due to SEIZURE. At the time of the report, SEIZURE (seizure) and WEIGHT INCREASED (14 pound weight gain) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In March 2021, Weight: abnormal (abnormal) gained 14 pounds in 1-2 weeks. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. It was reported that it was not sure if the patient was getting her diuretic in the hospital.
1262789	4/27/2021		48	F	3/8/2021	3/8/2021	patient suffered a 2-minute long seizure. She has a history of known seizure disorder. Her last seizure was 3 months ago. She also suffers from severe anxiety. patient was alert and oriented times 3 and refused transport to a local hospital by EMS.
1262130	4/27/2021	CA	33	M	4/27/2021	4/27/2021	About 10 minutes after the vaccination was given, our technician noticed that pt leaned back and called out to his mom. Then, pt started to have a seizure.

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1261513	4/27/2021		53	F	3/15/2021	3/15/2021	Was scheduled for 2nd dose 10Apr2021, caller felt body was not in best shape to receive dose, so declined vaccine; Seizure like activity; Jaw pain; Chest pain; Shortness of breath; Soreness to arm at site of injection; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SEIZURE LIKE PHENOMENA (Seizure like activity) in a 53-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 Seizure like phenomena since an unknown date. Concurrent medical conditions included Brain neoplasm malignant. Concomitant products included LACOSAMIDE (VIMPAT) and PREDNISONE for an unknown indication. 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 DYSPNOEA (Shortness of breath) and VACCINATION SITE PAIN (Soreness to arm at site of injection). On 18-Mar-2021, the patient experienced PAIN IN JAW (Jaw pain) and CHEST PAIN (Chest pain). On 02-Apr-2021, the patient experienced SEIZURE LIKE PHENOMENA (Seizure like activity) (seriousness criterion medically significant). On an unknown date, the patient experienced INTENTIONAL PRODUCT USE ISSUE (Was scheduled for 2nd dose 10Apr2021, caller felt body was not in best shape to receive dose, so declined vaccine). At the time of the report, SEIZURE LIKE PHENOMENA (Seizure like activity), PAIN IN JAW (Jaw pain), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), VACCINATION SITE PAIN (Soreness to arm at site of injection) and INTENTIONAL PRODUCT USE ISSUE (Was scheduled for 2nd dose 10Apr2021, caller felt body was not in best shape to receive dose, so declined vaccine) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood test: elevated dimer (High) elevated dimer. On an unknown date, Computerised tomogram: unknown (Inconclusive) unknown. On an unknown date, Magnetic resonance imaging: unknown (Inconclusive) unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment includes Vimpat, Prednisone. Company

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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.

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1261527	4/27/2021		42	F	4/20/2021	4/20/2021	<p>two grand mal seizures; migraine; under skull feels like it itches; persistent cough; body aches; chills; pain at vaccination site; extreme n/v; extreme n/v; This spontaneous case was reported by a consumer and describes the occurrence of GENERALISED TONIC-CLONIC SEIZURE (two grand mal seizures) in a 42-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 002C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Seizures. Concomitant products included VALPROATE SEMISODIUM (DEPAKOTE), CARBAMAZEPINE (TEGRETOL), TRAZODONE and POTASSIUM GLUCONATE for an unknown indication. On 20-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Apr-2021, the patient experienced GENERALISED TONIC-CLONIC SEIZURE (two grand mal seizures) (seriousness criterion medically significant), MIGRAINE (migraine), PRURITUS (under skull feels like it itches), COUGH (persistent cough), MYALGIA (body aches), CHILLS (chills), VACCINATION SITE PAIN (pain at vaccination site), NAUSEA (extreme n/v) and VOMITING (extreme n/v). On 20-Apr-2021, VACCINATION SITE PAIN (pain at vaccination site) had resolved. At the time of the report, GENERALISED TONIC-CLONIC SEIZURE (two grand mal seizures), MIGRAINE (migraine), PRURITUS (under skull feels like it itches), COUGH (persistent cough), MYALGIA (body aches), CHILLS (chills), NAUSEA (extreme n/v) and VOMITING (extreme n/v) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment medication: Norco 10mg, Zofran 8mg, Tylenol, Motrin. 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. Patient's hx of seizures and conmeds of Depakote, tegretol, trazadone, and potassium gluconate are confounding factors that may play a possible contributory role to the event PT seizures. ; 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. Patient's hx of seizures</p>

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and conmeds of Depakote, tegretol, trazadone, and potassium gluconate are confounding factors that may play a possible contributory role to the event PT seizures.

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1261203	4/27/2021	IL		F	4/1/2021		NEUROLOGIC ISSUES; DYSTONIC REACTIONS; DIFFICULTY IN BREATHING; CHEST TIGHTNESS; SEEING ISSUES; BRAIN FOG; SWEATING UNCONTROLLABLY; CONVULSIONS; FLU-LIKE SYMPTOMS; PAIN IN ARM; STOMACH PAIN; 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: 1808980, expiry: UNKNOWN) dose was not reported, administered on 07-APR-2021 to left arm for prophylactic vaccination. No concomitant medications were reported. Immediately after vaccination on 08-APR-2021 the patient felt arm pain, felt okay when she got home and was able to take care of family. Woke up with a fever the next day and body aches with flu-like symptoms. The next morning she felt okay, by the next day she felt something was really wrong, she started sweating uncontrollably and she collapsed on her bedroom floor and started shaking uncontrollably and could not breathe/see very well. Patient was able to get to the entrance of the house and lost control of her bladder and continued to have convulsions. On 08-APR-2021, the patient was hospitalized. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from sweating uncontrollably on APR-2021, flu-like symptoms/fever/body ache on 09-APR-2021, and pain in arm on 07-APR-2021, was recovering from dystonic reaction, difficulty breathing, and convulsions/collapsed on bedroom floor/shaking uncontrollably/lost control of bladder, had not recovered from neurologic issues, seeing issues, brain fog, and chest tightness, and the outcome of stomach pain was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210429120- covid-19 vaccine ad26.cov2.s- Convulsions,dystonic reaction, difficulty breathing, chest tightness, neurologic issues, seeing issue, brain fog, sweating uncontrollably. 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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1261720	4/27/2021	WI	33	F	4/12/2021	4/12/2021	the tv (tricuspid valve incompetence); This is a spontaneous report from a contactable physician. A 33-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Right on 12Apr2021 at 13:15 (Batch/Lot number was not reported) as single dose for COVID-19 immunization. Medical history included Stroke, and seizure. The patient's concomitant medications were not reported. On 12Apr2021 at 13:15, the patient experienced the tv (tricuspid valve incompetence). The patient did not received treatment for the event. The outcome of the event was unknown. The patient did not had COVID prior to vaccination and not tested for COVID post vaccination. Information about lot/batch has been requested.; Sender's Comments: Based on the information currently available, the event is considered most likely associated with intercurrent or underlying medical conditions, appears unrelated to the suspect drug.
1261766	4/27/2021	FL	1	M	4/8/2021	4/10/2021	increased body temperature, seizure, death
1261783	4/27/2021	OH		M			Convulsions; 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), via an unspecified route of administration on an unspecified date (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. It was reported that patient experienced convulsions on an unspecified date with outcome of unknown. Follow-up attempts are completed. No further information is expected.

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1261787	4/27/2021	OH		U	4/9/2021	4/9/2021	This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, administered in a clinic facility on 09Apr2021 as SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 09Apr2021, the patient experienced convulsions. The outcome of the event was unknown. No follow-up attempts are completed; information about batch/lot cannot be obtained.
1262097	4/27/2021	PA	59	M		4/7/2021	RIGHT OPHTHALMIC STROKE; LEFT SIDED WEAKNESS; CHILLS; This spontaneous report received from a physician concerned a 59 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included hypertension, and seizures. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 202A21A expiry: UNKNOWN) dose was not reported, administered on 07-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, the patient experienced chills, tremor. On 10-APR-2021 15:00, the patient presented to hospital he was hunched over, gait was unsteady, and stated that over the past day left side gotten weaker, unable to decide the feeling, reports of numbness, decreased strength to left side, shuffling gait. On the same day, 10-Apr-2021, patient was hospitalized with symptoms of stroke, and was diagnosed with right ophthalmic stroke. The patient was in the hospital for 4 days. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0 : 20210427690-covid-19 vaccine ad26.cov2.s -RIGHT OPHTHALMIC STROKE, LEFT SIDED WEAKNESS . 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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1259278	4/26/2021	TX	51	F	3/27/2021	3/27/2021	Patient started feeling dizziness, feeling hot, passed out 20 secs. Legs raised, alert and active, no seizure. BP 94/76, P- 70 1:03 Has M/O feeling dizziness when she wakes up in the morning at times. No signs of stridor, no seizures, no vomiting or nausea. 1:14 82/68, P- 70 Alert, active, sweating, color is pink, no change in color, no Shortness of breath, no stridor 1:23 104/76 P-70 Alert, Oriented x 3 1:28 110/80, P-70 1:32 cold and sweaty 1:35 sitting on chair, feel well. Alert, active, oriented x 3 1:42 92/68 P- sitting position chair 1:46 103/72 P-64 lying down 1:50 Vomiting, feel better afterwards 2:01 105/82, P-65
1257469	4/26/2021	NV	29	M	4/25/2021	4/25/2021	Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: patient had a seizure that lasted a few seconds-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Seizure-Mild

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1258552	4/26/2021	PA	70	M	4/9/2021	4/14/2021	Patient became unconscious the evening of 4/14/21. This event occurred five days after his second Covid vaccination. Patient had just gotten up from a living room chair and was walking over to the stairs to go to the second floor when he became rigid, lost consciousness and fell backward. 911 was called by his girlfriend. He was unconscious for a couple of minutes. When EMT's arrived he was conscious but very groggy. His blood pressure was 250/157. He knew his name and year and SSN but did not correctly answer several other questions. He was taken to ER. After numerous tests over the course of several days, he was diagnosed as having a stroke. In the ER, they performed CAT scans, EKG, blood work, urine test and chest xray. Blood pressure remained high. Complained of headaches. Patient was also having trouble voiding urine in the ER so a foley catheter was inserted. He was admitted to the hospital. After admission, an MRI, echocardiogram and EEG were performed. The MRI showed three small blood vessels had burst in his brain. Echocardiogram showed functions were normal. The EEG showed some slowing but no signs of seizure. The conclusion was a stroke. Physical and occupational therapy examined patient. No need for further therapy. Blood pressure remains slightly elevated but he does not appear at this time to have lost any physical or mental functions. Patient does NOT have a history of high blood pressure or heart issues. Tests showed his heart was functioning properly. Per his family doctor, his BP ran approximately 124/64 when tested during the previous 12 months.
1259060	4/26/2021	PA	57	F	4/9/2021	4/10/2021	Patient states she was shopping in the am and woke up in the ambulance. She was told she had a seizure and fell and hit her head. She was admitted site from 4/10/21 to 4/13/21.
1257656	4/26/2021	VA	75	M	3/2/2021	4/7/2021	extreme confusion and memory loss that has not cleared up, seizure

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1259701	4/26/2021	MI	16	F	4/26/2021	4/26/2021	Patient was vaccinated and left with her mother to sit in her car for 30 minute monitoring period. Patient's mother stated patient was experiencing extreme anxiety getting the vaccine and after 20 minutes was wheezing. She brought patient inside and a Pharmacist came to check on her and her mother stated that she has had a reaction to a medication in the past and just needed Benadryl. Benadryl was given to her and she took it orally. Her pulse and blood oxygen were measured with a finger pulse oximeter and were both normal. Shortly after she was panicking more and had a seizure. Her mother reported that she has frequent seizures when she has anxiety/panic episodes. Her seizures were persisting so 911 was called. Paramedics arrived shortly after and took patient to the hospital. A few hours later the patient's mother came back to us to inform us that she was released from the hospital and was feeling fine and back to normal.
1259727	4/26/2021	ME	51	F	1/23/2021	2/16/2021	Left frontal lobe focal headache all day, at 7:30pm, feeling of overwhelming doom, followed by sudden onset uncontrollable crying, culminating in a seizure without loss of consciousness. Legs, arms, abdomen jerking in contraction and release. Extreme fatigue following event.
1260022	4/26/2021	OR	16	M	4/23/2021	4/23/2021	Patient presents with a potential reaction to the COVID19 vaccine. I was called to the patient's vehicle just outside the vaccination area. The patient appeared to having a moderate to severe vasovagal episode without total syncope. There did appear to be slight pseudoseizure activity present, however, there was no LOC or loss of bowel or bladder tone. The patient was placed in a supine position and moved to the monitoring area. With positional changes and aggressive hydration, he rapidly improved to baseline. He did endorse that he has had similar episodes with blood draws, etc. He was returned home with his mother as the driver and with preventative instructions for his second dose.

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1257845	4/26/2021	VI	50	F	4/22/2021	4/23/2021	Per patient contacting pharmacy, she indicated approximately 24 hours after her first COVID-19 vaccine (Moderna), patient experienced a grand mal seizure that caused unconsciousness for approximately 2 minutes. While unconscious, she bit her tongue and her time to get full functionality was 30-60 minutes after. Patient indicated she contacted her primary neurologist via email and left messages at the office, however still has not heard from her doctor. She did not seek out other medical treatment. Patient has a history of grand mal seizures, but has not experience an event since starting medication.
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.

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1254579	4/25/2021	MO		M	4/6/2021	4/6/2021	seizure; This is a spontaneous report received from a contactable pharmacist (patient) via medical information team. Follow-up (06Apr2021) was received from same reporter and processed together with initial information. A male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: ER8729; Expiration Date: 20Jul2021), via an unspecified route of administration on 06Apr2021 as SINGLE DOSE for covid-19 immunization. Other suspect medications included: saline [sodium chloride], via an unspecified route of administration from an unspecified date (Lot Number: 6023228), at unspecified dose for an unspecified indication. The patient medical history and concomitant medications were not reported. The patient reported that after administering the Covid 19 vaccine on 06Apr2021, within about 20 minutes there were 4 patients with reactions. One patient had a seizure and 3 patients passed out. These patients had just received the Covid 19 vaccine and were still being watched within the 15-minute post vaccination time. All 4 patients received the Covid 19 vaccine from the same lot number but not from the same vial. Seriousness of event was medically significant. The outcome of event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information in the case report and strong temporal relationship, A possible causal relationship between event Seizure 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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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. ~~
1257136	4/25/2021	NY	42	F	4/9/2021	4/10/2021	Vomiting, Fever, Diarrhea, Nausea, Vertigo, Convulsions, Extreme Fatigue, Disorientation, Extreme Blurred Vision, Problems With Night vision, Extreme Chest Pain, Short of Breath, Extra Sleeping, Decreased Productivity, Confusion, Getting Lost Abnormally, Decreased to NO appetite

<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>
1254668	4/25/2021	CT	64	F	4/6/2021	4/6/2021	I felt very tired and weak; I felt very tired and weak; my heart was skipping really bad I could hear it, could felt it in my chest. Then trembling; heart palpitations and it was skipping and trembling off and on; arm is sore; weird feeling; trembling; trembling, shaking and she thought she was going to have a seizure, she had no control over her muscles; muscles twitching, like if I had no control over the muscles; she had to use the bathroom a couple hours after the shot. She stated she has been drinking a lot; didn't feel good last night; This is a spontaneous report from a contactable consumer (patient). A 64-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Right on 06Apr2021 13:00 (Batch/Lot Number: ER8737) as SINGLE DOSE for covid-19 immunisation, at 64 years old. Medical history included cholesterol (abnormal, takes cholesterol medication 3 times a week as she gets side effects from it), cutaneous lupus (She always has to do bloodwork and goes in every 3 months), heart problem that is not major (she takes 1 medication, patient stated once in a while she sees her cardiologist every 6 months and she did get a halter monitor for 24 hours for a week and they take an average and said it wasn't as bad and knows that is a problem), 2 cervical spine surgeries, arthritis, allergic to contrast dye for CAT scans, allergy to medications (sensitive to medications), shrunk a lot because of issues, and had surgery which shrunk her because of her spine from an unknown date. Concomitant medication included atorvastatin calcium (LIPITOR) taken for blood cholesterol abnormal from 2016 and ongoing; and nadolol (CORCARD) taken for an unspecified indication from 2001 and ongoing. Patient's son got COVID on an unspecified date. Patient previously took generic atorvastatin which made her sick on an unspecified date and LIPITOR and experienced muscle weakness on an unspecified date. No additional vaccines administered on the same date of the Pfizer vaccine. No prior vaccinations. Patient never got a flu shot as she was scared. On 06Apr2021, her arm was sore which is normal. Normal side effects from the arm did not concern her, patient had no fever nothing else. She stated she came home and felt like she had to use the bathroom a couple hours after the shot. She stated she has been drinking a lot and she made sure of that. At

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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19:00 (also reported as 7-8pm), patient experienced her heart was skipping really bad. Patient could hear it and could feel it in her chest. Patient clarified her heart was not fast, it was more skipping, and she could feel it beating in her throat. She commented has a problem but that has not happened in a long time. Patient then experienced trembling described as lots of body trembling concerned like a seizure. She thought she was going to have a seizure. It was not chills; she had no fever or anything. The trembling came on and off. Her muscles were twitching, like if patient had no control over the muscles. Patient did not feel dizzy, it was a weird feeling. She did not feel good. On 07Apr2021 at 02:00, patient felt very tired and weak, her heart was better. About 02:00 she fell asleep. She woke up at 6:30 and she felt tired but that does not bother her. Her concern was the body trembling. She called her doctor but was not available. She was advised that it does not sound like a symptom of the vaccine. She was worried she needs to go to the cardiologist and see what is happening. She stated if it keeps happening, she will go, and she does not know if this is a side effect other people are reporting. Patient was wondering if this is a reaction as she cannot find it, one says a severe reaction is a fast heartbeat, really fast and skipping and she does not know. She expected anything, tired, headache, muscle aches but these did not happen, but she was expecting them to. Patient is wondering why her heart is doing that is it from the shot or what is going on with her which is weird, and stated the shaking, trembling of her whole body is weird. She mentioned she is sensitive to medication and gets reactions to a lot of medications. She stated this is why she was scared to get the vaccine and what the reaction was with the 1st. Patient stated her heart is a lot better than it was last night, that she feels very tired and feels unwell. She stated she took her temperature (Apr2021) and she had no fever, no nothing a little unwell, a weird feeling. Patient stated she is not trembling anymore and has no heart skipping, that went away about 2am when she fell asleep for a few hours (also reported as went away after about an hour, she had it off and on 3-4 times in an hour). Patient clarified she has not had testing done for the reported symptoms. The patient stated she is concerned and does not know what to do about second dose, which is scheduled for 04May2021. She does not if

<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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it was a reaction and stated she is very sensitive to medicine. Events did not require emergency room and physician office visit. Outcome of the event heart was skipping, tremor and palpitations was recovered on 07Apr2021 02:00 while unknown for the other events. Follow-up attempts are completed. No further information is expected. Lot number has been obtained.

<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>
1254632	4/25/2021	MI	58	M	4/4/2021	4/4/2021	Full blown seizure; Fatigue; Confusion; Breathing was off; breath was heavier; patient's blood pressure was very low; Real sluggish/get slow; Speech started to get slow; This is spontaneous report from a contactable consumer (patient's wife). A 58-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: ER8734) via an unspecified route of administration in left arm on 04Apr2021 12:00 at age of 58-year-old at single dose for COVID-19 immunization. It also stated the patient was one of the most vulnerable against virus so he took the Covid-19 Vaccine. Medical history included ongoing cardiac failure congestive diagnosed probably 10 years ago, ongoing diabetes mellitus diagnosed probably 20 years ago, ongoing dialysis for 3.5 years. Concomitant medication included ongoing unspecified blood thinner. Caller reported that the patient didn't take any blood pressure medications and that she knew the patient took a blood thinner. Caller unable to provide further detail for the patient's medications as she doesn't have the patient's list of medications with her. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EP7534) injected in left arm in Mar2021 at age of 58-year-old for COVID-19 immunization and experienced fatigue after the first dose of the Covid-19 vaccine. Caller reported that it was hard to determine the cause of the fatigue because the patient was on dialysis, but that the patient has been more fatigued since he received the first dose of the Covid-19 vaccine. The patient was a compromised fellow with a host of pre-existing conditions as far as heart disease, diabetes, and dialysis. Caller was calling in regard to the Pfizer Covid-19 vaccine. Caller reported that she was calling to report a bad reaction that her husband, the patient, received on Sunday, 04Apr2021, following his second dose of the Covid-19 vaccine. Approximately 3 hours after receiving the Covid-19 vaccine, the patient had a full blown seizure at 15:00 on Sunday, 04Apr2021. Caller reported that she had to call emergency responders following the patient's seizure. The patient was doing better but the experience with his seizure was quite traumatic. Caller stated that if it was going to happen, it was going to happen to us. About 3 hours after receiving his Covid-19 vaccine on 04Apr2021, the patient became real sluggish and his speech started getting slow

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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before the seizure occurred. Caller reported that the patient made a gradual descent downwards. Caller reported that she swears the patient has not been the same as far as fatigue goes since the patient received his first dose of the Covid-19 vaccine 3 weeks prior. Caller reported that she thought the fatigue was maybe from dialysis. The patient started to get slow just before the seizure, about 2.5 hours after he received the second dose of the Covid-19 vaccine. The patient was laying down following the second dose of the Covid-19 vaccine. Caller reported that the patient's breathing was off. The patient's breath was heavier. Caller reported that after she noticed the patient's breathing was off, she asked the patient if he was ok. Caller reported that this is when she noticed that the patient's speech was really slow and that he was experiencing confusion. The patient has had no more seizure activity. The patient was still being monitored in the hospital. Caller reported that the patient didn't remember any of it. It's hard to say if the patient's sluggishness and fatigue were ongoing. Caller reported that she couldn't go see the patient while he was in the hospital but that the patient's voice sounds much stronger. For Confusion and Speech: Caller reported that the patient seems to be back/ returned to normal. Caller reported that she knew that the patient's cardiologist went to see the patient. The patient's cardiologist said that there was nothing that happened to the patient's heart, that what the patient experienced was not a heart issue, and that the event had no effect on the patient's heart. The medical staff stated that the seizure the patient experienced was related to a blood pressure drop. Caller reported that the patient's blood pressure was very low on 04Apr2021. The patient required a visit to Emergency Room for event seizure, no visit of physician office. Admitted on Sunday, 04Apr2021 for seizure, and still hospitalized. For investigations: Caller reported that the medical staff at the hospital definitely did lab work but she was not sure if any imaging was performed. Caller reported that she has no results available for tests that were performed. The outcome of events confusion and "speech started to get slow" was recovered in Apr2021, the outcome of other events was unknown. Follow-up attempts are completed. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021380129 same patient,

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different product(dose)/event

<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>
1254611	4/25/2021	MO		M	4/6/2021	4/6/2021	fainted/passed out; Fainted/passed out; This is a spontaneous report received from a contactable pharmacist via a medical information team. This report is in reference to one of the patients the caller states passed out. A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: ER8729, Expiration date: 20Jul2021), via an unspecified route of administration on 06Apr2021 as a single dose for COVID-19 immunization, sodium chloride (SALINE, Formulation: Unknown, Batch number: 6023228), via an unspecified route of administration on an unspecified date at an unknown dose and frequency for an unknown indication. The patient's medical history and concomitant medications were not reported. The patient had fainted/passed out on 06Apr2021. It was reported that, vaccine coordinator said that they use the same lot number for all three of their facilities. An hour ago, at one of their facilities, he said 3 people fainted and 1 had seizure after receiving the 1st dose of the Pfizer-BioNTech Covid-19 Vaccine. HCP wants to know if there have been any reports of having these reactions associated with the specific lot number: ER8729. He said he already has 56 vials of the vaccine mixed up with the same lot and wants to know if he should still continue using it. HCP also added that out of 3,200 vaccines that they have out of the same lot, they only had 4 incidences. Pharmacist told the HCP that there was no information available about fainting and having seizures associated with the lot: ER8729. However, pharmacist told him that I would forward his concern to someone from our team for further research. Escalating to second line for further research and handling. Caller was a pharmacist who was heavily involved in the COVID-19 vaccine. He manages 3 locations and more than 1500 COVID-19 vaccine doses. Today he's reporting that at one of his other locations, administering the COVID-19 vaccine within about 20 minutes there were 4 patients with reactions. One patient had a seizure and 3 patients passed out. These patient's had just received the COVID-19 vaccine and were still being watched within the 15-minute post vaccination time. All 4 patients received the COVID-19 vaccine from the same lot number but not from the same vial. One of the patient's that passed out said that she has had some

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issues with vaccines in the past. Caller reports that his COVID-19 vaccine facilities are busy today giving COVID-19 vaccines and about half the people receiving the vaccine are waiting inside and about half are waiting outside. It's about 84F outside and he's reporting that he's not seeing anything to eat or drink in these individuals waiting for the COVID-19 vaccine. He believes the NDC number for the COVID-19 vaccine ends in "02". Caller did not have any information on the patients involved. The outcome of the events was unknown. Information on Lot/Batch number was available. No further information is provided or obtained. Additional information has been requested.; Sender's Comments: As there is limited information in the case provided, the causal association between the events of syncope, loss of consciousness and the suspect 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 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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1254579	4/25/2021	MO		M	4/6/2021	4/6/2021	seizure; This is a spontaneous report received from a contactable pharmacist (patient) via medical information team. Follow-up (06Apr2021) was received from same reporter and processed together with initial information. A male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: ER8729; Expiration Date: 20Jul2021), via an unspecified route of administration on 06Apr2021 as SINGLE DOSE for covid-19 immunization. Other suspect medications included: saline [sodium chloride], via an unspecified route of administration from an unspecified date (Lot Number: 6023228), at unspecified dose for an unspecified indication. The patient medical history and concomitant medications were not reported. The patient reported that after administering the Covid 19 vaccine on 06Apr2021, within about 20 minutes there were 4 patients with reactions. One patient had a seizure and 3 patients passed out. These patients had just received the Covid 19 vaccine and were still being watched within the 15-minute post vaccination time. All 4 patients received the Covid 19 vaccine from the same lot number but not from the same vial. Seriousness of event was medically significant. The outcome of event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information in the case report and strong temporal relationship, A possible causal relationship between event Seizure 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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1254435	4/25/2021		58	F	3/26/2021	3/27/2021	numbing on the left side of face - eye, cheek, mouth and left fingers, thumb to pinky; numbing on the left side of face - eye, cheek, mouth and left fingers, thumb to pinky; numbing on the left side of face - eye, cheek, mouth and left fingers, thumb to pinky; numbing on the left side of face - eye, cheek, mouth and left fingers, thumb to pinky; This is a spontaneous report received from a contactable consumer (patient). A 58-year-old female patient received the first dose of BNT162B2 (lot number: ER8727), via unspecified route of administration in left arm on 26Mar2021 11:45 AM at single dose for COVID-19 immunisation. The patient's medical history included primary central nervous system lymphoma and seizure. The patient had allergies to tree nuts. The patient's concomitant medications included vitamins, fish oil. 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. The patient previously received levetiracetam (KEPPRA) (anti-seizure medication) that she had stopped in end of Jan2021. Approximately 21 hours after injection of vaccine, the patient experienced numbing on the left side of face - eye, cheek, mouth - and left fingers, thumb to pinky. Lasted about 10 minutes and feeling came back. Same thing happened 15 minutes later and then stopped. Events onset date reported as 27Mar2021 09:15 AM. The event resulted in doctor or other healthcare professional office/clinic visit. The patient contacted her oncologist, she resumed taking levetiracetam and will continue until 2 weeks after next shot (if decide to get it). The patient had routine brain MRI and all clear. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the event was unknown. No follow-up attempts are needed. No further information is expected.

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1254132	4/25/2021	CA	68	F	2/21/2021	2/21/2021	Racing heart within 10 minutes; vicelike headache; extreme nausea; pain in fingers and toes; bloody nose; pain in hips; swollen eyes; itching at injection site; no appetite; General weakness; insomnia; This is a spontaneous report from a contactable consumer or other non hcp (Patient). A 68-years-old female patient (Non-pregnant) received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot No: EN6200), via an unspecified route of administration, administered in Arm Left on 21Feb2021 13:45, as SINGLE DOSE for COVID-19 immunisation. Medical history included colostomy, osteoporosis and seizure (Grand Mal Seizures). The patient had no known allergies. Concomitant medications included felbamate (FELBATOL); levothyroxine sodium (SYNTHROID), lisinopril (ZESTRIL); calcium carbonate (OSCAL [CALCIUM CARBONATE]) and vitamin c [ASCORBIC ACID]). On 21Jan2021, the patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot No: EL9261), via an unspecified route of administration, administered in Arm Left, as SINGLE DOSE for COVID-19 immunisation. Patient not received COVID prior vaccination. Patient not tested for COVID post vaccination. On 21Feb2021 (13:00), the patient experienced racing heart within 10 minutes; vicelike headache; extreme nausea; pain in fingers and toes; bloody nose; pain in hips; swollen eyes; itching at injection site; no appetite; general weakness; insomnia. Patient not received treatment for the events. At the time of this report event outcome was recovering. No Follow-up attempts are needed. No further information is expected.
1257111	4/25/2021	LA	28	M	3/31/2021	4/1/2021	Recieved the vaccine and the following morning around 5am had a seizure which lasted for about 20 minutes. Was transported by ambulance to medical center and recieved care until he was stable and able to go home, but told to follow up with his neurologist as soon as possible. The neurologist saw him within 2 weeks and increased the dosage of his Vimpat and has ordered for him to have a 3 day EEG as soon as possible.

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1254611	4/25/2021	MO		M	4/6/2021	4/6/2021	fainted/passed out; Fainted/passed out; This is a spontaneous report received from a contactable pharmacist via a medical information team. This report is in reference to one of the patients the caller states passed out. A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: ER8729, Expiration date: 20Jul2021), via an unspecified route of administration on 06Apr2021 as a single dose for COVID-19 immunization, sodium chloride (SALINE, Formulation: Unknown, Batch number: 6023228), via an unspecified route of administration on an unspecified date at an unknown dose and frequency for an unknown indication. The patient's medical history and concomitant medications were not reported. The patient had fainted/passed out on 06Apr2021. It was reported that, vaccine coordinator said that they use the same lot number for all three of their facilities. An hour ago, at one of their facilities, he said 3 people fainted and 1 had seizure after receiving the 1st dose of the Pfizer-BioNTech Covid-19 Vaccine. HCP wants to know if there have been any reports of having these reactions associated with the specific lot number: ER8729. He said he already has 56 vials of the vaccine mixed up with the same lot and wants to know if he should still continue using it. HCP also added that out of 3,200 vaccines that they have out of the same lot, they only had 4 incidences. Pharmacist told the HCP that there was no information available about fainting and having seizures associated with the lot: ER8729. However, pharmacist told him that I would forward his concern to someone from our team for further research. Escalating to second line for further research and handling. Caller was a pharmacist who was heavily involved in the COVID-19 vaccine. He manages 3 locations and more than 1500 COVID-19 vaccine doses. Today he's reporting that at one of his other locations, administering the COVID-19 vaccine within about 20 minutes there were 4 patients with reactions. One patient had a seizure and 3 patients passed out. These patient's had just received the COVID-19 vaccine and were still being watched within the 15-minute post vaccination time. All 4 patients received the COVID-19 vaccine from the same lot number but not from the same vial. One of the patient's that passed out said that she has had some

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issues with vaccines in the past. Caller reports that his COVID-19 vaccine facilities are busy today giving COVID-19 vaccines and about half the people receiving the vaccine are waiting inside and about half are waiting outside. It's about 84F outside and he's reporting that he's not seeing anything to eat or drink in these individuals waiting for the COVID-19 vaccine. He believes the NDC number for the COVID-19 vaccine ends in "02". Caller did not have any information on the patients involved. The outcome of the events was unknown. Information on Lot/Batch number was available. No further information is provided or obtained. Additional information has been requested.; Sender's Comments: As there is limited information in the case provided, the causal association between the events of syncope, loss of consciousness and the suspect 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 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.

1256687 4/25/2021 WI

43 M

4/23/2021

4/23/2021

Patient experienced a seizure resulting in cardiac arrest. Witnesses described patient "began convulsing and then tipped over". AED applied with no shock advised. Unknown down time prior to initiation of CPR. Rhythm PEA upon arrival of EMS. 7 mins CPR before ROSC obtained. Initial troponin 12. 12 lead EKG without ischemic changes, arrhythmia, etc. Transthoracic echo without regional wall abnormalities or significant findings. CT of head negative for acute intracranial process. No history of seizure, cardiac issues, drug use, etc.

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1254770	4/25/2021	MA	62	F	4/1/2021	4/1/2021	She was shaking, she thought she was having a seizure with how bad she was shaking; She was shaking, she thought she was having a seizure with how bad she was shaking; Chills; Fever; sore hands and wrists; sore hands and wrists; totally exhausted; Diarrhea; This is a spontaneous report from a contactable consumer (patient). A 62-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Right on 01Apr2021 15:00 (Lot Number: EPT533) as single dose for covid-19 immunisation. The patient previously took flu shot. Medical history included diabeticc, thyroid is done, real bad psoriasis, high blood pressure, triglycerides, cholesterol , anxiety, to replenish potassium. Concomitant medications included metoprolol taken for hypertension; acetylsalicylic acid (ASPIRIN (E.C.)); citalopram taken for anxiety; amlodipine taken for blood pressure; hydrochlorothiazide; fenofibrate taken for blood triglycerides; atorvastatin taken for blood cholesterol; losartan potassium to replenish potassium; colecalciferol (VITAMIN D3); metformin taken for diabetes mellitus; levothyroxine; hydroxyzine; guselkumab (TREMFA) taken for psoriasis,. The patient was shaking, she thought she was having a seizure with how bad she was shaking, chills, fever, sore hands and wrists, totally exhausted, diarrhea on 01Apr2021. The outcome of events chills, Wrist pain, Pain in hand was recovered on 05Apr2021; The outcome of event Fever and Diarrhea was recovered on 06Apr2021; outcome of other events was recovering.

<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>
1254905	4/25/2021			M	3/1/2021	3/1/2021	Started shaking uncontrollably like a seizure; He felt energized; Shaking uncontrollably like a seizure/shaking (jerking side to side) on a very strong tremor; This is a spontaneous report from a contactable consumer (the patient) 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, lot number was not reported), via an unspecified route of administration on Mar2021 as single dose for COVID-19 immunization. Medical history was not reported. Concomitant medications included clonazepam and gabapentin taken as mood medications (as reported). It was reported that after the patient was administered with the first dose of the Pfizer COVID vaccine on 18Mar2021 or 11Mar2021 (he said that he does not remember it very well since he has bad memory), the next two hours (in Mar2021), he felt energized and then started shaking uncontrollably like a seizure although he takes a variety of medications that could cause that. He mentioned that it was like shaking (jerking side to side) on a very strong tremor. He wanted to know if someone has reported seizures as a side effect of the vaccine. He also mentioned that he is scheduled to get the second dose on 15Apr2021. He stated he has never had tremors like the one he is reporting. The outcome of the events was unknown. Follow-up attempts are completed. 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>
1254945	4/25/2021	DC	38	M	4/8/2021	4/8/2021	Convulsion; Syncope; This is a spontaneous report from a contactable consumer (patient). A 38-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration, administered in Arm Left on 08Apr2021 14:15 (2:15 PM) (Batch/Lot Number: ER8729) as SINGLE DOSE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient had no covid prior vaccination and not covid tested post vaccination. There were no other vaccines in four weeks. It was reported that the patient experienced Syncope and Convulsion on 08Apr2021 at 14:30 (2:30 PM). The outcome of the events was recovered in Apr2021. No treatment for the reported events. The event resulted in Emergency room/department or emergent treatment.
1255067	4/25/2021	PA		F	4/6/2021	4/6/2021	jerking movements; keeps shaking her head and her arms/trembling; a couple of seizures; swelling on her arm; This is a spontaneous report from a contactable consumer (patient's parent). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration on 06Apr2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included nonverbal, Cerebral Palsy and seizure disorder. The patient's concomitant medications were not reported. The patient had swelling on her arm when they got home from getting the vaccine and they gave her some Tylenol. On 07Apr2021, the patient has been having these jerking movements, something like if she had Parkinson's, it was a trembling. The patient kept shaking her head and her arms. After the shot, the patient had a couple of seizures when they got home on 06Apr2021, which is not uncommon because she has a seizure disorder and has them pretty frequently. The jerking that the patient was doing was not like her seizures. The patient did have Cerebral Palsy, a seizure disorder, and other conditions. The event outcome for 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>
1255133	4/25/2021	MN	16	F	4/9/2021	4/9/2021	(name) had a seizure within 5 minutes or less of the first dose.; This is a spontaneous report from a contactable consumer or other non-HCP. A 16-years-old non-pregnant female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot Number: ER8729) via an unspecified route of administration in Right Arm on 09Apr2021 00:30 as single dose for covid-19 immunization. Medical history included depression and seizure. The patient's concomitant medications were not reported. On 09Apr2021 00:30, the patient had a seizure within 5 minutes or less of the first dose. Therapeutic measures were taken as a result of had a seizure within 5 minutes or less of the first dose. The outcome of event was recovering.
1255702	4/25/2021	WI	50	M	4/8/2021	4/10/2021	Generalized seizures without ever having a seizure before; This is a spontaneous report from a contactable consumer (patient). A 50-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number and expiry date not available), via an unspecified route of administration, Left arm on 08Apr2021 at 09:00 AM (at the age of 50-years-old) at a single dose for COVID-19 immunization. The patient's medical history was reported as none. The patient had no known allergies. Concomitant medication included celecoxib (CELEXA). The patient was vaccinated at a hospital. No other vaccine was given in four weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient experienced generalized seizures without ever having a seizure before on 10Apr2021 at 15:00. The event caused hospitalization in Apr2021 and was also reported as life-threatening. The patient underwent lab tests and procedures which included nasal swab test: negative on 10Apr2021. Therapeutic measures taken as a result of the event included hospitalization and med flight, as reported. The outcome of the event was not recovered. Information about lot/batch number 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>
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?
1256114	4/25/2021		42	F	4/21/2021	4/22/2021	Patient received 1st dose of Pfizer Covid vaccine on 4/21, and on 4/22 had 2 generalized tonic clonic seizures. No previous seizure history prior to this event. Workup for etiology of Seizure was unremarkable (MRI Brain, CSF studies, UA/CXR)

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1255135	4/25/2021		21	M	4/7/2021	4/7/2021	Seizure; Cough; Sore Right Arm; physical ability to do things has worsened, he is really tired, states she has no good words to describe it, but he is physically not able to do things after the two seizures; physical ability to do things has worsened, he is really tired, states she has no good words to describe it, but he is physically not able to do things after the two seizures; This is a spontaneous report from a contactable consumer (reporter's boyfriend). A 21-years-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection), dose 1 via an unspecified route of administration, administered in arm right on 07Apr2021 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunization. There were no medical history and concomitant medications reported. It was reported that, seizure (within the 15-minute wait time he experienced a seizure), cough, sore right arm, physical ability to do things has worsened, he is tired, states she has no good words to describe it, but he is physically not able to do things after the two seizures on 07Apr2021. No therapeutic measures were taken. The outcome of the event was unknown for seizure, for cough and physical ability to do things has worsened, he is really tired, states she has no good words to describe it, but he is physically not able to do things after the two seizures outcome of the event was not recovered/not resolved and for sore right arm outcome of the event was recovering/resolving. Information about lot/batch number has been requested.
1256221	4/25/2021	TX	16	M	4/25/2021	4/25/2021	Immediately after receiving the Pfizer COVID19 vaccine, patient began feeling sick, dizzy, lightheaded. Patient was shaking and went unconscious for a few seconds. Patient regained consciousness but was able to sit and drink water until paramedics arrived. Administering pharmacist suspects it was a seizure but that was not verified. Patient left with paramedics.

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1254667	4/25/2021	NC	76	F	3/24/2021	3/25/2021	This is a spontaneous report from a contactable consumer (patient). A 77-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection; Lot Number: ER8730) via an unspecified route of administration on 24Mar2021 at 10:30 (at the age of 76-years-old) as a single dose for COVID-19 immunisation. Medical history included ongoing pollen allergy from an unspecified date and ongoing ribs sore from an unspecified date. The patient stated that the pollen was bothering her and that she had been taking Zyrtec in the morning and at night. Medical history (including any illness at time of vaccination) was also reported as none. Family medical history relevant to the event was reported as "her son also had a seizure after the polio vaccine when he was 7 years old". Concomitant medications were not reported. It was reported that the patient denied any medications or medical conditions relevant to symptoms. There were no additional vaccines administered on the same date as the COVID-19 vaccine and there were no prior vaccinations received within 4 weeks of the COVID-19 vaccine. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection; Lot Number: EN202) via an unspecified route of administration on 24Feb2021 (at the age of 76-years-old) as a single dose for COVID-19 immunisation. The patient previously received the polio vaccine on an unspecified date for immunization and experienced seizure and the patient previously received the flu shot on an unspecified date (6 years ago) for immunization and 8 hours after the vaccine was achy, sick, in bed for 9 days. Developed bronchitis and coughed so hard she cracked her ribs. Stated her ribs were still sore at times to this day. The patient stated that she would never get another flu shot and that her doctor agreed with her on that decision. On 25Mar2021 the patient experienced headaches, dizziness, dizziness comes and goes but it affects her vision, numb, head feels fuzzy/fuzziness is constant and eyes are crossing. The patient stated that she got her second dose of the vaccine on 24Mar2021. She reported that after her first shot she was fine. She stated that she started having headaches and dizziness the day after her second vaccine and this had lasted for 14 days. It has gone on now for several weeks and was not getting any

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

better. She felt her symptoms went in different degrees at different times of the day. She might go one day without a headache. Today her headache was more like a numbness all around her head. She stated that her headaches come and go, sometimes start when her eyes pop open in the morning or at 10 AM. If she was going to have a headache that day, it usually started by 10 AM and was a full-blown headache. Stated her head always felt fuzzy and woozy and sometimes she felt like her eyes were crossing. She stated that she never got headaches; not since her early 20s. Dizziness continued to come and go, but it affected her vision and she was scared to drive and have a wreck. She reported that the symptoms were driving her bonkers. She also reported that she had to hold onto walls when she walked. The dizziness did not go away even when she laid down. She was dizzy when sitting on the sofa. Her head also felt fuzzy and numb, the fuzziness was constant. She reported that she felt disabled and felt like she was turning 100 instead of 77. She cannot lay in bed all the time and wanted to know how long these symptoms would last. The patient denied any labs, testing or treatment relevant to symptoms. She had not been to the doctor or to the emergency room in relation to these symptoms. She stated that she thought about it at times. She stated that she would have to call an ambulance to take her since she was scared to drive. Yesterday she thought she was not doing so bad and drove to the store. She stated that while in the store, her dizziness had her to where she could hardly pay for her items. Stated that it kind of felt like she was drunk, but she was not drunk. The patient stated that her experience with the polio vaccine made her almost not get the COVID-19 vaccine for fear it would bring on a similar situation. The clinical outcomes of the events headaches, dizziness, dizziness comes and goes but it affects her vision, numb, head feels fuzzy/fuzziness is constant and eyes are crossing were all not recovered/not resolved. 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>
1255695	4/25/2021			F		4/15/2021	Seizure activity; potential cardiac arrest; This is a spontaneous report from a non-contactable consumer (patient). An adult 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) at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. It was unknown if she was pregnant. The patient experienced seizure activity / potential cardiac arrest (unknown etiology) on 15Apr2021. She was in ICU as of now. The adverse events resulted in emergency room/departement or urgent care, hospitalization, life threatening illness (immediate risk of death from the event). Treatment and outcome for the events were unknown at the time of report. No follow-up attempts are possible. Information on lot/batch cannot be obtained.
1255573	4/25/2021	SC	62	F	4/9/2021	4/12/2021	itchiness; This is a spontaneous report received from two contactable consumers. A 62-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 09Apr2021 at single dose for COVID-19 immunization. Patient medical history included seizures and heartburn bot are ongoing. Concomitant medications included levetiracetam and phenobarbital both for seizures and dexlansoprazole (DEXILANT) for heartburn. It was reported as patient received her first dose of the Pfizer vaccine Friday. She is experiencing itchiness post vaccination on 12Apr2021. Outcome of event was unknown. No follow-up attempts are possible; information about lot/batch number cannot 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>
1255315	4/25/2021			U	3/30/2021		<p>seizures; tired; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age (reported as Age: 65, Unit: Unknown) and gender 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 30Mar2021 as a single dose for COVID-19 immunisation. Medical history included cancer. Concomitant medication included unspecified pills. The patient called in to find out how they could reschedule their appointment for their second dose of Pfizer-BioNTech COVID-19 vaccine. During the call, the patient stated "I have seizures, I got a shot but I was supposed to get another today but I couldn't make it cause I have seizures. I have seizures so you have to be careful with me. You know when they shot you in your arm so you won't get sick. It's people in my building that was sick, sick from that stuff." When asked by the call agent if the patient was calling with regards to Pfizer-BioNTech COVID-19 vaccine. The patient stated "Yes, exactly I got the first shot on the 30th of March I got that shot that day, but I was supposed to come today, I should have been up there this morning but I didn't make it." The agent asked if the patient felt their seizure was brought on by the vaccine. The patient stated "No, I don't know, to be honest with you, I feel better I mean really feel better but I was scared because I know I should have got another shot. It's not because of where they shot me, it's just what I didn't do. I didn't take my pills. I got ran over my head so I have seizures if I don't take those pills then I'll have a seizure. It was not cause by the shot and it has nothing to do with where I'm at. It messed with me cause I hadn't taken my pills and that's what the problem was. I'm skinny anyway I will be for the rest of my life cause I had cancer. I'm sorry I'm just tired". The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: The event "seizures" was most likely an underlying condition, unrelated to suspect vaccine BNT162B2.</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>
1255301	4/25/2021	IL	41	F	3/23/2021	4/7/2021	Grand mal seizure; This is a spontaneous report from a contactable consumer (patient). A 41-year-old non-pregnant female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported), via an unspecified route of administration, administered in arm right on 23Mar2021 at 08:30 (at the age of 41-years-old) as a single dose for COVID-19 immunisation. Medical history included hypothyroidism and Tourette's syndrome from an unknown date and unknown if ongoing. The patient previously received the first dose of BNT162B2 on 23Feb2021 at 10:30 A.M. (at the age of 41-years-old), administered in right arm for COVID-19 immunisation. Concomitant medications included duloxetine hydrochloride (CYMBALTA), levothyroxine and birth control pills, all taken for an unspecified indication, start and stop date were not reported. The patient experienced grand mal seizure on 07Apr2021. The patient was hospitalized for grand mal seizure for 2 days. Therapeutic measures were taken as a result of grand mal seizure (anti-seizure medication). The outcome of the event was recovered with sequelae on an unspecified date. Information on the lot/ batch number 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>
1255293	4/25/2021	MN	24	F	4/7/2021	4/10/2021	fainting; seizure; Tachycardia; dizziness; This is a spontaneous report from a contactable consumer. This 24-year-old non-pregnant female consumer (Patient) reported that she received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 Vaccine; Solution for injection; Lot number: unknown; Expiry date: Unknown) via an unspecified route of administration in the right arm on 07Apr2021 at 12:45 PM. The patients past medical history included Postural orthostatic tachycardia syndrome. The patient was allergic to Phenergan and Zofran. 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 vaccination, patient had not tested for COVID-19. Concomitant medication was not reported. On 10Apr2021, at 12:00PM the patient developed Tachycardia, dizziness, fainting and seizure. The patient did not receive any treatment for the events. The outcome for the events was recovering. 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>
1255215	4/25/2021	IL	57	F	4/8/2021	4/8/2021	possible seizure; fainting; chills; headache; joint and long bone pain; dizziness; Right abdominal pain; temperature spike at 101; unquenchable thirst; sweating; This is a spontaneous report from a contactable consumer (patient) reported for herself that the 57-year-old female patient received second dose of bnt162b2 (BNT162B2), intramuscular, administered in Arm Right on 08Apr2021 04:00 PM (Lot Number: EW0151) at single dose for covid-19 immunization. Medical history included multiple allergies from an unknown date and unknown if ongoing, asthma from an unknown date and unknown if ongoing, chronic obstructive pulmonary disease from an unknown date and unknown if ongoing, orthostatic hypotension from an unknown date and unknown if ongoing, traumatic lung injury from an unknown date and unknown if ongoing, metaplasia from an unknown date and unknown if ongoing, hiatus hernia from an unknown date and unknown if ongoing, polyp from an unknown date and unknown if ongoing, diverticulum intestinal from an unknown date and unknown if ongoing, exposure to toxic agent from an unknown date and unknown if ongoing. Concomitant medications included pantoprazole taken for an unspecified indication, start and stop date were not reported; famotidine taken for an unspecified indication, start and stop date were not reported; cyclobenzaprine taken for an unspecified indication, start and stop date were not reported; calcium carbonate;soya isoflavones;vitamin d nos taken for an unspecified indication, start and stop date were not reported; ibuprofen;phenylephrine hydrochloride taken for an unspecified indication, start and stop date were not reported. The patient previously took firs dose of bnt162b2 (BNT162B2) intramuscular, administered in Arm Right on 18Mar2021 04:15 PM(Batch/Lot Number: ER2613) at single dose for covid-19 immunisation. The patient experienced possible seizure on 08Apr2021 20:00 with outcome of recovering, chills on 08Apr2021 with outcome of recovering, headache on 08Apr2021 with outcome of recovering, joint and long bone pain on 08Apr2021 with outcome of recovering, dizziness on 08Apr2021 with outcome of recovering, fainting on 08Apr2021 with outcome of recovering, right abdominal pain on 08Apr2021 with outcome of recovering, temperature spike at 101 on 08Apr2021 with outcome of recovering, unquenchable thirst on 08Apr2021 with

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
1256320	4/25/2021	MA	17	F	4/25/2021	4/25/2021	<p>outcome of recovering , sweating on 08Apr2021 with outcome of recovering. The patient underwent lab tests and procedures which included body temperature: temperature spike at 101 on 08Apr2021. Therapeutic measures were taken as a result of possible seizure. She is not pregnant at the time of vaccination. Facility where the most recent COVID-19 vaccine was administered was other. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The clinical course was reported as follows: 4 hrs post vax: chills, sub normal temperature drop >96 f oral, eat, and airmptit , sub normal low BP, headache, joint and long bone pain, dizziness, 2 episodes of warned fainting (vasovagal); followed by temperature spike at 101 F oral onset @21 hrs. post vax rigors and falls, with warned loss of consciousness & possible seizure, followed by lower right abdominal pain w/rebound tenderness, sweating, unquenchable thirst, until fever broke 30 hrs post onset. At febrile onset 400 mg ibuprofen, followed by 200 mg every 8 hrs until symptom resolution. The adverse event result in any of the following Doctor or other healthcare professional office/clinic visit. Treatment was received for the adverse event included Public Health RN telephone consult, ibuprofen see. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Allergies to medications, food, or other products:Yes a long list that does not include PG. Other diagnosed illnesses/medical history/chronic health conditions:IMMUNE SYSTEM: multiple allergies including anaphylaxis; R.A., reactive asthma; CARDIOPULMONARY: reactive asthma, chemical exposure lung injury scaring, COPD, orthostatic hypotension; GI: Barrets esophagial metaplasia, hiatal hernia, colonic polyps adenocarcinoma, diverticula. Follow-up (20APR2021): Follow-up attempts completed. No further information expected.</p> <p>Patient arrives from vaccines site, having a witnessed seizure after receiving Covid -19 vaccine injection. Patient has no previous history of seizures.</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>
1252426	4/24/2021	TN	16	M	4/24/2021	4/24/2021	PATIENT PASSED OUT AND EXPERIENCED CONVULSIONS APPROXIMATELY 1-2 MINUTES POST VACCINATION. HE WAS UNRESPONSIVE FOR 5 - 10 SECONDS AND THEN BECAME ALERT COMPLAINING OF "FEELING HOT" AND HAD TROUBLE BREATHING. EMS WAS CALLED AND PATIENT WAS TRANSPORTED TO LOCAL HOSPITAL.
1253986	4/24/2021	GA	60	M		3/25/2021	STROKE; This spontaneous report received from a consumer concerned a 60 year old white, Not Hispanic or Latino male. The patient's height, and weight were not reported. The patient's past medical history included epileptic seizures when seeing flashing lights, he had no prior history of stroke or any surgery, and concurrent conditions included high blood pressure, and type 2 diabetes. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: Unknown) dose was not reported, administered, on 16-MAR-2021 around 10:30 in the morning for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 25-MAR-2021, the patient had stroke. The reporter did not know what kind of stroke the patient had. He was not found immediately when he had the stroke and when patient arrived at the hospital he was paralyzed on the left side and was put on the feeding tube and ventilator and moved to hospice after 8 days. On 09-APR-2021, the patient died from stroke. 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, Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210428085-COVID-19 VACCINE AD26.COV2.S -Stroke. 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.; Reported Cause(s) of Death: Stroke
1251831	4/24/2021		17	F	4/24/2021	4/24/2021	Pt received vaccine at 306p and at 316p began to have seizure like activity for 30 seconds. VSS EMS here to assess pt, pt to ER

<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>
1253987	4/24/2021	NY		F		4/13/2021	FEELING UNWELL; GENERALISED SEIZURE; This spontaneous report received from a physician concerned a 21-year-old female. The patient's height, and weight were not reported. The patient's concurrent conditions included absence seizures (last episode was in 2012), and asthma. The patient was previously treated with ethosuximide for absence seizures. 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 01-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 13-APR-2021, the patient experienced generalized seizure that lasted about 10 minutes or maybe a little longer. On an unspecified date, the patient was feeling unwell. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the generalized seizure and feeling unwell was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 : 20210428279- covid-19 vaccine ad26.cov2.s- GENERALISED SEIZURE- 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

<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>
1253692	4/24/2021	MI		F		3/23/2021	TEETH SENSITIVITY; SHAKING STATING I THOUGHT I WAS GOING TO HAVE A CONVULSION; CHILLS SO BAD I FELT LIKE YOU WERE IN A FREEZING RIVER; NAUSEA; 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: 1802068, expiry: UNKNOWN) dose was not reported, administered on 23-MAR-2021 approximately at 09:30 in right arm for prophylactic vaccination. No concomitant medications were reported. On 23-MAR-2021 12:30, the subject experienced teeth sensitivity. On 23-MAR-2021 12:30, the subject experienced shaking stating i thought i was going to have a convulsion. On 23-MAR-2021 12:30, the subject experienced chills so bad i felt like you were in a freezing river. On 23-MAR-2021 12:30, the subject experienced nausea. On 23-MAR-2021 12:30, the subject experienced fatigue. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from teeth sensitivity on 23-MAR-2021, and shaking stating i thought i was going to have a convulsion, chills so bad i felt like you were in a freezing river, nausea, and fatigue on 24-MAR-2021 03:00. This report was 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>
1253394	4/24/2021	WI		U		3/1/2021	FACIAL SWELLING; DRY COUGH; DIZZY; FLU LIKE SYMPTOMS; HEADACHE; FEVER; TIREDNESS; 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 edema, copd, asthma, htn, seizure, sleep apnea, and hashimotos. 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 16-MAR-2021 on right arm for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On MAR-2021, the subject experienced dizzy. On MAR-2021, the subject experienced flu like symptoms. On MAR-2021, the subject experienced headache. On MAR-2021, the subject experienced fever. On MAR-2021, the subject experienced tiredness. On 20-MAR-2021, the subject experienced facial swelling. On 20-MAR-2021, the subject experienced dry cough. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the headache, facial swelling, dry cough, fever, tiredness, dizzy and flu like symptoms was not reported. This report was 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>
1249689	4/24/2021	NJ	63	F	4/10/2021	4/11/2021	seizure; very tired; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SEIZURE (seizure) in a 63-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 036B21A and 044A21A) 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-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 11-Apr-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced FATIGUE (very tired). On 12-Apr-2021 at 3:00 AM, the patient experienced SEIZURE (seizure) (seriousness criterion medically significant). At the time of the report, SEIZURE (seizure) and FATIGUE (very tired) outcome was unknown. No Treatment related information was reported. Patient went to bed like normal that night. Patient called a nearby family member, who took patient to her neurologist later the next day.; Sender's Comments: This case concerns a 63-year-old female with a serious unexpected event of seizure, and nonserious expected fatigue. Event onset 1 day after first dose mRNA-1273, with seizure occurring 2 days after vaccination. Event outcomes unknown. 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.

<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>
1252698	4/24/2021	CO	18	M	4/11/2021	4/11/2021	VACCINE CONSENT FORM SHOWS NO ADR, NO SEIZURES OR NEUROLOGICAL CONDITIONS , NO SERIOUS REACTION TO VACCINE IN PAST, PT HAS BEEN EXAMINED BY PROVIDER IN PAST YEAR. AS VACCINE WAS BEING ADMINISTERED THE FATHER WHO ACCOMPANIED HIS SON THE PT SAID THAT THE PT WOULD PASS OUT. THE PT DID NOT CONFIRM NOR DENY THIS, UPON ADMINISTRATION OF VACCINE PT BECAME QUIET, GLASSY EYED AND BEGAN TO GO LIMP. HE RESPONDED TO QUESTIONS UNCLEARLY. THE FATHER RESTRAINED PT FROM BEHIND CHAIR AND I IN FRONT OF HIS KNEES TO PREVENT HIM FROM FALLING TO FLOOR. AFTER APPROXIMATELY 3-4 MINUTES, HIS UPPER BODY MUSCLES SHOOK AND THEN THE LOWER BODY, MAYBE 10 SEC?, THEN HE OPENED HIS EYES AND SEEMED RECOVERED. HE WAS ASKED TO REMAIN IN THAT CHAIR UNTIL HE HAD TOTALLY RECOVERED, WHICH HE ASSERTED APPROX 15 MIN LATER. I REQUESTED THE PT AND HIS FATHER REMAIN ANOTHER 15 TO 20 MIN IN WAITING AREA AND TO CHECK OUT WITH ME BEFORE LEAVING. PT WALKED OUT WITHOUT ASSISTANCE, WITHOUT FALTERING OR DIZZINESS.

<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>
1252076	4/24/2021	VA	16	F	4/24/2021	4/24/2021	16 year old female came to the triage to utilize the cot to lay down to get vaccinated. Patient had no chief complaint at the time of arrival to the triage area. Patient lay down to get the vaccine due prior history of seizure after vaccine in 2018. Patient vaccinated at 4:50pm, at 5:12 pm patient wanted to stand up to see how she feels, prior to standing patient denies reporting any complaint. at 05:12 Per EMS, as soon as she stood up she went into Tonic-clonic seizure that last for one minute. Patient Stumped into EMS COT. Blood sugar 130. Bp at 17:10 136/96 Pulse 78, RR 24,)2 sat 100, PERLA, Normal sinus Rhythm. BP at 17:30 136/88 pulse 76 RR 20, O2sat at 100 %, PERLA, Normal sinus Rhythm. Patient has history of asthma, seizure after shot, NKDA. patient was postictal after seizure.no sob or any acute distress. This Nurse Practitioner was radio at 05:14 pm, i arrived at 05:17pm, Patient mental status was assessed, patient was awake and alert x 4, patient report history of seizure after shot and Asthma. Patient did not appear to be in any acute distress. Patient mother was present at bedside. Patient and patient mother was informed that patient will be transported to the hospital to be further evaluated, patient mother agree to the plan of care.
1252046	4/24/2021	OH	16	M	4/24/2021	4/24/2021	Patient began to seize less than 5 minutes after receiving vaccine. the seizure lasted less than 1 minute. registered nurse on site laid patient down and supported head and neck. EMS was called and patient was taken to hospital
1251893	4/24/2021	CO	23	F	4/7/2021	4/7/2021	Per EMS observation staff: "Patient experienced throat tightness, feeling funny, and had syncope after receiving the vaccine. Patient had a syncopal episode with convulsions for approximately 30 seconds. Patient was given 50mg of IM Benadryl at 11:18 and 911 was called. After administering IM Benadryl patient seemed to improve. Patient was transported by Fire Department at 11:26 and transported to Hospital." VS per obs staff: 11:18: BP 80/palp, HR 54, resp 24 labored, oxygen 94% on RA. 11:23: BP 80/40, HR 56, resp 20 semi labored, oxygen 92% on RA. Per roommate pt received dose of epi upon arrival in ED. Attempted to make FU phone call. No answer at this time. Will continue to call and verify patients condition.

<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>
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
1253238	4/24/2021	OR	18	M	4/13/2021	4/13/2021	Patient had a seizure about 5 minutes after having the vaccination while they were in the waiting area. The patient had the seizure for about 30 seconds and then regained their senses and were able to have a conversation with me, the pharmacist, and had a cup of water while we waited for the ambulance. The patient was then transferred to the hospital.
1249745	4/24/2021	TX	37	F	3/2/2021	3/10/2021	Seizure a week after each shot
1247522	4/23/2021	PA	16	M	4/22/2021	4/23/2021	Physician assistant at Patient's pediatrician office call pharmacy and informed us that patient had a grand mal seizure after yesterday's vaccine and was being sent to the ER at Hospital.
1247759	4/23/2021	NE	80	F	4/21/2021	4/22/2021	Resident had a stroke and seizures the next morning.
1247764	4/23/2021	WI	35	M	4/16/2021	4/17/2021	Was at the golf course. His arms flew up and he had a seizure falling to the ground and striking head on ground. Blood from nose and mouth. He was transported to hospital. Diagnosed a brain bleed.
1247872	4/23/2021	GA	27	M	4/8/2021	4/8/2021	Woke up about 7 hours after receiving vaccine with violent shaking or shivering almost like a seizure except was alert and oriented and could hold conversation. Every part of body was shaking so hard the whole bed was moving. Lasted about a full hour. Was ready to go to hospital when the shaking died down to flu-like shakes which lasted on and off for the next 24 hours. Felt incredibly sick and exhausted for next three days.

<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>
1248045	4/23/2021	IL	39	F	4/10/2021	4/11/2021	<p>J&J COVID Vaccine EUA J&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>

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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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.

<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>
1248068	4/23/2021	CA	17	F	4/5/2021	4/6/2021	The day after the vaccine I felt very weak and fatigued on April 7th. A couple days later on April 9th I developed a fever. A few days after that my muscles started twitching and haven't stopped. I feel like something is crawling under my skin and the vaccine is extremely affecting my nervous system. I did not have this problem before I had the vaccine. It has not gone away and it is now April 23rd I still feel weak, not the same as I used to feel before having the vaccine, and my muscles are twitching all over my body. My face is twitching and my eye and there is nothing I can do to make it stop. I am so young and I thought the vaccine was safe but I am suffering from it. Especially in my feet I feel like they are tingling and vibrating and my calves are convulsing too. Meanwhile, my heart is fluttering and I feel like it is very hard for me to focus and I feel things crawling under my skin in my brain. The muscle convulsions are happening everywhere.
1248276	4/23/2021	CA	17	M	4/23/2021	4/23/2021	As soon as the injection was complete the patient started acting like he didn't feel well and that he might vomit. Then he started to seem like he might pass out. Then he was shaking for a few moments and his body straightened out on the chair and he seemed like he might be having a seizure. I had someone call 9-1-1. I stayed with him until the paramedics arrived. He kept seeming like he was nodding off, but when I spoke to him he was responsive. By the time the paramedics arrived he said he was feeling better, but they checked him out, BP and HR and blood O2 were normal. The paramedics offered transport to hospital but patient and his adult family member declined, and patient went home with his family member.

<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>
1249177	4/23/2021	KS		M		4/10/2021	SHAKING/DIZZY/IMBALANCE/DISORIENTED/CONVULSION; CHILLS; 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: 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 10-APR-2021, the patient experienced shaking/dizzy/imbalance/disoriented/convulsion and chills. After about 48 hours later the patient reported that the adverse event did not get resolved and in addition the patient felt dizzy, experienced imbalance and disoriented. Through call it was not possible to provide medical advice for which he was upset and he was asked to get in touch with local HCP. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from chills, and shaking/dizzy/imbalance/disoriented/convulsion. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210422232-covid-19 vaccine ad26.cov2.s -CONVULSION. 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.
1246771	4/23/2021	FL	57	F	4/12/2021	4/12/2021	57yo female received COVID-19 vaccine (Pfizer) dose #1 on 3/22/21 at external location. On 4/12/21, patient received dose #2. Approximately 60 minutes later, patient reports falling from chair at work; co-worker apparently witnessed seizure-like activity and called 911 for transport to ED. Patient denies ever having a seizure in the past or being on AEDs. Per discharge note from Neurology, "Presentation with likely seizure suspected to be due to early post-stroke seizure, in setting of cortical based infarct, likely triggering acute seizure event at time of onset." Possible temporal relationship with COVID vaccine.

<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>
1249204	4/23/2021	NY		F		4/12/2021	SEIZURE; 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, 1 total administered on 08-APR-2021 to left deltoid for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 12-APR-2021, the patient experienced seizure which lasted for one minute 30 seconds. The patient did not take any medication for her seizure. She never had a seizure before and did not know if there was a correlation with vaccine or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from seizure on 12-APR-2021. This report was serious (Other Medically Important Condition).; Sender's Comments: V0;20210424312-covid-19 vaccine ad26.cov2. s-seizure. 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.
1246578	4/23/2021	TX	30	M	4/8/2021	4/9/2021	Seizure - I have never had a seizure before and there is no history of epilepsy in my family. I had the Janssen vaccine shot at around 5PM on Thursday and felt mostly fine on Friday. I had typical shot symptoms (tired and soreness near injection sight). On Friday night around 10:00, I was standing talking to one of my friends in the living room when I had a blackout seizure without any warning. The seizure only lasted about 30-45 seconds, and then I became conscious again. It took me about 5-10 minutes to become completely aware and able to stand up. I have never had a seizure before and have not had one since then. Later the following week, I did have a couple of hours where I felt extremely dizzy and lightheaded, but it went away without another seizure. This is also not typical for me.

<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>
1249214	4/23/2021	MI	21	M		4/10/2021	RESTLESS; LACK OF SLEEP; LACK OF MOTIVATION; FELT ROSY IN THE CHEEKS; FELT HOT; FEVER; BODY ACHES; DIZZINESS; WEAKNESS; INJECTION SITE PAIN; EXTREMELY FATIGUE AND TIRED, FELT REALLY WORN DOWN; FELT OFF; SENSITIVITY TO LIGHT; SENSITIVE TO SYMPTOMS OF A SEIZURE ONSET; CRAMPING STYLE PAIN THAT TRAVELLED UP AND INTO THE SHOULDER AND UP INTO THE NECK MUSCLE INTO THE BASE OF SKULL WRAPPING AROUND HEAD CAUSING A MIGRAINE; HARD AND HOT TO THE TOUCH GOLF BALL SIZES LUMP SLIGHTLY PROTRUDING; DISORIENTED; This spontaneous report received from a patient concerned a 21 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included epileptic. 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 15:00 for prophylactic vaccination. The batch number was not reported and has been requested No concomitant medications were reported. On APR-2021, treatment medications included: paracetamol. On 10-APR-2021, the subject experienced sensitive to symptoms of a seizure onset. On 10-APR-2021, the subject experienced cramping style pain that travelled up and into the shoulder and up into the neck muscle into the base of skull wrapping around head causing a migraine. On 10-APR-2021, the subject experienced hard and hot to the touch golf ball sizes lump slightly protruding. On 10-APR-2021, the subject experienced disoriented. On 10-APR-2021, the subject experienced body aches. On 10-APR-2021, the subject experienced felt off. On 10-APR-2021, the subject experienced sensitivity to light. On 10-APR-2021, the subject experienced dizziness. On 10-APR-2021, the subject experienced weakness. On 10-APR-2021, the subject experienced injection site pain. On 10-APR-2021, the subject experienced extremely fatigue and tired, felt really worn down. On 11-APR-2021, the subject experienced felt hot. On 11-APR-2021, the subject experienced restless. On 11-APR-2021, the subject experienced lack of sleep. On 11-APR-2021, the subject experienced lack of motivation. On 11-APR-2021, the subject experienced felt rosy in the cheeks. On 11-APR-2021, the subject experienced fever. Laboratory

<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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data included: Body temperature (NR: not provided) 103.1 F. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from dizziness, weakness, disoriented, fever, felt hot, felt off, sensitivity to light, and felt rosy in the cheeks, and had not recovered from injection site pain, cramping style pain that travelled up and into the shoulder and up into the neck muscle into the base of skull wrapping around head causing a migraine, extremely fatigue and tired, felt really worn down, body aches, restless, lack of sleep, lack of motivation, sensitive to symptoms of a seizure onset, and hard and hot to the touch golf ball sizes lump slightly protruding. This report was non-serious.; Sender's Comments: V0: Medical assessment comment was not required as per standard procedure as case assessed as non-serious.

<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>
1249217	4/23/2021	MO	30	F	4/8/2021		<p>WOKED UP WITH PAIN AROUND 5-6 INCH BELOW BELLY BUTTON; HEART BEAT LIKE PAIN; LEFT LEG MIDDLE OF CALF FEELS LIKE CRAMP; BLURRY VISION; FELT PRESSURE BEHIND BOTH EYES; PAIN IN RIGHT HAND JOINTS FROM SHOULDER BLADE TO MIDDLE FOREARM; SHARP PAIN IN KNUCKLE; FULL BODY CHILLS; HEADACHE; BODY PAIN; SPINE HURTING BAD; CONVULSION; DIFFICULT TO TURN OVER; FEVER; This spontaneous report received from a patient concerned a 30 year old white and Not Hispanic or Latino female. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included 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: 207A21A, expiry: UNKNOWN) dose was not reported, 1 total, administered to left arm on 07-APR-2021 14:16 for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, after vaccination patient had no issues for 12 to 14 hours. On 08-APR-2021, the patient experienced convulsion, body shaking, difficult to turn over, spine hurting bad, and fever. On 08-APR-2021 03:00, the patient experienced full body chills, headache and body pain. On 08-APR-2021 01:00, treatment medications included: acetylsalicylic acid/caffeine/paracetamol/salicylamide. On 08-APR-2021 19:00, treatment medications included: ibuprofen. On 10-APR-2021, the patient experienced sharp pain in knuckle, pain in right hand joints from shoulder blade to middle forearm. On 12-APR-2021 17:10, the patient experienced blurry vision, felt pressure behind both eyes. On 13-APR-2021, the patient experienced left leg middle of calf feels like cramp, heart beat like pain. On 13-APR-2021 08:00, the patient experienced woke up with pain around 5-6 inch below belly button. Laboratory data on 08-APR-2021 included: Body temperature (NR: not provided) 100.5 Fahrenheit. The action taken with covid-19 vaccine ad26.cov2.s was not reported. The patient recovered from woke up with pain around 5-6 inch below belly button, body pain, pain in right hand joints from shoulder blade to middle forearm, and headache on APR-2021, and the outcome of full body chills, fever, convulsion, difficult to turn over, sharp pain in knuckle, blurry vision, felt pressure behind both eyes, left leg</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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middle of calf feels like cramp, spine hurting bad and heart beat like pain was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210425698-covid-19 vaccine ad26.cov2.s-convulsion. 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>
1249253	4/23/2021	CA	43	M	4/6/2021		INCREASED SEIZURES; THREW UP; INCREASED PHLEGM / INCREASED COUGHING; This spontaneous report received from a parent concerned a 43 years old white Hispanic or Latino male. The patient's height, and weight were not reported. The patient's past medical history included cerebral palsy, mental retardation, and epilepsy, and concurrent conditions included seizures, cough, and phlegm. 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: 042A21A, expiry: UNKNOWN) dose was not reported, 1 total administered on 06-APR-2021 on right deltoid for prophylactic vaccination. No concomitant medications were reported. On 06-APR-2021, the patient experienced increased phlegm / increased coughing. On 07-APR-2021, the patient experienced increased seizures. On the same day, he experienced threw up. The patient usually had a cough and phlegm. On the following day of vaccination, the patient's amount of phlegm and cough was increased and he throw-up and had 2 seizures. On 08-Apr-2021, the patient had 10 seizures. The patient regularly had seizures but the number per day increased after vaccination. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from increased seizures on 09-APR-2021, and threw up on 07-APR-2021, and had not recovered from increased phlegm / increased coughing. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210428761-covid-19 vaccine ad26.cov2.s-increased seizures. 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

<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>
1249596	4/23/2021	DC	32	F	2/3/2021	3/3/2021	Seizure; Weakness; Difficulty Breathing; tiredness; Lethargy; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (Seizure) in a 32-year-old female 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 event (No medical history reported). 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) (unknown route) dosage was changed to 1 dosage form. On 03-Mar-2021, the patient experienced LETHARGY (Lethargy). On an unknown date, the patient experienced SEIZURE (Seizure) (seriousness criterion medically significant), ASTHENIA (Weakness), DYSPNOEA (Difficulty Breathing) and FATIGUE (tiredness). At the time of the report, SEIZURE (Seizure), LETHARGY (Lethargy), ASTHENIA (Weakness), DYSPNOEA (Difficulty Breathing) and FATIGUE (tiredness) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) and mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not provided by the reporter. No treatment information was provided. Action taken with mRNA-1273 in response to the event 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 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.

<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>
1249619	4/23/2021	MO	60	M	4/9/2021	4/9/2021	<p>Passed Out; Suspecting Seizures pending EEG Results; Sore Arm; This spontaneous case was reported by a pharmacist and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed Out) and SEIZURE (Suspecting Seizures pending EEG Results) in a 60-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 (medication history was not reported) and Pacemaker insertion (cardiac) since an unknown date. On 09-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 09-Apr-2021, the patient experienced VACCINATION SITE PAIN (Sore Arm). On 13-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed Out) (seriousness criteria hospitalization and medically significant) and SEIZURE (Suspecting Seizures pending EEG Results) (seriousness criterion hospitalization). On 10-Apr-2021, VACCINATION SITE PAIN (Sore Arm) had resolved. At the time of the report, LOSS OF CONSCIOUSNESS (Passed Out) and SEIZURE (Suspecting Seizures pending EEG Results) 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 information was not reported. diagnosis yet to be determined Suspecting Seizures pending EEG results 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 is available at this time. 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 events, a causal relationship cannot be excluded. However, Very limited information is available at this time. Further information is 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>
1249628	4/23/2021	VA	68	F	2/24/2021	3/24/2021	Breakthrough seizure (with no shaking, confusion, loss of consciousness); Numbness in left foot; Tingling in left foot; Sharp pain in left ear; Upper arm, back, neck and above shoulder starting aching and Whole torso aching; Back, neck and above shoulder starting aching and Whole torso aching; Neck and above shoulder starting aching and Whole torso aching; whole torso was aching; Shoulder starting aching; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (Breakthrough seizure (with no shaking, confusion, loss of consciousness)) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 022M02A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Epilepsy (had not had an episode in two years.). On 24-Feb-2021 at 4:00 PM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 24-Mar-2021 at 9:00 PM, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 24-Mar-2021, the patient experienced SEIZURE (Breakthrough seizure (with no shaking, confusion, loss of consciousness)) (seriousness criterion medically significant), HYPOAESTHESIA (Numbness in left foot), PARAESTHESIA (Tingling in left foot), EAR PAIN (Sharp pain in left ear), PAIN IN EXTREMITY (Upper arm, back, neck and above shoulder starting aching and Whole torso aching), BACK PAIN (Back, neck and above shoulder starting aching and Whole torso aching), NECK PAIN (Neck and above shoulder starting aching and Whole torso aching), PAIN (whole torso was aching) and ARTHRALGIA (Shoulder starting aching). On 31-Mar-2021, SEIZURE (Breakthrough seizure (with no shaking, confusion, loss of consciousness)), HYPOAESTHESIA (Numbness in left foot), PARAESTHESIA (Tingling in left foot) and EAR PAIN (Sharp pain in left ear) had resolved. At the time of the report, PAIN IN EXTREMITY (Upper arm, back, neck and above shoulder starting aching and Whole torso aching), BACK PAIN (Back, neck and above shoulder starting aching and Whole torso aching), NECK PAIN (Neck and above shoulder starting aching and Whole torso aching), PAIN (whole torso was aching) and ARTHRALGIA (Shoulder starting aching) outcome was

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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unknown. Not Provided

DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Electroencephalogram: seizure Seizure. No concomitant medication was reported. Patient reported she recognized the event as a seizure due to her electroencephalography (EEG) and her vagus nerve stimulation (VNS) machine overshooting. Patient reported taking naproxen (Aleve) and lorazepam (Ativan) to treat the events. Action taken with mRNA-1273 in response to the event was not applicable. Company Comment: This case concerns a 68-year-old female with a serious unexpected event of seizure, and nonserious unexpected hypoaesthesia, paraesthesia, ear pain, pain in extremity, back pain, neck pain, pain, and expected arthralgia. Event onset the same day as second dose mRNA-1273. Event outcomes unknown. 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. This case was linked to MODERNATX, INC.-MOD-2021-080130 (E2B Linked Report).; Sender's Comments: This case concerns a 68-year-old female with a serious unexpected event of seizure, and nonserious unexpected hypoaesthesia, paraesthesia, ear pain, pain in extremity, back pain, neck pain, pain, and expected arthralgia. Event onset the same day as second dose mRNA-1273. Event outcomes unknown. 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. MODERNATX, INC.-MOD-2021-080130:1st Dose

<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>
1249638	4/23/2021			F	4/12/2021	4/13/2021	<p>Legs were yellow; sore throat; Lost my voice; Fever of 109F; could not raise body from floor because joints were hurting; could not raise her body from the floor because her joints were hurting; legs felt like jelly legs; This spontaneous case was reported by a consumer and describes the occurrence of HYPERPYREXIA (Fever of 109F) in a 65-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 046821A) 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 given). Concomitant products included QUETIAPINE FUMARATE (SEROQUEL). On 12-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Apr-2021, the patient experienced GAIT DISTURBANCE (could not raise body from floor because joints were hurting) and ARTHRALGIA (could not raise her body from the floor because her joints were hurting). On 14-Apr-2021, the patient experienced HYPERPYREXIA (Fever of 109F) (seriousness criterion medically significant), YELLOW SKIN (Legs were yellow), OROPHARYNGEAL PAIN (sore throat) and APHONIA (Lost my voice). On an unknown date, the patient experienced ASTHENIA (legs felt like jelly legs). At the time of the report, HYPERPYREXIA (Fever of 109F), GAIT DISTURBANCE (could not raise body from floor because joints were hurting), YELLOW SKIN (Legs were yellow), OROPHARYNGEAL PAIN (sore throat), APHONIA (Lost my voice) and ASTHENIA (legs felt like jelly legs) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Additional medications listed are: "blood pressure meds, cholesterol meds, antidepressants, anti-seizure meds".</p> <p>Company Comment This case concerns a 65-year-old female with a serious unexpected event of hyperpyrexia, and nonserious unexpected oropharyngeal pain, aphonia, asthenia, gait disturbance, yellow skin, and expected arthralgia. Event onset 3 days after first dose mRNA-1273. Event outcomes unknown. 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.</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>
1249643	4/23/2021	IN		F	4/15/2021	4/15/2021	seizure; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (seizure) in a 37-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Seizure since an unknown date. Concomitant products included TOPIRAMATE (TOPAMAX) for Seizure. On 15-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Apr-2021, the patient experienced SEIZURE (seizure) (seriousness criterion medically significant). At the time of the report, SEIZURE (seizure) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No treatment medication information was provided.

<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>
1249198	4/23/2021	IN		F	4/10/2021		2X GRAND MAL SEIZURE; TENDER; SORE; LUMP AT INJECTION SITE; INJECTION SITE FELT HOT; This spontaneous report received from a patient concerned a white, not hispanic or latino female of unspecified age. The patient's height, and weight were not reported. The patient's concurrent conditions included seizure which was under control with medications. 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 07-APR-2021 in left arm for prophylactic vaccination. No concomitant medications were reported. On 10-APR-2021, the patient experienced tender, sore, lump at injection site, injection site felt hot to touch. On 11-APR-2021, the patient had two grand mal seizure and had to visit an emergency room/hospital. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from lump at injection site, and injection site felt hot on 11-APR-2021, was recovering from tender, and sore, and the outcome of 2x grand mal seizure was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210424069-covid-19 vaccine ad26.cov2.s -2x grand mal seizure. 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

<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>
1245436	4/23/2021	OH	24	F	4/2/2021	4/2/2021	couldn't sleep; Felt sick; Fell; Body went stiff; Hit head on the wall; Vomiting; Fainted; Had seizures twice; Back pain; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SYNCOPE (Fainted) and SEIZURE (Had seizures twice) in a 24-year-old female patient who received mRNA-1273 for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 in October 2020. On 02-Apr-2021, the patient received first dose of mRNA-1273 (Intramuscular) 1 dosage form. On 02-Apr-2021, the patient experienced BACK PAIN (Back pain). On 03-Apr-2021, the patient experienced SYNCOPE (Fainted) (seriousness criterion medically significant), SEIZURE (Had seizures twice) (seriousness criterion medically significant), INSOMNIA (couldn't sleep), MALAISE (Felt sick), FALL (Fell), MUSCULOSKELETAL STIFFNESS (Body went stiff), HEAD INJURY (Hit head on the wall) and VOMITING (Vomiting). At the time of the report, SYNCOPE (Fainted), SEIZURE (Had seizures twice), BACK PAIN (Back pain), INSOMNIA (couldn't sleep), MALAISE (Felt sick), FALL (Fell), MUSCULOSKELETAL STIFFNESS (Body went stiff), HEAD INJURY (Hit head on the wall) and VOMITING (Vomiting) outcome was unknown. The action taken with mRNA-1273 (Intramuscular) was unknown. For mRNA-1273 (Intramuscular), the reporter did not provide any causality assessments. Labs included Electrocardiogram: and Urine analysis, no test results provided. Treatment information not provided. Company comment: Very limited information regarding these events has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.
1245349	4/23/2021	IL	29	F	4/22/2021	4/22/2021	pt began having n/v in the evening and then seizures at night. pt does have seizure history but does not usually have breakthrough seizures.

<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>
1245358	4/23/2021	NJ		M	3/10/2021	3/10/2021	passed out; seizure; fever; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) and SEIZURE (seizure) in a 39-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 040A21A and 045A21A) 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 relevant medical history provided.). On 10-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 07-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 10-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant), SEIZURE (seizure) (seriousness criterion medically significant) and PYREXIA (fever). On 10-Mar-2021, LOSS OF CONSCIOUSNESS (passed out) and SEIZURE (seizure) had resolved. At the time of the report, PYREXIA (fever) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. 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. Further information has been requested This case was linked to US-MODERNATX, INC.-MOD-2021-072687 (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. Further information has been requested US-MODERNATX, INC.-MOD-2021-072687:1st dose vaccine

<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>
1245385	4/23/2021	NY	21	F	3/16/2021	3/16/2021	extrapyramidal syndrome from vaccine; shaking uncontrollably/ body tremors; uncontrolled convulsions/ seizure type activity; jaw was locked; This spontaneous case was reported by a physician (subsequently medically confirmed) and describes the occurrence of EXTRAPYRAMIDAL DISORDER (extrapyramidal syndrome from vaccine), TREMOR (shaking uncontrollably/ body tremors) and SEIZURE (uncontrolled convulsions/ seizure type activity) in a 21-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 16-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Mar-2021, the patient experienced TREMOR (shaking uncontrollably/ body tremors) (seriousness criterion hospitalization), SEIZURE (uncontrolled convulsions/ seizure type activity) (seriousness criterion medically significant) and TRISMUS (jaw was locked). On 30-Mar-2021, the patient experienced EXTRAPYRAMIDAL DISORDER (extrapyramidal syndrome from vaccine) (seriousness criterion hospitalization). The patient was hospitalized on 30-Mar-2021 due to EXTRAPYRAMIDAL DISORDER and TREMOR. At the time of the report, EXTRAPYRAMIDAL DISORDER (extrapyramidal syndrome from vaccine), TREMOR (shaking uncontrollably/ body tremors), SEIZURE (uncontrolled convulsions/ seizure type activity) and TRISMUS (jaw was locked) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Electroencephalogram: Diagnosed Extraparalydral syndrome from vaccine. On an unknown date, Magnetic resonance imaging: normal. 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. Patient has always been healthy. She was prescribed high strength Benadryl and Vistaril. These treatment medications did not help her and she went back again to emergency room. She was a college student and got vaccinated so she could continue her

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

education in person. Concomitant medications were not reported. 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.

<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>
1245409	4/23/2021	MN	36	F	4/11/2021	4/12/2021	seizure; passed out due to extreme vomiting as per doctor in ER; vomiting every 40 minutes; stomachaches; body pain; Sweating; Headache; This case was received via an unknown source no reference has been entered for a health authority or license partner on 15-Apr-2021 and was forwarded to Moderna on 15-Apr-2021. This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SEIZURE (seizure) and LOSS OF CONSCIOUSNESS (passed out due to extreme vomiting as per doctor in ER) in a 36-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 027B21A) 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 provided.). On 11-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-Apr-2021, the patient experienced SEIZURE (seizure) (seriousness criterion medically significant), LOSS OF CONSCIOUSNESS (passed out due to extreme vomiting as per doctor in ER) (seriousness criterion medically significant), HEADACHE (Headache), ABDOMINAL PAIN UPPER (stomachaches), VOMITING (vomiting every 40 minutes), PAIN (body pain) and HYPERHIDROSIS (Sweating). The patient was treated with IBUPROFEN at an unspecified dose and frequency. At the time of the report, SEIZURE (seizure), LOSS OF CONSCIOUSNESS (passed out due to extreme vomiting as per doctor in ER), HEADACHE (Headache), ABDOMINAL PAIN UPPER (stomachaches), VOMITING (vomiting every 40 minutes), PAIN (body pain) and HYPERHIDROSIS (Sweating) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No medical history or concomitant medications provided. Patient used ibuprofen for treatment of headache. 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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1246686	4/23/2021	IN	52	F	3/8/2021	3/17/2021	Vomiting, vision impairment (read very slow to me), and seizure(s). Rushed to ER in ambulance. Was put on a ventilator (sedation). Received a CT scan showing a CVST and hemorrhaging in her right temporal lobe. Life-Lined to Hospital. Wore an EEG on her head to monitor seizure activity for 4-5 days. Was put on 4 types of seizure medication and blood thinner for the clot. Did another CT scan which showed her Mid-Line shift was pushing into the left side of the brain by 15mm. Discharged from Hospital on 3/27/21 to Rehabilitation Hospital. She was discharged to home with a caregiver on 4/16/21. She will continue outpatient therapy at the rehabilitation hospital. She will see Speech, Vision, PT, and OT every week until further notice.

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1245431	4/23/2021	IN	63	F	3/13/2021	4/10/2021	<p>Bleeding stroke; This spontaneous case was reported by a consumer and describes the occurrence of HAEMORRHAGIC STROKE (Bleeding stroke) in a 63-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 017B21A and 030A21A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No relevant medical history provided). Concomitant products included ROPINIROLE HYDROCHLORIDE (REQUIP) for an unknown indication. On 13-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-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 HAEMORRHAGIC STROKE (Bleeding stroke) (seriousness criteria hospitalization, disability and medically significant). The patient was hospitalized from 11-Apr-2021 to 14-Apr-2021 due to HAEMORRHAGIC STROKE. At the time of the report, HAEMORRHAGIC STROKE (Bleeding stroke) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Apr-2021, Computerised tomogram head: brain bleed Brain Bleed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient states an Anti seizure medicine was used for treatment. After discharge from hospital, patient states she now has to take therapy. 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, Very limited information regarding 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 event, a causal relationship cannot be excluded. However, Very limited information regarding this event has been provided at this time. Further information has been requested.</p>

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1246665	4/23/2021	PA	16	M	4/22/2021	4/23/2021	Patient received vaccine around 745 am on 4/22/21. He did not have any side effects or concerns until 4/23/21 at approximately 9:30 am when he had what Mom describes as a grand mal seizure while at school. Patient was reportedly sitting in his chair at school. He stretched his arms above his head then fell onto the floor with full body convulsions for just under 1 minute. Patient vomited about 20 minutes later. Our office was informed by mother around 10:30 am. Patient at home and sleeping. Advised Mom to take patient to local ED for further evaluation and monitoring.
1245442	4/23/2021	FL	47	M	4/11/2021	4/16/2021	seizure; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (seizure) in a 47-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 037B21A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No reported medical history). On 11-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Apr-2021, the patient experienced SEIZURE (seizure) (seriousness criterion medically significant). At the time of the report, SEIZURE (seizure) 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 medications were 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 start date of this event, a causal relationship cannot be excluded.

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1245483	4/23/2021			M			<p>grand mal seizures; absence seizures; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of GENERALISED TONIC-CLONIC SEIZURE (grand mal seizures) and PETIT MAL EPILEPSY (absence seizures) 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 Seizures (Patient had a history of seizures but had not had any since a very long time.). On an unknown date, the patient received first 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) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced GENERALISED TONIC-CLONIC SEIZURE (grand mal seizures) (seriousness criterion medically significant) and PETIT MAL EPILEPSY (absence seizures) (seriousness criterion medically significant). At the time of the report, GENERALISED TONIC-CLONIC SEIZURE (grand mal seizures) and PETIT MAL EPILEPSY (absence seizures) outcome was unknown. Not Provided Concomitant medication use was not reported. Treatment information was not reported. The patient reported that he had a grand mal seizure approximately 8 hours after the first vaccine dose. Thereafter, the patient stated that he is now averaging 3 -4 seizures per week. The patient endorses that he has never had daytime seizures before. The patient saw his neurologist who said there was no concern and advised that he continue to monitor. The patient stated that he did receive his second dose of the vaccine, dates 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. However, patient's hx of seizure is a confounding factor that may play a possible contributory role.; 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, patient's hx of seizure is a confounding factor that may play a possible contributory role.</p>

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1246091	4/23/2021	NJ	26	F	4/22/2021	4/22/2021	Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Mild, Additional Details: Pt fell face flat on her face within 5 minutes of her injection and scratched her left cheekbone. Look like she was having a seizure but she was already conscious when we flipped her over. She felt fatigue from working a night shift yesterday, and a morning shift today. She ate a couple hours before the appointment. FS associate, monitored her for an extra 15 minutes before she walked home. I followed up with her at 4:40pm and 7:30pm on 4/22. Recommended that she report this to her PCP.
1246269	4/23/2021	CA	46	F	4/5/2021	4/5/2021	I'm writing this as a former, trained healthcare professional (physical therapist). 30sec-after injection I raised my left (injected) arm and my deltoid/bicep had a sudden hard spasm. I told my husband (who was in the middle of getting his shot) and the administrator that I was passing out. I blacked out. They ran over. They said 5 minutes passed in which my eyes were wide open and dilated. I suddenly began profuse sweating and convulsions/ severe full body shaking. They could not keep me lucid, and called 911. Paramedics came and got a systolic BP of 36 (I'm unaware of the diastolic BP) with blood sugar at 111 ish. I could not form words and kept going in and out of consciousness. I was transported by ambulance to the ER. A few minutes into the ambulance ride I was able to form words, and vitals started to return. I've passed out a few times and this WAS NOT a normal episode of syncope.

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1246360	4/23/2021	GA	19	F	4/9/2021	4/9/2021	<p>She has a history of Bipolar II, dx about 2 years ago. She has been in counseling for the past 5 years. She just changed from effexor to lexapro about 1 month ago. She has been on abilify 10mg for the past ~6months. On 4/8/21 she went to bed around 11pm and awoke on 4/9 around 8:30am. She had her JJ covid vaccine on 4/9/21. She had 2 handfuls of goldfish crackers on the way to her vaccine appointment around 11am. She had ~6-8oz of water when she awoke. She arrived at the Clinic on campus. She sat down for ~5 minutes and then the staff came to get her. She had the shot administered in left deltoid. When she first felt the pain her vision started to go black and she felt like she was going to pass out. She denies feeling hot or dizzy prior to event. Her vision went completely black, then when she "came to" she was bent over in her chair with arms drawn up to body and fists clenched. Immediately her body relaxed and she felt very confused. She was told she just had a seizure - bend forward and had whole body shaking for ~30 seconds. She felt extremely nauseated and had some dry heaving. Someone helped her to the floor and put up her legs. She was told she looked very pale. She felt much better within 5 minutes. Vitals were checked and were stable. She was given granola bar to eat and drank ~12oz of water. No one sided weakness, no incontinence, no tongue bite. She stayed there for ~45 minutes for monitoring. Someone walked her to her car, asked her if she was ok, and then she drove herself home. Of note, the room she was in was warm and they were going to open doors to get some air. She was not ill or tired at the time. After the event she drove for 5 minutes to her home. Once in her room she felt extremely tired and then slept until 7pm (~6-7 hours). She then called Mom. Mom reports that patient sounded different on the phone. Speech was slow and she seemed "off." Mom drove to her and was at her room by around 7:40pm. At that time, patient looked very pale to Mom. Mom took her home, gave her chicken soup. She did not have an appetite. She just wanted to go to sleep. Mom tried to have her stay up until around 10pm. She had ~8oz of water and then went to bed. She slept through the night. She awoke the next morning and reports that her brain felt like it hurt to work. She had chills, body pain, shakiness during the day on 4/10/21. This was easily managed by tylenol q4. Of note, she did</p>

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							have covid19 in 8/2020. She was ill for ~1 week with lack of smell/taste, febrile, shakiness, headache. She had an odd event on 4/19/21 while giving a presentation at school. She had sudden onset of left pinky numbness/tingling with radiated up the side of her forearm. This lasted ~1-2 minutes. However, her left arm hurt for a few hours afterward. She denies any fatigue after event. She has a Mirena IUD. She smokes nicotine via vape numerous times per day. She smoke weed up to 3X/day but not every day. She drinks beer a few days per week.
1246454	4/23/2021	IN	27	M	4/21/2021	4/21/2021	Patient received vaccine at approx 1645. Prior to vaccination, patient denied history of severe allergies to medications, vaccines, or anything requiring an epi-pen. Patient denied allergy to Miralax and was feeling well that day. Patient finished with injection and walked into the observation room. Observation provider FNP walked up to patient after he had sat down and the patient appeared to have a seizure for approx 90 seconds, was leaning to the side where provider was supporting him, and was unresponsive. Provider called for help and this provider & FNP responded. Patient was awake and looking at us but was not responding to questions. Patient was assisted fully to a wheel chair and moved to a private room. Vitals were obtained - oxygen saturations were low and patient began to look dusky and cyanotic around lips. AGNP, FNP, and Dr also arrived. Oxygen was applied. Blood pressure was in the 60s systolic and 30's diastolic. Patient started to pink up after oxygen was given. Patient's phone had an active call (girlfriend). She was unable to provide any history for the patient. Patient started answering questions slowly. EMS arrived and transported patient to Hospital Emergency Dept.

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1246547	4/23/2021		52	M	3/20/2021	3/21/2021	52 yo male received first dose of Pfizer vaccine on 3/20 at outside institution. The next morning, pt experienced uncontrollable tremors and twitching and presented to the ED. In the ED, patient had generalized tonic-clonic seizure that lasted for about 1-3 minutes. CT head scan was unremarkable. Neurology started pt on Keppra 500 mg BID and plan for MRI and routine EEG. The next morning, pt felt back to baseline and was alert and oriented. Patient has a history of HIV and stroke with residual right-sided weakness. He has no history of seizure nor reactions to vaccines. Physician advised patient that he should not receive second dose of vaccine.

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1245415	4/23/2021	TN	55	F	2/26/2021	4/6/2021	<p>Vomited for an hour; light headed; broke out in a cold sweat; body cramped up; nausea; Sore left Arm; convulsions; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SEIZURE (convulsions) and VOMITING (Vomited for an hour) in a 55-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 020B21A and 031L20A) 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 26-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1. On 06-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 2. On 06-Apr-2021, the patient experienced SEIZURE (convulsions) (seriousness criterion medically significant), VOMITING (Vomited for an hour) (seriousness criterion hospitalization), DIZZINESS (light headed), COLD SWEAT (broke out in a cold sweat), MUSCLE SPASMS (body cramped up), NAUSEA (nauseus) and VACCINATION SITE PAIN (Sore left Arm). The patient was hospitalized from 06-Apr-2021 to 08-Apr-2021 due to VOMITING. On 08-Apr-2021, SEIZURE (convulsions), VOMITING (Vomited for an hour), DIZZINESS (light headed), COLD SWEAT (broke out in a cold sweat), MUSCLE SPASMS (body cramped up), NAUSEA (nauseus) and VACCINATION SITE PAIN (Sore left Arm) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood lactic acid increased: increased (abnormal) increased. On an unknown date, Blood potassium: decreased (abnormal) decreased. On an unknown date, Blood pressure decreased: decreased (Low) decreased. On an unknown date, Body temperature: decreased (Low) decreased. No concomitant medications were reported. No treatment medications were reported. 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.</p>

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1243022	4/22/2021	NY	63	M	3/27/2021	3/28/2021	IN 24HOURS my husband had a seizure and I found him unresponsive and was taken to the hospital in an ambulance, 2 weeks in hospital with organs failing etc and his kidneys are still coming back. He appears to hopefully be a full recovery. Doctors say they do not know enough about the vaccine to say it was the cause although he had blood work taken 3 days prior. and all good. He had a lot of tests due to finding that he had 2 very old strokes.
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.
1244816	4/22/2021	NJ	39	F	4/10/2021	4/18/2021	Patient complained of fever and chills on 4/18. Patient continued to have symptoms, suspected to be acute frontal sinusitis. On 4/21, patient complained of bilateral leg heaviness, felt weighed down, difficult to walk, no weakness, swelling, or redness. Patient elevated legs and felt better on 4/22. Patient later presented to the ED with acute mental status changes. Patient fell at home and had a seizure according to family. Patient is currently intubated and critically ill.

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1244351	4/22/2021	AZ	29	F	3/31/2021	3/31/2021	<p>** Backache - As of this visit today, April 21, 2021, pt still has c/o continuous back pains all down her spine since receiving the Johnson & Johnson COVID-19 Vaccine on March 31, 2021. patient continues to report pain in her neck (cervical), thoracic, and lumbar spine. She insists that the cervical pain radiates into both shoulders and down to her arms bilaterally. She states these pains started almost immediately after receiving the vaccine and persists as of today. On a scale of 0-10, patient rates her spine and shoulder pains at 3 continuously. -- I've added methocarbamol 750mg tid for muscle relaxant with ibuprofen 400mg q6h. ** Severe headache - As previously noted in my previous findings with patient she reported having moderate headaches for two days after receiving the J&J COVID-19 Vaccine on March 31, 2021 but she states her headaches have now subsided. *** Other: On my first visit with patient on April 6, 2021, she was very concerned about a sudden loss of hair since taking the J&J Vaccine in addition to the spine pains and bruising. ** Leg swelling - patient reported both leg and hand swelling for 2 days after receiving J&J COVID-19 Vaccine with some new neurologic symptoms as noted below: ** New neurologic symptoms -patient continues to report significant weakness and fatigue. -- Her headaches that were present after receiving the vaccine have subsided after the first two days following the vaccine being administered. -- She reported new numbness x 2 days in both fingers and toes bilaterally with both hands and legs swelling immediately after receiving the vaccine. -- She also reported 2 hours of dizziness immediately after receiving the vaccine on March 31, 2021. -- patient reported a new onset of hand tremors that suddenly came on a week ago Sunday, April 11, 2021 while fishing that lasted for a few hours. She stated that the tremors would come and go for a while. -- patient has been and is currently negative for loss of consciousness, seizures, and migraines. ** Severe abdominal pain - patient initially reported episodic sharp shooting pains in abdominal area on multiple occasions after receiving the vaccine but have mostly now subsided. However, today, April 21, 2021 she reports more abdominal shooting "Sharp Pains" in her RUQ this morning that she rated 3/10 pain, and LLQ "Sharp Shooting" pain last Friday, 4/16/21. She states that the shooting pains last approximately 3</p>

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							<p>minutes in duration. ** Shortness of breath ? patient has continuous episodic shortness of breath complaints that have persisted since receiving the vaccine on March 31, 2021. Her last episode was again this morning, April 21, 2021 and she also states she is feeling like she is having trouble breathing during the exam today. Her SaO2 is 98% on Room Air during triage. She also reported yesterday, the same at the Clinic. She reported being at work on Monday, April 19, 2021 and became short of breath and had to lay down on the floor to breath easier. patient is a Kindergarden teacher. She also became short of breath Monday evening while at home while cleaning her closet. -- Yesterday, April 20, 2021 at Clinic I added a rescue inhaler for her shortness of breath. ** Petechiae (tiny red spots on the skin) - patient reported a new eruption on her upper back and shoulders after receiving J&J Vaccine. While the red spots are not bleeding, there was a significant notable rash to bilateral shoulders and upper back when I last saw her a week ago on April 13, 2021 at the Clinic. Today, the rash has cleared significantly. She was prescribed TRIAMCINOLONE 0.025% (80GM) OINT, TOP in Urgent Care last week, when I referred her to Dr. in the ER. ** New or easy bruising - multiple new bruising noted today on her left bicep arm. Yesterday, April 20, 2021 at the Clinic, I noted new bruising on lower extremities in addition to the bruising noted the week prior. The bruising started after receiving the J&J COVID-19 Vaccine that I noted in my previous findings last week.</p>
1243633	4/22/2021	IL	16	F	4/21/2021	4/21/2021	<p>Patient was on observation having a conversation with her father when suddenly she started passing out and exhibiting twitching like having Petit mal convulsions and not able to arouse, and later in 2 minutes she recovered eyes open appears pale in face and lips, not aware that she had passed out, and became responsive. Father claims that HR is always running on low side because she is an athlete. On around 4:40pm she was released under the care of her parent and recommended to get an appointment with her PCP for further evaluation Patient status was checked the following day 4/22 and Pediatrician said that it must be a vasovagal Syncope per Neurologist he consulted no further appointment will be needed at this time</p>

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1243590	4/22/2021	CO	43	M	4/7/2021	4/13/2021	I had a seizure 6 days after receiving my 2nd vaccine.
1240620	4/22/2021	FL	50	F		4/12/2021	BODY ACHES; LIGHTHEADEDNESS; This spontaneous report received from a health care professional concerned a 50 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included kidney stones, left breast lump, and seizure disorder, and other pre-existing medical conditions included 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: 1805025 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 body aches. On 12-APR-2021, the subject experienced lightheadedness. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from body aches, and lightheadedness on 13-APR-2021. This report was non-serious. This case, from the same reporter.
1243371	4/22/2021	OR	79	M	4/21/2021	4/21/2021	Patient came for vaccination in the morning, then went out to breakfast. During breakfast, the patient slumped forward in his seat and was unresponsive for about a minute. There was no incontinence or seizure activity. On regaining consciousness, patient seemed to quickly get back to his usual level of mentation. He was diaphoretic and nauseous. He denies any preceding lightheadedness, nausea, visual changes, chest pain or palpitations. He presented to the emergency room, also had nosebleed and UTI. Was admitted for observation overnight and discharged the next day.
1243087	4/22/2021	MA	66	F	3/1/2021	4/22/2021	Cortical sinus thrombosis with intracerebral hemorrhage, seizures. Admitted to ICU.
1240214	4/22/2021	SC	72	F	3/25/2021	3/27/2021	4 seizures over a 2 Week period involving hospitalization.

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1240473	4/22/2021	MN		U		3/6/2021	SHAKINESS (LIKE SEIZURE); CHEST AND RIBS BEING PAINFUL; FELLING COLD; FEELING AWFUL; This spontaneous report received from a patient 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, intramuscular, batch number: 1805018, expiry: 25/MAY/2021) dose was not reported, administered on 06-MAR-2021 for prophylactic vaccination. The vaccination site was left arm. No concomitant medications were reported. On 06-MAR-2021, the patient experienced shakiness (like seizure), chest and ribs being painful, felling cold and feeling awful. The patient felt "gassed out", but not as "offal as yesterday". The action taken with COVID-19 vaccine ad26.cov2.s was not reported. The patient recovered from shakiness (like seizure) on 06-MAR-2021, and chest and ribs being painful on 07-MAR-2021, and was recovering from felling cold, and feeling awful. This report was serious (Other Medically Important Condition).; Sender's Comments: Shakiness (like seizure), chest and ribs being painful, felling cold and feeling awful. This event(s) is considered related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and is scientifically plausible. There are no other factors more likely to be associated with the event(s) than the drug.

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1240533	4/22/2021	TN	44	M		4/9/2021	LOSS OF CONSCIOUSNESS(PATIENT WAS COMING IN AND OUT OF CONSCIOUSNESS); BRADYCARDIA; SEIZURE (EYES ROLLED BACK, HEAD WENT BACK); ARM WEAKNESS; PROFUSELY SWEATING; This spontaneous report received from a consumer concerned a 44-year-old male. The patient's height and weight were not reported. The patient's pre-existing medical conditions included patient did not have any known allergies. The patient did not have any reaction to vaccine before. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 041A21A, and expiry: UNKNOWN) dose was not reported, 1 total administered on 09-APR-2021 at right arm for prophylactic vaccination. No concomitant medications were reported. On 09-APR-2021, five minutes after vaccination, patient started profusely sweating and he had a seizure (eyes rolled back, head went back) and lost consciousness. Paramedics were on site came and they did a Electrocardiogram. He had bradycardia (heartrate was very low : 30 bpm). During all this time, he kept on coming in and out of consciousness. Patient also had arm weakness. Paramedics took him by ambulance to the emergency room; they administered some kind of medication because of his heart rate. Reporter thought it was atropine and took him to the hospital. In emergency room, they did a chest x-ray, Computerised tomogram scan and blood work, they did not see anything abnormal that would have caused the seizure. Emergency room Doctor determined that, it was the vaccine or a component of the vaccine that caused the reaction. Laboratory data included Blood test (NR: not provided) Normal, Computerised tomogram scan (NR: not provided) Normal, Chest X-ray (NR: not provided) Normal, and EKG (NR: not provided) 30 bpm. Treatment medications included atropine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from seizure (eyes rolled back, head went back) on 09-APR-2021, and bradycardia on 10-APR-2021, and the outcome of arm weakness, loss of consciousness (patient was coming in and out of consciousness) and profusely sweating was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210422272-covid-19 vaccine ad26.cov2.s-loss of consciousness

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1240685	4/22/2021	WI	61	F		4/11/2021	(patient was coming in and out of consciousness), bradycardia, seizure (eyes rolled back, head went 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).
						4/11/2021	BLURRED VISION FOR THREE DAYS; HEADACHE; TIREDNESS; This spontaneous report received from a patient concerned a 61 year old female. The patient's weight was 193 pounds, and height was 64 inches. The patient's concurrent conditions included seizure disorder, non-alcoholic, and non-smoker, and other pre-existing medical conditions included the patient had no known allergies. The patient had 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: 043A21A, expiry: UNKNOWN) dose was not reported, administered on 10-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 11-APR-2021, the subject experienced blurred vision for three days. On 11-APR-2021, the subject experienced headache. On 11-APR-2021, the subject experienced tiredness. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from blurred vision for three days on APR-2021, and headache, and tiredness on 12-APR-2021. This report was non-serious.

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1241190	4/22/2021	NJ		F		4/1/2021	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 brain injury, and concurrent conditions included endometrial cancer, fibromyalgia, supraventricular tachycardia, focal seizure, penicillin allergy, and shellfish allergy, and other pre-existing medical conditions included the patient was allergic to floxin based drug and zicor. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 041A21A, and batch number: 041A21A expiry: UNKNOWN) dose was not reported, administered on 01-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On APR-2021, the subject experienced left leg swelling. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from left leg swelling. This report was non-serious.
1241341	4/22/2021	MA	34	M	4/9/2021	4/14/2021	On day 5 started not feeling well began to run a low grade fever lasted several days. On day 3 after symptoms started patient woke up in the middle Of the night to use the restroom something that is done every night. Patient passed out and hit his head and started having a seizure
1241577	4/22/2021	FL	17	M	4/20/2021	4/20/2021	Systemic: Dizziness / Lightheadness-Mild, Systemic: Seizure-Mild
1242922	4/22/2021	CA	17	M	4/14/2021	4/21/2021	My son developed headache, vomiting, nausea, and worst of all a 45 second seizure.
1241913	4/22/2021	MN	16	F	4/19/2021	4/19/2021	Within a minute of receiving the vaccine, my daughter fainted and had a short seizure. She did not hit her head because I was able to help her on her way down - it was a ver small room with 3 people in it. The pharmacist was there and he said it was a seizure, she just jerked her chin up, sharply 3 or 4 times. She laid on the ground for about five minutes, then sat on the ground, then sat in a chair for a total of about 20 minutes. She felt dizzy and nauseated for about 15 minutes after. She drank a juice and felt better so we drove home, no other symptoms since.

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1242048	4/22/2021		18	M	4/22/2021	4/22/2021	SYNCOPE EPISODE, SEIZURE ACTIVITY. Evaluated by EMS-Refusal to transport.
1242212	4/22/2021	CA	40	F	3/31/2021	3/31/2021	Nausea, vomiting, palpitations starting 10 minutes after vaccine administration. Generalized Tonic Seizure 2 days after vaccine. CT head negative in ED, discharged 8 days after vaccine, presented to clinic with continued daily seizure like activity, inability to stand due to leg shaking. Exam notable for Lower extremity myoclonus. Then, admitted to hospital on 4/8. MRI brain unremarkable. EEG with potential epileptiform activity. Patient discharged on 4/10 on keppra for seizure prophylaxis, Home health physical therapy and neurology follow up.
1242425	4/22/2021	RI	45	M	3/20/2021	3/20/2021	Patient does not remember most of the adverse event. Patient's partner reports that patient started feeling a tingling sensation on his left arm about 10 minutes after vaccination. Partner also reports that patient was hallucinating and sending her confusing text messages during his 15 minute observation period. The patient did not report feeling any adverse symptoms at the checkout station after his 15 minute observation period and before leaving the vaccination clinic. After patient returned home, his partner reports considerable swelling on his left arm, continued hallucinations and trying to dismiss her concerns. Subsequently, that same day, partner reports the patient had a severe migraine and began to lose feeling on his left arm and leg, at which point the patient also lost consciousness. Also at this point, the partner calls 911. After arrival of emergency personnel, the patient regains consciousness, but does not remember name and complains of continued pain on his arm. He is transported to hospital where he spends 3 nights and receives treatment and care for stroke symptoms. Patient reports that he does not remember much of anything 1.5 days after vaccination. After returning home from hospital, patient complains of memory lapses and begins seeing neurologist for minor seizures during his sleep. Wife reports that patient now lashes out and easily loses temper due to the fact that his memory is foggy.

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1242504	4/22/2021	OK	16	F	3/17/2021	3/27/2021	My daughter has been diagnosed with catamenial epilepsy, and typically only had seizures very sporadically (months apart). However, she recently had a cluster of seizures, which was very atypical for her. I read a news story last night about the vaccine affecting some women by making their period come back after years of not having it. In reviewing my daughter's seizure events, a pattern emerged in relation to her Covid shots: -Dose 1 of Pfizer on March 17, and the worst seizure she ever had was on March 27 (10 days after first Covid shot) -Dose 2 of Pfizer on March 31, and the second worst seizure she ever had was on April 10 (10 days after second Covid shot) Prior to the Pfizer Covid shots, the shortest frequency between seizures was one month, and that was prior to her starting epilepsy medication (Keppra). She was taking her Keppra (morning and night) at 1000 mg twice daily as prescribed, and had not missed any doses when the seizures occurred. We now suspect that the two recent seizures might be adverse reactions to the Covid shots.
1242849	4/22/2021	TX	66	F	4/16/2021	4/16/2021	Had a seizure/stroke beginning at 8 pm and was brought to the ER. Was admitted in ICU
1241908	4/22/2021	VA	16	F	4/21/2021	4/21/2021	pt started feeling really dizzy and nauseated immediately after taking the vax. she started having a seizure and made a growling type of noise and urinated on herself. The nurse at the vax site helped bring her back and was told to take her to a doctor. She was monitored and released from the vax clinic when her BP was 107/76. She was taken to medical center where she saw. She was told she had Syncope due to the stress of the situation of getting the vaccination. She is resting today and seems to have some fatigue.

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1240499	4/22/2021	GA		U		4/7/2021	SEIZURE-LIKE ACTIVITY; PAIN IN ARM; This spontaneous report received from a health care professional concerned multiple patients 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: 201A21A, expiry: unknown) dose was not reported, 1 total administered on 07-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, the patients experienced seizure-like activity and pain in arm. It was reported that, while the patients sat in the observation area, seizure-like activity was noted for 5 seconds. The patients complained of dizziness (subsumed under seizure-like activity), and pain in arm. The patients were observed for 2 hours and discharged. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the seizure-like activity and pain in arm was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210417256, 20210417209 and 20210417456.; Reporter's Comments: The case is a multiple patient case.; Sender's Comments: V0: 20210418457-covid-19 vaccine ad26.cov2.s-seizure-like activity. 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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1236233	4/21/2021	NJ		F			<p>BODY ACHE; WENT FROM HOT TO COLD; BRAIN COULD NOT FOCUS; CHILLS; HEADACHE; FEVER; This spontaneous report received from a consumer concerned an 18 year old female. The patient's height, and weight were not reported. The patient's past medical history included seizure, and concurrent conditions included seasonal allergy, no alcohol, and non smoker. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 202A21A expiry: UNKNOWN) dose was not reported, administered on 11-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, the subject experienced body ache, feeling cold, brain could not focus, chills, headache, and fever. Treatment medications (dates unspecified) included: ibuprofen. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the chills, body ache, headache, feeling cold, fever and brain could not focus was not reported. This report was non-serious.</p>

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1236195	4/21/2021	WA	58	M		4/1/2021	BODY ACHES AND BODY SORENESS; DIFFICULTY IN BREATHING; TIRED; 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 non alcohol user, non smoker, colitis, seizures, diabetes, and cholesterol, and other pre-existing medical conditions included the patient had no known drug allergies, not allergic to any medications. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 1808982 expiry: UNKNOWN) dose was not reported, administered on 10-APR-2021 14:30 for prophylactic vaccination. Concomitant medications included azathioprine for colitis, lamotrigine for seizures, zolpidem for sleeping, meclizine for vertigo, amoxicillin, atorvastatin, hydrochlorothiazide, infliximab, olmesartan, ondansetron, potassium, potassium chloride, propranolol, and venlafaxine. On APR-2021, the subject experienced body aches and body soreness. On APR-2021, the subject experienced difficulty in breathing. On APR-2021, the subject experienced tired. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the body aches and body soreness, difficulty in breathing and tired was not reported. This report was non-serious.

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1236104	4/21/2021	OH	18	F	4/1/2021		SPASMS ON LEGS, ARMS AND HEAD; SLIGHT HEADACHE; EXTREME TIREDNESS; SLIGHT FEVER; NAUSEA; BODY ACHES; PROFUSE SWEATING; POSSIBLE SEIZURE; This spontaneous report received from a consumer concerned an 18 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included food allergy. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 201A21A, and expiry: unknown) dose was not reported, 1 total administered on 11-APR-2021 around 11:30 to left arm for prophylactic vaccination. No concomitant medications were reported. On 11-APR-2021, after vaccination patient had done lower body workout. On 11-APR-2021, the patient experienced nausea, extreme tiredness, slight fever, slight headache, body aches, and profuse sweating by evening. She took some children's liquid paracetamol (Tylenol). On 12-APR-2021 about 02:00, she also had spasms of her arms, legs, and head that lasted about 20 minutes. She took paracetamol (Tylenol) at about 03:00 and was pretty out of it. The patient's mother was concerned that it could had been a seizure (possible seizure). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from spasms on legs, arms and head on 12-APR-2021, and the outcome of nausea, extreme tiredness, slight fever, slight headache, body aches, profuse sweating and possible seizure was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210423951-Covid-19 vaccine ad26.cov2.s-seizure. 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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1235970	4/21/2021	CA		F	4/6/2021		<p>HIVES ON HER RIGHT ARM; BLOODY DIARRHEA; BLOOD FROM A HEMORRHOIDS; HUGE MIGRAINE/VISION IMPACTED; This spontaneous report received from a patient concerned a 64 year old female. The patient's weight was 208 pounds, and height was not reported. The patient's past medical history included breast cancer left side, and hay fever, and concurrent conditions included allergic to anti-seizure drug cipro, pregabalin (Lyrica) and gabapentin, irritable bowel syndrome (IBS) (C and D), chronic migraines, hashimoto disease, seizures, non alcohol user, and non smoker. 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, Expiry: Unknown) dose was not reported, 1 total dose administered on 06-APR-2021 in right arm for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 06-APR-2021, after 45 min of vaccination, the patient experienced a huge migraine, which was worst in her life due to which she could hardly make it home. Her vision was impacted. On the same day, in evening she developed bloody diarrhea, blood from a hemorrhoid. She believed, the vaccine has exacerbated her underlying medical conditions. She also reported that, when she took off her clothing, she noticed that she developed hives on her right arm. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from huge migraine/vision impacted on 07-APR-2021, and had not recovered from hives on her right arm, bloody diarrhea, and blood from a hemorrhoids. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210420554-Covid-19 vaccine ad26.cov2.s-Bloody diarrhea. 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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1235969	4/21/2021	CT	18	M		4/1/2021	<p>VOMITING/EMESIS; SHAKES; LEGS NUMB; FEVER; WEAKNESS; TIREDNESS; UNABLE TO WALK; This spontaneous report received from a physician concerned an 18 year old male. The patient's height, and weight were not reported. The patient's past medical history included Lyme disease, and seizure, and concurrent conditions included attention deficit hyperactivity disorder, intermittent asthma, migraines, psoriasis, and penicillin allergy, and other pre-existing medical conditions included currently not on any medications. 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 at 14:45 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 08-APR-2021 around 19:30, the patient experienced vomiting, had fever, shakes and complained of numb legs and was unable to feel them. He was instructed by his physician to go to the nearest Emergency room (ER). The patient visited emergency room or department and physician office for treatment of the events. He went to ER but was unable to walk at that time and was carried in. The patient was evaluated, had normal chest X-ray (CXR), temperature up to 104, had emesis, underwent rapid covid test which was negative. He was given intravenous (IV) fluids, Zofran, Tylenol and was discharged home. It was reported that the patient was doing better but with continued tiredness, weakness, his legs were feeling better, temperature was down, coherent and was tolerating fluids. Laboratory data included: Body temperature (NR: not provided) 104, COVID-19 antigen test (NR: not provided) Negative, and CXR (NR: not provided) Normal. Treatment medications (dates unspecified) included: paracetamol, and ondansetron. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from vomiting/emesis, fever, shakes, and legs numb, had not recovered from weakness, and tiredness, and the outcome of unable to walk was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210420466-covid-19 vaccine ad26.cov2.s-vomiting/emesis, shakes, legs numb, unable to walk. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal</p>

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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1235957	4/21/2021	OH					
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1235957	4/21/2021	OH		U			
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1235957	4/21/2021	OH		U	4/2/2021		<p>relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). 20210420466-covid-19 vaccine ad26.cov2.s-Fever. This event(s) is labeled per RSI and is therefore considered potentially related.</p> <p>SEIZURE; FELL ON THE FLOOR; This spontaneous report was received from a consumer and concerned multiple patients. The patients' weights, heights and medical histories were not reported. The patients received COVID-19 vaccine Ad26.CoV2.S (suspension for injection, route of administration not reported, batch number 1808978; expiry date not reported) doses not reported, administered on 02-APR-2021 for prophylactic vaccinations. No concomitant medications were reported. On 02-APR-2021, a total of 24 patients fell on the floor and experienced seizure. The consumer reported that they observed 4 people fall within 15 minutes of vaccination and have seizures, and they also reported that a fire chief had stated to them that an additional 20 patients had also fallen and had seizures. The action taken with COVID-19 vaccine Ad26.CoV2.S was not applicable. The outcomes of the seizures and falls were not reported. This report was serious (other medically important condition).; Sender's Comments: v0 This report received from a consumer who reported seeing 4 people fell within 15 minutes and had "seizures" after receiving Janssen COVID-19 Vaccine Ad26.COV2 and also hearing that of an additional 20 patients who fell and had "seizures" from a fire chief. Medical history, concomitant medications, and details of the events 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.</p>
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1235774	4/21/2021	MO		M	4/6/2021	4/6/2021	fainted/passed out; patient passed out; This is a spontaneous report from a contactable pharmacist reporting same events for suspect products for 4 patients. This report is for the 4th patient. Follow-up (06Apr2021) was received from same reporter and processed together with initial information. A male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: ER8729; Expiration Date: 20Jul2021), via an unspecified route of administration on 06Apr2021 as SINGLE DOSE for covid-19 immunization. The patient medical history was not reported. Concomitant medication(s) included saline [sodium chloride] (SALINE [SODIUM CHLORIDE]). The patient reported that after administering the Covid 19 vaccine on 06Apr2021, within about 20 minutes there were 4 patients with reactions. The patient experienced fainting/passed out on an unspecified date and patient passed out on 06Apr2021. Three people fainted and one had seizure after receiving the first dose of the Pfizer-BioNTech Covid-19 Vaccine. These patients had just received the Covid 19 vaccine and were still being watched within the 15-minute post vaccination time. All 4 patients received the Covid 19 vaccine from the same lot number but not from the same vial. Seriousness of events was medically significant. The outcome of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Considering close temporal association, a possible contributory role of bnt162b2 to the events fainted and passed out cannot be completely excluded. Relevant medical history and details of clinical course are missing for further assessment. 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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1235669	4/21/2021	CA	50	F	4/9/2021	4/10/2021	episode of passed out; severe allergic reaction at injection site; injection arm is irritating; itchiness; injection arm is hurting; redness; swelling at injection site; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (episode of passed out) 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 Blind (patient is legally blind in the left eye). Concomitant products included QUETIAPINE FUMARATE (SEROQUEL) for Seizure, PARACETAMOL (TYLENOL), CYCLOPENTAMINE, ESZOPICLONE, CLONAZEPAM (KLONOPIN), VITAMIN B COMPLEX and CYANOCOBALAMIN (VITAMIN B12 FORTE) for an unknown indication. On 09-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (episode of passed out) (seriousness criterion medically significant), VACCINATION SITE PRURITUS (itchiness), PAIN IN EXTREMITY (injection arm is hurting), IRRITABILITY (injection arm is irritating), INJECTION SITE HYPERSENSITIVITY (severe allergic reaction at injection site), VACCINATION SITE ERYTHEMA (redness) and VACCINATION SITE SWELLING (swelling at injection site). At the time of the report, LOSS OF CONSCIOUSNESS (episode of passed out) outcome was unknown and VACCINATION SITE PRURITUS (itchiness), PAIN IN EXTREMITY (injection arm is hurting), IRRITABILITY (injection arm is irritating), INJECTION SITE HYPERSENSITIVITY (severe allergic reaction at injection site), VACCINATION SITE ERYTHEMA (redness) and VACCINATION SITE SWELLING (swelling at injection site) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Jan-2021, SARS-CoV-2 test positive: Positive. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medication not reported. Treatment medication not provided.; Sender's Comments: Based on the current available information and temporal association between

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1235685	4/21/2021	OH	62	F	3/9/2021	4/6/2021	<p>the use of the product and the start date of these events, a causal relationship cannot be excluded.</p> <p>Dizzy; Fever 101 degrees Fahrenheit; Nausea; Body aches; Seizure; Symptoms like the flu; Felt like she was going to faint; This spontaneous case was reported by a non-health professional (subsequently medically confirmed) and describes the occurrence of SEIZURE (Seizure) in a 62-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 016B21A and 029A21A) 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 provided.). On 09-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 06-Apr-2021, the patient experienced SEIZURE (Seizure) (seriousness criterion medically significant), INFLUENZA LIKE ILLNESS (Symptoms like the flu), DIZZINESS (Dizzy), PYREXIA (Fever 101 degrees Fahrenheit), NAUSEA (Nausea) and MYALGIA (Body aches). On an unknown date, the patient experienced PRESYNCOPE (Felt like she was going to faint). At the time of the report, SEIZURE (Seizure), INFLUENZA LIKE ILLNESS (Symptoms like the flu), PRESYNCOPE (Felt like she was going to faint), DIZZINESS (Dizzy), PYREXIA (Fever 101 degrees Fahrenheit), NAUSEA (Nausea) and MYALGIA (Body aches) 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. This case was linked to US-MODERNATX, INC.-MOD-2021-054366 (E2B Linked Report). This case was linked to MOD-2021-077998, MOD-2021-077998 (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. US-MODERNATX, INC.-MOD-2021-054366:</p>
1236864	4/21/2021	IN	17	F	4/15/2021	4/20/2021	<p>patient woke up with aphasia. per ER note, differential TIA vs focal seizure vs stress.</p>

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1239064	4/21/2021	CA	58	M	4/16/2021	4/18/2021	He presented to the ER via ambulance after he had 3 witnessed seizures which included full loss of consciousness and rhythmic jerking lasting for an unknown duration. En route apparently he was seizing and prehospital personnel gave him 5 mg IM versed as well as 5mg iv versed which did seem to abate the seizure. He was apparently quite combative and has no prior history of seizures. In the ER the patient was apparently having right sided eye deviation and was given 2mg of Ativan. A stat CT of the head did not reveal any acute process. Telemetry neurology was consulted. During his work up the patient was found to have a urine toxicology positive for amphetamines as well as opiates. Telemetry neurology recommended loading the patient with Keppra, initiating regular Keppra doses and indicated they believed the etiology of his seizures was polysubstance abuse.

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1235769	4/21/2021	CA	28	M	4/6/2021	4/6/2021	seizures/Convulsions; weird metal or acidic taste in my mouth; felt heavy; feel shaky; back spasms; blood pressure spiked to higher than normal levels; nauseous; weakness on my left side; pain at the injection site; pain at the injection site, my back, and neck; pain at the injection site, my back, and neck; feel super tired; This is a spontaneous report from a contactable consumer (patient). A 28-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in arm left on 06Apr2021 11:15 (Batch/Lot Number: EP7533) as single dose for COVID-19 immunisation. Medical history included axenfeld reigers, bilateral congenital iris coloboma, bilateral glaucoma, hearing loss. Known allergies: peanut, albuterol, amoxicillin-pot clavulante, doxycycline, fentanyl, levosalbutamol (LEVALBUTEROL), oxycodone-acetaminophin, sedation. Concomitant medications in two weeks: cryofood (unspecific), folic acid, cyanocobalamin (B12), timolol and dorzolamide hydrochloride/timolol, all from unknown date for unknown indication. First, patient had a weird metal or acidic taste in mouth. Following that, patient felt heavy. Next, began to feel shaky having back spasms. His blood pressure spiked to higher than normal levels and started feeling shakey dropped. Patient was laid down by nursing staff and blood pressure dropped. After being laid down, patient started having seizures/convulsions, paramedics were called and patient was given midazolam hydrochloride (VERSED, anti-seizure meds) and was taken to the ER (emergency room). Once patient arrived at the ER, he felt nauseous and was given anti-nausea medication, after about 4 hours patient was released. But he was experiencing weakness on left side and pain at the injection site, back, and neck, and felt super tired. AEs onset at 11:30 of 06Apr2021. Outcome of the events was resolving. Patient had no COVID prior vaccination and had no COVID tested post vaccination.
1237161	4/21/2021		16	M	3/22/2021	3/22/2021	Seizure like activity and racing heart immediately after administration, BP 75/35 and HR 48

<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>
1237216	4/21/2021	IL	23	M	4/1/2021	4/9/2021	The patient developed fatigue, malaise, skin allodynia, fever (103.5F) and took acetaminophen and ibuprofen. The fever resolved but he was diaphoretic. He also had a headache, vomiting, then lost consciousness overnight and had a tonic-clonic seizure lasting 10 minutes. He was brought to the emergency department and had 2 more seizures there which was controlled with lorazepam. He was admitted to the hospital and started on broad spectrum antibiotics (acyclovir, ceftriaxone, and vancomycin). On 4/11/21, the patient was extubated and improved symptomatically, and antibiotics were narrowed to doxycycline. He was then discharged on doxycycline and levetiracetam.
1237686	4/21/2021	NY	55	F	3/9/2021	3/15/2021	6 days after shot I got a debilitating headache (the worst headache of my life 10/10 pain). I went to the ER and they proceeded to do a CT scan and blood work. Nothing abnormal was found. The next day I went to Hospital ER due to the head pain, shortness of breath, chest pain and high blood pressure. They put me on steroids and pain meds and I was referred to a Cardiologist and neurologist. 4 days later I was in the ER again for head pain, my BP was 220/125 due to pain when entering the hospital. After about 2 weeks, I saw a neurologist. He prescribed various pain meds including anti- seizure meds and shots. The cardiologist feels that it is not a heart issue. I remain having daily headaches 6 weeks later but the intensity is lower (5/10). My BP is now back at a normal level. I am awaiting 2 more tests. MRV and spinal puncture test.
1237779	4/21/2021	IL	30	M	4/14/2021	4/14/2021	Patient experienced syncope and possible seizure post vaccination, transported to hospital via ambulance

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1237846	4/21/2021	IN	28	F	4/5/2021	4/21/2021	Patient received the Johnson & Johnson / Janssen COVID-19 vaccine on April 5, 2021. Patient woke up overnight with severe headache that was different than her typical migraines headaches. Headache was "like I never had before", "it's really painful." When I asked if this was the worst headache of her life she responded "probably." No photophobia, no phonophobia, no nausea, and no vomiting, which she gets every time she has migraines. "This is a different type of headache," she said. "I usually throw up and my headaches get better." This headache feels like a "balloon in my head." She reported vision changes (blurred vision) 45 minutes prior to our visit which started at 8:19 a.m. on April 21, 2021. ("I was having a problem with peripheral vision, about 45 minutes ago," but not so much now. Patient denies loss of balance (dizziness), seizures, focal weakness, radicular symptoms, saddle anesthesia, sensory changes, slurred speech, numbness, chills, and fever. She was sent to the emergency department for further evaluation. She is a female patient with new, severe headache that is between 18 and 48 years of age, and has received the Ad26.COV2.S (COVID-19) vaccine within 3 weeks of headache onset.
1237948	4/21/2021	CO	51	M	3/20/2021	4/16/2021	After receiving the 2nd dose of the Covid 19 Moderna vaccine started having seizure auras culminating on April 17 with a grand mal seizure. Paramedics came to the scene and took to the hospital. He was evaluated by the ER doctor and given a CAT Scan that didn't show any change from previous scans.

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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>

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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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

<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> II-XII intact, motor strength equal & normal bilaterally upper extremity, sensation equal & 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>
1238366	4/21/2021	IL	41	M	4/9/2021	4/9/2021	<p> Patient became pale, diaphoretic, and experienced a syncopal episode, laid flat and then had simple partial seizure lasting 10 seconds, became incontinent, IV started, A and O x4 , transported to hospital via ambulance </p>
1238935	4/21/2021	MN	47	F	4/10/2021	4/11/2021	<p> Two seizures the following day (more severe from her typical seizure disorder) that led to ankle fracture in both ankles. </p>
1239806	4/21/2021	MD	35	F	4/7/2021	4/8/2021	<p> Started around 12:30am, convulsions, chills, rapid heart rate and high blood pressure, took 2 Advil 104 fever, profuse sweating Given 2 Tylenol at hospital </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>
1236956	4/21/2021	NC	27	M	4/2/2021	4/2/2021	Patient reported no significant medical history or conditions prior to vaccination. About five minutes post-vaccination, he appeared to have a seizure. EMS was called and patient responded well to water and crackers. He then reported a history of seizure activity.
1238908	4/21/2021	CA	18	F	4/21/2021	4/21/2021	1:50 Called into observation room by RN. for assistance with this patient. Pt had Dose 2 of Phizer at 1: 16 pm and was now complaining of nausea and lightheadedness. Pt asissted to floor, legs elevated up on a chair. Pt is alert .He stated, his name is (unlisted). Skin: pale, hands diaphoretic. Immediately, pt 's chest was pounding;HR was elevated , pt's eyes closed and he appeared attempt to answer this RN's questions as to how he feels, however, could not. Would not/could not open eyes. It appeared that he was shaking/mild jerking as with the chills, however, this RN was discerning if it was seizure like activity. Upper body flushed/red. This lasted about 30-45 seconds. Then pt.'s shakiness slowed down, heart pounding resolved and he opened his eyes. Able to squeeze nurse hand. 1:53 pm DPN Came to assist.Ice pack to forehead Pt was still shaky, but now responding. Still w/ complaints of nausea, lightheadedness. 2:05 still lying on floor with legs elevated. 2:10 Sat up for 5 minutes. C/o nausea. Placed in wheelchair. Within 1 minute, pt. Is pale, shakiness returns, and c/o nausea. Returned to the floor , legs elevated and 9-1-1 initiated. HR steady, respirations -steady. MOC now present.Pt. now responding to MOC or RN's commands to squeeze hand or Speak. Eyes closed. HR and RR steady. 9-11 arrived at 2: 15 pm and pt. Left facility with paramedics and MOC.
1236550	4/21/2021	IL	16	M	4/20/2021	4/20/2021	Customer 30 seconds -1 minute after administration of the vaccine became unresponsive, and had facial twitching and overall body clenched down for 15 seconds--seizure like. Customer woke and assisted customer to ground, he reported lightheadedness, customer was pale. Customer was fasting. Customer reports within 5 minutes on the floor that he felt better. Assisted customer into sitting position and observed for 20 more minutes. customer reports being 100% at time of departure. Customer with his father.

<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>
1233470	4/20/2021	VA	49	M	4/20/2021	4/20/2021	Within 3 minutes after vaccine administration at 11:00am, person had two seizures within 5 minutes of each other. Decreased pulse, blood pressure and oxygen saturation. Loss of consciousness for several minutes each time. Emergency measures initiated, including IV and oxygen. Transported by EMS to Emergency Department at 11:25am.
1232874	4/20/2021	CA	18	F	3/30/2021	3/30/2021	Patient reports she felt dizzy two hours after the shot. She went to a quiet area and had a witnessed syncopal episode and seizure like activity for 10 seconds with urine incontinence. She said she woke up on the ground. She did not go to the ER or call 911. She didnt report the episode until April 20, 2021, when she showed up for her second vaccination. She was declined the second vaccination.
1232947	4/20/2021	IN	31	F	4/19/2021	4/20/2021	Possible seizure, low grade fever, spasms, chills, difficulty breathing, lethargy.
1233103	4/20/2021	OK	52	F	4/10/2021	4/10/2021	Night of vaccine stomach convulsions, twisting Next day high fever (102.5) and high hear rate (105).....went to Emergency Room for treatment....5 1/2 hours.....left feeling much, much better.

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1233117	4/20/2021	TX	50	M	3/22/2021	3/27/2021	CC: patient was watching TV as reported by his mother. started seizing and having difficulty breathing. EMS was called for transport. On arrival to ED, patient was breathing 60-70 BPM, tachy at 135-140 sinus rythm. B/P stable at 140's/90's. his pupils were equal and reactive to light. no response to aggressive sternal rub. slight seizure like activity with arm and leg jerking. Ativan IVP given Patient is on non-rebreather sao2 at 90-100 fluctuating. IV established. he desats to 80-85 on room air. Has frothy sputum from mouth. RSI performed with succs and versed to secure airway and ventilate patient. 7.5 tube placed with one attempt at 27/teeth. verified via direct auscultation and capnography. Tube secured. maintenance medications given to ensure sedation. transfer initiated and aimed launched. Dr. accepted. patient left building at 1940 via aimed. Patients labs (electrolytes WNL) normal wbc. D-dimer at 1500. suspect for PE or flash pulmonary edema although his breathsound are clear bilateral. 18:10 03/27/21. BP: 124/89. MAP: 100. HR: 135. RR: 54. O2 saturation: 94%. Temp: 99.2 F. Pain level now unable to obtain due to patient condition. --20:05 3/27/21 Weight: 81.6 kg estimated
1233130	4/20/2021	NY	47	M	4/17/2021	4/17/2021	Patient experienced at least 4 severe seizures on the day after the vaccine was administered. It is now three days since the vaccine and he has been unable to eat anything and has been incapacitated in bed with severe headaches and body aches and pain whenever he tries to move. He also fell during the seizure and sustained scrapes and rug burn.

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1233159	4/20/2021	CT	56	F	3/17/2021	3/21/2021	At the time of the vaccine, I felt fine, soreness at the injection site but nothing. For days later, I began to feel, ill all over and could not get out of bed. I had severe abdominal pain, aches and pains all over my body. Particularly in places where I had pre existing conditions. As the day progressed, I continued to have severe GI issues, could not eat (pain like food was stuck) heart burn, constipation (clammy like flu). Shortness of breath, I could not walk far. I took 3 trips to the ER where they treated for the abdominal spasms, UTI, and pain. By the end of the week I had a slight fever. I tested negative for COVID during that time. For two weeks I was unable to eat, get out of bed. I had several petite mal seizures. If felt like my body was fighting the vaccine and the vaccine was attaching all of me weak or any preexisting conditions. Eventually, after 3.5 weeks I was able to sit up, and walk. I still have shortness of breath, some fogginess, Muscle strain, walking with a cane and a lump at the injection site.
1233174	4/20/2021	OH	42	M	4/16/2021	4/16/2021	While in waiting area client experienced loss of consciousness and seizure-like activity lasting approximately 48 seconds per nurse that responded to incident. Loss of bladder control noted. Squad responded and transported patient to the hospital via ambulance. Patient was coherent prior to transport. He states he was admitted to the hospital and Observation x 24 hours. He had a CT scan and bloodwork, both normal. Neurologist at the hospital told him he experienced syncope and no seizure activity was suspected. He states a history of feeling faint when he sees blood. He sates the Neurologist advised he get the second dose and lay down after the shot.

<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>
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.
1233237	4/20/2021	FL	52	F	4/19/2021	4/19/2021	At 10:15, writer arrived to resident's home. Resident made writer aware she was allergic to PNC and had a hx of seizure. Writer continued registration process and flagged for 30 minute observation. Resident then received 1st dose of pfizer. Less than two minutes shortly after vaccine was administered resident verbalized that she was feeling numb starting from her throat and moving down her chest. She denied having SOB, was alert and responding to my questions. At 10:35 patient started gasping for air holding her throat. Epi pen was immediately administered to thigh and was not effective. Resident began to seize lasting for about 5 minutes. 911 called at 10:43 am. Resident turned on side resident continue gasping and started seizing again. All safety measures in place. At 10:50 am, 911 staff arrived provided and took resident to the hospital.
1234238	4/20/2021	NC	22	F	4/20/2021	4/20/2021	Patient became pale, diaphoretic. She was moved to a room where her feet were elevated and BP was taken. BP was low, pulse normal, but I was told patient lost consciousness and had seizure-like activity. Lasted less than 15 seconds and patient came to. Juice given to patient as she states she has a history of hypoglycemia. She reported eating something an hour before her appointment. Patient was examined by doctor. BP was back to normal and patient states she was feeling much better after drinking juice. Patient had ride home and was told by provider to follow up with PCP as soon as possible.

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1233406	4/20/2021	MO	41	M	4/20/2021	4/20/2021	Patient had an episode with convulsions and loss of consciousness lasting a couple seconds after eating a marijuana edible.
1232756	4/20/2021		27	M	4/15/2021	4/15/2021	Patient had syncope, dizziness, flushing/sweating, seizure, urinary incontinence. BP 119/79 -- > 103/53 -- > 108/50, HR 47 -- > 38 -- > 37 -- > 64 -- > 62, RR 16, O2 100%, Temp 97.3F. EMS called at 17:06, arrived at 17:13.
1233489	4/20/2021	NY	20	M	4/4/2021	4/20/2021	Felt dizziness and lightheaded about two minutes after receiving shot. I passed out and when I woke up I was struggling to regain consciousness control of my body as I was having a seizure.
1233515	4/20/2021	NY	76	M	4/10/2021	4/11/2021	Patient starting feeling chills on Sunday, patient stayed home then had a seizure 4-12-21. They were admitted to the hospital on the evening/ night of 4-12-21 . Still in hospital as of 4-20-21.
1233580	4/20/2021	MO	32	F	4/16/2021	4/16/2021	Full body convulsions and Paralysis. Left-arm went numb first and traveled throughout the body. Convulsions started in left hand and also traveled throughout the body. It took six minutes from the shot to the first convulsion. Convulsions didn't stop until lorazepam was administered. Benadryl was administered immediately on-site in pill form. The hospital also gave additional Benadryl as well. Blood sugar dropped to 50 within the first half-hour. Extreme eye sensitivity to light and extreme exhaustion afterward. Pain felt extreme as well. Many side effects such as very low pain tolerance, head ache, light sensitivity, confusion, loss of memory, severe muscle pains, muscle numbness throughout body, blood sugar dropping, etc.

<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>
1233702	4/20/2021	MO	43	F	3/26/2021	3/26/2021	7 hours after: temperature spiked to 103 within the course of an hour. 8 hours after: chills so severe I considered seeking urgent care, wondering whether they were seizures. 12 hours after: felt some sort of mass move through my heart, wondered if it was a transient ischemic attack; but nothing followed. 7 days after: bridge of nose (only) turned red, almost burgundy, unusually/strangely/ heavily flushed; woke up with unexplained headaches for 3 out of 4 days that week (and I never get headaches). 12 days after: nose flushing had faded; no more headaches; but routine exercise (even stairs) feels unusually/ markedly more difficult. 4 weeks later: gradually beginning to run/ jog again, slowly improving times/ getting back toward normal cardiopulmonary strength.
1233755	4/20/2021	FL	55	M	3/25/2021	3/30/2021	rcvd shot 3/25/2021, symptoms started 2 days after ... two days later swollen neck glands , higher bp than usual, numb face...Mar 30 th 6:am facial numbness, thick tongue, anaphylaxis went to ER, could not breathe , trouble speaking...by the time got to er BP diastolic was about 200. discharged after 4 hrs. Multiple body symptoms since include all over numbness, balance, Balance issues, fatigue, loss of taste, Heat spikes, myoclonus and stare seizures, sense of Euphoria, infusion, many more symptoms, contact me
1233779	4/20/2021		58	M	4/13/2021	4/13/2021	The patient is a 58-year-old male who presents as a transfer from Hospital for evaluation and of recurrent syncope and management of a left-sided mandibular fracture. The patient reports that his symptoms first started after his first dose of the moderna vaccine. He reports that he felt recurrent nausea and diaphoresis however had no syncopal episodes. Following his second dose of vaccine on 4/13 he reports 3 episodes of syncope. He describes the sensation of nausea and diaphoresis followed by loss of consciousness. After the first episode he passed out and he hit him his jaw and has pain in his left jaw since that time. He had 2 further episodes of syncope 2 of which were witnessed. No seizure activity was described by by witnesses and the episode lasted approximately 1-1/2 minutes. He denies any palpitations or chest pain or incontinence or tongue biting. He denies similar symptoms previously.

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1233884	4/20/2021	PA	44	F	3/3/2021	3/12/2021	Patient had a seizure 9 days after dose #1. First ever seizure. Was not initially recognized as a seizure since she was post ictal and did not show up at ED until 36 hours later. Patient received dose #2 on 3/24/2021 and then a second seizure on 3/27/2021 and was hospitalized. Had MRI and EEG. Started on keppra.
1234139	4/20/2021		21	M	4/17/2021	4/17/2021	Patient received the COVID vaccine (Pfizer dose 1, lot #EW0171, expiration date 8/2021) in his left deltoid at 1437. The client was observed to fall out of his chair in the observation area, fall to the ground, and hit his head. The client made no attempt to protect his head or break his fall. RN, PHN, RN, and RN responded at 1438. PHN called EMS at that time as well. The client was observed to jerk his arms twice. The client was unconscious for approximately 90 seconds, and was turned on his side at this time. When the client regained consciousness, he was alert and oriented, complained of no pain in his head or any dizziness or lightheadedness. No difficulty breathing. Pupils were equal and reactive to light. At 1439, the vital signs obtained were: blood pressure 130/90, heart rate 57, O2 98, respiratory rate 26. The client denied any history of seizures, epilepsy, or any other medical history. The client stated he has no allergies and that he takes no medications. Upon examination, there were no cuts observable on the client's head. The client denied any feelings of dizziness before his loss of consciousness but stated he did not eat any breakfast or lunch that day. At 1443, the repeat vitals were as follows: 128/94 blood pressure, heart rate 60, respiratory rate 22, temperature 98. A manual pulse was 88 and thready. At 1447, EMR responded to the scene and assumed care of the client. Client transported to hospital.

<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>
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 & 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 & 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 & 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
1234168	4/20/2021	NY	30	M	4/18/2021	4/18/2021	after about 5 to 6 minutes, pt was seated in waiting area and became rigid seizurelike. Pharmacist immediate went to aid to make sure did not fall to floor from chair. Seizure lasted about 10-15 seconds. Patient was diaphoretic and was pale. He regained consciousness within 15 seconds. Was able to answer questions and alert. Waited about 5 minutes he ask for water & I gave about 4 ounces of water. kept him seated in waiting area for another 5 minutes then moved to a sofa in adjacent room . he was evaluated for about 30-45 minutes. was hungry had not eaten all day. remembered he had a similar reaction when blood was taken. I offered to call ambulance various times he stated no. After about 45 minutes he stated he was feeling fine and wished to go. Patient seemed in good shape. Told him to please make the reaction known to health care practitioner administering second shot. He will return in 28 days to receive second shot in 28 days.
1233279	4/20/2021	IL		M	4/16/2021	4/16/2021	HX OF VASOVAGAL RESPONSE. VS : 67, O2 SAT 100%, 68/112. FELT DIZZIE UPON STANDING AND FELL. APPEARED TO BE RAPID SEIZURE. RESOLVED WITHING SECONDS

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1232131	4/20/2021	CA	16	F	4/19/2021	4/19/2021	Systemic: Chills-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Nausea-Medium, Systemic: Seizure-Medium, Systemic: Weakness-Medium, Additional Details: Patient fainted in chair shortly after receiving vaccine. She came to within a minute, but body became very rigid and she began to seize throughout her whole body. This lasted less than 30 seconds and she was very pale and lightheaded. Patient described feeling extremely nauseous with chills, slowed breathing and lightheadedness. Moved patient to a new area to elevate feet, stated feeling better but was extremely nauseous and unaware that she had fainted or seized. 911 called per parents request
1231451	4/20/2021	CO	28	M	4/19/2021	4/19/2021	Short duration, while still seated, seizure event, patient recovered quickly, EMS called to site to assess patient even though patient had seemed to be fully recovered already.

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1231543	4/20/2021	AZ	55	M	4/6/2021		SEIZURE; HIT HIS HEAD ON THE CONCRETE; This spontaneous report received from a consumer 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) dose was not reported, 1 total administered on 06-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 06-APR-2021, the patient was sitting with his wife after receiving the JANSSEN COVID-19 vaccine, when he had started to slump over. Patient experienced seizing (passed out and slipped out of his chair and started). It was reported that the patient hit his head on the concrete. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the seizure (pass out and slumped over) and hit his head on the concrete was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210414732 and 20210414751.; Sender's Comments: V0 20210415021-Covid-19 vaccine ad26.cov2.s-Seizure. 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.

<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>
1231550	4/20/2021	GA		U		4/7/2021	LOSS OF VISION; SEIZURE; DIZZINESS; 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: 1805031, and expiry: UNKNOWN) dose was not reported, 1 total administered on 07-APR-2021 on right deltoid for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, the patient experienced loss of vision, seizure and dizziness. The seizure was for few seconds. The patient was not sent to hospital. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the dizziness, loss of vision and seizure was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210417256, 20210417122, 20210417456, 20210417469, 20210417550, 20210417620 and 20210418457.; Sender's Comments: 20210417209-covid-19 vaccine ad26.cov2.s-Loss of vision, seizure. 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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1231613	4/20/2021			F			<p>BRAIN ANEURYSM; CHEST PAIN; This spontaneous report received from consumer (company representative) and concerned a female patient of unspecified age received via social 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, start therapy date were not reported administered 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, one day after vaccination, the patient started with chest pain and paralysis on her left side. She rushed to the hospital where numerous tests were performed. She had about 8 seizures in previous 2 days. She never had seizures before. Patient was continuously monitoring via EEG (electroencephalogram). Doctor found 3 millimeter brain aneurysm. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of brain aneurysm and chest pain was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0-20210421076- Covid-19 vaccine ad26.cov2.s- Brain aneurysm and chest pain. These event are considered unassessable. The event 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>
1231642	4/20/2021	IL		F	4/12/2021		<p>FAINTED/PASSED OUT; NOT FEELING QUITE RIGHT; VERY TIRED; This spontaneous report received from a parent concerned a white and Not Hispanic or Latino female of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included faint, and concurrent conditions included seizure, non-alcohol user, and non-smoker. The patient had no history of drug abuse or illicit drug usage. The patient experienced drug allergy when treated with erythromycin, and ketamine. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 207A201A, expiry: UNKNOWN) dose was not reported, 1 total, administered on right arm on 12-APR-2021 for prophylactic vaccination. No concomitant medications were reported. It was reported by the patient's parent that, on 12-APR-2021, within 5 minutes after vaccination the patient had fainted/passed out. On the same day, the patient was not feeling quite right and was very tired. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from fainted/passed out, very tired, and not feeling quite right. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210422792-JANSSEN COVID-19 VACCINE Ad26.COV2.S- Fainted/Passed out. 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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1231684	4/20/2021	MD	48	F	2/26/2021	3/14/2021	I suffered a severe hypoglycemic seizure which nearly took my life and I believe that it was caused by my recent covid vaccine (moderna). I?m not a diabetic nor have I ever been. I received my second covid vaccine on February 26 and on March 14th at around 6:45 PM and while at work, I suffered a grand mal seizure while working at the Hospital (I?m a respiratory therapist). I was alerted overhead and a team of clinicians rushed to my aid. My glucose was measured and it had decreased to the low 40?s. They had a difficult time getting it to normalize and I ended up being admitted into the ICU. I had a severe tongue laceration and headaches afterwards. Strangely, less than an hour before the seizure, I had eaten a piece of cheesecake so my glucose had no reason to all of a sudden bottom out as it did. There were no other circumstances that could or would have led to a hypoglycemic seizure.
1231718	4/20/2021	KS	31	F	4/19/2021	4/19/2021	Site: Pain at Injection Site-Mild, Site: Redness at Injection Site-Mild, Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Headache-Severe, Systemic: Hyperventilation-Severe, Systemic: Seizure-Medium, Systemic: Shakiness-Severe, Additional Details: Patient was given Moderna Covid Vaccine in Right Deltoid at 10:50. About 30 seconds later patient slid down from sitting position and was shaking uncontrollably and reported difficulty in breathing. Patient was given Epi 0.3mg pen IM in right outer thigh and 911 was called.

<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>
1231770	4/20/2021	FL	32	F		4/12/2021	BODY ACHES; LOSS OF APPETITE; DYSPESPIA; UPPER CHEST DISCOMFORT; SORE THROAT; CHILLS; NAUSEA; SHAKING; This spontaneous report received from a health care professional concerned a 32 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included iodine allergy, personality disorder, alcohol dependence, opioid dependence, seizure, and adjustment disorder. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 1805025 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 shaking. On 12-APR-2021, the subject experienced chills. On 12-APR-2021, the subject experienced nausea. On 13-APR-2021, the subject experienced body aches. On 13-APR-2021, the subject experienced loss of appetite. On 13-APR-2021, the subject experienced dyspepsia. On 13-APR-2021, the subject experienced upper chest discomfort. On 13-APR-2021, the subject experienced sore throat. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from body aches, loss of appetite, dyspepsia, nausea, chills, shaking, upper chest discomfort, and sore throat. This report was non-serious. This case, from the same reporter.
1232030	4/20/2021	CA	19	F	4/8/2021	4/15/2021	My daughter had a seizure one week after receiving the vaccine. She has no history of seizures nor do we have any in our family.
1232855	4/20/2021	IN	17	F	4/14/2021	4/15/2021	Chills, nausea, fatigue, right side chest pain, hard to breathe, excessive seizure like shaking.
1232125	4/20/2021	OH	25	F	4/18/2021	4/20/2021	small seizure, headache, nausea, dizzy, lightheaded
1232829	4/20/2021	CA	56	F	4/10/2021	4/11/2021	Patient's husband awakened patient from seizure like activity and sweats day after vaccination. Since then, patient has cough, body aches, fatigue to the point that she remains unable to return to work

<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>
1232226	4/20/2021	GA	57	F	4/15/2021	4/17/2021	Nausea, vomiting, multiple falls, and ongoing multiple seizures. Patient required intubation and sedation. After admission, the patient experienced cardiac arrest.
1232231	4/20/2021		45	F	4/20/2021	4/20/2021	Syncope w/ poss seizures down for 2 min. Shallow reps placed on NRB 21. BP 167/110. Hr112. RR 15.oxygen sat 100%. BGL 339mg/dl. 911 and transferred to ER.
1232368	4/20/2021	MO	38	F	3/5/2021	3/9/2021	Seizure. I've been put on an anti-seizure medication. I've also been scheduled for an MRI and an EEG
1232409	4/20/2021	KS	36	U	4/13/2021	4/13/2021	Tremors - Mild Petit mal seizures Oxygen administered by members of the clinic Oxygen sat - 100% Mother & patient to follow-up with PCP
1232564	4/20/2021	OK	23	F	4/15/2021	4/15/2021	Client was given 1st dose of Covid Vaccine at 8:07 am. Client was sitting in chair on phone when she fell off chair and hit the floor at 8:15 am. Client hit her head and was lying prone on the floor. Client was unresponsive and was noted to be having a possible seizure as she was contracting. Client was placed on left side and head was secured . Client took approximately 2-3 minutes to respond and give name and date of birth. Vitals were taken WNL 132/83 HR 78, Oxygen 99. EMS was called and client was taken to hospital.
1232575	4/20/2021	MA	28	M	4/18/2021	4/18/2021	Patient had vasovagal response to injection. Has history of vasovagal response to needles. Pt became lightheaded, diaphoretic, pale. Was incontinent of bladder. Denied hx of seizures. Patient stated he woke up late and didn't eat breakfast or drink fluids. Assessed by onsite paramedics -HR 83, SPO2 100% on room air, BP 132/84. Pt was observed for 30 minutes and provided with water. Refused transport to hospital for further assessment. Advised patient to seek emergency help if symptoms return. Pt verbalized understanding.

<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>
1232629	4/20/2021	WA	18	F	4/20/2021	4/20/2021	Pt and father moved into the waiting area with vehicle. According to dad, pt began seizing in the car one minute after the vaccine administration. Dad called out to waiting area Monitor. Monitor called for help. LT and SPC appeared on scene. 1257 Pt was visibly having tonic clonic seizure. SPC administered EpiPen in Right Leg. 911 was called. Pt stopped seizing and was awake and confused. She then became AOx4. Pt visibly distressed and hyperventilating. 1259 Pt had tonic clonic movements and seizure again. Seizure last less than 15 seconds. Pt then became AOx4 again, distressed, and became nauseous. HR 56 SpO2 98% 1300 Pt vomited while sitting up. Still distressed and hyperventilating. RR 30. Post vomiting HR 116, SpO2 97%. Pt moved to stretcher and moved to shade. 1306 Firefighters arrived. HR 114 BP 141/46 SpO2 97% RR 24 AOx4 1312 Ambulance arrived. 1320 Pt left for medical center.
1232668	4/20/2021	CA	17	M	4/20/2021	4/20/2021	Patient was sitting in observation for approximately 5 minutes , started feeling light headed and passed out. Patient was out for approximately 15 seconds before recovering. There were no seizure like symptoms or post-ictal state. Patient was helped onto a cot and a set of vitals was taken, BP 118/84, O2 98%, HR 84. Patient was advised to wait at least 15 more minutes and told not to leave until after the 15 minutes had passed and he was no longer having any symptoms. Patient was brought home by a family member.

<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>
1232691	4/20/2021	WA	43	M	4/20/2021	4/20/2021	1110: Alerted that we had a medical patient. 1111: At patient side to find the patient wa slouched over and having snoring respiration?s. The patient appeared pale and diaphoretic. 1112: Contacted Safety Supervisor and also contacting 911. 1113: The patient was seated upright to open airway and asked if he could wake up. Patient was breathing on his own, eyes open, but not tracking. The patient was not responding to painful stimuli. 2 person lift assist to get the patient off the chair and laying on the floor. The patient then had seizure like activity, arms clenched at his side. 10 second passed by, the patient having minimal postictal phase, and the patient immediately sat upright, asking what happened. The patient informed mobile crew that he started to feel hot and dizzy before he started to dream. Vitals taken: BP: 110/54, HR: 40, R: 18, SPO2: 99%, CBG: 108. 1116: Patient care transferred to paramedic unit to transport to closest hospital.
1232825	4/20/2021	MI	56	M	4/1/2021	4/17/2021	Seizure
1232116	4/20/2021	MA	26	M	4/19/2021	4/19/2021	Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Mild, Systemic: Seizure-Mild, Additional Details: Patient was found unresponsive on the floor by bystanders with ? siezure like activity, this RN and RN responded. EMS called to store and was sent to the ER.
1234263	4/20/2021	PA	16	U	4/19/2021	4/19/2021	Pt was anxious about getting shot, has gotten dizzy after a previous shot (he has low BP and is slender). 1 to 2 minutes after shot, he told me he felt dizzy and nauseous, then he was seeing spots. We sat for a few minutes, he got pale and then his body ` went into rigid extension for a few seconds. I called his father and brother over, we made sure he did not fall out of chair. He slowly started to feel better and was able to leave after 30 minutes. BP was 96/58 at approx. 5:06, 103/70 at 5:16. I suggested his parents consult with his Dr about a possible seizure and what to do about 2nd dose.

<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>
1234502	4/20/2021	AK	51	F	4/15/2021	4/15/2021	Pt received her first pfizer covid vaccine at 1519 in R delt. Approx 9 minutes later patient began having a seizure. Patient's 3 children were present and getting their vaccine that day as well. They informed staff she had a history of seizures. Patient was moved from chair to the ground in a laying position on her left side. RN was called immediately into the room. Her first seizure was approx 6 minutes long and the shortest was 45 seconds. Patient had 4 seizures in approximately 17 minutes prior to EMS arriving. No meds were administered in clinic.
1234871	4/20/2021	CA	46	F	4/6/2021	4/6/2021	The night of receiving the vaccine I experienced an involuntary convulsion at the onset of sleep. As this reminded me of a previous experience when I expect I experienced COVID I was afraid and fought hard to stay awake. However, I drifted off to sleep a second time and immediately experienced another convulsion. I stayed awake deliberately all night. Another night I awoke with a racing heartbeat. Again, a repeat of a previous experience approximately 1 year ago. Yet, another night I awoke and my arm was numb from shoulder to fingers. Also, a repeat of a prior experience. However, other than the fear these repeat experiences aroused I have had no other considerable effects. I am not sure if these experiences classify as adverse events but they did concern me sufficiently to submit for review and I have slight trepidation about taking the second dose. I have a teaching credential and I believe I need it if I wish to work in the school system. Thank you!
1235127	4/20/2021	IL	24	M	4/20/2021	4/20/2021	Within 5 minutes after the shot, patient had a seizure-like episode that last about 5 seconds while sitting in the lobby chair. On duty rph, Bright, questioned pt to check mental status, vision affected. The patient stated he was fine, remained in the lobby for another 30 minutes, No other reaction was seen nor reported within this time frame.

<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>
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

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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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 sinus. 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

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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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

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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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

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

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

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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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

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

(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..

<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>
1232700	4/20/2021	IA	77	F	3/3/2021	3/20/2021	<p>Pfizer COVID Vaccine EUA Patient received Pfizer vaccine 3/3/21. COVID Positive 3/20/21 3/20/21: Patient is a 77-year-old female with past medical history of bilateral breast cancer (post bilateral mastectomy), CHF, CAD, CKD stage II/III, HTN, obesity, obstructive sleep apnea (not on CPAP), and spinal stenosis presenting today. Patient presented via ambulance her daughter. Patient was unable to cooperate, HPI obtained from patient's daughter. Patient's daughter stated approximately 1 week ago patient started to be "unresponsive" and was not talking/responding often. Mostly answered "yes/no" questions. She seemed to be "acting different". When asked, pt denied any pain over the last week. Her daughter denies any infectious process such as fever/chills or cough cough. Her daughter notes approximately 2 years ago patient has similar event, was seen in the ED, but nothing remarkable was found. Reviewed today, patient's daughter stated the patient had a "shaking" episode in had "on responses ". It was described as "shivering" and a blank stare during this unresponsive state. Episode lasted approximately 1 minute. The daughter denied any history of strokes or seizures. Pt usually lives with another daughter and so the daughter present was unable to verify if pt takes her prescribed medications daily. Her daughter denies knowing any Advance Directives or POA set up. Smoking, alcohol, and illicit drug use were denied. Pt was seen 9/2019 for a similar event with concern of stroke vs syncope vs TIA that resolved on its own. 3/25/21: 77-year-old F presented on admission that began approximately 6 days prior. HPI obtained from patient's daughter on admission. Patient's daughter stated approximately 1 week ago patient started to become "unresponsive" and was not talking/responding often. Mostly answered "yes/no" questions. Patient's daughter stated the patient had a period of unresponsives and was shaking her left arm on the day of admission. It was described as "shivering" and a blank stare during this unresponsive state. Left sided weakness was noted. In the ED, vitals signs significant for 88% on room air. CXR showed bilateral infiltrates in lower lobes, CT of head was unremarkable, EKG normal sinus with sinus arrhythmia, CT of chest completed due to elevated D-Dimer showed no PE but showed ground-glass airspace disease and stable 14mm nodule at lower</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>pole of right thyroid. Pt was admitted for Acute Encephalopathy with unknown etiology. COVID testing came back positive. Patient started on Routine COVID management protocol which included IV dexamethasone, remdesivir, vitamin D, vitamin C, zinc, with daily labs (d-dimer, CPK, CRP, CMP, LDH until stable/not upward trending). Patient to continue vitamin D, vitamin C, and zinc upon discharge to rehab. Patient had MRI obtained which showed scattered foci of acute infarcts right posterior parietal lobe/multiple foci of acute microhemorrhages likely hypertensive. Neurology consulted, stated infarct could be due to COVID so continued on lovenox and stopped aspirin. Recommended to keep blood pressures 110-140/80-90. Last documented note from neurology was 03/22/2021 - contacted multiple times but unable to reach afterwards. Discharging patient on xarelto for 30 days and recommending to follow-up outpatient to transition to aspirin and plavix. With this management on board, patient's symptoms improved significantly since admission. Patient discharged in stable condition to rehab.</p>
1230043	4/19/2021	MD	33	M	3/22/2021	3/22/2021	<p>The patient experienced a seizure after administration of first Moderna Covid-19 dose approximately 4-5 hours and was involved in a car crash resulting from the seizure. The patient was taken to the emergency room Medical Center and was discharged in the afternoon with a diagnosis of vasovagal syncope. The patient also experienced a second seizure in his sleep later that evening and was hospitalized and discharged Wednesday of that same week (03/24/21). Witnesses of the car crash noticed patient had convulsed and crashed into three parked cars in a parking lot. His wife also witnessed convulsions during the evening seizure.</p>
1230368	4/19/2021	CA	28	M	4/19/2021	4/19/2021	<p>PATIENT RECIVED 1ST DOSE OF MODERNA VACCINE, HE WAS SENT TO SIT DOWN FOR 15 MINUTES AFTER VACCINES. AFTER 5 MINUTES SITTING, THE PATIENT STARTED TO SEIZING IN THE CHAIR. THE SEIZURE LASTED LESS THAN 1 MINUTE AND HE BECAME CONCISOUS AGAIN.</p>
1230281	4/19/2021	IL	31	F	4/13/2021	4/15/2021	<p>seizure, she will follow up with a neurologist</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>
1230277	4/19/2021	CO	72	M	2/20/2021	2/22/2021	Pfizer-BioNTech COVID-19 Vaccine EUA: patient with cerebral amyloid angiopathy, parenchymal microhemorrhages, and seizure disorder with recurrent seizures presents to emergency department with altered mental status and left-sided weakness immediately following a seizure and two days after vaccination. Admitted to hospital, anti-epileptic medications adjusted, and patient discharged home in good condition.
1230275	4/19/2021	CA	23	F	4/19/2021	4/19/2021	Patient fainted, dropped out of the chair, had a seizure
1230433	4/19/2021	WI	21	F	4/15/2021	4/15/2021	WEAKNESS, NAUSEA, VOMITING, SYNCOPES WITH URINARY INCONTINENCE. DESCRIBED FEELING WEAK AND NOT GOOD BEING UP EVERY HOUR WITH NAUSEA. WOKE UP AT 7AM, VOMITED AND PASSED OUT ON BATHROOM FLOOR WITH INCONTINENCE OF URINE. ROOMMATE DESCRIBED SEIZURE LIKE ACTIVITY WHILE PT WAS ON THE FLOOR. PALLOR. DIZZINESS. PT GIVEN 1L NS, CT SCAN AND LABS.
1230059	4/19/2021		68	M	3/10/2021	3/12/2021	Pt has a history of CVA and aspiration pneumonia in Feb 2021. Pt had been on olanzapine since 2/24 at Institute. He was given his second Moderna Covid-19 vaccine on 03/10/21. Per note on 3/12, pt had seizure like symptoms at 0545 for approx. 45 seconds (eye rolling, lack of response, increased confusion) Per staff, there was no flexing of limbs or loss of bowel or bladder control. No noted stroke like symptoms but he appeared more confused at neuro check. Pt was back to baseline at 15 min neuro check. Pt reported to have had additional seizure, of approx. 4 minutes duration, during morning report that day-but when MD got to his room, he appeared ?post ictal with a mildly agitated restless delirium? rolling back and forth on the floor, moaning, and not making eye contact. Pt did lose control of his bladder. Olanzapine was discontinued on 3/12, due to potential to lower the seizure threshold. Divalproex was initiated for seizures. Per note 3/22-no additional seizure type symptoms have occurred.

<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>
1230527	4/19/2021	TX	75	F	3/11/2021	3/12/2021	At 4:40 AM the morning after the first vaccination shot, patient experienced the onslaught of the first of three epileptic seizures that day. Two more occurrences happened at 8:30 AM and 10:00 AM. At the beginning of each event I (husband & caregiver) administered prescribed prn 'breakthrough' medication to forestall a gran mal. After each administration of medication, patients symptoms subsided and she slept. Also it should be noted: she experienced anxiety about two hours after the vaccination shot on 3/11/2021. We were near the vaccination site, away from home. She self-administered a pain management pill at that point and the symptoms disappeared. Sometimes anxiety episodes evolve into seizures.
1230021	4/19/2021	TX	59	M	4/19/2021	4/19/2021	PATIENT STARTED HAVING A SEIZURE after 10 MINUTES VACCINE. HE BECAME CLAMMY AND WET TO THE TOUCH. B/P 66/45 P. 60 EMERGENCY CALLED AND DR. RESPONED- B/P 61/41 P. 76 -- PATIENT VINITED GREEN BILE nd second seizure. EMS CALLED AND EVALUTED. BLOOD SUGAR NOTED TO BE 99. TRANSPORTED AT 2;25
1230205	4/19/2021	CA	65	F	3/4/2021	3/9/2021	I experienced a severe brain seizure! I am a 4 year Brain Cancer survivor and I have never had a seizure

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1230470	4/19/2021	VA	53	F	3/13/2021	3/17/2021	March 15th: Day 2 after vaccine: noticeable shortness of breath when walking March 17-18: Days 4 and 5 after vaccine: extreme fatigue/exhaustion March 20-24: Burning chest pain, pain in jaw, continued shortness of breath when walking and fatigue March 24: Went to doctor, D-Dimer = .51 March 25: Chest X-ray to rule out pulmonary embolism. No pulmonary embolism found. Enlarged lymph nodes on left side found. April 4: After 1/2 mile walk was exhausted. Experienced loss of strength in both hands, but more so in right hand. Experienced "general feeling of doom/unwellness" previously associated with seizure due to oligodendroglioma. April 3: Follow up with doctor. Suggested my brain tumor (oligodendroglioma) may be growing. April 6th: MRI. Tumor had not grown. April 7th: Meeting with oncologist who did not feel symptoms were due to tumor growth. Suggested possibility that vaccine could have triggered breakthrough seizure. Increased seizure medication in mornings from 50 mg Vimpat to 100 mg Vimpat. Sent me to my regular doctor. Met with regular doctor, who didn't think symptoms were due to the vaccine, but didn't know because it was so new. Did bloodwork. Severe fatigue in afternoon. April 10th: Was scheduled for 2nd vaccine, but did not feel well enough to get it. April 12th: All bloodwork normal except high LDL (but good ratio with HDL), high TPO (thyroid antibodies). Still fatigued. April 11-17: Fatigue gradually improving. Shortness of breath going away. Stamina returning, gradually. April 18-19: Feeling much better. Able to walk. No shortness of breath.
1230493	4/19/2021	KS	66	M	1/29/2021	2/16/2021	Patient had just been advised that his cancer had stopped growing and would be able to resume his immunotherapy drug Tagrisso. After receiving his first dose he went downhill very quickly. On the evening of 2/23 he had an unexplained seizure and went to the ER through 2/26. He was discharged to Hospice and passed away on 2/28.

<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>
1229870	4/19/2021	PA	44	F	3/3/2021	3/12/2021	I had a seizure and fell out of bed between the night of March 12th and the morning of March 13, 2021. I injured my face badly as well as my eye. I had to go to the Emergency room here on 3/16/21. I had a second seizure at the entrance to event on Saturday March 27, 2021 . It was a grand mal, clonic-tonic seizure. I was life flighted to Medical center on March 27, 2021 I was not discharged until 3/31/21.
1230562	4/19/2021	NV	49	M	4/6/2021	4/11/2021	HAD A SEIZURE AND THEN RUSHED TO THE ER AND ALSO HAD A BRAIN BLEED ALSO.
1230567	4/19/2021	TX	22	F	3/28/2021	3/28/2021	Dry heaving, hands and feet went numb while driving (16 hours after). Fever of 102 (while taking max dose Tylenol ATC), myoclonic jerking, hypersensitive skin- it was painful to touch sheets/blankets, muscle aches, DTRs +3: I was concerned I was going to have a seizure. Signs and symptoms resolved at around 0100 on 03/30/2021.

<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>
1230967	4/19/2021	AZ	80	F	2/27/2021	4/8/2021	<p>Loss of control of bladder; Patient got her second dose after 35 days of first dose; fever; Convulsions; terrible contractions of muscles; This spontaneous case was reported by a non-health professional (subsequently medically confirmed) and describes the occurrence of SEIZURE (Convulsions) in an 80-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 019B21A and 010A21A) 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 27-Feb-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 08-Apr-2021, the patient experienced SEIZURE (Convulsions) (seriousness criterion medically significant), MUSCLE CONTRACTIONS INVOLUNTARY (terrible contractions of muscles), INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Patient got her second dose after 35 days of first dose) and PYREXIA (fever). On 09-Apr-2021, the patient experienced URINARY INCONTINENCE (Loss of control of bladder). On 08-Apr-2021, INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Patient got her second dose after 35 days of first dose) had resolved. At the time of the report, SEIZURE (Convulsions), MUSCLE CONTRACTIONS INVOLUNTARY (terrible contractions of muscles), URINARY INCONTINENCE (Loss of control of bladder) and PYREXIA (fever) had resolved. No relevant concomitant medications were provided. No treatment information was 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>

<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>
1230973	4/19/2021	LA	53	M	2/26/2021	3/12/2021	Multidrug resistant infection; Aspiration Pneumonia; This spontaneous case was reported by a pharmacist (subsequently medically confirmed) and describes the occurrence of PNEUMONIA ASPIRATION (Aspiration Pneumonia) and PATHOGEN RESISTANCE (Multidrug resistant infection) in a 53-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031M20A) for COVID-19 immunization. The patient's past medical history included Aspiration (Patient has history of recurrent aspiration) since an unknown date. Concurrent medical conditions included Drug allergy (Cepacol), Cerebral palsy, Spastic quadriplegia, Seizures and Mental disability. 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 12-Mar-2021, the patient experienced PNEUMONIA ASPIRATION (Aspiration Pneumonia) (seriousness criterion hospitalization). On an unknown date, the patient experienced PATHOGEN RESISTANCE (Multidrug resistant infection) (seriousness criterion hospitalization). The patient was hospitalized from 12-Mar-2021 to 16-Mar-2021 due to PATHOGEN RESISTANCE and PNEUMONIA ASPIRATION. On 16-Mar-2021, PNEUMONIA ASPIRATION (Aspiration Pneumonia) outcome was unknown. At the time of the report, PATHOGEN RESISTANCE (Multidrug resistant infection) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication use was not reported. Patient was transferred to a facility for long-term antibiotic treatment. Regarding Aspiration pneumonia, 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. Regarding Multidrug resistant infection, very limited information has been provided at this time. Further information has been requested. This case was linked to MOD-2021-076748 (Patient Link).; Sender's Comments: Regarding Aspiration pneumonia, based on the current available information and temporal association between the use of the product and the start date of the event, a causal

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							relationship cannot be excluded. Regarding Multidrug resistant infection, very limited information has been provided at this time. Further information has been requested.
1231048	4/19/2021	CA	18	F	4/19/2021	4/19/2021	pt told her dad that she was not feeling well and lost consciousness and had seizure for about 5 seconds. vitals monitored, WNL. Pt A&Ox4, observed for additional 30 minutes while constantly monitoring vitals, stated she felt better and was driven home by her dad.
1231130	4/19/2021	MI	77	M	3/23/2021	4/11/2021	Grand mal seizure while visiting daughter, length of duration unknown.
1230485	4/19/2021	NC	32	M	4/6/2021	4/6/2021	0 mins: Discomfort in arm flowing from injection site to the rest of the body 2-4 mins: Light-headedness 5-10 mins: About 2 minutes after sitting down at the 30-min waiting area, I began to feel more light-headed while checking my phone, though I don't remember it, I fainted and hit my head on the gym floor ~15 mins: I am awake and feel extremely foggy and have low blood-pressure and heart rate ~25 mins: I am told to sit back up in the chair ~26 mins: I start feeling light-headed again and lose consciousness again and am told that I had a seizure for 20 seconds before coming back again
1229152	4/19/2021	NJ	65	F	4/16/2021	4/17/2021	101.5 fever Friday night, followed by a seizure at 3am. She was found unresponsive late Saturday afternoon, and was pronounced dead at the hospital. Sudden cardiac arrest.

<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>
1227816	4/19/2021	IA		F		4/7/2021	<p>FAINTED; SEIZURE; STOPPED BREATHING; LIGHT HEADED; CYANOSIS; This spontaneous report received from a health care professional (public health nurse) 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 not reported, batch number: 043A21A, and expiry: 31-DEC-2069) dose was not reported, 1 total, administered on left arm on 07-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, about 5 minutes after vaccination, the patient experienced lightheadedness, then fainted, had a seizure, stopped breathing (for 10 seconds), and developed cyanosis (turned blue). The nurse did cardiopulmonary resuscitation (CPR) and the Emergency Medical Services (EMS) was called. By the time the EMS arrived, the patient felt better. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from stopped breathing on 07-APR-2021, and was recovering from light headed, fainted, seizure, and cyanosis. This report was serious (Other Medically Important Condition, and Life Threatening). This case, from the same reporter is linked to 20210417723.; Sender's Comments: v0 This report involves a female patient of unspecified age who experienced lightheadedness, then fainted, had a seizure, stopped breathing and developed cyanosis about 5 minutes after receiving Janssen COVID-19 Vaccine Ad26.COV2.S for prophylactic vaccination. Given the close temporal relationship the events are considered possibly related to the vaccination.</p>
1227827	4/19/2021	LA	53	F	4/8/2021	4/8/2021	<p>53yo female with a Hx of migraines/seizures/normal pressure hydrocephalus received her second dose of COVID-19 vaccine 04/08/2021. 10 minutes after vaccination she started feeling nauseated and then doesn't remember what happened next. Was transported "unresponsive" to ER. CT MRI negative. Upon lab exam it was noted that her platelets had dropped from 245K to 86K. Received dose of epinephrine/solumedrol, pepcid. Diagnosed with having a seizure and thrombocytopenia. The next day her platelets had recovered to normal. Patient recovered and was discharged.</p>

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1227881	4/19/2021	MA	26	M	4/3/2021	4/3/2021	<p>Patient unresponsive; presented with seizure like activity; Patient fall from chair within 15minutes of receiving Pfizer vaccine dose 1; pale; diaphoretic; nausea; Full body clonus; This is a spontaneous report from a contactable nurse. A 26-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 26 years of age), dose 1 intramuscular, administered in arm left on 03Apr2021 10:45 (Batch/Lot Number: ER8737) as a single dose for COVID-19 immunisation. The patient's medical history included penicillin allergy. The patient's concomitant medications were not reported. The patient had no other vaccine prior to Covid vaccine. He was not diagnosed with COVID-19 prior to vaccination. It was unknown if patient has been tested for COVID-19 since the vaccination. It was reported that the patient fell from chair within 15 minutes of receiving Pfizer vaccine dose 1. Patient was unresponsive, pale, diaphoretic. Awakened within minutes, placed in recovery position on left side. Patient complained of nausea then presented with seizure like activity. Full body clonus. 911 notified. Patient woke within seconds able to state, name, location, date of birth accurately. He was placed on stretcher. EMS arrived. VS 154/80 HR 84, POx99% 2LO2. He continues to be pale. Family of patient notified of event at patient's request. He was transferred to ED via EMS. The events started on 03Apr2021 at 10:45 AM (as reported). Therapeutic measures were taken as a result of the events. The outcome of the events was unknown. Additional information has been requested.; Sender's Comments: Bases on the information in the case report and a strong temporal relationship, A causal relationship between adverse events Unresponsive to stimuli, Seizure and suspect product 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.</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>
1227889	4/19/2021	AZ	53	F	4/2/2021	4/3/2021	Unconscious; Stood up and became very dizzy; Fell to the floor; Legs and arms were seizing; Legs and arms were seizing; This is a spontaneous report from a contactable consumer (patient). A non-pregnant 53-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EW0150), via an unspecified route of administration, on 02Apr2021, at a single dose, for COVID-19 immunization. The patient's medical history included seizures (but they are rare). The patient had unspecified concomitant medications. 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-19 vaccine. On 03Apr2021 at 10:30 AM, the patient stood up and became very dizzy, she fell to the floor and was unconscious. When she came to a few moments after (unknown time), her legs and arms were seizing. The patient did have a history with seizures, but they are rare. No treatment was received for the adverse events. Since the vaccination, the patient has not been tested for COVID-19. The patient was recovering from the events.
1228251	4/19/2021		65	M	3/8/2021	3/9/2021	Patient with PMH of epilepsy, alcohol use disorder, CVA, dementia presented to ED with witnessed seizures while in bed. History of non-compliance, multiple admissions for seizures previously.
1228479	4/19/2021	TX	43	F	4/17/2021	4/17/2021	Pt had seizure and went to the emergency room
1228620	4/19/2021	IN	56	F	4/15/2021	4/15/2021	Received vaccine at 12:30 p.m. on Thurs., 4/15. By bedtime, I was experiencing body aches quickly followed by severe chills and a splitting headache. Was awful. Lasted all evening. At 9:10 a.m. on Fri, 4/16, I had a seizure that I believe was caused by the vaccine since I haven't had a seizure for over a year (and the last one was triggered by a med change). After the seizure, my symptoms increased to include vomiting and nausea along with a severe headache. The vomiting stopped around noon. My headache lasted until Saturday morning. I felt okay Saturday, just a slight headache.

<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>
1228776	4/19/2021	NY	18	F	4/17/2021	4/17/2021	Usual issues: Headache began about 2 hours after injection #1 moderna. Dizziness began about 4-5 hours afterwards and lasted through the evening. Unusual issues: The day after receiving the vaccine she had several hand tremors, and feeling as if she had several "mini seizures" throughout the day, a few longer staring spells, some twitches. She felt "out-of it" all day. She has petite mal seizures and a history of interictal epileptiform discharges. Also history of an intention tremor in her hands. (The mild tremors were primarily in her right hand, to a lesser extent the left). Today, 2 days afterwards, today, so far, she feels better. Yesterday was terrible, but we waited it out assuming it was injection related.
1229940	4/19/2021	NC	48	F	3/29/2021	3/29/2021	3-4 hours - Flu like symptoms, body aches 12-14 hours - severe nausea and seizure
1229119	4/19/2021	MI	23	F	4/14/2021	4/14/2021	Appx 2-3 mins following vaccine administration pt had generalized Tonic-clonic seizure with apnea. Seizure lasted appx 30-45 seconds. Pt gently laid on floor by mother and clinic staff. Pt with very brief post-ictal period. Pt evaluated by EMS and pt's mother requested discharge home and follow with neurologist. Pt with history of epilepsy, no rescue medication, last seizure appx 2 years PTA.
1229996	4/19/2021	MI	26	M	3/12/2021	3/19/2021	Grand Mal Seizure on March 19, 2021 at 7:00 am - Ambulance arrived to take patient to the hospital. and Grand Mal Seizure on April 11, 2021 at 8:00 am - Guardian knew of event so kept patient home.
1229328	4/19/2021	NC	39	M	4/8/2021	4/16/2021	Was at the grocery store and was having a hard time focusing. All of the colors were running together. I then fell backwards, and began having a seizure. Bystander said my eyes got huge and mouth and tongue turned blue as I couldn't breathe. I had a seizure for about 5-8 minutes and was totally blacked out. During the seizure I lost control of my bladder and dislocated my jaw.

<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>
1229531	4/19/2021		21	M	4/13/2021	4/13/2021	Patient received the vaccine and moments after passed out (head and eyes rolled back), starting slouching on his right side and started to show twitching/convulsions and turned pale. Regained conscience soon after his name was spoken to him. Called RRT, took vitals while waiting for RRT. Mother of patient explained that this happens every time the patient receives a shot or blood drawn. RRT showed up and assisted soon after.
1229552	4/19/2021	AL	50	F	4/16/2021	4/16/2021	We administered the second dose of the Moderna COVID-19 vaccine on Friday, April 16th. We were contacted by the patients family to report that the patient began a fever and chills the night of 4/16, she subsequently began having nausea, vomiting, and sweating followed by a seizure, and was taken to the emergency department where she died the following day. She was encouraged to receive the vaccine at the encouragement of her oncologist.
1229623	4/19/2021	TX	21	F	4/19/2021	4/19/2021	Patient with known seizure disorder, on Keppra, had a 3-minute seizure 5-10 minutes post second Moderna vaccine. This was observed by the officer and safety nurse. She had no reaction with the first vaccine four weeks ago, and stated that over the last four months she has had five seizures; her physician is aware and they are modifying her medication. Immediate return to baseline, no post-ictal period, no soiling with urine or feces. Patient reports new onset of seizures at age 18. She did not have rescue medication with her. She declined EMS transport. Nurse waited with her while her husband came to pick her up. No additional seizure activity in the time she was observed, although she was shaking. She
1229632	4/19/2021	MD	26	F	4/15/2021	4/15/2021	Employee had a seizure and LOC approx. 2 hrs post second vaccine. EMS was called and employee was transported to the hospital. Employee was hospitalized for observation. Discharged home after 2 days. Employee still reports feeling weak. Following up with primary care MD.
1229710	4/19/2021	NJ	30	M	1/9/2021	2/2/2021	Nocturnal seizure on the morning of February 2, 2021. First seizure/epileptic event of lifetime.

<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>
1229759	4/19/2021	MD	26	F	4/15/2021	4/15/2021	Employee had a seizure and LOC approx. 2 hrs post second vaccine. EMS was called and employee was transported to the hospital. Employee was hospitalized for observation. Discharged home after 2 days. Employee still reports feeling weak. Following up with primary care MD.
1231306	4/19/2021	MI	36	F	4/9/2021	4/9/2021	20 minutes after shot while passenger in vehicle I passed out and went into convulsions for 2 minutes The next day after shot at 7am I passed out again and went into convulsions while blacked out The next few days I did not feel right
1229889	4/19/2021	NJ	56	F	4/12/2021	4/14/2021	The first night I was ok, just felt slightly nauseous in the middle of the night. I woke up THursday AM with a little head ache, but was fine all morning. Got a little tired in afternoon, but was ok. In the middle of the night (Thurs into Fri), I felt like I had to throw up. I was in the bathroom, and the next thing I know, my husband is trying to wake me up. He said it looked like I was having a seizure. HE heard me groan and bang my head on the side vanity. After the 2nd time, he got out of bed to check on me. He got in the bathroom as I hit my head for the 3rd time.. He could not wake me up. I finally heard him call my daughter's name who was sleeping upstairs. I don't remember any of this but I banged
1229026	4/19/2021	CA	58	M	4/16/2021	4/17/2021	Seizures
1231071	4/19/2021	CA	16	F	4/19/2021	4/19/2021	pt informed mom that she was not feeling well. nurse in observation lane witness seizure. pt was unconscious for 5-10 seconds. pt vomited as well. bp was 104/54 at 1154a, 107/52 at 11:52a, rest of vitals WNL. Md assessed, observed for additional 30 minutes. pt stated she was feeling well and was driven home by her mom
1225538	4/18/2021	CA		M	4/9/2021	4/9/2021	Felt dizziness within approximately 1-minute of injection. Lost consciousness/ seizure. Regained consciousness within 1-minute. Tingling/ numbness in back/ spine lasting up to 3-hours afterward. Weakness in left hand currently (day 4).

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1224379	4/18/2021	FL	43	F	3/25/2021	3/27/2021	broke out with hives on her face and hands; Swollen lymph nodes in throat; This is spontaneous report received from a contactable consumer, the patient. A 43-year-old non-pregnant female patient received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration in left arm on 25Mar2021 16:30 (Batch/Lot Number: ER8732) (at the age of 43-years-old) as a single dose for COVID-19 immunisation. Medical history included benign brain tumor removal, seizures (previous seizures prior to surgery), penicillin (PCN) allergy and sulfa drugs allergy. Concomitant medications included topiramate (TOPAMAX), eletriptan hydrobromide (RELMAX), ergocalciferol (VITAMIN D) and ascorbic acid (VITAMIN C), all were 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 had not been tested for COVID-19. The patient broke out with hives on her face and hands and had swollen lymph nodes in throat on 27Mar2021 08:00. The patient went to emergency room/ department or urgent care due to the events, broke out with hives on her face and hands and swollen lymph nodes in throat. The patient received antihistamine as the treatment for the events, broke out with hives on her face and hands and swollen lymph nodes in throat and the patient was also offered steroid but she declined it. The outcome of events, broke out with hives on her face and hands and swollen lymph nodes in throat, was recovering. 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>
1224537	4/18/2021	FL	66	F	3/26/2021	3/26/2021	seizures; muscle fatigue; hives; rash from head to toe; sore muscles; wrap around headache; This is a spontaneous report received from a contactable healthcare professional (patient herself). A 66 -year-old female patient received her second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 26Mar2021 (Batch/Lot Number: EN6208; Expiration Date: 30Jun2021) as a single dose for COVID-19 immunisation. She provided a brief history from 2017. She was walking her dog and she fell and suffered a concussion, she had a seizure, then she developed bipolar disorder. She's been taking sodium valproate (DEPAKOTE) for her seizures since 2017. She reports she's very active. She's not an old lady. She can run circles around some 22 year old's. In September of 2017, she had a concussion and had seizures. She's been on sodium valproate (DEPAKOTE) since that time. She's not mentally ill, the concussion she got in 2017 caused her brain to turn bipolar. It's hard for people to understand that. Sodium valproate (DEPAKOTE) was 500mg. She takes 1 tablet in the morning and 2 tablets at night because it can make you sleepy. She reports she was recently hospitalized in Feb2021 for atrial fibrillation with rapid ventricular rate (RVR). Her heartrate was 181 beats per minute, her blood pressure was dropping, she tested positive for rhinovirus and the doctor thinks the atrial fibrillation with RVR was caused from the rhinovirus. She was allergic to bee venom and carries an EPI PEN. Medical history also included ongoing high blood pressure from an unspecified date (controlled with medication). Concomitant medications included ongoing metoprolol tartrate (LOPRESSOR) taken for blood pressure; ongoing lisinopril; ongoing valproate semisodium (DEPAKOTE) taken for seizure from 2017; ongoing hydrochlorothiazide, lisinopril (LISINOPRIL HCTZ) taken for blood pressure; paracetamol (TYLENOL) from an unspecified date in 2021. The patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 05Mar2021 (Batch/Lot Number: EM9810; Expiration Date: 30Jun2021). The patient did not receive any recent vaccines for any other conditions or any recent vaccines for any other conditions prior to the event being reported; or any other vaccines

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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around the time of Pfizer-BioNTech COVID-19 Vaccine vaccination. The patient reported that with the second Covid 19 vaccine she had two seizures on 27Mar2021. The seizures were back to back. The seizures resolved within 2 minutes. She had fatigue from an unspecified date, sore muscles and a wrap around headache on 26Mar2021. The wrap around headache felt like she was going to have a stroke even though her blood pressure was fine. She monitored her blood pressure at her home. She feels it's weird that they publish that the second Covid 19 vaccine is going to be worse. She thought she'd have muscle soreness and fatigue but not seizures. She looked it up and the wrap around headache and seizure are the rarest things that can happen after receiving the Covid 19 vaccine. She stayed in bed from Friday afternoon after she received the second Covid 19 vaccine on 26Mar2021 and started to feel better Sunday afternoon, 28Mar2021. Her blood pressure and pulse were both fine with her wrap around headache. She had fatigue with both Covid 19 vaccines. She also developed hives, which she still has. She has a rash from her head to her toes. It looked like she rolled around in an ant bed. The hives were clearing up. She was using an anti-itch cream. The hives and the rash started midday on Saturday, 27Mar2021. She only has around 5 hives now on her chest. She hasn't taken Benadryl. She doesn't like to take it. Her doctor didn't want her to open the hives and cause impetigo. She never had any soreness in her arm. She doesn't think the headache was serious because she had a blood pressure cuff at home. She just knew the hives and the rash were a reaction to the Covid 19 vaccine. She didn't go to the hospital for her seizures. She was not seen in the Emergency Department, hospitalized, or admitted to an Intensive Care Unit. She tries to do holistic medicines and treatments. She doesn't run to the hospital every time something happens. She tries to stay out of the hospital. She's fine now and she loves Pfizer. If she can get a medicine she needs that Pfizer makes she tries to get it. She tries to see every side of things. Outcome of seizures was recovered on 27Mar2021 and sore muscles was recovered on 28Mar2021; of remaining events was recovering. Follow-up attempts are completed. No further information is expected.; Sender's Comments: A causal association between BNT162B2 and seizure cannot be excluded

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

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.

<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>
1224541	4/18/2021	FL		F		3/26/2021	fatigue; felt like she was going to have a stroke; hives; two seizures; rash from head to toe; wrap around headache; sore muscles; This is a spontaneous report from a contactable other healthcare professional (patient). A 66-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EN6208), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient's medical history included seizure, high blood pressure, and atrial fibrillation with rapid ventricular response on 03Feb2021, all ongoing. The patient's concomitant medications included metoprolol tartrate (LOPRESSOR) taken for blood pressure measurement, lisinopril taken for an unspecified indication, valproate semisodium (DEPAKOTE) taken for seizure from 2017 to an unspecified stop date, and hydrochlorothiazide, lisinopril (LISINOPRIL HCTZ) taken for an unspecified indication. The patient experienced two seizures on 27Mar2021. Patient felt like she was going to have a stroke on an unspecified date. The patient experienced hives on 27Mar2021, fatigue on an unspecified date, rash from head to toe on 27Mar2021, wrap around headache on 26Mar2021, and sore muscles on 26Mar2021. The outcome of the events wrap around headache and sore muscles was recovered on 28Mar2021, for hives and rash from head to toe was recovering, and the outcome of the rest of the events was unknown. Events relatedness was reported as related.; Sender's Comments: Other than a close temporal association, there was no other evidence or argument in support to causality for BNT162B2 in the serious events, Seizure and Cerebrovascular accident. Seizure was consistent with underlying medical condition, still on treatment with VALPROATE SEMISODIUM. Chronic hypertension may have increased the risk of vascular accident, despite the poly-medication with different type of antihypertensive agents. 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.

<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>
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.

<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>
1224599	4/18/2021	CO		F	3/20/2021		breathing/unresponsive; seizures; blood sugar was 35/Blood sugar dropped into the 60's again; This is a spontaneous report from a contactable reporter. A 75-year-old female patient (reporter's mother) received second dose of bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 20Mar2021 at single dose for covid-19 immunisation. Medical history included parkinson's disease from 2018 to an unknown date, the progressive type, covid-19 from Nov2020 to an unknown date (She had mild case of covid in November), she was not symptomatic, rheumatoid arthritis from 2018 to an unknown date, Heart failure from 2018 to an unknown date(which she was diagnosed in 2018 with and was being managed appropriately), spinal operation from an unknown date and unknown if ongoing PRESS (Posterior reversible encephalopathy syndrome) Complication, posterior reversible encephalopathy syndrome from an unknown date and unknown if ongoing (Complication after Back surgery). The patient's concomitant medications were not reported. The patient had the first dose of dose of bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE) on 27Feb2021 for covid-19 immunisation. The patient experienced breathing/unresponsive but breathing on her bi-pap (hospitalization) on an unspecified date with outcome of unknown, seizures (hospitalization) on an unspecified date with outcome of recovered, blood sugar was 35/blood sugar dropped into the 60's again, blood sugar low (hospitalization) on an unspecified date with outcome of unknown. The patient underwent lab tests and procedures which included lumbar puncture: proteins and white blood cells on unknown date, Presence of proteins and white blood cells, magnetic resonance imaging(MRI): something that happened with brain on unknown date, assault from something that happened with brain, white blood cell count: nothing crazy on unknown date. Therapeutic measures were taken as a result of seizures, blood sugar was 35/blood sugar dropped into the 60's again. The clinical course was reported as follows: She states, "Her mother was in a rehab facility up until the 26Mar2021, the CNA came in at noon and her mom wanted to keep sleeping. Thursday afternoon was the last time she got to talk to her. PT/OT came in at noon on Friday - found to be breathing/unresponsive. blood sugar

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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was 35, gave her glucose, came up to 111. Still not responsive but breathing. Sent her to ER, she was breathing but still not responsive, then started she started having seizures. Blood sugar dropped into the 60's again, having seizures from Friday until Monday. managed it with Keppra and another seizure medicine and now she is in ICU. Her mother is 75 years old with degenerative Parkinson's Disease, wheelchair bound, and a history of PRES (Posterior reversible encephalopathy syndrome). She was about to be discharged but then all of this happened. The only thing that was really different is the vaccine that she received. She had mild case of covid in November, she was not symptomatic. Waited 3 months to get the covid vaccine after she had covid. The caller states that her mother received the first dose of the Pfizer COVID-19 vaccine on 27Feb2021 and the second dose on 20Mar2021. The caller would like to know if there have been any reports of low blood sugar associated with receiving the Pfizer COVID-19 vaccine. The caller wants to know if anyone has reported seizures as a side effect from receiving the Pfizer COVID-19 vaccine. Responded per page 23 of the attached EUA Prescribing Information LAB-1457-6.0 Revised: 25Feb2021: "Throughout the safety follow-up period to date, Bell's palsy (facial paralysis) was reported by four participants in the Pfizer-BioNTech COVID-19 Vaccine group. Onset of facial paralysis was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of Bell's palsy were reported in the placebo group. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuroinflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine. 6.2 Post Authorization Experience: The following adverse reactions have been identified during post authorization use of Pfizer-BioNTech COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. Immune System Disorders: severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria,

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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angioedema)". The caller has her best friend on the line with her in case the caller forgets something. The caller's is calling on behalf of her mother who had both doses of the covid vaccine. The patient is currently in the Intensive Care Unit. The patient was supposed to go home from a rehabilitation facility on 27Mar2021 and staff found the patient on 26Feb2021 unresponsive but breathing on her bi-pap. Prior to the patient being found like this she was tired at noon and asked the staff to hold her lunch for her because she was tired and wanted to lay down because she had been up late the previous night. When physical therapy and occupational therapy came in a couple of hours later to do therapy they found the patient unresponsive and the patient's blood sugar was 35 so they gave her glucose and the blood sugar came up to 111. Emergency medical services came and took the patient to the emergency room and then she was put in the Intensive Care Unit, this was all within 30 minutes. The glucose dropped one more time and she started having seizures. The medical staff stabilized the patient with Keppra and another seizure medicine that starts with a V on a drip. The patient has been off her sedatives since Tuesday and she has eye movement under the eyes, she withdraws from pain, and when (name withheld) was talking to the patient on speakerphone the patient moved her head towards the phone. The caller mentions that the patient was not protecting her airway when the emergency medical service showed up and so the staff placed a king airway and then the patient moved to a normal ventilator. Wednesday the patient was being weaned on the ventilator and was able to breathe on her own for 7 hours. The caller was only able to breathe on her own on the ventilator for 2 hours yesterday, split up into 2 different trials. The medical team is pressuring the caller talking about tracheostomy and peg tubes and the medical staff wants to talk about that next week if the patient is not coming around. Investigations: MRI showed basically an assault from something that happened with the brain from having a low blood sugar. The patient has no history with diabetes or low blood sugars. Maybe the patient had a seizure prior? The patient had signs of infections, her white blood cell count is nothing crazy. The patient's lumbar puncture showed proteins and white blood cells present. The caller is trying to figure out what may have caused this incident. The patient had 4 strokes

<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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on her left side and has come back from that and has been driving and fine after. The patient's outpatient neuro person said it is from the seizures. The caller is trying to rule out if there is anything weird with this vaccine that may have caused this or been reported? PRESS is a rare complication after back surgery and the patient had that. If something is super weird and rare then the patient usually has it, she usually gets weird things. Is this related to the vaccine? The caller knows it may not be likely but it was the only thing she hadn't looked into yet. Information on the lot/batch number 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>
1224607	4/18/2021	NM	28	F	3/23/2021	3/23/2021	<p>12 hours after receiving the vaccination I was speaking to my husband and my neck and face started to uncontrollably move and spasm. This was painful and concerning. It got violent and much worse over; This is a spontaneous report from a contactable consumer (patient). A 28-year-old female patient started to receive second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number en2613) on 23Mar2021 11:30 at single dose in right arm for COVID-19 immunisation. Medical history included Covid-19, asthma, gastroparesis, surgeries, gastric pacemaker, allergies to Penicillin, soya. Concomitant medications included dicyclomine, sucralfate, famotidine, and ondansetron. The patient previously received cefalexin monohydrate (KEFLEX) and Amoxicillin and had drug allergy. The patient previously received first dose of BNT162B2 (Lot number: en6202) on 02Mar2021 11:30AM in right arm. 12 hours after receiving the vaccination the patient was speaking to her husband and her neck and face started to uncontrollably move and spasm. This was painful and concerning. It got violent and much worse over the next few minutes, She could not control the movements. She called emergency responders and got an ambulance to the hospital. She was given muscle relaxers and sent home. Over the next two days it got worse and more painful so she went to the ER hospital again and they did a CT and blood work and said it was dystonia. She was given ativan and it stopped the convulsions. Again she was sent home. The dystonia continued to happen all day every day. She had returned to the ER one more time and needed medical intervention to control the awful, life changing adverse reaction. This was a horrible experience. She was completely devastated. The events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The patient had no COVID tested post vaccination. The outcome of convulsions was resolved. The outcome of other events was not resolved.</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>
1224830	4/18/2021	WA	29	F	4/2/2021	4/2/2021	<p>passed out from exhaustion; Fever; was unable to stand unassisted.; writhing in pain/so much pain; in and out of consciousness/passed out; tongue swelled up, making it hard to breathe and impossible to speak; tongue swelled up, making it hard to breathe and impossible to speak; tongue swelled up, making it hard to breathe and impossible to speak; sweating profusely; couldn't support her own body without tipping over.; seizure; lymph nodes in her left armpit swelled up so much that she couldn't put her arm down without extreme pain; lymph nodes in her left armpit swelled up so much that she couldn't put her arm down without extreme pain; chills; extreme muscle pain; spasms; This is a spontaneous report from a non-contactable consumer (patient herself). A 29-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), dose 2 via an unspecified route of administration, administered in left arm on 02Apr2021 13:15 (Batch/Lot Number: ER8737) as single dose, for COVID-19 immunisation. Medical history was reported as no. Patient did not have COVID-19 prior to vaccination. Patient did not receive other vaccines within 4 weeks prior to COVID-19 vaccine. Patient's concomitant medication includes omeprazole, ethinylestradiol, levonorgestrel (MARLISSA), venlafaxine and gabapentin from unspecified dates, received within 2 weeks of vaccination, for unspecified indication. Patient historically took first dose of Pfizer BNT162B2 (Lot number: EN6204) on 13Mar2021 at 11:00 AM on the left arm for COVID-19 immunisation. Patient previously took hydrocodone bitartrate, paracetamol (VICODIN) on an unspecified date and indication and had allergy. On 02Apr2021, around 10pm, patient began having chills and extreme muscle pain and spasms, and the lymph nodes in her left armpit swelled up so much that she couldn't put her arm down without extreme pain. By midnight (03Apr2021 00:00), patient had a fever and was unable to stand unassisted. She was writhing in pain and arching uncontrollably off the bed. She believed in hindsight that this was a seizure as she went in and out of consciousness and her tongue swelled up, making it hard to breathe and impossible to speak. She was sweating profusely, and had to drink water constantly. Her husband had to help her get to the bathroom because she couldn't support her own body without tipping over. The chills and fever alternated all night, and</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>
							she finally passed out from exhaustion at 03Apr2021 at 7am. The next 2 days, she was in a cycle of fever and chills again, and the fever got so bad that she seized twice more on Saturday (03Apr2021). She had to take the day off work on Monday (05Apr2021) as she was still in so much pain that she could barely leave bed except to use the bathroom. Events were reported as life-threatening, immediate risk of death from the events. Patient was not hospitalized. Treatment for the adverse events were cool baths, naproxen (ALEVE) for fever and pain, and PEDIALYTE. COVID-19 was not tested post vaccination. Vaccination facility type was at a hospital. The outcome of the events was recovering. No follow-up attempts are possible. No further information is expected.
1224974	4/18/2021	FL	42	F	4/16/2021	4/16/2021	Fever of 103.1, seizures needing 911 to be called by my child and a trip to the ED, and entire body aches. The fever started within the hours after the injection and lasted through the night and and my child found me seizing the next morning.
1225207	4/18/2021	CA	34	M	4/17/2021	4/17/2021	Site: Pain at Injection Site-Mild, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Additional Details: Patient passed out the first time for about 15-20 seconds then was sat down. Patient passed out again the 2nd time with some convulsions. Paramedics came and took pt away.
1225294	4/18/2021	MI	57	M	4/16/2021	4/16/2021	Patient developed acute mental status change, gait instability, confusion, and seizure like activity several hours after vaccine administration. Presented to the ER the following day for evaluation and was found to have acute CVA with embolic phenomenon confirmed on MRI, radiologist felt possible demyelination

<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>
1225396	4/18/2021	WI	28	F	4/18/2021	4/18/2021	Patient presented to clinic today for 1st Covid vaccine. After receiving vaccine, patient complaining of seeing "colored spots". Patient brought to reclining chair from waiting room. Patient has multiple comorbidity's - please see list in CMR. Patient's aunt in room with patient. 0807: Patient c/o having a "heavy face". VS 159/98, 89, 96% on RA. Patient denies any issues with breathing. Per patient when she swallowed some water, she felt as if it was hard to get down. Patient given 50 mg PO Benadryl (own supply). 0811: Patient stating that colored spots are now gone. VS: 169/95, 87, 98% on RA. 0817: VS 133/90, 96, 93%. Patient had small seizure in room; patient eyes rolled back, patient appeared to be non-responsive. Total time for seizure was approximately 30 seconds. After seizure, patient responsive and alert X3.
1225448	4/18/2021	FL	21	M	4/12/2021	4/12/2021	The patient had a seizure 4 hours after receiving his first dose of the Pfizer Covid Vaccine. He has no history of seizures. As a result of his seizure, he was driving a moped which turned over and he has sustained severe brain injury/ Diffuse Brain Injury with left and right side nerve cell damage. He has been at the Medical Center, ICU Unit. Case Mgr., and Dr., Neurologist was called and was available for my questions.
1224348	4/18/2021			M			Seizures; This is a spontaneous report from a contactable consumer (patient's mother). A 27-year-old male 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 dates unspecified, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient had seizures. The patient's mother was worried that patient might develop fever; and was asking how soon after the vaccination could she give paracetamol (TYLENOL). The outcome of the event, seizures, was unknown. Follow-up attempts are completed. No further information is expected.
1225667	4/18/2021	IL	25	M	4/18/2021	4/18/2021	post vaccine patient went into a seizure state lasting no greater than 15/30 seconds. post seizure patient displayed fatigue with sweating as expected. No medical interventions required .

<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>
1225705	4/18/2021	TX	24	M	4/18/2021	4/18/2021	Patient was administered his first dose of Pfizer at 0955 was sent to regular observation unit after administration where EMS staff noted patients girlfriend leaning over to shake him then she began screaming for help as patient had become unresponsive to her. Patient was in the passenger seat of the vehicle when EMS staff arrive to the vehicle patient was unresponsive to commands and was showing signs of possible seizure like activity. Staff in observation called for charge nurse and notified 911 for further evaluation by county EMS staff. Patient BP 144/92, Sats 94% R/A. Patient did began to wake up and stated he could not see anything everything was black staff attempted to keep the patient calm until EMS arrived on the scene. EMS/Fire department arrived at 10:05am per the chief EMS officer patient had a syncopal episode all vitals were stable at this time and patient refused to be transported to the ER for further evaluations. Charge nurse stated to patient i would feel more comfortable if you stayed on site for at least 30 mins prior to leaving the site and education was given in the even the patient has another syncopal episode after leaving the site today. Patient left site at 10:45am with girlfriend in the driver seat. Patient was stable and verbalized understanding of education provided he was alert and oriented at time of dismissal from the site.
1227387	4/18/2021	NM	44	M	4/16/2021	4/16/2021	Approx 15mins after having the shot administered I sat in my car and felt the medication coming on by it clouding my vision then causing me to faint (and by description from my fiancé) I had what appeared to be a mild seizure. I was out for a minute or two and when I was conscious again my vision was blurry and I felt very drunk for the next 45mins - hour. I also felt like I could taste the chemicals from the vaccine when I became conscious again. The drunk/vertigo feeling subsided slowly over time but I was given a Benadryl from the pharmacist so I?m not sure when the dizziness stopped but I definitely could not drive home. My fainting was not due to any anxiety due to having a shot or anything, I was perfectly fine for approx 10-15 mins after the vaccine then I felt a cold feeling coming on from my right shoulder then up my neck then I got foggy and dizzy and passed out

<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>
1227170	4/18/2021	MD	47	F	4/16/2021	4/16/2021	During observation period member had what appeared to be a seizure lasting less than 1 minute - head fell back, rolled eyes, trembling. Confused when episode ended for about 15-20 seconds then became oriented and answering questions appropriately. Patient vomited face became very pale, complained of feeling hot and "not right" transported to ER via EMS
1227127	4/18/2021	GA		U		4/7/2021	TONIC- CLONIC SEIZURES; LOW BLOOD PRESSURE; 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: 1805031 and expiry: UNKNOWN) dose was not reported, 1 total administered on 07-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, the patient experienced tonic- clonic seizures for 3 minutes and the patient's blood pressure was low 94/72 and then the Emergency medical services (EMS) was called and the patient was transported for evaluation the same day. The patient visited emergency room or department/urgent care facility for treatment of the events. On APR-2021, Laboratory data included: Blood glucose (NR: not provided) 97, CT scan (NR: not provided) Negative (units unspecified) and Blood pressure (NR: not provided) 94/72. On 08-APR-2021, patient was discharged from emergency room/urgent care facility and followed up with neurology. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the tonic- clonic seizures and low blood pressure was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210417256, 20210417209, 20210417456 and 20210417122.; Sender's Comments: V0:20210417620-Covid-19 vaccine ad26.cov2.s-Tonic-clonic seizures. 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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1226718	4/18/2021	GU	31	F	4/2/2021	4/2/2021	Approximately 10 minutes after injection, I passed out. Witness said that I was unconscious for approximately 1 minute. My body shook, and it appeared that I had a seizure. Immediately upon waking I started vomiting and having uncontrollable bowel movements for about an hour. I felt confused for about 30 minutes and was unable to speak for a few moments upon waking. When I arrived at the hospital I was still vomiting and having uncontrollable bowel movements. I was given fluids and zofran and sent home without further testing.
1226710	4/18/2021	GA	56	M	4/1/2021	4/1/2021	Patient was given Covid-19 vaccination and 5-10 mins later patient had a seizure. Appeared to be an absent seizure and came to after about 3-5 mins. Patient was sweaty and clammy to the touch. EMS was called and took over. Patient did not fall and was breathing at all times.
1226667	4/18/2021	OK	47	F	4/16/2021	4/17/2021	Pt had chills starting 4/18/21 evening that lasted through the night. She then had 1 seizure that self resolved. Pt reported to pharmacy today with a rash on the left full forearm.
1226424	4/18/2021	CO	50	M	4/15/2021	4/15/2021	Fever, chills, aches, difficulty breathing, confusion, shaking, Swollen joints hands, neck, throat, and tongue lasting from 4/15-4/18. Convulsions began 4/16-4/17. Treated with benadryl and ibuprofen and Tylenol and albuteral inhaler.
1226410	4/18/2021	NM	60	M	3/26/2021	3/26/2021	Approximately 1 hour after the vaccination, Patient reported feeling a sudden "pop" in his head. That was followed by loss of balance, weakness, and inability to walk. He collapsed and either passed out or slept for 2-3 hours. Upon awakening he still felt weak and unbalanced. He also had bitten his tongue and lip while unconscious. He slowly recovered over a period of 3-4 days after the vaccination. He has never before had a stroke or a seizure. No one was with him to observe any of his symptoms.

<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>
1226380	4/18/2021	WA	31	F	4/5/2021	4/9/2021	On 4/9/2021 patient had odd sensation / chest pain unlike seizure or migraine pain and went to emergency room. Was evaluated and released same day and told to follow up with neurologist. On 4/10/2021 patient became dizzy and fell and hit her head. She was unconscious of a few minutes. On 4/11/2021 patient had speech issues and muscle issues (cramping and spasms). All symptoms resolved by next day. Evaluated by neurologist 4/15/2021. Patient was told they thought symptoms were related to migraines and she is scheduled for MRI.
1225415	4/18/2021	CA	64	F	4/12/2021	4/12/2021	When the patient entered the observation area within a few minutes she fell to the ground and appeared unresponsive. When I arrived I noticed foaming around her mouth and she urinated on herself. No clonal movements noted. Pulse could not be felt so CPR was initiated. She woke up in about 30 seconds. Paramedics called and arrived within 5 minutes. Patient was awake and oriented. When asked she indicated that she had a history of a seizure many years ago. Paramedics transported her to a Medical Center.
1226321	4/18/2021	CA	63	M	4/16/2021	4/17/2021	Seizure

<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>
1224350	4/18/2021	MI	66	M	2/4/2021	3/24/2021	COVID19 pneumonia, bilateral infiltrates, hypoxia/COVID-19 confirmed by positive COVID-19 test; COVID19 pneumonia, bilateral infiltrates, hypoxia/COVID-19 confirmed by positive COVID-19 test; This is a spontaneous report from a contactable physician. A 67 years old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), the second dose via an unspecified route of administration on 04Feb2021(at age of 66 years old) (Lot Number: EN5318), the first dose via Intramuscular route on 14Jan2021 (at age of 66 years old) (Lot Number: EL3249), both at single dose for covid-19 immunisation . Medical history included closed head injury, migraine headaches, nephrolithiasis, seizure disorder, HTN (as reported). No Known allergies to medications, food, or other products. The patient's concomitant medications were not reported. The patient was exposed to COVID by contact with a friend developed COVID symptoms around 24Mar2021, and had to be hospitalized with COVID19 pneumonia, bilateral infiltrates, hypoxia. Events resulted in Hospitalization. Still hospitalized as of the time of this writing. Remdesivir, steroids, supplemental oxygen received as treatment for the adverse events. No other vaccine received in four weeks. Prior to vaccination, the patient was not diagnosed with COVID-19, Since the vaccination, the patient been tested for COVID-19, Covid test type was Nasal Swab and tested with positive result. Outcome for events was unknown. No follow-up attempts possible. No further information expected.; Sender's Comments: Based on known drug safety profile, the events of vaccination failure and COVID-19 pneumonia are assessed as related to the suspect vaccine BNT162B2.

<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>
1222863	4/17/2021	NC	28	F	4/17/2021	4/17/2021	Approximately 4 minutes after vaccination (12:55pm) patient experienced a syncopal episode. Characteristics observed: profuse sweating, clammy extremities, tonic-clonic seizure-like movements, eye rolled toward the back of the head. When the patient regained consciousness water and cold compress was provided. 911 was called (12:57pm); EMS arrived in approximately 3-4 minutes. The responders asked the patient a multitude of questions - she indicated she was fine and needed to lay down. A bench was provided for her to regain composure. The responders also collected her blood pressure reading once she was more comfortable . She refused transportation to the hospital.
1222781	4/17/2021	VA	55	M	4/13/2021	4/16/2021	On April 16 had absence seizure. I have not had one in over 7 months and felt no warning or precursors. That night fatigue, chills (freezing) headache, nausea, foggy thinking, tense shoulder neck muscles, foot cramps. Day of 17th (ongoing) fatigue, tense shoulders/neck/ lack of hunger, foggy thinking, headache went away with Ibuprofen and Tylenol. Have ate yet so unsure of nausea.
1222204	4/17/2021	HI	37	M	4/16/2021	4/16/2021	Systemic: Dizziness / Lightheadness-Mild, Systemic: Seizure-Mild, Additional Details: patient had a history of seizure not related to vaccination.
1222208	4/17/2021		68	F	4/15/2021	4/15/2021	Seizure lasting ~ 2minutes, patient incontinent of urine. Patient transported to ER via ambulance for treatment and observation. Patient post-ictal for several hours prior to discharge.

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1222253	4/17/2021	MI	51	F	4/12/2021	4/12/2021	COVID-19 Vaccine Johnson and Johnson Covid vaccine yesterday 1330 Chest hurts, nasal congestion, chills last night after the vaccine Pt had negative covid test 5 days ago pt had screening while in the hospital for chest pain pt had normal ekg then Pt has achy and tingling in chest and body aches denies fever states does have chills also c/o diarrhea one to two episodes last night and not today is drinking water well Pt states was very tired last night Since yesterday patient has worsening symptoms, Today she has increased her oxygen use and continues to feel that she cannot breathe, she presents with chest pain, fatigue, nose is running, chills, cold sweats, cough, abdominal pain and dizziness. She received the Johnson Covid vaccination four days ago and is concerned this is related to her blood clotting disorder. She needs transportation to the ED. Hospital admission on 4/16/21 - remains inpt. Diagnosis patient is a 51 y.o. female with complex past medical history. Including chronic obstructive pulmonary disease currently on 4 L nasal cannula at night. Active tobacco use, remote history of alcohol and polysubstance abuse she has been in remission for 20-25 years from crack cocaine and alcohol. She used methamphetamine 6 months ago. Benign essential hypertension and insulin dependant diabetes mellitus, gastroparesis, bipolar disorder, schizoaffective disorder, psychogenic nonepileptic seizure. Presented to the emergency department with chief complain of worsening shortness of breath along with right side lower abdominal pain and urinary symptoms including dysuria and burning sensation. Upon arrival to the emergency department patient was hypertensive and her oxygen saturation was 87 on room air, with moderate respiratory distress. Initial ABG showed pH of 7.25 with pCO2 of 98 following ABG showed 7.1 and pCO2 of 104 she was placed on BiPAP which has improved her breathing and respiration follow-up ABG showed pH of 7.3 with pCO2 of 73. CT angiogram was negative for pulmonary embolism, showed finding of acute bronchitis/aspiration, CT of the abdomen and pelvis was unremarkable. Urinalysis was negative. Patient was giving 125 mg Solu-Medrol along with magnesium and DuoNeb breathing treatment, and admitted for further management.

<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>
1222267	4/17/2021	KS	49	F	4/13/2021	4/13/2021	<p>Patient received a Covid-19 vaccination manufacturer Pfizer. The patient experienced symptoms of nausea and patient felt throat swelling. These symptoms were Mild and were treated with diphenhydramine, supportive care and glass of water. The patient was discharged to Rapid Response Team to the Emergency room after close observation for 20 minutes in stable condition. In ED patient further treated - Review of Systems Constitutional: Negative. HENT: Negative. Negative for drooling, facial swelling, trouble swallowing and voice change. Eyes: Negative. Respiratory: Negative. Negative for cough, chest tightness, shortness of breath, wheezing and stridor. Cardiovascular: Negative. Negative for chest pain. Gastrointestinal: Positive for nausea. Negative for abdominal pain and vomiting. Genitourinary: Negative. Musculoskeletal: Negative. Negative for myalgias. Skin: Positive for itching. Negative for rash and wound. Neurological: Positive for dizziness. Negative for seizures, syncope, light-headedness and headaches. Psychiatric/Behavioral: Negative for confusion. All other systems reviewed and are negative. Medications given in ED: diphenhydrAMINE (BENADRYL) injection 25 mg (25 mg Intravenous Not Given 4/13/21 1508) ondansetron (ZOFTRAN) 4 mg/2 mL injection (has no administration in time range) sodium chloride 0.9% (NS) IV Bolus (0 mL Intravenous Stopped 4/13/21 1540) methylPREDNISolone sod suc(PF) (Solu-MEDROL) injection 125 mg (125 mg Intravenous Given 4/13/21 1507) famotidine (PEPCID) injection 20 mg (20 mg Intravenous Given 4/13/21 1508) sodium chloride 0.9% (NS) IV Bolus (0 mL Intravenous Stopped 4/13/21 1700) Symptoms resolved discharged to home</p>

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1222377	4/17/2021	GA	32	M	4/16/2021	4/16/2021	Pt fainted. Staff alerted by customers that someone was laying in floor. We immediately ran out. Pt was laying face door on floor. Pt was tapped, and verbally asked if he could hear us. Initially there was no response. Checked for breathing, then begin checking for pulse, but he came to. He started speaking with us, saying he was feeling light headed, and got up to notify us, but then he couldn't remember the rest. Asked if he had a history of seizures or diabetes and he said no to either. At some point he went out again, briefly. Meanwhile, the tech called 911. He came to again, begin talking with us. At some point he requested water, which we got. After seeping, he wanted to sit up. We asked him to place his back against the wall, if he wanted to. He did so, and after a few seconds said he wanted to lay down again. EMS came. They asked if he wanted to go to the ER which he consented to. They rolled him out on a stretcher.
1222401	4/17/2021	MD	24	F	4/16/2021	4/16/2021	The patient received the Pfizer vaccine, given by HCP. After the vaccine, the patient felt a little anxious with increased heart rate so she asked HCP for a bottle of water. HCP went to get the water and informed the pharmacist on duty. Both pharmacist and HCP came back to the patient. She got the bottle and was about to open the bottle, but closed her eyes and started shaking like having a seizure and passed out. She came back right after passing out but didn't know what happened. She then started shaking again for a few seconds but didn't pass out. Everything happened so quickly when she remained sitting on the chair. We called 911 and paramedics came. She mentioned that the seizure happened to her before, maybe once or twice a year. When paramedics came, they checked her blood pressure and it was ok. We asked her and she wanted to come to the hospital to check out to make sure that she is ok.
1222446	4/17/2021	IN	50	F	2/12/2021	2/12/2021	Syncope, collapse, seizure, amnesia, brain fog, migraine, nausea, vomiting, double vision; all ongoing since time of second dose administration

<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>
1222520	4/17/2021	MI	16	F	4/16/2021	4/16/2021	PT SUFFERED APPROXIMATELY 4 SEIZURES, 1 IN LINE TO VACCINE CLINIC AND 3 IN OBSERVATION POST VACCINATION. SEIZURES WERE MILD LASTING NO MORE THAN ONE MINUTE EACH. PT CAREGIVER ADAMANT THAT SEIZURES WERE WITHIN SPECTRUM OF NORMAL FOR PATIENT.
1222551	4/17/2021	MT	54	F	4/16/2021	4/16/2021	Time Course/Signs/Symptoms: 8-10minutes after vaccine -> bilateral arm "paralysis", Then, syncope. Was laid down. Awake and spoke her name. Then, Hyperventilation x 3-5 minutes @ about 100 rpm. Lost consciousness. O2 applied. BP=135/90; HR = 90/min. No wheezing, good B breath sounds. Ambulance arrived @ about 11:40am. Reportedly prolonged seizures and severe hypertension. Helicopter ambulance met road ambulance in route. Personnel immediately intubated the patient. Reportedly, this led to "a fountain of blood".
1223781	4/17/2021	TX	60	F	4/17/2021	4/17/2021	pt received vaccine. waited at pharmacy for 15 min. then went shopping. she returned to pharmacy with complaint of shortness of breath about 25 min after receiving vaccine. i sat her down and as i was talking to her about how she was feeling and she began to have convulsions. i laid her on ground and made sure she had an airway and pulse . pt was unresponsive for approx. 5 min. she regained consciousness and ems took over and took her to er
1222851	4/17/2021	NY	76	F	3/11/2021	3/12/2021	12 hrs after receiving, did not feel well headache , nausea, 48 hrs later had seizure during sleep ,affecting her speech , speech got worse over the day drs were running test , then had another seizure causing them to resuscitate, hospital was giving he4 seizures medications , she was giving 5 and a small amount of sedation, 1# days later they had them almost to a halt , ran several test to determine what could have caused the seizures and could find no reason , she never regained consciousness, she passed away 18 days later . I would like to know if the vaccine caused the seizures .

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1222942	4/17/2021	MA	57	F	4/17/2021	4/17/2021	The patient had reported to the site for her second shot of COVID. During her assessment she did not mention any adverse reactions with the first shot. She did mention a hx of pseudoseizures during blood draws. She mentioned that her husband was waiting in the paring lot for her in case she had any reactions after her second shot, and that she would know during the first 15 minutes if she would have one or not. After receiving her vaccination, the patient reported to the observation area. The nurse in the observation area had checked on her, and in response the patient mentioned that her arm felt tingly. The nurse asked if this happened during her first shot, and she said yes. The patient then stated that she felt shaky. The nurse signaled for the medics to assess her further. The medics transferred as a two assist, as the patient was unable to support her own weight. The patient was then brought to a private area, and her husband was called by one of the nurses to come into the site per the patients request because he knew what to do for her when she had pseudoseizures. Medics maintained the patients safety throughout the event. As the husband approached the entrance of the vaccine site, he was escorted to the private area where his wife was. Upon reaching his wife, the patient began to shake and breathing hard. The husband stated that she hadn't had any of these pseudoseizures in awhile and that it must have been from the shot. The medics advised bringing her to the hospital at that time for further evaluation and support, and the husband agreed.
1223031	4/17/2021	FL	59	M	4/8/2021	4/16/2021	seizures starting 8 days after vaccine, unable to c ok control with medication
1223049	4/17/2021		17	M	4/17/2021	4/17/2021	Pt sustained seizure like activity for approximately 20 seconds. Pt became postictal without intervention. Pt maintained an open airway and breathing during the seizure activity. Pt was able to ambulate after the activity. Pt's vitals were assessed and found to be within limits. Pt refused transport to a medical facility. Pt was released to parent.
1223248	4/17/2021	FL	28	M	4/16/2021	4/16/2021	Pt lost consciousness and convulsed for about 10 seconds.

<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>
1223316	4/17/2021	IN	60	M	4/17/2021	4/17/2021	<p>Patient had the vaccine in the arm for approximately 1 minute before becoming pale and beginning to shake. The patient had a representative that stated he was a diabetic and did not eat before the vaccine, believing that his glucose was dropping. He was given a shot of glucose before having an episode similar to a seizure. Diphenhydramine and an EpiPen were obtained but were not needed to be administered as the side effects subsided. The patient wanted EMS to be called. EMS arrived at the facility and the patient was assessed. Patient left on his own will.</p>

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1223549	4/17/2021	CA	62	F	4/16/2021	4/16/2021	At 1450 patient approached Paramedic with concern regarding left wrist pain and vein protruding more than right. This occurred approximately 10 minutes into her 15 minute observation period following a 1st dose Pfizer (Lot # EW0162, Exp: 07/31/2021). Client denied any other symptoms. Paramedic noted that client was able to ambulate to chair in observation without assistance and with a steady gait. Client rated the pain as 2/10 on a 0-10 pain scale and was non-radiating. Paramedic observed there was no asymmetry between left and right wrists, there was mild distention of left radial vein, negative for pain on palpation, negative for temperature difference between right and left extremity. At 1502 client began to complain of neck discomfort, then a headache on forehead which she rated a 5/10. Client reported a history of epilepsy and stated she has a headache aura prior to seizures. Paramedic advised client to sit in the zero gravity chair for further assessment and noted client was able to ambulate to chair on her own accord and with a steady gait. Client denied complaints of dizziness, shortness of breath, blurry vision. At 1508 client stated left radial pain was gone, headache was now rated a 3/10. Client was given a bottle of water. At 1510 vitals were taken with client sitting in zero gravity chair: blood pressure 110/80, respiratory rate: 14, heartrate: 78, client was alert and oriented to time, space, situation and person (CAOx4). Client stated symptoms were diminishing. At 1520 a second set of vitals were taken: Blood pressure: 112/82, Respiratory rate: 14, Heartrate: 78, CAOx4. Client stated she had no complaints. Client was advised to stay an additional 15 minutes. At 1540 client released from observation and she left the observation site on her own accord with a steady gait.

<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>
1223552	4/17/2021	AL	30	F	4/14/2021	4/15/2021	I had two seizures one on Thursday night and one on Friday night. It is very unusual for me to have two episodes back to back like that without there being a trigger. I did not experience any of my normal triggers for it. I was taking my medicine on time and going to sleep at a decent hour (those are my biggest triggers) I will send in another report if I have one again tonight. (mine are only at night) I will be going to see my doctor on Monday since they are not open on the weekend. There is not really any treatment to prevent this. Please do some research on the effects
1223670	4/17/2021	OH	16	M	4/17/2021	4/17/2021	pt was getting his first covid vaccine with his mom. pt was vaccinated first then mom was vaccinated. After mom was vaccinated I had my bad to the patient and his mom throwing away supplies, Pt passed out and was not responsive to mom or to myself the pharmacist. I thought the patient needed an EpiPen and went to get the EpiPen out of the pharmacy and while my back was turned mom stated that the patient convulsed a few times. By the time I returned with the EpiPen pt was not convulsing and had passed out and started to recover and become responsive. Pt was pale but was aware of his name, birthday, date, and current president. A tech called EMS. Pt was talking when EMS arrived and color had started to return to normal. pt was able to walk out to the ambulance to be checked out. Mom stated she wanted to take pt to ER for more evaluation.
1221616	4/17/2021	FL	54	F	4/15/2021	4/16/2021	Extreme pain in arm, sever headache, dizzy, nausea, high fever of 102, confusion, entire body pain, severe neck pain and stiffness, seizure like body tremors, fatigue
1223745	4/17/2021	AL	24	F	4/12/2021	4/12/2021	Patient had a mild seizure several hours after receiving the J&J vaccine. She is epileptic and generally has two seizures a year that would last 30 minutes or longer. The seizure she had after receiving the vaccine only lasted around 40 seconds. She had her last regular seizure in January so she stated she was not due to have a seizure anytime soon based on her previous medical history. Her father was present and able to keep her safe during seizure so no medical treatment was received.

<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>
1223753	4/17/2021	NM	24	M	4/12/2021	4/12/2021	after approximately 10 minutes of receiving Covid-19 vaccine, the patient fell out of chair in which he was seate. patient was unconscious for approximately 1 minute while I rolled him over and checked for pulse. his eyes were wide open and he seemed to have had an absense seizure lasting upto a minute before regaining consciousness. he was quickly cognizant and I asked if he had any history of seizures or if he might be hypoglycemic. He did say that he had not eaten and it was 3:00pm. paramedics soon arrived and removed the patient from the scene. I did text patient the next day and he said only that he had a sore arm and symptoms consistent with having a vaccine administered.
1222122	4/17/2021	NE	30	M	4/17/2021	4/17/2021	Pt recieved dose and after sitting for a few minutes started to sweat and convulse pt regained awareness shortly paramedics called and patient was transported to receive care
1222649	4/17/2021	NH	19	M	4/17/2021	4/17/2021	Several minutes after receiving the vaccination, while waiting in the post vaccine area, patient had either a seizure or fainted. I did not witness the occurrence. 911 was called and patient was transported to the hospital.

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1222572	4/17/2021	DE	67	F	1/18/2021	2/4/2021	<p>entered room drooling . right sided neglect BP elevated . not following command send to ER Admitted to hospital with CVA</p> <p>PCP Note upon return - Patient is a 67-year-old female with past medical history of hypertension, MS, dementia, CHF, chronic kidney disease and hyperlipidemia who was sent from the facility to the emergency room for altered mental status and possible CVA. In the emergency room, blood pressure was elevated at 170/100 and she was noted with more pronounced weakness in left upper extremity and lower extremity and left gaze. Neurosurgery was consulted and deemed patient a poor candidate for TPA due to recent GI bleed. Stroke workup was negative for acute findings and a brain MRI x2 was negative. EEG was ordered to rule out seizure and it was normal and neurologist recommended to start patient on Keppra. Patient was initially started on aspirin which was stopped due to drop in H&H. Patient was also noted with low-grade fever and infectious workup including blood cultures, UA and extensive imaging did not have evidence of infection and COVID-19 was negative. Social services spoke to patient's sister who is the POA regarding advanced directives and she requested to change advanced directives to DNR/DNI/no PEG and orders noted in chart. Patient's symptoms progressively improved and discharged back to the facility and resting in bed comfortably in no acute distress</p>

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1220369	4/16/2021	AZ	36	F	4/16/2021	4/16/2021	Patient is a 36 y/o F here for her 2nd Moderna vaccine this AM. After being observed for 15 minutes pt c/o N/V and ran to the bathroom. Vitals 140/89, 98% RA, 105. Retook vitals after pt stood up (140/95, 100% RA, 83) and pt still c/o Nausea and dizziness. While exiting the restroom the pt fainted as I was assisting her out. I called for help and guided her to the floor. Dr. was on site and assessed the pt. She was initially tachycardic but improved immediately. cool and clammy to touch. Pt had LOC for approximately 15-20 seconds following episode. Vitals: 135/89, 98%RA, 79. After symptoms improved pt was escorted to an exam room where we monitored her for the next hour. Vitals: 0842-129/89, 99% RA, 84; 0847-134/94, 100% RA, 77 with c/o nausea 7/10. At 0852 Dr. assessed pt again. Pt still c/o nausea; isopropyl alcohol sniff provided and PO water; sx improved, but pt needed to "urinate" and was escorted back to the bathroom by myself and her husband. Pt was able to urinate, upon finishing she stood to walk out; I noticed pallor and clamminess, and she then fainted again. I guided her into the chair I had brought into the bathroom and Dr helped me to guide her to the ground; he auscultated a rapid weak radial pulse; slowed breathing: then she "snapped to". Pt did not have any seizure activity but RUE wrist flexed, pressed against wall. Vitals: 132/84, 100% RA, 71. After the second episode; called 911 to help transport the pt for farther evaluation. FD arrived at 0937 to evaluate the pt. Blood glucose was 80, vitals WNL. Pt still c/o Nausea/dizziness/headache on evaluation. Pt transported by EMS to Hospital.
1219105	4/16/2021	OR	24	F	4/13/2021	4/13/2021	She was sitting in the 15 minute observation area when she reported pain in the arm of the vaccine and felt diaphoretic and fainted falling off chair & onto floor. She lost consciousness and both arms and legs trembling appeared like seizure like in nature; Medix ambulance called and assessment BP 94/58 P 74 O2 sat 98% blood sugar 89 L shoulder with approx 4cm red area bruising noted from fall onto floor ; when sitting up pt c/o dizziness and lite headed layed back down and was Alert and Oriented X 3; Medix to transfer to local hospital when transferring pt to gurney she has having tremors in her arms and legs eyes closed and able to answer questions appropriately

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1219279	4/16/2021	NY	52	F	4/16/2021	4/16/2021	Pt lost consciousness in waiting room unwitnessed by staff. Transferred to the ED. Seizure activity noted.
1219374	4/16/2021	UT	75	M	2/15/2021	3/17/2021	After vaccine I had a sore arm and on 3/17 I ended up in the ER because I had a seizure. Both me and my wife had the same reaction, a month ago both have had seizures and have never had seizures in our lives. We've seen the neurosurgeon and neurologist . I am on seizure medication now, Keppra 500mg bid.
1219443	4/16/2021	UT	77	F	2/22/2021	3/14/2021	After vaccine it was almost a month later, the bed was shaking and she was having a seizure. I tried to get her back on target and called the ambulance. In the ER she started having a seizure again and I called the ER doctor. He said if that's what happened earlier and said its definitely a seizure.
1219537	4/16/2021	RI	41	F	4/16/2021	4/16/2021	Vasovagal syncope with seizure-like tonic-clonic motion observed during syncopal event
1219630	4/16/2021	OR	50	F	4/14/2021	4/14/2021	12 hours after I received the vaccination I got fever and chill, and extreme joint pain. 24 hours after the vaccination I began vomiting, had a splitting headache, and then my vision blurring, I called my husband to be near me and completely passed out for about 15 seconds. I woke up with no recall of what happened. I thought I had had a heart attack or stroke. My left side ached where I had the injection. I have NEVER fainted before. We were unsure if I had fainted or had a seizure. Apparently my head was shaking and my hand was also when I unconscious. I stayed in bed with a 101 fever the rest of the day. Today, 2 days from vaccination, I am feeling better. It was terrifying and we were considering going to the ER. I am pro vaccine but was inadequately prepared for what could have been a dangerous reaction. I was sitting when I passed out. I was home. I had someone with me....otherwise it could have been really terrible.
1219748	4/16/2021		53	M	4/8/2021	4/8/2021	Patient experienced seizure like activity. EMS was on site to evaluate patient and transported him to emergency room. Spouse reports frequent seizure activity.

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1219832	4/16/2021	AR	32	M	4/16/2021	4/16/2021	patient lost consciousness and then had a seizure for approximately 15 to 20 seconds
1220094	4/16/2021	NC	28	M	4/16/2021	4/16/2021	patient sitting in post-vaccination area has a witnessed seizure at 1525, patient had twitching, LOC and eye rolling. EMT and RN were there and observed. Patient returned to consciousness, and moved behind curtain. Patient had another witnessed seizure @ 1532 lasting 10 seconds, with LOC, twitching, eyerolling and vomiting. Patient came to and placed on floor, alert and awake, able to answer questions but feeling foggy. EMS was called during 1st seizure. EMS arrived and took patient to hospital @ 1558.
1220160	4/16/2021	GA	81	M	4/9/2021	4/12/2021	Seizure 4/12/2021 go to ER, stayed in hospital 4 days
1220206	4/16/2021	CA	22	M	4/16/2021	4/16/2021	Patient was sitting upright in chair looking down at phone. Had a syncopal episode, fell to floor, had seizure activity that lasted 5-10 secs. Patient awakened on his own, confused. Tried to get off of floor. Asked to stay on right side of floor. Vitals obtained. A/Ox2. Patient diaphoretic, pale, with shivering. Abrasions to right side of forehead and right posterior shoulder. BP 89/56, HR 56, O2 99% at 1257. Patient able to go from sitting to standing position to be sat in chair. Father notified of events. Father wanted patient to stay here at site for one hour. Within 5 mins of sitting in chair, patient became diaphoretic and pale again with focal stare. Per patient, "I can't hear or see you at the moment." EMS activated. BP obtained again, 78/52, HR 63, O2 at 99%. EMS arrived and assessed patient. Decided to take to Hospital. Father called and notified. Father will meet son at emergency dept.

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1220940	4/16/2021	FL		F			Seizure; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (Seizure) 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 Epilepsy. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Three hours after the first dose, the patient experienced SEIZURE (Seizure) (seriousness criterion medically significant). At the time of the report, SEIZURE (Seizure) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. Description: The consumer got the first dose and developed seizure (medically significant) for three hours. No treatment information was provided.; 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
1220364	4/16/2021		31	F	4/14/2021	4/14/2021	Sudden loss of consciousness; Claimed one h/x of same episode 1 year ago. H/x of seizures - denied. BP 113/64 - 131/72; HR 75 -- > 92, RR 18, SpO2 100%

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1219015	4/16/2021	FL	23	M	4/16/2021	4/16/2021	<p>Patient (002956225) - received Moderna vaccination (Lot # 0011A21A) on 04/16/2021 at 09:02 in the left arm by RN. 0904 Patient began walking from the Vaccine station towards Observation. After approximately 20? feet, LPN in another vaccine station down the line, noticed the patient stumbling towards the wall. She observed him stumble/fall into the wall, hitting his head, then began falling to the floor. LPN came around her partition, called for help and was immediately assisted by LPN. The two nurses assisted the patient to the floor. They reported his eyes were fully dilated and he began having light, full-body shakes. The two nurses turned the patient on his side and held his head. Waters said the patient was able to answer all questions appropriately. The full body shakes lasted approximately 30 seconds. The Patient did not lose consciousness. 0905 Lead Nurse arrived noting the patient was lying on the floor in the prone position exhibiting mild seizure like activity and his pupils were dilated. Patient was rolled onto his side until the seizure like activity subsided, lasting for approximately 30 seconds. 0905 IC/PSC called 911, PD. The site Medical Protocols plan was activated. 0906 Vital signs were obtained: Blood pressure: 96/80, HR 78, O2 at 91% on room air. A neuro check was performed on the patient and he was noted to be alert and oriented x3. Patient stated he had not eaten anything prior to coming in. Patient was assisted to a seated position while still on the floor. Patient was given water, juice, a banana and other snacks. Nurses in the Observation Station noticed the incident from across the arena and brought the EpiPens, AED, Blood Pressure Cuff and med bag. 0910 Vital signs were obtained: BP 104/47, HR 50, O2 98% on room air and respirations 18. Patient remained fully alert and oriented but noted to have mild tremors of both hands. 0915 TFD, followed shortly by EMS, arrived on scene at and assumed care of the Patient. 0926 Patient decided to be transport to the Hospital and was removed from facility via stretcher.</p>
1220406	4/16/2021	CA	19	M	4/16/2021	4/16/2021	<p>Patient had a dizzy spell, fainted twice for about 15 seconds each. appeared to have seizure like activity. Called 911 for furthur assistance. Patient was pale and cyanotic, became alert by the time paramedics got to the site.</p>

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1220415	4/16/2021	LA	34	M	4/15/2021	4/15/2021	<p>Within an hour of receiving the vaccine, I began to feel "odd" (i.e heart racing, spine tingling, strange sensations in my hands, and dizziness). At the hour mark, while trying to "walk it off" inside my backyard, things escalated quickly. As I came back inside, I suddenly collapsed and and lost consciousness. Luckily my best friend was with me and she described my behavior as a full on seizure (which I am not predisposed to). According to her, I was flopping around, spitting wildly and drooling all over my face, my eyes wide and glazed staring into nothing, lips turning blue. She immediately called 911 and within 5-10 minutes, two EMT's arrived and began to speak to me and take my vitals. For a good 15 minutes I couldn't sit up and had to lay on the ground, still extremely out of it - unable to think, merely in extreme discomfort similar to the most intense flu I've ever experienced. After a half hour or so, I sat up and was able to thank them for helping me and answer some of their questions. Over another 15 or so minutes they said all my vitals were perfect and they were not worried about me - sure I'd make a full recovery, which I hope I did. I am feeling MUCH better today. The reason I felt it so important to submit this report is because I had never heard of anyone experiencing side-effects that severe. Of course I had heard it could wipe you out, give you chills, aches, and exhaustion - but I had never heard that it could lead to a seizure so scary that my best friend thought I might be dying. I truly don't know what might have happened without her. People should know to have someone at home with them after the second dose. I am not over-exaggerating about my symptoms whatsoever. My body still hurts all over and I feel as if I went through some type of gauntlet yesterday. I absolutely do NOT want to discourage anyone from getting the vaccine, but I wish I had some notion that something so severe could happen to me.</p>

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1220454	4/16/2021	CA	29	M	4/14/2021	4/14/2021	This patient had received vaccination and was scheduling next appt in observation area. Medical alert called overhead. RN responded to alert. Pt conscious, but per RN, in observation area, she stated he had a loss of consciousness and although she tried to break his fall, he did hit his head on the wall. Pt was sitting in chair, vitals attempted to be assessed, no reading, but patient alert. Before vitals were repeated, 16:18 pt eyes drifted left and closing, another loss of consciousness, followed by convulsions and gasping sounds from the throat. Pt convulsed and left leg /foot turned inward torsion. Pt was removed from chair by 3 RN's to floor safely. approximately 15-30seconds of convulsion. pt regained consciousness AOX4. Pt remained laying, head propped on cushion. vitals taken 16:24 BP 108/69 86bpm, 100%O2Sat. MD assessed and pt stable. MD provided recommendation for pt to be evaluated at ED for further evaluation due to the convulsions. Pt accompanied by friend, friend agreed to drive pt to ED. Blood Glucose 90, which was taken at 1630. Wheelchair was provided for patient, RN rolled pt out to car and friend designated driver.
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
1220589	4/16/2021	WA	27	F	3/23/2021	3/23/2021	Patient was in 15 min waiting area after her vaccination. She suddenly fell to the floor and began convulsing. 911 was called. Clinic staff provided comfort , basic assessment with vital signs (110/58, 80, 100%RA), and oxygen on standby. Staff agreed convulsions lasted for about 1 minute. Pt began to awake, then promptly vomited clear watery fluid. Staff continued to provide comfort and awaited 1st responders-arrived after about 6min. Pt gradually awoke and was awake alert (A x O x 4) by the time the first responders took over care and were interviewing her. Secondary transport (AMR) was called and showed up shortly after, pt was transported to ED for further w/u.

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1220657	4/16/2021		29	M	4/14/2021	4/14/2021	<10 minutes after vaccination, patient had syncope episode, fall broken by another person, slight bump to head. Patient became conscious, was seated on a chair, and then had second syncope episode followed with convulsions. Stabilized patient. Vitals monitored, assessed by MD and released with referral to PCP.
1220714	4/16/2021	NC	59	F	4/15/2021	4/15/2021	Symptoms within a few minutes of vaccine administration: body aches and headaches (although these two specifically are not uncommon for pt), jaw pain, left arm shaking until bedtime that night, twitching (also not uncommon for pt per seizure disorder). Symptoms resolved by next morning at 7am, but within 2 hours, symptoms returned, including swollen face that is painful to the touch, intense fatigue, burning/throbbing/tingling sensation in arms and legs, worsening of arthritic pain, jaw pain, chills/hot flash-like episodes, decreased appetite, stinging sensation in the eye, home measurement had pulse ox 98% and HR at 93 bpm (pt endorsed). Note that pt was COVID positive on Dec 1st, 2020
1220756	4/16/2021	CA	37	M	4/16/2021	4/16/2021	While RN BSN CCM was conducting educational facts about the covid 19 vaccination. Observed patients body went stiff and fell backwards in sitting position in his chair and started to exhibit seizure like symptoms in his chair for approximately 8-10 seconds. RRT called immediately and arrived 1 minuted after. Pt had beads of sweat dripping off forehead. Temp obtain 86.6. SpO2 95% Attempted to obtain BP vitals but machine did not complete cycle before pt blacked out again. ED transferred at 1055.

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1220772	4/16/2021	CA	49	M	4/14/2021	4/15/2021	<p>The night after the vaccination I developed a mild fever (under 100 F) and had a severe headache. It lasted most of the night. When I got up in the morning, both symptoms were gone and I assumed I made it through any side affects. That whole day I felt great. I had delayed my daily 7 mile run, which I normally do in the morning, to make sure the symptoms were really over. So by 4 pm, still feeling great, I decided to go for that run. I didn't run particularly hard or fast, It was a relaxing, enjoyable run. No issues. When I got back home around 5:30 pm, I went straight back to my office to keep working. I was feeling hot, as you would expect after a run, so I turned on the ceiling fan. after about 15 minutes I started to feel like I was shivering from the cold, so I turned off the fan. Within less than 5 minutes, I was shacking and my muscles were spasming uncontrollably. It was similar to the couple of times in my life where I have gone into shock from an injury. So I dropped everything and made my way as quick as I could to a very hot shower. I was scared enough to ask my 17 year old daughter to check on me to make sure I don't pass out. A couple time I thought about calling 911, but I didn't have my phone and I was afraid to leave the shower. After about 20 minutes in the near scolding shower, I stopped shaking enough to where I decided to wrap up and get under a bunch of covers laying on the bed. The shacking completely stopped after 5 or 10 minutes in bed, but the fever shot up and I developed a debilitating headache. I took Tylenol and eventually Excedrin Migraine to ease the pain. The fevered stayed over 100 F most of the night (my normal temperature is a little above 97), and the headache remained but gradually declined. By 7 am the this morning I was fine and I've been fine all day. The only reasons I'm reporting this is because the shaking was very severe, at times I wondered if I was heading for a seizure, and, being a runner, I want to make sure there is not a link between severe reactions and distance running shortly after the vaccination.</p>

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1220896	4/16/2021	FL		M	3/25/2021		Myoclonic seizures; Vaccination related malaise; This spontaneous case was reported by a consumer and describes the occurrence of MYOCLONIC EPILEPSY (Myoclonic seizures) 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 reported.). On 25-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 MYOCLONIC EPILEPSY (Myoclonic seizures) (seriousness criterion medically significant) and VACCINATION COMPLICATION (Vaccination related malaise). At the time of the report, MYOCLONIC EPILEPSY (Myoclonic seizures) and VACCINATION COMPLICATION (Vaccination related malaise) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant product use was provided. Treatment information was not available. 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
1220212	4/16/2021	NE	49	F	4/16/2021	4/16/2021	Patient was seizing while in wheelchair 10 min after receiving her covid vaccination. Moved to medical tent, Seized for ~ 1.5 min. followed by 2 30 second seizures following initial . Post ictal after seizures but airway maintained. no other clinical complications noted. pulse and BP was normal. 911 contacted transferred to Medical Center.

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1218359	4/16/2021	PA	47	F	4/8/2021	4/8/2021	pt reports she developed a headache and dizziness while eating dinner this evening - reports she had a syncopal episode. Patient is a 46-year-old female who was brought in by EMS after witnessed syncopal episode tonight. States did get her 1st COVID vaccination today around noon was fine then sitting at the dinner table when started to feel hot with a headache went to the ground down for an unknown amount of. Per family. Though no reported shaking or seizure activity. Patient now with generalized headache and some mild dizziness. No nausea vomiting no numbness weakness or tingling.

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1215759	4/16/2021	CA		F		3/31/2021	<p>POUNDING HEADACHE; CONVULSION; BODYACHES; WEAKNESS; NAUSEA; This spontaneous report received from a patient concerned a 70 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included fibromyalgia, Crohn's disease, and migraine. 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 dose, administered on 31-MAR-2021 (Wednesday) on left arm for prophylactic vaccination. No concomitant medications were reported. On 31-MAR-2021 on Wednesday, the patient experienced severe chills to the extent of teeth chattering ,body shaking and convulsion, due to which her husband kept covering with blankets. At 19:00, she developed pounding headache. She experienced body aches. As per her doctor, fibromyalgia might exacerbate the body aches due to which she stayed in bed for 2 days. She also experience weakness and nausea. On 02-Apr-2021 (Friday), she was finally able to cook. She was still experiencing weakness, nausea and excruciating headache for which she was not sure if it was due to vaccine or from migraine that she had. The patient also informed that she underwent unknown test for six times on unknown dates and the test result was found to be negative. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from body aches, convulsion and had not recovered from weakness, nausea, and pounding headache. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210409019 -COVID-19 VACCINE AD26.COV2.S-convulsion. 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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1215767	4/16/2021	PA	37	M	4/5/2021		SEIZURE; DIARRHEA; This spontaneous report received from a patient concerned a 37 years old male. The patient's height, and weight were not reported. The patient's concurrent condition included fear of needle. 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 on 05-APR-2021 for prophylactic vaccination. Batch number was not reported and has been requested. No concomitant medications were reported. On 05-APR-2021, after receiving vaccination, the patient experienced seizure (fainting, tremor, tachycardia and bladder incontinence) and diarrhea. Upon examination of his vitals, heart rate was 112, showing tachycardia, blood pressure (BP) was 135/83, oxygen saturation was at 98 and glucose was 90. The patient was taken to the emergency room where he was released after evaluation. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from diarrhea on 05-APR-2021, recovered with sequelae from seizure on 05-APR-2021. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210411486, 20210411395 and 20210410874.; Sender's Comments: V0: 20210410630 -COVID-19 VACCINE AD26.COV2.S-seizure. 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.

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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.
1216676	4/16/2021	NY	26	F	4/16/2021	4/17/2021	Seizure like activity

<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>
1216824	4/16/2021	TX	58	F		4/7/2021	SWOLLEN LIPS; RASH; ITCHING; 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 concurrent conditions included seizures, shellfish allergy, spinach allergy, almond allergy and brown rice allergy, non-alcohol user, and non smoker, and other pre-existing medical conditions included the patient did not have any history of drug abuse or illicit drug use. The patient was previously treated with cannabidiol for seizures. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 203A21A 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 itching. On 07-APR-2021, the subject experienced rash. On 09-APR-2021, the subject experienced swollen lips. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from rash, itching, and swollen lips. This report was non-serious.

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1217478	4/16/2021	IA		U	4/7/2021	4/7/2021	<p>DIFFICULTY IN SPEAKING; RASH; STOPPED BREATHING; SEIZURES; DIZZINESS; CLAMMY; This spontaneous report received from a health care professional concerned a patient of unspecified age, sex, ethnic origin, and race. 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) dose was not reported, administered on 07-APR-2021 to left arm for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, the patient experienced dizziness, clammy, seizures, stopped breathing, and rash. On an unspecified date, the patient experienced difficulty in speaking. The patient was seen by EMS and was taken to the hospital. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from rash, dizziness, clammy, seizures, and stopped breathing, and the outcome of difficulty in speaking was not reported. This report was serious (Life Threatening). This case, from the same reporter is linked to 20210414577.; Sender's Comments: v0 This report involves a patient of unspecified age, sex who experienced rash after 5 minutes after receiving Janssen COVID-19 Vaccine Ad26.COV2.S for prophylactic vaccination then the patient developed light headed associated with dizziness and later had difficult in speaking. Events also reported included clammy, seizures, "stopped breathing", however details of these events were not provided. Medical history and concomitant medications were not reported. Given the close temporal relationship and the nature of the events, the events of lightheaded associated with dizziness and later had difficult in speaking are considered possibly related to the vaccination. The insufficient information precludes a meaningful medical assessment of the events of clammy, seizures, stopped breathing.</p>

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1217751	4/16/2021	NC		M	3/24/2021		<p>HEART ARRHYTHMIA; CARDIAC ARREST; SWOLLEN BRAIN; LACK OF OXYGEN; SHORT-TERM MEMORY LOSS; COMPROMISED MOTOR SKILLS; COMA; SEIZURES; LETHARGY; This spontaneous report received from a consumer concerned a 59 year old male. The patient's weight, height, and medical history were not reported. The subject was a veteran and retired. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose was not reported, administered on 24-MAR-2021 for prevention of symptomatic sar-cov-2 virus infection. No concomitant medications were reported. On 24-MAR-2021, the patient felt lethargic that night, and went to bed early. On 26-MAR-2021, he had seizures. On 29-MAR-2021, patient was admitted in the intensive care unit (ICU) after driving and slumped over due to a coma. Doctors noted that he had heart arrhythmia and cardiac arrest. He had foam coming out the mouth. On 29-MAR-2021, X-ray were done that showed no blockage and no heart attack. The patient was intubated. Doctors also noted a swollen brain due to a lack of oxygen. On 03-APR-2021, the patient woke up from his coma and was out of ICU. The patient long-term memory (things that happen 5-10 years ago and earlier) was fine, but his short-term memory had been compromised. For example, he was unable to remember his name. He was unable to complete normal motor skills like walking and dressing. At the time of this report, patient was in rehab. He had a heart defibrillator placed in his body. His wife emphasized that he did not have any pre-existing conditions. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from coma, cardiac arrest, and lack of oxygen on 03-APR-2021, had not recovered from short-term memory loss, and compromised motor skills, and the outcome of lethargy, seizures, heart arrhythmia and swollen brain was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: A 59-year-old male patient with no pre-existing medical conditions felt lethargic the night after vaccine and went to bed early. Two days after vaccine he had seizures (details not reported.) Five days after vaccine, the patient was admitted to the intensive care unit (ICU) after slumping over while driving with "foam coming out" of his mouth.</p>

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1217877	4/16/2021	MD	26	F	4/15/2021	4/15/2021	<p>Doctors noted that he had heart arrhythmia and cardiac arrest. "X-rays" were done that showed no blockage and no heart attack. The patient was intubated. Doctors also noted brain swelling due to a lack of oxygen. 10 days after vaccine, the patient woke up from his coma and was out of ICU. The patient's long-term memory (things that happen 5-10 years ago and earlier) was intact, but his short-term memory had been compromised. He was unable to complete normal motor skills like walking and dressing. An internal cardiac defibrillator was placed. At the time of this report, patient was in rehab and recovering. The lethargy is likely related to vaccine. It is possible that the subject experienced new onset seizure disorder, although a direct causal association to vaccine cannot be established based on the information provided. It is unlikely that the cardiac arrhythmia, subsequent cardiac arrest, or resulting anoxic event were related to vaccine, without a plausible mechanism.</p> <p>APPROXIMATELY 12 MINUTES AFTER THE VACCINE WAS GIVEN THE PATIENT STARTED TO COMPLAIN OF FEELING LIGHTEADED AND HAVING BLURRED VISION ALSO ASSOCIATED NAUSEA. SHE WAS BROUGHT BACK TO A STRETCHER AND VITALS WERE TAKEN AND STABLE. SHE SUBSEQUENTLY STARTED TO HAVE SOME DRY HEAVES AND FEELING OF ITCHING IN THROAT WITH PROGRESSION OF HER SYMPTOMS. HER PULSE OX WAS 93-98%, bp 110/82 AND HR 67. IT WAS DECIDED TO ADMINISTER AN EPIPEN AND SHE HAD AN INCREASE OF HR TO 102; AT THIS POINT EMS WAS CALLED. SHE DID START TO DEVELOP THROAT TIGHTNESS, ITCHING, AND COUGH AT WHICH TIME OXYGEN WAS ADMINISTERED. SHE WAS TRANSFERRED TO ER AT THE MEDICAL CENTER FOR FURTHER EVALUATION. REPORT FROM ER NOTES SHE DID HAVE SEIZURE WHILE ENROUTE WHICH WAS TREATED. THE PATIENT WAS KNOWN TO HAVE UNDERLYING SEIZURE DISORDER.</p>

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1217946	4/16/2021		74	F	2/3/2021	2/13/2021	Patient is a 74 year old female with PMH of morbid obesity and seizure disorder who presented to the ER on 2/13/2021 with weakness and fever. Patient tested positive for COVID-19 on 2/13 and was treated with a five day course of oral dexamethasone and remdesivir. Antibiotics were started on admission, but serial chest x-rays were mostly stable and all culture results remained negative. Antibiotics were discontinued on 2/15. Patient discharged to home on 2/18/2021
1218063	4/16/2021	KY	25	F	4/8/2021	4/8/2021	Pt sister reported that: Pt. after receiving the first dose had a severe allergic reaction within minutes of being vaccinated and required an ambulance and was transported to Hospital ED and then discharged. Then her sister said she was taken later to another hospital where she was admitted to the ICU. She said her sister was later discharged but is "still having seizures". Note: our clinic staff that observe patients with no allergy history for the minimum recommended time of 15 minutes post vaccination do not have any recollection of an allergic reaction or an ambulance coming to clinic to transport this patient.
1218165	4/16/2021	IA	24	M	4/15/2021	4/15/2021	After injection patient went to waiting room with mother for 15 minutes. Within 5 minutes he began seizing, He stiffened and hit his head on a shelf behind him. Pharmacist called over and did witness second (or continued) seizure. Mom and I held him steady until done. Patient breathing fine and responsive after seizure though not wanting to move. Called 911, stayed with him until paramedics arrived. He was talking to us, though very pale and weak. Refused to lie down. Paramedics transferred the patient to the hospital for further evaluation and treatment.
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 unresponsive 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.

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1218279	4/16/2021	MN	98	F	2/19/2021	2/26/2021	On 2/26/21 patient had tingling and numbness in legs. Legs wouldn't move. Patient fell, provider not contacted 3/27/21 called 911, patient had maybe had seizure couldn't talk. Patient had EEG,MRI and CAT scan- all came back negative for stroke or seizure.
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. Hematology 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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1218466	4/16/2021	SC	64	F	4/6/2021	4/9/2021	Pt is a 64yo F with no known PMH who presented today with Left side facial droop with left side neglect. She reports that around 1230, she felt like her knees became weak and she fell to the ground. She notes that the landlord found her and called EMS. Pt reports that she did not feel any other symptoms such as N/v, CP, dizziness, lightheaded, slurred speech, abd pain, visual changes, seizure like activity, incontinence, sore tongue, or SOB. It was noted by EMS that she had left side facial droop. Pt reports that she felt normal prior to this event and was able to do all ADLs and ambulate without assistance. She does not report any medical hx but admits to not seeing a PCP in years. She denies smoking and excessive etoh use as well as illicit drug use. She notes that she has a family hx of MIs with her brothers and sister all in the ages of 60. Her father had diabetes and HTN for which he passed from "GI blockage" and her mother passed from hemorrhage giving birth. She does not recall a family hx of stroke or abnormal bleeds. In the ED, her vitals were significant for a BP 231/114. She had an NIH of 12 and a HCT was ordered showing right basal ganglia hemorrhage concerning for HTN cause. NSY has been called with patient started on cardene gtt and keppra. CBC significant for hgb 12.6 and CMP with K low at 3.1. EKG was obtained showing LVH with potential ischemia. Cardiology was called and noted that changes were likely in relation to LVH. A troponin was obtained and negative. Lastly, she has had a Head and neck CTA without evidence of Carotid artery blockage but an occlusion present at the distal P2 right PCA.
1218610	4/16/2021	OH	24	M	4/1/2021	4/10/2021	Severe headache with seizures
1218654	4/16/2021	OH	35	F	3/31/2021	3/31/2021	POST VACCINATION- IN OBSERVATION AREA--- APPROXIMATELY 10 MIN LATER- FELL OUT OF CHAIR LANDING PRONE BESIDE CHAIR. UNCONSCIOUS 1-2 MINUTES. INCONTINENT OF URINE. DISORIENTED TO TIME. ASKED" HAVE I RECEIVED MY VACCINATION YET?" STATES HAS HISTORY OF "PASSING OUT FOLLOWING MEDICAL PROCEDURES" BUT DENIED SEIZURE DISORDER. EMS ATTENDED WITH TRANSPORT TO HOSPITAL FOR ASSESSMENT.

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1218682	4/16/2021	WA	44	F	4/14/2021	4/15/2021	Seizure on 4/15/21, 1-2 minutes, post-ictal for a few hours prior to return to baseline. No prior history of seizures.
1218704	4/16/2021	NY	75	F	4/9/2021	4/12/2021	Patient was admitted due to feeling jittery, with history of seizure, possible non-compliance. Dose of Keppra increased, chest imaging negative for pneumonia.
1218725	4/16/2021	CT	28	M	3/19/2021	3/23/2021	pt had a massive stroke at 6:15 pm on 3/23/2021 when he was using the bathroom trying to have a bowel movement. He used his phone to text his mom to tell her he had a seizure. He was slurring, vomiting, and falling down. Ambulance was called. He was transport him to Hospital. Pt was aspirating. He was never treated as a stroke patient. He was monitored overnight. On 3/24/2021 the ER physician had a phone consult w/ a neurologist. He was referred to be transferred to another hospital. He was was being bagged in transit to hospital. He went into the ER stroke unit. Dr. called mother to let her know that if he didn't have emergency brain surgery he would die. Mother told him to save her son. He survived brain surgery and was put in the Neuro ICU. On 4/3 He was transferred to the Stroke Team floor. On 4/8 he was transferred to Rehabilitation Hospital. He will be at this location for weeks or months.
1218777	4/16/2021	LA	53	F	4/8/2021	4/8/2021	received her 2nd dose of Pfizer on 4/8@8:32am, was given discharge information, education and directed to our monitoring area. About 8:40am the clinic RN, went to assess the patient as she began to feel nauseated, began dry heaving without vomiting, had generalized redness, then complained of feeling light headed. She passed out so the RN eased her to the floor. A Rapid Response(RR) was called and the patient was moved to the stretcher. VS were taken and at about 8:50am the RR team arrived and assumed care. Once they arrived the patient began to seize. She was taken to the ER where she had another seizure. She remained in a post-ictal state for most of her stay at our facility.

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1218785	4/16/2021	IL	61	M	4/15/2021	4/15/2021	Patient told the vaccinating pharmacist he had a history of fainting after receiving vaccinations. Patient was feeling okay after vaccination and went into waiting area. Pharmacist was called over because patient fainted. By the time we got to the patient he was awake, alert and sitting upright. He knew who he was, where he was, and that he just received a covid vaccine. The patient said he felt light headed. We offered water and an ice pack as the patient was sweating but he did not say he was hot. The patient was able to get up after a few minutes of sitting and sat in a chair. After another few minutes, the patients head went backwards and he was making a snoring sound. I tried to talk to the patient but he didn't respond. We called 911. We placed the patient on the floor and turned him on his side. After about 1 minute he was with it again. He knew where he was and thought he fainted again. Upon speaking with the patient we received details about his history of seizures due to alcohol withdrawal. He also confirmed the last time he drank was that morning and he had "a few shots and was cutting back." Patient told us he was not on any medications but did take 50 mg of benadryl around 12:00pm that day. The paramedics arrived and took him to the hospital.

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1218829	4/16/2021	WI	73	F	3/25/2021	3/28/2021	Patient reports she started to experience feeling a sense of doom, stool incontinence, left-sided numbness, altered mental status in the early hours of 3/28/21. Of note, patient received her second dose of the Moderna vaccine on 3/25/2021 and felt poorly the day after with body aches and fatigue. The patient was admitted to ED with suspected stroke, but no ischemia or hemorrhage was shown on MRI. In addition, her blood pressure at the ER was 196/104 and her troponin was elevated and reached a peak of around 5. Cardiac Catheterization showed no acute disease but chronic and unsubstantial changes that did not require intervention. An EEG from 3/29 was concerning for subacute seizure like activity and She was started on IV Keppra. MRI at the same time, also revealed a right-sided cavernoma. During her hospital stay, she had ongoing confusion and disorientation with hallucinations, concerning for an encephalitis. She also received 3 days of ceftriaxone for a potential unseen infection, but cultures were negative and PCR for viral pathogens was also normal. She was seen to have leukocytosis but the cause was not determined. Eventually, she regained her baseline mentation with no residual deficits and was discharged on Keppra to follow up with neurology.
1218965	4/16/2021	MO	26	M	4/13/2021	4/15/2021	Per provider notes, 26-year old male was brought to the emergency room after he had an out of the hospital cardiac arrest/seizure. Mother of patient provided initial history. Patient received his first COVID vaccine 2 days ago and the next day he started complaining of some chest pain. Patient woke up on the 15th, mother made breakfast and acting normal. Mother went up to room and found him unresponsive foaming at the mouth and may have been shaking. Paramedics arrived and started CPR and noted he was in V fib and shocked once into an organized rhythm. Patient experienced another seizure in the ED. Patient's family was positive for COVID in January. Patient was tested then and tested positive at hospital. Cycle threshold was 39.9. Patient was intubated initially yet extubated on 4/16/2021

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1220959	4/16/2021	NJ	39	M	3/10/2021	3/10/2021	Passed out; Seizure; Fever; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) and SEIZURE (Seizure) in a 39-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 040A21A) 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). No concomitant medication were reported. On 10-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form Lot # 040A21A.. On 10-Mar-2021, the patient experienced had a fever, passed out and had a seizure On 07 Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form Lot # 045A21A. After 12 hours he passed out and had a seizure. The patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant), SEIZURE (Seizure) (seriousness criterion medically significant) and PYREXIA (Fever). The outcome of passed out, seizure and fever is resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) is not applicable as both vaccines had been administered. Description: On 10 Mar 2021, the patient had a fever, passed out (medically significant) and had a seizure (medically significant). No treatment information was provided. This case was linked to (E2B Linked Report).; 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 is consistent with the known safety profile of mRNA-1273. MOD-2021-072699:2nd dose case
1218185	4/16/2021	FL	41	F	4/15/2021	4/15/2021	patient fainted and had a seizure
1221232	4/16/2021	OH	43	F	4/15/2021	4/16/2021	Patient had a severe shaking experience. It lasted about 5 minutes. Not a seizure but very similar. Patient was aware during the experience. very disoriented afterwards. Patient said she had tingling in her head. which lasted about 1-2 hours.

<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>
1220927	4/16/2021	VA		M	3/9/2021	4/6/2021	seizure or mini stroke; hallucinations; seizure or mini stroke; pain; This spontaneous case was reported by a consumer and describes the occurrence of TRANSIENT ISCHAEMIC ATTACK (seizure or mini stroke), HALLUCINATION (hallucinations) and SEIZURE (seizure or mini stroke) in a 74-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 019B21A and 030b21A) 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 Relevant medical information provided). Concomitant products included GALANTAMINE and LEVETIRACETAM (KEPPRA) for an unknown indication. On 09-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Mar-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 06-Apr-2021, the patient experienced TRANSIENT ISCHAEMIC ATTACK (seizure or mini stroke) (seriousness criterion medically significant), HALLUCINATION (hallucinations) (seriousness criterion medically significant) and PAIN (pain). On an unknown date, the patient experienced SEIZURE (seizure or mini stroke) (seriousness criterion medically significant). At the time of the report, TRANSIENT ISCHAEMIC ATTACK (seizure or mini stroke), HALLUCINATION (hallucinations), PAIN (pain) and SEIZURE (seizure or mini stroke) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment medication included Aspirin. The drug history included "blood pressure medication"; Sender's Comments: 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>
1221179	4/16/2021			M	2/26/2021	3/27/2021	Fever; This spontaneous case was reported by a pharmacist (subsequently medically confirmed) and describes the occurrence of PYREXIA (Fever) in a 53-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 Aspiration pneumonia from 12-Mar-2021 to 16-Mar-2021. Concurrent medical conditions included Cerebral palsy, Spastic quadriplegia, Seizures and Mental disability. 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 27-Mar-2021, the patient experienced PYREXIA (Fever) (seriousness criterion hospitalization). The patient was hospitalized from 27-Mar-2021 to 05-Apr-2021 due to PYREXIA. On 05-Apr-2021, PYREXIA (Fever) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter considered PYREXIA (Fever) to be related. No concomitant medications were reported. Reported confirmed patient was transferred to a long term acute care hospital for antibiotics treatment. 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-2021-078392 (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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1221171	4/16/2021	TX	34	F	4/10/2021	4/11/2021	Went into a seizure; Completely unconscious; Extreme arm pain; Arm swelling; Woke up freezing; Did not feel well; Body aches; Felt tiredness; Felt like fever; Chills; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (Went into a seizure) and LOSS OF CONSCIOUSNESS (Completely unconscious) in a 34-year-old female 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 No adverse event (No reported medical history). Concomitant products included ESCITALOPRAM OXALATE (LEXAPRO) for an unknown indication. On 10-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Apr-2021, the patient experienced SEIZURE (Went into a seizure) (seriousness criteria hospitalization and medically significant), LOSS OF CONSCIOUSNESS (Completely unconscious) (seriousness criteria hospitalization and medically significant), PAIN IN EXTREMITY (Extreme arm pain), PERIPHERAL SWELLING (Arm swelling), FEELING COLD (Woke up freezing), MALAISE (Did not feel well), PAIN (Body aches), FATIGUE (Felt tiredness), PYREXIA (Felt like fever) and CHILLS (Chills). At the time of the report, SEIZURE (Went into a seizure), LOSS OF CONSCIOUSNESS (Completely unconscious), PAIN IN EXTREMITY (Extreme arm pain), PERIPHERAL SWELLING (Arm swelling), FEELING COLD (Woke up freezing), MALAISE (Did not feel well), PAIN (Body aches), FATIGUE (Felt tiredness), PYREXIA (Felt like fever) and CHILLS (Chills) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Apr-2021, Body temperature: 99.5 (High) 99.5. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment medication included paracetamol. 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

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							excluded.
1221150	4/16/2021	CA	46	F	3/16/2021	3/16/2021	Patient experienced tinnitus four hours after injection. The tinnitus occurred 24 hours per day and 7 days per week. The volume fluctuated and was enough to interfere with level of focus and sleep. Small seizure was experienced by the patient approximately 7 hours after second Moderna dose.
1221031	4/16/2021	CA	32	M	3/21/2021	4/15/2021	I was diagnosed with type 1 diabetes in 1997. I have never had any complications. On Thursday, 4/15/21, I had a seizure in bed and was taken to the emergency room. While the cause is unknown at this time, and I doubt it is related to the vaccine, I thought I should report it.

<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>
1220985	4/16/2021	VA	19	M	4/9/2021	4/9/2021	4 seizures; anaphylaxis; This spontaneous case was reported by a physician (subsequently medically confirmed) and describes the occurrence of SEIZURE (4 seizures) and ANAPHYLACTIC REACTION (anaphylaxis) in a 19-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 037B21A) for COVID-19 vaccination. The patient's past medical history included Seizures. Concomitant products included ACETAMINOPHEN, ATOMOXETINE HYDROCHLORIDE (STRATTERA), CLONIDINE, DIAZEPAM (VALIUM), FLUOXETINE HYDROCHLORIDE (PROZAC), LEVETIRACETAM (KEPPRA), ONDANSETRON (ZOFTRAN [ONDANSETRON]), OXYCODONE and OMEPRAZOLE (PROTONIX [OMEPRazole]) for an unknown indication. On 09-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) (unknown route) 1 dosage form. On 09-Apr-2021, the patient experienced SEIZURE (4 seizures) (seriousness criteria hospitalization and life threatening) and ANAPHYLACTIC REACTION (anaphylaxis) (seriousness criteria hospitalization and life threatening). On 09-Apr-2021, SEIZURE (4 seizures) had resolved and ANAPHYLACTIC REACTION (anaphylaxis) was resolving. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter considered SEIZURE (4 seizures) and ANAPHYLACTIC REACTION (anaphylaxis) to be related. Hospitalization unknown meds. This is a 19 -year-old, male patient who received Moderna COVID-19 Vaccine) (batch no. 037B21A) and experienced seizures and anaphylactic reaction one day after receiving second dose of vaccine. Medical hx includes seizures Some relevant conmeds atomoxetine, clonidine, diazepam, fluoxetine, levetiracetam, and oxycodone were provided. Very limited information has been reported at this time. No further information is expected Reporter did not allow further contact; Sender's Comments: This is a 19 -year-old, male patient who received Moderna COVID-19 Vaccine) (batch no. 037B21A) and experienced seizures and anaphylactic reaction one day after receiving second dose of vaccine. Medical hx includes seizures Some relevant conmeds

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

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1220970	4/16/2021	VA	68	F	2/24/2021	3/25/2021	Grand seizure; Circulation of left side was dead; upper back and shoulders and arm aches; upper back and shoulders and arm aches; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (Grand seizure) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 006B21A and 022M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Epileptic seizure. Concomitant products included TIAGABINE HYDROCHLORIDE (GABITRIL) for Epileptic seizure. On 24-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 24-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 SEIZURE (Grand seizure) (seriousness criterion medically significant), ANGIOPATHY (Circulation of left side was dead), PAIN (strong body pain), BACK PAIN (upper back and shoulders and arm aches), PAIN IN EXTREMITY (upper back and shoulders and arm aches) and ARTHRALGIA (upper back and shoulders and arm aches). At the time of the report, SEIZURE (Grand seizure), ANGIOPATHY (Circulation of left side was dead), PAIN (strong body pain), BACK PAIN (upper back and shoulders and arm aches), PAIN IN EXTREMITY (upper back and shoulders and arm aches) and ARTHRALGIA (upper back and shoulders and arm aches) outcome was unknown. Other concomitant medication included: cardatril. Description: The patient experienced on 25 Mar2021, around 15 hours after vaccination grand seizure (medically significant), circulation of left side was dead. The patient also experienced on 25 Mar 2021, strong body pain, upper back and shoulders and arm aches. Treatment information included lorazepam at home. 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-2021-073130 (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. Patient has a Hx of seizure

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1220969	4/16/2021		54	F			Was driving and had a seizure; Banged her head; This spontaneous case was reported by an other and describes the occurrence of SEIZURE (Was driving and had a seizure) 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 (No medical history 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 SEIZURE (Was driving and had a seizure) (seriousness criterion medically significant) and HEAD INJURY (Banged her head). At the time of the report, SEIZURE (Was driving and had a seizure) and HEAD INJURY (Banged her head) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Very limited information regarding these events has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.
1212193	4/15/2021	TN	52	M	4/8/2021	4/8/2021	CHILLS WITH SEVERE TREMORS/CONVULSIONS . EXTREME HEADACHE AND DEHYDRATION. DISORIENTATION. CONTINUED OCCASIONAL CHILLS
1213945	4/15/2021	GA	25	F	4/14/2021	4/14/2021	Systemic: Seizure-Severe, Additional Details: pt had seizure approximately 5 minutes after receiving vaccination,was sitting in waiting are,stood up,passed out,hit head,then seized.was short.called 911.pt apparently has history of seizures with vaccination.was cleared by ems. worker called pt at 6 pm and pt was fine..

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1212935	4/15/2021	HI	69	M	2/18/2021	2/19/2021	The patient is a poor historian and history is obtained from him and his partner. His symptoms have started yesterday after receiving the second dose of a Covid vaccine. The couple went to eat a meal of Chinese food, and that evening the patient developed persistent nausea and vomiting. He had multiple episodes of emesis. According to his partner, he continued to have episodes of emesis this morning. The emesis was nonbilious and nonbloody, described as watery. The patient says he woke up this morning and may have felt some palpitations. He thinks the palpitations may have been worse than usual. He says he generally just felt unwell. He could not get out of bed and move around very much due to the nausea and vomiting. He says that for this reason, he activated EMS who brought him to the hospital. Regarding his atrial fibrillation, he says he is mostly compliant with taking his medications, however he did not take any of his home medications today. In the ER, he was hypertensive to 141/111 and tachycardic to 141, tachypneic to 23. His heart rate went up to the 170s and he was given multiple doses of IV metoprolol. On labs, he had a leukocytosis with a white blood count of 12 and the D-dimer was elevated greater than 20. CTA was obtained to rule out pulmonary embolism which was negative. However, down in the scanner he developed an episode of unresponsiveness with questionable seizure symptoms. He was treated with an LR bolus 500 cc but due to the findings of increased pulmonary vascular congestion, was diuresed with Lasix 80 mg IV x1. Blood cultures x2 were obtained.
1213381	4/15/2021		17	M	4/13/2021	4/13/2021	After receiving first Pfizer vaccine, patient had a vasovagal episode. Patient states he became dizzy, lightheaded, and became diaphoretic prior to syncope. There were some mild seizure-type activity after the syncope. Patient was transferred to the ED. In the ED, patient experienced no further episodes of seizure activities. Patient was evaluated, observed, and later discharged with PCP and neurology referral.

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1213342	4/15/2021	KS	16	F	4/7/2021	4/8/2021	Parent reports seizure on 4/8 at 4:15 an child transported to Hospital. Sent home with ibuprofen. 4/9 at 10:30 PM seizure taken to Hospital. Sent home at 2:00AM with script of Kefir. 4/10 3 seizures back to back went back to Hospital. EEG done and told the are not epileptic seizures may be stress induced . Sent home on 4/11 with appt set up to see neurologist June 28. 4/12 had more seizure went to Med Cent then transferred to Hospital. Stay there and was released on the 13th told seizure could be cause by Migrain and IUD or homones Sent home on reglin and ibuprofen.
1213239	4/15/2021	WI	48	F	4/12/2021	4/12/2021	Grand mal seizure and upper body rash Emergency room treatment (4/12/2021 @ 9:30Pm) including IV saline and magnesium CT scan results were normal Magnesium level normal Follow-up with GP within 48 hours
1213232	4/15/2021	MI	56	M	4/13/2021	4/14/2021	Seizure, convulsions
1213139	4/15/2021	KY	42	M	4/1/2021	4/2/2021	2 grand mal seizures the day after shot, mild (99 degree) fever the night of shot
1213084	4/15/2021	NJ	19	M	4/12/2021	4/13/2021	About 5pm after the vaccine I developed a cramp in my left leg, felt really tired and the fever began. About 10pm the symptoms got worse so I took nyquil because I was feeling horrible. My fever elevted to 101 causing me to have a seizure. EMT transported me to the ER about 12midnight and I was given meds for nausea, pain and monitored and about 3:30am I was released. The next day I was really tired, fatigued and had a really bad headache but by that Wed all symptoms had subsided.
1213022	4/15/2021	NM	29	M	4/11/2021	4/11/2021	This is a secondary VAERS for the same pt. Pt originally was very anxious before the vaccine, got the vaccine and subsequently had lightheadedness and nausea. He was treated for this by laying him down which resolved his sx's almost immediately. Vitals were all normal. He denies CP, SOB, nausea resolved and so did his lightheadedness. About 6 hours after the vaccine, pt was seen in the ER for a seizure. Pt has a hx of a brain tumor with surgical removal. No sz since March 2020, per pt. He was treated for a sz and for sinusitis.

<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>
1213396	4/15/2021	FL	58	F	3/24/2021	3/24/2021	Pt c/o "not feeling well" about 5 minutes after receiving Janssen Covid-19 vaccine on 03/24/2021 at 10:17am. I immediately ran to her car. She was responsive but very pale. She c/o nausea, laid back in care seat and looked to have seizure activity, pulling her left arm up her chest and biting her lip. This lasted several seconds then pt was A&O and in NAD. I yelled to nurse to call 911 and get other provider. HE arrived in 2 minutes. He checked pt's pulse and reported it to be weak and thready. He reported her O2 sat was 83%, but her hands were ice cold. Pt was still answering out questions at this point with no breathing difficulties. PA reported O2 sat back up to 93%. Pt's BP 122/62, HR 100 and RR 20. EMS paramedics arrived in 5 mins. Pt A&O x3 with paramedics and refused transport to local hospital ER for further evaluation and treatment. Paramedics confirmed pt was AMA. Our nurse dialed pt's husband on her cell phone. Pt talked to husband and told him to come get her. Pt was able to move from driver's seat to passenger seat. Her husband picked her up 30 mins later. I continued to check on pt until her husband arrived. Pt remained A&O x3 with NAD.
1212666	4/15/2021	PR	21	F	3/31/2021	4/1/2021	SYMPTOMS PRESENTED: SEIZURES, PALPITATIONS, FEVER, PULSE IN 125-130 FOR SEVERAL HOURS EVEN WHEN I WAS RESTING, BLOOD PRESSURE 86/66
1212496	4/15/2021	CO	60	M	4/8/2021	4/8/2021	Pt. with hx of hypoxia, oxygen at night, CAD, seizure disorder. Started feeling light headed, SOB of 4-5 min. after injection. Pt.brought to procedure room. Initial vs at 4:20, 118/78, p 105, r 18. O2 placed, sat up to 98% on 2l. 911 called. Started feeling better on o2. SOB improved. Due to hx of CAD, epi not given. PE: heart rate reg 95, lungs cta, upper airway without stridor, swallowing well. Squad arrived. Repeat bp 120/80, sat 98%, r 16. pt. exhibited some shakes and felt he might seize. Shakes stopped in 10 sec. Transported in stable condition to ED.
1213973	4/15/2021	AK	31	M	4/7/2021	4/7/2021	No symptoms during the 15 minute waiting period after the vaccine. Started to appear at around 7:30pm according to patients wife. Patient experienced sweating, fast heart rate (140bpm according to wife). The called 911, went to the emergency room. Wife reported patient had seizures in ER.

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1212199	4/15/2021		30	F	4/15/2021	4/15/2021	Soon after receiving shot, PT experienced dizziness and felt like she was going to pass out, medical team arrived to assess. PT was conscious but shortly thereafter, she had a tonic-clonic seizure. This lasted about 2 minutes, then she was post-ictal for about a minute. Then PT was able to answer questions appropriately and knew where she was. V/S were normal including a BP of 105/70, SPO2-100%, HR-70. EMS was called to transport to ER. Over the next several minutes, PT felt dizzy and tingly. She remained stiff in extremities and had a hard time verbalizing, trying to say that her tongue felt stiff. When EMS arrived, they took her blood sugar, which was 120. She was then taken to ER for further evaluation.
1214267	4/15/2021	VA	37	M	4/15/2021	4/15/2021	Patient came to shot ex clinic for 2nd dosing of COVID vaccine. Was screened and received 2nd dose of vaccine then proceeded to waiting area with his spouse for 15 min observation period. After aprox 7 min patient and spouse called over nurse as patient was experiencing one of his "normal-see medical explanation above of patient condition" non-epileptic seizures. Staff of nurse and 4 men performed immediate first aid measures lowering the patient to floor for safety, supporting airway and 911 was called as patient vital signs were elevated. EMS services arrived within 5 min from call and proceeded to care for patient. Patient was given po fluids and nasal versed with good rapid resolution of symptoms. Patient and spouse both declined transfer to local hospital emergency services.
1212121	4/15/2021	OH	18	F	4/7/2021	4/8/2021	Systemic: Body Aches Generalized-Medium, Systemic: Nausea-Medium, Systemic: Seizure-Medium, Additional Details: patient was taken to er after having a seizure. patient has been feeling sick ever since injection and has missed her period. The physicians at the Emergency room said they could not find anything wrong with her. But mother is convinced something is not right. she is seeking a second opinion from different hospital

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1212002	4/15/2021	MD	30	F	4/9/2021	4/9/2021	my daughter, 30 year old, on disability with POTS, MCAS, EDS, dysautonomia, received the JJ COVID vaccine at 1:30 PM on 4/9/2021.. She started vomiting 20 minutes after the vaccine was administered and the pharmacist said it was because she was anxious and has not eaten much. We went home, she was very tired and slept most of the afternoon. At 6 PM she started vomiting again. It continued till 10:30 PM when she could not drink anything. We went to the hospital where she exhibited what looked like a seizure in the waiting room and was admitted to the hospital for observation. Discharged 4/10/2021 evening. 4/11/2021 exhibited restless leg syndrome, could not sit, lay down, whole body aches. 4/12/2021 extremely sore arm, could not move it without pain. Area of injection looks red but not hot and no swelling.
1211965	4/15/2021	CA	27	M	4/14/2021	4/14/2021	Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Medium, Additional Details: Patient presented with seizure like symptoms for 15 seconds. The health hub concierge noticed and called myself over. He was out of it for maybe 15-20 seconds. I asked him questions to see if he was coherent. He was able to tell me where he was and his name. Patient stated he has history of vasovagal syncope so no EMS was required. BP taken at 101/59 on right arm. He waited an hour before leaving with his mother.
1211451	4/15/2021		65	M	4/8/2021	4/10/2021	Pt received Moderna vaccine on 8 Apr. Had partial complex seizure w secondary generalization 9APR c/b tongue bite and bleeding requiring intubation for airway protection. Admitted to hospital, tongue lac repaired, CT w/o evidence of CVA. Transferred to LPMC 10APR. Pt was extubated, had a normal EEG, MRI brain, and discharged home.

<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>
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.
1216226	4/15/2021	MI	21	M	4/15/2021	4/15/2021	Patient experienced a seizure approximately 3 minutes after vaccination.
1212234	4/15/2021	FL	57	F	3/5/2021	3/6/2021	5:30AM 3/6/21 STARTED WITH NAUSEA, VOMITING AND HEADACHE DYSPNEA -- STOPPED AT DUNKIN DONUTS AND DRANK COFFEE WITHOUT IMPROVEMENT. SHE PULLED OVER AND CALLED 911 AND REPORTS PASSING OUT IN THE CAR. EMS ARRIVED AND HAD TO BREAK THE WINDOW TO EXTRACT HER. MEDICAL CENTER EMERGENCY ROOM. SHE HAD TWO WITNESSED SEIZURES WHILE IN THE EMERGENCY AND WAS ADMITTED AND DISCHARGED ON 3/8/2021. WEAKNESS AND SEIZURE WAS HER DIAGNOSIS UPON DISCHARGE. NEUROLOGIST FOLLOW UP WAS YESTERDAY AND SHE IS BEING RX LAMICTAL. EEG SCHEDULED 5/11/21. HISTORY OF SEIZURE TWO YEARS AGO. HER NEUROLOGIST SAID THAT THE VACCINE COULDVE PROMPTED PRE EXISTING CONDITION.

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1214636	4/15/2021	NE	25	F	4/14/2021	4/14/2021	Patient experienced a seizure within 2 minutes of receiving vaccine. seizure lasted approximately 30 seconds. patient recovered and then experienced another brief seizure approximately 5 minutes later. This lasted about another 30 seconds. Seizures displayed muscle rigidity, slight shaking, and dilated pupils. patient became pale and unconscious during these seizures.
1216273	4/15/2021	TX	42	F	3/6/2021	3/6/2021	Muscle Seizures 5-6 hours post vaccine. Full body muscle spasms/seizures that lasted 5-6 hours. Ice cold extremities. Violent shakes. Migraines over the course of the following 4 days and a itchy rash over my face, neck and torso that lasted a full 2 weeks.
1216170	4/15/2021	UT	61	F	4/1/2021	4/1/2021	right after the vaccine in the pharmacy my throat felt like it was closing. and medicine taste going down my throat , pharmacist said no big deal. I went home 4 hours later i had fever and shakes and convulsions and my right finger were numb and my right leg and right low side hurt. My neighbor call the pharmacy and they said its normal to work thru. april6 pain in side was unbearable and i went to the doctor. had a ct scan and they put me on antibiotics.I had had headache for 15 days now. I don?t know how i am going to pay mymedica bill for a free covid vaccine.
1216091	4/15/2021	AZ	39	M	3/23/2021	4/13/2021	Patient at gym working out and had a seizure, when 9-1-1 crews arrived patient was post-ictal, while treating the patient he had another seizure, during transport patient went into cardiac arrest, crews provided ACLS care and transported patient to hospital for treatment. Resuscitation efforts were terminated by physician in emergency room.
1216032	4/15/2021	CO	76	M	3/4/2021	4/11/2021	Patient received 1st Covid-19 Pfiser Vaccine shot on Thursday February 11, 2021. Patient received the 2nd Covid-19 Pfiser Vaccine on Thursday, March 4, 2021. 7 days after second vaccine shot on Thursday, March 11, 2021, patient showed some symptoms of a itchy-horsed throat & a slight dry cough. Called doctors - they said nothing to worry about, drink hot fluids and take couch drops. It went away in 2-3 days. Exactly 4 weeks after second Covid-19 Pfiser vaccine on Thursday, April 1st 2021, patient was sent to the ER for a seizure.

<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>
1215978	4/15/2021	CA	19	F	3/24/2021	3/24/2021	Severe vertigo day of and day after Continued dizziness since vaccination 2 seizures on 4/13/2021, taken to Hospital via ambulance
1215963	4/15/2021	NY	36	F	4/15/2021	4/15/2021	patient was very nervous before getting vaccine. I tried to reassure her, then she seemed ok to proceed. she was sitting in the waiting area after getting the vaccine when she started to feel faint. She told my tech that she is "passing out". I came out to check on her.....and her head was going back. I ran to then chair she was sitting in and held her by her shoulder in the chair so not to fall on the floor. she stiffened up and didn't respond to me calling her name . then suddenly she woke up. she asked ,"did I pass out?" She was ok to sit in the chair after that. we called 911. the EMTs checked her out. She told them that she has had a history of passing out after getting a needle. she also told them she had seizures as a child but that was over 25 years ago. she refused to go to the hospital. EMTs called her family and they came to get her. EMTs said that it seems that she had an anxiety attack. no anaphalactic reaction. They said her pressure normalized before she left.
1215871	4/15/2021	PA	27	F	4/15/2021	4/15/2021	Pt received Moderna dose #1. Pt experienced whate looked to be seizure and temprry loss of consciousness about 8-10 mins. into 15 min post-vaccine observe time. Pt was gently placed on floor and legs elevated by staff 911 called. EpiPen on hand, but not used as patient regained consciousness within 1 min or so and no c/o SOB, airway constriction - could verbalize same. Pt lucid and conversational, but did ask "why am I on the floor" - no recollection of syncope or seizure. No hx of seizure disorder, diabetes, or needle phobia, but states she did feel similar when naval piercing took place.
1215857	4/15/2021	NC	21	F	4/3/2021	4/4/2021	101 fever, Extreme Headache with pain to touch hair, left hand pain, and body twitching. VNS implant device for seizures constantly provided autostimulations, which is not a normal occurrence. Provided OTC Ibuprophen 800mg every 6 hrs and kept hydrated.

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1215581	4/15/2021	MN	25	F	4/15/2021	4/15/2021	At 2:43pm patient received the vaccine in her arm. At 2:50pm my pharmacy technician witnessed the patient standing up from her chair and walk up to the pharmacy counter then faint into the pharmacy immunization booth. My technician states the patient did not hit her head on a wall. At 2:51pm my pharmacy technician brought the incident to my attention and we both ran to the patient to address the situation. The patient was unresponsive, so I ran and dial 911 then instructed my tech to take the phone. I then ran back to the patient and patted her back, said her name and asked her if she could hear me. It was at that moment the patient's eyes flickered and the patient had what looked to me like a 10 second seizure in the chair inside the pharmacy booth. Once the patient was done what I could only identify as seizing, she came to and I asked her if she new her name and where she was. The patient answered correctly and then asked me "Have you had anyone with a reaction like this before?". I answered that I have not personally witnessed a reaction like this before. My technician had 911 still on the phone and they instructed her to stand out front of the store to await the ambulance. A first responding officer came in and asked about the witnesses to the incident then took over for caring for the patient.
1214206	4/15/2021	CA	27	M	4/6/2021	4/6/2021	Seizure. Lasted approximately 5 minutes. Outcome was positive and no lingering effects.

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1214872	4/15/2021	NY	42	F	4/8/2021	4/8/2021	During 15 minute waiting period, I started having increased heartbeat and overwhelming nausea. I reported it to the nurse, she took my vitals and my heartbeat was 140-150. My O2 levels were fine and my lungs were clear. Approximately 15 -20 min post vaccine I started having seizures.(I have no history of seizures) I was given Epinephrine, benadryl to calm my body down. It did not change any of my symptoms. I had approx. 5 seizures in the facility before they called the ambulance. I had 3-4 on way to hospital and more once I arrived. I was given ativan to help me relieve the symptoms. I was given a CAT scan and there were no issues as per doctor. I did not have any more seizures and I was sent home. The next morning I had a doctors appointment and started having seizures again. I had about 4 at home, ambulance was called and had more seizures throughout the day. I was admitted to hospital since my seizures were not stopping. I was given another CAT scan and MRI and nothing was was found in either test.
1214014	4/15/2021	WA	33	M	4/15/2021	4/15/2021	Patient was in post observation and reported to post observation RN dizziness. While Pt was speaking with RN, he had "full body convulsions/twitching and his eyes rolled back". The post observation RN reported this event happened 2 times and was done in less than 2 min. EMT's called to scene. Pt reported ringing in ears, and was diaphoretic after the event. Pt was immediately able to speak, and drank water. Pt was not postictal. Pt became pale after vaccine administration. No PMH, No Allergies, No meds taken daily or given at site. VSS throughout. EMTs took over care of Pt and stayed with Pt until wife came and picked him up. VS: BP: 118/78 HR: 68 RR:22 O2 sat: 99% on RA
1214631	4/15/2021	NC	18	F	4/9/2021	4/10/2021	Chills, shortly followed by shivering and chattering. The shivering is so intense it essentially renders the patient in a state of involuntary writhing; muscles across the body, even if not in movement, may be tensed to the point of pain. Muscles affected lie in the legs, arms, and torso. An observer might mistake the event for a seizure, though the patient is fully conscious for the duration. The episode lasts only a few minutes; such an episode has only occurred once.

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1214542	4/15/2021	MN	36	F	3/28/2021	3/28/2021	Lightheaded then passed out, woke up with chest pain, gradually very low pressure and seizure
1214500	4/15/2021	WA	42	F	4/2/2021	4/14/2021	Patient at 27 weeks of pregnancy, reported to midwife at regular visit on 4/14/21 that she was experiencing SOB but all blood work normal - assumed normal SOB with pregnancy. Night/morning of 4/15 started seizures, transported to ED. Diagnosed with massive pulmonary embolism. Emergency C-section performed by Dr. Pt. did not survive.
1214393	4/15/2021	PA	57	F	3/14/2021	4/6/2021	Started having a headache on Tuesday afternoon, took migraine pill (excedrin) with minimal improvement. Went out to dinner later that night and couldn't finish dinner d/t HA. Describes head pressure, pain, and pounding sensation. On Wednesday worked from home, felt like she was in a fog and continued to have pain/pressure in the back of her head. Pt took a nasal decongestant which pt is unsure if made any better. Thursday continued to have headache but improved compared to Tuesday and Wednesday. Had taken benadryl at school which was somewhat helpful. Saw PCP today via telemedicine visit. PCP prescribed steroid; had not started taking this because started feeling worse and came into the ED for this. Earlier today, had worsened HA and felt like she was going to pass out (did not pass out). She felt like her left hand was numb/pins/needles as her son was taking her BP; lasted for a few minutes. Later, her right hand started feeling numb/pins/needles and had difficulty picking up objects. 57-year-old female presented with a headache and found to have a subdural hematoma of unknown etiology. Neurosurgery was consulted. Patient was initiated on Keppra 500 mg b.i.d. for seizure prophylaxis. Serial CT scans were done Which showed stable subdural hemorrhage. Blood pressure was monitored during her stay but did not require any as needed medication. Further imaging including MRI and MRV were performed to assess for aneurysm or venous malformation however nothing was seen. Bleeding disorder workup was not performed. Neurology was consulted. EEG was ordered to assess for seizure activity however this was negative.

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1214363	4/15/2021	NH	36	M	4/10/2021	4/10/2021	After receiving vaccination recipient was driving into observation when seizure like activity was observed. Car was put into park, scene safe. Chief Medical Officer on scene. EMS called to scene. Recipient c/o nausea and appeared diaphoretic. Vitals @1009 - BP 122/76 - O2 99% r/a - P48- RR 16. 12 Lead EKG completed by EMS reviewed by Drs. It was recommended by Dr. that recipient be transported to Hospital for further evaluation. Recipient refused transport against medical advice. Recipient signed refusal of transport with EMS and had a friend pick him up. Vitals @ 1045 - P113/68 - O2 95% r/a - P49 - RR 16 AAOx4 per EMS.
1215813	4/15/2021	AL	43	F	3/30/2021	4/1/2021	Got shot on the 30th, on April 1st, 5th, 14th and 15th I have had mini seizures. No history of any either. They can't find out what has caused the seizures. But the vaccine is the only thing that has changed. All test have come back clear so far.
1214232	4/15/2021	IL	43	F	4/15/2021	4/15/2021	Patient with a long standing history of complex partial seizure disorder. Patient was taken to the ER with a concern for seizure onset as witnessed by the nurse observer post vaccination
1214071	4/15/2021	OK	27	F	3/19/2021	3/19/2021	Passed out and experienced involuntary shaking (possibly tonic-clonic seizure)

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1214068	4/15/2021	IN	20	F	4/13/2021	4/14/2021	Before I went to bed at around 11:30pm the day of my shot (4/13), I took one extra strength tylenol as prevention. I woke up around 2:40am 4/14 trembling as if I was having a seizure (it did not feel like chills) and extreme aches. I took my temperature and was at 100.8. I took another extra strength tylenol and tried to calm down. At around 3:30 the trembling stopped and I was finally able to relax a bit. I fell back asleep around 5am and woke up at 9:00am with more extreme aches and pain. I switched to ibuprofen (400mg) and that worked way better. My fever was at 101.8 when I woke up. Around mid morning and afternoon I was feeling fine just a bit achy and fatigued and my fever broke to 99. I took a nap around 2pm and woke up feeling bad again with a fever of 100.6. I took another 400mg of ibuprofen and that got me through my class and the evening feeling okay. Before bed, I was feeling achy and fatigued yet again. I took 200mg of ibuprofen and went to bed just fine. I woke up at 4:30am 4/15 for my clinical feeling back to normal. I have been fine ever since.
1215142	4/15/2021	PA	23	M	4/15/2021	4/15/2021	Post vaccine pt experienced multiple sneezes and became lightheaded. Pt assisted to floor by staff. Transported to med obs at 1300 via stretcher. Vitals obtained and monitored. While in med obs pt became nauseated and had several episodes of emesis. Water and saltine crackers given. All symptoms resolved. Pt released to home by self at 1405. After pt was released, med obs staff was informed by vaccinator that pt appeared to have seizure like activity after vaccine was given. Pt was then in and out of consciousness and was assisted to the floor at that time. Vitals as followed: 1303 LYING BP 115/64 HR 61 RR 12 SPO2 94% 1310 LYING BP 123/59 HR 63 RR 12 SPO2 96% 1314 LYING BP 102/45 HR 86 RR 14 SPO2 95% 1322 LYING BP 113/59 HR 65 RR 14 SPO2 95% 1337 SITTING BP 93/66 HR 67 RR 14 SPO2 97% 1339 SITTING BP 115/67 HR 74 RR 14 SPO2 96% 1343 STANDING BP 108/66 HR 69 RR 14 SPO2 96% 1354 STANDING BP 132/65 HR 64 RR 14 SPO2 97%

<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>
1216510	4/15/2021	OH	58	F	4/8/2021	4/9/2021	I carried a fever, and had flu symptoms , with a horrible headache, and body aches for over a week. I also had quite a few seizures which is unusual for me. Some trouble thinking at times .(this could be from the seizure activity) Extreme fatigue.
1215460	4/15/2021	DE	23	M	4/15/2021	4/15/2021	PT APPEARED TO BE HAVING A SEIZURE THE PHARMACIST WAS PREPARING THE EPI-PEN WHEN THE PATIENT CAME AROUND. THE PARAMEDICS WERE CALLED. WHEN THE PARAMEDICS ARRIVED PT WAS ORIENTED AS TO TIME AND PLACE WHILE PARAMEDICS WERE TALKING TO THE PATIENT HE AGAIN APPEARED TO HAVE ANOTHER EPISODE. AT THAT TIME THE DECISION WAS MADE TO TAKE THE PATIENT TO EMERGENCY DEPARTMENT
1216541	4/15/2021	NM	30	F	3/28/2021	3/31/2021	Had approx 10-15 min convulsive seizure Went to ER, no treatment given Followed up with neurologist who increased Zonegran to 500 mg
1208976	4/14/2021	NY	52	M	4/14/2021	4/14/2021	52 y/o (M/F) with PMHx of chronic lower back pain began to feel lightheaded 1 minute after receiving the Covid vaccine (2nd dose). He LOC for 10 seconds. He became diaphoretic and pale. Denies headache, vertigo, seizures/PMHx of seizures, numbness/tingling/parasthesias, throat irritation, throat tightness, SOB, dyspnea, palpitations, chest pain, chest tightness/heaviness, hives, rash, peripheral or facial edema, nausea, vomiting. Patient was immediately assessed by EMT and clinical leads. Vitals were taken immediately. Given oral fluids (water/orange juice) and cookies.
1208985	4/14/2021	NY	52	M	4/14/2021	4/14/2021	52 y/o (M/F) with PMHx of chronic lower back pain began to feel lightheaded 1 minute after receiving the Pfizer vaccine (2nd dose). He LOC for 10 seconds. He became diaphoretic and pale. Denies headache, vertigo, seizures/PMHx of seizures, numbness/tingling/parasthesias, throat irritation, throat tightness, SOB, dyspnea, palpitations, chest pain, chest tightness/heaviness, hives, rash, peripheral or facial edema, nausea, vomiting. Patient was immediately assessed by EMT and clinical leads. Vitals were taken immediately. Given oral fluids (water/orange juice) and cookies.

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1209041	4/14/2021	CT	18	F	4/12/2021	4/12/2021	Mild seizure, passed out
1209101	4/14/2021	OH	26	M	4/6/2021	4/7/2021	Within 12 hours of injection: Body aches, fever, severe chills (convulsions), headache, nausea, threw up three times, passed out.
1209176	4/14/2021	CA	49	M	3/14/2021	3/15/2021	>Vaccination given- Janssen 03/14/2021 c/o onset of headache 03/15/2021 lasted 3 wks, resolved and started again 04/13/2021, pain to bilateral temporals radiates to occipital area, current pain 7/10, best pain 5/10, worse 10/10, pain is continuous, improves with Acetaminophen, exacerbated with activity, no Hx of chronic headaches not described as "worse headache of my life" >denies pain, swelling to injection site, fever, chills, fatigue, body aches, abdominal pain, leg pain, hives, trouble breathing, n/v, diarrhea, neurological deficits, change in level of consciousness, seizure activity, visual disturbances
1209922	4/14/2021	TN	46	M	4/12/2021	4/14/2021	The patient reports that he had 8 seizures the day after receiving the vaccine.
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
1209268	4/14/2021		29	U	3/6/2021	3/6/2021	Collapsing or losing consciousness & Seizure.

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1209338	4/14/2021	CA	49	F	3/15/2021	3/18/2021	Vaccination given- Janssen, 03/15/2021, right deltoid c/o fever day of vaccine, subjective lasted 3 days 03/18/21,onset of upper abdominal pain,left arm pain, left foot swelling, ankle to toes, currently swelling to foot has resolved, continues to have left arm pain, tingling sensation to left arm and abdominal pain with intermittent SOB "It is not related to my asthma" abdominal pain is intermittent, happens at random times, currently abdominal pain 4//10, best 0/10, worse 9/10, Acetaminophen relieves the symptoms, not sure what is exacerbating the pain >denies pain, swelling to injection site, fever, chills, fatigue, bodyaches, leg pain, hives, n/v, diarrhea, neurological deficits, change in level of consciousness, seizure activity, visual disturbances
1209359	4/14/2021	PR	40	M	4/13/2021	4/13/2021	After vaccine was given at clinic, patient had a seizure episode as per nurse staff
1209572	4/14/2021	GA	21	M	4/13/2021	4/13/2021	Patient stayed in pharmacy area for 15 minute observation time. Was released from pharmacy in good condition and left to shop with parents and sister. Approximately 5 minutes later, sister came and said he was very dizzy and sitting in chair in store. Pharmacist checked BP 131/75 HR 97. Patient had not eaten breakfast, was dizzy and shaking. Parents had gotten him a sandwich and orange juice was added in case due to blood sugar drop. Parents stated he was not presenting as having a seizure. He began feeling nauseous and vomited 3 times while waiting for EMTs to arrive. EMTs checked him out, blood sugar 93. They took him to ER to be examined and was released to go home later same day. Per conversation with parent that evening, he was doing better after having several episodes of vomiting at hospital.

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1209733	4/14/2021	NJ	43	F	4/7/2021	4/7/2021	I felt very dizzy about 15 minutes after the vaccine. The girl next to me that had just had it had a seizure so thought it was nerves at first. That went into pressure in my head, my tongue got numb and started to swell, started coughing up blood. I took prednisone and used my epipen. When I got home I was terrified to go to the hospital. The oral swelling subsided. The head pressure lasted at least 12 hours. My bp was real low (70/45). It did slowly come back up. Cough and chest congestion is still present. Brain fog. Fever lasted about 4 days. This is the second report I'm putting in. I did not hear back on the last one submitted 4/8
1209236	4/14/2021	OH	32	F	4/14/2021	4/14/2021	Patient felt hot and then she felt syncopal then appeared to have a grand mall seizure. She displayed posturing and was unresponsive for ~ 10-15 seconds. No loss of bladder control. BP 125/78 HR 42. Squad was called. BP 136/76 HR 75 O2 sat 99% Squad arrived. Patient is now responsive. Nursing staff has called her husband. He states this happens when she has an injection. He stated that he will come pick her up and he did not want her going with the squad. Patient spoke to her husband. Patient is refusing transport with squad stating that her husband is a PA and is on his way to pick her up. BP 126/80 HR 69 O2 Sat 98%. Squad left. Patient states that she feels better, She sat up. Patient now reports that she feels nauseated. Patient vomited. BP 127/55 HR 76 O2 Sat 99%. Patient's husband has arrived. Patient reports feeling well. Vitals standing BP 117/86 HR 69 O2 Sat 100%.

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1210672	4/14/2021	SC	37	F	4/14/2021	4/14/2021	37 yo obese dependent female with severe vasovagal reaction after a 30 minute wait time someone walking by noticed patient was not looking well and informed the observation staff. Nurse called for assistance and began talking with the patient. Provider arrived and patient was pale, slumped in chair but conversive. Upon assisting patient to the floor she became unconscious and we laid her down. EMS was requested. Over the next few minutes had 3 episodes of LOC with brief ~5 seconds of breathing cessation and seizure like activity with significant head shaking sometimes involving upper torso followed by coughing and retching without actual vomiting. Due to this she was placed in left lateral recumbent position with the first episode. Each time she awoke she appeared confused but was able to answer questions. Oxygen was applied with pulse oximetry but unable to obtain BP during this time. After the third episode she suddenly asked what happened and mentation returned to normal. Upon Fire/EMS arrival was conversing normally on the floor on her left side. Reported multiple food/environmental allergies and metformin allergy. History of suspected seizure but nothing proven. Reported before her vaccine that last time she experienced a brief LOC hours ~12 hours after her first vaccine. She had arranged for someone to stay with her tonight in case she felt faint again.
1209856	4/14/2021		66	M	4/14/2021	4/14/2021	received 2nd dose today and approximately 2 minutes after receiving vaccine, became unresponsive. I was present and carried behind the curtain and placed the on the floor. began to posture and have tonic clonic movement. Pupils were fixed and dilated. This lasted nearly 3 minutes during which time his airway and C spine was protected and an ambulance was called. regained consciousness and stated that he has passed out from vaccines several years ago. does not have a history of seizure. A complete neuro exam was performed: intact as tested, cerebellar exam is intact, speech is of a regular and steady cadence, transported to ED

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1208704	4/14/2021	TX	37	M	4/14/2021	4/14/2021	The patient experienced a generalized seizure lasting approximately 30 seconds with urinary incontinence. The patient remained unconscious for approximately 1 min post seizure and remained in a post-ictal state for approximately 3 minutes until normalization of mental status. The patient was transported to the hospital via ambulance for further evaluation.
1209957	4/14/2021	FL	27	F	4/14/2021	4/14/2021	PT FAINTED ABOUT 10 MINUTES AFTER VACCINE WAS ADMINISTERED, FELL FORWARD FROM SEATED, HIT HEAD ON GROUND, HUSBAND CALLED EMT, PARAMEDICS ARRIVED TO TAKE PT TO EMERGENCY ROOM, PT HAD SUFFERED FROM POSSIBLE SEIZURE AND CONCUSSION
1209977	4/14/2021	OH	26	F	4/14/2021	4/14/2021	Client experienced seizure-like activity immediately following receipt of the first dose of Pfizer vaccine. Client reaction lasted for approximately 45 seconds while inside of the vehicle. Vehicle was in park during the reaction. Client regained consciousness and was then moved from the vehicle onto a stretcher by EMS team. EMS team provided treatment onsite including starting an IV, checking blood sugar, and checking vital signs. Blood sugar was 103 and BP 92/53. Client was transported to Hospital by EMS.

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1210043	4/14/2021	CA	64	M	4/9/2021	4/9/2021	Medical Summary - Friday, April 9, 2021 Patient received 2nd Moderna vaccination at Care Center. (1st Vaccination at Care Center unremarkable.) Approximately five minutes after vaccination, seated in Observation area patient leaned forward with elbows on knees, when asked stated he felt light-headed, put his head between his knees, wanted to lie down. He lowered himself to floor, with help transferred to different chair, sipped water, given lollipop, suddenly unresponsive, eyes glazed and rolled back, teeth clenched on lollipop stick, leaning to left side, incontinent of urine, no abnormal arm or leg movements, duration ~ or under 1 minute. Lollipop removed by staff, vitals: BP 1 Additional information for Item 18: Lollipop removed by staff, vitals: BP 117/72, P68, SpO2 Room Air 96%: now alert and oriented x4, no shortness of breath, no chest discomfort, able to sit in chair without support, was surprised by incontinence. Stated he felt sleepy, tired, and with staff assistance walked to next room for observation where he laid down on carpeted floor. He had no further episode of LOC, remained alert and oriented but continued to feel "tired". No complaints of chest discomfort or shortness of breath. ~ One hour post-incident BP 94/58 with repeat BP 120/82. ~ Two hours post-incident BP 118/80 (his usual he said) sipped water and electrolytes solution. Patient verbalized several times this event much different from previous events associated with blood draws which he described like typical vasovagal reactions with recovery within ~ 15 minutes. Drs. spoke with patient via telephone: PLAN o Can go home today o Do not drive today o Son will pick him up and stay with him for about 24 hours until wife returns from out of town o Appointment scheduled with PA at PMD office for Monday April 12 @ 8:00am – Patient called the office and I listened via speaker, his PMD is out-of-office till later in month, this is first available at the practice o Dr. recommend PMD work-up to also include EEG and CT Scan o R/O vasovagal event v. seizure v. other etiology o Dr. will contact him by phone later today PA-C MD

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1210142	4/14/2021	TX	20	F	4/7/2021	4/14/2021	Patient was working and fell on the job due to what was perceived to be a seizure. Paramedics were called, and patient was taken to the emergency room. Initial reports from the hospital are that patient has clotting in the arm around the injection site. Patient is still at the hospital at the time of this report.
1210317	4/14/2021	OH	58	M	3/17/2021	3/22/2021	We both got our shot at the same time on March 17, 2021. Then on March 22, 2021 at 9:20 PM my husband suffered cardiac arrest and a seizure. His heart was revived however, due to lack of oxygen to his brain he suffered brain damage and never regained consciousness and passed on 4/3/21 with acute respiratory failure.
1210338	4/14/2021	VA	18	F	4/1/2021	4/2/2021	Seizure
1210459	4/14/2021	TX	29	F	4/9/2021	4/9/2021	patient fainted, loss of hearing in ear, had a brief seizure
1210580	4/14/2021	OH	19	F	3/27/2021	4/7/2021	Seizure for about 1 minute - convulsing.
1210607	4/14/2021	MS	32	M	1/1/2021	4/11/2021	I had a grand mal seizure in April.
1209798	4/14/2021	PR	23	M	4/10/2021	4/10/2021	PATIENT PASSED AT HOME, BEGAN TO SWEAT COLD AND FELT UNCONSCIOUS. THE PATIENT WAS COLD TO THE TOUCH, GOT UP A LITTLE DAZED, HE WAS COLD HIS PULSE WAS LOW, THE BLOOD PRESSURE WAS OK. THE COUPLE REPORT THAT LOOKED LIKE A TYPE OF SEIZURE WHAT HAPPENED.
1208044	4/14/2021	IL	28	M	4/13/2021	4/13/2021	Client fell out of chair and hit his head. Began to seizure Left arm pain after pfizer injection. EMS called
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.

<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>
1206363	4/14/2021	CA	16	M	4/12/2021	4/12/2021	Within a few seconds of receiving vaccine, patient had a seizure last approx 10 sec. Code blue called, transferred to ED for evaluation. Stable and discharged home following event. Mom later reported previous hx of seizure following vaccination.
1206564	4/14/2021	TX	45	M	4/7/2021	4/7/2021	I started shivering uncontrollably in the evening. I could not warm up, and my body was shivering. I wasn't sure if I had a fever, but I did not feel well. My wife was trying to warm me up and she thought I was having a seizure because she had never felt someone shiver so violently. My eyes were watering abnormally as well. The shivering subsided after about 30 minutes. I was soar and weak over the couple of days, but I believe those are normal symptoms.
1206890	4/14/2021	OR		U	4/1/2021	4/1/2021	Major motor seizure; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a physician (subsequently medically confirmed) and describes the occurrence of SEIZURE (Major motor seizure) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event (No recorded 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, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced SEIZURE (Major motor seizure) (seriousness criterion medically significant). At the time of the report, SEIZURE (Major motor seizure) 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. Concomitant product use was not provided by the reporter. 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 this 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>
1206907	4/14/2021	NY	73	M	3/1/2021	3/27/2021	Seizures; fall; was scheduled for his 2nd dose on 29-Mar-2021 but did not receive it due to him being in the hospital; This spontaneous case was reported by a patient family member or friend (subsequently medically confirmed) and describes the occurrence of SEIZURE (Seizures) and FALL (fall) in a 73-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. The patient's past medical history included Seizure (Has a history of a stroke and seizure for the past 2 years.) and Stroke. On 01-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 SEIZURE (Seizures) (seriousness criterion hospitalization) and FALL (fall) (seriousness criterion hospitalization). On an unknown date, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (was scheduled for his 2nd dose on 29-Mar-2021 but did not receive it due to him being in the hospital). The patient was hospitalized on 27-Mar-2021 due to FALL and SEIZURE. At the time of the report, SEIZURE (Seizures), FALL (fall) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (was scheduled for his 2nd dose on 29-Mar-2021 but did not receive it due to him being in the hospital) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medications were not reported. Treatment information was not provided. The patient has been hospitalized since. He was waiting to go to rehab but was uncooperative. No fractures were noted.

<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>
1206911	4/14/2021	FL		M	3/25/2021	3/27/2021	Myoclonus seizures; His face went numb and the rest of body went numb/everything feels springing when walking on the inside and the outside of his body because of the numbness; face red swollen and thick tongue swollen; blood pressure lower one was 121 elevated; constant so sore throat and throat swelling; deep hoarse sound to his throat which is not how he normally sounds when speaking; spikes of heat within his body, almost neurological and like hot flashes; lost ten pounds of weight; decreased appetite; loud ringing in ears; inside of his mouth described as chewed up, due to loss of sensation due to numbness and swelling; constant so sore throat and throat swelling; severe anaphylactic reaction including that he could not breath; tongue was thick and swollen; swollen glands on both sides of neck; feels like he is almost in a dream state; trouble keeping his balance, described as being still wobbly; Severe anaphylactic reaction including that he could not breath; left side chest pain; blurry vision; This spontaneous case was reported by an other and describes the occurrence of ANAPHYLACTIC REACTION (Severe anaphylactic reaction including that he could not breath) and SEIZURE (Myoclonus seizures) in a 56-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 018BZ1A) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Allergy to arthropod sting. Concomitant products included VERAPAMIL, HYDROCHLOROTHIAZIDE and CELECOXIB (CELEXA [CELECOXIB]). On 25-Mar-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 27-Mar-2021, the patient experienced VISION BLURRED (blurry vision) and CHEST PAIN (left side chest pain). On 29-Mar-2021, the patient experienced ANAPHYLACTIC REACTION (Severe anaphylactic reaction including that he could not breath) (seriousness criterion medically significant). On an unknown date, the patient experienced SEIZURE (Myoclonus seizures) (seriousness criterion medically significant), HYPOAESTHESIA (His face went numb and the rest of body went numb/everything feels springing when walking on the inside and the outside of his body because of the numbness), SWELLING (face red swollen and thick tongue swollen), BLOOD PRESSURE

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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INCREASED (blood pressure lower one was 121 elevated), STOMATITIS (constant so sore throat and throat swelling), DYSPHONIA (deep hoarse sound to his throat which is not how he normally sounds when speaking), HOT FLUSH (spikes of heat within his body, almost neurological and like hot flashes), DREAMY STATE (feels like he is almost in a dream state), BALANCE DISORDER (trouble keeping his balance, described as being still wobbly), WEIGHT DECREASED (lost ten pounds of weight), DECREASED APPETITE (decreased appetite), TINNITUS (loud ringing in ears), SENSORY LOSS (inside of his mouth described as chewed up, due to loss of sensation due to numbness and swelling), OROPHARYNGEAL PAIN (constant so sore throat and throat swelling), DYSPNOEA (severe anaphylactic reaction including that he could not breath), TONGUE DISORDER (tongue was thick and swollen) and LYMPHADENOPATHY (swollen glands on both sides of neck). The patient was treated with ACETAMINOPHEN (TYLENOL) on 05-Apr-2021 at an unspecified dose and frequency and DIPHENHYDRAMINE HYDROCHLORIDE (BENADRYL A) on 05-Apr-2021 at a dose of 50 mg. At the time of the report, ANAPHYLACTIC REACTION (Severe anaphylactic reaction including that he could not breath), SEIZURE (Myoclonus seizures), HYPOAESTHESIA (His face went numb and the rest of body went numb/everything feels springing when walking on the inside and the outside of his body because of the numbness), SWELLING (face red swollen and thick tongue swollen), BLOOD PRESSURE INCREASED (blood pressure lower one was 121 elevated), STOMATITIS (constant so sore throat and throat swelling), DYSPHONIA (deep hoarse sound to his throat which is not how he normally sounds when speaking), HOT FLUSH (spikes of heat within his body, almost neurological and like hot flashes), VISION BLURRED (blurry vision), DREAMY STATE (feels like he is almost in a dream state), BALANCE DISORDER (trouble keeping his balance, described as being still wobbly), CHEST PAIN (left side chest pain), WEIGHT DECREASED (lost ten pounds of weight), DECREASED APPETITE (decreased appetite), TINNITUS (loud ringing in ears), SENSORY LOSS (inside of his mouth described as chewed up, due to loss of sensation due to numbness

<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>
							and swelling), OROPHARYNGEAL PAIN (constant sore throat and throat swelling), DYSPNOEA (severe anaphylactic reaction including that he could not breathe) and LYMPHADENOPATHY (swollen glands on both sides of neck) was resolving and TONGUE DISORDER (tongue was thick and swollen) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Based on the current available information and the temporal association of 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 of the product use and the start date of the events a causal relationship cannot be excluded.
1206968	4/14/2021	TX	46	F	4/13/2021	4/13/2021	Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Additional Details: patient passed out and fell over and hit the floor face forward. bruised face and chipped tooth.911 was called and patient was taken to er. Not sure on final outcome. Called husband to check on patient and have not received a call back. will call again.
1207107	4/14/2021	TX	25	M	4/13/2021	4/13/2021	Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Severe, Systemic: Vomiting-Medium, Additional Details: Syncope; normal bp; hr 80; hx of syncope from dental procedure. No hx of seizure.
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.

<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>
1207446	4/14/2021	TX	21	M	4/13/2021	4/13/2021	Client passed out while seated in observation falling to the right side of the chair and onto the ground Client landed face down on the floor and was turned over onto his side first before being flipped onto his back Client's head did hit the ground Client reportedly appeared to be having a seizure when he was turned over Multiple people were present to assist client including nurse and EMT At 12:09, LVN called 911 and relayed information to the dispatch While on the phone, nurse went to get an Ambu-bag because staff present reported that the Client stopped breathing but had a pulse Upon bringing the Ambu-bag, the Client had already regained normal breathing pattern and no longer needed assistance breathing . Ambu-bag was present but was not used Client was assisted into a wheelchair and taken to the private recovery area. Physician, nurse, and EMT were present Client was alert enough to answer questions Client began to vomit / dry-heave for a short moment Client asked EMT about transport billing and was informed that he might possibly get a bill but that he had the option to choose not to pay it At 12:20, Vitals taken BP 155/112, Pulse 64 Client informed of the need to be further evaluated at the hospital Client verbalized multiple times that he did not want to be transported even after speaking with the physician Physician suspected that the client had some underlining reason that he did not want to disclose regarding his refusal to be transported At 12:25, Vitals taken BP 135/83, Pulse 58, O Sat 97% Blood sugar reading 104 Client reports no pain in the head, no nausea Client reports that he did not eat anything prior to coming At 12:31, Ambulance arrives EMT briefs paramedic regarding the incident and the client's history Paramedics questioned client Client signed form and verbalized that he did not want to be transported and felt well enough to leave Client called his brother to drive him home At 12:41 Client was wheeled in the wheelchair to the car Client informed of selfcare and instructed to go to the hospital / ER if symptoms worsen or headaches develop Client informed to let further vaccine administrators know that he passed out in the past and needs to have the injection lying down Client verbalized understanding Client's brother drove him home

<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>
1207734	4/14/2021	CO	25	F	3/26/2021	3/27/2021	Patient experienced an elevated temperature up to 104 degrees F 24hrs post vaccination along with some reported confusion. Over the next 48 hrs temperature fluctuated between 102-103 degrees. She reports confusion and difficulty with movement to lower extremities. Per her report she "felt like she had a stroke". Presented to the ER on 4/3/21 due to chest pain, no physical findings diagnosed with the exception of potential psychosis per patient report. Over the next week, patient reports experiencing seizure-like activity and pronounced difficulty with speech (stutter). Again went to ER on 4/10/21. Diagnosed with conversion disorder. on 4/13/21, seizure like activity persisted along with speech disturbances. ER referred to outpatient neurology. Additional symptoms experienced include headache and weight loss since 3/26/2021
1207815	4/14/2021	AR	27	M	4/13/2021	4/13/2021	Syncope with seizure like activity. Bradycardia and hypotension, HR 30-40 BMP

<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>
1208926	4/14/2021	FL	19	F	4/14/2021	4/14/2021	<p>This is a 19 y.o. female status post 1st dose of Moderna vaccination on 04/14/21 at 130PM. Patient was outside under the tent waiting 15 minutes post vaccination when she fell out of her chair and onto the ground. Upon arrival, patient was lying face down and unresponsive. 10 seconds later patient regained consciousness, but was lethargic, clammy and pale. Patient is nauseous and vomiting. With assistance, patient was transported via wheelchair inside the modular unit in the parking lot. Reports eating a cookie this morning. Last meal was last night and it was a bowl of spaghetti. Patient reports having a syncopal episode and seizure 5 months ago after getting a COVID-19 nasal testing. Denies any medical history, no NKDA, no medications, no recent illness. Initial VS at 1400 was 90/56 HR 52, O2 sats 98% on room air. Denies SOB, denies difficulty breathing, denies chest pain, denies HA, denies dizziness. VS 1408- 90/56 HR: 57 BPM, RR: 12 BPM, O2 Sats: 98% Room Air VS 1425-91/57 HR 50 BPM, RR: 12 BPM O2 Sats 98% Room Air VS 1440- 94/57 HR: 54 BPM, RR: 12 BPM, O2 Sats: 98% RA Plan: Syncope and collapse- Patient was evaluated for 1 hour. Patient reports that she was feeling much better and was eager to go back to her room. Her pallor improved, she was AOx3 and speaking in clear sentences. , RN was advised to try patient with sips of clear liquids and provide her some crackers and have patient ambulate prior to discharge. When the nurse was repeating her VS and providing the patient the crackers, patient experienced another syncopal episode, but regained consciousness immediately. VS at 1450: HR 49 BPM, O2 Sats 99%, BP 82/50. Because patient experienced another syncopal episode, 911 was dispatched for ER evaluation. Patient asked that I speak to her mother, mother updated on patient's condition and that she needs to go the ER for further evaluation. Mother agrees and verbalizes understanding of care. Spoke to with the local health department and she reports that this case will need to be reported to VAERS. Patient is being transported by stretcher to the hospital. Will follow up with the patient. Nausea and Vomiting- Patient refusing Zofran IM, prefers PO. Zofran 4 mg SL given once at 1400 for nausea and vomiting. Nausea and Vomiting improved within 20 minutes. No nausea or vomiting upon discharge from the health center.</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>
1208003	4/14/2021		26	F	3/31/2021	3/31/2021	Pt presented for COVID vaccine after being cleared by PCP this morning. Approx. 5 mins after injection pt c/o palms sweaty/lightheadedness. BP: 122/81, P: 75, RR: 18 non lab, SaO2: 98%, ice pack to back of neck and pts head down, then assisted onto stretcher. 1036: drank apple juice, feeling a "little fuzzy" but better. 1038: BP: 114/78, P: 76, RR: 16, SaO2: 97%. 1049: C/o R hand sweaty/tingling which is similar to her aura prior to seizures, BP: 127/78, P: 68, RR: 16, SaO2: 97% taken to ED via stretcher, assigned to bed 6, placed on cardiac monitor and pulse ox, no changes noted. Pt still symptomatic "off and on". Stayed with pt until report given to ED nurse. ED visit, Monitoring at vaccine site.
1208894	4/14/2021		49	U	3/8/2021	3/8/2021	Patient suffered a 2-minute long seizure. She has a history of known seizure disorder. Her last seizure was 3 months ago. She also suffers from severe anxiety. patient was alert and oriented times 3 and refused transport to a local hospital by EMS. She left.
1208062	4/14/2021	PA	36	F	4/12/2021	4/13/2021	Seizure w/ no loss of consciousness Severity: Moderate
1208125	4/14/2021	TN	73	F	4/13/2021	4/14/2021	Resident with temperature and seizure activity.
1208132	4/14/2021	NC	66	M	4/8/2021	4/8/2021	Patient received 2nd Pfizer Vaccine approximately 11:10 am. Patient reported burning sensation in chest and lightheadedness and feeling warm. Taken to medic room. Initial vitals: BP: 144/94, P: 83, O2: 98%. Approximately 11:43 am: Patient reported left arm numbness and numbness in bilateral legs. Also reported blurry vision. Patient with of CVA, MI, Pulmonary Emboli, Seizure disorder. He did stop Protonix 2 months ago per patient and Keppra discontinued by PCP 2 weeks ago. On exam: grip bilaterally intact, sensation intact, oral mucosa intact, Heart regular rate and rhythm, Lungs CTAB. No rash noted. No oral swelling. Alert and oriented x3. Recheck vitals: 145/97, HR: 80, O2 saturation 97%. Continued numbness on left side and lower extremities. Burning sensation/reflux in chest still ongoing. EMS was called for further evaluation.
1208141	4/14/2021	CA	28	M	4/10/2021	4/11/2021	Seizure

<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>
1208245	4/14/2021	NC	34	F	4/8/2021	4/8/2021	Patient came in apprehensive and anxious about receiving shot, fearful of needles. After administration of the vaccine she appeared relieved afterwards and received a card with a note to wait for 15 minutes for any reactions. Her mother escorted her to her car, 10 minutes later, her mother came in saying "she's having a seizure!" We had a certified nurse that was administering the shots that went out to check on her and we had a technician call 911. Patient appeared disoriented in the car and clammy to touch. We checked her blood pressure, and the nurse reported it was a little low. After paramedics arrived was being treated as a vaso-vagal response and she was transported to the nearby hospital.
1208322	4/14/2021	IA	27	M	4/14/2021	4/14/2021	seizure
1208438	4/14/2021	IN	62	F	3/12/2021	3/13/2021	12-24 hours after the Covid -19 vaccine the patient had a seizure like event: eyes wide open, moaning, unresponsive for 2-3 mins. Patient had reported occurrences of blacking out. These are new events. The patient does not have any history of seizures or seizure like symptoms. Patient was placed in isolation at the hospital for 03/13/2021 thru 03/16/2021
1208446	4/14/2021	MO	26	F	4/12/2021	4/12/2021	Patient was experiencing convulsions the evening/night of the vaccine administration. She also experienced shivers and had back pain. However, it was reported the patient is prone to back pain. Post convulsion, the patient was experiencing extreme sweating.
1208453	4/14/2021	TN	23	F	4/14/2021	4/14/2021	Patient started complaining of becoming very hot/over heated and showed slight signs of a mild seizure. Unresponsive for around 10 second and eyes rolled back into her head. Patient came to and then she became unresponsive again and eyes rolled back into her head once again for around 10 seconds. Patient woke back up and then vomited several times. Patient was fine afterwards. EMS was called to check vitals.
1208536	4/14/2021	MI	16	M	4/14/2021	4/14/2021	had a seizure shortly after receiving his first dose of Pfizer Covid 19 vaccine. After EMS arrived they performed a fingerstick to check blood sugar and he had another seizure.

<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>
1208569	4/14/2021	CT	62	M	3/20/2021	3/23/2021	Received the vaccine Saturday am 3/20/2021. Saturday pm had numbness in right foot that lasted a few minutes. Headache off and on started Sunday 3/21/2021. No medication taken for headache. On Tuesday evening 3/23/2021, driving home from work had a sensation of something being wrong. After arriving home at 7 pm had a short term memory loss. Could not remember details of the day, for instance, or that he'd already had the Moderna shot three days prior. Was driven to the emergency room at about 9:30 pm. Memory gradually improved over the hours following the spell. They kept him in hospital until 3/25/2021, doing tests to rule out stroke, seizure, brain tumor etc. All tests came back negative. Was diagnosed with Transient Global Amnesia.
1210200	4/14/2021	PA	33	F	4/2/2021	4/2/2021	Noticed feeling extremely lethargic, heart rate increased, had grand mal seizure. Spouse said that the event was not as long or aggressive as typical grand mal episodes. Previously seizure-free for over a year and a half. Last blood lamotrigine levels tested 3/02/2021 and was out of standard range on the low end. Dosage of lamotrigine increased to compensate (225 mg AM/200 mg/PM) after obtaining results. Dosage increased again (225 mg 2x/day) after seizure episode. Pending blood level retest in May. Event is likely due to low medicinal levels aggravated by immune response. First pregnancy, event occurred at 30 weeks gestation. Estimated delivery 6/17/2021. Seizure occurred in bed and no physical external damage happened to the abdomen. Fetal movement is typical and predictable.

<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>
1207905	4/14/2021	IN		F	3/6/2021	4/9/2021	<p>Patient admitted on 4/9/21 (unsure where they received J&J COVID vaccine on 3/6/21) Per clinical pharmacist internal event report: Pt received Johnson and Johnson Covid vaccine on 3/6/21. Has chronic sub dural hematomas FYI (seen on scans in Feb). Patient is a 80 y.o. female patient who presented with complaints of dyspnea and BLE edema and was admitted with a principal diagnosis of Acute on chronic congestive heart failure with left ventricular diastolic dysfunction (HCC). Cardiology consulted. Initially diuresed however became hypotensive. Patient had episode of slurred speech and disorientation on 4/11. Code stroke called. CTH with stable SDH. CTA of head had no acute cerebral occlusion. Incidentally was found to have bilateral PEs on CTA h/n. Full CTA chest ordered for further evaluation, noted extensive bilateral pulmonary emboli, associated with Rt heart strain. She was started on heparin drip, Dr. cleared with neurosurgery prior to starting on 4/11 given subacute SDH which has been stable on imaging. Heparin transitioned to eliquis. Additional chart information: ht: 5'4" weight: 108.3 kg CrCl: 50.3 mL/min platelets since admission: 160 - 173 Admission Diagnosis: Acute on chronic congestive heart failure, unspecified heart failure type (HCC) [I50.9] Expected discharge: 4/14/21 Active Problems: Hypertension associated with diabetes (HCC) Gastroesophageal reflux disease without esophagitis Non-insulin dependent type 2 diabetes mellitus (HCC) Seizure disorder (HCC) Dyslipidemia associated with type 2 diabetes mellitus (HCC) OSA on CPAP Pulmonary hypertension due to left ventricular diastolic dysfunction (HCC) Subdural hematoma (HCC) Class 2 obesity due to excess calories in adult Dizziness Acute on chronic diastolic CHF (congestive heart failure) (HCC) Hospital course: Patient is a 80 y.o. female patient who presented with complaints of dyspnea and BLE edema and was admitted with a principal diagnosis of Acute on chronic congestive heart failure with left ventricular diastolic dysfunction (HCC). Cardiology consulted. Initially diuresed however became hypotensive. Patient had episode of slurred speech and disorientation on 4/11. Code stroke called. CTH with stable SDH. CTA no acute occlusion. Suspecting breakthrough seizure. Neuro consulting, EEG normal. Titrating up zonegran - patient will discharge on 100mg in</p>

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							AM and 200mg in PM. Incidentally was found to have bilateral PEs on CTA h/n. Full CTA chest ordered for further evaluation, noted extensive bilateral pulmonary emboli, associated with Rt heart strain. She was started on heparin drip, Dr. cleared with neurosurgery prior to starting on 4/11 given subacute SDH which has been stable on imaging. Heparin transitioned to eliquis. Will need to follow up with PCP. Valsartan was held on admission for hypotension. Blood pressure has remained well controlled off of all antihypertensives. She will need to follow up with PCP for further management of BP, may need valsartan resumed in near future. Patient is medically stable for discharge to home.
1211289	4/14/2021	NJ	74	F	3/3/2021	3/15/2021	On March 15 2021,in the ten o'clock hour my Mother experienced aphasia which progressed to muteness. In the ambulance she is reported to have had two gran mal seizures(no hx of such). She was intubated and, after a negative head ct, given tpa.
1210711	4/14/2021	CO	48	M	4/9/2021	4/11/2021	Sudden seizure event (never experienced before). Out for 5 mins.

<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>
1211301	4/14/2021	MI	38	F	4/13/2021	4/13/2021	<p>Patient was in observation area after receiving first dose of Moderna COVID19 Vaccine. Patient was asked to wait 30 minutes in observation following vaccine administration due to history of severe allergy to Codeine. During observation wait time, patient notified writer (observation nurse) that she was "not feeling well," and decided to lay on the floor. Writer assessed patient's vital signs and the vital signs were within normal limits. At 1310 VS were: BP 110/70, HR 85bpm, O2 95%, and RR: 20 bpm. Patient told writer that she does have a history of "blank seizures" during high stress situations. Soon after stating this, patient stopped responding to questions, and her eyes were noted to be "blank," and were staring off to the right side. No tonic/clonic activity noted. This seizure like activity was noted to last about 1 minute. Patient began answering questions again and was AOx4. Vital Signs remained stable during this seizure like activity. After a few minutes of talking with patient about her health history, writer noted patient having another "blank seizure," episode. Again, patient was not responding to questions and her eyes were noted to be "blank," and were staring off to the right side. No tonic/clonic like activity noted during this episode. Writer noted this episode to last about 2 minutes. Patient began answering questions again and was AOx4. Vital Signs remained stable during this seizure like activity. During this time, hives started to appear on patients left side of her face and front side of her chest and when patient began answering questions again after this seizure like activity, she started itching at the hives. 50mg Benadryl was given IM in her Right arm. EMS was called to site to assess patient and patient care was handed off to EMS staff.</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>
1210069	4/14/2021	LA	36	F	4/5/2021	4/10/2021	Patient has a history of epilepsy. She has not had a seizure since age 13 and is not currently medicated. She received her first dose of Pfizer Covid 19 vaccine into her LEFT DELTOID on 4/5/21 at 8:40 am. Patient left a message on voicemail on 4/11/21 reporting a seizure on 4/10/21 and COVID 19 symptoms (fever, chills, body aches, etc.) The seizure was minimal compared her prior seizure history (she did not lose consciousness and did not require medical intervention). Patient wanted us to be aware of this issue and see if we recommended proceeding with her second Pfizer Covid 19 shot when due. I spoke to the patient and she told me she had had Covid 19 in February 2020. We have seen clinical reports of more pronounced reactions to 1st dose vaccines in patients who had the Covid 19 virus and explained that to the patient. I spoke to the patient on 4/14/21 and she was feeling much better. I recommended to patient that she delay getting her second dose indefinitely.
1211245	4/14/2021	CT	59	F	4/8/2021	4/10/2021	The E.M.T's said my wife was having a "mini stroke" but cat scan was negative so it must have been a seizure. My wife is now home recovering. She is still experiencing headaches and is lethargic
1211091	4/14/2021	NC	46	M	4/12/2021	4/12/2021	EMS, who was working in the clinic, stated that the patient had a partial seizure and directed the Clinic Lead Nurse to call EMS. Patient became pale, 5 second seizure, dizziness and vomiting. EMS was called and vital signs were taken but patient declined to go to the hospital. Patient recovered and drank some water and ate some crackers. Patient waited another 30 minutes and stated he felt much better. Clinic Lead Nurse called the patient, on April 13, 2012, who stated that he went home, ate some food and relax the rest of the day. He stated he felt better and had no more problems. He did not seek additional medical care.
1211087	4/14/2021	WA	38	M	4/6/2021	4/7/2021	Patient began seizing after several hours of fever of >100 degrees F, post-vaccination. He was transported by ambulance from his home to the Emergency Department where he experienced another seizure. Patient was hospitalized overnight and discharged with medication for control of seizures.

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1210841	4/14/2021	FL	52	M	4/8/2021	4/13/2021	Diarrhea since 04/06/2021 everyday two times per day. On April 8th developed heavy abdominal pains and fainted became rigid, clenched fists, and shook like a seizure. My wife stood by my side and witness me waking up pale and confused after about 10 seconds of episode. I continue to have diarrhea.
1210836	4/14/2021	CA	27	M	3/15/2021	4/9/2021	pt with an new onset single episode of tonic-clonic seizure on 4/9 (3 weeks after vaccination) that lasted 60-90 seconds. patient with no predisposing trauma, no recreational or illicit drug use or alcohol use, no history of seizure disorder or family history of seizure disorder. pt with postictal state lasting 10-15 minutes. Patient went to ER following episode and treated with Ativan. Patient with no reports of seizure like activity or episodes since the event.
1210826	4/14/2021		23	F	4/13/2021	4/13/2021	Patient fainted and had a short seizure roughly 5 minutes after the injection. EMT came and drove patient to hospital for further evaluation. Outcome - unknown.
1210773	4/14/2021	OR	18	M	4/13/2021	4/13/2021	5 minutes after getting the shot I fainted / had a seizure. I heard from people around me that my face had turned pale and that my hands were cramping up. I woke up not knowing what had happened, or where I was for a good 30 seconds. They had to call an ambulance and take me to the hospital to get checked on.
1211330	4/14/2021	OK	44	M	3/9/2021	3/27/2021	Patient was seen at Hospital for seizure, fall and head injury. Subsequent workup following transfer to another hospital revealed L frontal lobe parenchymal hematoma with overlying subarachnoid hemorrhage, no underlying aneurysm or vascular malformation. He had MRI with and without contrast revealing partial occlusion and thrombus of the superior sagittal sinus with adjacent hemorrhage and edema. Treated with heparin, transitioned to coumadin.

<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>
1203485	4/13/2021		35	F	4/7/2021	4/7/2021	History of anxiety around injectables Symptoms: diaphoretic, pale, light headed, husband stated she had first syncope episode after receiving the vaccine. As EMT arrived to assess the patient she had a second syncope episode that presented as seizure activity that lasted for 40-50 seconds. After the second episode patient came alert stated she felt much better, which she state she didn't feel well after the first syncope episode. We witnessed patient ambulate to the stretcher and loaded into ambulance for further assessment and transport then patient refused transport. VS: BP 140/95, RR, 18, pulse 70, Oxygen 98%
1203692	4/13/2021	TN	40	F	4/9/2021	4/9/2021	Seizure-like incident while at a restaurant. Eyes rolled back in to my head, according to my friend who was with me. My vision got blurry, I started feeling nauseous, shivers, cold sweats, body felt shaky, and at first I thought I had been drugged. This "attack" lasted for a couple of minutes. After being able to get home I was in bed until 4 pm the next day. At first I had several hours where I was freezing despite being in bed fully dressed with the heat blasting, the following hours, I was sweating. I had a headache, felt nauseous, and uncomfortable all day Saturday. My reaction to the vaccine was much worse than having Covid-19. Missed work due to the symptoms from getting the vaccine.
1203594	4/13/2021	VA	21	M	4/8/2021	4/8/2021	Patient fainted and fell to the floor within 15 minutes of vaccination. He was observed to have seizure-like activity for approximately 20 seconds. Patient was transported to ER by EMS.

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1203537	4/13/2021	CA	60	M	4/10/2021	4/10/2021	Patient was with Medical Examiner. She was reviewing his allergies (PCN, bee stings) and discussed with patient need to wait 30 minutes after vaccine for observation. She then gave him pfizer vaccine. Within 1 minute of giving vaccine, patient began to have seizure. He was assisted to ground by MD and RNs at vaccination site. He was assessed and assisted to remain safe throughout seizure, 911 called and arrived on scene. Meanwhile, caregiver with patient stated seizures are "normal" for him and he has 4-5 a day. She reported that in line he was not feeling well and had precursors to seizure. Patient had reported to MD that he felt fine today and did not report seizure history to her previous to giving vaccine. It was also later reported that he had a seizure the night before as well. IVF were started by RN's. When emergency services arrived, patient was recovering and refusing to go to ER - against medical advice. He was assisted back into wheelchair by emergency services personnel. Patient was alert, and oriented and able to make decision not to go to emergency room. Patient left facility with caregiver in private vehicle. Patient was instructed to contact his primary care physician and let them know what happened and ask if 2nd dose of pfizer is appropriate for him. Patient was also instructed if MD wants him to get 2nd dose to go to a more controlled setting then Mass vaccination site.
1203527	4/13/2021	IA	50	F	3/17/2021	3/25/2021	Vasovagal syncope. Had vaccine on the 17th on the 25th in the early morning hours I got out of my bed, passed out or had a seizure in my kitchen. Went to doctor 4 days later because I was in pain mainly in feet, was told I broke my foot. I asked if vaccine could have caused it and was blown off by 3 different healthcare providers, I thought by law they were supposed t report adverse effects like this.

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1203517	4/13/2021	PA	29	F	4/6/2021	4/6/2021	within 30 seconds from vaccine parient became very light headed cold and clammy. and passed out blood pressure was very low 82/54. patient was awaken and immedietly started asking lots of questions stating that it felt like a dream a 2nd bp was taken and was 100/78. 3minutes later patient passed out again with what appeared to look like seizures.. Patient was lied on the ground a vitals continuously watched ambulance was called. Patients vitals were stabilizing and was decided to move patient out of way when having patient to walk patients pressure once again dropped patient was sent to er for further evaluation. It was later passed on to us by patient that er statred that patient has such a low tolerance for pain that this caused this occurance as the same thing happened the next day when patient got out of bed and arm hurt from the vaccine. Patient passed out.
1206041	4/13/2021	MD	31	M	4/9/2021	4/9/2021	Patient was in attendance at the JANSSEN vaccination clinic on 4/9/21. After vaccination while he was in the observation area, PT experienced a syncopal episode and hit his head on the window sill next to where he was sitting. Staff responded and assessed PT and decided to initiate a MET call. There was concern that the patient may have experienced a seizure. Patient was taken to the Emergency Department. Patient was ultimately admitted on 4/9/21 with new onset of a. fib. He was discharged on 4/11/21. While hospitalized, the patient received IV cardizem
1203461	4/13/2021	TX	28	M	4/11/2021	4/11/2021	I got the Covid 19 Vaccine Pfizer at the pharmacy. After I got the Vaccine I was waiting in the waiting room for 15 minutes but before my time was up and it was my time to leave I felt really dizzy & light headed as I was sitting down on a chair. Then I just felt some one tell me to wake up because I had fainted, fell face down to the floor & convulsed for 5 seconds.

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1205165	4/13/2021	PA	55	F	3/27/2021	3/28/2021	When she was able to fall asleep she woke biting my tongue like a seizure; Severe left arm and shoulder pain; Severe left arm and shoulder pain; Fever that gradually went higher to 103.7; Severe headache; Jaw pain; Blurred vision; Tired; Sweaty; This is a spontaneous report from a contactable consumer. A 55-year-old female patient received her second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EP6955), via an unspecified route of administration, administered in Arm Left on 27Mar2021 15:00 as SINGLE DOSE for covid-19 immunisation. Medical history included Known allergies: Sulfa's and sulfurs, Unknown blood clotting disorder, Arnold chiari malformation syndrome, sinusitis. Concomitant medication included apixaban (ELIQUIS) taken for Unknown blood clotting disorder. The patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EP6199) on 06Mar2021, 04:00AM on left arm for covid-19 immunisation (55 years old). On 28Mar2021, 04:00, the patient stated that she had severe left arm and shoulder pain, fever that gradually went higher to 103.7 then a day later the fever went down. Severe headache with jaw pain, blurred vision. When she was able to fall asleep she woke biting my tongue like a seizure. Currently she is tired and sweaty, fever has gone, arm pain gone within a day and a half. Therapeutic measures were taken as a result of all the events included At home pain and fever medicine. The patient was not pregnant. Outcome of the events pain in arm and fever was recovered on an unspecified date while outcome of the remaining events was recovering.
1203762	4/13/2021	VA	32	M	4/1/2021	4/1/2021	Client received his J&J vaccine and immediately afterwards he had a seizure-tonic clonic. Seizure lasted about 40 seconds, he was immediately evaluated by the paramedics on site. BP laying down was 117/74 p62 and later 116/82 p66. Client indicates that has a history of passing out when he gets his blood drawn. 911 was called and Medic arrived, client was transported to the hospital for further evaluation.

<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>
1203162	4/13/2021	TX	37	M	3/11/2021	3/15/2021	multiple seizures; fever; This spontaneous case was reported by a pharmacist and describes the occurrence of SEIZURE (multiple seizures) in a 37-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. Concurrent medical conditions included Epileptic seizure. On 11-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 15-Mar-2021, the patient experienced SEIZURE (multiple seizures) (seriousness criterion medically significant) and PYREXIA (fever). At the time of the report, SEIZURE (multiple seizures) and PYREXIA (fever) 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.; 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.
1204032	4/13/2021	RI	29	F	4/13/2021	4/13/2021	EMS called over to vaccination cubicle for a 29 y/o female AOx3 stating she feels like she's she's going to pass out. Past medical history of anxiety with prescribed Xanax which she did not take today. Allergic to Bactrim She was assisted to stretcher and taken to the hallway for further evaluation. Pt is hyperventilating stating "what did I just take, I feel like I'm going to have a seizure, my hands are contorted, I cant move my hands, why is my stomach twitching like that" Per vaccine administrators pt appeared to be anxious prior to actual administration of vaccine. Vitals obtained BP 138/87 SPO2 99% HR 130 PT was placed on Oxygen 2lpm via nasal cannula for comfort, she was coached and encouraged to take deep breaths. 4-lead ECG- sinus tachycardia Vitals reassessed BP 132/82 SPO2 99% HR 120 PT called her sister who is a nurse and that seemed to help her calm down. PT requested 911 transport to hospital. 911 notified Pt care was transferred over to hospital

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1203140	4/13/2021		21	F		3/29/2021	Seizures; Redness; Soreness; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (Seizures) in a 21-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.). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 29-Mar-2021, the patient experienced SEIZURE (Seizures) (seriousness criterion medically significant), ERYTHEMA (Redness) and PAIN (Soreness). At the time of the report, SEIZURE (Seizures), ERYTHEMA (Redness) and PAIN (Soreness) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications provided. No treatment provided. Reporter did not allow further contact
1203256	4/13/2021	CA	45	F	3/23/2021	4/7/2021	Grand mall seizure
1204336	4/13/2021	TX	34	F	4/10/2021	4/11/2021	Had seizure symptoms at 2:30 am the following day. Husband woke to our dog whining. I was very disoriented before it happened, I was freezing cold, aching, shooting pains, could hardly move or speak but got out the words, ?im not ok, I?m having a sever reaction? My husband said I then went into what he saw as a seizure. Head throat, neck, back tensed-unconscious, unable to arrouse. Lasted about a minute. Where I lied unconscious and he didn?t think I was breathing. 30 seconds later I opened my eyes, but then had a similar but shorter episode 30 seconds and then was able to get me to come to. He called 911, and they took me to hospital. All vitals came back normal. Blood pressure was on the low side. I have no history of seizures.
1205002	4/13/2021	TX	34	F	4/12/2021	4/12/2021	Convulsions began about 6 hours after vaccine. With each convulsion I lose ability to speak and struggle to breathe. I cannot control the shaking. I get very dizzy and have had a headache since about 2 hours after the vaccine.

<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>
1204784	4/13/2021	NJ	53	F	3/4/2021	3/4/2021	breakthrough seizures; sinus infection; She also missed her 2nd appointment on 5APR2021 due to sinus infection; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SEIZURE (breakthrough seizures) in a 53-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 002A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Seizure. On 04-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Mar-2021, the patient experienced SEIZURE (breakthrough seizures) (seriousness criterion medically significant), SINUSITIS (sinus infection) and PRODUCT DOSE OMISSION ISSUE (She also missed her 2nd appointment on 5APR2021 due to sinus infection). On 04-Mar-2021, PRODUCT DOSE OMISSION ISSUE (She also missed her 2nd appointment on 5APR2021 due to sinus infection) had resolved. At the time of the report, SEIZURE (breakthrough seizures) and SINUSITIS (sinus infection) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. There were no concomitant medications reported. Treatment included antibiotics for the event sinus infection.; Sender's Comments: This report refers to a case of Product dose omission issue for mRNA-1273. Based on the current available information and temporal association between the use of the product and the start date of the events (seizure and sinusitis), a causal relationship cannot be excluded.

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1204748	4/13/2021	TX	55	F	3/26/2021	3/26/2021	pain and swelling in arms and leg; nausea; fatigue; EPILEPTIC SEIZURES; chills; pain and swelling in arms and leg; fever; headache; This spontaneous case was reported by a consumer and describes the occurrence of EPILEPSY (EPILEPTIC SEIZURES) in a 55-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. Concurrent medical conditions included Mental disability and Epilepsy. Concomitant products included CARBAMAZEPINE (CARBAMAZEPIN) and PHENOBARBITAL (FENABBOTT) for Convulsion. On 26-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Mar-2021, the patient experienced EPILEPSY (EPILEPTIC SEIZURES) (seriousness criterion medically significant), CHILLS (chills), PERIPHERAL SWELLING (pain and swelling in arms and leg), PYREXIA (fever), HEADACHE (headache), NAUSEA (nausea) and FATIGUE (fatigue). On an unknown date, the patient experienced PAIN IN EXTREMITY (pain and swelling in arms and leg). On 28-Mar-2021, EPILEPSY (EPILEPTIC SEIZURES) outcome was unknown. At the time of the report, CHILLS (chills), PERIPHERAL SWELLING (pain and swelling in arms and leg), PYREXIA (fever), HEADACHE (headache), PAIN IN EXTREMITY (pain and swelling in arms and leg), NAUSEA (nausea) and FATIGUE (fatigue) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Company comment:Based on the current information and the temporal association between the use of the product and the event start date a causal relationship cannot be excluded.; Sender's Comments: Based on the current information and the temporal association between the use of the product and the event start date a causal relationship cannot be excluded.
1204643	4/13/2021	NM	19	F	3/16/2021	3/16/2021	Weakness/Fatigue starting the evening of the injection and persisting for about 48 hours. Chills/fever, nausea, and lightheadedness starting the next morning. Loss of consciousness (Uncertain if it was vasovagal syncope or seizure) 10:30 pm the next day.

<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>
1204625	4/13/2021	TX	46	F	4/10/2021	4/10/2021	About five minutes after receiving the vaccine I began to feel something was terribly wrong. I then blackout for several minutes. From my son's description I believe I might of had a seizure. He said my eyes were wide open, I was slumped over, and gurgling. I was completely unresponsive to him. He summoned the paramedics who loaded me in an ambulance soon after I came to. They checked my vitals. My heart rate was 47 bpm and blood pressure was 80/40. They also checked my blood sugar. It was 116. They decided I needed to go to the hospital and began giving me iv fluids in route. At the hospital an EKG was taken, which came out normal, they continued iv fluids, and did a urinalysis on me. All test indicated I was healthy. It about three hours before my blood pressure and heart rate stabilized. Just as long for me to feel like I would be ok. They discharged me at this point. Since they I have just been extra tired and have had muscle discomfort.
1203939	4/13/2021		87	M	3/17/2021	3/30/2021	NA Septic shock Aspiration pneumonia Acute encephalopathy Pancytopenia Seizure
1204354	4/13/2021	FL	64	F	4/13/2021	4/13/2021	Vaccine in at 2:27 pm. Taken to Observation for 30 minutes. Left Observation at 2:57 pm. Was being assisted outside clinic entrance into a car (while in her walker) and was noted to have seizure like activity. Taken back into Observation area. NP and EMS onsite assessed patient. 15:20 VS: 97/71; p.88; Sat 97; R 10 and shallow. Airway opened. 15:20. EMS called per Police Officer onsite. Pupils pinpoint and non reactive. Bilateral downward gaze noted. Did not respond to verbal commands. Moaned to sternal rub. IV started in R arm TKO. O2 administered at 2 L. 15:29; BP 190/92; p 94, fingerstick BS 89; R. 12. on cardiac monitor showing NSR. 15:42. BP 192/109; HR 90. Transferred to Fire Dept care @ 3:49 pm.
1203865	4/13/2021	CO	77	M	3/31/2021	4/1/2021	Rapid mental decline, seizure activity, possible 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>
1199705	4/13/2021	AK	31	M	4/7/2021	4/7/2021	Around 8PM, began feeling cold/chills. Began shaking / having seizures. Heart rate went up to 150. No loss of consciousness, however, was unable to control body. Was taken to ER and was stabilized. With some pain medications and an IV, I was released. Had fever for 24 hours, reaching 104 F. By the third day my fever broke, but energy levels have remained low since the episode occurred.
1202332	4/13/2021	NY	27	M	4/7/2021	4/7/2021	4/07/21 12:40 PM B/P 140/78 Pulse 71, 12:56 PM B/P 144/72 Pulse 69. Chief Complaint loss of consciousness. No history of diabetes mellitus or seizure disorder, loss of consciousness with seizure like activity, not post ictal, recovered in less than 5 minute, then alert and oriented per EMT notes. EMS called and transferred to Hospital.
1204010	4/13/2021	TX	73	F	3/21/2021	3/21/2021	hives, seizure

<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>
1202978	4/13/2021	TX	72	F		3/27/2021	SEIZURE; JOINTS LOCKED UP/WHOLE BODY LOCKED UP; NO APPETITE; SWEATING; BARELY BEEN OUT OF BED/HOME BOUND; CHILLS; WEAKNESS; 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 had no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029, expiry: 25-MAY-2021) dose was not reported, 1 total, administered on 27-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 27-MAR-2021, after 23:00 the patient began shaking and had seizure, her mouth was drawn up. On the same day, the patient experienced fever, chills, sweating, weakness, no appetite and her whole body locked up and her joints locked up. According to the patient, she had barely been out of bed and had been home bound since vaccine was administered. The patient visited doctor/healthcare professional's office for events seizures, shaking, mouth drawn and fever. It was reported that, on 02-APR-2021, a nurse came to the patient's home and tried to encourage her to go to the hospital but she declined. On the day of this report, the patient had an appointment via phone video for her pulmonologist and with her primary care physician. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from joints locked up/whole body locked up on 28-MAR-2021, was recovering from fever, chills, and sweating, had not recovered from seizure, no appetite, and barely been out of bed/home bound, and the outcome of weakness was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: covid-19 vaccine ad26.cov2.s-seizure. 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)
1203926	4/13/2021	VA	27	M	4/11/2021	4/11/2021	Patient fainted and exhibited seizure-like activity within 15 minutes of vaccination. Patient was transported to ER by EMS.

<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>
1203871	4/13/2021	CA	41	M	4/12/2021	4/12/2021	Seizure and lost of consciousness 3 minutes after vaccine was administered. No treatment was given at pharmacy, but patient was taken by paramedics.
1204620	4/13/2021	WV	48	M	4/1/2021	4/4/2021	Seizure lasting 2 minutes. Taken to er. Hospitalized for 3 days and all tests negative. Started on anticonvulsants
1201667	4/13/2021	NC	37	F	4/12/2021	4/12/2021	102 fever, chills, convulsions, headache, fatigue, rapid heart rate, nausea
1199710	4/13/2021	NM	53	F	3/29/2021	4/4/2021	By 6PM my arm was swollen and red on outter left shoulder vaccine injection site. I could barely lift my left arm. Day #2, developed large baseball sized lump under left arm pit Day #3 and #4, couldn't put my arm down because of large lump under left arm. Day #5 swelling went down Day #6, returned from going out to dinner and tried to get out of car and my legs would not work. I fell to the ground in the garage. I couldn't speak or respond..... then my left side started to seize and convulse. My left clave, thigh, hamstring, glute and abdomen was in the worst ever constriction of cramping and convulsion. I could only scream out and cry. After about 10 minutes my sons had to carry me into the house. I was exhuasted and fell asleep. I had a bad headache for 3 straight days and loss of dexterity and strength on my left side.
1199824	4/13/2021	OK	47	F	4/12/2021	4/13/2021	Body aches, fainted followed by a Seizure
1200007	4/13/2021	OH	18	M	4/12/2021	4/12/2021	Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Seizure-Mild
1200263	4/13/2021	NJ	34	F	4/12/2021	4/12/2021	Systemic: Seizure-Medium, Systemic: Shakiness-Medium, Additional Details: PATIENT WAS PANICKING BEFORE GETTING THE SHOT. AFTER RECEIVING THE VACCINE SHE STARTED HAVING A PANIC ATTACK. AFTER ABOUT 10 MINUTES OF THE ATTACK SHE FELT A LITTLE BETTER. A FEW MINUTES AFTER SHE STARTED HAVING A SEIZURE. THE EMERGENCY ARRIVED RIGHT BEFORE SHE HAD THE SEIZURE.

<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>
1200281	4/13/2021	NY	23	M	4/12/2021	4/12/2021	Systemic: Chills-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe
1200294	4/13/2021	NV	51	F	4/12/2021	4/12/2021	Systemic: Seizure-Medium, Additional Details: pt was given moderna vaccine, as per technician onsite, patient tripped and fell to the ground and started having a seizure. pt has history of epilepsy as per husband who was with her at the time. i was in the pharmacy for a minute and got called to the immunization area. i asked technicia to call 911 immediately and had on her side on the floor as per 911 instruction. paramedic arrived shortly after and pt left in stretcher
1200530	4/13/2021	CA	25	F	4/12/2021	4/12/2021	Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Additional Details: Pateint fainted after getting her first dose of the vaccine. Patient fainted while sitting in the chair, the immunizer led her down to the floor. Patient was alert in 20 seconds of fainting, she was not aware of what had happend. Patient was asked if she was having difficulty breathing. Patient was having hard time resposing, epinephrin was adminstered and 911 was called at 11:29am.
1200830	4/13/2021	GA	42	F	3/13/2021	3/16/2021	The week after receiving the 2nd dose, I had multiple grand mal seizures and loss of consciousness. Debilitating pain, weakness, & numbness in left side of body especially the leg. I went to the ER 2/21 & 2/2/26 because I was worried I was having strokes. BP 177/90, d-dimer 662 ng/ml, oxygen saturation ven - resp 56.2%, Ct scans done on upper thorax multiple nodules Brain scans small region of encephalomacia in right post. Perirolandic frontal lobe remote lacuna infarction left inf basal ganglia

<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>
1200962	4/13/2021	KY	34	F	4/12/2021	4/12/2021	At 5pm after taking the shot that morning, I started having cold chills that turned into full body convulsions and spasms that were uncontrollable for over an hour. Almost 24 hours later I'm still experiencing cold chills. I also developed full body aches to where my bones feel like they are breaking and weak. Around 10 PM I started vomiting and that lasted for a couple of hours. At 2 AM a headache started and is still going on as of 9:46 AM. My bones pop and feel weak. At other times my body will become extremely hot and soaked in sweat just to go back to cold chills.
1201190	4/13/2021	CO	28	M	4/10/2021	4/10/2021	entered clinic with red bull energy drink, spouse reported Patient drank a soda earlier, skin appeared pale, reported he did not do well with vaccines as a child in the past, still wanted to proceed with vaccine. Had seizure for 2 mins, family reported past history of fainting. EMS attended, responded to questions appropriately, fainted a second time, monitored, pt was released home with spouse
1201297	4/13/2021	OH	26	F	4/9/2021	4/10/2021	Severe abdominal pain, headache, supposed seizures, labored breathing
1201302	4/13/2021		39	M	4/4/2021	4/11/2021	seizure one week after second dose
1202543	4/13/2021	NY	22	M	4/13/2021	4/13/2021	Pt fell and hit his head, An eyewitness said pt was having a seizure, but pt said he does not have seizure disorder. Ambulance was called. Pt was alert and oriented. Patients dad was going to take him to the hospital.
1201661	4/13/2021	IN	19	M	4/6/2021	4/7/2021	Seizure-like symptoms for around 3 minutes. Struggled to breath, move, talk, intense pain in chest and head. Fever and headache for several days after.

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1202770	4/13/2021	CT	24	F	4/12/2021	4/12/2021	Prior to administration of Janssen Covid-19 vaccine the patient was anxious but was completely fine once the procedure commenced and concluded. After finishing explaining the possible side effects of the vaccine and handing the patient the V-Safe handout, she got up slowly and proceeded to our designated post vaccination monitoring seating arrangement. Upon concluding the vaccination process with the patient's partner, she alerted the pharmacist that she does not feel well. To which he asked her to further elaborate on what she is experiencing. She began to say she thinks she's going to faint as she is attempting to drink water. As she was having a drink of water she fainted. To which he responded by running over and catching her before she hit the ground, cradling her upper torso, specifically the head and laid her down on the floor with the assistance of pharmacist and her partner. In the midst of everything he instructed another pharmacy technician to call 911 for the paramedics. As she was in the process of drinking water I saw her other hand go to the region of the neck, thinking it was also an allergic reaction and administered a dose of Epi-Pen. He administered the Epi-Pen on the upper side of her thigh, directly to the skin not through clothing. There was a very brief moment where the patient began to convulse but gradually regain consciousness. The patient became lucid and was conversing with him, apologizing for the incident. He assured her there was nothing to apologize for and to which she told me she had similar incidents from vaccinations as a child. She did not mention this prior to administration of the vaccine and through conversation we believe the incident may be caused from high anxiety of needles / vaccinations. When the paramedics arrived, they assisted the patient from the floor and gave a warning that she believed she was going to faint again, and fainted in the arms of the paramedics.
1201808	4/13/2021	FL	40	M	4/11/2021	4/12/2021	uncontrollable shivering/convulsions to the point that my muscles started cramping and were sore the next day difficulty breathing and hyperventilating night sweats, vomiting (1 time), confusion, body aches
1201832	4/13/2021	NM	40	F	3/19/2021	4/2/2021	seizure like symptoms two weeks after administration, then continual headaches

<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>
1201847	4/13/2021	FL	31	M	4/13/2021	4/13/2021	Patient was shaking and sweating. His muscles contracted in his hands and it appeared he might have been having a seizure. He came to and got very cold.
1201893	4/13/2021	NM	40	F	3/19/2021	4/2/2021	seizure like activity then continual headache
1202024	4/13/2021	KY	43	F	4/10/2021	4/10/2021	seizure like episode ER visit following up with neurology may have been febrile seizure
1202034	4/13/2021	NC	42	M	3/12/2021	3/15/2021	Two different Seizures one on March 15th and the other on April 5th
1202162	4/13/2021	LA	39	F	3/6/2021	4/8/2021	Syncope, seizure like activity. Negative scans and blood work in the Emergency Room on April 8. Fatigue presently
1202263	4/13/2021	NM	35	F	4/9/2021	4/9/2021	About 8 minutes after vaccination client fell and hit her head, she has a large lump to right side of her head. After hitting the floor patient begin to show seizure activity for about 1-2 minutes. BP 140/20 P62. Ambulance service on site and transported to Hospital for follow up care.
1202325	4/13/2021	WA	32	F	4/8/2021	4/11/2021	I got the vaccine on Thursday afternoon, and had a grand mal seizure on Sunday. I was taken to the ER where I was given Ativan, and had blood and urine samples taken and a CT scan. All test results came back normal. I have a follow up appointment with a neurologist today (Tuesday 4/13).
1202360	4/13/2021	NY	29	M	4/8/2021	4/8/2021	Patient had a seizure on the day of the Pfizer vaccine as well as arm & leg pain due to fall
1202567	4/13/2021	WV	41	F	4/13/2021	4/13/2021	Patient was intially responsive.. After waiting approximately 5 minutes patient informed staff at pharmacy that she felt like she was going to have a seizure. Patient moved to floor from chair. Was conscious for about 5 more minutes. Lost consciousness during seizure (approximately 2-3 minutes). Emergency medical personnel was called at that time. Patient regained consciousness and went with EMS to hospital for further testing.

<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>
1202627	4/13/2021	MA	50	M	4/10/2021	4/11/2021	Pt reports that 23 hrs after receiving the vaccine he experienced " a massive seizure" and was transported by paramedic to the Hospital. A neurologist he saw mentioned that he had seen "other seizures like this ' and they presumed he meant after COVID vaccines
1202761	4/13/2021	MO	30	M	4/13/2021	4/13/2021	Pt had decerebrate seizure like activity. This lasted approx. 1-2 mins. Pt was postictal for approximately 5 mins. Pt remained Hypotensive and dizzy for approximately 25 mins until EMS arrived.
1201458	4/13/2021	NC	30	M	4/13/2021	4/13/2021	Patient received Moderna vaccination at 10am. Ten minutes after receiving the vaccine patient started to have seizure-like convulsions for 45 seconds to 1 minute. Patient regained consciousness, but remained very faint and ambulance was called. Patient was able to speak to give EMT symptoms and they took the patient to the hospital.
1205853	4/13/2021	VA	27	M	4/8/2021	4/8/2021	patient with seizure disorder, within 10 minutes patient had a seizure with typical presentation for this patient.

<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>
1205170	4/13/2021	OH	36	F	3/21/2021	3/23/2021	increased seizure activity; I had the normal yet severe side effects of sore arm & neck; I had the normal yet severe side effects of sore arm & neck; stiffness behind the ear, stiffness of the neck; stiffness of the neck and injection site arm; fatigue; fever; headache; sore throat; chills; I started suffering from tinnitus; dizziness; nausea; confusion; This is a spontaneous report from a contactable consumer (patient). A 36-year-old female patient received the second dose of BNT162B2 (Lot Number: EN6208) via an unspecified route of administration, administered in left arm on 21Mar2021 14:45 (at the age of 36-year-old) as single dose for COVID-19 immunization. Medical history included epilepsy and asthma. The patient is not pregnant. Concomitant medication included levetiracetam. No other vaccine in four weeks. The patient previously received the first dose of BNT162B2 (Lot Number: EN6203) administered in left arm on 28Feb2021 14:30 (at the age of 36-year-old) as single dose for COVID-19 immunization. The patient had the normal yet severe side effects of sore arm & neck, stiffness behind the ear, stiffness of the neck and injection site arm, fatigue, fever, headache, sore throat, chills, for the first few days her 2nd dose. But on day 2, she started suffering from tinnitus, dizziness, nausea, confusion in both ears and increased seizure activity. The events started about 2 days after the second shot on 23Mar2021 12:00 PM; its been a week now and it still hasn't gotten better or gone away. She had an appointment with her pcp tomorrow but so far nothing has helped. Its debilitating and extremely hard to focus & function. She mainly just wanted to know if any other vaccine trial participant/recipients have reported anything similar & if so, how long can she expect this to last. The adverse events resulted in Doctor or other healthcare professional office/clinic visit. It was unknown if treatment was received for the events. No COVID prior vaccination. No COVID tested post vaccination. The outcome of the events was not recovered.
1206243	4/13/2021	AZ	19	F	4/13/2021	4/13/2021	Syncopal episode followed by 15 seconds of seizure activity.

<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>
1206216	4/13/2021	CA	20	M	4/13/2021	4/13/2021	Client had seizure activity approx. 10 mins after receiving vaccine. He was sitting on chair in observation area then fell to the left, hitting his head on the ground. He then proceeded to have what looked to be seizure activity, jerking movements of arms and legs. 911 was called by lead RN. Client regained consciousness approx. 10-15 seconds later. V/S taken @ 12:07pm: BP 133/72, HR 118, O2: 88, RR 22, AOX3 Client appeared diaphoretic, pallor to face, slurred speech. Denied hx of seizures. V/S taken @ 12:18pm: BP 133/71, HR 118, O2 88, RR 22, AOX3. Reported hx of asthma and uses an inhaler. Reported smoking marijuana prior to receiving vaccine. At 12:20 EMS arrived and assumed care of client. Was transported to hospital
1206211	4/13/2021	OR	18	M	4/13/2021	4/13/2021	Patient fell from chair in waiting area and experienced seizure-like activity for 5 to 10 seconds. EMS was called and promptly arrived and took patient to hospital.
1206068	4/13/2021	WA	44	F	4/7/2021	4/7/2021	Was not instructed to wait after shot so I went to my car. Drove for a couple of hours. Got out of car, walked forward and passed out with a seizure then throwing up when I came to. Received concussion. Taken to ER and admitted for 5 days. Still experiencing vertigo and nausea
1206012	4/13/2021	ME	42	F	4/8/2021	4/8/2021	Starting out feeling like I was gonna pass out, then got nauseas and vomiting, then the cold set in my whole body was painfully cold, then was having seizure like shakes till 3am, had cold and shakes set in every time I moved the whole next day along with nausea and severe headache, the shakes were horrible., then body aches for three days
1205830	4/13/2021	WA	30	M	4/10/2021	4/11/2021	Janssen Covid-19 Vaccine EUA First 12 hours after the shot I experienced headaches, body aches, and chills. Within the next 24 hours all of these symptoms increased severely, and around 5pm on 4/11/21 I experienced a seizure that resulted in me being taken to the ER.

<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>
1205238	4/13/2021			F	3/21/2021	3/21/2021	Seizures; dazeli-like stance for many days; forgetfulness; Feeling like sleepwalking; Memory loss; This is a spontaneous report received from a contactable consumer (patient) . A adult no pregnant female patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in Arm Left on 21Mar2021 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation . The patient medical history was not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID . The patient's concomitant medications were not reported. On 21Mar2021 the patient experienced seizures, dazeli-like stance for many days, forgetfulness, feeling like sleepwalking and memory loss The adverse events resulted_in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care.No treatment received for the events.The outcome of the events was not recovered. Since the vaccination, the patient has not been tested for COVID-19 Information about the lot/batch number has been requested. Follow-up attempts are completed. No further information is expected.
1205704	4/13/2021	MI	39	F	4/3/2021	4/7/2021	Right side nose burning, numbness in face. Severe sweating, nausea, dizziness. Passing out. 4 episodes over 2 hours 3 with black out. Hospital diagnosed with seizure disorder even though mri, eeg, ekg, and ct showed no seizure activity.
1205652	4/13/2021	CA	32	F	4/13/2021	4/13/2021	During vaccine observation period, patient reports "heaviness of legs" and vision difficulties RN. RN instructed to put patients seat back to rest and removed patient's seatbelt. Patient began to convulse and was unresponsive to verbal stimuli for <1 min. EMS was immediately called and arrived shortly after. EMS assessed the patient who was AO x 4 after encounter with EMS. EMS plan of care is have her take uber/lyft home. Arrangements are made to pick car up next day at vaccination site. Patient left without further incident.
1205591	4/13/2021	KS	31	F	4/8/2021	4/8/2021	patient reports that 1.5 hours after show she began to have what felt like mini seizures-, headache, and extremity pain. the symptoms had mostly resolved at time of report 5 days after 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>
1205525	4/13/2021	VA	27	M	4/13/2021	4/13/2021	Patient walked to waiting area and when he sat down he fainted, hit his head, and started having seizure-like activity (jerky, twitchy). Patient was down about 15 seconds and when he sat back down his blood pressure was 74/48 and his vision was black. Called EMT, patient refused to go with EMT, because he felt better after 30 minutes of sitting
1205449	4/13/2021		30	F	4/13/2021	4/13/2021	Nurse reported to myself and Regional lead that patient had a seizure at 1617 that lasted 90-120 seconds. Patient was lethargic but A&O x 4. Patient's mother reported hx of epilepsy. Vitals were stable at this time. 121/77, 68, 98.8, 100%, 16. Patient and mother present denied need for EMS to come out. No further reactions were noted at this time. Patient left in passenger seat with mother driving.
1205204	4/13/2021	CA	54	F	3/27/2021	3/28/2021	neurological grand mal seizures; difficulty breathing; tight chest; sore achy bones, muscle; sore achy bones, muscle; This is a spontaneous report received from a contactable consumer (patient). A 54-year-old non pregnant female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number: ER8737), via an unspecified route of administration at the left arm on 27Mar2021 12:45 pm at single dose for COVID-19 immunization. The patient's medical history included juvenile rheumatoid arthritis, asthma, diabetic Type 2, neurological seizure disorder from traumatic brain injury. The patient had known allergies to penicillin, tetracycline, sulfonamide. Concomitant medications included methotrexate (withheld for 2 weeks 25mg injection). On 28Mar2021 1:15 AM, the patient experienced neurological grand mal seizures, sore achy bones, muscle, tight chest, and difficulty breathing. The patient was treated with nebulizer for difficulty breathing. It was reported that patient had no covid prior vaccination nor tested post vaccination. Outcome of events was reported as not recovered.
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.

<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>
1195742	4/12/2021	WI	8	M	4/10/2021	4/10/2021	Patient was administered a Janssen COVID vaccine lot # 043A21A at approximately 10:33 on 4/10/2021. Patient expressed no history of difficulty with shots or vaccinations. Patient gave no indication he was not feeling well or any indication he was experiencing difficulties. Shortly after administration of the vaccine, approximately 3 minutes and while handing Patient his paperwork, he became unresponsive. Patient was lowered to the floor where he exhibited what could be described as minor convulsions that were very short lived. His feet were elevated and he regained consciousness after approximately 2-3 minutes. His vitals were taken and recorded. Patient reported that he has no remarkable medical.
1195740	4/12/2021	FL	16	F	4/11/2021	4/11/2021	Systemic: Flushed / Sweating-Medium, Systemic: Seizure-Medium, Additional Details: was laid down and legs elevated once calmed down, ems were called and further treated by them
1195720	4/12/2021	PA	33	F	4/11/2021	4/11/2021	Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Additional Details: Patient felt dizzy for 5 minutes after getting the vaccine, she got on her knees, and then passed completely out. Her body was rigid and was unresponsive for about 30 secs. The patient woke back up and thought she has urinated. We took her vitals and her BP came up 141/131 Pulse 88. The paramedics arrive and when they took her BP it was 137/82. She refused transport to the hospital. When she left the store she was feeling normal.
1195823	4/12/2021	FL	16	F	4/11/2021	4/11/2021	Systemic: Flushed / Sweating-Medium, Systemic: Seizure-Medium, Additional Details: was laid down, epi given by imer, legs elevated once calmed down, ems called and treated, recovered soon after

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1197219	4/12/2021	IL	41	F	4/7/2021	4/7/2021	11pm: Fever, chills and muscle aches 3am: Chills and muscle aches worsen 6am: Weak and short of breath 7:30am: Body begins to tingle, cant really feel hands or feet, trouble breathing, shaking, eyesight worsens, chest tightens, headache 7:43am: Call husband for help, begin sweating a lot 8am: Call 911, begin convulsing, trouble talking, cant see well, trouble breathing, urinate on myself Continue to have convulsions. Taken by ambulance to hospital. Continue to have involuntary contractions, tightening of chest, trouble breathing, bad eyesight, headache. etc. Diagnosed with Dystonic Reaction and Neurologic Problem because of a vaccine complication
1196532	4/12/2021	VA	48	F	4/6/2021	4/6/2021	Patient went to bed and woke up having something like a grand mal seizure around 10 p.m.. She felt hot but didn't take her temperature. She is perimenopausal and couldn't say for sure if she was having a hot flash or a fever. Her previous seizure was a year ago she said. Around 2:00 a.m. she woke up with stretching movements with her arms over her head that she couldn't control, but didn't feel like a seizure to her. Patient went back to bed, but woke up around 5:30 a.m.. with temp of 102 degrees F. She took 2 ibuprofen 200mg (total dose 400mg) every 4 to 6 hours starting at 5:30 a.m. for a total of 3 doses. She felt better by later afternoon. She complains that her arm is still sore today. She just reported this to us this morning when she was back in the pharmacy.

<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>
1197228	4/12/2021	CT	30	F	4/8/2021	4/8/2021	30 year old female received Janssen vaccine Lot# 1808982 exp: 6/23/21 at approximately 3pm in the left deltoid. Immediately after being vaccinated, pt. requested to remain seated. The nurse noted that the pt. was getting pale so she suggested the pt. take off the surgical mask to get some air. Before pt. had a chance to take off the mask she lost consciousness. Together with another nurse patient was lowered onto the floor. Pt. regained consciousness for 30-45 seconds and then began to have seizure like activity. Her eyes rolled back and her body became stiff and began a jerking motion. 911 was called. This seizure like activity lasted 4-6 seconds at which time pt. regained consciousness and immediately sat up. Pt was pale and diaphoretic. BP 98/64, HR 78, Pulse Ox 99%. Pt vomited multiple times. Ice was applied to the posterior neck and a cold compress to the forehead. EMS arrived and took vitals: BP 78/40. Pt. was aware of person, place and situation. Pt. was taken to Hospital accompanied by her husband. Pt was called by me Friday and she was home. All tests showed no sign of having a seizure.
1198288	4/12/2021	CA	62	M	3/24/2021	3/24/2021	Warm feeling followed by fainting and slight convulsions. Nausea, gas, feeling faint, and inability to drive a vehicle for approximately 75 minutes. Slept for several hours, faint feelings subsided after 15 hours.
1195995	4/12/2021	KY	73	M	4/9/2021	4/10/2021	I received both my Covid-19 vaccines at the Health Department. I got my second one on 4/9/2021. I had no problem with the first shot but Saturday Morning on 4/10/2021 I woke up at 5:14 am in horrible condition. I was running a 103 fever, was freezing horribly causing my entire body to shake like I was having a seizure. I could not move. I felt like an elephant was sitting on my chest. My entire body was hurting badly. I am better today, 4/12/2021 but still feel slightly ill and very tired.
1197933	4/12/2021	CO	40	M	1/29/2021	1/30/2021	Patient's behavior appears more in line with focalized or petit mal seizure activity. Grand Mal activity NOT witnessed.

<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>
1196497	4/12/2021		41	F	4/9/2021	4/9/2021	Patient was in her 15 minute wait after vaccination, and complained of swelling, itching, tingling, difficulty in breathing, coughing and gagging while in our observation tent. Client was brought inside by wheelchair to our emergency area for further evaluation. Client was answering questions, pulse ox read 100%, pulse 106. Client had increased complains of tightness in throat, was coughing. 4:11 pm- 0.3 Epi pen given in right thigh. Lot # OFM534, exp: 9/20222. Call made to 911. Client then lost consciousness, eyeballs were fluttering underneath lids. Sternal rub- did rouse client, but then she became unconscious again. Daughter then reported a history of allergy to MRI dye, Pulse 110, 2 L O2 started. Client remained unresponsive, but was breathing normally. 415- call to Dr to assess whether Benadryl should be given or not- since client was unconscious. 415 shaking/chills began, and daughter reported history of non-epileptic seizures, but none since 2019. 416pm EMS arrived- IV started and seizure #2 witnessed by EMS. Seizure meds given per EMS- client transported to hospital.
1199537	4/12/2021	IL	62	F	4/4/2021	4/4/2021	Fever aches chills started after 12 hours, 24 hours after dizziness, weakness fatigue. Passed out at home after the 24 hour mark. After coming "to" was vomiting. Perhaps was a seizure. The paramedics were called and I was evaluated and all was ok- O2 was fine, sugar 138, BP 110/60. I was to drink pedialyte, rest .
1196672	4/12/2021	OH	28	F	4/11/2021	4/11/2021	After sitting in chair to be monitored pt felt dizzy and had seizure for 15 min. VS right after seizure@1113: BP 138/94, HR 42, Oxsat97%. Rechecked vitals after sitting back up for 20 min: Blood sugar 108, Oxsat: 99%, HR 56, BP 117/75. This was the first seizure for the patient. He does not want to go to ER. Pt was monitored longer. EMS reported he could be released to go home. Parents were instructed to notify MD and to monitor pt status if any seizure like activity call 911. This patient frequently passes out with shots.
1196750	4/12/2021	CA	37	M	4/10/2021	4/10/2021	loss of consciences after injection was given, seizure, vomiting and confusion, monitoring in EMS and transferred to higher level of care via EMS services

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1196758	4/12/2021	KY	40	F	3/26/2021	3/26/2021	About 1.5 hours after second dose of Pfizer COVID-19 vaccine, patient was driving and experienced what she believed was a seizure. She has a past medical history of seizures, but had not had one for over 15 years after being stable on Keppra. Patient did have a minor motor vehicle accident and went to ER. At ER, she returned to baseline and it was determined it was either a seizure or syncopal episode. She was instructed to follow-up with neurology.
1197087	4/12/2021	MT	25	F	4/7/2021	4/7/2021	1 minute after receiving vaccine, patient was seated in a chair. Large sigh, then head went back. Staff immediately by her side, full grand mal seizure lasting 90 seconds. During this time assist of two to floor. After seizure assisted to side for rescue position. Public health attached to hospital and MD and PA arrived quickly. Patient transported to ER for further follow up. When patient regained consciousness she stated she had "passed out several times before and has felt more stress in this past year.~~
1197115	4/12/2021	SC	38	F	4/8/2021	4/8/2021	About 2 minutes after injection, patient began complaining of being dizzy. She then lost consciousness in what appeared to be a seizure: body stiffness, eyes rolled back, shallow breathing, lock jaw. After 30 seconds, she regained consciousness and function. She was a little light-headed and nauseous. 3 minutes later she vomited and 5 minutes later EMS arrived, After the incident and prior to EMS arrival, spouse stated that the patient had a history of similar incidents with needle exposure. Patient left with husband. We have tried to get in touch with the patient for follow-up and she has yet to return our calls.
1196491	4/12/2021	CO	85	M	3/25/2021	3/26/2021	Spouse reports that the following day after receiving the vaccine, Patient had 5 seizures. Spouse reports no history of seizure activity prior to the 5 reported. States client is homebound, and an ambulance was called to the home.
1199143	4/12/2021	CA	59	F	3/27/2021	4/3/2021	Headache and vomiting starting one week later (4/3/2021); seizure due to hemorrhagic stroke 04/5/2021; continued bleeds 04/06/2021, 04/07/2021; life support removed 04/08/2021.

<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>
1198417	4/12/2021	MI	41	M	4/8/2021	4/8/2021	I immediately past out twice and was told I had two minor seizures. I declined ambulance and have felt dizzy spells since. I have appointments to get checked out.
1198510	4/12/2021	PA	26	M	4/10/2021	4/10/2021	According to vaccinating nurse, a few minutes after vaccination patient experienced a short (less than one minute) generalized seizure. She was able to lower him to the ground and patient did not hit his head or suffer fall. Two EMTs were on site and attended to patient. 911 was called and patient evaluated by medics. Blood sugar and vital signs within normal limits. Patient' s father also came to the scene. Patient and father refused transport to the local hospital. Father stated they will go directly to the local emergency room for evaluation.
1198515	4/12/2021	MO	23	M	4/12/2021	4/12/2021	patient was post pfizer covid vaccination about 5 minutes seated in chair. fainted and appeared to have a seizure of around 1 min. his mother and I were trying to revive/wake pt during this time. called 911. pt was disoriented upon awakening and vomited about 5 times. emt arrived in about 7 mins. pt left in ambulance.
1198644	4/12/2021	MO	30	F	4/7/2021	4/8/2021	Fever, severe body aches, spine pain, convulsions, shaking, difficulty turning torso/spine without pain (still occuring), fatigue
1198700	4/12/2021	NV	58	F	2/12/2021	4/2/2021	Seizure that left me unable to breath and rushed to ER then placed in a medically induced coma and intebated for 2 days. Cavernous malformation with venous anomaly that experienced a leak or bleed. Intracranial bleed, acute kidney injury, acute respiratory failure, altered mental status, leukocytosis, status epilepticus
1198785	4/12/2021	NY	58	F	3/21/2021	3/21/2021	myoclonic seizure; fever; dizziness.
1198786	4/12/2021	CA	79	F	4/8/2021	4/9/2021	Seizures started Friday. Patient sent to hospital. Patient back at rehab

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1198132	4/12/2021	TX	28	M	4/11/2021	4/11/2021	Patient received the vaccine and while waiting at the post vaccine observation lobby, fainted. He stated he was not diabetic, did not have breakfast that morning and was nervous about the vaccine. Fainting episode lasted less than 1 minute, and afterwards patient was alert to person time and place. He was taken by ambulance by paramedics for further evaluation because his fiance stated that she saw him have a small seizure. I did not witness the seizure.
1199094	4/12/2021	TX	20	F	4/12/2021	4/12/2021	Patient fainted and had seizure like symptoms with eyes rolling back in head, clamminess, sweating, severe stomach cramps, blurred vision, and temporary loss of hearing
1197949	4/12/2021	TX	18	F	4/8/2021	4/8/2021	dizziness and fainted, shivers/chills, 4 x episodes of break through seizures
1197174	4/12/2021	TX	30	M	4/12/2021	4/12/2021	Pt reported not feeling well in less than 5 minutes after shot. Initially he was sweating, followed by dizziness. In few seconds, he started convulsing. I administer Epi-pen 0.3 mg, 1 adult dose in his left thigh. His convulsion stopped at very moment, paramedics took over from there. His vitals were checked and monitored by paramedics for few minutes. He did not require hospitalization at this moment, however advise to seek medical attention if he feels something abnormal. He was able to walk himself to his car, where his family member drove him to home.
1199359	4/12/2021	ME	46	F	3/30/2021	3/30/2021	I had increased arm pain from the second dose, swelling in the upper arm, a splotchy rash that was raised, and increased neurological seizure activity with loss of sleep, mania, and weakness in the upper torso. I had issues with speech, reading, and word pronunciation. I called the neurologist who referred me to psychiatry and went to the ER who determined there was " nothing they could do", to check in with my GP who had referred it to neurology and the ER.
1199543	4/12/2021	PA	91	F	3/12/2021	3/17/2021	Facility manager informed us that patient had a seizure on 3/17/21, which was 2 days after the vaccine was given (3/15/21) which then lead to a stroke. Patient passed died on 3/17/21.

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1199230	4/12/2021	MT	33	M	4/12/2021	4/12/2021	After the vaccination patient sat down in waiting room next to the pharmacy. He passed out in his chair and appeared to have a seizure. He was pale in color and had sweat dripping off his forehead. Blood pressure was 150/90 and pulse 80 bpm. He was given a cold compress and two bottles of water to drink. After 45 minutes patient felt fine and was able to leave on his own.
1198076	4/12/2021	PA	29	M	4/12/2021	4/12/2021	About five minutes after the vaccine patient reported that "he wasn't feeling well.". When I went to evaluate the patient he was very warm and was breaking out in sweats. He said his vision was very blurry. The patient lost consciousness and had convulsions/lower extremity rigidity for about 30 seconds to a minute. Patient regained consciousness and did not have any more convulsions. Patient was drenched in sweat but slowly regained color and he said his vision was returning to normal. Patient did not remember losing consciousness. EMS was called during the episode and patient was taken for further evaluation by EMS.
1197996	4/12/2021	TX	26	M	4/9/2021	4/9/2021	Stood up, sat down and got light headed before blacking out. Nurses on-site said I had a seizure. Rushed to hospital. Blacked out for 1.5 minutes
1198845	4/12/2021	AR	65	F	4/1/2021	4/2/2021	She experienced weakness & aches shortly after midnight (10-12 hours after 2nd dose). She fell in the middle of the night and was too weak to get herself up. The weakness subsided, but tremors (she has had essential tremors her whole life) are significant & began the day after the shot. She can "feel them from the inside," they are much more significant than she has ever experienced, and sometimes violent, involuntary convulsions. She finds difficulty performing day-to-day functions such as eating or drinking. She first reported about 5 days after the shot (not to this severity, and she complained more about the weakness), now reports they still persist. She is of good spirit. Her doctor is doing telemedicine & knows of the events. He was to get with her this afternoon after we talked.

<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>
1195217	4/11/2021	WA	32	F	4/1/2021	4/2/2021	Thurs, 04/01/2021, She exhibited excitability episodes (no triggers) multiple times after vaccine, starting within 45 minutes. Fri, 05/02/2021, when she woke, she had first grand mal seizure in 4-5 years; called 911 EMS to ck her before driving her to urgent care. She was cked by Dr & no severe tongue injury noticed. He sent referral for neurologist to followup. Called her primary Dr. & was told Dr out for several days. Call back from another Dr who refilled ATAVAN script in case further seizures. Apt set w/neurologist, for Wed. 04/14/2021.
1194241	4/11/2021	TX	38	M	4/10/2021	4/11/2021	After the first dose, I experienced only mild fatigue and a mild headache within a couple hours of the injection. Later within 10 hours, I developed strong injection site direness that affected my sleep but abated within 12 hours. Therefore, I was expecting more or less similar symptoms with the second dose. Instead, I felt absolutely nothing for nearly twelve hours until I fondly felt mild injection site soreness. I went to bed around 1 am. At around 2 am I awoke with such strong chills that they were almost like convulsions. I was sweating and had a headache. More concerning though was the tachypnea and wheezing. I was wheezing as if I had asthma to the point that my lunch?s were whistling and I found it difficult to take sufficient breaths. This lasted 30 minutes to one hour before a sting enough that I fell asleep again, still with mild left arm soreness, sweating, mild fever, headache and wheezing. When I awoke a few hours later at around 8 am, I was so fatigued that I could not move. I had a mild headache still but the breathing was better without wheezing and now only hampered by frequent belching (passing off the CO2 buildup from the tachypnea most likely). However, I was so exhausted that I lay in bed for another four hours. When I forced myself up to shower and move, I had a sudden severe depressive attack of uncontrollable crying in the shower. I also had body aches throughout the morning. These symptoms are the same or similar to those felt when I had COVID, so I knew them and that they should pass, yet I did not expect them to be so strong and the tachypnea with wheezing was initially very disconcerting until it began to ease. By approximately 11 hours later, all symptoms had passed.

<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>
1192864	4/11/2021	NY	27	F	4/10/2021	4/10/2021	Systemic: Seizure-Medium
1192879	4/11/2021	TN	25	M	4/10/2021	4/10/2021	Approximately 5 minutes after vaccine patient was in 15 minute lot, car in park. Observer Called on emergency radio for RN with bag. RN noted patient was actively Seizing. the patient's wife was in the vehicle and confirmed the seizure. The patient was conscious within 2 minutes, vomited x 1 and stated he was stating to feel better. EMS was activated as son as the seizure was noted and took approximately 10 minutes to arrive. The patient was conciuos and walked to the ambulance and was transported to hospital
1192894	4/11/2021	TX	60	F	4/10/2021	4/10/2021	Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Medium, Additional Details: Thirty minutes after shot, patient passed out and urinated on herself. Plus, had what she discribed as a seizure.
1192904	4/11/2021	CA	31	F	4/10/2021	4/10/2021	Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Mild, Additional Details: Pt felt lightheaded after receiving vaccine. Instructed to sit for a few minutes before heading to the post vaccination area. Pt fainted within 10 secs onto the immunizer (me). Asked for help to move pt to a lying down position. Upon lifting pt up, her body/arms seized up. Asked someone to call 911 and I went to grab an epipen just incase. Within 5 secs, patient woke up, so did not admin epi. Pt was alert but did not know what happened. Pt refused ambulance, left after 30 min, was feeling ok.
1192907	4/11/2021	CA	31	F	4/10/2021	4/10/2021	Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Mild, Additional Details: Pt felt lightheaded upon admin and fainted on immunizer after 10 sec. Asked others to help move pt to lying position. Upon moving pt, her body/arms seized up. Instructed others to call 911. Went to grab epipen. Within 5 secs of seizing, pt woke up, so epipen was no admin. Pt was alert, but did not know what occurred. After 30 min of resting, pt was ok and left pharmacy.

<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>
1192963	4/11/2021	WI	47	M	4/10/2021	4/10/2021	Systemic: Confusion-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hyperventilation-Medium, Systemic: Seizure-Severe
1193006	4/11/2021	CA	64	M	4/9/2021	4/11/2021	At 5:05 am on April 11, approx. 37 hours after I received the shot, I awakened to a rapid muscle convulsion in my left shoulder muscle, at the approximate location of the injection. I counted between 2 to 6 contractions per second (yes, it was a very quick twitch that involved my whole upper arm). It went on for at least 10 minutes, then paused for less than a minute and then resumed. This was a pronounced muscle spasm which I cannot remember having before. I have had twitching eyelids or facial muscle that would twitch for a few minutes in the past, but this went on for over 30 minutes, and I am not sure it is done. Also, this was much more intense than the above-referenced twitches. The location and time relative to my shot makes me fairly certain that this is an effect of the vaccine. I have not exercised or done anything to cause this to my knowledge. Of course, this seems like a harmless side effect, but my concern is that my heart muscle reacting to this in a similar fashion could be more serious.
1193142	4/11/2021	NJ	46	M	4/10/2021	4/10/2021	Seizure-like episode. Patient was seated when his body went rigid and he lost postural control and started to slide sideways. His body was shaking slightly and his eyes were open but there was no cognitive awareness. This lasted no more than 90 seconds and then patient came to abruptly and reoriented himself on the chair before I had the opportunity to get him to the floor. Patient then stated that he was lightheaded, warm and sweaty. EMT had been called and upon assessment of the patient transported him to the ER.
1195476	4/11/2021	AR	28	M	4/10/2021	4/11/2021	Seizures (never had before), high fever 102+, dizziness, severe back pain, convulsions and confusion
1194211	4/11/2021	TN	44	F	4/10/2021	4/11/2021	Convulsion type chills at night Skin and organs hurt Eyes hurt Headache Tires

<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>
1195363	4/11/2021	CA	43	M	3/20/2021	3/20/2021	I was feeling fine directly after getting the injection. All of a sudden, after about 5 minutes, I felt a rush go through my body and managed to declare "I'm not feeling well" before I lost coherence and clarity. My wife called for help from the attendants as I started to convulse, get dizzy, start sweating, and feel like I was going to pass out. I then proceeded to throw up a couple of times and had to lie back for 30 minutes before switching to the passenger side of the vehicle for the ride home. I was completely worn out and weak, with flu-like symptoms and nausea for the rest of the day and for several days afterward.
1194550	4/11/2021	CA	35	F	4/11/2021	4/11/2021	feeling dizzy, passing out and seizure
1194560	4/11/2021	FL	51	M	4/11/2021	4/11/2021	patient had a seizure and lost consciousness; pt regained consciousness after a couple minutes; pale and perspiring, paramedics came and provided care from there
1194628	4/11/2021	RI	32	F	4/4/2021	4/6/2021	Diagnosed with JME. Seizures well controlled for over a decade with medication. Repeated nocturnal myoclonic seizures for multiple days. Has gotten better, but not resolved fully. Neurologist had no answer.
1194864	4/11/2021	NY	22	F	4/7/2021	4/10/2021	Patient had a generalized tonic-clonic seizure while at work, three days after receiving the COVID vaccine. The seizure self-resolved after about 4 minutes and patient returned to baseline soon after. She was taken to the emergency department for further evaluation. Patient had been feeling well after the vaccine. Patient was seen by neurology and started on keppra.
1194962	4/11/2021	PA	28	M	4/10/2021	4/11/2021	5pm felt warm, temp at 99.3. clingy behavior. Gave one advil, settled down. Advil relieved his behavior. Ate dinner, off balance afterwards, fell asleep..possible seizure activity occurred 6pm. I increased his klonopin by .5mg. To monitor.

<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>
1195013	4/11/2021	NY	45	F	4/11/2021	4/11/2021	45 y/o F with PMHx of vasovagal with seizure c/o not feeling well around 1:14 pm (which was 14 minutes after receiving her second dose of Pfizer vaccine). She began having a tonic-clonic seizure at 1:15 pm lasting around 90 seconds. Patient was post-ictal for approximately 1-2 minutes. When EMS and Clinical Leads were notified, patient was not actively seizing. Patient was not responsive to verbal stimuli while post-ictal. After ~3min pt was able to respond and follow verbal and tactile commands. Pt was c/o feeling tired / nauseous. Pt was AOx3 and able to follow commands. Patient was assessed by EMS and clin leads, she was placed on a stretcher, attached to monitor, vitals and BGM taken, 18g IV started on right hand and 20g IV access point attained on left hand. 15L NRB O2, 250mL NS bolus, 1L NS bolus Pt remained stable and transport was called, pt was transferred to hospital for further evaluation/workup. Pt's father accompanied pt to vaccination site and followed EMS to the hospital. 15L NRB O2, 250mL NS bolus, 1L NS bolus, 1L NS bolus started via transport Denies HA, numbness, weakness, parathesias, tingling, trauma, hitting her head, erythema/induration at injection site, palpitations, chest pain/tightness/heaviness, SOB, dyspnea, wheezing, facial or peripheral edema, cyanosis, hives, pruritis 2nd Pfizer dose administered @13:00pm, symptoms began @13:14pm, seizing began @13:15pm @1:25pm: HR 80bpm, SpO2: 100% NRB @15L @1:28pm: 3 lead: sinus arrhythmia with notched R waves in leads I, II, III, avR, avL, avF (unspecific QRS abnormality), notched p-waves in all leads, EKG not acutely concerning and patient is not actively infarcting @1:29pm: IV access with 18g @1:30pm: BGM: 99 @1:31pm: 12 lead @1:37pm: BP: 102/70 (manual large cuff on left arm) @1:42pm: BP: 80/50 (automatic large cuff on left arm) Lungs: clear to auscultation b/l, no respiratory distress, no wheezing, no rales cardiac: normal S1S2, rate, rhythm Eyes: PERRLA Throat: airway patent, no trismus Neuro: AOx3, sensation/motor/strength intact in all 4 extremities, Motor 5/5, DP/PT 2+ B/L

<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>
1195089	4/11/2021	CO	44	M	4/9/2021	4/10/2021	He had his first vaccine March 19th, 2021 at 12:15, same lot as above, and 24 hours later he had difficulty breathing, shortness of breath, fatigue, shakes, chills and feeling of weakness/dizziness. It lasted a few days. Then, April 9, 2021, he received his second Covid19 Pfizer shot, same lot at 12:15 pm and the next morning, Saturday, April 10th around 9 am Ira felt the same symptoms from shot 1, but more intense. He was feeling weak, had chills, shakes, profuse sweating, difficulty breathing, shortness of breath, dizziness and vomiting. He was unable to keep water down and stayed in bed. A little after 12pm, he complained of difficulty breathing and possibly not getting enough oxygen so I grabbed my equipment (since I'm a CNA) and checked his vitals. His B/P was very high (166/107), no fever (96.7), pulse was normal 72, and low respiration but oxygen was above 90. He said he needed to use the bathroom, I suggested using his urinal but he said he needed to have a bowel movement. Once he was in the bathroom, I went downstairs for a glass of water and then suddenly I heard a huge thump. I ran upstairs, knocked on the bathroom- no response but I could hear noises, so I opened the door and I saw he was face down on the floor, head under the bathroom sink counter, blood everywhere, and he was convulsing. I grabbed him immediately and moved him to his side (I had my fitbit on, it said it was 12:30pm), and he kept seizing. He looked discolored almost blueish color. I held him on his side, he vomited, making noises, but unable to speak, continuing to have a seizure. Seizure lasted three minutes. At 12:33pm, once he had calmed, I ran downstairs to find my phone. I was back at his side calling 911 at 12:35. Paramedics arrived 9 minutes later and took him to the hospital. My brother picked me up and took me to the hospital. Once outside his door, I noticed he was finishing taking X-Rays when he suddenly had another seizure.

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1195138	4/11/2021	CO	45	M	3/21/2021	4/1/2021	I received the vaccine on 3/21. On 4/1 I had a breakthrough grand mal seizure walking down the street after being seizure free for almost 5 years. The seizure resulted in a fractured vertebra (T12). On 4/5, while resting at home I woke up and had another seizure sitting in a relax the back chair. I had a mri on my brain that I understand came back normal. The doctors aren?t sure what caused the seizures but increased my dosage by 500 mgs per day despite my previous dosage controlling my seizures for about 5 years prior to my vaccine. No doctor has definitively stated the seizures were caused by the vaccine. However, the timing has prompted me to notify you of these events.
1194352	4/11/2021	FL	45	F	4/11/2021	4/11/2021	described pre-seizure aura and described as having eyes rolling back in head
1193790	4/11/2021	VA	19	M	4/7/2021	4/7/2021	~~Asyncope followed by apparent seizure activity. Palor, stiffness with jerking motion of muscles to extremities. Pt. lost conciousness multiple times (2 to 3). Patient was transported to hospital via EMS

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1194240	4/11/2021		42	F	3/22/2021	3/23/2021	Blackout; Sleeping a lot; This is a spontaneous report from a contactable consumer (patient). A 42-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Mar2021 (Batch/Lot Number: EN6204) at the age of 42-years-old as single dose for covid-19 immunisation. Medical history included seizure from 1994 to an unknown date (it is been happening since the patient was a teenager), epileptic from an unknown date and unknown if ongoing. Concomitant medication included levetiracetam taken for seizure from an unspecified start date and ongoing. The patient reported that she had like blackout from, assuming the vaccine the next day on 23Mar2021. It was kind of later in the day and then next day, 23Mar2021, she was just having kind of had a blackout and she was sleeping a lot and may have had a seizure, she was not really sure as she was sleeping a lot and may had a seizure; she was not sure and she was epileptic. The patient was grateful that she got the vaccine. The patient underwent lab test and procedures which included blood test: unknown on an unspecified date. The patient was recovering from the events. Information on the lot/batch number has been requested
1191639	4/10/2021	OH	18	F	4/10/2021	4/10/2021	fainting, followed by seizure like involuntary movement for 15 secs. patient regained consciousness and left with family to healthcare providers.
1191727	4/10/2021	OH	40	M	4/10/2021	4/10/2021	Lost consciousness and had convulsions for 30-45 seconds
1191747	4/10/2021	CA	18	F	4/10/2021	4/10/2021	Vagal, Tremors, hypotension, seizures,

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1191774	4/10/2021	TX	73	M	3/22/2021	3/22/2021	Weakness; dizziness; cold; seizure; This is a spontaneous report from a contactable consumer reporting for himself. A 73-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Right on 22Mar2021 10:45 (Lot Number: EN6205) as single dose for COVID-19 immunisation. Medical history included Heart stent. There were no known allergies to medications, food, or other products. Concomitant medications included atorvastatin; cyanocobalamine; loratadine (LORADINE); metoprolol, all taken for an unspecified indication, start and stop date were not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient experienced Weakness, dizziness, cold, seizure on 22Mar2021 16:45. The events resulted in Emergency room/department or urgent care and hospitalization. The patient was hospitalized for Weakness, dizziness, cold, seizure for 2 days. Since the vaccination, the patient has been tested for COVID-19. The patient underwent lab tests and procedures which included COVID test Nasal Swab post vaccination: negative on 25Mar2021. Therapeutic measures were taken as a result of events which included Anti seizure meds.

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1191782	4/10/2021	OR	40	F	3/24/2021	3/24/2021	Seizure like events; Began sputtering; My shoulder and neck seized up; Eyes rolled back in her head and she had no control over it; Did not remember some of it; Confused; Unable to focus with her eyes; Extreme fatigue; Walking is unsteady; This is a spontaneous report from a contactable consumer (the patient). A 40-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: 59267-1000-03), via an unspecified route of administration, administered in left arm on 24Mar2021 16:45 as single dose for COVID-19 immunization. Medical history included asthma, bronchitis, anxiety, allergy to Aspirin, NSAIDs, agave, soy, and dairy. The patient has no history of COVID prior vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not COVID tested post vaccination. Concomitant medications included venlafaxine and progesterone taken for an unspecified indication. On 24Mar2021, 19:30, the patient experienced seizure like events. She began sputtering, her shoulder and neck seized up, eyes rolled back in her head and she had no control over it and did not remember some of it. It happened twice in a row. She had been confused, unable to focus with her eyes, extreme fatigue, and her walking was unsteady. The adverse event resulted in Emergency room/department or urgent care. The patient received treatment for the events. The patient was requested for testing and referral for neurologist for MRI. The patient has not recovered from the events. Follow up attempts are possible. Further information is expected.

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1191847	4/10/2021	NJ		U			lost consciousness; vomiting; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as a single dose for COVID-19 immunization. Medical history included scarring on heart and frontal lobe neural observation (like epilepsy or seizure). There were no concomitant medications. 6-12 hours after shot, patient became ill; described as vomiting and lost consciousness. Patient was admitted to ICU and remained there for 4 days. Patient has recovered from the events on an unspecified date. The second shot is scheduled for the upcoming week. Information about lot/batch number has been requested.
1192612	4/10/2021	AL	35	F	4/6/2021	4/7/2021	Seizure- first in medical history 26 hours after vaccine was administered
1191892	4/10/2021			U	3/1/2021	3/1/2021	I'm a little off balance; This is a spontaneous report from a Pfizer-sponsored program. A non-contactable consumer(patient) reported that a patient of unspecified age and gender received BNT162B2 (Pfizer-BioNTech COVID-19 Vaccine, Solution for injection, Lot number was not reported, expiration date: Not reported), via an unspecified route of administration on Mar2021 as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. It was reported that patient called due to takin the Pfizer-BioNTech COVID-19 Vaccine and stated that they gave the Pfizer vaccine yesterday, patient was little off balance on Mar2021. Patient had seizure medicine changed on Monday or Tuesday and feel like patient was off balance. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.
1191589	4/10/2021		45	M	4/10/2021	4/10/2021	Questionable seizure activity x 30 seconds.

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1191910	4/10/2021	ME		F			seizure; fell out of bed; bruises; This is a spontaneous report from a contactable consumer. A female 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 who received the vaccine experienced and similar seizure same day she fell out of bed/ bruises/spent night on an unspecified date. The outcome of the events was unknown. Additional information on lot/batch number has been requested.
1191929	4/10/2021			F	3/18/2021	3/20/2021	severe seizure; This is a spontaneous report from a medical information team. A contactable consumer (patient mother) reported that a 37-years (severely disabled) old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration on 18Mar2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Caller stated both she and her daughter received the Pfizer Covid vaccine first dose on 18Mar2021. On 20Mar2021 her daughter had a severe seizure and was hospitalized for 4 days (from 20Mar2021 to an unspecified date in Mar2021). The patient mother wants to know if it's safe for her daughter to get the second dose of the vaccine. The seriousness for the event was hospitalization and medically significant. The outcome of the event was unknown. Information on the lot/batch number has been requested.

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1192110	4/10/2021	WA	84	F	3/25/2021	3/29/2021	<p>bilateral DVT; This is a spontaneous report from a contactable physician. An 84-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 intramuscular, administered in Arm Right on 25Mar2021 (at the age of 84-years-old) (Batch/Lot Number: EP6955) as SINGLE DOSE for covid-19 immunisation. Medical history included CKD, Allergic Rhinitis, basal cell carcinoma, vertigo, dupuytren's contracture, Gerd, hypothyroidism, hypertension, osteoarthritis, osteoporosis, prediabetic, palpitations, sleep apnea, seizures, anxiety, Allergies to medications, food, or other products: BACITRACIN, LATEX, MORPHINE, POLYSPORIN, ADHESIVE TAPE. Concomitant medication(s) included azelastine (AZELASTINE); enalapril (ENALAPRIL); famotidine (FAMOTIDINE); fluoxetine (FLUOXETINE); fluticasone (FLUTICASONONE); ipratropium (IPRATROPIUM); levetiracetam; levothyroxine; zonisamide; all taken for unspecified indications, start and stop dates were not reported. The Patient was not diagnosed with Covid-19 prior to vaccination. The patient received first dose of BNT162B2 (lot number: EN6198) via intramuscular in right arm for COVID-19 immunization on 26Feb2021 at the age of 84-years-old. On 29Mar2021, the patient experienced bilateral dvt (life threatening). Therapeutic measures were taken as a result of bilateral dvt: ELIQUIS. The outcome of the event was recovering. Since the vaccination, the patient has not been tested for COVID-19. Information on Lot/Batch number is available.; Sender's Comments: There is not a reasonable possibility that event DVT is related to BNT162B2. This elderly patient had multiple underlying diseases. The event is more likely intercurrent medical condition. 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>
1192135	4/10/2021	NY	18	F	3/29/2021	3/30/2021	<p>Severe vomiting, diarrhea, stomach pain. Trouble breathing... shaking like a seizure.</p>

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1192175	4/10/2021	IL	31	F	4/8/2021	4/8/2021	She reports about 5 minutes after receiving the vaccine she went to stand up, felt lightheaded, next thing she knew she was on the ground with staff around her. Of note patient was called as a rapid response initially to the vaccination area. Few compressions had been done as the nurse who initially noted her to be down had difficulty filling a pulse. However patient had not lost the pulse. Patient does however report that she did lose some control of a small amount of urine which is never happened her before. No seizure activity was noted by staff and patient reports no prior history of seizure activity. States that she did used to faint frequently when she was a child in the setting of shot/pain. But reports she has not had to have vaccinations in many years. Rapid response team came to vaccine observation area and pt went to emergency department.
1192453	4/10/2021		42	F	4/9/2021	4/9/2021	Immediately after the vaccine was administered the patient complained of pain in the arm. I escorted her to a chair in the waiting area for 15 minute observation and she said she didn't feel right and I should get her husband . She began seizing in the chair and I held her safely during the episode. Her husband came in and she became oriented, but still complained that her arm hurt from the injection. . Before her vaccine I questioned her about her seizures and she said the seizures were being controlled by medicine. After the episode when talking with the patient's husband he said her seizures are quite frequent, the last one being about 1 month ago. EMT's came to the pharmacy to monitor her before she was released to go home.

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1192544	4/10/2021	NV	34	M	3/29/2021	3/30/2021	He had flu-like symptoms after receiving the vaccine on Monday 3/29. He woke up on Tuesday 3/30 with fatigue and a low-grade fever. He was scheduled for a routine doctor's appointment late Tuesday afternoon. At the doctor's office he had a seizure, which caused him to lose consciousness for 15 seconds. Upon waking, he was transferred to the Hospital. He was released later that day. On Wednesday 3/31, he experienced a headache & went to the hospital. He was admitted and stayed in the hospital for 2 nights. An MRI found micro-bleeds on his brain. He was treated with lamotrigine and sent home with a prescription for 25mg/twice daily. He has a follow up appointment with a neurologist in 3 weeks.
1191880	4/10/2021	CA	39	M	3/25/2021	3/26/2021	seizure like violent tremors in the middle of the night.; This is a spontaneous report from a contactable consumer (patient). A 39-year-old male patient received second dose of BNT162B2 [PFIZER-BIONTECH COVID-19 VACCINE (also reported as MODERNA; pending clarification), solution for injection, lot number and expiry date were not reported], via an unspecified route of administration, administered in the left arm on 25Mar2021 13:00 (at the age of 39 years old) at a single dose for COVID-19 immunization. Medical history included COVID-19 from an unknown date and unknown if ongoing. There were no allergies to medications, food, or other products. The patient's concomitant medications were not reported. The patient previously received first dose of BNT162B2 (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 experienced seizure like violent tremors in the middle of the night on 26Mar2021 04:00. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There were no other medications received within 2 weeks of vaccination. The outcome of the event was recovering. Information on the batch/lot number has been requested.

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1190545	4/10/2021	IL	24	M	4/10/2021	4/10/2021	Pt received Covid vaccine, was told you wait 15 minutes to be monitored. While waiting, he was adjusting his sweatshirt and was flailing with the sleeves and hood. It was witnessed that his face became red, he started to convulse and fell to the ground while pulling on the handle of his shopping cart. He was able to sit up on his own; at which time 911 was dispatched. Paramedics arrived quickly and assessed patients blood pressure and condition. They cleared him and they left at 11:40am. Pt was escorted to his truck by staff pharmacist and left before noon.
1188426	4/10/2021	KY	44	M	3/29/2021	3/30/2021	High grade fever that lasted for 32 hours total and peaked at 103.5. Severe cold chills that led to involuntary convulsions. Body aches that last for three days. Extreme fatigue.

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1188733	4/10/2021	TX		U		3/30/2021	<p>ARM FEELS LIKE HIT BY BASEBALL BAT; JUST ABOUT PASSED OUT; FELT FEELING HOT; DEVELOPED LACE TYPE RASH; PHYSICALLY EXHAUSTED, TIRED, FATIGUE; FEVER; FELT FREEZING COLD; SEIZURE LIKE TREMORS UNCONTROLLED; PAIN AT INJECTION SITE; 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 genetic liver mutation, and other pre-existing medical conditions included the patient had sensitivity to blood thinner product. 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 30-MAR-2021 16:00 on Right Arm 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 22-MAR-2021, Laboratory data included: Blood test (NR: not provided) negative. On 30-MAR-2021, the subject experienced pain at injection site. On 31-MAR-2021, the subject experienced seizure like tremors uncontrolled. On 31-MAR-2021, the subject experienced felt freezing cold. On 31-MAR-2021, the subject experienced fever. Laboratory data included: Body temperature (NR: not provided) 100.2. On 01-APR-2021, the subject experienced felt feeling hot. On 01-APR-2021, the subject experienced developed lace type rash. On 01-APR-2021, the subject experienced physically exhausted, tired, fatigue. Laboratory data included: Body temperature (NR: not provided) 97.1. On 01-APR-2021 12:18, the subject experienced just about passed out. On 02-APR-2021, the subject experienced arm feels like hit by baseball bat. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from seizure like tremors uncontrolled, and fever on 2021, and developed lace type rash on APR-2021, had not recovered from pain at injection site, and physically exhausted, tired, fatigue, and the outcome of just about passed out, felt freezing cold, felt feeling hot and arm feels like hit by baseball bat 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.</p>

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1188821	4/10/2021	NV		M	3/23/2021	3/23/2021	An episode of seizure; Syncope; Unconscious; Dizziness; Fever; Nausea; Muscle aches; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (An episode of seizure), SYNCOPe (Syncope) and LOSS OF CONSCIOUSNESS (Unconscious) in a 43-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. No Medical History information was reported. On 23-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 23-Mar-2021, the patient experienced SEIZURE (An episode of seizure) (seriousness criterion medically significant), SYNCOPe (Syncope) (seriousness criterion medically significant), LOSS OF CONSCIOUSNESS (Unconscious) (seriousness criterion medically significant), DIZZINESS (Dizziness), PYREXIA (Fever), NAUSEA (Nausea) and MYALGIA (Muscle aches). On 23-Mar-2021, SEIZURE (An episode of seizure) and LOSS OF CONSCIOUSNESS (Unconscious) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Mar-2021, Chest X-ray: normal (normal) normal. On 23-Mar-2021, Computerised tomogram head: normal (normal) normal. On 23-Mar-2021, Electrocardiogram: normal (normal) normal. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route) was unknown. Patient was taken to the emergency room (ER). Treatment included intravenous fluids.; 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.

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1189401	4/10/2021	CA	38	F		4/1/2021	TERRIBLE MUSCLE ACHES IN NECK BACK AND LEGS; HEADACHES; TIRED; This spontaneous report received from a patient concerned a 38 year old female. The patient's weight was 115 pounds, and height was 64 inches. The patient's concurrent conditions included seizure disorder, and other 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: 1805029 expiry: UNKNOWN) dose was not reported, administered on 01-APR-2021 at left deltoid for prophylactic vaccination. No concomitant medications were reported. On APR-2021, the subject experienced tired. On 02-APR-2021, the subject experienced terrible muscle aches in neck back and legs. On 02-APR-2021, the subject experienced headaches. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from terrible muscle aches in neck back and legs, and headaches, and the outcome of tired was not reported. This report was non-serious.
1189537	4/10/2021	VA	74	F	4/9/2021	4/9/2021	About 1hour after shot, I became extremely cold and smelled a metallic substance I could not identify. My sense of smell was damaged by an infection about 10 years ago. after the coldness, I had flu like symptoms. When I went to bed, I think I had a seizure. Head was up/down. Arms were twitching and going up/down. Back was arching. Legs were also moving. All this was involuntary. I decided to calm down my brain. I played a game on tablet. Motion stopped. I realize it might just have been over. I drank 1/2 cup of tea and vomited several times. Just liquid. Now I feel feverish.

<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>
1189620	4/10/2021			F	3/31/2021	3/31/2021	Passed out and convulsed; Passed out and convulsed; Vertigo; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out and convulsed) and SEIZURE (Passed out and convulsed) 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 (No reported medical history.). On 31-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 31-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out and convulsed) (seriousness criterion medically significant), SEIZURE (Passed out and convulsed) (seriousness criterion medically significant) and VERTIGO (Vertigo). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out and convulsed), SEIZURE (Passed out and convulsed) and VERTIGO (Vertigo) outcome was unknown. She received 2nd dose of Moderna vaccine 31 MAR 2021 and while she was at the pharmacy she passed out and convulsed, and later that night while at home she passed out and convulsed again. Treatment information was not provided.; Sender's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.
1191637	4/10/2021	CO	54	F	3/11/2021	3/14/2021	Seizure

<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>
1190299	4/10/2021	GA	43	M	4/9/2021	4/9/2021	Pt had 1st dose of Moderna vaccine yesterday 4/9. Less than 5 min after vaccination pt had some jerking of limbs lasting about a minute per nurse & wife account. No LOC, no foaming at mouth, no incontinence. Did have eye deviation upwards & was groggy for about a minute but quickly was alert & able to answer questions & had a normal MSE. Vitals stable. Pt reports he is afraid of needles/blood. No hx of seizures & not on any meds. He also reported he felt faint after receiving vaccine. He was sent to ER by ambulance for further evaluation of possible seizure. Spoke to pt at home today 4/10, had ER evaluation - lab tests and heart studies; no radiological studies. All results normal. Pt reports he is feeling fine and has had no further symptoms or side effects. Recommended pt to discuss with PCP whether to take 2nd dose Moderna.
1191597	4/10/2021	FL	29	F	4/10/2021	4/10/2021	Patient suffered unconsciousness, then a brief seizure 10 minutes following her vaccination. Patient was moved to treatment area where paramedics discovered she was bradycardic, hypotensive, and in a junctional cardiac rhythm. Patient was treated with IV fluids, and monitoring and then transported to Hospital of her choosing.

<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>
1190937	4/10/2021	PA		F	3/16/2021	3/16/2021	Possible seizure; Swelling inside brain frontal cortex; Brain hurts; Loss of short term memory; Tremors; Heart rate elevated upon movement; Loud tinnitus; Ears hurt; Teeth hurt; Neurological symptoms; This is a spontaneous report received from a contactable consumer (patient herself). A 59-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: Expiry date: Unknown) via unspecified route of administration in the left arm 16Mar2021 12:15 at SINGLE DOSE for COVID-19 Immunization. The patients medical history included Spinal degeneration and Red Yeast Rice (Mycotoxins-Citrinin) from an unknown date and unknown if ongoing. Concomitant medication includes Tramadol 0.25 occasionally but quit all 3 days prior. 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 not tested for COVID-19 since vaccination. The patient experienced Neurological symptoms, loss of short term memory, tremors, possible seizure, heart rate elevated upon movement, loud tinnitus, swelling inside brain frontal cortex, ears hurt, teeth hurt, brain hurts on 16Mar2021 00:45. Mycotoxin alert Citrinin - needs to check their source for the lipids to see if red yeast rice is used or any derivative. The patient visited physicians office. The treatment included Tylenol every 6 hours helped, but EEG may be order. The outcome of the event was recovering. Information on the lot/batch number was available.

<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>
1190957	4/10/2021	NY	58	F	3/4/2021	3/1/2021	<p>developed acute delirium; redness in arm; Right arm swelling; After that very wild, I was screaming. Very scary. My memory was gone; she passed out at home; she is very depressed has anxiety; she is very depressed has anxiety; panic attack; gained 16 pounds; vomited; loss of appetite; body ache/pain; This is a spontaneous report from a contactable Other HCP (patient). A 58-years-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Solution for injection, Lot number: NN6206 and expiration date: Not available), via an unspecified route of administration in the right arm on 04Mar2021 12:00 as a single dose for COVID-19 immunisation. Medical history included removed brain tumor, she has sciatic nerve damage on left arm and left leg and is paralyzed, coma, chronic body aches, seizures, bad vision, high blood pressure and three brain surgery, short term memory. The patients historical vaccine included Flu vaccine injection in right arm deltoid muscle. The patient's concomitant medications included Oxycodone (5mg three times a day tablet) been taking for 3 years since she has brain tumor removed and for chronic body aches and Lyrica. On an unknown date, the patient gained 16 pounds. In Mar2021, the patient experienced she passed out at home and she was very depressed, anxiety, panic attack, body ache/pain, vomited and loss of appetite. On 04Mar2021, the patient experienced right arm swelling, screaming, scary, memory was gone. On an unknown date, she experienced developed acute delirium. On 06Mar2021, the patient had redness in arm. The patient was in the hospital for 4 days and was admitted on 14Mar2021. Her memory came back little by little and side effect of vaccine it says that if she had side effects from first one do not take second dose because it is worse and she is scared to be admitted to the hospital and does not want to experience that again. She was taking pain medication and did not tell her she cannot take Tylenol of course with body aches they did not tell her. It was not specific acute delirium it is a psychiatric disorder and she was wild and has never been like that before, she was tied up to the bed. The reporter states that she is disabled. She has bad vision and she is by herself at home. She is 5 1/2 already going down. She is not going to get the second one until get report results because it is ridiculous, and she is very nervous as she</p>

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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was admitted at night to the hospital. Body ache happened 24 to 36 hours after vaccine not that severely unusual as it went away, and she has a chronic illness and is in a wheelchair from chronic pain. Reporter stated she could not swallow liquid or eat food and she was scheduled for a cat scan, but she could not go since she has been on the phone with Pfizer to get truth and fairness. Reporter stated yesterday this started getting better. Reporter stated was discharged from hospital last Tuesday but had pain at home. Developed acute delirium: stated when she woke up in the ER the next day in few hours she was admitted and in the ER she was crazy and tried running even though she cannot run because she is paralyzed and she did not remember nothing. Reporter stated no she did not get it that when she was discharged, it had been 48 hours. Pain started 48 hours after the vaccine. She has chronic pain the pain is not that excruciating, and it has stopped. She could not remember what happened but just knew it was redness and hurt a lot. Her memory and everything came back. States she had MMR (as provided by Reporter) done, because of pain in her whole body and everything came back negative. She had terrible pain, she asked to be given pain medication, and was given pain medication. Reporter stated it disappeared about one week now it disappeared and has recovered completely. Reporter stated black and blue inflammation and it does not hurt and the pain it went away. She was discharged from the hospital and discharge paper said second vaccine on 26Mar2021. She has been taking Oxycodone pain medication, reporter thinks she even got a higher dose since the pain was excruciating. The patient did not take any vaccines with 4 weeks. No Relevant Tests were performed. While providing an AE for the COVID vaccine she took Tylenol and Motrin as treatment, on top of it, but the pain didn't go away. She has been taking Oxycodone pain medication, reporter thinks she even got a higher dose since the pain was excruciating. The clinical outcome of events gained 16 pounds, passed out at home, depressed, anxiety, panic attack, body ache/pain, vomited and loss of appetite, right arm swelling, screaming, scary, developed acute delirium, redness in arm was unknown whereas of memory gone it was recovering/resolving.; Sender's Comments: Based on known drug safety profile, there is reasonable possibility

<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>
							of causal association between the events peripheral swelling, amnesia, delirium, loss of consciousness, depression, anxiety, panic attack, and erythema 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 regulatory authorities, Ethics Committees, and Investigators, as appropriate.
1191098	4/10/2021	IL	21	M	4/9/2021	4/9/2021	Flu like symptoms. Headache, shaking and convulsions. Soreness
1191410	4/10/2021	KS	84	F	2/19/2021	2/21/2021	3 days after the covid-19 vaccine, she had a seizure and was taken to the hospital. She was diagnosed with sepsis and died 02/22/2021.
1191495	4/10/2021	FL	19	F	4/10/2021	4/10/2021	After receiving her vaccine, patient moved into our waiting/observation area at my request to wait for 15 minutes of observation. Within a few minutes I heard the patient's mom calling out for help. I quickly ran over to help. I observed the patient who was now sitting on the floor. Her eyes were wide and she looked shocked. I helped her mother to calm patient and asked her to remain seated. I asked her mom what happened and she stated patient twitched a couple of times and began to fall off of her chair at which point mom caught her. Mom had blood on her arm and I noticed it had come from patient's ear where a couple of earrings were pulled as she fell. I asked if she wanted water and quickly provided her a bottle of water. Mom stated that patient had fainted from vaccine(s) in the past, but mom stated that this appeared to look like a seizure. Mom went to get a chocolate bar since patient had had nothing to eat and they were worried about low blood sugar. After patient looked like she was back to normal I left to administer another vaccine but asked mom to remain until she felt necessary. Mom and patient advised my tech that they were ok and they left the store.

<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>
1191506	4/10/2021	FL	35	M	4/10/2021	4/10/2021	After giving the vaccine, I was talking with the patient and he said he felt dizzy. He passed out and while he was out/when he was regaining consciousness, he started having seizure like movement. EMS was called and were here within 5 minutes. The paramedics took his vitals which were all WNL. Approximately 15 minutes later, the patient had a repeat episode. The paramedics and I suggested that the patient go to the emergency room via ambulance. He declined and left with his wife. They both reported that he would seek care at the emergency room.
1190732	4/10/2021	NY	32	M	2/25/2021		12 seizures so far after getting 1st dose of coronavirus vaccine; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (12 seizures so far after getting 1st dose of coronavirus vaccine) in a 32-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. unknown) for COVID-19 vaccination. Concurrent medical conditions included Seizures. Concomitant products included VALPROATE SEMISODIUM (DEPAKOTE SPRINKLE), CLONAZEPAM, LEVETIRACETAM, PYRIDOXINE HYDROCHLORIDE (VITAMINE) and CANNABIDIOL (CBD OIL) for an unknown indication. On 25-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 SEIZURE (12 seizures so far after getting 1st dose of coronavirus vaccine) (seriousness criterion medically significant). At the time of the report, SEIZURE (12 seizures so far after getting 1st dose of coronavirus vaccine) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Very limited information regarding this event/s has been provided at this time. Further information has been requested Reporter did not allow further contact; Sender's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.
1190055	4/10/2021	FL	41	F	4/8/2021	4/8/2021	Passed out, had a seizure. Required hospital transport.

<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>
1190366	4/10/2021		25	F	4/10/2021	4/10/2021	Observed patient fixated looking at the floor and seemed to be confused. We asked medical hx and she has seizure and clonazepam prescription. Pt was able to verbalize name and location but struggled in talking. Paramedics responded. Vitals within normal range.
1186902	4/9/2021	IN	37	M	4/8/2021	4/8/2021	Seizure, high fever of 104 with Tylenol, extreme chills, loss of consciousness
1187971	4/9/2021	CA	23	F	4/9/2021	4/9/2021	23 yo FM who received first dose of Pfizer vaccine and then was noted to have shortness of breath and complaining tongue closing sensation immediately after at Vaccine Clinic --I was called to evaluate the patient. When I arrived patient was laying down on a chair with a friend, shaking with seizure like activity but alert and oriented to person place and time. Upon my arrival she was shaking, vomited x 1 and then complained about chest pain. Vitals upon my arrival: HR 58, o2 100% RR appeared to be around 22-24 (hyperventilating) BP 88 systolic (manual)--repeated by medics upon arrival minutes later 110/72. Given throat closing sensation, vomiting, shortness of breath I advised to call 911 and ordered Epinephrine x 1 which was given by RN immediately. Pt was then placed on the gown chin up, she continued to shake throughout entire body but continued to be alert and oriented. Medics then arrived on scene, started an IV, glucose by medics 84, IVF started by medics. Pt was transported to ER via medics. Pt is not a patient, last visit 2017. Pt did state she has hx of POTS and DRESS syndrome to Lamictal. Reports taking cetirizine this AM, Zofran and Oxycodone and Baclofen (prescribed by external PCP?). Prior to transport to ER pt continued to be alert oriented, but shaking and twitching throughout her body. MD verbally communicated to patient to not receive the 2nd dose given her severe anaphylaxis like reaction to the first dose of the vaccine. Pt can be referred to allergist after ER follow up by PCP. Denied pregnancy.

<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>
1186371	4/9/2021		24	M	4/9/2021	4/9/2021	Sitting in general observation area, began screaming and holding his head with clenched arms and hands. 1000 became rigid, suspect seizure, EMT reports syncopal episode. Assisted per EMT to w/c and taken to private observation area. BP 84/52 HR 54 O2 96% on room air. Color pale. EMT remains present. Offered patient water. Patient oriented x 3, Educated on taking next vaccine while lying down. Sister states patient has history of passing out while donating blood. Patient has needle phobia 1011 patient eating cookies and drinking water without difficulty. PB 105/79 HR 80 O2 98%. Denies dizziness, lightheadedness, Denies headache. 1015. STood at w/c - no dizziness. Patient states he feels well enough to leave, gait steady, ambulated to POV
1186446	4/9/2021	TN	32	F	4/4/2021	4/8/2021	The vaccine recipient is a breastfeeding mother. She received her vaccine on 04/05/21. On 04/08/21, her 11 month old son had new-onset seizure activity. The child was evaluated in the emergency department and hospitalized in the PICU for status epilepticus.

<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>
1186537	4/9/2021	PA	46	F	3/28/2021	3/28/2021	I received the vaccine at approximately 1:08 pm. Once administered I was instructed to sit in the auditorium for 15 minutes for observation. During that time I had a few heartrate increases and nausea but nothing out of the ordinary or concerning. After the 15 minutes, I walked out to my car and thankfully my husband had driven because what happened next would have caused an accident. Our drive home is approximately 20 minutes from where vaccine was administered. In the car I began to feel a tingling all over my body that gradually began to feel like ?pins and needles? (like when you sit on your legs for too long and they ?fall asleep?), with the worst of the feeling being in both of my hands. I began opening and closing my fingers to try and get them to feel normal. By the time we pulled into the driveway, my hand had locked up in a weird position and I was no longer able to communicate with them and make them move. They were temporarily paralyzed. My husband opened the door for me because I wasn?t capable of doing so. Once I stepped out of the car, my body began to convulse and shake. We stood there for a few minutes because one, I couldn?t make my body cooperate and two, we didn?t want our children seeing me that way. My husband kept asking me if he should call an ambulance. Of course, he should have but I think he was so scared and shocked that he just didn?t know how to react. I had trouble forming words and sentences at that point and could not tell him to call. I felt pretty calm considering what was happening to me and I could not control myself. My husband decided to walk away from me and coerce me to go to him. I stood there for a few minutes trying to communicate with my legs. Once I took my first step, my body stopped shaking and I started to regain feeling in my hands. I went and laid down for a bit and began to feel a bit better. Around 7pm I was feeling extremely cold. So cold that I put on three layers of clothing and two comforters to try and warm myself. That did not work though, as it was more of a cold from nerve endings than it was from temperature. I went to bed around 9pm but didn?t fall asleep until around midnight. I was feeling waves of cold down my body. Like a skin prickling when you hear a beautiful song and you get goosebumps and your hairs stand up. I woke around 3am to an extreme headache and a fever of 102.6. I took Tylenol and went back to bed. When I woke in the morning, I felt better but

<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>
							had weird and random muscle twitching. For the past few days I've been suffering with extreme fatigue which is not like me at all. Even when I'm tired, I can still manage to function throughout the day. Not only have I been tired, my body is weak, my muscles are weak and my joints hurt. I'm hoping this ends soon and doesn't get any worse. It will be two weeks this Sunday.
1186545	4/9/2021	CO	39	M	4/8/2021	4/8/2021	Patient lost consciousness about 10-15 seconds after vaccination administered. Concerned initially that patient may have been having a seizure due to twitching motion of head lasting 2-3 seconds. Then patient appeared to be sleeping. He was breathing, but audibly snoring and it seemed somewhat irregular. I moved patient from chair to floor and had staff call 911. Patient was still breathing but remained unconscious for about 1.5-2 minutes. He then woke abruptly and was immediately lucid. He was awake when EMS arrived. He stated he has passed out on previous occasions of abrupt pain/use of needles. EMS monitored patient for around 20-30 minutes, and he also had a bottle of orange juice and a granola bar and appeared to feel better. Patient declined transport to hospital by emergency personnel.
1186556	4/9/2021	WI	49	M	4/9/2021	4/9/2021	Patient reported feeling dizzy. About 5 mins later had syncopal episode w/syncopal seizure. BP 70s/40s, P 45-47. 911 called. Patient became more alert but was transported to ED based on hypotension and bradycardia.
1186632	4/9/2021	CA	28	M	4/9/2021	4/9/2021	Generalized tonic clonic seizure with post-ictal state, 1 minute after the shot, 2 episodes, each lasting about 15 seconds. -stable vital signs, patient has no prior h/o seizure disorder, no h/o allergies to food, vaccine or meds, -patient was not on any meds at the time. -patient was stabilized and transferred to the ER for further evaluation.
1186674	4/9/2021	NY	19	F	4/9/2021	4/9/2021	passed out 2 minutes after moving from vaccine seat to observation area 20 ft away, very brief mild, seizure less than 30 seconds. regained complete alert and consciousness

<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>
1186682	4/9/2021	TX	23	F	4/8/2021	4/8/2021	PT FAINTED AND APPEARED TO BE HAVING SEIZURES FOR ABOUT 3 MINUTES, SHE STATED THAT IT HAPPENED TO HER BEFORE! 911 WAS CALLED, HER VITALS WERE CHECKED SHE WAS STABLE AND COHERENT. SHE WAS ADVISED TO SEE HER PCP AND REPORT WHAT HAPPENED TO HER PREVIOUSLY AND AFTER SHE RECEIVED THE VACCINE.
1186686	4/9/2021	OH	56	M	4/8/2021	4/8/2021	Pt became dizzy and called for help. Upon arrival ambulance was called and pt was ALOC w/bilateral weakness slowly progressing and sweating profusely. Pt was A&O x 3 to self and location. Then patient seemed to have lost consciousness completely for about a minute. Pt was still breathing normally, and was tachycardic. Left sided drooling was present. By the time the ambulance arrived patient regained consciousness and strength. Pt stated this happened before when he had a root canal fixed. Stated he seems to have anxiety induced seizures. Pt VS were taken by EMTs and where stable, Pt refused to go to the hospital. He called his wife to pick him up and pt was monitored until she arrived.

<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>
1186297	4/9/2021	NC	34	F	4/7/2021	4/7/2021	34yr old female with shellfish allergy (reaction: anaphylaxis), exercise induced asthma, previous issues with injections/blood draws (reaction: dizziness) and other comorbidities presented for COVID-19 J&J vaccine on 4/7/21. CMA administered the JANSSEN COVID19 VACC (LOT # 043A21A, exp 6/21/21) IM in patient's left deltoid at 1318. Within 2 minutes of administration, patient became lightheaded and shortly after passed out. Patient had one convulsion (arching back, tense limbs) lasting 5-6 seconds. Once relaxed, patient was arousable. Patient denied hives, shortness of breath, throat swelling, or chest pain. At 1325, BP 48/31, MAP 76, HR 79. Patient assisted to Trendelenburg position and remained lying for 20m. Patient developed chills and tremors during this time stating she was cold. At unknown time later, patient endorsed feeling better and was lifted to sitting position and allowed to sit for another 10minutes. At 1346, final BP 105/58, HR 73. Patient endorsed feeling back at baseline. Provider released patient and patient discharged. Of note, provider notes patient with vasovagal syncope and convulsions after receiving J&J COVID vaccine. Patient has history of vasovagal reactions.
1186848	4/9/2021	OR	60	F	4/9/2021	4/9/2021	Pt arrived to vaccination clinic stating she had multiple allergies and after her shingles vaccination she had an allergic reaction. 3 RN's present in room during this time. Vaccination given and patient ambulated to observation location. Within 30 seconds patient started complaining of feeling dizzy, SOB, and passed out. Patient assisted to floor by 2 RN's while 3rd RN called RRT. Patient not responded to verbal commands. Pt with pulse and respiratory effort. Patient began shaking in seizure like activity. Oxygen applied at 4 L NC. Unable to get B/P or SPO2 due to shaking. Epi 0.3 mg administered SQ by RN. Patient began to mumble words and laughed at husband. RRT present and patient accompanied to stretcher and transferred to ER for evaluation. Report given to ED RN by Primary RN.

<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>
1186296	4/9/2021	MN	52	M	4/7/2021	4/7/2021	Patient did say before vaccine that he has fainted in the past from previous vaccines. I had a Representative administer vaccine while i stood next to patient and talked with him as a distraction from the shot. After Representative gave the vaccine patient asked "did you give vaccine?", he then immediately started to sweat very hard and said he was light headed (he was sitting down), then his eyes rolled back and he slouched down in chair, at which point I held him so he did not fall on floor. He started to jerk and twitch, perhaps was having a seizure, and was sweating very hard. I held him in chair so he would not hit his head or get hurt. After about 30 seconds he regained consciousness and asked how long he was out. His T-shirt was soaked in sweat and he said he felt very dizzy. The Representative got him an ice pack and placed at base of neck, which he said helped alot. I sat with him for 10-15 minutes until he said he felt fine. I asked if he needed medical care and he said he did not, just needed to sit for awhile, and said this has happened before. I gave him a chair to sit in after he was fully alert and he sat for close to half an hour, at which point he said he was back to himself and felt fine. I did offer he could stay as long as needed and I could call anyone if he needed me too, he insisted he was fine and after about 45 minutes he left. I did call him the next day to check on him and he said he was fine.

<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>
1186953	4/9/2021	CA	17	F	4/9/2021	4/9/2021	The patient experienced the following reaction(s) during the immediate of observation: 1240- pt received first dose of Prizer vaccine at 1220. Pt was ready to leave and had a syncopal episode in her chair. Pt was lowered to the ground and was not alert or oriented. Mother was at the patient side. Pt was able to open her eyes and state her name. At this time the patient was placed into a wheelchair and during movement to post vac area, pt lost consciousness and had generalized muscle twitching resembling seizure like activity. At no time did patient have airway compromise. Pt was placed on the floor with feet up on the wheelchair. Vitals are as follows BP: 92/52 P: 72 R:18 99% spO2. Pt continued to answer questions appropriately with mother at her side. 1246: repeat vital signs BP: 118/64 P: 85 R:18 98% spO2 on RA Pt A&Ox4. Mother stated pt had same type episode 4 years ago while they were out of the country. EMS Was called to assess pt with possible transport to a higher level of care. 1259: BP: 110/72 P: 83 R:18 99% SpO2 Fire Department on scene speaking with mother and pt. All pt care given released at this time to FD. Mother spoke with FD and decided against transport to the hospital. Pt was observed 10 minutes longer and final set of vital signs done prior to pt leaving the facility. BP: 102/82 P: 75 R: 18 99% SpO2. Pt A&O x4, placed in a wheelchair and helped to vehicle. All questions answered prior to leaving the facility.

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1187113	4/9/2021	CO	47	M	4/9/2021	4/9/2021	<p>Patient was coherent during initial injection, as I removed my gloves and asked he remain in the waiting area for 15 minutes his chin fell to his chest and he began to breath heavily. I spoke to him and there was no response. He then began making snoring type noises and lifted his head but again was unresponsive. Patient then slumped sideways in the chair. I made one last attempt to arouse him with firm strikes to the chest and calling his name. I retrieved the EpiPen from the e-kit and as I removed it from the box he became conscious. He opened his eyes and gasped and tremored slightly. He was not immediately responsive verbally. I observed him carefully to evaluate if he was going to have a seizure, but he then became coherent. He was alert and oriented to time and place but did ask how long it had been since the vaccine. He admitted to having a problem with needles and stated that was the root of the reaction. He does not remember any reactions to previous vaccines but also could not recall his last vaccination. We brought the patient water and offered snacks while he recovered in the patient care area. Approximately 20-30 minutes after the initial event the patient began vomiting. After a few minutes of vomiting he said he felt a little better and wanted to go to his car to lay down. Multiple times we asked if we could call someone to come pick him up and offered to have him seen by paramedics that happened to be shopping in store. He declined both offers and stated he would lie down in his car and call someone if he did not feel well after awhile. Staff checked on him in his car and he was instructed to call in before leaving. Upon trying to check on him again it was noted his car was gone. I called the patient and he assured me he was ok and he was now at home.</p>

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1187357	4/9/2021	CA	62	F	4/1/2021	4/1/2021	<p>Patient is a 62-year-old, female. Alert, oriented X3, clear speech, able to answer to the questions before being vaccinated. At 3:34 pm, the patient received her first dose of Pfizer, (lot number EW0150, expires on 07/2021) on left deltoid, given by RN. The patient was able to give her verbal consent to receiving the Pfizer vaccine. RN, reports patient sounded "normal" and was responsive to all pre-vaccination questions. Patient reported mild anxiety to RN, immediately after being vaccinated. RN, followed the patient to the EMT observation area and assisted the patient to a zero-gravity chair. At 3:41 pm, while waiting in observation area, patient reported feeling "anxious" and "faint". EMT (Name), EMT (Name), EMT (Name) and RN, responded. At 3:41 pm, the patient became unresponsive to verbal stimulation. Her pupils were fixed and dilated. During this time, EMT took the patients vitals and found her BP to be 132/98 and HR 73 BPM. At 3:41 pm, RN called 9-1-1. The patient continued to be unresponsive for an additional 5 minutes with normal respirations of 17 per minute. At 3:45 pm, the patient jumped up out of the anti-gravity chair, screamed and proceeded to run down the hallway toward the patient restrooms. EMT followed the patient down the hall and RN followed. The patient collapsed to the floor and started to scream and convulse. While on the ground, EMT took the patient's blood pressure which was found to be 209/162 with a HR of 101 BPM. The patient was assisted to her feet by EMT (Name) and EMT (Name) and assisted her back to the anti-gravity chair at 3:47 pm. FD arrived on site at 3:48 pm and took over monitoring the patient's vital signs. The patient was A&Ox1 to self at 3:48 pm. She was unable to follow direction. Medical response assisted the patient to a stretcher chair with her arms and legs strapped to the chair. She left with EMS at 4:02 pm.</p>
1187365	4/9/2021	CO	37	F	4/9/2021	4/9/2021	<p>After the vaccination, her arm started to swell up about 1 cm immediately. Benadryl was offered but the patient refused. After a couple minutes, the patient was lightheaded and dizzy. After two minutes the patient became unconscious, was not breathing, and was turning purple/blue. She then began having a seizure and was placed on to the ground. One dose of EpiPen was given to her and she regained consciousness.</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>
1187388	4/9/2021	TX	34	M	4/6/2021	4/6/2021	Minutes after receiving the injection (4pm) my blood pressure dropped and I lost consciousness. I recovered well enough to drive home within 15 minutes afterwards. That night (10pm) I began shivering, which escalated to periods of convulsions, to which a mouth guard was needed to prevent chipping teeth and/or biting my tongue. There was no fever present, and to subside the uncontrollable shivering I sat in a very hot shower until motor functions gradually returned. Periods of headaches, joint pains and sweating ensued for the remainder of the night. There were no other symptoms in the following days.
1187447	4/9/2021	TX	41	M	4/9/2021	4/9/2021	Pt started to become lethargic and was placed on cot. Pt was laying down and started to have seizures. She would become alert and more responsive between seizures. She was laying down to keep her safe and prevent a head injury. 911 was called and arrived. She did not want to be touched, not even for vital signs, she only talked by emergency services.
1187465	4/9/2021	IL	24	F	4/9/2021	4/9/2021	Client received 1st dose of Moderna vaccine at 9:55 am. The client who was learning disabled, became extremely anxious, rocking and hyper-ventilating at approximately 10:10 AM. She had two events that may have been seizures, each lasted approximately 5 seconds. Vitals taken at 10:12 were BP 130/74, O2 98%, HR 102. 911 was called at 10:15 am. When the paramedics arrived, they knew the client by name and transported her to Hospital. Client's PCP was called and a message was left. PCP called back and confirmed message was received.
1187801	4/9/2021	MD	27	F	3/9/2021	3/9/2021	Extreme chills, Right leg pain / jumping within 3 hours of getting vaccine, shortness of breath / Heart racing started around 11:00 pm, fever 101.3, Started over night, severe headache. Had a seizure during the night and the following day. Symptoms continued for a few days. My arm pain lasted for a couple weeks.

<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>
1187968	4/9/2021	CA	39	F	4/9/2021	4/9/2021	Pt with known hx of seizures, rec'd her 2nd dose Pfizer at COVID-19 vaccine clinic @1505. Pt had "aura" while in observation area w/ husband and observation RN. Pt took her own home Ativan dose PO. At approx 1519, pt had focal seizure with mild arm flexion; no head/oral trauma; no falls/injury. Her husband reported this to be a normal seizure for her and stated her seizures usually last <5min. At 1521, pt was taken to extended observation area room via personal wheelchair; VS were stable upon arrival to extended observation. The Dr.was also notified and came to observation room for evaluation @1525. Per husband, seizure lasted approx 10 mins. Pt then post-ictal and responsive. VS obtained & stable; BP129/84, HR99, RR20, O2 Sat97% on RA. Approx 1543, pt had second seizure while sitting in wheelchair. MD & 2RNs at bedside for safety. 911 was called at this time. IV access established 22g R wrist with IVF NS infusing. Placed pt on 2L O2 via NC per MD request. VS remained stable throughout seizure. Patient post-ictal, verbal, interacting, maintaining own airway. Paramedics arrived @ 1603; report given to medics and transferred to the Hospital for further valuation by ambulance.

<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>
1186698	4/9/2021	NM	35	F	4/8/2021	4/8/2021	Patient was seen at offsite UNM-Gallup COVID vaccine event today 4/8/21. At ~1305, provider was asked to assess this 35yo who had received her 2nd dose of Pfizer COVID vaccine at 1247, with complaint of itchy rash to neck and throat "tightening." She has a hx of multiple drug allergies and is on multiple medications as below for seizure disorder and other comorbidities. She had reported a hives rash after her first dose of COVID vaccine 3wks ago. As such, she had taken 50mg benadryl at ~1200 today to attempt to prevent a reaction. On limited evaluation, her oral airway was clear without obvious angioedema. She did have hives to her neck and was quite pruritic. Her lungs were clear and she was moving air without wheeze. She began slurring her speech and seemed confused, which her family member reported is how she becomes before seizures. With concern for anaphylaxis, gave a dose of 0.3mg IM epinephrine. EMS was called to transfer patient to ED. Dose epi given at 1320, with almost immediate improvement in hives, pruritus and notable improvement in mentation and slurring of speech. EMS arrived at ~1325, patient found to have HR 106, BP 180/84 after epi. She was transferred in stable but acute condition.
1184874	4/9/2021	IL	33	M	4/8/2021	4/9/2021	Triggered a grand mal seizure, with hot and cold chills and a slight fever. Patient is doing much better this morning.

<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>
1183792	4/9/2021	UT	36	F	1/4/2021		Having chills like she was convulsing; Arm felt unusable; Disoriented; Felt like she was hit by a bus; Extreme body aches; Temperature range of 102-104F that lasted around 24 hours; Chills like she was convulsing; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (Having chills like she was convulsing) in a 36-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 recorded medical history). On 04-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced SEIZURE (Having chills like she was convulsing) (seriousness criterion medically significant), LIMB DISCOMFORT (Arm felt unusable), DISORIENTATION (Disoriented), ILL-DEFINED DISORDER (Felt like she was hit by a bus), MYALGIA (Extreme body aches), PYREXIA (Temperature range of 102-104F that lasted around 24 hours) and CHILLS (Chills like she was convulsing). At the time of the report, SEIZURE (Having chills like she was convulsing), LIMB DISCOMFORT (Arm felt unusable), DISORIENTATION (Disoriented), ILL-DEFINED DISORDER (Felt like she was hit by a bus), MYALGIA (Extreme body aches) and CHILLS (Chills like she was convulsing) was resolving and PYREXIA (Temperature range of 102-104F that lasted around 24 hours) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Concomitant product use was not provided by the reporter. Treatment for the event included Ibuprofen and cold showers to relieve her symptoms. 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.

<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>
1183842	4/9/2021			F	1/29/2021	2/2/2021	I was diagnosed with Covid; This is a spontaneous report from a Pfizer sponsored program. A contactable female consumer reported for herself that she received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Batch/lot number: E0249), via an unspecified route of administration on 29Jan2021 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. On 02Feb2021, the patient was diagnosed with Covid. The patient went to the emergency room and she had one of those infusion for seizures. The outcome of the event was unknown. Information on Lot/Batch number has been requested. Follow-up attempts are completed. 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>
1183897	4/9/2021	NY	31	F	2/26/2021	2/26/2021	convulsions; bronchospasms; throat closure; difficulty breathing; Felt an "aura"; joints loosening; dizziness; This is a spontaneous report from a contactable nurse (patient). A 31-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at the age of 31-year-old, via an unspecified route of administration, administered in left deltoid on 26Feb2021 15:15 (Lot Number: EN6202) as single dose for COVID-19 immunisation. Medical history included known allergies to opioids, Toradol, Valium, and a lot of foods; mast cell activation disorder, eosinophilic oesophagitis (EoE), asthma, celiac disease, Hashimoto, and hypothyroidism. The patient was not pregnant at the time of vaccination. Concomitant medications included montelukast sodium (SINGULAIR), levocetirizine dihydrochloride (XYZAL), meloxicam (MOBIC), paracetamol (TYLENOL), and levothyroxine sodium (SYNTHROID); all taken for an unspecified indication, start and stop date were not reported. It was reported that one min later after the vaccination (26Feb2021 15:16), the patient felt an "aura" (joints loosening, dizziness), gave herself two puffs of albuterol and pulled out her epi pen and called for help. Two mins later (26Feb2021 15:17), the patient experienced convulsions, bronchospasms, throat closure, dizziness, difficulty breathing. Two rounds of epi, non-rebreather O2, rescue efforts. The patient was then transferred to emergency department (ED) to continue rescue efforts. The patient was treated with O2, Ativan, Steroids, Epinephrine, and Benadryl. The patient underwent lab tests and procedures which included Covid nasal swab PCR test: negative on 26Feb2021 (post vaccination). The patient was recovering from the events.; Sender's Comments: Considering temporal relationship, a possible contribution role of vaccination with the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) to the onset of the reported 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

<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>
							to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
1184018	4/9/2021	SC	51	F	4/7/2021	4/7/2021	Systemic: Seizure-Severe, Additional Details: Patient was taken to the ER via ambulance after having a seizure in the pharmacy. She was given Benedryl as she was thinking she was having allergic reaction. She has been on Tegretol to control her seizures. She didn't let us know she had seizures in her past. She did not let the pharmacist know until the next day that she is not allowed to be given the Flu or Pneumonia shot. She will not be getting her second dose even though her doctor at the ER told her not to be scared to.
1184031	4/9/2021	GA	30	M	4/8/2021	4/8/2021	Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Medium, Additional Details: THE PATIENT FELL FROM A CHAIR IN THE POST-VACCINATION AREA AND WAS FACE-DOWN, NOT RESPONSIVE. THE PATIENT WAS TURNED ON HIS BACK WHEN HE BEGAN TO SEIZE, SO HE WAS PLACED ON HIS SIDE. HE RECOVERED AND OPENED HIS EYES SHORTLY THEREAFTER. HIS BP WAS 120/59 MMHG, AND HE WAS PROVIDED CRACKERS AND WATER. THIS PATIENT DENIED ANY EPISODES LIKE THIS IN THE PAST BUT ALSO DENIED HAVING BREAKFAST THIS MORNING. THE PHARMACIST RECOMMEND FOLLOWING UP WITH HIS PCP, AND A RELATIVE PICKED HIM UP FROM THE CLINIC.
1184280	4/9/2021	GA	33	F	4/7/2021	4/7/2021	After vaccination, nurse observed seizure activity while patient sitting in chair. Tonic-clonic motion in arms. Seizure activity lasted approximately 3-4 minutes. Skin pale, cool and clammy. Blood pressure 94/72, pulse 68. Respirations 16. O2 sat 97%. EMS called and patient was transported for evaluation. Follow up phone call to patient 4/7 at approx. 5 pm. Patient resting. Stated she had negative CT at the hospital and has neurology appointment tomorrow, 4/8. Follow up phone call will be placed 4/8 after neuro appointment.
1184306	4/9/2021	GA	25	F	4/7/2021	4/7/2021	After vaccination, patient complained of dizziness and loss of vision. Patient's eyes rolled back and patient had brief seizure activity with jerking motions lasting a few seconds.

<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>
1184402	4/9/2021	GA	33	F	4/7/2021	4/7/2021	After vaccination, patient had seizure-like activity lasting approximately 5 seconds. After seizing activity ended, patient complained of dizziness and pain in the vaccinated arm. Patient remained at the fairgrounds with her husband (who was also vaccinated) for approximately 2 hours after episode. Patient was driven home by her husband.
1184486	4/9/2021		30	F	4/9/2021	4/9/2021	Seven minutes after receiving the vaccine client began to convulse followed by syncope. EMS was called. Client was caught before she fell. and stabilized shortly after. She states "this is something that happens to her regularly bc she has a fear of needles." Vitals taken are as follows BP 176/123, SPO2 99%, pulse 74.
1184767	4/9/2021	NH	38	M	4/9/2021	4/9/2021	Patient passed out within a couple minutes of injection, had seizure like activity, was sweating. He was alert shortly after. Ambulance came and took the patient
1186349	4/9/2021	NY	39	F	4/9/2021	4/9/2021	within a minute of patient leaving the consultation room after receiving the vaccine - patient sat down and passed out. When I looked over, I saw patient experiences minor convulsions. She was still in her chair. Episode lasted not even 10 seconds. Patient awoke and said she blacked out. She was coherent and responsive. We called 911. Patient said she has no history of seizures or low blood sugar. She said she tends to faint when giving blood or during vaccines due to the needle. Paramedic checked patient out and cleared the patient. No ambulance was taken. Will call patient tomorrow to follow up.
1184847	4/9/2021	VA	16	F	4/9/2021	4/9/2021	Pt received first dose pfizer covid vaccine. Approx 1-3 min later pt lost consciousness and experienced upper extremity myoclonic jerks for approx 5-7 seconds before regaining consciousness with fists clenched. Upon regaining consciousness, pt was A&Ox4, reported slight lightheadedness; denied CP, SOB, or cutaneous sx suggestive of anaphylaxis. Pt denies anything like this in the past, denies family hx of seizures, and denies needle phobia. Pt instructed to recline supine in car seat with legs elevated on dashboard, and soon reported feeling better, less lightheadedness.
1187896	4/9/2021	CA	29	M	4/7/2021	4/7/2021	Reported seizure, Heart rate at 40 bpm. For 15 mins.

<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>
1185192	4/9/2021	OR	22	F	4/8/2021	4/9/2021	Tonic/Clonic seizure, 2 in a row. Hx of seizures.
1185380	4/9/2021	MA	28	F	4/9/2021	4/9/2021	Patient had an episode of vasovagal syncope about 2 minutes after vaccine administration followed by about 10 seconds of seizure.
1185450	4/9/2021	IL	28	F	4/9/2021	4/9/2021	Patient with previous hx of seizure disorder started convulsing within 10 minutes of vaccination, fell to the ground and convulsed for approximately 7 minutes. Convulsions reduced significantly and patient was coherent without post-ictal state. EMS was called and she was taken to nearby hospital for further evaluation. Patient had reportedly taken ativan and depakote this morning prior to arrival.
1185515	4/9/2021	TN	45	F	3/26/2021	3/26/2021	Around 135pm patient was sitting in chair in a stiff position, bilateral arms to her side with wrist flexed out. 5 mins prior to incident patient just received her first shot of Moderna lot #031A21A , received in left arm. Stiff position lasted less the 1 min. nurse called out to staff to help and to call 911. Patient started to come back to her self and stated that she has had this happen before. Patients was oriented x3 to person place and thing. She denies and shortness of breath or difficulty breathing. Patient stated her husband was in the car and ask for him to come in. Husband stated she has had seizure activity in the past. Upon retrieving her vitals BP- 93/62 Temp- 98.4 Pules 60 Respirations- 16. Patient also stated her having a history of low blood pressure as well. Around 145 EMS arrived and patient was able to communicate feelings of incident. Patient and husband then walked outside with EMS. Doctor informed of incident and was gave the report of patients activity.
1185909	4/9/2021		39	F	4/9/2021	4/9/2021	PATIENT FAINTED AND HAD A 20SEC SEIZURE SEVERAL MINUTES AFTER RECIEVING VACCINE. PATIENT HAD EXTREME ANXIETY ABOUT BEING VACCINATED BEFORE HAND AS WELL AS HAD NOT EATEN DAY OF. PATIENT SYMPTOMS SUBSIDED AND HSOPITLIZATION WAS NOT REQUIRED.
1185928	4/9/2021	NY	35	F	4/9/2021	4/9/2021	Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe

<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>
1185958	4/9/2021	NJ	19	F	4/7/2021	4/7/2021	About 3-4 minutes after I vaccinated the patient, while she was in the 15 min observation seat, she lost consciousness, her fiance caught her from falling out of her chair. I ran over, and as soon as I got there she started to convulse, therefore appeared to be having a seizure. I help her fiance get her onto the ground safely and placed her on her side, then called for my tech to call 911. The seizure/convulsions only seemed to last 10-15 seconds. She then came to, and was disoriented. Then she felt nauseous, and threw up a small amount. The paramedics arrived, checked her out. She said she was felt fine, and refused to go with them to the hospital.
1186020	4/9/2021	FL	21	F	4/9/2021	4/9/2021	While waiting the 15 minutes after vaccination patient attempted to get up to go to the restroom fainted, and fell. Patient get up and seat again looking pale, sweating and skin was cold. While seated she started to have some involuntary movements in her left arm and leg (possible seizure) for a few seconds.
1186023	4/9/2021	TN	44	M	4/9/2021	4/9/2021	Five minutes after shot started losing consciousness, sweating, hot flashes, trouble breathing, numbness on tongue, seizure (several minutes) came in and out of consciousness during it, eyes rolled back in head. Arms flailing.
1186198	4/9/2021	VA	40	F	3/18/2021	3/18/2021	Patient developed shaking (reported as seizure-like activity) and became non-responsive within 15 minutes of vaccination. IV started and patient was transported to ER by EMS.
1184823	4/9/2021	TX	25	F	4/7/2021	4/7/2021	- got my phizer vaccine in my left arm - walks to 10-15 min waiting room - sits down and is looking at my phone for 3-5 mins - slight nausea hits and I start feeling dizzy - my eyes start going black and I feel really hot - I tell the lady watching everyone that I don't feel good. A nurse and another woman come and put me in a wheelchair so I don't fall out of a chair if I faint - my eyes are going more black and I'm profusely sweating all over my body - I faint and convulse for 5 seconds - I wake up from passing out and my hands and feet are extremely tingly and feel like they have a million pins in them - my hands started cramping really bad and I can almost not open them for 5 minutes - over the next 15 mins the tingleynes and hand cramps completely fade away and I feel normal

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1188048	4/9/2021	NH	25	M	4/9/2021	4/9/2021	after 2 to 3 minutes of giving vaccine patient went unconscious for 30 seconds, i was holding him, got conscious and sat on chair spoke for few seconds saying he is ok, then went unconscious again for 15 to 20 second this time it looked like mild seizures but got awake very quickly and he looked ok within 3 to 5 minutes first responders came with ambulance , they were with him for about 30 minutes and looks like they offered to drop him or take hospital patient wanted to home , will follow op tommorow
1188205	4/9/2021	WI	34	U	4/9/2021	4/9/2021	After 90 seconds felt warm and dizziness come on, then I fainted, the EMT that administrated the shot said I had a seizure. I have never had one before this vax and never had issues with the navy and vaccinations then.
1187537	4/9/2021	VA	19	M	4/9/2021	4/9/2021	During post vaccination wait time. Patient noticeably anxious/restless/bouncing legs. Initial assessment patient reported feeling like he had a hot flash and arms and were itchy. Vitals taken every five minutes, potential seizure activity noted, patient positioned for safety on cot. EMS activated, hives noted on left upper shoulder and left side of face. Patient complained of shortness of breath and crying. Patient became pale and LOC and temporary apnea noted, 0.3mg EpiPen administered in left leg x 1 dose, by RN. After administration patient gasped became combative. EMS arrived and patient transported via EMS to ED.
1188311	4/9/2021	PA	98	M	2/20/2021	2/20/2021	Major Complex Seizure with post-ictal period of 2 hours, occurring 3 hours after receiving injection. 16 days later on March 6, 2021 was unable to void, sustained breathing difficulty with peripheral edema. Received diuretic from Nurse,. Indwelling Catheter was inserted. On day 17, after receiving Corvid Vaccine, DECEASED on March 7, 2021 at home. Sustained Complex Seizure 6 hours prior. Death Certificate ruling Cause of Death as Cardiac Arrhythmias.

<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>
1188330	4/9/2021	CA	76	M	4/5/2021	4/5/2021	Pt recieved 2nd Moderna Covid Shot, April 5. thirty min later, pt lowed to the ground with generalized Seizure lasting about one min. followed by post ictal confsuion. Pt remained confused, so brought to the emergency room on the 6th where I saw him. He was awake, but confused, knew his name, but that is about it. He was released from the hospital today. I speak with his daughter, he has been in a stupor, but today his mental status is improving..
1188377	4/9/2021	CA	18	M	4/8/2021	4/8/2021	Perfectly healthy, fit, thin 18 year old young man with no allergies and no previous reactions to vaccines or medications... immediately upon receiving J&J injection his eyes rolled back into his head and he was unconscious for two to three minutes, then in and out of consciousness for another eight to ten minutes. He convulsed for around ten seconds after about two minutes of being unconscious. Four to five healthcare workers attended to him, asking him to "stay with us." They called an ambulance, and the medics monitored him for awhile. Heart rate dropped to 34 bpm, clothing drenched with perspiration. Blood sugar was slightly low, although he had eaten a late brunch of two fried eggs, sourdough toast and fruit salad. The last thing he remembers is a cold sensation shooting down his arm and into his left hand. He tried to talk to say he wasn't feeling well, but he couldn't form the words, so he raised his arm and then fainted. He felt generally unwell the rest of the day, and today he is still not fully recovered.

<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>
1181879	4/8/2021	SD	17	M	4/8/2021	4/8/2021	Shot given around 1125 am. Pt and pt's mother went to sit in front of pharmacy. At around 1135, pt fell out of chair, sounded/looked like he may have hit his head on blood pressure machine that he was sitting near. We thought he had fainted. Pt woke within 10 or so seconds after fall and was confused. Said his head didn't hurt. His skin did lose it's color and he was looking "white as a sheet". We had pt lie on floor and elevated his feet. After a few minutes he was feeling better and was able to sit in a chair. Pt and his mom left the pharmacy area about 15-20 minutes after pt fainted. Upon looking at video of the event, it appears that before the patient fell out of his chair that his right arm raises up and his elbow is bent in a very stiff way. A split second later his whole body appears to stiffen and bend to the left, then he falls out of the chair and is lying on the floor. When on the floor, his legs appear to be fairly stiff as well. This whole episode seems to last about 10 seconds or less. The video makes it look more like a seizure than a case of syncope.
1181846	4/8/2021	VA	48	F	4/2/2021	4/2/2021	Regular adverse events - bedridden from Friday night until Sunday afternoon - chills, joint pain, muscle weakness, chest pain, lung tightness, shortness of breath, hip trying to pop out of socket due to joint weakness - all experienced with covid in January 2021;Irregular adverse event: two seizures at approx. 11:30 p.m. uncontrollable body stiff, shaking, eyes roll back in head, moaning
1181795	4/8/2021		25	M	4/8/2021	4/8/2021	25 years old in otherwise good health. Presented to observation area and within 5 minutes reported feeling lightheaded to staff member, then almost immediately had a syncopal episode with +LOC. He was caught by staff member and noted to have seizure like jerky movements for about 20 seconds. He regained consciousness and was A&O x 3. He was not post ictal. Brought to 1st aid bay. BP initially 87/47, HR 66. Offered water. BP recheck 104/58, 76. Lungs clear. HRR. No chest tightness, chest pain or SOB. Symptoms completely resolved. He reports episode like this in 7th grade which he think was secondary to anxiety. EMS offered to take to ED for further evaluation but he declined. His father took him home.

<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>
1181674	4/8/2021		59	F	4/2/2021	4/2/2021	Patient experienced vasovagal episode in response to 1st dose of Pfizer vaccine. After an hour of observation, water, snack and trendelenburg, symptoms were not improving. Patient was admitted to ER. In the ED, she stated something similar occurred in the past when she was getting her Shingles vaccine. No hx of irregular heart rhythm or seizures. No prodromal symptoms or postictal state. Vitals significant for elevated BP 180s/100s, otherwise vitals stable. Labs significant only for Na 134. EKG was NSR. Most likely pt suffered from a vasovagal syncopal episode triggered by stress/anxiety. Pt's BP remained elevated as was in the ED, with an anxious affect that resulted in further increase in her BP. She was given xanax 0.25mg with recheck of her BP in 170s/90s. She was also counseled to maintain her hydration to prevent orthostatic changes. Pt agreed with plan, was happy with care, and discharged home in stable condition.
1182328	4/8/2021	NC	27	M	4/8/2021	4/8/2021	Approximately 5 minutes after vaccine patient felt lightheaded. Pharmacist immediately checked on patient who was beginning to become incoherent. He had a mild seizure and ems was called. Patient was sweating and pale. He remained onsite with EMS and later left with a family member.
1181559	4/8/2021	DC	38	M	4/8/2021	4/8/2021	Patient was being observed after vaccine and passed out. While laying on the floor, he seized x 2 for about 45 seconds. No memory of seizure/seizure-like activity.
1181918	4/8/2021	CO	76	F	2/20/2021	2/22/2021	Two days after receiving second dose of fizer COVID-19 vaccine at a vaccine event patient admitted to hospital after fall and presumed seizure: diagnosed with brain glioma.

<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>
1181482	4/8/2021	KY	29	M	4/1/2021	4/2/2021	The patient had an observed seizure. Patient was asleep when convulsions were observed by roommate; hospital staff alerted and seizure activity observed by nursing staff and medical students. Tonic clonic movements lasted approximately one minute, spontaneously resolved, then patient entered post-ictal state, and recovered approximately 5 minutes later. Vital signs were taken (WNL) and patient observed until return to being stable. Patient did have a history of seizure occurrence and was on anti-epileptic medication, which he was compliant with. Patient was stable and seizure free for at least the previous six months per hospital records. Medications reviewed and levetiracetam dose was increased to 1,000mg PO
1182118	4/8/2021	FL	21	F	4/8/2021	4/8/2021	Patient was sitting with her mother and family member when she slumped down. They noticed when the patient slumped down and was immediately at the patients side. Paramedics were also called to patient side. Mother states that patient with history of Seizures (3-4 times a week). Mother describes that patient puts her head down and bends forward in a sitting position with her Seizure activity. Patient was immediately placed on stretcher and frequent vitals taken. Patient vitals stable throughout visit. Patient Seizure like activity lasted for 5-6 mins then became post ictal and crying. At that time it was determined that patient be transported to the nearest ER for further evaluation. Patients pediatrician called and notified of patient condition and plan for transport. office agrees for patient to be transported to the nearest ER. Fire rescue on site at 1220 pm and patient transported to ER by 12:23pm. Mother followed with her paramour in separate vehicle.
1181437	4/8/2021	FL	50	F	4/8/2021	4/8/2021	Patient had a seizure while in the observation area. It was witnessed by staff and EMS was on site. Seizure activity lasted 15 seconds and patient became conscious, alert, and oriented within 5 minutes of being post seizure. Patient refused transport to the hospital after being evaluated by on site paramedics.
1181499	4/8/2021	WI	34	F	3/31/2021	4/7/2021	Had a gran mal seizure lasting for about 2 minutes

<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>
1182867	4/8/2021	CA	20	M	4/8/2021	4/8/2021	On 4/08/21 at 3:08 pm, 20 years old Asian male received first dose of Moderna vaccine lot #026B21A, 0.5 ml to his left deltoid. At 3:24 pm Patient sitting in the observation area, he was complaining of blurred vision, feeling dizzy, diaphoretic, at 3:25 BP 120/80, pulse 72, O2 sat 98%. As per patient mother who currently in facility, four years ago after received his MMR and VRA vaccine: he had a seizure. Patient was placed on low dose of Keppra for the seizure. However, patient has been off the Keppra for five years as instructed by his neurologist. Past medical history as followed: Seizure, HTN, Acne, Rhinitis, Sinus Brady Cardia. Patient currently on Acne medication: Tretinoin and Clindamycin cream. PO fluid given as per patient request, he stated? I am feeling much better? 3:31pm rechecked Vital signs Bp 128/78, pulse 88, resp 18, O2 sat 97% on room air. Denies any further symptom at present. Patient observed for 30 minutes. Patient AAOx4, Ambulate independently, patient released accompanied his mother and father in stable condition.
1181436	4/8/2021	IN	18	F	4/6/2021	4/6/2021	patient briefly lost consciousness for a few seconds, less than 1 minute during administration- mother warned me that was likely due to past syncopal episodes with injections not due to vaccine-sensitivity. Remained in pharmacy area for about 30 minutes post-administration with no further incident. Patient's mother notified us today that patient had a seizure several hours later that same day at approx 12 noon.
1182286	4/8/2021	MA	45	M	4/8/2021	4/8/2021	Patient post Johnson and Johnson vaccination and in observation period when EMS and Nursing staff noticed patient to be unresponsive with 10-20 seconds of mild jerking movements. Patient able to regain consciousness and state that he has a history of seizures Blood pressure 124/80, blood glucose 63. Patient transported by EMS to hospital.

<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>
1181300	4/8/2021	NC	23	M	4/2/2021	4/2/2021	RN saw seizure activity for 30-45 approximately 3 minutes after receiving the Janssen Vaccine. Pt had an arched back and slid down in his chair. LOC occurred during the seizure event. Approximately, 10 minutes after the event (1:56pm), the patient was A&Ox3 and PERRLA. Called EMS to advise. They arrived at 2:15pm, checked in on the pt and decided not to transport. No further action was necessary. Patient went home under his own power.
1182049	4/8/2021	TX	24	F	4/8/2021	4/8/2021	PATIENT HAD A SEIZURE AND FELL. SHE DID HIT HER HEAD. FALL WAS NOT WITNESSED BY THE RESPONDERS. VITAL SIGNS WERE TAKEN: BP 142/88, PULSE 98, O2 SATS 100%, RESPIRATIONS 20, BLOOD SUGAR LEVEL 84. HELPED PATIENT TO WHEELCHAIR AND SECURED HER TO THE FIRST AID AREA. AMBULANCE WAS CALLED AND SHE WAS TRANSPORTED TO THE ER.
1182044	4/8/2021	MA	23	F	4/7/2021	4/7/2021	At 11:32 patient noted to faint in chair and fall to the floor and begin seizing about 1 to 2 min post vaccine. Seizure lasted about 15 seconds. RN supported patients head at time of seizure. Patient was aware of where they were and noted that they were feeling nauseous and dizzy. Patient was eventually helped to a seated position where EMS transported patient.
1182029	4/8/2021	GA	55	M	4/8/2021	4/8/2021	Patient has had fainting issues in past with vaccinations. About 5 seconds after injection, the patient fainted, fell asleep, started to snore, then had seizure symptoms. After about one minute, the patient woke up and said he was okay. He was observed in the room for 2 hours, given hydration, towels, a pillow, and a fan to keep him comfortable. Signs and symptoms were normal when before he was allowed to leave after 2 hours.

<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>
1181945	4/8/2021	NV	71	F	4/8/2021	4/8/2021	Patient received her Moderna vaccine. She waited the 15 minutes and went around the store to shop. She then started to feel sharp chest pain and shortness of breath and returned to pharmacy. Patient did not report swelling in the airways, was able to breathe however with some difficulty. Patient reported having history of asthma and high cholesterol when asked. With patients consent, took patients blood pressure and the reading was 130/87. Told daughter what was going on, most likely not an allergic reaction/anaphylaxis. Patient then started to have "pseudo-seizures." Asked daughter and patient if we can call ambulance, and they both agreed. Stood by patient in post-vaccination area waiting for ambulance. Patient was still able to breath and her chest pain has decreased per patient - said pain lessened when sitting down. Ambulance arrived and took patient away. Both daughter and patient thanked pharmacy for helping and taking care of patient.
1182553	4/8/2021	NY	35	M	4/8/2021	4/8/2021	Patient was having seizure symptoms within 10 mins of receiving his first dose of the COVID-19 Pfizer vaccination. 911 was called immediately and while the EMS was arriving to the scene patient was starting to feel better. There was no reports of any signs of trouble breathing. EMS arrived on the scene and assessed the patient. Patient refused to go to the hospital with the EMS and reports to be feeling fine. Recommendations to follow up with a physician was advised.
1182615	4/8/2021	CA	18	M	4/8/2021	4/8/2021	Patient at Vaccination table, just received dose of vaccine when patient's arm went limp. Also developed generalized weakness. Mother stood in front of him and held his head with both hands. Patient then passed out with eyes rolling in back of head. Also had convulsions for a few seconds that mimicked seizure. Patient soon became alert. Vitals obtained with BP 92/52, HR 34, O2 96% on RA. Patient also diaphoretic to touch. EMS activated and arrived at 1:30pm. Placed in reclining wheelchair and taken to private area. Started to feel better after given cold water. Suggested ER due to having seizure first time. Declined ambulance but mother will take to ER in private car. Patient and mother left with no further incident.

<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>
1182681	4/8/2021	OH	89	F	2/26/2021	3/3/2021	Began with large baseball sized red area at site 24 hours after, then fatigue, flu like symptoms, Blood Pressure uncontrolled , then 3-7-21 squaded for tremor/seizure like episodes and high BP, Hyponatremia/Sodium low 135. Tremors/seizures continued, squaded on 3-14 for seizure/tremor episode, Hyponatremia Sodium 129, NS IV given. 3-17-21 Squaded again for seizure/tremor episode, admitted to hospital, Sodium 129. Calcium 8.2. Diagnosis r/o focal seizures/myoclonic episodes, Hyponatremia, r/o Moderna. Following up with Nephrology and Neurology currently. Still symptomatic.
1182767	4/8/2021	AL	21	F	3/12/2021	3/13/2021	Had grand mal seizure; This is a spontaneous report from a contactable consumer (patient). A 21-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 12Mar2021 08:00 (Lot Number: EN6205) as SINGLE DOSE for COVID-19 immunisation; and pefloxacin mesilate (PEFCID), route of administration, start and stop date, batch/lot number and dose were not reported for an unspecified indication. Medical history included, iodine allergy, yellow dye allergy and dysautonomia; all from an unknown date and unknown if ongoing. Concomitant medications included fexofenadine hydrochloride (ALLEGRA) taken for an unspecified indication, start and stop date were not reported. The patient was not pregnant at time of vaccination. The patient previously had first dose of BNT162B2 (lot number: EN6200,) on 19Feb2021 13:15 in left arm for COVID-19 immunization. On 13Mar2021 05:30, the patient had grand mal seizure reported as serious and life threatening since in an immediate risk of death. The event resulted in visit to emergency room/department or urgent care. The facility where the most recent COVID-19 vaccine was administered was in the Vaccine Clinic. 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 outcome of the event was recovering. The patient underwent lab tests and procedures which included COVID-19: negative on 13Mar2021. The patient received treatment for the event. The action taken in response to pefloxacin mesylate for the event 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>
1182304	4/8/2021		76	M	4/2/2021	4/2/2021	Vasovagal/pre-syncopal event. Accompanied by paresthesia/ weakness/ blurred vision/ lightheadedness.;a seizure-like episode followed' patient was transported to ER via EMS.
1182288	4/8/2021	TX	17	F	4/5/2021	4/5/2021	Patient had a reaction to the Pfizer Covid-19 vaccine. While waiting for 15 minutes after the shot, patient had a 'seizure' according to patient's mom. She was flapping her hands, staring, and sliding down the chair. 911 was called. Patient was pale and calm but responding to the immunizer (technician) and pharmacist. Patient said she was fine. EMS came and checked the patient and said patient is fine. Patient said she was fine again. EMS left without the patient since she was fine.
1180221	4/8/2021	GA	33	F	4/7/2021	4/7/2021	Pt had seizure lasting approx 5 seconds. After seizure pt complained of continued dizziness and pain in the arm that vaccine was given. she remained at vaccine site for an hour or more with her husband , then they left together.

<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>
1181931	4/8/2021	NJ	18	F	4/8/2021	4/8/2021	<p>Patient is an 18 year old female with no PMHx that presented with lightheadedness and three subsequent episodes of syncope approximately 3-10 minutes post-vaccination. Patient was found to have an abrasion to the outer corner of her right eyebrow following an unwitnessed. It was unknown if patient was seated or standing at the time. The nurse first on scene states the patient lost consciousness briefly again and experienced approximately 10 seconds of upper extremity muscle contractions (described as convulsions). Patient experienced a loss of bladder control upon loss of consciousness. Patient was lowered to the ground to be in a supine position by healthcare staff. At this time, patient was alert and oriented without agitation or confusion. Patient denies memory of the event. She states she had prior episodes of fainting after blood draw. Patient has no allergies to medication or food. No past surgical history. No prior hospitalizations. Denies personal and family history seizure disorders, cardiac disturbances, and hypoglycemic or hyperglycemic events. Patient was hooked up to cardiac monitor and found to be in normal sinus rhythm with a heart rate of 64bpm. Vitals Orthostatic BP measurements Lying supine - 110/72 Seated - 124/76 Standing - 128/72 HR: 64 bpm RR: 16 breaths/min without distress SO2: 99% On examination, patient was A&Ox3 without lethargy, agitation, or confusion. Patient has an abrasion to the superior aspect of the right orbit (outer eyebrow) without laceration or bleeding. Patient was diaphoretic and pale following event. Normal cardiac rate and rhythm. Radial pulses intact, strong and equal bilaterally. No obvious nystagmus. Upon standing, patient steady on her feet without abnormal gait.</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>
1182844	4/8/2021	IL	20	M	4/5/2021	4/5/2021	About 3 mins after Janssen vaccine was given, pt was very white and faintish. I rushed out of pharmacy and had a tech call 911. As I was running to him pt started slipping out of his chair, as a women, who I later found out was his mother and I helped keep pt in chair as he fainted and then seized for about 2 seconds and then gained consciousness. Upon awakening pt said , what just happened?" The mother answered "oh you just had a little seizure, you're fine." To my surprise, I asked the mother is this has happened before and she said yes when he sees needles/get shots. I told them the ambulance was on it's why and the mother asked "why?!" I told her because your son just fainted/had a seizure and we want to make sure he is ok. The pt refused to go to the hospital. I did go back out there and mentioned to them that it is very important to answer questions truthfully any time they are asked as they failed to honestly answer our questions about ever feeling faint after receiving a vaccine. His blood pressure normalized and once the paramedics left so did they.
1179394	4/8/2021	CT	33	M	4/6/2021	4/6/2021	Systemic: Seizure-Mild, Additional Details: Patient sitting after vac. was administered. Patien was about to stand up but fainted while on floor he had a seizure for about 3 secs. After the event he was alert & oriented, but did not remember the episode. BP #1 was 98/70 . Client was provided water and stayed in lying position for 40min with the supervision of the nurse. He wanted to drive himself to work but was told he should have someone pick him up however client refused stating his job was only \"5 min away\".BP before leaving 110/70.
1179437	4/8/2021	SC	32	F	4/7/2021	4/7/2021	Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe, Systemic: Weakness-Severe, Additional Details: Patient reported a history of \"passing out\" with injections. Pt experienced diaphoresis and dizziness immediately following injection. Two to three minutes later she said she was feeling better. Five minutes after dose, she began to present with seizure symptoms; blank stare, arms and hands contracting. First seizure lasted 30 seconds. One minute later, her second seizure began(45 seconds) with the same sytptoms, plus convulsions. We transferred her to the floor and on her side. VSS. EMS called

<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>
1179626	4/8/2021	MD	18	M	4/7/2021	4/7/2021	Pt. C/O feeling dizzy and nauseated. Had an episode of seizure that lasted for 5 sec, vomited small undigested food particles and became diaphoretic afterwards. A pkt of 125 mls of apple juice and water offered. (11 call made. Pt. finished the apple juice but had few sips of water. Pt reported having had similar episodes whenever he got blood draws and confirmed the reaction was related to sensitivity to needles (vaccination needle) than the vaccine. Paramedic team arrived at 3:25 p m. Pt. and mom refused the Ambulance services to the ER, but agreed to remain in the observation room for further observation.at about 4:05 p m. Pt and mom left the recovery hall .
1179642	4/8/2021	OH	17	F	4/6/2021	4/6/2021	Patient received dose 1 of Pfizer vaccine LOT ER8733 on 4/6/21 at 0955. Patient had witnessed seizure at 0957. EMS called at 1000. Seizure lasted 15 seconds. Patient alert after seizure. Appeared very pale. Advised patient mother that she needed to be seen at the ED for further evaluation. 1004 attempt made to call ED Lead but unable to reach. 1005 called House Supervisor to confirm correct number for ED Lead. 1007 EMS arrives. Pt mother declines transport to ED. EMS assists patient to car. Patient and mother sat in car for long period of time prior to leaving lot. Further follow up documents there is no documentation of visit to ED.
1179927	4/8/2021	GA	74	M	4/1/2021	4/1/2021	Felt dizzy and paralyzed. It lasted a couple of minutes. Two days later had an episode that appeared like a seizure. Taken by ambulance and admitted to hospital.

<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>
1180048	4/8/2021	MS	78	F	4/6/2021	4/6/2021	Noted change of consciousness in evening following vaccination. She had a tonic gaze to the right when EMS 1st arrived at the scene. She was not having any overt epileptic activity. She is normally very debilitated and moderately demented but conversational and jovial according to the daughter. She is normally able to be fed, taken to the toilet, and has no trouble with day-to-day living. She was brought to this hospital day after vaccination. She was alert at the time of the vaccination. She had COVID in August of this last year. In ED, she was given a very small dose of Ativan. She had immediate effect from this with resolution of the tonic gaze, developed a voluntary gaze and had minimal but clear-cut purposeful conversation. She was also able to move her extremities after the Ativan. Prior to that she was fairly rigid in her extremities. She did not have any obvious seizure activity however. She was transferred to another hospital for higher level of care and continued management.
1180096	4/8/2021	VA	69	M	3/4/2021	3/14/2021	SEIZURES LEFT LEG AND LEFT CORE, TEN EPISODES SINCE 03/14/2021
1180199	4/8/2021	LA	39	M	3/30/2021	4/2/2021	Patient experienced a "seizure" during his workday on 4-2. Store Management called 911 and he was sent with ambulance personnel. Patient reported another event a couple of days later. Patient reported 4-8 that he is Covid positive.
1181388	4/8/2021	NC	24	M	4/8/2021	4/8/2021	The patient fainted 10 minutes after his shot and fell from the chair he was sitting in. He had a brief seizure while on the ground and someone called for help. I ran over and yelled for someone to call 911. He stopped seizing and stood up when he came to. I supported him and asked him to have a seat. He sat down and I asked how he felt and if he would like food or water. He said he felt okay but accepted the food and water. At that time, firefighters that had been shopping in the store arrived and started interviewing the patient. They took his pulse and blood sugar levels. Medics arrived and he continued to be monitored. After several minutes, he refused the ambulance and said he was feeling good enough to leave.

<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>
1179192	4/8/2021	OH		F	3/25/2021	3/25/2021	<p>very weak; very tired; heart was pounding; vomit; headaches; passed out 3 times; seizure; lost control of her bowels; very low blood pressure; migraine; very low temperature; chills; fever; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (passed out 3 times), SEIZURE (seizure), ANAL INCONTINENCE (lost control of her bowels) and HYPOTENSION (very low blood pressure) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Thyroid disorder. Concomitant products included DILTIAZEM for Arrhythmia, LEVOTHYROXINE SODIUM (SYNTHROID) for Thyroid disorder. On 25-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Mar-2021, the patient experienced PYREXIA (fever) and CHILLS (chills). On 26-Mar-2021, the patient experienced SYNCOPE (passed out 3 times) (seriousness criterion medically significant), SEIZURE (seizure) (seriousness criterion medically significant), ANAL INCONTINENCE (lost control of her bowels) (seriousness criterion medically significant), HYPOTENSION (very low blood pressure) (seriousness criterion medically significant), MIGRAINE (migraine), BODY TEMPERATURE DECREASED (very low temperature), VOMITING (vomit) and CLUSTER HEADACHE (headaches). On 28-Mar-2021, the patient experienced PALPITATIONS (heart was pounding). On 29-Mar-2021, the patient experienced ASTHENIA (very weak) and FATIGUE (very tired). On 26-Mar-2021, SYNCOPE (passed out 3 times), SEIZURE (seizure), ANAL INCONTINENCE (lost control of her bowels), HYPOTENSION (very low blood pressure), BODY TEMPERATURE DECREASED (very low temperature), PYREXIA (fever), VOMITING (vomit), CLUSTER HEADACHE (headaches) and CHILLS (chills) had resolved. On 28-Mar-2021, PALPITATIONS (heart was pounding) had resolved. At the time of the report, MIGRAINE (migraine) had resolved and ASTHENIA (very weak) and FATIGUE (very tired) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. This case was linked to MOD21-</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>
							064116 (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. Further information has been requested.
1181430	4/8/2021	KS	32	F	3/24/2021	3/24/2021	racing heart, ringing in ears, shaky, convulsions, head and face pressure, left side of body
1180228	4/8/2021	MI	55	F	4/5/2021	4/5/2021	on Monday 4/5/2021, approximately 5 hours after the shot it started with fever and chills, then convulsions and tremors. Muscle contractions were so severe that both knees dislocated. The spasms and contractions lasted for about 4 hours. fever , chills, body aches, and headache lasted until late Wednesday 4/7/2021. Currently still have headache, body aches, fatigue, and loud non-stop ringing in my ears. I already had ringing in my ears before the shot but now it's much louder and constant.
1180254	4/8/2021	NY	38	F	4/5/2021	4/6/2021	Patient had a seizure after being seizure-free for several years. It resolved without intervention. However it lasted longer than usual approximately an hour and 45 minutes. Neurologist was notified. Levetiracetam levels taken within in the month was WNL.
1180323	4/8/2021	TN	49	M	2/24/2021	2/25/2021	He got the vaccine, 15 minutes later he got very fatigued, could not walk in his house and could barely make it to the bed and had to lie down. He had headache, nausea, disoriented. Then he went to bed, woke up at 9:00 AM and had a seizure, which he has had in the past but it had been over a year. He rested after the seizure and knew what to do and it took 2-3 days to recover from that due to the weakness in the legs, disoriented. He has gotten stronger and is pretty much back to his normal self. He has not had any additional seizures since then. He had his FU physical today and she is aware of the seizure and told them to report the incident.
1180353	4/8/2021	ID	36	F	3/26/2021	3/29/2021	Seizure occurred three days after vaccination.

<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>
1180614	4/8/2021	IN	18	F	4/6/2021	4/6/2021	Initially she passed out following the vaccine - within 90 seconds- she has a history of passing out with injections and blood draws. Around noon she had a seizure. She describes a feeling of darkness and dread closing in on her and she was unable to speak or move. She was on the stairs at the time. I witnessed her stiffen, then go limp and fall between the electric stair hair and the wall. She hit the hardwood floor face first then she began to shake/twitch. She was unconscious. She awoke screaming, incoherent speech, and flailing limbs. It took about 5 minutes to calm her and be able to understand her speech. She only remembers the darkness and waking up scared and feeling awful. She was put supine on the floor with feet elevated, blood pressure monitored, given juice to drink, and vitals checked routinely. After about an hour supine and conscious, she felt good enough to sit up. She sat up for 15 minutes before she was able to stand with assistance. Family physician was notified immediately and we are still waiting for a response. She has a goose egg sized knot on her forehead, a bruise on the side of her face and a black eye from hitting the floor. She has a huge bruise on her outer thigh and lower leg where she hit the stair chair and then seized and it it repeatedly on the metal. She has underarm pain from where her armpit hit the edge of the stairs when she fell and seized. She has no history of any types of seizures.
1180677	4/8/2021	AZ	16	M	3/31/2021	3/31/2021	Approximately 5 minutes after receiving his first shot he passed out and seized for approximately 15 seconds. Fire and EMT called and stabilized him then taken to hospital for tests.
1180786	4/8/2021	NY	18	F	4/6/2021	4/6/2021	PT EXPERIENCED CONVULSIONS & DID NOT RESPOND TO EXTERNAL STIMULI FOR ~15 SECONDS. RECOVERED CONSCIOUSNESS W/ TEMPORARY ALTERED MENTAL STATUS. VITALS: BP: 118/74 SP02: 98% PULSE: 85
1180874	4/8/2021	IL	63	F	4/7/2021	4/8/2021	Sore arm for the night, slight fever 99.9 but the big issue is I had two seizures the morning after the first at 4 am and the 2nd at 7:30 am... missed no doses of me seizure meds
1181273	4/8/2021	GA	22	M	4/8/2021	4/8/2021	Systemic: Seizure-Severe

<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>
1181340	4/8/2021	NY	31	M	4/7/2021	4/7/2021	NON-MOTOR ABSCENCE SEIZURE, NON-POSTICAL SPO2: 96% BP: 138/82 ALERT X4
1180214	4/8/2021	FL	28	M	4/8/2021	4/8/2021	Patient had a witnessed seizure while in observation area. Patient seizure activity lasted approximately 15 seconds. Patient became conscious, alert, and oriented, within 5 minutes of seizure activity starting.
1183051	4/8/2021	UT	29	M	4/8/2021	4/8/2021	Collapsed and had convulsions. Was lightheaded and Became completely pale and lips turned white
1182767	4/8/2021	AL	21	F	3/12/2021	3/13/2021	Had grand mal seizure; This is a spontaneous report from a contactable consumer (patient). A 21-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 12Mar2021 08:00 (Lot Number: EN6205) as SINGLE DOSE for COVID-19 immunisation; and pefloxacin mesilate (PEFCID), route of administration, start and stop date, batch/lot number and dose were not reported for an unspecified indication. Medical history included, iodine allergy, yellow dye allergy and dysautonomia; all from an unknown date and unknown if ongoing. Concomitant medications included fexofenadine hydrochloride (ALLEGRA) taken for an unspecified indication, start and stop date were not reported. The patient was not pregnant at time of vaccination. The patient previously had first dose of BNT162B2 (lot number: EN6200,) on 19Feb2021 13:15 in left arm for COVID-19 immunization. On 13Mar2021 05:30, the patient had grand mal seizure reported as serious and life threatening since in an immediate risk of death. The event resulted in visit to emergency room/department or urgent care. The facility where the most recent COVID-19 vaccine was administered was in the Vaccine Clinic. 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 outcome of the event was recovering. The patient underwent lab tests and procedures which included COVID-19: negative on 13Mar2021. The patient received treatment for the event. The action taken in response to pefloxacin mesylate for the event 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>
1183381	4/8/2021	NM	68	F	4/2/2021	4/3/2021	Patient developed 105 degree fever which would not go down, experienced severe chills and shaking and developed bruises. She also had 2 seizures, and had been seizure free for over two years.
1183361	4/8/2021	TN	21	F	4/8/2021	4/8/2021	At approximately 10 minutes after receiving vaccine, patient developed dizziness, fainted for approximately 2-3 seconds patient then came too, patient then fainted again and began seizing, seizure symptoms last 5-10 seconds, patient then came too and stayed stable and alert, 911 was called and patient was monitored until ambulance arrived, patient was transported to emergency room, for additional evaluation and treatment
1183172	4/8/2021	ID	23	M	4/1/2021	4/2/2021	Patient had many auras and a seizure the day after his first vaccine. We needed to use rescue medicine (Nayzilam nasal spray) to stop the seizure. It took him 3 days to fully recover from the seizure. He had a hard time thinking of the correct word and many strange thoughts and experiences. We called his doctor and talked to him over the phone. He told us to watch the patient for further problems.
1182699	4/8/2021	WI	32	M	4/8/2021	4/8/2021	Patient had an episode of fainting about 10 mins after vaccine administration. after regaining consciousness he had rolling eyes and seizure and 2nd episode of fainting. The fainting episodes were for few seconds (30-45 sec). Patients feet were elevated and paramedics were called. while waiting for the paramedics we had patient drink water and orange juice as he was on diet and had taken only 300 calories per patient. Used cold compress on his face and neck, patient was comprehending well afterwards. paramedics arrived and examined the patients vital and asked if he would like to go to the hospital even though patient seemed fine. Patient denied going to the hospital and paramedics left afterwards. patient waited for 30 minutes afterwards and then left. we called the patient later and he was doing fine.

<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>
1183057	4/8/2021	NM	29	M	4/8/2021	4/8/2021	gave patient vaccination in designated vaccine area after going over possible side effects. vaccine was given in left arm. I asked patient if he felt ok to move to observation area. patient said yes and stood up and walked to observation area. he sat down and I told him I would be right back. I turned around and was walking back into the pharmacy when I heard a loud crash. I turned around and patient was slumped side ways about to fall out of chair. He had fainted or had a seizure (he was very stiff, redness to face, eyes open and fixed). I ran over to him and a pharm tech and I got him to the floor immediately. He regained consciousness within 5-10 seconds after placing him on floor. he asked how long was he out. he stated he had this seizure happen before but never after a vaccine. he said he has had multiple vaccines like hepatitis b and this never happened. he states it happens when he has something done to him that causes intense pain. he said it happened after hurting his ankle or when he hit his hand in a fan. checked his BP-172/100 pulse-65. paramedics came to check him out. BP still elevated. he walked out with paramedics.
1183052	4/8/2021	GA	43	F	4/7/2021	4/7/2021	Right at the time I got my vaccine. Three people in the group started fainting and having seizures immediately after. I had my vaccine at 1:46pm I wanted to report it since Im not sure the facility or nurses will. One you g lady fainted, then and old man passed out, then another young man in his 30s had a violent seizure. Even ripped his shirt. The organizers stopped the vaccinations until the ambulances left. I was left horrified, as was everyone else there. Im not sure what kind of poison. We have been injected with. Please send more information about the ingredients of this vaccine to me. Thanks

<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>
1177264	4/7/2021	CA	55	M	4/7/2021	4/7/2021	<p>Patient received 2nd dose of Pfizer at 10:14 am on left deltoid, lot # ER8729, expiration date on 07/2021. Patient reports no adverse reaction to first dose of Pfizer vaccine. Patient has history of epilepsy, stroke, hemiplegia left upper extremity. Patient takes medication daily for seizure, medication was last taken this morning. At 11:37 am, patient started to have a seizure in the chair. The three EMTs, and a RN responded immediately. No fall occurred, no clusters in observation room. At 11:38 am, EMS was activated. Patient remained in chair throughout seizure and was physically stabilized by EMT . His seizure lasted approximately 1 minute. At 11:38 am, patient was non-verbal, but breathing at a rate of 20 res/min. Patient nodded to respond to neurological assessment. Vital signs were taken every 5 minutes. At 11:38 am, BP 150/77 sitting, HR 103, SpO2 97% RA, RR 20 res/min labored. Patient was transferred to anti-gravity chair with assistance from EMTs. At 11:39 am, patient was able to verbally respond to questions. Patient was alert and oriented to person, place, time and situation. Patient states "I just had a seizure". At 11:42 am, BP 152/98, HR 104, Spo2 at 95%, RR 22 res/min, labored, patient stated "I feel palpitation". Staff approached patient calmly, encouraged deep breathing, provided quiet environment. Upon assessment, patient was alert, oriented X4, clear speech, communicated in Spanish and English. At 11:45 EMS arrived. patient stated "I feel a lot better". Patient was transferred into a gurney and transported to hospital. Emergency responders left with patient at 11:57 am. Patient was accompanied by his brother .</p>

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1178485	4/7/2021	CA	48	F	3/23/2021	3/23/2021	48 yo female who presented today for her first dose of the Moderna vaccine. Vaccine was administered at 1400 in the left deltoid. Patient was directed to go to the observation area for a 15 minute observation period after administration of her Moderna vaccine. While walking, patient was assisted to the floor by two volunteers, amid a suspected seizure. Arriving on scene, patient was unconscious and having a tonic-clonic seizure that lasted 20 seconds. EMT's were on scene placing an 18g PIV in the right forearm, collecting a BG, and had placing the patient on the monitor. Patient was placed on a NRB mask at 15 L of O2. Patient again fell unconscious and had a second tonic-clonic seizure that lasted 20 seconds. Patient regained consciousness and requested that provider unlock cell phone to collect patient medication list and husband's information. Husband was contacted and requested to enter to be by her side. Husband reported a history of seizures (tonic clonic) and current treatment/management. He requested that patient not to be taken to the ER. Provider advised husband and patient that the paramedics would determine the necessity of her transfer to the ER. Ambulance was notified and Fire reported to the patient's side by 1435. Upon arrival, husband and patient requested not to be transferred to the ER. While answering questions, patient again was assisted to the floor and sustained a third tonic-clonic seizure lasting approximately 20 seconds. Provider aided paramedics in transferring patient to the gurney. Patient was transferred to hospital with husband and all personal belongings.

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1178250	4/7/2021	NJ	51	F	3/22/2021	3/23/2021	<p>Convulsions; In and out of consciousness; extreme pain throughout the body; Vomiting; Inability to speak; Couldn't walk; Couldn't raise limbs; Sustained premature ventricular tachycardia; Heart collapsed to 20 BPM; This spontaneous case was reported by a nurse (subsequently medically confirmed) and describes the occurrence of VENTRICULAR TACHYCARDIA (Sustained premature ventricular tachycardia), BRADYCARDIA (Heart collapsed to 20 BPM), SEIZURE (Convulsions), GAIT INABILITY (Couldn't walk), MUSCULOSKELETAL STIFFNESS (Couldn't raise limbs), SEIZURE (In and out of consciousness), APHASIA (Inability to speak), PAIN (extreme pain throughout the body) and VOMITING (Vomiting) in a 51-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 047A21A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No historical condition reported). On 22-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, the patient experienced VENTRICULAR TACHYCARDIA (Sustained premature ventricular tachycardia) (seriousness criteria hospitalization, medically significant and life threatening), BRADYCARDIA (Heart collapsed to 20 BPM) (seriousness criteria hospitalization, medically significant and life threatening), SEIZURE (Convulsions) (seriousness criteria hospitalization prolonged and medically significant), SEIZURE (In and out of consciousness) (seriousness criterion hospitalization prolonged), PAIN (extreme pain throughout the body) (seriousness criterion hospitalization prolonged) and VOMITING (Vomiting) (seriousness criterion hospitalization prolonged). 23-Mar-2021, the patient experienced GAIT INABILITY (Couldn't walk) (seriousness criterion hospitalization), MUSCULOSKELETAL STIFFNESS (Couldn't raise limbs) (seriousness criterion hospitalization) and APHASIA (Inability to speak) (seriousness criterion hospitalization). The patient was hospitalized on 23-Mar-2021 due to APHASIA, BRADYCARDIA, GAIT INABILITY, MUSCULOSKELETAL STIFFNESS and VENTRICULAR TACHYCARDIA. At the time of the report, VENTRICULAR TACHYCARDIA (Sustained</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>
							premature ventricular tachycardia), BRADYCARDIA (Heart collapsed to 20 BPM), SEIZURE (Convulsions), GAIT INABILITY (Couldn't walk), MUSCULOSKELETAL STIFFNESS (Couldn't raise limbs), SEIZURE (In and out of consciousness), APHASIA (Inability to speak), PAIN (extreme pain throughout the body) and VOMITING (Vomiting) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Mar-2021, Heart rate: 20 (Low) 20 BPM. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter considered VENTRICULAR TACHYCARDIA (Sustained premature ventricular tachycardia), BRADYCARDIA (Heart collapsed to 20 BPM), SEIZURE (Convulsions), GAIT INABILITY (Couldn't walk), MUSCULOSKELETAL STIFFNESS (Couldn't raise limbs), SEIZURE (In and out of consciousness), APHASIA (Inability to speak), PAIN (extreme pain throughout the body) and VOMITING (Vomiting) to be related.
1177352	4/7/2021	WI	25	M	4/7/2021	4/7/2021	patient walked to the observation room independently and about 5 mins after arrival to the observation room, he become very pale, eyes rolled back, and appeared to have a seizure type of activity. Patient was transferred to a cart with assistance, was able to respond to commands, and was transported to the Emergency department.
1177390	4/7/2021		34	M	4/7/2021	4/7/2021	patient developed seizure 5 to 6 minutes after vaccine administration . 911 was called and patient was taking to the hospital
1177416	4/7/2021		19	M	4/2/2021	4/2/2021	vasovagal reaction with syncope including multiple episodes of transient loss of consciousness and tonic-clonic seizure motions
1178001	4/7/2021	TN	36	M	4/6/2021	4/6/2021	I had a seizure around 5 minutes after the shot. I was feeling sweat and my vision started to fade...I can explain further on a call or email.
1178083	4/7/2021	FL	24	F	4/6/2021	4/6/2021	Patient had just received covid vaccine. She was still seated in immunization room and said she felt dizzy and then passed out. She then started having a seizure a few seconds later. She seized for about 2 minutes. Patient was breathing but unconscious.

<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>
1178162	4/7/2021	NC	31	F	3/29/2021	3/29/2021	Vision disturbances beginning about 20 minutes after shot. The rest of the day was followed by extreme light sensitivity, without pain, which resolved the next day. Visual disturbances (vision sometimes blurry, shaky, or glitchy) continued for about 8 days, especially when looking at screens or the lights of traffic. This became accompanied by a jumpy feeling, feeling of fear that I may trigger a seizure, and extreme sensitivity to smells and nausea, strange body sensations. General hard-to-describe feeling of something being off, not painful but scary at times.
1178186	4/7/2021	NJ	21	F	4/7/2021	4/7/2021	Pt completed her 15 minute wait time without complaints (at 1601). She exited the building with her brother into the parking lot. It was reported that she "slumped to the ground" and appeared to have had a seizure. I arrived at her side (at 1603) with EMS checking vital signs. Pt was able to whisper and acknowledge me. She was oriented to person and place. Her pupils were constricted, but was lying in the sunshine. EMS had already called for ambulance. I talked with Pt to obtain any medications, history and allergies - to which she denied all. She then began to tremor with her eyes rolling into her head, unresponsive during this episode. After about 20 seconds, she focused on me and was able to respond to some direction. By that time ambulance was present. She was lifted by 6 people and placed onto stretcher. Stretcher placed into ambulance and went to hospital
1177348	4/7/2021	CO	22	M	4/7/2021	4/7/2021	Patient fainted about 2 minutes after vaccine and had a seizure after falling

<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>
1178267	4/7/2021	FL	61	M	2/6/2021	2/8/2021	He had 2 seizures that following Monday, 08 Feb 2021 and another seizure on Friday, 12 Feb 2021.; discovered he had COVID; discovered he had COVID; This is a spontaneous report from a contactable consumer (patient) reported for himself. A 61-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 1 via an unspecified route of administration on 06Feb2021 (Batch/Lot number was not reported) at age of 61 years old as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received his first dose of Pfizer's COVID vaccine on 06Feb2021. He had 2 seizures that following Monday, 08Feb2021 and another seizure on Friday, 12Feb2021. He also stated he discovered he had COVID. He was at the hospital for the seizures and diagnosed with Covid. He was due for the second dose which was supposed to be given the third week. He he spoke to the nurses there and they advised him not to do anything until after 90 days or something like that. He was told by the doctor that his second dose should be delayed until 30 to 90 days and heard from Department of Health that he had up to 42 days that he'll be ok. He stated that he just spoke to themDepartment of Health. He stated that they said after 40 or 42 some odd days, and there was an extra 7 days of leeway, he could get the second dose. He stated that his 42 days was up either today (24Mar2021) or yesterday (23Mar2021). He had an opportunity this Friday (26Mar2021) to get the second shot. He had to get the shot at the same location. He was tired of this. The patient stated when should he take the second shot? Should he wait the 90 days? He stated his primary said to see a neurologist, but he didn't see them until 05May2021 and the neurologist said they couldn't say anything because he was a new patient until they see him, so they say to go to his primary care. Dates for tested positive for covid after first dose of Covid Vaccine was unspecified. The outcome of events was unknown. Information on the lot/batch number 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>
1178401	4/7/2021	NJ	16	M	4/7/2021	4/7/2021	This patient has a history of epilepsy. He received the vaccine approximately 1pm. This is a minor who was here with his father. At approximately 1:10pm we were alerted that he started to seize. 911 was called. The father had him on the floor. He came out of the seizure prior to EMS arriving. Once they arrived, the parent declined ambulance transportation to the hospital and said he would call his physician.
1177229	4/7/2021		53	M	3/26/2021	3/27/2021	Admit for progressive fever post-COVID-19 vaccination 2nd dose. Pt w/ recurrent aspiration and hx cerebral palsy, spastic quadriplegia, seizure disorder and severe mental disability. Recent discharge x1month ago for asp PNA. For multidrug resistant infection, pt was transferred to LTAC for long term abx tx.
1178462	4/7/2021	KY	45	F	4/7/2021	4/7/2021	was called to waiting room because it appeared the patient was having a seizure. When reached the patient, she was slumped over in her chair, diaphoretic, and pale. She was initially responsive and reporting feeling "shaky". Patient briefly became unresponsive which prompted 911 EMS call. While waiting for EMS, pt blood pressure taken (88/66) as well as pulse (55). Patient regained consciousness about a minute after becoming unresponsive. Smelling salts administered and cold rag placed on back of patient's neck. Once EMS arrived, they removed patient via stretcher from the clinic and were encouraging her to seek treatment in the ER. Unsure if patient was actually taken to ER or UC since she was removed from the facility.
1176789	4/7/2021	FL	31	F	4/7/2021	4/7/2021	Patient had a tonic-clonic seizure approximately five minutes after receiving the first dose of the Moderna covid-19 vaccination. Post seizure the patient reported feeling a fever leading up to seizure. Patient had no history of seizure but has experienced fainting in the past. 911 was called immediately and paramedics cared for her.

<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>
1178551	4/7/2021	CA	46	F	4/7/2021	4/7/2021	Immediately following administration, patient appeared to be slumped into the chair, unresponsive to verbal cues. Patient began making seizure-like movements a couple of seconds later. That episode lasted 2.5 minutes - timed by attending RN. Mobile response team called. Patient responsive when mobile response team arrived. Obeyed commands but appeared lethargic.
1178623	4/7/2021	FL	28	F	4/6/2021	4/6/2021	Fainted 5 minutes or so after receiving vaccine for unknown amount of time. Seizure-like head bobbing and hand numbness.
1178664	4/7/2021	CA	63	M	3/17/2021	3/19/2021	Grand mal seizure at 11:30 a.m. Continued having seizures until 2:00 a.m. 3/29/21 He had not had a seizure for 3 weeks. He had not had seizures for this long a period of time for as long as we have on record. His neurologist stated to give him Ativan each time they were becoming constant,
1178729	4/7/2021	CO	57	F	4/7/2021	4/7/2021	Passed out, threw up myself while passed out went into convulsions. Ambulance/EMTs were called.
1178762	4/7/2021	KS	26	M	4/7/2021	4/7/2021	Patient seemed to have a seizure lasting 1 minute, hitting head as he fell out of his seat. He then became aware of surrounding. Paramedics came and took patient to ambulance.

<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>
1178441	4/7/2021	CA	37	F	4/5/2021	4/5/2021	37 y/o female with known hx of epilepsy c/o 2 episodes of witnessed grand mal seizure over a 2 minute period s/p receiving 1st dose of Moderna. Time of Moderna dose unknown. 1st witnessed seizure while sitting in chair in observation room @ 15:34, lasted approximately 30 seconds. Assisted patient to wheelchair and placed on cardiac monitor in med bay bed. Turned patient on side and @15:35 had second witnessed grand mal seizure. Lasted approximately 50 seconds, 911 called during this time and patient placed on oxygen. Pt post-ictal until 15:42, not alert or oriented to person place or time. Pt slowly became A & O x 4, states currently on Keppra and Diltiazem, no skipped doses. Informed pt 911 was called and on their way, pt stated that she did not want to go to ER. EMS arrived at this time @ 15:52 and took over evaluation of patient. Per EMS, long discussion with patient and is signing out AMA. Pt informed EMS she will go by private transport, husband will drive her to nearest ER. Upon dc, pt alert and oriented x 4. EMS transported patient to outside of the center to join husband. Vital Signs: Time: 15:34 BP: 124/56 P: 98 O2 Sats: 100% on 3L Time: 15:52pm BP: 127/62 P: 98 O2 Sats: 100% on no oxygen Labs/tests done: none Medications given: none Outcome of the adverse event (if paramedic please list hospital taken to): EMS arrived on scene at 15:52 and took over care of patient. Informed pt EMS their rec is to transport to ER for further evaluation however pt refusing. Pts husband contacted and states will drive patient to nearest ER at the hospital.
1176055	4/7/2021	FL	36	M	4/6/2021	4/7/2021	Involuntary shaking/convulsions/shivering across entire body. Was able to walk, but very difficult going up/down stairs. No fever nor did I feel cold. Shaking subsided after about 15 minutes.

<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>
1175027	4/7/2021	OH	36	M	2/25/2021	3/26/2021	grand mal seizure; This spontaneous case was reported by a consumer and describes the occurrence of GENERALISED TONIC-CLONIC SEIZURE (grand mal seizure) in a 36-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 022M20A and 017B21A) for COVID-19 vaccination. The patient's past medical history included Grand mal seizure since an unknown date. Concurrent medical conditions included Mental disability (Mentally handicapped). Concomitant products included PRIMIDONE (MYSOLINE) and LEVETIRACETAM (KEPPRA) for an unknown indication. On 25-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 25-Mar-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 GENERALISED TONIC-CLONIC SEIZURE (grand mal seizure) (seriousness criterion medically significant). At the time of the report, GENERALISED TONIC-CLONIC SEIZURE (grand mal seizure) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment information included midazolam and diazepam for seizures.; 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.

<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>
1175030	4/7/2021	MA	73	F	3/22/2021	3/23/2021	grand mall seizure; mouth foaming; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of GENERALISED TONIC-CLONIC SEIZURE (grand mall seizure) 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 Cholesterol, Penicillin allergy and Allergy to animal. Concomitant products included MULTIVITAMIN [VITAMINS NOS], VITAMIN D NOS and CALCIUM ASCORBATE (VITAMIN C [CALCIUM ASCORBATE]) for an unknown indication. On 22-Mar-2021 at 10:45 AM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021 at 5:30 AM, the patient experienced GENERALISED TONIC-CLONIC SEIZURE (grand mall seizure) (seriousness criterion hospitalization) and FOAMING AT MOUTH (mouth foaming). The patient was hospitalized from 23-Mar-2021 to 24-Mar-2021 due to GENERALISED TONIC-CLONIC SEIZURE. At the time of the report, GENERALISED TONIC-CLONIC SEIZURE (grand mall seizure) and FOAMING AT MOUTH (mouth foaming) 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. Treatment of these events were not provided.; Sender's Comments: This case concerns a 73-year-old female hospitalized with a serious unexpected event of generalized tonic-clonic seizure, and nonserious unexpected foaming of the mouth. 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.

<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>
1175155	4/7/2021	TX	61	F	3/1/2021	3/1/2021	Went to dialysis and within 2 to 3 hours had symptoms of a seizure. Loss of memory for 2 to 4 hrs acting stiff and unusual behavior; Went to dialysis and within 2 to 3 hours had symptoms of a seizure. Loss of memory for 2 to 4 hrs acting stiff and unusual behavior; Went to dialysis and within 2 to 3 hours had symptoms of a seizure. Loss of memory for 2 to 4 hrs acting stiff and unusual behavior; temp of 101.6; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose via an unspecified route of administration, administered in Arm Right on 01Mar2021 17:15 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. Medical history included end stage renal disease (ESRD), high blood pressure and pulmonary hypertension; all from an unknown date and unknown if ongoing. The patient has no COVID prior vaccination and not tested to COVID post vaccination. There was no other vaccine in four weeks. Concomitant medications (reported as Other medications in two weeks) included clonidine (CLONIDINE), macitentan (OPSUMIT), minoxidil (MINOXIDIL), carvedilol (CARVEDILOL), and tadalafil (ADCIRCA); all taken for an unspecified indication, start and stop date were not reported. The patient previously took BNT162B2 (lot number: unknown) first dose on 22Jan2021 at 02:45 PM right arm for covid-19 immunization. The patient also previously took Hydralazine and experienced allergies. It was reported that on 01Mar2021 08:00 PM the patient went to dialysis and within 2 to 3 hours had symptoms of a seizure. Loss of memory for 2 to 4 hrs., acting stiff and unusual behavior. The patient's daughter took the patient and had a temp of 101.6 was sent home Tuesday morning. The events resulted in: Doctor or other healthcare professional office/clinic visit. The outcome of the events was recovered with sequelae (reported as with lasting effects). No treatment was given for the events. Information on the lot/batch number 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>
1175193	4/7/2021	TN	44	M	3/22/2021	3/1/2021	seizure; I fell of my hight; headache; total amnesia; my waking is wobbly and not steady; This is a spontaneous report from a contactable consumer (patient). A 44-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; Lot Number: ER8727) via an unspecified route of administration, administered in Arm Left on 22Mar2021 12:30, at the age of 44-year-old, as SINGLE DOSE for covid-19 immunisation. The patient medical history was not reported. The patient was not diagnosed with COVID prior to vaccination. Concomitant medications included vitamin c [ascorbic acid] (VITAMIN C [ASCORBIC ACID]); colecalciferol (VITAMIN D [COLECALCIFEROL]); fish oil (OMEGA 3 [FISH OIL]). On 23Mar2021, at 03:00 AM, the patient fell off his height and had a seizure. This was his first seizure in his life. The patient was rushed to the ED where a CT of the head and neck was done in Mar2021. The CT did not show any bleeding or fracture. The Neurologist dismissed the patient home and had the patient go back and see him in 2 days. The patient has been complaining of headache and taking Tylenol PRN for it. His walking was wobbly and not steady. The patient had a total amnesia of the accident. The patient did not receive treatment for seizure, fall, total amnesia and walking was wobbly and not steady. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not tested for COVID since the vaccination. Outcome the events was not recovered.
1175473	4/7/2021	GA	21	M	4/6/2021	4/6/2021	The participant passed out and had seizure-like activity, then would arouse and be coherent. No history of seizures. Several brief episodes occurred. EMS called. B/P and pulse un-obtainable. EMS arrived and assessed participant. Taken to Medical Center E.D.
1175500	4/7/2021	VA	58	F	4/2/2021	4/3/2021	Legs and arms started shaking uncontrollably and I passed out or had a seizure for several minutes. I woke/came to and my husband helped me to bed. He said I was all sweaty. I slept for about an hour and got up. I fed my dogs, made tea, sat down and fell asleep. After waking I got up and continued my day with extreme fatigue, nausea, and a headache.

<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>
1175510	4/7/2021	NY	16	F	4/7/2021	4/7/2021	Patient presented for her first COVID-19 vaccine. Approximately a minute after vaccine was given, she was noted to be seated upright in the passenger seat of her car, with head bent forward and eyes open. She was unresponsive, stiff posture, and was placed into a reclined position. She then had some posturing with head turned to the left, no eye deviation or nystagmus, no tonic-clonic movement. Radial pulse was thready, bradycardia was noted, with normal respirations. She was noted to become diaphoretic and pale/ashen color noted to the face and arms. She became responsive within a few minutes, however initially was not able to answer questions clearly. She had no loss of bowel or bladder function. EMS assisted with evaluation. Initial blood pressure 78/31, HR 54, SpO2 100%. EMS then transferred her to the stretcher and she was transitioned from her car to the ambulance. She continued to improve spontaneously with BP 94/61 then 103/60 and HR 86 then 74. SpO2 remained stable at 100%. Skin color improved. She had normal responses to questions, no complaints of headache, dizziness, chest tightness, shortness of breath, numbness or tingling. She had some shaking/voluntary movement of the limbs and body noted, but she could control and stop this voluntarily, no myoclonic or tonic-clonic jerking noted. After syncopal event occurred, mom reported that the patient has a history of syncope routinely with blood draws and vaccines in the past, however this episode was slightly more prolonged and seizure-like activity was different. She has had some jerking movement previously with syncope which lasts 20-30 seconds, different from today's response. No known history of seizure disorder.
1175530	4/7/2021		72	M	3/12/2021	3/16/2021	On 3/16/21 his wife found him poorly responsive so EMS was called. He had seizures on the way to the hospital and was found to be COVID positive. He required intubated. Discharged on 3/24/21.
1175549	4/7/2021	MI	58	M	4/5/2021	4/5/2021	Patient head was bobbing and the nurse thought it might have been a seizure. Onsite EMS was called vitals BP 149/88 HR 56 97% O2. He felt better and was released home.

<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>
1177007	4/7/2021	TN	28	M	4/7/2021	4/7/2021	Pt started to faint and then had a seizure. The patient awoke from seizure and 1 minute later had another seizure. EMS arrived and took the patient to a hospital facility.
1175790	4/7/2021	CT	72	M	4/1/2021	4/4/2021	Patient had a seizure in the middle of the night on Sunday. Wife called 911 and patient was transported to ER where he stayed for observation and then prescribed seizure medication. Patient has no history of seizures.
1177181	4/7/2021	AL	53	F	4/7/2021	4/7/2021	Approximately 5 minutes after injection, patient started feeling faint. Pallor skin color, skin was moist. Patient then proceeded to faint, followed by a 15 second seizure. Once patient became alert, a second fainting spell occurred.
1176079	4/7/2021	VA	93	M	3/20/2021	3/21/2021	The evening after vaccine she had trouble speaking and fatigue 3/20/2021. She went to lay down and outx 24 hours, on 3/21 friends were not able to wake her and went to the hospital where she was admitted. Had BP at the time of 220/100s. She was treated for PRES with seizure started on Keppra. She was discharged from the hospital 3/27
1176115	4/7/2021	FL	53	M	4/7/2021	4/7/2021	Patient received vaccine approx 5-10 minutes patient fainted in his chair. A cardiac nurse was waiting to receive their vaccine and rushed over to help too. Patient began to convulse. We tried to get patient to respond approx 2 min later patient woke up and complained about being thirsty. We gave him Apple juice and placed a cold pack on his neck. Called 911, We took BP it was 77/49 pulse 45, we laid patient down and retook BP 123/73 Pulse 68. After 5 more min BP 135/85 pulse 72. EMS arrived and took patient away

<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>
1176129	4/7/2021	FL	27	M	4/6/2021	4/6/2021	Patient had no reaction at time of vaccination, got up out of chair and walked approx. 20 feet to sit down in a chair with arms in the vaccine observation area at 1715. At 1722 patient fell out of chair and onto floor. PharmD started emergency chain including 911 call and call to patient's emergency contact. PharmD ran to patient and observed him lying facedown with head facing left. Eyes open but unresponsive, his name was called with no response. Right as he was observed to be breathing normally with a steady pulse, patient had mild seizure with jerking movements. He was turned to his side during seizure event lasting no longer than 2 minutes. Patient then regained consciousness and was kept on his side. Was alert and oriented. He knew where he was, who he was, what day it was. He was able to answer all 911 dispatcher questions relayed to him. Dispatcher advised he could sit up on floor, which he did. PharmD stayed right behind him until paramedics arrived. He was kept talking to stay alert. It was unknown if he hit his head on the initial fall. Paramedics arrived and checked BP/Pulse/EKG. Pt then had a gasp/shake attack that paramedic notated as a panic induced episode. He calmed and was transferred to ER
1176226	4/7/2021	CO	35	F	4/7/2021	4/7/2021	Light headed, convulsions , vasovagal, then passed out, then convulsion for second time. Nausea Anxiety around needles Diaphoretic Vitals 140/95, HR -70, Oxygen -98
1176528	4/7/2021	TX		F		3/26/2021	FEVER OF 103F; 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 concurrent conditions included special needs, crohn's disease, cerebral palsy, seizures, gi issues, and bladder issues. The patient received covid-19 vaccine (suspension for injection, route of admin not reported, batch number: 1805029, expiry: UNKNOWN) dose was not reported, administered on 26-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 26-MAR-2021, the subject experienced fever of 103f. Laboratory data included: Body temperature (NR: not provided) 103 F. On 27-MAR-2021, treatment medications included: paracetamol. The action taken with covid-19 vaccine was not applicable. The patient recovered from fever of 103f on 27-MAR-2021. This report was 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>
1178336	4/7/2021	MS	19	M	4/7/2021	4/7/2021	Pt. was administered immunization and directly following had a spell of unconsciousness that was assumed to be seizure. Pt. has not history of seizures in the past. EMS was contacted for pt. evaluation. Pt. recovered consciousness after about 90 seconds, evaluated by EMS at their arrival shortly after, and taken on own accord for follow up at local hospital.
1176871	4/7/2021	TX	28	F	3/26/2021	3/26/2021	Started having seizures. One after the other. 3 within 20 minutes. Became completely unresponsive for 1 1/2 hours. Was taken to the ER to be monitored.
1178783	4/7/2021	CA	36	M	4/7/2021	4/7/2021	I had an intense fever within 5 minutes of the administration of the shot. I was sweating profusely, experience nausea and then fainted and had a mild seizure. After coming to consciousness, I vomited and the pharmacy staff called the paramedics. I was extremely pale and the fever persisted for several minutes while waiting for the paramedics. I recovered and felt mostly normal after being given saline solution and anti-nausea medication. Hours after being released from the hospital, I have waves of cold chills and hot flashes.
1177015	4/7/2021	NE	20	F	4/7/2021	4/7/2021	After receiving her vaccine, she sat with her friend that she came with and told her that she felt lightheaded. She placed head between her knees initially, then sat up and leaned over to her left where she landed prone unresponsive. PCPH staff attended and turned her supine and noted that she was having a seizure like movements, not breathing for 10 sec., incontinent of urine, gurgling at one point. While assessing for need for CPR and with stimulation of sternum, regained consciousness and took deep gasp, asking "did I pass out?" "I usually get dizzy and sometimes faint with shots." VSS initially 98/60-71 hr-16-99% ox reading. EMTs summoned by Director of PCPH on site encouraged her to call her parents as s
1175740	4/7/2021	MA	60	M	4/1/2021	4/1/2021	Seizure (convulsive) 1 minute following vaccination of approx 30 seconds.
1178910	4/7/2021	PA	33	M	4/5/2021	4/7/2021	Grand mal seizure, 2:30 a.m. , second night after injection, 3-5 minutes.

<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>
1178264	4/7/2021	TN	56	M	3/22/2021	3/22/2021	Complex seizures; Explosive diarrhea; Profuse vomiting; Chills; sweats; This is a spontaneous report from a contactable consumer (patient). A 56-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EN6207), via an unspecified route of administration in the left arm, on 22Mar2021 at 09:30 (at the age of 56-years-old) as a single dose for COVID-19 immunisation. The patient had no medical history. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had no known allergies to medications, food, or other products. Concomitant medications included lisinopril (MANUFACTURER UNKNOWN) and atorvastatin (MANUFACTURER UNKNOWN). The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced complex seizures, explosive diarrhea, profuse vomiting, chills, and sweats on 22Mar2021 at 19:00. All of the events required hospitalization from an unspecified date to an unspecified date for one day. The patient underwent lab tests and procedures which included nasal swab: negative on 22Mar2021. Therapeutic measures were taken as a result of all of the events, which included intravenous fluids. The clinical outcome of complex seizures, explosive diarrhea, profuse vomiting, chills, and sweats was recovered on an unspecified date. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

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1178853	4/7/2021	MN	40	M	4/7/2021	4/7/2021	Approximately seven minutes after the patient received the Janssen COVID vaccine, he had called out to his wife/pharmacy technician at the pharmacy stating he did not feel well. His head had fallen back and his eyes were starting to roll back into his head. Patient had saliva starting to foam at the corner of his mouth and it appeared to be the onset of a mild seizure (per wife, patient has had seizure once before after a head injury) and he was turning very pale. Patient seemed to be unresponsive at that time - not answering to questions. At this point, one of the pharmacists ran to the clinic to get help and the other pharmacist administered an Epi-pen to patient's thigh. Patient immediately came around after the injection, looked up and began talking. Staff called 911 and patient was monitored by pharmacy and clinic staff. When the paramedics arrived, the patient was doing better and was able to ride home with his wife.
1172972	4/6/2021	ME	54	F	4/6/2021	4/6/2021	Patient received vaccine no issues, waited 15 minutes reported no issues, left pharmacy for approximately 5 min, returned complaining for dizziness, we got her water and had her sit down, she began having seizures, she had 5 episodes before emd arrives, she was taken by ambulance
1172404	4/6/2021	MI	40	F	3/24/2021	3/27/2021	I received the injection on Wednesday, by Saturday I was feeling very sick. I had a fever of around 102.5 on average and was feeling very weak. By Monday I was so weak I had to go to the doctor. In the dr. office I had a syncope event with tongue out, convulsions. Dr called 911 and was transported to the hospital via ambulance. The dr at the ER tested for Covid (negative) and stated this was a moderate adverse reaction to the vaccine. It took me a full 8 days to be able to not sleep all day and get some strength back.

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1172407	4/6/2021	NC	40	M	3/31/2021	3/31/2021	Patient received first dose Pfizer COVID vaccine and was sitting in observation area. Nurse came to get me and patient was found lying on the floor. Patient was cool, clammy, eyes closed but easy to arouse. Patient's friend states he sometimes has a seizure associated with feeling like this. Patient alert and oriented, able to converse, and states he did not fall but sat down in floor prior to lying down. 1119 VS: 98% RA, pulse 69 and regular, b/p 118/72. Ice pack applied to patient along with fanning of patient. Patient states feeling better and brought to sitting position without difficulty. Patient offered juice which he was able to drink without difficulty. Patient assisted into wheelchair and brought back to observation area. 1128 VS: 98% RA, pulse 79 and regular, b/p 122/72. Patient no longer clammy, able to converse and follow directions without difficulty. Patient states he is feeling much better, able to stand without feeling dizzy or lightheaded. Friends present with patient and will drive patient home. Patient transported to car via wheelchair. Able to transfer into car independently.
1172547	4/6/2021	MO	50	F	3/26/2021	4/5/2021	Started having mild to moderate seizures 4/5/2021. Continued off and on through 4/6/2021. Called Dr. She said do not get a second dose. Monitoring symptoms still.
1172584	4/6/2021	MS	18	F	4/6/2021	4/6/2021	Within 5-10 minutes after receiving vaccine, patient began to become very pale. Her symptoms included dizziness, syncope, stomach ache, foaming at the mouth, vision disturbances. 911 was called and paramedics arrived.. Her vital signs were all normal. Patient did not wish to go to hospital, and her mother took her home. Other pertinent information is that patient has a history of seizures and had been off of her seizure medication for 4 weeks. I believe that I understood her mother to say that her neurologist knew she was getting the vaccine today. Patient reported no allergies to any other vaccine, medication, or other.

<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>
1172639	4/6/2021	CA	75	F	4/6/2021	4/6/2021	within 3 minutes of injection within 3 minutes had a seizure with (per nurses) generalized increased tone, gasping and unresponsive. Patient with multiple medical problems including sz disorder (off meds past 6 months), copd, anxiety, glaucoma, pacer When I got there patient breathing well, slumped back in wheelchair, not gasping and not seizing. VSS (110-120/54-68, pulse 70s, RR 18-20, O2 sat initially 95% on room air, put on oxygen while watching her), skin color pink. Initially unresponsive but when I was discussing with husband that we were going to call 911 and have her taken to ER, she opened her eyes and responded. Both patient and husband refused 911/ER saying that patient with sz disorder (also dissociative convulsions) and that she has a seizure at least daily, sometimes due to stressful situations, and that afterwards sometimes awakens quickly and sometimes takes longer. Usually sleeps for a few hours afterwards. As patient and husband refused transfer and VSS, patient was monitored for about 45 mins and released.
1172754	4/6/2021	CA	27	F	4/6/2021	4/6/2021	Janssen -COVID 19- EUA 04-06-21 Adverse Event #1 Approximately 3 minutes following vaccination Pt had seizure. Personnel on scene assisted her to the ground and protected her head. No injuries from event. Pt assessed by Team 1 crew member, then turned over to ALS Medic unit.
1172807	4/6/2021	NH	57	F	4/6/2021	4/6/2021	Patient lost consciousness and possibly had a seizure (was observed twitching on the floor) approximately 13 minutes after receiving vaccine during the 15 minute post-vaccination waiting period. Patient was observed and blood pressure monitored for approximately 10 minutes while waiting for the ambulance to arrive. Patient was also given an ice pack for bump on her head that occurred during fall. Patient was transported to the local hospital. Unknown at this time what occurred after that.
1172874	4/6/2021	MO	24	F	4/6/2021	4/6/2021	Pt has syncopal episode/seizure following first dose of covid vaccine
1172905	4/6/2021	MO	41	F	4/6/2021	4/6/2021	Pt had syncopal episode and seizure following first dose of covid vaccine, resulting in calling 911, transferred to the ED

<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>
1176372	4/6/2021		92	M	3/10/2021	3/31/2021	Narrative: Per law enforcement report, patient's death appears to be natural causes. Wife found 91 yo patient on the floor having seizures. Patient was treated for seizure disorder and had recent Primary Care visit with updated labs. Seizure medication lab monitoring was monitored with no concerns.
1172915	4/6/2021	TX	18	F	4/6/2021	4/6/2021	Patient had seizure-like activity about 10 minutes after receiving the Johnson & Johnson Covid Vaccine. Nurse saw her eyes rolling back and struggling to breath. She was placed on her side until wheelchair was brought to her side and then transferred to wheelchair and taken to the ER. While in transit she regained consciousness and was lethargic but was responding appropriately to questions. Patient was checked by Dr. and his review was tachycardic and mild dyspnea. Skin was pink and warm. She was taken to the ER for further evaluation.
1172254	4/6/2021	IN	30	M	4/3/2021	4/3/2021	I suffered an apparent seizure according to the multiple pharmacists working that day. It happened within less than a minute of the injection. I went to sit down to be monitored and the next thing I know is I have a pharmacist in my face asking me if I am ok and telling me an ambulance was on the way. No idea what caused it or how severe the seizure was.
1173082	4/6/2021	NY	18	F	4/6/2021	4/6/2021	PT EXPERIENCED CONVULSIONS, TEMPORARY LOSS OF CONSCIOUSNESS, WITNESSED BY BYSTANDER. PT THEN REGAINED CONSCIOUSNESS BUT PRESENTED W/ ALTERED MENTAL STATUS FOR APPROXIMATELY 5-10 MINUTES. PATIENT PRESENTED W/ FOLLOWING SYMPTOMS: LOSS OF CONSCIOUSNESS CONVULSIONS BP: 118/74 O2: 98 PULSE: 85 PT DECLINED TRANSPORT, WAS TRANSPORTED TO HOSPITAL IN PRIVATELY OWNED VEHICLE.
1173404	4/6/2021	NH	37	F	4/6/2021	4/6/2021	Patient fell off chair, appeared to be having a seizure. Patient was very pale, clammy and reported nausea. Patient was given cold compress to back of neck, blood pressure and pulse monitored. 911 was called and arrived approx 10 minutes after event. Patient was conscious and aware when EMS arrived. Patient reported history of fainting and appearing to have seizures in the past.

<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>
1173600	4/6/2021	IL	67	M	3/6/2021	3/6/2021	seizure; sore arm; A spontaneous report was received from a consumer, concerning a 67-years old male patient, who received Moderna's COVID-19 vaccine and experienced seizure and sore arm. The patient's medical history included brain tumor removed. No relevant concomitant product was reported. On 06 Ma 2021, prior to the onset of events, the patient received his first of two planned doses of mRNA-1273 (lot number 036A21A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On the same day patient experienced sore arm for couple of days. On 12 Mar 2021, 6 days after the first shot, the patient experienced seizure. The patient was hospitalized for a night and laboratory tests were performed. There was no indication of stroke and everything else came back inconclusive. No treatment information was reported. Action taken with mRNA-1273 in response to the events was unknown. The outcome of the event sore arm was resolved on 08 Mar 2021 and the outcome of the event seizure 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.
1173667	4/6/2021	CA	30	M	4/6/2021	4/6/2021	Seizure like activity. Transported to ER.
1173880	4/6/2021	NJ	23	F	3/23/2021	3/26/2021	Vomiting, severe headache, 2 seizures , muscle aches and weakness in the legs, unable to walk, knee paralysis
1174015	4/6/2021	MD	22	M	4/5/2021	4/6/2021	Grand mal seizure

<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>
1172911	4/6/2021	FL	17	F	4/6/2021	4/6/2021	Presented at 0905 for vaccine. 0912: Staff were called to the patient vaccine area. Patient did seem vaso vagal post vaccine (loss of color and diaphoretic), patient then appeared to have a Grand Mal type seizure with arm contracture and vomiting x4. Patient was unresponsive for around a minute. Only meds patient: BCP Patient accompanied by her mother. o2 98% HR 81 BP taken at 920 130/80. 0935: Patient seemed post-dictal, very sensitive to touch and disconnected. As per Mother, the patient had a history of a prior Grand Mal seizure 4 years ago; that was never worked up. Patient complaining that she is "Very Lightheaded." Spoke with patients primary PCP MD, she stated that it was not likely a seizure and that it was extreme vaso-vagal response and that the patient could go home if now drinking and responsive. Patients mother also spoke with PCP and I gave her the option to decline EMS or to go be evaluated. Patients mother chose for her to be evaluated. EMS was contacted by the local police who were working the vaccine clinic. Vitals taken by EMS: BP 127/61 Blood Glucose 97 0955: EMS arrived / Patient transported to ED.
1171176	4/6/2021	OH	17	F	4/6/2021	4/6/2021	Syncopal episode within 1 minute of injection, seizure like active posturing, unresponsive. Alert and oriented by the time she was transferred to ER.
1171143	4/6/2021	OH	37	M	3/31/2021	3/31/2021	3-31-21 6PM STATING PT PASSED OUT AND HAD A SEIZURE; HE WAS HOLDING HIS VACCINATION CARD IN HIS HAND - REQUESTING PHONE NUMBER. CALLED FOR TRANSPORT TO ER. 4-6-21 10AM PT STATES HE HAS A HX OF BECOMING LIGHTHEADED FOR MANY YRS. HE WAS IN THE CHECK OUT LINE AND 'FELT LIGHTHEADED AND WAS GOING TO GET SOME CANDY TO FIX IT(HADN'T EATEN MUCH THAT DAY)'. BYSTANDER STATES HE PASSED OUT AND HAD A SEIZURE. HE DID FX RT SHOULDER. HAS AN APPT TO SEE PCP FOR F/U.

<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>
1171107	4/6/2021	VT	57	F	4/5/2021	4/5/2021	I started shaking uncontrollably and shivering that lasted about 3 hours. I could not stop shivering, even though the house was much warmer than usual. I had shooting pain all over, especially in my shoulders. I could not move, or even reach for my water glass, without extreme pain. It felt like nerve pain, muscle and joint pain. I am very active, strong and healthy. When I walked to go to bed I was in so much pain that I could not stop moaning and saying Oh my god, oh my god, (that's not like me ? I have a high tolerance for pain and consider myself stoic) and I was shaking so hard I thought I was going to have a seizure or something. I was very tired and slept through the night. This morning I feel like I have the flu ? headache, body aches, fatigue. Thank you.
1170900	4/6/2021	IL	54	M	4/5/2021	4/5/2021	Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe
1170889	4/6/2021	FL	19	M	4/5/2021	4/5/2021	Site: Pain at Injection Site-Mild, Site: Redness at Injection Site-Mild, Systemic: Chills-Mild, Systemic: Confusion-Mild, Systemic: Diarrhea-Severe, Systemic: Dizziness / Lightheadness-Medium, Systemic: Nausea-Medium, Systemic: Seizure-Mild, Systemic: Tingling (specify: facial area, extremities)-Medium, Systemic: Tinnitus-Mild, Additional Details: na
1170886	4/6/2021	IL	54	M	4/5/2021	4/5/2021	Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe
1170873	4/6/2021	FL	27	M	4/5/2021	4/5/2021	Systemic: Chest Tightness / Heaviness / Pain-Medium, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Seizure-Mild
1170842	4/6/2021	OH	20	F	4/5/2021	4/5/2021	Systemic: seizure-Medium, Systemic: Seizure-Medium, Additional Details: Patient was fine for approx 5 min after vaccination, fell off chair with seizure, paramedics were called and came, watched her for any sign of further problems, she did not require a trip to the hospital, they left and she remained for approx 20 more minutes, during which time she slept for a little while

<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>
1170835	4/6/2021	FL	21	M	4/5/2021	4/5/2021	Systemic: Confusion-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe, Additional Details: patient had an absense seizure immediately after sitting down
1172341	4/6/2021	NC	28	F	4/6/2021	4/6/2021	Patient passed out in waiting lobby within 5 minutes after receiving vaccine. Patient was hot to touch and felt hot herself. Patient lost consciousness and other patients asked for help. 911 was called due to her appearing to have a seizure. Patient taken back into Immunization Room to lay with feet elevated. Given water. in about 5 to 10 minutes patient was feeling better but still weak and now cold. EMS arrived. Patient passed out again when EMS took her blood sugar level.
1170831	4/6/2021	FL	32	M	4/5/2021	4/5/2021	Systemic: Confusion-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe, Additional Details: Pt was advised to set down in the waiting area for 15 minutes to be monitored, once in a sitting position patient started convulsing into a grand mal seizure, I immedietly ran to him, started restraining him and holding his head to prevent him from hitting the wall, patient was laid flat and restrained by family members and the nurse practitioner, seizure lasted for les than a minute, and patient started to regain consiousness. called 911

<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>
1172316	4/6/2021	CA	24	F	4/6/2021	4/6/2021	<p>Patient given educational material regarding vaccine and advised to continue to self-monitor per the CDC guidance. PT. was given her first dose of Moderna Vaccine in R deltoid at 1012 on 4-6-2021. Pt. began to have an adverse event at 1015. Pt. began to have LOC, then began to fall out of the chair face forward. Pt. had LOC approx.. 5-7 secs. PT. was assisted back to chair where she regained alertness. She was then transferred to W/C and moved to corner for privacy. She then began to have another episode and displaying seizure-like movements. Pt. was transferred out the chair onto the floor. She regained consciousness after approx. 7 seconds. She was A&Ox4 after episode, able to answer all questions, no respiratory distress observed. Face was assessed after falling face forwards, there was no signs of bleeding. Approx 1037 pt. felt vision going dark again, pulse dropped to 42 BPM, LOC 15 secs, assisted back to floor, no trauma observed. arrived on scene approx at 1057, pt. refused further medical care, verbalized boyfriend is coming to take patient home. 1018 VS: 112/82 P 63, RR 20, 98% 1023 VS: 108/70 P 62 RR 19, 99% 1038 VS: 88/50 P 70, RR 20, 98% (Pt. awake, verbalized tingling in hands and feet) 1048 VS: 104/68 P 62, RR 20, 100%</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>
1170761	4/6/2021	CA	30	F	3/23/2021	3/24/2021	Left side of body weakness; This spontaneous case was reported by a consumer and describes the occurrence of HEMIPARESIS (Left side of body weakness) in a 30-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 001B21A) for COVID-19 vaccination. Concurrent medical conditions included Learning disability and Seizure. On 23-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 24-Mar-2021, the patient experienced HEMIPARESIS (Left side of body weakness) (seriousness criterion medically significant). At the time of the report, HEMIPARESIS (Left side of body weakness) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No relevant concomitant medications were reported. No treatment information was 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 event, a causal relationship cannot be excluded
1170610	4/6/2021	CA	30	M	4/5/2021	4/5/2021	Convulsion- eyes rolled back, involuntary contraction of muscles, unresponsive, lasted 10 seconds other symptoms: chills, nausea, sweating
1171332	4/6/2021	FL	19	F	4/6/2021	4/6/2021	Patient looked like she had a slight seizure for about a minute at about 10:30 am. EMT called 10:31am and arrived at 10:39am. Patient was alert and refused transport.
1171370	4/6/2021	TX	41	F	4/5/2021	4/5/2021	Got the vaccine at 10:30am on 4/5/21 and felt ok all day. About 10:30pm when trying to go to bed I started having severe body aches, extremely high fever, all over and uncontrollable body shaking (thought I was having a seizure), racing heart, severe headache, very sensitive and sore injection site. This lasted through the night, for a good 6 hours. As of 10:30am on 4/6/21 I still have a very bad headache and mild to moderate body aches and an extremely sore injection site.

<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>
1171376	4/6/2021	PA	23	M	4/6/2021	4/6/2021	Patient received J&J IMZ at 9:45 am. After receiving dose was sitting in waiting area for 10 minutes. Patient then lost consciousness and fell off chair. Patient bump head on floor and had mild case of tonic clonic seizure for approximately 6 seconds. Patient came regained consciousness within 1 to 2 minutes. 911 was called in and EMTs arrived for assistance. Taking patient out in stretcher. Patient did not have any alerts or allergies noted on PQCF form to alert of any issue
1171426	4/6/2021	MI	28	M	4/1/2021	4/4/2021	seizure
1171428	4/6/2021	TX	43	M	4/6/2021	4/6/2021	While waiting 15 minutes after receiving the shot patient suffered a seizure roughly 5 minutes after receiving the vaccine. Seizure lasted approximately 10 seconds. Paramedic was on site and assisted in monitoring the patient until ambulance arrived. While waiting patient was sweating, nauseas and 'didn't feel well'. Patient suffered a second smaller seizure before the ambulance arrived. Patient was monitored and taken to ER.
1171567	4/6/2021	OR	31	F	4/6/2021	4/6/2021	I felt the vaccination spreading through my body as I got really heavy and lost consciousness. I woke up to my husband holding my head and yelling my name. I had been seizing and had bitten my tongue. I was very white and nauseous and cold and shaky. They gave me water and a cold pack. The seizure probably only lasted for 5 seconds but it's hard to say. I felt very fatigued afterwards. I stayed for 10 more min and drank water and then they sent me on my way.
1171305	4/6/2021	NJ	30	M	4/6/2021	4/6/2021	At end of 15 minutes, pt collapsed and then had a seizure < 15 s. No history of seizures. Pt declined going to the hospital. Wife drove him home. Instructed to see physician prior to dose 2.
1168440	4/5/2021	TX	54	M	4/1/2021	4/1/2021	PATIENT WIFE CALLED AND INFORMED PHARMACY PT DEVELOPPED SEIZURE AND DIFFICULTY BREATHING THE EVENING OF HIS FIRST COVID VACCINATION. PT IS NOW BETTER STAYED AT HOME
1169201	4/5/2021	TX	69	F	3/25/2021	3/25/2021	Patient having seizure like activity was not postictal between events, Patient bit tongue, hit head pt was alert between but unable to communicate effectively .

<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>
1167680	4/5/2021	NC	49	F	4/3/2021	4/3/2021	Within a few minutes of receiving the shot I passed out and possibly had a seizure and threw up.
1170224	4/5/2021	NY	36	F	4/5/2021	4/5/2021	A few minutes after vaccination the pt had what appeared to be a seizure with momentary loss of consciousness. Profuse sweating, tunnel vision and syncope also present. EMS was called and patient was transported to hospital directly from the pharmacy.
1170184	4/5/2021	AL	61	M	4/3/2021	4/4/2021	Pfizer BioNTech COVID-19 Vaccine EUA Patient experienced a seizure 9 hours after receiving his first dose of COVID-19 Pfizer vaccine. Patient has a history of seizures but has been well controlled with levetiracetam and has been seizure free for several years. Patient's wife called the pharmacy to report the event 6 hours later, and the pharmacist recommended the patient to follow up with primary care physician as soon as possible. Patient was evaluated by his physician and had dosage of levetiracetam increased. Patient was referred for further testing.
1170150	4/5/2021	OH	17	F	4/5/2021	4/5/2021	Pt had reaction in the waiting room. Pt became pale, diaphoretic, passed out and had brief seizure x 3-5 seconds. She suddenly became aware again with no recollection of what happened. She continued to be pale and diaphoretic and c/o confusion and blurry vision. Pulse ox 98-100, HR dropped to 40's and BP 90/60. Squad was called, they assumed care and transported pt to ER with her mother present.
1170091	4/5/2021	WA	50	M	3/24/2021	3/24/2021	Patient received first Johnson and Johnson, 2 minutes into a 30 min observation, patient began to have seizure like activity. Patient's eyes rolled back and he started to quickly shake for about 1 minute. Patient came to and was responsive. Provider arrived, vitals and physical exam were within normal limits. Patient was recommended to schedule an appointment with PCP and ask for a referral to Neurology, since patient had seizure like activity with a Tdap a few years ago.
1170062	4/5/2021	IA	24	M	4/5/2021	4/5/2021	Had fainted for few seconds. Started to have seizures. Gave Epipen autoinjector. Called 911. EMS arrived.

<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>
1170021	4/5/2021	NH	54	F	4/5/2021	4/5/2021	VR appeared to pass out, stiffened up and had seizure like activity, VR was sweaty and pale. Vitals were taken, pt presented hypotensive. VR regained consciousness. A&Ox4. Ambulance called and transported pt to hospital for further evaluation.
1169987	4/5/2021	FL	25	M	4/5/2021	4/5/2021	Patient became unconscious and fell out of his chair about 5 minutes after receiving his first Moderna vaccine. He came too but loss conscious two more times. He was clenching his arms and fist like someone having a seizure. When he came too he was not aware of what happened but he knew his name. Blood pressure was taken several times and each time was low. 911 was called and paramedics arrived about 15 minutes after he first loss consciousness. Paramedics took blood pressure and started IV fluids and took patient to hospital.

<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>
1169938	4/5/2021		58	F	3/27/2021	3/30/2021	Monday, April 5, 2021 Thank you for this opportunity to share my experience. Healthy, no underlying conditions, active, On Saturday, March 27th at around noon, I had my 2nd Pfizer vaccine, administered in my right arm at the The injection was painless, I had zero symptoms initially following the injection and none the rest of that day. On Sunday, upon waking, my arm was uncomfortable but not painful. No symptoms on Sunday. On Monday, upon waking, my arm was more uncomfortable, I felt a little off; minor headache, minor light headed feeling, so I took 2 Tylenol. On Tuesday, upon waking, my arm was very painful at the injection site. It was difficult to raise my arm above my shoulder. I did not take any Tylenol although I still felt a little off. I massaged the injection site. We have a brand new 2021 hot tub that we use daily so I got in and positioned my right arm injection site on a bubbly jet to massage the area. It helped alleviate the severe pain and muscle stiffness. I had an English muffin, 1 poached egg and banana, I showered, got dressed and my husband and I went to the bank and to store. While in store, around 12:30 ? 1:00 PM, I began to feel light headed, very hot; not a fever hot, just very temperature hot. I told my husband I needed to leave NOW. He got me a cold water and we left. Upon arriving home ? say 20 minutes later, I was very light headed and nauseous. I went directly to bed to lie down. By 2:00 PM, my nausea was extreme as I laid in bed. I knew I would feel better if I could throw up, but I also knew I would have to make my self do it because it wasn?t happening on it?s own. I went to the bathroom and began to put my finger near my mouth and that?s all it took and I violently vomited 3 times. The vomit was liquidy, and old blood red. Remember, for breakfast I had had a dry English muffin, poached egg and banana. NOTHING red! I screamed for my husband who came in and was shocked to see the color and volume of vomit. He helped to clean me up and help me back to bed, where I immediately returned to the bathroom with severe diarrhea?the same old blood red color. Again, he helped to clean me up and help me to lie down. He got me cool water which I sipped. Within an hour, I rushed back to the bathroom and VIOLENTLY threw up again. Severe convulsions, unable to breath in between each convulsion. Old blood red, liquid, and to make matters even worse, the same color liquidy

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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diarrhea. This went on for another 20 minutes. My husband was with me the entire time as the extreme convulsions contorted me and I could not keep aim to the toilet. I thought I had internal bleeding and was dying! I have never been this sick!!! Again, he cleaned me up, helped me back to bed where I was exhausted. He encouraged me to sip cool water which I did. On Wednesday morning upon waking, I was less nauseous. My husband urged me to try a dry English muffin (my normal morning routine). I was able to eat a few bites and keep them down. I showered to clean myself up and that did me in. I made it to the couch for the day. Sipping water and trying to complete the dry English muffin. On Wednesday I did not have a bowel movement. On Thursday morning upon waking, I was less nauseous and was able to drink a cup of tea and finish a dry English muffin. On Thursday I did not have a bowel movement. On Friday morning upon waking, I was not nauseous. I was able to drink a cup of tea and finish a dry English muffin and 1 poached egg. On Friday I did not have a bowel movement. On Saturday, now 1 week following the injection, I was better. Able to shower, able to eat, able to get out of the house. I had a small bowel movement that was the same dark color but somewhat in tact. On Sunday, Easter, I felt really good. Ate breakfast, lunch and dinner. Had a better bowel movement; not dark but ?my? normal color and condition. My theory (and I am not a scientist or medical person in ANY way!!!). When my arm was SO painful at the injection site and I got in the hot tub and placed my arm on a bubbly jet, it?s like I released the full burst of vaccine ? like a bolus ? into my system, rather than letting the muscle spasm release allowing the vaccine to gently circulate through my body. In July and I can assure you that in my all of my years of owning this body, I have NEVER experienced any flu or sickness with this severe or this violent convulsing vomiting and NEVER experienced the color of the contents!!!! My husband, with no underlying conditions, has also had both of his shots. He had no side effects. Yeah!! Since this experience, I have not been able to drink coffee or wine, of which both were a regular part of my diet. Now on a lighter note, less coffee and wine isn?t a bad thing, however since this episode I cannot fathom the thought of either of those entering my system. Thank you again for this opportunity

<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>
							to share my experience. I am glad to have both shots and I hope I am NEVER this sick again!!!!
1169930	4/5/2021	NJ	61	M	3/17/2021	3/19/2021	While sleeping had heart attack, seizure, went into cardiac arrest. No warning signs and did not have a previous heart condition. CPR was performed, shocked four times at home once in ER and placed on a ventilator. Catheterization procedure performed, full blockage of the right coronary artery received two stents. After surgery was in ICU on a ventilator for three days then went to step down unit for two days. Now being treated by cardiologist, pulmonologist, neurologist and primary care physician.
1169730	4/5/2021	AL	54	F	4/5/2021	4/5/2021	Patient medical history: Seizures, Hypertension, Cancer Allergies: None Patient received her Moderna Vaccine at 9:30 a.m. 9:45 a.m. pt complained of dizziness and metallic taste. Pt instructed to lie down and elevate feet. VS: B/P 160/88 HR: 69 O2 sat: 97% room air (Lying) Pt has no complaints of shortness of breath, rash or difficulty breathing 9:50 a.m. Pt states dizziness is better. 9:55 a.m. Pt sat up on the side of the bed. PT states no dizziness. VS: B/P 150/88 HR: 65 O2 sat: 97% (room air) 10:00 a.m. Pt stood up to side of bed and complained dizziness had returned. Pt instructed to lie back and elevate feet again. Dizziness subsided when laying down and sitting on side of the bed. 10:05 Orthostatic Blood Pressure taken: VS: Lying - B/P 160/90 HR: 65 O2 sat: 98% Sitting - B/P 160/90 HR: 66 O2 sat: 98% Standing - B/P 150/80 HR: 64 O2 sat: 98% 10:10 Patient still complaining of dizziness upon standing. EMS notified for evaluation. 10:15 EMS arrived. Pt states dizziness improving when standing. EMS evaluating. 10:25 Pt signed refusal to transport with EMS and stated dizziness had stopped. Pt husband at bedside. Pt ambulated to vehicle with no further complaints. 4:45 p.m. Called to follow-up with patient. No answer. Left a message to return my call. Will continue to attempt follow-up with patient.
1169692	4/5/2021	CO	28	M	4/5/2021	4/5/2021	Dizziness, Seizure pt was giving some water and elevated feet.

<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>
1169409	4/5/2021	OH	22	M	4/1/2021	4/1/2021	Patient became dizzy and in and out of consciousness. Patient was then taken to a private room where he had a 10 second seizure with no reported hx of epilepsy or other medical conditions (according to the patient) Needed EMS transport off site. This occurred at a mass vaccination site and patient was transported off facility grounds. Resolved at clinic level, not monetary reimbursement.
1168366	4/5/2021	IA	22	M	4/1/2021	4/3/2021	Pfizer-BioNTech COVID-19 vaccine EUA Seizure
1168656	4/5/2021	MA	60	F	3/27/2021	3/27/2021	Pt got a pfizer COVID vaccine on Saturday 3/27 States that she was out in the sun over an hour to get a vaccine and then waited another 40 mins inside a warm building before she got her vaccine States that she had nothing to drink and barely anything to eat and prior to her appt she had been doing yard work States that about 10 mins after she got her vaccine she blacked out, clinic staff noted seizure like activity which resolved prior to EMS arrival. States that this is not the first time she was outside in the sun without water and she passed out before States that the vaccine site thought that this was a reaction to her getting the vaccine but she thinks it was due to her being in the sun for over an hour waiting to get the vaccine States that she has never had any reaction to any vaccines before States that the vaccine site informed her to call her PCP to inform them of what happened States that once she got a few sips of water she felt normal again. Was refereed to PCP who felt most likely related to orthostasis and cleared patient to receive dose # 2.
1167676	4/5/2021	TX	22	M	4/1/2021	4/1/2021	I got the injection then went and sat down in a chair at the back of the room and started getting light-headed about 3 minutes after I sat down, so I called a nurse over. Then the inside of my chest started getting really hot and my vision started going white in both of my eyes, it took about 10 seconds for me to completely lose vision. Then I passed out, I have no idea how long I was out for but when I came too I had a sort of epileptic-type seizure but I do not know how long it lasted. I woke up completely disoriented, had no idea where I was at and had a severe cognitive dysfunction. I still have moments where I just can't follow or complete a thought or just kind of go blank.

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1167948	4/5/2021	FL	61	F	4/5/2021	4/5/2021	Approximately 10 minutes after administration, patient stated her chest felt heavy and she was feeling sweaty/hot. Approximately 5 minutes later, patient went into a absence seizure for roughly 5 minutes.
1167956	4/5/2021	KY	65	M	4/3/2021	4/5/2021	The patient is a 65 yr/o male with a history of Afib on Xarelto and HTN presents via EMS for evaluation of AMS that was noted by wife this am. The wife states as soon as the pt woke up he was altered mainly acting confused and not speaking normally. She also states that his side of the bed was wet this am but is unsure if it was sweat or urine. LKW 2200 last night before the pt went to bed. Upon EMS arrival the pt was sitting on the floor, playing with a toilet brush, and speaking non-sense. While en route to the ED the pt reportedly had convulsive seizure like activity and was non-responsive 15-20min following the activity. He is now awake but not verbally responsive and still acting confused. No hx of seizures per wife. Hx otherwise limited as pt is non-verbal at this time
1167971	4/5/2021	PA	56	F	3/26/2021	3/27/2021	Started with high fever on Sat (101), extreme weakness on Sunday, Monday and Tuesday. Went back to work on Wednesday, still not feeling but felt I should be trying to do something by then. Drove to work (35 min from my home), parked my car and that is the last thing I recall for approx 2 hours. Had grand mal seizure 1 hour later that lasted 2-3 minutes. Also found to have UTI that had no symptoms of as well severe in nature.
1168252	4/5/2021	NY	46	M	4/2/2021	4/2/2021	PT became dizzy and had a seizure like response with LOC and tonic/clonic activity only lasting 2-3 seconds. PT spontaneously woke up and was mildly confused. BP 143/93 other vitals stable

<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>
1169376	4/5/2021	NJ	71	M	4/5/2021	4/5/2021	client is the doorman at the apartments (building where a number of seniors reside). The Health Department was holding a COVID-19 vaccine clinic in the building. Client received his #2 Moderna vaccine about 10 :15 am, was observed x 15 mins, no reported side effects. the client was back at his desk in the area of the clinic, either sitting or standing in the area. Almost an hour after receiving the vaccine, the client was standing but fell to the floor, hit his head and began having a grand mal seizure. We turned him on his side, he was unresponsive and in a seizure x 5 mins, 911 was called and responded. The superintendent of the building said the client had a seizure disorder. Another co worker reported the client had had seizures at the building on 3 other occasions. We do not know what medication the client had taken that day. Client was in a postictal state and was transported by paramedics to the hospital.
1168464	4/5/2021	NC	52	F	4/5/2021	4/5/2021	PATIENT HAS A HISTORY OF SEIZURES AND WAS GETTING VACCINE AT THE RECOMMENDATION OF HER PROVIDER. SHE STARTED SEIZING AT 12:25PM, AND HAD RECEIVED VACCINE AT 12:03PM. SHE LEFT THE STORE WITH THE PARAMEDICS
1169268	4/5/2021	OH	55	F	4/3/2021	4/3/2021	4-3-21 APROX 11:15AM PT SHAKING, VERY ANXIOUS WITH REDNESS AND ITCHING ALL OVER - PT PLACED IN WHEELCHAIR AND TAKEN TO MEDIC TENT PER, RN. PT STATES SHE HAD A RASH LAST TIME SO SHE TOOK BENADRYL AT 6:30AM AND 10:30AM TODAY (PT TOOK 2 MORE OF HER OWN BENADRYL AT 11:15AM). RAPID BREATHING, 'BAD HEADACHE'. SQUAD CALLED FOR TRANSPORT. PT W/D. HUSBAND AT HER SIDE. COMFORT GIVEN. 11:27AM TO ER PER SQUAD, HUSBAND TO FOLLOW IN AUTO. 4-5-21 11:23AM TC: PT STATES SHE HAD A 'GRAND MAL SEIZURE IN THE SQUAD'. THEY TOLD HER SHE HAD LACTIC ACIDOSIS, ELEVATED POTASSIUM AND WAS DEHYDRATED. 'CT WAS NEG.' STATES HIVES/RASH IS GONE TODAY.
1168696	4/5/2021	IL	18	F	4/5/2021	4/5/2021	Had seizure activity post vaccine. Transported via ambulance to Hospital

<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>
1168846	4/5/2021	NY		F			MMR Vaccine gave me bad reaction.; This spontaneous report was received from a health professional via other company, referring to a 58-year-old female patient. The patient's concurrent conditions, medical history and concomitant therapies were not reported. On unknown dates, the patient was vaccinated with measles, mumps, and rubella (wistar ra 27-3) virus vaccine, live (M-M-R II) (strength, dose, frequency, route of administration, anatomical location, lot # and expiration date were not reported) as prophylaxis; with influenza virus vaccine (unspecified), and with tuberculin purified protein derivative (reported as PPD) vaccine (strengths, doses, frequencies, routes of administration, anatomical locations, lot # and expiration dates were not reported) as prophylaxis. On an unspecified date, the measles, mumps, and rubella (wistar ra 27-3) virus vaccine, live (M-M-R II) gave her a bad reaction (vaccination complication). The tuberculin purified protein derivative (PPD) vaccine caused her a skin reaction of 40 millimeters "very huge"; and the influenza virus vaccine (unspecified) gave her "Malesia" syndrome and she lost 16 pounds. At the reporting time, the outcome of vaccination complication was not provided. On unspecified dates between 2020 or 2021, the patient was vaccinated with the first dose of SARS-CoV-2 spike protein mRNA vaccine (reported as PFIZER-BIONTECH COVID-19 VACCINE). On 04-MAR-2021, the patient had severe side effects of vaccine including seizure disorder and right arm swelling. Her husband brought her to the hospital, and she was admitted. After that, she was very scary, very wild and screaming, her memory was gone. On an unspecified date (reported as today), the patient was scheduled for second dose of the vaccine, but she was scared to go, as it affected her mental status. The causal relationship between vaccination complication and measles, mumps, and rubella (wistar ra 27-3) virus vaccine, live (M-M-R II) was related.

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1169005	4/5/2021	OH	63	F	3/9/2021	3/9/2021	went into seizure; felt a metallic taste; felt dizzy; nearly fainted; not able to walk; had chest tightness; did not feel like she could breathe; did not feel well; her face was flushed like she was on fire; A Spontaneous report was received from a physcian concerning a 63 Year old Female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced Dysgeusia/Felt like metallic taste, Dizziness/Dizzy, Presyncope/ Near fainting, Gait Disturbance /Walking difficulty, Chest discomfort/ Chest tightness, Dyspnoea/ Breathing difficult, Malaise/ Feeling unwell, Seizure, Blood pressure abnormal, Blood sugar abnormal and Flushing. The patient's medical history included Asthma. 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 9 Mar 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: unknown) via intramuscular route and unknown location for prophylaxis of COVID-19 infection. had chest tightness and she is an asthma patient. She did not feel like she could breathe and did not feel well. She went back to the pharmacy and they did not want to give her EpiPen. She went into seizure because she already had seizure disorder. Her blood pressure went to 162/80 and her blood sugar went to 152 when she was on her way to the hospital and her face was flushed like she was on fire. She took Zofran during her 5 hours of hospitalization and got a CT scan. They diagnosed her with a post vaccination reaction but she still wants to get the second dose. Action taken with mRNA-1273 in response to the events was not reported. The outcome for the event Dysgeusia, Dizziness, Presyncope, Walking difficulty, Chest discomforts, Dyspnoea, Malaise, Seizure, Blood pressure abnormal, Blood sugar abnormal and Flushing was considered unknown.; 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 events, and excluding other etiologies but for history of asthma, 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>
1169180	4/5/2021	IL	26	M	4/5/2021	4/5/2021	About 5 minutes after administering vaccine I found patient sitting in chair experiencing a seizure and was unresponsive for a couple of minutes. Patient was pale and had profuse sweating. After a couple of minutes patient was able to speak and was coherent. We called paramedics and they checked hi out in ambulance. Patient was released and was ok
1169184	4/5/2021	LA	22	M	4/5/2021	4/5/2021	Patient had fallen out of chair approximately 5 minutes after being vaccinated and showed signs of having seizure (jerking motions) for approximately 30 seconds. We rolled patient on his side while he was having seizure and rolled him onto his back when he stopped seizing. Patient regained consciousness and was profusely sweating. Fire department showed up to take over. They had questioned patient on his medication history and whether he had a history of seizures. Approximately 15 minutes from then, the paramedics arrived and performed vital check on patient and deemed patient unwell to leave on his own accord. Patient was then transmitted to hospital.
1167438	4/5/2021	UT	40	F	4/3/2021	4/3/2021	5 minutes after receiving COVID vaccine, the patient reportedly had a seizure like event. Patient was monitored and rapid response was called. The patient was transferred to the ED where VS monitoring, EKG (normal sinus), and labs were collected. blood glucose was elevated, patient received fluids. Patient's glucose appropriately decreased following crystalloid administration the patient was feeling improved and no labs were of concern. Patient was discharged from the ED.
1168430	4/5/2021	MO	38	M	4/5/2021	4/5/2021	Patient slumped in chair, very faint, pale, sweaty, light headed and clammy. Looked like having a seizure (but wasn't) with arms up. Gave Epi-pen and called 911. EMTs came and evaluated patient and he left about 30 to 45 minutes later ok. Patient appeared to have recovered from adverse reaction, will check on patient 4/6/21
1167496	4/5/2021	SC	47	M	4/4/2021	4/4/2021	Systemic: Flushed / Sweating-Medium, Systemic: Seizure-Mild, Systemic: Shakiness-Mild

<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>
1167015	4/4/2021	NC	30	M	4/4/2021	4/4/2021	Patient given 0.5ml dose of covid-19 vaccine by Janssen. Patient stated was scared of needles. He immediately stated he thought he was going to pass out. Patient passed for approximately 30 seconds and jerked/like a seizure then came back but still felt dizzy, passed out again and jerked came back but still felt bad, Patient stated he did not feel right was not wanted to lie down on floor. 911 was called made patient comfortable until EMT's arrived and patient was taken to ambulance and released.

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1165584	4/4/2021	AZ		F	2/26/2021	2/26/2021	<p>Blood pressure dropped down to 85; Patient could not get out of bed; Slept on and off; Temperature of 100.4 °F; More than a shivering, like having convulsions; cold; Shaking; Left arm was a little bit tender; A spontaneous case was reported by a consumer concerning an 83-year-old female patient who experienced More than a shivering, like having convulsions, feeling cold/chilliness, shaking, Left arm was a little bit tender, blood pressure dropped down to 85, patient could not get out of bed, slept on and off) and temperature of 100.4 °F. The patient's past medical history was not provided. Concomitant medications included blood thinners (unspecified). On 26-Feb-2021, prior to the onset of the events, 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. On 26-Feb-2021, the patient experienced SEIZURE (More than a shivering, like having convulsions), NASOPHARYNGITIS (Cold), TREMOR (Shaking) and TENDERNESS (Left arm was a little bit tender). On an unknown date, the patient experienced BLOOD PRESSURE DECREASED (Blood pressure dropped down to 85), BEDRIDDEN (Patient could not get out of bed), SLEEP DISORDER (Slept on and off) and PYREXIA (Temperature of 100.4 °F). Treatment information was not provided for these events. The action taken with mRNA-1273 in response to these events was unknown. On 26-Feb-2021, SEIZURE (More than a shivering, like having convulsions), NASOPHARYNGITIS (Cold) and TREMOR (Shaking) outcome was unknown. On 28-Feb-2021, TENDERNESS (Left arm was a little bit tender) outcome was unknown. At the time of the report, BLOOD PRESSURE DECREASED (Blood pressure dropped down to 85), BEDRIDDEN (Patient could not get out of bed), SLEEP DISORDER (Slept on and off) and PYREXIA (Temperature of 100.4 °F) outcome was unknown. The patient consented for safety follow-up.; Reporter's Comments: Based on the current available information which includes a temporal association between the use of the product and the start date of the reported event, and excluding any other etiology, a causal relationship with the event cannot be excluded</p>

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1165586	4/4/2021	NJ		F	2/10/2021	3/1/2021	disorientation; couldn't properly respond/was speaking gibberish; weakness; cough; now she's dealing with fluctuating fever/running a slight temperature; Chills; was physically shaking, like a convulsion; doesn't feel she's completely okay; A spontaneous report was received from a consumer, who was the husband of a 72-year-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced extreme chills, was physically shaking, like a convulsion (seizure), disorientation, couldn't properly respond/was speaking gibberish (disorganized speech), weakness (asthenia), fluctuating fever/running a slight temperature (pyrexia), cough, and doesn't feel she's completely okay (malaise). The patient's medical history was not provided by the reporter. Concomitant medications included acyclovir. On 12 MAR 2021, the patient received their second of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On the same day, the patient had extreme chills and was physically shaking, like a convulsion where her husband had to hold her up. On 12 Mar 2021, she experienced disorientation, she couldn't properly respond/was speaking gibberish, and had weakness. The husband called 911 and a stroke was ruled out. At the time of the report, the patient was dealing with a fluctuating fever/was running a slight temperature and a cough. The husband didn't feel she was completely ok. Treatment for the events included Gatorade and paracetamol. The reporter considered the events of disorientation and couldn't properly respond/was speaking gibberish to be disabling. Action taken with mRNA-1273 in response to the events was unknown except for stroke it was resolved. The outcome of the events of chills, was physically shaking, like a convulsion, disorientation, couldn't properly respond/was speaking gibberish, and weakness were unknown. The events of fluctuating fever/running a slight temperature, cough, and doesn't feel she's completely okay were considered not resolved at the time of this report.

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1165927	4/4/2021	CA	32	M	4/3/2021	4/3/2021	Systemic: Flushed / Sweating-Severe, Systemic: Hypotension-Severe, Systemic: Seizure-Severe, Additional Details: Patient expressed that he didn't like needles. Patient stated that he has gotten flu shots in the past. Immediately after administering the vaccine, patient stopped responding, his eyes bulged, and his arms tensed and both arms went up to his chest. I was calling his name and asking if he was doing okay, he kept staring straight ahead and wasn't responding. Patient eventually came to after a minute. Measured blood pressure twice &, average ~90/55. Offered patient ambulance, patient declined.
1166581	4/4/2021	CA	30	F	4/4/2021	4/4/2021	9:45 patient received vaccine, at 9:52 she announced to EMT she was having a "panic attack". Patient lost consciousness briefly, and convulsed for about 1-2 seconds. Patient woke up quickly, 911 was called to evaluate. BP 98/80 at 9:52. 9:58 911 medics arrived, all vitals were within normal limits, patient declined transport. Patient was monitored for another 30 minutes and was able to walk to her car on her own with steady gait .
1166968	4/4/2021	PA	36	F	4/3/2021	4/3/2021	Nausea, fever, chills, body aches, convulsions, fatigue, difficulty sleeping, arm pain, headache
1166612	4/4/2021	TX	39	M	3/30/2021	3/30/2021	Felt like had the flu, second day after shot had extreme chills where full body tensed up and thought i was going to have a seizure, i am now left with trouble with breathing hard to take full breath, a swollen lungs, on the 5th day since shot still really fatigue
1163829	4/3/2021	CA	62	F	3/31/2021	4/1/2021	Had a seizure the morning after receiving her 1st dose of the Moderna Vaccine. 911 was contacted and she was hospitalized at a local hospital.

<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>
1163279	4/3/2021	NJ	26	F	4/2/2021	4/2/2021	Systemic: Fainting / Unresponsive-Severe, Additional Details: Before vaccination, patient briefed pharmacist regarding very probable likelihood of fainting. Per patient's own account, this event occurs very frequently when receiving vaccines. Pharmacist understood and with consent of patient continued vaccination. Within a minute after administration patient did pass out into catatonic state, followed by epileptic-like convulsions. RPh provided physical support with patient as she was convulsing out of chair and onto floor. Convulsions ended within 2 minute
1163261	4/3/2021	IL	27	M	4/2/2021	4/2/2021	Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Headache-Medium, Systemic: Seizure-Medium, Systemic: Shakiness-Medium, Additional Details: unconscious for less than a minute.Has a history of fainting from many years ago but no incidents since.Epi pen given 4:10p and 911 called. Paramedics arrived ~4:18p.Bp was 110/80 @4:13p, 128/88 @ 4:18p, 132/86 (pulse 70) @4:21p.Was clammy, shaky, sweaty,and had a headache post.Paramedics monitored sitting and standing.Advised to followup with physician.
1163221	4/3/2021	OH	17	M	3/29/2021	3/31/2021	At 9:15 am on 3/31/21, patient experienced a seizure characterized by unconsciousness and full-body rigidity. He had never previously experienced a seizure. The episode lasted for approximately 5-8 minutes; the patient gradually regained consciousness, but was confused and complained of a headache, eye pain, and nausea for some time afterward. He does not remember the event or what preceded it. He visited the ER that morning. He received an injection of lorazepam and ondansetron. He was held for observation for about 4 hours. He was prescribed a 3 day supply of lorazepam 0.5 mg (taken every 12 hours) upon discharge.

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1163498	4/3/2021	MN	21	F	3/25/2021	3/26/2021	Patient was at her day treatment program and had a two and a half minute seizure while sitting at a table. She bit her tongue during the seizure. She slowly came out of the seizure and was out of it for a while and confused. 911 was called due to the length of the seizure and a lack of seizure history. Seizure was two minutes; thirty seconds long about 21 hours after 1st Moderna Covid vaccine.
1163648	4/3/2021	TX	66	F	3/31/2021	3/31/2021	body aches, Severe headache, sore throat, ear ache, was awoken in the night with what seemed like a convulsion, severe shakes, all my joints hurt so bad I couldn't walk, hard time breathing. 2 days later i still feel fatigue and have a headache
1164374	4/3/2021	TX	26	F	4/3/2021	4/3/2021	Patient was administered vaccine around 1PM and was being observed as required after the dose. At around 1:05PM the patient began to convulse (which lasted about 15 seconds) I immediately had my technician call 911 as I tended to the patient. She was in and out of consciousness, as I grabbed our emergency kit to bring out she became conscious. She stated she was ok, but I still insisted on waiting for an ambulance and her husband agreed. I spoke more with her husband to see if the patient had any type of seizure condition and he said she did not. By that time the patient was able to drink water and seemed to stabilize. The EMS personnel arrived around 1:20PM and took over after that.
1163814	4/3/2021	IN	40	M	4/1/2021	4/1/2021	Time-line: - Started with achiness in both legs - Chills onset about 30 minutes after achiness - Chills briefly (1-2 minutes) were so severe I was shaking (convulsion like), only time this happened - Chills persisted for over 2 hours, covered up and took a nap - Upon waking, entire body had a hot/searing sensation (under skin), but no elevation in temperature - Eyes were extremely dry - Body aches continued into the next morning, hot/searing sensation had stopped - Was fairly fatigued the entire next day, dry eye issue persisted - After more rest than normal, I seem to be back to normal, no body aches, fatigue, or dry eye issues.

<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>
1164300	4/3/2021	TX	24	M	4/3/2021	4/3/2021	Earlier today, a Moderna patient at 3213 experienced a 15-30 second seizure after receiving his 1st Moderna vaccine. Shortly after sitting down for his 15-minute post immunization observation period, patient X began seizing resulting in him falling to the ground from a seated position to his left side and seizing for about 15-20 seconds. Patient was positioned in a left lateral recumbent position. Code white was called and EMT arrived on site within 10 minutes. Patient's immunization questionnaire did NOT have any contraindications that would warrant he should not receive the vaccine. Patient reported no allergies to medications/past immunizations/foods and reported no seizure and/or neurological condition. Once recovered and at baseline, patient reported having a light breakfast this morning and also having a needle phobia that may have played a role in his adverse response. Shortly after recovering, patient was coherent and aware of person, place, and time. He remained weak and fatigue and BP readings from EMT indicated hypotension. EKG was normal. Patient's mother happened to be waiting outside in the car. One of my associates was able to call her in and we updated here on the event. EMT recommended, and patient agreed, to be taken to the hospital for further examination.
1164976	4/3/2021	TX	36	F	3/30/2021	3/30/2021	Per EMT report, approximately 5 minutes after vaccination, client had seizure lasting approximately 3 minutes. Client is hearing impaired and has a history of epileptic seizures. Spouse reports last seizure event x3 weeks ago. Per EMT/Paramedic, airway was maintained. EMS was called, after seizure event, client was awake, respirations even and unlabored, skin warm and dry, client was incontinent of urine, no acute distress. Spouse answered EMS questions on behalf of client as client is deaf. Client refused transport to hospital, but was transported to vehicle without further incident.

<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>
1164890	4/3/2021	TX	22	M	4/3/2021	4/3/2021	* not sure directly related to vaccine but was to vaccination?? Pt did not disclose any seizure disorders and when asked if pt had had prior adverse events from vaccines it was stated that sometime he got nervous, nauseous and would vomit. immediately after injecting the vaccine the patient seemed fine, but was getting over excited having been given the vaccine (anxious) pt then went stiff and eye rolled back, I believe seizure. The father wasn't surprised and said that it has occurred before with other injections/ blood draws. pt recovered within a minute or two and was lucid and reported that he was fine. I monitored the patient for 30 minutes and recommended to the father that the patient be seen regarding the event, and that subsequent vaccinations be given at the doctors office.
1164718	4/3/2021	CA	37	M	3/30/2021	3/30/2021	Fear of needles, syncope. Seizure-like activity for 4 seconds. Alert. Patient states this has happened before.
1164653	4/3/2021	TX	45	M	4/3/2021	4/3/2021	Patient began having a seizure approximately 5-10 minutes after receiving the vaccination. Patient came to before epipen was given. EMS were called to the scene and continued care for patient.
1164647	4/3/2021	IN	22	F	4/3/2021	4/3/2021	Patient had absence seizure immediately following dose. Patient has history of seizure of this type and kind at this time of day (mom says has one every evening around this time).
1164612	4/3/2021	CA	77	M	2/19/2021	3/5/2021	Grand Mal Seizure, called 911, went to hospital, took mri and cat scan. Appointment with neurologist on going. Meds perscribed.
1165082	4/3/2021	OH	35	F	3/28/2021	3/31/2021	Hot sensations all over body, dizziness, light headed, shortness of breath, convulsions ? main episode lasted about 5 minutes. After that, continued light headedness and shaking. Tremors in extremities. Left chest pain/pinching sensations

<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>
1164560	4/3/2021	MA	36	F	3/31/2021	3/31/2021	Pt had syncopal episode; upon waking: BP 102/88, P 64, EKG unremarkable. Had a 2nd syncopal episode, about 12 seconds with right leg extended and arms jerking briefly. Then awoke fully alert without complaints of dyspnea headache, uricaria etc. 4:15 97/56, HR 66 PM 4:26 PM 111/71 Encouraged to go to ER due to possible seizure activity but signed consent refusing EMS care
1164523	4/3/2021	NY	46	F	3/8/2021	3/9/2021	temporal lobe seizure (focal impaired awareness seizure) Patient had one of her typical temporal lobe seizures. She had been seizure free on medication for years prior to this episode.
1164501	4/3/2021	NY	41	M	4/2/2021	4/3/2021	generalized tonic-clonic seizure
1160145	4/2/2021	IN	58	M	4/2/2021	4/2/2021	1st dose Pfizer administered at 0940 at clinic. patient experienced no reactions or symptoms during observation period at the clinic. Patient had been home for approximately 2 hours when he started experiencing some chest pain prior to his seizures around 1210. He does have a history of seizures which are uncontrolled ranging from having them twice a week to twice a month. patient reports the seizures were no worse than any other seizure he has had in the past. The seizures lasted periodically for approximately 20 minutes. patient reports he didn't consult with his PCP or neurologist prior to the vaccine. The patient was encouraged to seek medical treatment if symptoms persist or worsen over the next hours. He was also encouraged to reach out to his neurologists prior to the second dose.
1159214	4/2/2021	MD	24	M	3/10/2021	3/11/2021	3/11/21: patient presented and was admitted through ED for Shortness of Breath and choking on food. His saturation was as low as 70s and placed on nonrebreather. Patient was brought to ED and eventually required to be intubated because of hypoxic respiratory failure. During hospitalization patient has one episode of seizure. Patient had similar presentation in May 2019 and he had to be intubated for choking fluid. per the EUA, hospitalizations to be reported irrespective of attribution of vaccine.

<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>
1159281	4/2/2021	LA	16	F	3/30/2021	3/30/2021	Immediate intense headache. Feeling faint. Lay down on floor, semi conscious. Ems staff moved her to sitting position where she completed blacked out. They struggled to hold her, so they lay her on the floor where she had convulsions similar to a seizure. Completely unconscious at this point.
1159414	4/2/2021	KY	34	F	4/1/2021	4/1/2021	Pt rec'd Covid 19 vaccine. Reported to RN about 10 min post vaccine that she felt like she was "going to have a seizure". Pt has aunt accompanying patient and pt was A&Ox3. Pt reports hx of "pseudoseizures x 5 years". RN then noted pt eyes roll back in head. Pt unconscious and assisted to floor and turned on Left Side. Head protected by staff member. AED placed on patient. Seizure approx lasted about 1 min. Pt awoke and alert and arouseable to staff. Pt then began with another seizure lasting approx the same amount of time. Pt awoke non post ictal. She was alert & oriented. Refusing 911 call or go to ED as she reports "I've been checked out many times before, I do this". Bp 140/80's, HR stable and palpable. Pt then underwent 2 more seizures lasting approx same amt of time. 911 called at beginning of 2nd seizure. Upon arrival of EMS pt was still unarouseable and taken by EMS to ED. RN, BSN, CCM Nurse Navigator NMG
1159421	4/2/2021	MN	38	M	4/1/2021	4/1/2021	Patient became syncopal approximately 2 minutes after vaccine. Emergency services staff flagged down to assist patient. The event I am recording this from states patient had "seizure activity", but given the short duration and quick resolution, suspect this was muscular activity and not neurologic. Patient refused any sort of follow-up care afterwards.
1160330	4/2/2021	VA	27	M	3/20/2021	3/20/2021	Syncope possible seizure about 5 minutes after vaccine. Vitals stable. Refused transport to ED. Mother drove him home.

<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>
1160109	4/2/2021	CA	75	F	2/24/2021	2/25/2021	The day after the second vaccination, my wife's torso (back and shoulders) shook convulsively whenever she would relax her body before napping or sleeping. On the third day, I took her to the ER, where she was given a variety of blood tests and examined by the doctors on duty. They reported that everything teste out "normal" and released her in a few hours. Her neurologist, inidicated that the shaking would likely go away gradually and was not indicative of a seizure. He gave her an EEG, which tested out completely "normal.~~

<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>
1158683	4/2/2021	AZ	66	F	3/12/2021	3/1/2021	Had 2 seizures; Had 2 seizures; Tongue hurts; it was an allergic reaction; Patient reported that next the day her arm was so hot that she could have roasted a weenie over her arm and it was very swollen; Patient reported that next the day her arm was so hot; got shingles again after receiving the vaccination; got shingles again after receiving the vaccination; This is a spontaneous report from a contactable consumer (patient's husband). A 66-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot: EN6202), via an unspecified route of administration, administered in left arm on 12Mar2021 10:30 (at the age of 66-years-old) as single dose for covid-19 immunisation. The patient was not pregnant at the time of vaccination. The vaccination facility type was a health clinic. The vaccine was not administered at a facility. The patient had no additional administered vaccines. No prior vaccinations (within 4 weeks). Medical history included ongoing seizures from 1982 (began shortly after she had the surgery for her brain aneurysm (in 1982 to 1982). The patient had not had any seizure activity for 20 years before the seizures that occurred on 13Mar2021. Sometimes electrical activity in the brain hits the metal clamp used to treat the brain aneurysm and that triggers the seizures); migraines (suffered from migraines when she was younger but hasn't had one in umpteen years. The patient gets tension headaches like most people but not very often); shingles (patient had shingles three times. Patient's first case of shingles was in the early 1990's and that patient had recurrences in the mid 1990's and the early 2000's. The first incidence was the worst and that the second and third occurrences weren't nearly as bad as the first); blood pressure high; ongoing cholesterol; ongoing headache (tension headaches) and was adopted. Family history included migraines with grandkids, a couple of them had migraines and had MRI's she'd had a sister that was 6 years older than her that had died of a brain aneurysm. Concomitant medications included levetiracetam (KEPPRA) for seizures from an unspecified date (in the late 90's) to an unspecified date then from Mar2021 and ongoing; nadolol for headache from 2001 and ongoing; lovastatin for cholesterol from an unspecified date (been on it for a long time) and ongoing and on a low dose of medication for high blood. The patient had the Pfizer

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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vaccine first shot on Friday (12Mar2021). The husband stated his wife (patient) had a possible side effect to the vaccine shot and was concerned with getting the second dose of Pfizer's COVID vaccine. She had 2 seizures the next morning after the shot (on 13Mar2021) which she hasn't had in 20 years. The patient experienced her first seizure about 11:00 on 13Mar2021. It took the patient about 45 minutes to come out of the first one completely, until she was conscious again. The second seizure occurred about 13:00 on 13Mar2021, about an hour and a half after the patient recovered from the first seizure. After the second seizure, the fire department was called and she was transported to the Emergency Room. The doctor told the husband that it was up to them if they wanted to receive the second dose. The husband stated, "I know there is something out there that I heard about where you can disqualify yourself from getting the vaccine for medical reasons." Also on 13Mar2021, the patient's tongue hurts in the Emergency Room, no one was willing to give her a new tongue after she bit it. The patient's tongue was what hurt's the most, but that it was slowly healing. The patient seemed to be fine since Saturday. The patient's father was really persistent about them getting the Covid-19 vaccinations. A CT scan and blood work were performed while she was in the Emergency Room on 13Mar2021 and reported that everything was fine. The patient went to the emergency room on 13Mar2021 and physician office on 17Mar2021 as a result of the seizure activity on 13Mar2021. On 17Mar2021, the patient's blood pressure was 130/82 with blood work with result of everything was fine. The patient went to her physician on 17Mar2021 due to concern about getting the second dose of the Covid-19 vaccine. When asked about prior vaccinations within 4 weeks of the Covid-19 vaccine, the patient stated that she didn't want to get the first dose of the Covid-19 vaccine because she's never even had the flu shot. The patient stated that back in 1977 when they first came out with the flu shot, she was unable to receive the vaccine as she was pregnant and she has never gotten the flu. The patient reported that she was unable to get MRIs due to the metal clamp in her. Patient reported that the clamp in her head was metal, not surgical metal, and that she has to be very careful because getting an MRI could kill her. The patient reported that next the day (in Mar2021) her

<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>
							arm was so hot that she could have roasted a weenie over her arm and it was very swollen. The patient reported that she went to urgent care and was told that it was an allergic reaction. The patient also reported that she got shingles again after receiving the vaccination. The husband considered the case as non-serious. The patient recovered from seizure with associated disease recurrence on 13Mar2021; for tongue pain was recovering while for the remaining events was unknown.
1159449	4/2/2021	GA	88	M	3/30/2021		Patient had a syncopal episode previously thought it was a possible seizure. EEG and CT brain were negative. Pt became febrile on 04/01/2021 (101.9).
1162064	4/2/2021	GA	79	M	3/11/2021	3/13/2021	Seizure 2 days after shot. No history of seizures at all. Hospitalized for a week so far and still in there.; This is a spontaneous report from a contactable consumer (patient). A 79-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; unknown lot number and expiration), via an unspecified route of administration in right arm on 11Mar2021 at 13:00 as a single dose for COVID-19 immunisation. Medical history included chronic obstructive pulmonary disease (COPD), diabetes, and COVID-19 (if COVID prior vaccination: Yes). No known allergies. Concomitant medications included metformin; insulin lispro (HUMALOG); metoprolol; amlodipine; atorvastatin; vitamin D; and pioglitazone. The patient also received first dose of BNT162B2 on 18Feb2021 at 01:00 pm (at the age of 79 years old) for COVID-19 immunisation. On 13Mar2021 at 12:00am, the patient experienced seizure 2 days after shot. No history of seizures at all. Hospitalized for a week so far and still in there. Patient did not receive other vaccine in four weeks. The patient underwent lab tests and procedures which included COVID test: negative on 13Mar2021. The event resulted in emergency room/department or urgent care visit. The patient received treatment for the event. The patient had not yet recovered from the event. The event was assessed as serious (hospitalization). Information on the lot/batch number has been requested.
1160623	4/2/2021	GA	73	M	3/21/2021	3/29/2021	had headache, followed by seizures and confusion about 8 days later

<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>
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 >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>

<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>
							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.
1160785	4/2/2021	CA	20	F	4/2/2021	4/2/2021	Petite Mal Seizure- 20 seconds in length
1160876	4/2/2021	FL	48	M	4/2/2021	4/2/2021	Within 2 minutes of patient receiving shot his eyes started to cross and his hands formed a fist and he tensed up and brought them towards his chest. His head rolled back and his eyes started to rolled back. His wife was next to him and held his neck. the pharmacist administered an Epi-pen into his left thigh and 911 was called. He became conscious within seconds of receiving the Epi-pen. He was able to verbally communicate and was able to tell us his age. He was very thirsty & became very sweaty in the minutes after he came to. He said he's never had a severe reaction after vaccines, never gets the flu shot and doesn't have history of seizures. Paramedics came immediately and took him to the Hospital.
1161074	4/2/2021	CA	26	M	4/1/2021	4/1/2021	Patient got Shortness of breath, leg cramps, lost control on his body and seizures 2 hours after getting the vaccine and stayed for about 5 minutes. No medication or treatment was given. reported by his sister

<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>
1161937	4/2/2021	NV		F		3/1/2021	SEIZURE; FLU LIKE SYMPTOMS (CHILLS, HIGH TEMPERATURE, FEELS HOT,STUFFY NOSE); This spontaneous report received from a consumer concerned a 67 year old female. 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, batch number: Unk) dose was not reported, administered on MAR-2021 for prophylactic vaccination. Batch number was not reported has been requested No concomitant medications were reported. No concomitant medications were reported. On MAR-2021,On an unspecified date, the patient experienced seizure, shaking, chills, high temperature, feels hot, and stuffy nose. patient daughter report she was suffering from seizure symptoms include extremely stiff ,extreme dizziness, shaking, and eyes rolling in back of head, also reported her mother did not lost consciousness and has been coherent .Daughter stated symptoms seem almost like a stroke ,upon follow call she clarify about seizure which is subsided. seizure occurred 3 times over past 5 days prior to call (first night of vaccine, next morning, and reporting day.) Daughter also reported mother had flu-like symptoms for the first 3 days after vaccine, including chills, high temperature, feels hot, and stuffy nose, but these have resolved. Daughter reports mother has not had symptoms like these prior to vaccine. she also report pharmacist who gave vaccine is aware of symptoms. patient body temperature was high, patient not performed covid 19 test. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from flu-like symptoms (chills, high temperature, feels hot ,stuffy nose.), and the outcome of seizure was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: v0: 20210322863-Covid-19 Vaccine Ad26.Cov2.S-Seizure. 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.

<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>
1161942	4/2/2021	AR		M		3/9/2021	<p>RASH ON ARMS AND HANDS; EXTREME PAIN IN BOTH HANDS AND ARMS; SEIZURE; HEADACHE; This spontaneous report received from a consumer concerned a male of unspecified age. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included patient is not on any medication and has no known drug allergy. 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 09-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. patient got the Janssen Covid shot on March 9th Tuesday and then experienced headache started same day and Wednesday 10th march, took Tylenol and headache recovered, then seizure on 11th mar, went to the ER and spoke to the doctor on reporting day. consumer also started patient experiencing rash and extreme pain on both arms and hands on reporting day 12th mar and getting worse. On 09-MAR-2021, the subject experienced headache Treatment medications (dates unspecified) included: paracetamol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from seizure, and headache, and had not recovered from rash on arms and hands, and extreme pain in both hands and arms. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210325468 - Covid-19 Vaccine Ad26.Cov2.S - Seizure. 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>

<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>
1161948	4/2/2021	VA		M			SEIZURE; 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) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Company is unable to perform follow-up to confirm batch/lot number. No concomitant medications were reported. On an unspecified date, after administration of vaccine the patient started having a seizure and ended up going to hospital (date unspecified). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of seizure was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210333412 - JANSSEN COVID-19 VACCINE Ad26.CO2.S - Seizure. This event is considered Unassessable. The event has a compatible/suggestive temporal relationship, is unlabelled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the 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>
1161949	4/2/2021	MI	21	F	3/1/2021		SEIZURE/CONVULSION; LOW BLOOD PRESSURE; SORE ARM; FEVER; This spontaneous report received from a patient 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: UNKNOWN, expiry: UNKNOWN)) dose was not reported, administered on 16-MAR-2021 at 17:00 in the right deltoid for prophylactic vaccination. 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 20-MAR-2021, The caller called to report that her daughter developed some rare side effects. The patient reported that she got the shot on 16-MAR-2021 and went home and went to bed at 23:15 PM experienced convulsing/seizure, chills, shaking, low blood pressure, heart rate increased. The police came to take her to the Emergency room. The patient was hospitalized on 16-MAR-2021. On an unspecified date in MAR-2021, Laboratory data included: Body temperature (NR: not provided) 100.8 F. On 16-MAR-2021, Laboratory data included: Blood pressure (NR: not provided) 70/20 mmHg, 80/30 mmHg, and Heart rate (NR: not provided) 110 OR 115 BPM. The patient has no fever then was given an unspecified IV. At 06:00 On 17-MAR-2021, Laboratory data included: Blood pressure (NR: not provided) 98/38 mmHg, COVID-19 virus test (NR: not provided) NEGATIVE, CT scan (NR: not provided) NORMAL, Echocardiogram (NR: not provided) FINE, and Echocardiography (NR: not provided) FINE. Overall she took 6 Liters of IV fluid. The patient was discharged on 17-MAR-2021 at 14:00PM. The duration of hospitalization was two days. On 18-MAR-2021, Laboratory data included: Blood pressure (NR: not provided) 120/90 mmHg, and Heart rate (NR: not provided) 70 BPM. On an unspecified date, the patient experienced dizzy, lethargic, sore arm and fever. The patient gave permission to speak with her doctor who treated her there and was told to follow up with Primary Care Physician which she did on 18-MAR-2021. No medications were given at discharge. According to her, Blood pressure and Heart Rate was normal when she saw her Primary Care Physician. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The

<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>
1161969	4/2/2021	ME	94	F	3/23/2021		<p>patient recovered from shaking on 19-MAR-2021, low blood pressure and heart rate increased on 18-MAR-2021, was recovering from, chills and the outcome of, convulsing/seizure, dizzy, sore arm, lethargic and fever was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: 20210339790 - COVID-19 VACCINE AD26.COV2.S - Seizure, Blood Pressure Low. 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>SEIZURE; This spontaneous report received from a consumer concerned a 94 year old female. The patient's weight was 135 pounds, and height was 60 inches. The patient's past medical history included heart rate, oxalate and polysorbate sensitivity, and other pre-existing medical conditions included the patient had no known drug allergies. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular and batch number: 1805022 expiry: 25-MAY-2021) dose was not reported, administered on 15-MAR-2021 for prophylactic vaccination on the left arm. No concomitant medications were reported. On 23-MAR-2021, the patient experienced seizure, had to be taken by ambulance to hospital and was hospitalized for 5 days. She was in ICU for 3 days. On 26-MAR-2021, Laboratory data included: MRI (NR: not provided) MRI showed no damage Mitral Valve Regurgitation. The Patient was discharged on 27-Mar-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from seizure. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210400319- JANSSEN COVID-19 VACCINE Ad26.COV2. S- Seizure. 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>

<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>
1158840	4/2/2021	MA	37	M	3/31/2021	3/31/2021	Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Shakiness-Medium, Additional Details: the pt passed out 5 min after covid vaccine had possible seizure. ambulance was called at pt was given fluids by emts because of low pulse while sitting. pt was taken to er and his status 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>
1162029	4/2/2021	VA	57	M	3/25/2021	3/26/2021	<p>Did not sleep at all as he kept staring at the clock 2-3 times every hour; Feels bad now which was similar to the time when he had covid; Whole body was moving bad; Chills; Vomiting (" dry heaves" throwing up but nothing was coming out); Shaking was similar to having convulsions was hard; Very sick this morning; Sore injection site area; Shaking shaking so hard at 2am; 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 the events shaking was similar to having convulsions was hard, very sick this morning, chills, sore injection site area, vomiting (dry heaves throwing up but nothing was coming out), whole body was moving bad, shaking so hard at 2am, did not sleep at all as he kept staring at the clock 2-3 times every hour and feels bad now which was similar to the time when he had Covid-19. The patient's medical history included COVID-19. No relevant concomitant product use was reported. On 25 Mar 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: 048A21A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 26 Mar 2021, the patient experienced very sick, chills, injection site sore, vomiting (dry heaves throwing up, but nothing was coming out). On the same day, the patient was shaking so hard at 2 am and the shaking was similar to having convulsions. The patient also reported that, his body was moving bad. The patient went to bathroom and laid back down, but he was unable to sleep and kept staring at the clock 2-3 times every hour. The patient also reported that, he felt bad now and it was similar to the time when he had COVID-19. No treatment details were provided. Action taken with mRNA-1273 in response to the events was unknown. The outcome of the events very sick, chills, injection site sore, vomiting(dry heaves throwing up, but nothing was coming out), shaking so hard at 2 am, shaking was similar to convulsions, whole body was moving bad, did not sleep at al as he kept staring at the clock 2-3 times every hour and feels bad now which was similar to the time when he had 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. Very limited</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>
1159205	4/2/2021	IL	61	F	3/25/2021	3/25/2021	information regarding these events has been provided at this time. Further information has been requested Patient reported an episode which she is classifying as a "petit mal seizure." She says she had sweating, chills, pallor and tremors throughout the body but did not lose consciousness, it lasted about 30 minutes in total.

<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>
1162065	4/2/2021	OH	64	M	3/11/2021	3/11/2021	Kidney stone; Blood all over him; Falling down; Wobbliness; No energy; Could not sleep at all; Sweating like crazy; No appetite; This is a spontaneous report from a contactable consumer (patient). A 64-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), first dose (at the age of 64-years old) via an unspecified route of administration in the left arm (reported as injection in left shoulder) on 11Mar2021 at 13:00 (Batch/Lot number UNKNOWN) as a single dose for COVID-19 immunisation. Medical history included colitis ulcerative from 1982 and ongoing, ongoing seizure (he had seizures for about 6 years and they got worse, probably it has been 6 or 7 years he has had seizures), high blood pressure, heartburn and insomnia (comes and goes). Concomitant medication included atorvastatin (manufacturer unknown, Tablet) 40mg strength, oral administration, 20 mg daily (half a tablet at bedtime) taken for an unspecified indication from an unspecified start date and ongoing; cholecalciferol (manufacturer unknown, Tablets) oral administration, 2 tablets in morning taken for colitis ulcerative from an unspecified start date and ongoing; escitalopram (manufacturer unknown), oral administration, 20 mg once daily taken for seizure from an unspecified start date and ongoing; lacosamide (manufacturer unknown) oral administration, 200 mg twice daily taken for seizure from an unspecified start date (for approximately a couple of years) and ongoing; lisinopril (manufacturer unknown), oral administration, 20 mg daily taken for high blood pressure from an unspecified start date and ongoing; mesalazine (MESALAMINE, Tablet), oral administration, 4 tablets a day taken for colitis ulcerative from an unspecified start date and ongoing; omeprazole (manufacturer unknown) oral administration, 20 mg as needed (two or three pills daily as he feels like he needs) taken for heartburn and ulcerative colitis from 2001 (approximately 20 years ago) and ongoing and zonisamide (manufacturer unknown) oral administration, 100 mg twice a day taken for seizure from an unspecified start date (for a couple of years) and ongoing. The patient did not receive any other vaccines within 4 weeks prior to the COVID-19 vaccine. The patient received the vaccination on 11Mar2021. After he received his first dose of the vaccine he experienced a bunch of symptoms which he listed as sweating, he could not

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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sleep at all the first night, he was falling down, he had no appetite, and had no energy that same day. This occurred after the 15 minute window of waiting after getting the vaccination. On 11Mar2021, after the vaccination, the patient went to the store to buy groceries and started sweating like crazy. He could hardly carry the groceries to the car. He also had wobbliness. On 11Mar2021, the patient fell down and passed out coming home that night and he had blood all over him. He later clarified that he did not pass out, he got into the house and fell down and somehow landed on the recliner. He was covered in blood and all kinds of stuff. On 11Mar2021, he could not sleep at all that first night and his prescription Melatonin (Manufacturer Rugby) 3mg did not help at all. The falling down occurred roughly that same night on 11Mar2021. The patient stated that they told him they thought he was having seizures again but he was not. He had imaging which showed no seizures and Xray of his brain with unknown results in Mar2021. He had to have another Xray to make sure he did not have bleeding on the brain. Xray of his stomach showed kidney stones on 12Mar2021. The patient was not admitted to the hospital. The patient was scheduled to return for the second dose 01Apr2021. The patient inquired if he should get the second dose of the vaccine. The outcome of events kidney stone, blood all over him, could not sleep at all and wobbliness was unknown. The outcome of events sweating and falling down was recovered on 11Mar2021 and no appetite was recovered in Mar2021. The outcome of no energy was recovering. The lot number for the vaccine was not provided and will be requested during follow up.

<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>
1162096	4/2/2021	TX	48	F	3/16/2021	3/16/2021	Seizure that lasted about 10-15 minutes the next day; Headache; throwing up; arm tremors; not feeling well; sore arm; This is a spontaneous report from a patient. A 48-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 16Mar2021 09:30 at single dose for COVID-19 immunization. The patient's medical history included Epilepsy. The patient was not pregnant at time of vaccination. The patient's concomitant medications included oral levetiracetam (KEPPRA) for epilepsy at 4000 mg, daily, valproate semisodium (DEPAKOTE) for epilepsy at 500 mg, daily, and valproate semisodium (DIVALPROEX) for epilepsy at 500 mg. The patient stated that she got the vaccine on 16Mar2021. The patient had a seizure that lasted about 10-15 minutes the next day on 17Mar2021 at maybe 11pm-1130pm. The patient was out with someone and he took her back to her house and she wasn't feeling like, not normal, and he told her she needed to go to the hospital and it took her awhile as she doesn't realize she had a seizure and it sometimes takes a while to convince her she did. States sometimes with seizures you don't remember. The patient was advised to go to the ER to get checked out and he was really worried. States immediately after the seizure she threw up and was not feeling well at all. States she was not admitted to the hospital. States they did a Ct scan of her head and she had bit her tongue a little bit, which is normal with seizures. States she is improved but she still has the medical condition of epilepsy. The patient stated that after she drove home she noticed when she stretched her arm out she was still having tremors and these for lasted about an hour and then she went to sleep. Caller clarifies that after the hospital she went home and went to sleep. States she had been given Ativan at the hospital to ward off additional seizures and that makes you very tired. The patient also had headaches and still gets them, states they are getting less and less frequent. States the headaches started that same evening, that it was weird she had gone out to dinner and was talking with her friend and she thought I have a headache and he is normally fun and she was not feeling so good. Relays that she thought maybe it was a problem with the food

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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she ate, but states they ordered the same meal and she in confident it is not the food as he did not have any troubles. The patient hasn't had a seizure since age 14 and had she known the vaccine would likely cause one she would not have taken it. States she will not take the 2nd one. She said that this was ridiculous. States her arm was sore like from the flu shot or a little worse, but not a big deal. . States her main concern is the seizure. States she is a CPA and it is her busy season for tax returns and saying her arm being sore is eh maybe she wasn't waving it around as much as normal, she is like a praying mantis at her computer typing away. States the soreness started by the end of the work day or that afternoon. States it was no big deal and the next day she did work around the house and was using that arm more and then working from home that day thank God and it was St. Patrick's day and she went out to dinner. States she only noticed the arm soreness/sore arm 16Mar2021 and by the morning of 17Mar2021 she didn't notice it anymore. States she wasn't told she was at risk for a seizure and that would have been helpful as if she had known there was a chance of a seizure she would, like any medication, if there is a chance of seizures she doesn't take it. The outcome of the event Seizure was not recovered. The outcome of the event headache was recovering. The outcome of the event Pain in extremity was recovered on 16Mar2021. The outcome of the remaining events was unknown. Information about the lot/batch number 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>
1162105	4/2/2021	PA	27	F	3/11/2021	3/15/2021	<p>passed out; experienced seizure like activity; low fever; arm pain; fatigue; chills; feeling very weak and sick; feeling very weak and sick; This is a spontaneous report from a contactable consumer (patient). A 27-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration, administered in the left arm on 11Mar2021 at 15:45 (batch/lot number was not reported) as a single dose for COVID-19 immunisation. Medical history included asthma, Ehlers-Danlos syndrome, known allergies to red food dye and sulfa; all from unspecified dates. The patient was not pregnant at the time of vaccination. Concomitant medications included celecoxib (CELEXA), lorazepam (ATIVAN), VITAMIN D NOS (VITAMIN D), cyanocobalamin (VITAMIN B12), curcuma longa (TURMERIC); all taken for unspecified indications, start and stop date were not reported. The patient previously took gabapentin, escitalopram (LEXAPRO), and promethazine and experienced known allergies to all drugs. Facility type vaccine was pharmacy or drug store. No other vaccine in four weeks. It was unknown if the patient had Covid prior to vaccination. The patient was not Covid tested post vaccination. After receiving the first shot, the patient felt the expected side effects (low fever, arm pain, fatigue and chills) but they worsened over the next several days. After feeling very weak and sick all day, she passed out for approx 30+ minutes, she was alone but was found on the floor by her mother after she attempted to call her multiple times and she didn't respond. She experienced seizure like activity and was advised by her primary care doctor to go to the emergency room, and was seen there. Start date for the adverse events reported as 15Mar2021 at 16:00. The adverse events resulted in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. There was no treatment received for the events. The outcome of the events was recovering. Information on the lot/batch number has been 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>
1162129	4/2/2021	CO	27	M	3/19/2021	3/1/2021	<p>pain on the first day after the second vaccine dose was as bad as it was the first day after surgery; my atypical trigeminal neuralgia (had since 2009) was as bad as it has ever been; my atypical trigeminal neuralgia (had since 2009) was as bad as it has ever been; This is a spontaneous report from a contactable consumer (patient). A 27-year-old male patient received bnt162b2 (Pfizer/Bio-N-tech COVID vaccine), dose 2 via an unspecified route of administration, administered in left arm on 19Mar2021 13:15 (Batch/Lot Number: EN6203) as single dose for COVID-19 immunization. Medical history included major orthopedic knee surgery on 26Aug2020, atypical trigeminal neuralgia since 2009. The patient had pre-existing pain issues that also continued to be elevated on the 2nd and 3rd day after surgery but not nearly as bad as the first. The patient has known allergies to cephalosporins and elemental nickel. Other medical history: complex regional pain syndrome (CRPS), attention deficit hyperactivity disorder (ADD), anxiety, depression, asthma, epilepsy-prone, many more; rest will be provided if full list is needed. The patient was not diagnosed of COVID prior vaccination and has not been tested for COVID post vaccination. Concomitant medication included tapentadol, amphetamine and candesartan cilexetil, hydrochlorothiazide (CANDESARTAN HCTZ); all taken for an unspecified indication, start and stop date were not reported. The patient did not receive other vaccine in four weeks. The patient had the 1st dose of bnt162b2 (Pfizer/Bio-N-tech COVID vaccine), via an unspecified route of administration, administered in left arm on 26Feb2021 03:00 PM (Batch/Lot Number: EN6204) as single dose for COVID-19 immunization. The patient was tired after the first dose on days 2-3, and had a major seizure on day 8 of dose one despite nearly no history of seizures but that has been attributed to other issues by his doctor. The patient had a major orthopedic knee surgery on 26Aug2020 and his pain on the first day after the second vaccine dose (after getting the dose on 19Mar2021, going to bed, and waking up the next day) was as bad in Mar2021 as it was the first day after surgery, and his atypical trigeminal neuralgia (had since 2009) was as bad in Mar2021 as it has ever been. The patient mentioned he would advise and recommend for patients to speak to their doctors before the second dose to</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>
1162138	4/2/2021	MD	24	F	3/18/2021	3/22/2021	<p>obtain a few days of higher dose pain medication. The events resulted in: emergency room/department or urgent care and was considered serious due to life threatening illness (immediate risk of death from the event). No treatment given for events. Outcome of events recovered.</p> <p>nocturnal seizures; extreme fatigue; This is a spontaneous report from a contactable consumer (patient). A 24-years-old female patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in Arm Left on 18Mar2021 17:00 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. Medical history included Epilepsy (free for two years before the vaccine). No other vaccine in four weeks. Concomitant medications included zonisamide (ZONISAMIDE), sertraline hydrochloride (ZOLOFT), valproate semisodium (DEPAKOTE), ethinylestradiol, ferrous fumarate, norethisterone acetate (JUNEL FE). Prior to vaccination, the patient was not diagnosed with COVID-19. The patient previously took lamictal and experienced allergy. The patient experienced nocturnal seizures and extreme fatigue on 22Mar2021. The event nocturnal seizures was serious due to Life threatening. Detail clinical course was reported as the patient had epilepsy, she was seizure free for two years before the vaccine. Three days after the first shot, she began having nocturnal seizures, which have never happened before. All her past seizures have been while she was awake. Seven days later, she was still experiencing extreme fatigue and seizures. Nocturnal seizures result in Doctor or other healthcare professional office/clinic visit (Life threatening illness (immediate risk of death from the event)), and treatment included increased dosages of anti-convulsion medications. The event outcome was not recovered. Since the vaccination, the patient had not been tested for COVID-19. Information on the lot/batch number has been 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>
1162739	4/2/2021	SD	20	M	4/2/2021	4/2/2021	Patient stood up and went to seated waiting area while I finished filling out his COVID Record Vaccine Card. I walked over to him within 60-120 seconds after the vaccine administration and found him to be in a stiff full body extended position while sitting on a chair. I asked him if he was ok. He did not respond. Called over the nurse and we were about to bring him down to the ground after suspecting a seizure. Patient "came to" after about 90 seconds of no movement. Patient became alert and orientated. When asked about prior seizure history, patient stated they had a traumatic injury to their back within the last month which resulted with spontaneous seizures throughout the past 2 weeks. Patient was asked to follow-up with primary care provider or seek urgent care/emergency care if it happens again. Patient observed for 30+ minutes until his girlfriend came to pick him up.
1162965	4/2/2021		39	F	4/2/2021	4/2/2021	Seizure - 5 minutes
1158258	4/2/2021	OR	50	F	4/1/2021	4/1/2021	dizziness , Fainting, loss of consciousness , shaking ,chills, may be seizure
1158682	4/2/2021	MO	39	F	3/12/2021	3/1/2021	Increased seizures after 12 hours.; This is a spontaneous report from a contactable consumer (patient). A 39-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 right arm on 12Mar2021 09:30 as single dose for COVID-19 immunisation. Medical history included cerebral palsy and seizure and covid-19 (prior vaccination). The patient was not pregnant and had no known allergies. Concomitant medications included baclofen, rufinamide (BANZEL), levothyroxine sodium (SYNTHROID), and clobazam (ONFI) and valero acid syrup. In Mar2021, the patient experienced increased seizures after 12 hours. Had to call ambulance, and went to the emergency room (ER) at a hospital. The patient received Ativan, and Depakote and IV fluids. The patient had no other vaccine in 4 weeks and was not covid tested post vaccination. Outcome of event was recovered in Mar2021. 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>
1158772	4/2/2021	CA	22	F	4/1/2021	4/1/2021	Systemic: Seizure-Mild, Additional Details: Pt recovered. Fire dept called. Pt declined care of paramedics and returned home with boyfriend.
1161987	4/2/2021	FL		F	2/26/2021	2/26/2021	Convulsions that did not let up, shaking and tremors; severe twitching; Shortened time interval between first and second dose; A spontaneous report was received from a family member concerning a 72-years old, female patient who experienced convulsions that did not let up, shaking and tremors (seizure), twitching (muscle twitching) and shortened time interval between first and second dose (inappropriate schedule of product administration). The patient's relevant medical history included essential tremor. Concomitant product use was not provided by the reporter. The patient received their first of two planned doses of mRNA-1273 (Batch number not provided) intramuscularly on 29-Jan-2021. On 26-Feb-2021, prior to the event onset, the patient received their second of two planned doses of mRNA-1273 (Batch number not provided) intramuscularly for prophylaxis of COVID-19 infection. On 27-Feb-2021, 25 hours after vaccination, the patient experienced very severe twitching, shaking, tremors and convulsions that did not let up. Reportedly, it lasted 12 hours until she fell asleep and remained ongoing. Treatment information was not 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. The outcome of the events, convulsions that did not let up, shaking and tremors and twitching, were not provided. The event, shortened time interval between first and second dose, was resolved on 26 Feb 2021.; Reporter's Comments: This report refers to a case of inappropriate schedule of vaccine administered for mRNA-1273 (lot #unknown) with an associated convulsions reported. Very limited information regarding this event/s has been provided at this time. Further information has been requested.
1154478	4/1/2021	ME	68	M	3/30/2021	3/30/2021	Patient had a seizure following administration of second dose of COVID-19 vaccine. Versed was given.
1157222	4/1/2021		59	F	4/1/2021	4/1/2021	Patient lost consciousness, showed signs of seizure, ruled a pseudoseizure

<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>
1155255	4/1/2021	NM	60	F	3/23/2021	3/23/2021	She got her vaccine and within 15 minutes she was having a hard time breathing. She told her husband that she needed to go to the bathroom and see if she could get the feeling to stop. She went into the bathroom and she was gasping and choking for breathe. They got her into the ambulance and her BP was extremely high 128/90 and her BP normally is 98/60. They started an IV, breathing treatments and oxygen. She was gagging up saliva and having a hard time breathing. They got her to where she was calm. Her body when it is under extreme amounts of stress goes into seizures, which it did. She then was transferred to in for observation. By the time she arrived her BP had come down and was starting to stabilize. She was given steroids, discharged home. She has had problems breathing, extreme/sharp pain on the left side of her head behind the eye, which has been going on for over a week. By the end of the day she is exhausted. She has never had a hard time breathing at high altitudes and now she can walk up the stairs and be winded. This has all happened since receiving the vaccine. She sent a message to her doctor who did seem concerned. The pharmacist at the facility at the time said that she was fine, to leave her alone. The EMT's said that there was something wrong with her and took her to the hospital. The hospital did not give her any long-term medications to take. She does have a routine APT with her PCP on 4/6/21. On Thursday she woke up and asked her husband if her face was swollen, and he asked why, she stated that her face was numb, and some spots so sensitive that she could not brush her hair. This was on the left side. The sensitivity is still there, but not as intense.
1155618	4/1/2021	AL	59	F	3/29/2021	3/30/2021	Pt received 1st Dose of Pfizer vaccine on 03/29/21. Mother reported that patient began to experience Fever; Drooping & Swelling on right side of face on 03/30/21. Swelling is decreasing but there is still some drooping. The patient is Epileptic and is also taking Dilantin and Phenobarbital to control the seizures.

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1155703	4/1/2021	OK	19	F	3/24/2021	3/25/2021	Patient woke up at 1ma the morning after her second dose of the Pfizer Bio N Tech vaccine. She was having "convulsions" of arms and legs but remained fully conscious. this lasted 30 min. she was able to speak during this time. It stopped. She returned to sleep. no loss of bowel or bladder control. She went back to sleep once it stopped. she woke up later in the AM. she had mild headache. she called Health Clinic and advised what happened earlier. she was advised to go to ER for evaluation. She did She has made full Recovery.
1155817	4/1/2021	MO	62	F	4/1/2021	4/1/2021	pt syncopal episode 20 minutes after COVID vaccination cold, clammy, AMS, convulsions improved with supine position, leg raised BP 98/68 norm per patient STAT BG 118 likely vasovagal transported to ER by EMS
1156097	4/1/2021	PA	30	M	3/28/2021	3/29/2021	Patient woke up having seizures around 1:20am. He is a known epileptic. He tried to relax, and return to sleep which is normally fine for him, but the seizures continued to increase. At 1:30am he took additional medication to help try to arrest his seizures as they were increasing in number and length. By 6am, we headed to the hospital ER. There his seizures progressed despite further medication until he had to be restrained, sedated, and intubated in order to stop them (which has never happened before). Patient was further tested and eventually moved to the ICU for an overnight stay. He was also suspected to have an infection and was spiking a fever. On the second day in the hospital, the ventilator was removed. Tests came back in a positive manner, and patient ended up being moved to a regular hospital room, but had to remain into a third day. On the third day, he was finally well enough to be discharged. All tests came back with no real answer as to why this incident spiked this event for him.
1156126	4/1/2021	IL	76	M	4/1/2021	4/1/2021	Witness seizure activity by the patient's wife and observation clinical (RN) staff. Per the patient's wife this type of seizure happens on a regular basis. The patient was seated at the time of the seizure and did not fall from the chair. The patient was transported to the ER for evaluation and post seizure activity monitoring.

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1156178	4/1/2021	GA	24	F	3/31/2021	3/31/2021	Pt was waiting required 15 minutes in a chair. After about 8 minutes from receiving vaccine- Pt began to pass out and lose consciousness. Pt could not speak and her eyes began to roll back in her head and her body began to convulse slightly. Administered Epipen to pt in left thigh and she responded immediately. She came to and within a few minutes was able to say her name and count backwards from 10. 911 had been called. paramedics assessed pt. They asked her if she wanted to go to ER and she said yes.
1156207	4/1/2021	TX	49	M	4/1/2021	4/1/2021	Patient received 2nd dose of vaccine at 1120 today . He had 2 petite mall seizures, tingling, numbness to right hand, glazed stare, slurred voice within 30 min of receipt of vaccine. Patient transported to emergency room via wheelchair.
1156310	4/1/2021	TX	22	F	4/1/2021	4/1/2021	Vaccine administered at 10AM. At 1015 observer noticed she was feeling anxious patient walked to high observation area for further evaluation. Patient stated she was feeling anxious and that the light was bothering her, she used her inhaler prior to moving to high observation also stated the light triggered her epilepsy. Patient transfered to dark private area by high observation nurse to decrease stimuli. Patient stated she felt like a seizure was going to happen layed on her left lateral side vs 135/83 p 118 rr20 temp 36.7 sat 88%. Patient going in and out of sudden repeated episodes. 1035 ems activated.
1156321	4/1/2021		47	M	4/1/2021	4/1/2021	Pt received Pfizer vaccine dose 1 at 12:05pm, immediately experienced seizure for aproximately one minute. Postictal state symptoms include agitation and confusion. At 12:20 pt is AOx4, BP 188/118, HR 116, O2sat 99% 8 LPM NRB. Pt transported via EMS to hospital to receive further care.

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1156487	4/1/2021	CA	31	M	3/27/2021	3/27/2021	a 31 year old man who received the COVID-19 vaccine on March 27, 2021 in the Public Health Department parking lot. Upon arrival and check in, the patient declined any comorbidities and health history but did state that he was nervous. After administration of the vaccine by NP, the patient lowered himself to the ground, from a sitting position, and had a 60 second tonic clonic seizure. Seizure precautions such as turning the patient on his side, supporting his head, and calling EMS were taken during the seizure. After 60 seconds, the patient came to and asked what happened. PPHD staff oriented the patient to what had happened, to which he proceeded to say "oh that is normal for me when I get anxious." With the help of PPHD staff and his wife, the patient was brought to a sitting position and given a granola bar and water to his request. According to clinic lead RN, "his skin was normal in appearance for race, ethnicity, and age. He was mildly diaphoretic. He verbalized feelings of anxiety and worry surrounding the vaccine." As EMS arrived on the scene and began assessing vital signs the patient's anxiety appeared to increase; he became less verbal, closed his eyes, and his breathing pattern became shallow. The patient then had a second seizure at this time lasting approximately 25 seconds. When the patient came to he immediately verbalized, "I'm good, I'm good, I'm fine?". He was slow to respond to verbal cues, but persistently refused transport to the local acute care hospital for further evaluation. He rested on the ground in supine position for approximately 25 minutes, with his partner and EMS at his side. Upon further evaluation of the patient and his wife, it was determined that the patient has a history of seizure activities when he is nervous and that he was "expecting" this to happen. The patient continued to decline medical care and transportation to the hospital. The patient left in medically stable condition with his wife operating the vehicle.
1156610	4/1/2021	IL	57	M	3/30/2021	3/30/2021	syncope 2 hours after his vaccination. he felt nauseous and fainted. LOC lasted 30 seconds. no palpitations, dizziness, diaphoresis, chest pain. no seizure activity noted, but states he had urinary and fecal incontinence.

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1153924	4/1/2021	FL	72	F	1/17/2021	2/14/2021	Seizure; 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 light headache/headache, fever/pyrexia and seizure. Medical history or concomitant product use were not reported. On 17 Jan 2021, the patient received her first of the two planned doses of mRNA-1273 (batch number: 013620A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 14 Feb 2021, the patient received her second of the two planned doses of mRNA-1273 (batch number: 013M20A) intramuscularly in the right arm. Soon, she had a light headache and fever. She took treatment with paracetamol. On 16 Feb 2021, the patient was hospitalized. She had her CT scan of the brain and was reported to have seizure because of the symptoms. On 18 Feb 2021, the patient was discharged from the hospital. The action was taken with mRNA-1273 in response to the events was not applicable since they developed after the second dose. The outcomes of the event headache was resolved on 15 Feb 2021 and for other events 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.
1157220	4/1/2021	OR	61	M	3/31/2021	3/31/2021	Patient was in observation area after vaccine administration. Twelve minutes after vaccination, he fell to the floor and appeared to be having a seizure. Staff protected him from injury, and administered oxygen, and called EMS. He stopped seizing, then had another seizure before EMS came to transport him to the ER.

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1153998	4/1/2021	NY	21	M			A spontaneous report was received from a consumer (United States) concerning a 21-year-old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced fell out of the chair and passed out/Loss of consciousness, fell out of the chair and passed out/Fall, may have been a seizure but unsure/seizure. The patient's medical history included psychological problems. Concomitant product use was not provided by the reporter. 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) intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, after the injection he "fell out of the chair and passed out". The reporter stated that she heard it "may have been a seizure but unsure". She reported the male was obese. The events passed out and seizure was considered as 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 fell out of the chair and passed out, may have been a seizure but unsure was unknown at the time of this report.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.
1157278	4/1/2021	CA	55	F	4/1/2021	4/1/2021	Following administration of dose 2 of moderna covid vaccine. pt has syncope episode and fell landing on butt and hitting head on floor. LOC elapsed 30 seconds. No seizures. Pt evaluated by onsite MD and placed on gurney to be evaluated at triage bay area. 1020am: BP 220/126 P120. No meds and no previous allergies. 1050am: BP 176/104 P=85 . Pt was monitored and symptoms improved. Pt ambulated and was stable prior to d/c from vaccination site. onsite MD recommended for patient to follow-up with outside PCP if persistent elevated BP or symptoms.

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1157495	4/1/2021	NC		U	3/1/2021		GRAND MAL; SEIZURES; FAINT; CHEST PAIN; FLUSHED; This spontaneous report received from a health care professional concerned 49 patients 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 were not reported, expiry: 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 MAR-2019, post-vaccination many patients needed to be seen by EMS for various medical incidents such as faint, flushed, chest pain. Later it was 49 people needing EMS attention and several seizures and 1 grand mal experienced took place after covid-19 vaccine ad26.cov2.s vaccination. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the seizures, faint, flushed, chest pain and grand mal was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 20210342978-Covid-19 vaccine ad26.cov2.s-Grand mal, seizure and faint. These events are 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.

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1157517	4/1/2021	CA		U	3/22/2021		POSSIBLE SEIZURES; BODY ACHE; FEVER; HEADACHE; 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, intramuscular, batch number: Unknown) dose was not reported, administered on 22-MAR-2021 in left arm for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 22-MAR-2021, the patient experienced possible seizures, body ache, fever and headache after receiving the vaccine. The action taken with COVID-19 vaccine ad26.cov2.s was not applicable. The patient recovered from possible seizures, fever, and headache, and had not recovered from body ache. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210350457-COVID-19 VACCINE AD26.COV2.S-Possible seizures. 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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1157599	4/1/2021	TX		F	3/1/2021	3/1/2021	seizure; A spontaneous report was received from a healthcare professional concerning a 63-years-old patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events seizure. The patient's medical history was not provided. Concomitant medications reported were Phenytoin, Norvasc for drug use for unknown indication. On 1 Mar 2021, prior to the onset of the events the patient received first of two planned doses of mRNA-1273 (lot/batch: not provided) via unknown route for prophylaxis of COVID-19 infection. Lab parameters done was not provided. On 1 Mar 2021, in the evening she went to bed and had a seizure. She was fine in the morning and her husband told her that she had a seizure last night. She is allergic to peanuts and peanuts oil. She has Epilepsy and take medications for that but didn't have a seizure for a long time. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of event(s), seizure was unknown. Action taken with mRNA-1273 in response to the event 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.
1157706	4/1/2021	OR	40	M	4/1/2021	4/1/2021	10 seconds of tonic clonic seizure like activity 6 minutes after administration of the Moderna COVID-19 vaccine with associated hypotension, bradycardia, diaphoresis, and visual disturbance (spots in his vision) that self-resolved after being shaken.
1155074	4/1/2021	MA	26	M	3/31/2021	3/31/2021	Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Additional Details: patient was administered vaccine, was feeling well and walked to waiting area. patient \"lost balance\" and fell to floor, hitting his face and began bleeding from his nose and upper brow area. Technician retrieved an ice pack from pharmacy, and in the meantime, worker aided patient to sitting position, which was when patient began to seize. worker called EMS while holding patient's head steady. Patient regained consciousness and EMS arrived. Whole event lasted around 5 minutes.

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1157774	4/1/2021	UT	33	M	4/1/2021	4/1/2021	Numbness in left arm and face, overheating, fainting, Medical personal fist on site noticed shaking due to Seizure.
1158073	4/1/2021	CA	23	F	4/1/2021	4/1/2021	Patient received vaccine at 6:03 pm, patient was in recovery area and experienced syncope at 6:07 pm, patient fell to the group face down, nurses responded turned patient on left side, patient had 5-10 second seizure with full body seizing and eyes rolled backed. EMS called. Right frontal area hematoma due to hitting head on floor. Patient confused at first, BP 98/64, HR 80 at 6:10, patient diaphoretic, reassessed BP 105/60 HR 82, EMS assessed, patient LOC returning A&Ox4, able to remember she does have seizures and takes seizure medications but cannot remember medication name. Nurses advised patient to be transported by EMS, patient refused, patient boyfriend and mom also refused and stated they would take her themselves. Boyfriend to drive patient to ER for follow up per patient and family.
1157790	4/1/2021	OR	44	M	3/31/2021	4/1/2021	I have epilepsy. I have seizures about ever 9 months or so usually because I forgot to take my medication. I know I have been taking my medicine prior to the event. I had an epileptic seizure one day after the first does of the Pfizer vaccine.
1155052	4/1/2021	DC	27	F	3/31/2021	3/31/2021	Site: Pain at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Seizure-Medium, Systemic: Weakness-Mild, Additional Details: P/T stated she had not ate since yesterday. She has had these fainting spells in the past especially when she gets her blood drawn. Her bp & respirations were all within normal levels. Was a and O x 4. P/t stated she was feeling faint and dizzy then asked for water. Pharm tech then went to notify RN of the situation. At the moment p/t began to collapse from the chair and fell on her right upper forehead which started to bruise and swell. She then started to seize & 911 was called & emt arrived.

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1154506	4/1/2021	ME	69	F	3/30/2021	3/30/2021	Patient had a seizure post vaccination lasting less than 5 minutes. Patient has a known history of seizure disorder. Patient observed for 30 minutes post seizure (no more seizure activity was observed during that time). Patient was sent home with spouse @0945.
1155082	4/1/2021	FL	48	F	3/31/2021	3/31/2021	Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Seizure-Medium, Systemic: Vomiting-Severe, Additional Details: none
1156617	4/1/2021	AZ	23	F	4/1/2021	4/1/2021	At 10:02 am approximately in 14 minutes after being vaccinated patient (at 10:48 am) developed epilepsy seizure that lasted for 5 minutes. Paramedics arrived to take care of the patient, no treatment was administered. Patient declined hospitalization and was taken home by her partner after she recovered from the seizure. Per patient, she has seizures every 3 month, and she was on her 12th week on the day of the vaccination. Pt takes topiramate for seizure control. Dose of the medication is unknown to me.
1157772	4/1/2021	TX	48	M	4/1/2021	4/1/2021	AT ABOUT 1PM, PATIENT BECAME APPEARED TO BE HAVING A SEIZURE WITH HEAD BACK SITTING IN A CHAIR, WAS TONIC, CLONIC AND STIFFENED WITH A SHORT LOSS OF CONSCIOUSNESS. CALLED 911 AND ADMINISTERED EPI-PEN X 1 DOSE AT 1:03PM PATIENT WAS ALREADY CONSCIOUS AND TALKING. FELT CLAMMY TO TOUCH AND WAS PALE. BP 144/82 PULSE 97, O2 SAT 98. MOVED PATIENT TO BENCH IN SHADE WHILE WAITING FOR EMS. BP 140/95 PULSE 88 WHEN EMS ARRIVED AROUND 1:20, PATIENT DID NOT WISH TO BE TRANSPORTED TO THE HOSPITAL AS HE WAS FEELING BETTER AND EVERYTHING SEEMED OK. HE REMAINED WITH US AND HAD A CLIFF BAR, COKE AND WATER UNTIL 2:20PM AT WHICH TIME HE LEFT. I FOLLOWED UP WITH HIM AT ABOUT 3PM AND HE WAS STILL DOING WELL. HE WAS ADVISED TO FOLLOW UP WITH PRIMARY CARE PHYSICIAN AND IF HE HAD ANY OTHER SYMPTOMS TO GO TO THE ER/CALL 911.

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1152705	3/31/2021	MI	31	M	3/31/2021	3/31/2021	PATIENT HAD SEIZURE IN WAITING AREA AFTER RECEIVING FIRST DOSE OF COVID VACCINE. PT BECAME RESPONSIVE, EMS WAS CALLED AND MANAGED PATIENT AFTER
1154417	3/31/2021	CA	34	F	3/31/2021	3/31/2021	Administered Pfizer 2nd dose to patient at 1542 hrs. After injection was complete, patient's body went limp, and began to exhibit a tonic/clonic seizure for approx. 5 seconds at 1545 hrs. Patient became limp and I assisted her to the ground safely. Patient came to, no postictal state, A/Ox3, and does not recall seizing. EMS activated approx. 1553 hrs, and Engine 16 arrived on scene approx. 1556 hrs. VS (sitting) @ 1559 hrs: 90/53, 60 bpm, 100% room air. VS (standing) @ 1605 hrs: 101/60, 64 bpm, 100% room air. Patient went into M-14 ambulance for additional monitoring. No medications given. Patient AMA with M-14 and left with husband with husband driving at approx. 1630 hrs.
1152321	3/31/2021	CA	21	M	3/31/2021	3/31/2021	PT COLLAPSED AND FELL ON THE FLOOR FACE DOWN ABOUT 5 MINUTES, AROUND 9:35AM AFTER GETTING 1ST DOSE OF COVID VACCINE. PT WAS TURNED OVER WITH THE HELP OF A SAMARITAN WHILE WE CALLED 911. PT HAD SEVERAL SEIZURE EPISODES. PT REGAINED CONSCIOUSNESS AND BECAME RESPONSIVE AFTER ABOUT 2 MINUTES. PARAMEDICS CAME AND TOOK OVER. PER PT, NO PRIOR HISTORY OF SEIZURE OR MEDICAL CONDITION. PT CAME FROM 10 HRS NIGHT SHIFT (2 DAYS IN A ROW) TO GET HIS VACCINE. DAD WAS INFORMED PER PT'S AUTHORIZATION ABOUT INCIDENT AND HE SAID HE WILL BE ON HIS WAY. PT TO BE TRANSPORTED TO A NEARBY HOSPITAL PER ONE OF THE PARAMEDICS.

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1152380	3/31/2021	ID	31	F	3/19/2021	3/19/2021	New medication for seizure (mild-mod) petit mal seizure activity started at 14:05 Vital Signs: BP 118/84 HR 87 Resp 20 O2sat 99 Skin Signs: Warm and dry Circulation: Cap refill <2sec Respiratory: Breath sound clear bilaterally Refused to lie on cot. Seizure activity is common patient states with loud noises. 14:14 without seizure activity, breath sounds clear, speech clear 14:20 Vital Signs: BP 122/86 HR 88 Resp 20 O2sat 97 Skin Signs: Warm and dry Circulation: Cap refill <2sec Respiratory: Breath sound clear bilaterally Assess by MD Maintain quiet environment at home this afternoon and pm Disposition: Home with family
1152390	3/31/2021	IA	37	M	3/30/2021	3/30/2021	Pfizer COVID-19 Vaccine EUA Patient received Dose 1 Pfizer vaccine at 1240. Pt started not feeling well, was taken back to medical observation. Pt with grey apperance, not really comprehending commands, sweaty and hot, started to undo his jacket and flannel shirt. Patient started to go in and out of conciousness and was lowered to the floor. Pt became unconscious. Sternal rubs were performed and patient was arousable. Patient began to have generalized clonic seizure, patient was placed in left lateral decubitus position. EMS was called. BP 97/55, SpO2 100%, HR 98. Patient does have history of seizures and is not on any medications for these seizures. 1335: 75/50, 88, 100% (RA), two more additional seizures witnessed. Patient able to regain consciousness between seizures was alert and able to answer questions appropriately. 1340: 18g IV started to left AC. NS hung to open gravity, good flow. 1345: EMS arrived and assumed care, patient A&O x 3. Transported to the hospital. Reporter does not have access to hospital's health records. Bilateral breath sounds CTAB, no swelling of the face/lips/tongue or rash.
1152439	3/31/2021	KY	68	M	3/24/2021	3/26/2021	Started having muscle spasms and jerking. Affected his memory and had unsteady gait and fell twice and had to have help walking some. He had abdominal pain and decreased appetite lost 10 pounds in a week. He was on Keppra from EEG that was done 2 years ago and strikes was seen on the temporal and periorbital but never had no seizure activity. They increased his Keppra and told him not to get the second COVID vaccine.

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1152509	3/31/2021			U			4 seizures were documented and EMS and 911 was called, O2 given by nasal cannula
1152536	3/31/2021	TX	51	M	3/22/2021	3/25/2021	After 3 days he developed 2 new seizures according to him. Document pending since he was admitted in the hospital. Neurology consult placed. He was placed on keppra, atorvastatin and baby aspirin during the admission.
1152218	3/31/2021	MO	56	F	3/30/2021	3/30/2021	went today to get a COVID-19 vaccination (Johnson & Johnson) today. She is here for seizures. Apparently she was fine shortly after the shot and then this afternoon started having chills and fever and then had with the family said was a 30-minute seizure before EMS was called. EMS found her postictal and during the transport they had she had another seizure in route. In the emergency room she had a fever of 101 and was postictal
1152688	3/31/2021	TN	42	F	3/22/2021	3/22/2021	Vaccine 3/22/21, started with fatigue/generally feeling unwell 3/25/21, fever. Received Tdap vaccine 3/26/21. Persistent fever, pain around eye, ear and radiating into her head, nausea. Symptoms continued to worsen, developed chest pain and new onset seizure 3/31/21- Sent to ER for evaluation
1152198	3/31/2021	PA	24	F	3/31/2021	3/31/2021	Patient reported feeling nauseated and lightheaded a few minutes after administration, then became extremely pale and head went backwards. Moments later patient's face became red and body convulsed once. Blood pressure and HR taken three times by nurse in the clinic. 2:15 pm 75/58 HR 94 2:20 pm 68/50 HR 88 2:40 pm 80/58 HR 88 Patient felt better and left 3:00 pm
1152766	3/31/2021	TX	18	M	3/31/2021	3/31/2021	ABOUT 3 MINUTES AFTER RECEIVING COVID-19 MODERNA VACCINE CLIENT EXPERIENCED WHAT IT LOOKED LIKE SEIZURE ACTIVITY. ACCORDING TO MOTHER CLIENT WHO WAS SITTING ON A CHAIR FOR OBSERVATION POST VACCINATION, DROPPED HIS PHONE TO THE FLOOR AND RAISED BOTH OF HIS ARMS UP WITH PALMS OPENED AND STARTED TO SHAKE A LITTLE WITH EYES CLOSED. MOTHER ASKED FOR HELP. WHEN HELP ARRIVED CLIENT WAS CONSCIOUS AND NO SEIZING ACTIVITY WAS WITNESS. CLIENT LOOKED PALE AND SWEATY.

<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>
1153092	3/31/2021	KS	19	F	3/16/2021		SEIZURE; DEHYDRATION; This spontaneous report received from a pharmacist concerned a 19 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included dehydrated, anxious, non alcohol user, non smoker, and penicillin allergy, and other pre-existing medical conditions included the patient did not had history of drug abuse or illicit drug use. 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: UNKNOWN) dose was not reported, administered on 16-MAR-2021 on right deltoid for prophylactic vaccination. No concomitant medications were reported. On 16-MAR-2021, the patient had an seizures with in 1 minute after vaccine administration which was lasted for 10 second. The patient did not had history of seizure. The patient was taken to hospital via ambulance and they found that she was dehydrated and was given fluids. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from seizure on 16-MAR-2021, and the outcome of dehydration was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210332197 -JANSSEN COVID-19 VACCINE Ad26.COV2.S-Seizure, Dehydration. 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>
1153127	3/31/2021	TX	37	M	3/5/2021	3/14/2021	4 seizure episodes, lasting for 3-4minutes; A spontaneous report was received from a consumer and other healthcare professional concerning a 37 years old male patient, who received Moderna's COVID-19 vaccine (mRNA-1273), and experienced 4 seizure episodes, lasting for 3-4minutes(seizure) . The patient's medical history was not reported. Concomitant medications taken by the patient were not provided. On 5 Mar 2021, prior to the onset of the event, the patient received his first of two planned vaccine doses of mRNA-1273 (Lot number: unknown) through unknown route and dose, in the left arm, for prophylaxis of COVID-19 infection. On 14 Mar202,1 at 3:00am, patient had a seizure episode which lasted for around 3-4 minutes. The event seizure caused for the hospitalization and was considered as medically significant. An ambulance was called and on the way to the hospital, he had 2 more episodes of seizure. While in the hospital the episode had again recurred. Blood work was done but the results were not provided. Patient was prescribed Levetiracetam 500mg 2x a day. Treatment for event was levetiracetam. Action taken with mRNA-1273 in response to the events was unknown. The outcome of events, experienced 4 seizure episodes, lasting for 3-4minutes, 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.

<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>
1153143	3/31/2021	NC		F	3/15/2021	3/15/2021	very weak; teeth chattering; could not hold body still, both of her arms were jumping like a seizure; both arms and legs started jumping, head started moving side to side; could not talk clearly to understand; mouth numbness; left arm tingling; Blood pressure 200/95; back of neck sweating; A spontaneous report was received from a 67-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced could not hold body still, both of her arms were jumping like a seizure/ seizure like phenomena, both arms and legs started jumping, head started moving side to side/ dyskinesia, could not talk clearly to understand/ dysarthria, mouth numbness/ hypoesthesia oral, left arm tingling/ paresthesia, back of neck sweating/ hyperhidrosis, very weak/ asthenia, and teeth chattering/ chills. The patient's medical history was not provided. Products known to have been used by the patient, within two weeks prior to the event, included duloxetine hydrochloride, evolocumab, and metoprolol. On 15 Mar 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 038A21A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 15 Mar 2021, 5 minutes after the administration of the vaccine, the patient experienced mouth numbness, left arm tingling, sweating at the back of neck with both arms started jumping, head started moving side to side, teeth chattering, and the patient could not hold body still as both legs were jumping, and could not talk clearly to understand. A nurse gave the patient an injection of Epi-pen and Benadryl, which did not work and called emergency medical service. The patient went to the hospital for care, where both of her arms were jumping like a seizure. Blood pressure reading was 200/95 mmHg. On 16 Mar 2021, the patient was very weak. Treatment information included oxygen, Ativan, warm blankets and a warm room until the patient's discharge. Action taken with mRNA-1273 was unknown. The outcomes of the events 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.

<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>
1153497	3/31/2021	CT	25	F	3/18/2021	3/18/2021	Delirium; Fainting episode with convulsions; Fever with Chills; Nausea; Dizziness and disoriented; Dizziness and disoriented; This is a spontaneous report from a contactable consumer (patient). A 25-year-old female patient (not pregnant) received first dose of bnt162b2 (Batch/Lot Number: EN6207), via an unspecified route of administration, administered in left arm on 18Mar2021 08:30 as single dose for covid-19 immunization. Medical history included cystitis interstitial from an unknown date and unknown if ongoing. Concomitant medications included ethinylestradiol, ferrous fumarate, norethisterone acetate (LO LOESTRIN FE) taken for an unspecified indication, start and stop date were not reported. The patient experienced delirium, fainting episode with convulsions, fever with chills, nausea, dizziness and disoriented on 18Mar2021 09:00. No other vaccine in four weeks. The adverse event was not resulted in a visit to doctor or other healthcare professional office/clinic or Emergency room/department or urgent care. No treatment received. The outcome of events was resolving. No Covid prior vaccination. No Covid tested post vaccination. Not Known allergies.

<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>
1153556	3/31/2021		17	M	3/17/2021	3/19/2021	seizure; This is a spontaneous report from a contactable consumer. A 17-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection Batch/Lot Number: EP6955; Expiration Date: 30Jun2021), via an unspecified route of administration on 17Mar2021 as single dose for covid-19 immunisation. Zonisamide, via an unspecified route of administration from an unspecified date (Batch/Lot number was not reported) to an unspecified date, at 800 mg, (600 mg at night and 200 mg on the morning) for an unspecified indication; cannabidiol (CBD OIL), via an unspecified route of administration from an unspecified date (Batch/Lot number was not reported) to an unspecified date, at 7 mL, daily (4ml at night and 3 ml on the morning) for an unspecified indication. The patient medical history included ongoing seizure PMH of temporal epilepsy who has been having break through seizures since July 2020. The patient's concomitant medications were not reported It was reported that patient had received vaccine on Wednesday 17 2021 with no complaints after it until today Friday 19, 2021 at around 7 pm when he developed a seizure while working at his desk. We (the parents saw the end of it which looked more generalized than usual) and gave him 2 mg of Clonazepam, which is his usual rescue medication. He was awake after it and was able to do homework. The action taken in response to the events for Zonisamide and Cannabidiol was unknown. The outcome of the event was unknown.

<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>
1153557	3/31/2021	CO	27	M	2/26/2021	2/1/2021	had a major seizure on day 8 of dose one despite nearly no history of seizures; I was tired after the first dose (26Feb2021) on days 2-3; This is a spontaneous report from a contactable consumer (patient). A 27-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 26Feb2021 15:00 (Batch/Lot Number: EN6204) as SINGLE DOSE for COVID-19 immunization at doctor's office/urgent care. Medical history included atypical trigeminal neuralgia since 2009, complex regional pain syndrome (CRPS), attention deficit hyperactivity disorder (ADD), anxiety, depression, asthma, Epilepsy-prone and many more. The patient also had orthopedic knee surgery on 26Aug2020 which she had pain after surgery. She also had known allergies with Cephalosporins and elemental nickel. Concomitant medications included tapentadol (TAPENTADOL), amphetamine (AMPHETAMINE), and candesartan cilexetil, hydrochlorothiazide (CANDESARTAN HCTZ) all taken for unknown dates and indications. The patient stated that she was tired after the first dose (26Feb2021) on days 2-3 (Feb2021). She also had had a major seizure on day 8 of dose one (07Mar2021) despite nearly no history of seizures which require emergency room/department or urgent care visit. The seizure has been attributed to other issues by her doctor. The patient had no COVID-19 prior vaccination and was not tested post vaccination. The events were considered life threatening. The patient did not receive any treatments for the events. The patient recovered on unknown date in 2021.
1154372	3/31/2021	NH	66	F	1/15/2021	1/18/2021	Jerking movement were to hands when observed during med pass. Tonic clonic movements were assessed for approximately 2 minutes. Code called and patient sent to ER via 911 No history of Seizures she has ongoing seizures. there is a significant decline in her mental status. She is not speaking. She has to be fed. She is not walking.. She is scheduled to see a neurologist in June 2021.
1154411	3/31/2021		25	F	3/31/2021	3/31/2021	fainted/seizure ? loss of bladder control. EMT called and assisted. Said all vital were normal and no signs of seizure. EMT recc pt see primary MD for follow up.

<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>
1152562	3/31/2021	IL	43	F	3/31/2021	3/31/2021	Patient reportedly had seizure after placement of the Pfizer/BioNTech COVID-19 vaccine. The patient received the vaccine at a COVID vaccination clinic. The patient had vaccination needle in her arm, and then almost immediately after, within 3 minutes, that she had a seizure event. It was for extremity shaking lasting a couple minutes which then resolved. This was witnessed by family and they kept her from having any injury sustained. Reportedly she also was very scared receiving the vaccine and "when she gets scared she has her seizures". Mother reports that the patient seizes about once a month and has had other seizures with interventions like brushing teeth. The patient has been taking her medications for seizures. Patient was postictal when medics arrived. Glucose was 79. No recent illness. No recent injury or fever. Had coronavirus over the summer.

<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>
1151399	3/31/2021	NY	67	M	3/3/2021	3/1/2021	his blood pressure reading that was taken in the ambulance on his way to the hospital Emergency Room was 190/114; Sweating; he woke up in the morning, and the room was spinning / Vertigo symptoms; dizzy/extreme dizziness; he felt lightheaded, and was afraid he might fall; things were a little fuzzy in his head, and he couldn't remember exactly when he had gone to the Emergency Room; things were a little fuzzy in his head, and he couldn't remember exactly when he had gone to the Emergency Room; he was only nauseous when he was dizzy; Reported he eyes were not that good while he was reading the paperwork from the Emergency Room; he thought he had a heart attack; This is a spontaneous report from a contactable consumer (patient) A 67-year-old male patient received the first dose of the bnt162b2(PFIZER-BIONTECH COVID-19 VACCINE, Lot Number:EN6198, Expiration Date: Unknown), via an unspecified route of administration, left arm at single dose for Covid-19 immunization On 03-MAR-2021 (between 11:30-12:00). Additional vaccines administered on Same Date of the Pfizer Suspect was none. The patient medical history included depression reported he was diagnosed with depression years ago and has been on Wellbutrin for a while. No further details provided, Tinnitus he self-diagnosed himself a hissing sound mostly in his right ear for less than a year. He said he looked up his symptom on the internet and found someone else who had the same symptom as him, and that person said it was Tinnitus, Seizure he had a seizure about a year ago. Reported he had a seizure about a year ago. He said he had a brain scan afterward, and the doctor didn't find anything wrong. No further details provided. Concomitant medications were not reported. On 03Mar2021 Patient received his first Pfizer COVID-19 Vaccine (on) and was fine. He said about a week after getting his first COVID-19 Vaccine, he woke up in the morning, and was sweating, and the room was spinning, and he was dizzy. Little fuzzy in his head, and he couldn't remember exactly when he had gone to the Emergency Room: He said the room spinning and him being dizzy had been continuing to go on. He said he thought he had a heart attack, and went to the hospital (Emergency Room). He said his blood pressure was high. He said he was nauseous too. He said his dizziness hadn't stopped. He said the dizziness gets so bad, he can't get around, if

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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he lowered his head below his shoulders, the dizziness gets really bad. the dizziness won't go away. the Emergency Room doctor thought his dizziness may be due to his inner ear. The Emergency Room doctor told him he should see an ear doctor about his dizziness. He said the his dizziness happened directly after he got his first COVID-19 Vaccine. Reported he went on the internet, and read that other people who got the COVID-19 Vaccine were experiencing same thing he was. No further details provided. It was Reported patient blood pressure was very high. He clarified his blood pressure reading that was taken in the ambulance on his way to the hospital Emergency Room was 190/114. He said he believed his blood pressure was taken again, and his blood pressure was a little bit better. He said his dizziness hadn't stopped. He said the dizziness gets so bad, he can't get around. He said if he lowered his head below his shoulders, the dizziness gets really bad. He said the dizziness won't go away. He said he was nauseous too, but only when he was dizzy. He said his dizziness was fine last night, but then he got up this morning and the room started spinning out of control. He said he felt lightheaded, and was afraid he might fall. He said if he tried to pick up something off the ground, his dizziness really comes on. He said the Emergency Room doctor thought his dizziness may be due to his inner ear. He said the Emergency Room doctor told him he should see an ear doctor about his dizziness. He had an EKG done in the Emergency Room, and since the doctor didn't say anything about his EKG, he assumed there was nothing wrong with the EKG results. He stated that he went to hospital as he was fearful he was having a heart attack; it was determined that he was not. However, he was advised him to consult a specialist as he may be suffering from vertigo. Treatment was given a low dose of oral Lorazepam 0.3mg to calm him down. He stated he did not have the Lorazepam 0.3mg NDC. He said his paperwork from the Emergency Room listed his diagnosis as Vertigo symptoms, and it was recommended he go for a hearing test because his dizziness maybe caused by his inner ear. The outcome of event 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>
1149357	3/31/2021	CA	29	M	3/24/2021	3/27/2021	3 days after receiving the vaccine I had a seizure. I went to the hospital and they refused to listen to anything negative regarding the vaccine. The hospital was of no remedy to me. One doctor even boldly claimed that she wasn't there so they can't necessarily say I had a seizure. I received no medications and left the hospital with no CT scan.
1149669	3/31/2021	OK	23	F	3/30/2021	3/30/2021	Client passed out of chair face first on ground while sitting in observation right after receiving injection. Client convulsed for 15 seconds. Vital signs taken - BP 70/50, pulse ox 98% on room air, pulse 60. Client then became alert and oriented. EMS called and arrived on scene. Client refused EMS transport. Vital signs stable. Mom and boyfriend called via client phone. Boyfriend took client in his car. ER follow-up recommended by APRN on scene. Client has history of 1 other seizure. No other pertinent medical history. No injury from fall.

<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>
1149912	3/31/2021	MO	68	F	2/26/2021	3/9/2021	Infections; Patient is having a fit; Patient is having nervous breakdown; A Spontaneous report was received from a consumer concerning a 68-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced fit/seizure, nervous breakdown/mental disorder and infection. The patient's medical history was provided as "allergic to all things". No concomitant medications were reported. On 26 Feb 2021, approximately 11 days prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly in an unknown location for prophylaxis of COVID-19 infection. On 09 Mar 2021, patient developed fit and nervous breakdown for three days. After three days ,On 12 Mar 2021, patient was admitted in emergency room and was diagnosed with infection. Also the reporter inquired if it is safe to go for the second dose. The event fit /seizure was considered as important medical event term. The treatment medication was reported as antibiotics. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events patient developed fit and nervous breakdown was considered as resolved on 12 Mar 2021. The outcome of the event infection was 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 event, a causal relationship cannot be excluded.
1150114	3/31/2021	MI	25	F	3/29/2021	3/29/2021	Patient got out of car 15 minutes after vaccination when patient was being released and she sat on the floor & laid down. It was reported that patient did this after her first vaccine. Caregiver stated patient has been in and out of the hospital 3 times in 2 weeks, lives in an adult foster care facility. Has history of faking seizures per caregiver. Onsite EMS was called vitals BP 92/55 HR 106 BG 87. Patient was transported to ED by EMS.

<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>
1150477	3/31/2021	UT	69	F	2/19/2021	2/19/2021	She had seizure while driving home; Broken back as a result on an accident after receiving the vaccine; Previously diagnosed with seizure but it had been well controlled with medicine; A spontaneous report was received from a consumer concerning a 69 year old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced a seizure while driving home and a broken back as a result of an accident after receiving the vaccine. The patient's medical history was reported as she had previously been diagnosed with a seizure disorder but it had been well controlled with medication. It had been over three to four years since she had a seizure and last time she could remember was in 2017. Concomitant medications taken by the patient were not provided. On 19 Feb 2021, prior to the onset of the event, the patient received the first of two planned doses of mRNA-1273 (Lot number: 023N20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 19 Feb 2021, within about 30 minutes of getting the vaccine she had a seizure while driving home. This led to an vehicular accident and she had to be rushed to the hospital. Her car was totaled and she had a broken back. Treatment activities for event was not provided. Action taken with mRNA-1273 in response to the events was unknown. The outcome of events, Seizure, Spinal fracture , and Condition Worsened, 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.
1150558	3/31/2021	GA	26	F	3/19/2021	3/19/2021	Friend in vehicle stated participant briefly lost consciousness, when awoke was lethargic; incontinent of urine; B/P 90/60, pulse ox 98% Denise hx. of seizures ; EMS assessed participant; participant refused to go to E.D. with EMS, however, stated would have boyfriend take her to E.D. In f/u phone call, stated had lab work done on E.D. and fluids administered, and released home with no further issues.

<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>
1150666	3/31/2021	AL	21	F	3/12/2021	3/13/2021	Our daughter began having bone pain around 9 p.m. She threw up approx 11 p.m. Through the night, she began to develop a fever 101.9. Around 5 p.m she said something was wrong over and over. We got ready to go to ER. She wanted to go to bathroom and throw up. When she did, she had a grand mal seizure. My husband had to begin CPR. Fire Rescue team arrived and transported to ER. She was treated and released. Follow up with cardiologist, primary care, and neurologist.

<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>
1150917	3/31/2021	OH	52	F	3/8/2021	3/1/2021	high level of shortness of breath; Diarrhea; spinal column hurt the worst (the spine from the top of her neck to her butt); butt muscles hurt really bad; caller's spinal column hurt the worst, the front of her calves and hip joints; spinal column hurt the worst, the very edges of her back, the side of her back was excruciating; Dizziness; Vomiting; not feeling well enough; shaking; shivering/chills; pulse ox and it dropped down to 93; Excruciating body pain; Headache; sore arm / front of her calves, front of her thighs, left arm, 3 left fingers; Exhaustion; no appetite at all; This is a spontaneous report from a contactable consumer, the patient. A 52-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: unknown), via an unspecified route of administration in the left arm on 08Mar2021 at 10:15 (at the age of 52-years-old) as a single dose for COVID-19 immunization. Medical history included ongoing epilepsy since Oct2015 (officially diagnosed in Oct2015, but the doctors believed it was in her early 20s but she was misdiagnosed for decades), post-traumatic stress disorder (PTSD) from 2020 (diagnosed a year ago), sleep apnea since 2016 (patient thought she was diagnosed in 2016), COVID-19 in Nov2020 from which the patient almost died, memory loss (left over COVID symptom) for which the patient was in speech therapy, intermittent body pain (aftereffects of COVID-19), relapse in seizures due to COVID-19, her eyesight was terrible, epilepsy migraines. Concomitant medications included unspecified epilepsy medications. There was no other vaccine given on the same day, or 4 weeks prior to the vaccination. The patient previously received a flu shot and fainted, on an unspecified date. On 08Mar2021 at 11:15, the patient experienced sore arm (pain 2/10). On 08Mar2021 at 22:00, the patient had headache which got progressively worse, then it got so bad she wanted to pop her head off at midnight. On 09Mar2021 at 00:00, the patient had shaking and shivering where it looked like she was convulsing (she had history of epilepsy and knew what a seizure felt like, her husband may have thought she was having a seizure). The patient had chills to the point where she had multiple blankets and could not stop shaking, took her pulse ox and it dropped down to 93. The caller's baseline temperature was 97.1 and her daughter took her temperature and it was 98.9, most people wouldn't

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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consider that a temperature, but it was a temperature for her. The caller kept shaking like that for hours. On 09Mar2021 between 21:00-23:00, the patient had chills again. On 09Mar2021, the patient experienced excruciating body pain (pain 9/10) in very specific parts of her body. On 09Mar2021 by 12:00, the caller's spinal column hurt the worst, the front of her calves and hip joints, the very edges of her back, the spine from the top of her neck to her butt and then next to it was not so bad but the side of her back was excruciating, the butt muscles hurt really bad, the front of her thighs, left arm, 3 left fingers, but not the other 2 fingers. Oddly enough, she was considered a long hauler, it was the places that her occupational therapist and physical therapists were working on. On 09Mar2021 at 00:00, the patient experienced dizziness (that was on and off all day until bedtime last night on 09Mar2021) and vomiting (she couldn't hold down water). On 09Mar2021, the patient was not feeling well enough. On 10Mar2021 at 08:00, the patient experienced diarrhea (she's only gone to the bathroom twice). On Mar2021, the patient experienced exhaustion and no appetite at all. On an unspecified date, the patient experienced a high level of shortness of breath (patient was unsure if this was due to COVID-19). The patient underwent laboratory tests and procedures which included an echocardiogram on an unspecified date: her left atrium was enlarged and her cardiac numbers were high, they were going to monitor her heart and the doctors didn't know if it was because she had COVID-19 or if it was that the doctors got lucky and found it, they had nothing to compare it to because she only had this one echocardiogram. The patient had history of epilepsy migraines (can pinpoint the spot where it hurts), she thought she would try sumatriptan succinate (IMITREX) for this headache (her whole head hurt), as it didn't interact with her other medications. The patient also took acetaminophen/diphenhydramine (TYLENOL PM; Lot: GF6062, Expiry: Jun2022), ibuprofen (patient thinks the Lot is QWE2546A, but is unsure) for the headache. The patient took ondansetron (ZOFTRAN) which she had from a previous prescription and that made the vomiting stop. The events did not require an emergency room or physician office visit. The patient did not think that the reactions were due to her epilepsy medication. The clinical outcome of excruciating body

<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>
							pain was resolved on 09Mar2021 (it's hard for the caller to say if she has recovered because she had COVID-19 aftereffects and had body pains that come back intermittently), sore arm / front of her calves, front of her thighs, left arm, 3 left fingers, shaking, shivering/chills, pulse ox and it dropped down to 93, spinal column hurt the worst (the spine from the top of her neck to her butt), butt muscles hurt really bad, caller's spinal column hurt the worst, the front of her calves and hip joints, spinal column hurt the worst, the very edges of her back, the side of her back was excruciating, dizziness, vomiting, not feeling well enough, no appetite at all was resolved on 09Mar2021; headache was not resolved (unless the caller was asleep, she felt the headache); exhaustion was not resolved; diarrhea and high level of shortness of breath was unknown. Information on the lot/batch number has been requested.
1152271	3/31/2021	IN	53	M	3/29/2021	3/29/2021	dizziness, sweat passed out, seizures
1151220	3/31/2021	TX	20	F	3/31/2021	3/31/2021	The pt had a seizure about 10 minutes after the vaccine was given. She had reported to us ahead of time that she has a seizure disorder. This was discussed with Dr., and he instructed us to go ahead with vaccination. We had the patient lie down during and after vaccination, and she was under observation. Her father was with her in the room. Her seizure lasted less than 2 minutes, and she was then evaluated by Dr.. She was dismissed in stable condition, with instructions to follow up with her neurologist.

<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>
1152521	3/31/2021	LA	48	F	3/11/2021	3/15/2021	PT STARTED HAVING A FEELING OF HEAVINESS, MALAISE, FATIGUE, HEADACHES ABOUT AN HOUR OR TWO AFTER THE SHOT WAS ADMINISTERED. THE SIDE EFFECTS CONTINUED THRU THE WEEKEND AND SHE TOOK TYLENOL TO HELP WITH SYMPTOMS. ON MONDAY, 3/15/21 AROUND 720PM SHE COLLAPSED AT HOME AND WAS RUSHED TO THE HOPSITAL E.R. CT SCAN WAS ORDERED BECAUSE DR WANTED TO RULE OUT STROKE DUE TO WEAKNESS ON RIGHT SIDE,SPEECH IMPAIRMENT,HEADACHE,WEAKNESS, AND SHE HAD BITTEN HER TONGUE. SHE WAS ADMITTED INTO THE HOSPITAL. TUESDAY 3/16/21 - DR ORDERED CT SCAN AND MRI TO RULE OUT STROKE...PT WAS CONFIRMED TO HAVE HAD STROKE WEDNESDAY 3/17/21- EEG ORDERED AND PT POSITIVE FOR SEIZURES PT DISCHARGED FROM HOSPITAL 3/17/21 AND PRESCRIBED CLOPIDIGREL AND ATORVASTATIN AS TAKE HOME MEDS.

<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>
1151426	3/31/2021	TX	68	M	2/22/2021	3/12/2021	Fell out of bed; tonic clonic seizure; postictal (confusion); This is a spontaneous report from a contactable consumer (patient). A 68-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in right arm on 22Feb2021 10:15 (lot number: EN6203) as single dose for COVID-19 immunisation. The patient's medical history included hypertension. The patient's concomitant medications included losartan and OTC vitamin. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in left arm on 26Jan2021 03:45PM (lot number: EL9262) for COVID-19 immunisation. On 12Mar2021 06:30, the patient fell out of bed and wife witnessed tonic clonic seizure of 5+ minutes. And when EMS arrived on 12Mar2021 06:30, the patient was postictal (confusion). The events resulted to Emergency Room visit and patient was hospitalized for 3 days. The patient had no COVID prior vaccination and was tested for COVID post vaccination. The patient underwent lab tests and procedures and included blood test and scan, both with unknown results on an unspecified date and nasal swab/NAAT: negative on 12Mar2021. Therapeutic measures were taken as a result of the events and included numerous scans, blood tests and levetiracetam. The vaccination facility type was hospital. The outcome of the events were recovered with sequel.

<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>
1151447	3/31/2021	LA	52	F	3/16/2021	3/1/2021	feeling cold; running a fever 101.7; Headache; her muscles are seizing; she couldn't move her arms; muscles have gotten tired so she is a little sore; muscles have gotten tired so she is a little sore; seizures; This is a spontaneous report from a contactable consumer (patient) via Medical Information Team. A 52-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Lot number- EN6199) via an unspecified route of administration in left upper arm on 16Mar2021 at 15:10 (at the age of 52-years-old) at a single dose for covid-19 immunization. Relevant medical history included typical soreness. She says her son has sensitivity to vaccines. But she only ever has like typical soreness and stuff but normally she goes through fine. She went through the first dose of the vaccine fine. Patient's concomitant medications were not reported. Patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Lot number: EN6200) administered on an unspecified date via an unspecified route. No prior vaccinations within 4 weeks were received. Patient reported that she had the second one yesterday and she is having some symptoms. It started with a headache, then running a fever of 101.7 on 17Mar2021. The things she is concerned about and she has been making all these calls about this morning is her muscles are seizing, like her whole body, down her back and derriere and her legs seize up and become like a board, it does not hurt but after a while she guesses her muscles have gotten tired so she is a little sore but it is not like a horse, her muscles just seize up, she couldn't move her arms on 17Mar2021. Its happened several times. She wanted to report it and make sure this is within the norm or if she should be going further with it. The headache started during the night, she says it was after midnight so 17Mar2021. It is ongoing but much less. Last night it was horrible, she confirms ongoing but improved. Her fever is ongoing at this time it is going up. Started out at 100.6 now it is 101.7, that also began 17Mar2021. It is getting worse. Her seizing muscles she noticed that at about 1 AM this morning so 17Mar2021 as well. It is ongoing but seems to be lessened. There is more time in between them. It was every hour but right now it is happening every 2-2.5 hours so it is improving. Patient stated that

<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>
							during the night/early this morning patient began experiencing feeling cold, seizures (undiagnosed. Muscle involvement), She explains seizures as not brain related, neck down to my leg, Tighten up. Hold for 10-15 seconds. Flatten out like a board, then it'll go away. Vaccination Facility Type was Hospital. No history of all previous immunization with the Pfizer vaccine. Additional Vaccines Administered on same date of the Pfizer Suspect was none. Adverse events do not require a visit to Emergency Room or Physician Office. The outcome of the events seizure, feeling cold, myalgia, muscle discomfort and limb discomfort were unknown, while for headache and muscle disorder was recovering and for fever was not recovered.
1151485	3/31/2021	AL	36	M	3/24/2021	3/25/2021	Patient experienced a tonic clonic seizure less than 24 hours after receiving vaccine. He has a history of epilepsy which is well controlled and no seizure activity in over a year. Seizure started at approximately 10:00am and lasted 5 minutes or so... Pulse and breathing were lost for 2 minutes while CPR was started. EMT arrived and did a full work up. Patient woke up and was in a postictal state for an hour or so. ECG, BP, pulse, were all fine when patient was released from EMTs care to wife to go home.
1151494	3/31/2021	MO	22	M	3/31/2021	3/31/2021	1124 End of 15 minute observation period. Per witness, attempted to stand and fell forward onto floor. Seizure noted for one minute, responded to name and answered questions appropriately. Stated he "felt dizzy". Vital signs 118/60, 99%, 54. Blood glucose 97. Physician Assistant, present. Questions answered. 1131 Attempted to stand patient up again with assistance/supported X2. Stated he "felt dizzy again and blurry vision". Fainted while supported X2. Positioned on left side and immediately responded. Positioned supine. 1133 Vital signs 110/60, 96%, 72. 1142 Sitting up awaiting EMS, answers questions appropriately.. EMS present 1145 Vital signs 128/76, 100%, 72.
1151559	3/31/2021	TN	33	F	3/31/2021	3/31/2021	Grand mal seizure for 30 seconds occurring 20-30 minutes post-vaccine. No history of seizures in past.

<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>
1151585	3/31/2021	IN	64	F	3/29/2021	3/30/2021	Patient called stating she had her 2nd Moderna vaccine on 03-29-2021. She was recently diagnosed with Focal Sensory Seizures. She states that she started having seizures last evening and continues to have them today. Pt states she can not get her physician on the phone even after numerous tries. I advised to have someone other than herself drive her to the emergency room.
1151894	3/31/2021	MD	25	F	1/12/2021	1/22/2021	For 36 hours after the vaccine she had a low grade fever and chills. She also had fatigue and body aches that lingered for several days. 10 days after the vaccine she had an episode of partial loss of consciousness that was later diagnosed as a seizure and she has had 2 subsequent seizures and has now been diagnosed with epilepsy.
1152016	3/31/2021	LA	92	F	3/18/2021	3/29/2021	On 3/29/21, resident laying in bed and began on convulse . Sent out to ER and DX with new onset seizure disorder,
1152096	3/31/2021	MI	25	F	3/28/2021	3/31/2021	Focal aware seizure. 2 minutes long, left arm trearming. 10 minutes later a 5 minute long seizure with the same symptoms. Patient had been stable and seizure free on her meds for 6 months before receiving the vaccine.
1151129	3/31/2021		19	M	3/31/2021	3/31/2021	Pt had a seizure at 9:10 that lasted about 10 seconds. Pt.'s upper body stiffened and he turned pale. After the seizure pt. reported hx of seizures after vaccines that was not reported to the vaccinator. Pt was observed for an additional 30 minutes and left the observation area.
1154639	3/31/2021	MI	38	M	3/27/2021	3/27/2021	Patient began having seizures about four hours post vaccine while at a friends house and passed away
1152456	3/31/2021	OH	19	F	3/31/2021	3/31/2021	A few minutes after the vaccine was administered, the patient appeared to have a seizure for a few seconds. Her eyes rolled back, stiff arm, and she urinated herself. Her mom was holding her hand and after a few seconds, she was able to talk and said that she thought that she fell asleep for a few seconds. We called an ambulance and they are taking her to the hospital for a CT scan.

<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>
1146288	3/30/2021	MI	82	F	3/24/2021	3/24/2021	Vaccine administered at 1816. Patient walked to the observation area and while in the observation area, got up to use the restroom. Patient exited the restroom and said she needed assistance. She indicated to the observation nurse that "this ain't good" or "this ain't right". Patient reported seeing spots and having chest pain. The time was approximately 1830. She was assisted to the floor. Help was summoned and 911 called at approximately 1834. Upon being lowered to the floor patient was breathing, she was not cyanotic, her eyes were open and she was not responsive. The patient had a pulse. Sometime after 1830, but before 1835, the patient was observed to have seizure like activity as bilateral
1146614	3/30/2021	NY	44	F	3/21/2021	3/21/2021	I started having normal side effects such as sore arm, extreme tiredness and headache within 2 hours. By later that night I was in a daze-like state, had a lot of forgetfulness and lived life but as if I was sleepwalking and started having seizures over the next few days. A week later I'm still having seizures, have no recollection of anything starting from the night of the day I got vaccinated
1148462	3/30/2021	MD	36	M	3/17/2021	3/18/2021	The day after the 2nd dose of COVID19 vaccination series this person had a seizure while at work. EMS was called and he had another seizure for them before they could transport him to the hospital. He also had a fever 38.6. The individual was admitted and overnight became increasingly agitated and confused. Family reports that that after discharge from the hospital he has not returned to his normal functioning. Prior to this episode he was living alone and working. Now he cannot be left alone as his neurological status has quite deteriorated. He has had a ?substantial disruption of the ability to conduct normal life functions? Family have had to take time off of work and make arrangements to care for him.
1148480	3/30/2021	NY	37	F	3/22/2021	3/22/2021	Rash and broken blood vessels across shoulders High fever (103.5) Seizures Difficulty breathing Headache Fatigue Dizziness

<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>
1148563	3/30/2021	MI	50	F	3/29/2021	3/29/2021	3/29/2021 ERS Report: from Vaccination Clinic: Patient reported symptoms: Per ERS report: "Pt was walking to car after receiving her COVID-19 vaccine and a syncopal episode. Pt then had seizure like activity for approximately 1 min. Family states that she does have "stress seizures but is not on any anticonvulsants." Vital signs and blood sugar were assessed by onsite paramedic (AMR) and were within normal limits. Pt was then transported to hospital for further care." ED visit after Covid Vaccine 3/29/2021: HISTORY OF PRESENT ILLNESS: a 50 y.o. female who presents to the emergency department with history of bipolar and multiple psychiatric conditions including bipolar disorder. She presents today with episodes of ?seizure? and the desire to not speak to anybody. She has not been speaking to her husband since Friday and today while she was on the way out from getting a COVID vaccine fell to the floor and having shaking convulsing like episode. Husband states it lasted for 1 minutes and then resolved. He states that she has been unwilling to talk to him or medical staff and he does not know what is going on. He does affirm that she has been complaining about abdominal pain for the last 3 days and they did go to the hospital and have this worked up. He states that she has no known history of seizures and is not on any medications for this. CT head normal. Drug screen normal. Discharged to home.
1148879	3/30/2021	NC	18	F	3/30/2021	3/30/2021	patient lost consciousness, possible seizure following vaccination
1148362	3/30/2021		59	F	3/27/2021	3/27/2021	Severe headache starting 10 hours after the vaccine associated with nausea, vomiting, incontinence. Denied LOC/seizure like activity. Was monitored during the entire time by her husband.
1146342	3/30/2021	IL	54	F	3/26/2021	3/26/2021	Received second vaccine dose. Lay on cot and began to have a seizure. Vitals obtained and rolled on side. EMS called. Complained of headache dizziness fatigue after woke from first seizure. Then had another seizure.
1148274	3/30/2021	DC	62	M	3/30/2021	3/30/2021	Patient received 1st dose of Moderna Covid-19 and patient had a seizure while waiting in the waiting area.

<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>
1146270	3/30/2021	MA	28	M	3/29/2021	3/29/2021	Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe, Additional Details: Patient fell out of chair. Regain consciousness, fluttering eyes. Heart rate 35 , O2 was 98. Heart rate went up to 51 once paramedics arrived. O2 remained 95-98. Patient was brought to hospital by EMS.
1146246	3/30/2021	PA	66	M	3/25/2021	3/25/2021	I received the second vaccine injection, and in about an hour felt a little warm and clammy, I was having some joint and muscle pain, and stomach upset. I had no appetite and did not eat lunch. At supper I still did not want anything, so ate cereal instead. During the night I was restless, and expelled quite a bit of gas throughout the night. Stomach still uneasy. When I awoke, about 6:00 AM, I was hungry and attempted to pour a bowl of cereal but could not due to shaking. My wife found me in the middle of a grand mal seizure and called the ambulance. The ambulance, police, and fire company all responded. They provided medical care onsite and in route to Hospital. I had a fever of 102 degrees, had been biting my tongue raw, flailing arm and hyperventilating. I was somewhat disoriented and delusional. During my hospitalization the injection site was found to be very swollen and red. Ice was applied. An MRI was performed of the head and found to be normal. Several other blood tests were also completed. I remained inpatient from 3/25/21 through 3/21/21.

<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>
1146198	3/30/2021	IL	22	M	3/29/2021	3/29/2021	Pt received the first of the two-series COVID vaccination at 1512. Once in observation area, pt became unresponsive shortly after sitting down. This provider was called over by staff to pt, which was noted to have become unresponsive while sitting in the chair. Pt remained in the chair, did not fall or injure self. Upon arrival to patient, he was noted to have severe diaphoresis, prominent pallor, with shallow, slow breathing, no cyanosis noted. His head initially fell back and head was aligned/adjusted to maintain an open airway. This provider was speaking to the pt and performed a sternal rub to elicit a response, pt remained unresponsive and with eyes closed. Pt remained in this state for approximately 10 seconds. Pt noted to suddenly have some muscular rigidity to arms and torso and in order to prevent injury upon possible onset of seizure activity, pt was lowered to the floor by this provider and RN . Once on the ground the pt was relaxed and opened his eyes. Pt was immediately verbally responsive and asked if he passed out. Pt was able to sit up and was assisted into the wheelchair. Pt moved to treatment area where vitals and blood glucose were obtained. (@1525 BG- 104 mg/dL, VS BP 116/72, HR bradycardic @51 bpm, O2 sat 95%). Patient responses/speech was clear and pt was oriented to self, place, time and situation. Pt stated that he felt nauseated upon sitting in the observation area and admitted that he only had a coffee today, nothing to eat all day and attributed this as the cause of his reaction. Pt verbalized that he would not respond to the hospital with the paramedics and was encouraged to at least call someone to take him to the hospital. This provider spoke with the patient's mother and explained the events. The patient's mother stated that the patient had febrile seizures when approximately 4 years old, associated with asthma exacerbations; but pt was evaluated with a neurologist and there were no abnormal findings. Pt admitted that he has a similar syncopal episode after washing a laceration and seeing his finger bleeding. Pt states this was a few years ago and witnessed by his father that told the patient he initially fainted and then became momentarily rigid before responding appropriately (similar to today's events). Ambulance - arrival @1536 report given and pt stated he was feeling better and declined further evaluation in truck and also declined transport to ED (departed at 1545).

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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Pt's overall condition, appearance, including color was much improved. Pt denied any allergies or medication history. Past medical hx of febrile seizures at approximately age three and four, childhood asthma and one syncopal episode as an adult. Pt girlfriend arrival and she agreed to drive patient from the vaccine clinic. Pt and girlfriend were both provided with an explanation of the many concerning causes of syncope and the necessity for further evaluation in the Emergency department to rule out any underlying conditions. Both patient and girlfriend verbalized understanding and although they still declined to respond to ED directly from the clinic, both did agree to respond to ED if any changes in mental status occurred. Pt lives alone, but agreed to stay with parents and family in order to have others watch him for any changes. Pt was advised to followup with PCP and made aware that an provider would contact him tomorrow to check on his status, understanding verbalized and agreed with plan of care. Pt in no acute distress, awake, alert and oriented. Color within normal limits for and departed facility with girlfriend at 15:56, steady gait noted. Patient's appointment for second dose was cancelled and will need to obtain clearance prior to second vaccine dose.

<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>
1145729	3/30/2021	AR		M	3/9/2021	3/9/2021	This spontaneous report received from a consumer concerned a male of unspecified age. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included patient is not on any medication and has no known drug allergy. The patient received COVID-19 vaccine AD26.COV2.2 (suspension for injection, route of admin not reported, batch number: 1805020, and batch number: 1805020 expiry: UNKNOWN) dose was not reported, administered on 09-MAR-2021. No concomitant medications were reported. Patient got the Janssen COVID shot on March 9th Tuesday and then experienced headache started same day and Wednesday 10th March, took TYLENOL and headache recovered, then seizure on 11th Mar, went to the ER and spoke to the doctor on reporting day. Consumer also started patient experiencing rash and extreme pain on both arms and hands on reporting day 12th Mar and getting worse. On 09-MAR-2021, the subject experienced headache Treatment medications (dates unspecified) included: paracetamol. The action taken with COVID-19 vaccine AD26.COV2.S was not applicable. The patient recovered from seizure, and headache, and had not recovered from rash on arms and hands, and extreme pain in both hands and arms. This report was serious (Other Medically Important Condition).
1146345	3/30/2021	CA	16	M	3/29/2021	3/29/2021	Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Seizure-Medium
1148014	3/30/2021	OH	30	F	3/26/2021	3/26/2021	Pt was seen falling forward out of chair to the floor with hands shaking . Patient did not remember what happened but stated that she has a history of seizures and fainting after injections. Patient received an ice pack for her lip and no other treatments. EMS was called and patient was taken to hospital.
1147266	3/30/2021	OH	66	M	3/11/2021	3/11/2021	Mouth began to quiver/drool; was able to walk inside from outdoors; had been happening about 2 =3 minutes before I realized what was happening. Was standing so had him continue to do so while I held onto him to let the event pass. Recovered within 5 minutes with no adverse affects. Has been 1.5 years since any previous seizures so wanted to report this for fyi.

<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>
1147367	3/30/2021	NY	48	M	3/27/2021	3/27/2021	About 8 hours after receiving the vaccine I began to develop a fever. I understand that fever, muscle aches and head aches are possible side effects of vaccinations in general and this one in particular. Since I had tested positive for antibodies for the third time just two weeks prior to receiving this first dose of Moderna I was anticipating some reactions similar to what I have heard people experiencing for their second shot. What followed the initial onset of fever was the worst flu symptoms I have ever experienced in my 48 years. Fever continued to increase reaching 103 if not higher at times and staying elevated at level for over 6 hours. Chills to the point of convulsions. Nausea and one time vomiting. Fever dreams (mild hallucinations), profuse sweating, intense head aches. Muscle aches I could barely tolerate that I felt over every inch of my body. This continued until 10am the following morning when I took some advil and finally fell asleep to the point of being virtually unwakeable until 2:30pm. Upon waking I was able to sit up and drink water but the muscle soreness and slight fever continued throughout the day (101 fever). I was able to eat some toast that evening. That night the fever returned but not as high as the previous night. The sweating was still profuse throughout the night and the muscle aches continued but to a lessor degree. The following day the fever subsided though muscle soreness continued. That evening I was able to sleep regularly and now today (three full days after vaccination) I am roughly back to myself. I understand that reading this seems as if these symptoms fall in line with what is expected and understand to be the side effects of the vaccine. I am here today to tell you that I thought I was dying. I have never, ever felt so terrible ever. It was ten times worse than having covid. I cannot imagine anyone who is not healthy and string making through that and I can not believe I am expected to do it again to complete my vaccination.

<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>
1147548	3/30/2021	CA	26	F	3/30/2021	3/30/2021	Patient became dizzy approximately 10 minutes after vaccine. She had a syncopic episode accompanied by seizure like activity that lasted about 10 seconds. Once she regained consciousness, she was disoriented for about 1 minute. Within 3 minutes of regaining consciousness she had nausea and subsequent vomiting X2. HR 63, BP 117/70, O2 SAT 96% on room air. Zofran 4mg SL was administered. Patient evaluated by the Mass Vax Site physician. Patient recovered quickly, refused further medical treatment and was accompanied home by her mother who was with her during the event.
1147631	3/30/2021	OH	39	M	3/30/2021	3/30/2021	Patient presented on 3/30/21 for his first COVID vaccine appointment. Patient checked in at the pharmacy and came back to the clinic location. During the screening process, the patient did state he has an issue with needles in the past. Patient was with his wife who confirmed that it has never been due to the medication but just a fear of needles. Patient gets lightheaded. After giving the vaccine, the patient was fine at first but then did state he wasn't feeling well. The wife, came and held his hands and I was holding his back and head. Patient did tense up and shook once (not a seizure) and did lose consciousness for about 10 seconds. Had a tech call a code white and store management did come. Patient came back to and seemed fine. He had a Gatorade and drank that and also a bottle of water. Patient started to feel a little better but had a second minor episode (did not seem to lose consciousness). We also got a cold pack and placed on patient's head/neck. He ultimately took about 45 mins to an hour post dose and was able to leave under his own power. Patient and wife appreciative of efforts.

<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>
1147699	3/30/2021	CA	72	F	3/3/2021	3/3/2021	mini stroke or seizure; mini stroke or seizure; pinched nerve; left arm was weak, numb, cold; left arm was weak, numb, cold; left arm was weak, numb, cold; a fine tremor on extension of my arm; This is a spontaneous report from a contactable other hcp (nurse and patient). A 72-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 03Mar2021 14:45 (Batch/Lot Number: EN6198) as SINGLE DOSE (at the age of 72 years) for covid-19 immunisation. Medical history included partial seizures, autoimmune thyroiditis, eczema, osteoarthritis, asthma, irritable bowel syndrome, carpal tunnel syndrome from an unknown date and unknown if ongoing 10 years ago. The patient is not pregnant, and the patient did not have Covid prior vaccination. Concomitant medication included phenytoin (DILANTIN) taken for seizure, start and stop date were not reported; levothyroxine sodium (SYNTHROID); ergocalciferol (VIT D) and unspecified vitamin. The patient previously took amoxicillin and experienced drug hypersensitivity, erythromycin and experienced drug hypersensitivity, azithromycin and experienced drug hypersensitivity. The patient experienced mini stroke or seizure on an unspecified date with outcome of unknown, left arm was weak, numb, cold and a fine tremor on extension of arm on 03Mar2021 14:45 with outcome of recovered. On 06Mar2021, patient woke up and left arm was weak, numb, cold and she had a fine tremor on extension of arm. Symptoms resolved after 45 minutes but returned within 30 minutes and lasted another 45 minutes. No treatment was received for left arm was weak, numb, cold and she had a fine tremor on extension of arm. Patient called doctor, spoke to the advice nurse and was advised to go to the ER (emergency room) now. Patient did deep breathing and relaxation, symptoms resolved, and did not go to the ER. Instead spoke with a doctor and agreed to go to the ER if symptoms returned. Patient also had a video visit with primary doctor, and she was advised to take baby ASA. The Doctor said it could be a pinched nerve on unspecified date with outcome of unknown. Symptoms have not returned. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 08Mar2021. The case was reported as non-serious.; Sender's Comments: Based on

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							the information provided by the reporter, it appears unlikely that subject vaccine contributed to the CVA and other events. The reported events likely represent intercurrent medical conditions. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including Head CT/MRI, EEG, 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.
1147767	3/30/2021	GA	30	M	3/30/2021	3/30/2021	Client reported that he consumed a marijuana edible prior to coming to the vaccination site. Client received the vaccine and then stated he felt like he was going to faint, he appeared to be post-ictal and was unconscious for approx 30 seconds. Client regained consciousness and was given Gatorade. Client stated he has a history of seizures and marijuana use.
1148430	3/30/2021		33	M	3/30/2021	3/30/2021	Patient fell backwards from urinal in men's bathroom. Hit his head and suffered a seizure. Ambulance was called. Witness to the incident.

<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>
1147947	3/30/2021	WA	40	F	3/29/2021	3/29/2021	She was given her 2nd dose for the Pfizer covid vaccine. As she was waiting her allotted time in the waiting room she became lightheaded and felt like she might pass out. She became nauseated and was sweaty. A nurse was present getting her 2nd dose and helped to care for her until the fire dept came and took over. She lay on the ground with her feet up until the FD arrived. Listening to her interview by the fire dept, it was discovered that she normally suffers from epilepsy and probably had a small seizure. She wasn't able to remember everything but she was coherent and able to answer most other questions. Her blood pressure was elevated and slowly came down as they monitored her. Her boyfriend and son were also present and the fire dept released her to their care after seeing her blood pressure come down closer to normal and seeing her able to stand and walk.
1148019	3/30/2021	CA	25	M	3/30/2021	3/30/2021	I administered the vaccine to Jake and he sat down. About two minutes later, he slumped in his chair. My manager rushed to catch him from falling and I assisted in steadying him. He was breathing erratically, excessively diaphoretic, and his muscles were twitching frequently. His eyes were dilated and he became unresponsive. Fearing a seizure, we lowered him to the floor and turned him on his side. He became responsive and coherent again approximately one minute later and was speaking to us normally. Paramedics arrived several minutes later and took over care. He was taken to the hospital due to abnormal vital signs.
1148079	3/30/2021	MO	45	F	3/29/2021	3/29/2021	PATIENT RECEIVED VACCINE AT 1410. PATIENT STATED THAT SHE FELT DIZZY. PATIENT BEGAN SLURRING HER WORDS AND HER EYES BEGAN FLUTTERING. WHILE NURSE WAS EVALUATING HER SYMPTOMS. EMS WAS CALLED AT 1420 AND PATIENT WAS TRANSFERRED TO HOSPITAL VIA AMBULANCE. RECEIVED A CALL FROM A FAMILY MEMBER TO REPORT THAT SHE WAS EVALUATED IN THE ER. THEY PERFORMED LABS AND A CT. ACCORDING TO THE FAMILY MEMBER, EVERYTHING CAME BACK NORMAL AND THAT SHE HAD A SEIZURE DUE TO HER EPILEPSY. PATIENT WAS RELEASED FROM THE ER TO HER HOME.

<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>
1148095	3/30/2021		69	M	3/30/2021	3/30/2021	Patient. Experienced 2 seizures laying 15 seconds each. Patient has no medical history or taking any medical medications.
1148112	3/30/2021	CA	26	M	3/19/2021	3/19/2021	PATIENT HAD A SEIZURE FOR 2 TO 3 MINUTES THE EVENING OF HIS APPOINTMENT (HIS WIFE WITNESSED). HE HAS NO HISTORY OF SEIZURES. HE IS GETTING SEVERE HEADACHES STARTING FROM THE TIME HE HAD THE SEIZURE AND THEY HAVE CONTINUED FOR NOW ALMOST TWO WEEKS WITH NO IMPROVEMENT.
1148150	3/30/2021	RI	65	F	3/25/2021	3/26/2021	I had seizures as a child but was not diagnosed. In 2018, I had two seizures, but was diagnosed and have been on 100mg zonisamide for 2.5 years with no episodes. In 2014, I had a bad fever during an infection, and may have seized while sleeping. Not sure. In my adult life, I have received annual flu shots every year, and twice developed fevers as a side effect. After Moderna #2, I woke at 1:30am at my apartment with chills and fever. Took 2 acetaminophen and used the bathroom. I seized before I could take my temp. Upon reviving, I noted that about 15 minutes had elapsed since I first woke, so this seizure lasted under 10 minutes. I had a bruise on the back of my head, and later developed some bruising on the front of my thigh from the fall. I followed the protocol that my neurologist has established for me: called my sister for a ride to ER for evaluation. After several tests, I was released to my sister's care. Precautions we took for the next 24 hrs at sister's home: take temp every 2-3 hours to watch for fever, take acetaminophen every 6 hours. I'm fine now.
1147830	3/30/2021	CA	31	M	3/30/2021	3/30/2021	At approximately 1238 patient was noted to be on floor, experienced fall from chair. 911 called. came to patient. Pt placed in recumbent position. noted to be having seizure regained consciousness. Airway not obstructed no s/s if respiratory distress noted. Regain consciousness after 2 seconds. Vs bp130/82, O298% on RA, HR 72, RR 28. Denies pain or discomfort. Pt alert and oriented able to state his name date location. Mae x34 I neurologically intact. did not give Epi. No s/s of anaphylaxis noted. please patient and become a position. Ambulance and fire department on site at this time.

<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>
1143662	3/29/2021	VA	27	F	3/29/2021	3/29/2021	Patient appeared warm and RN asked her to consider taking her jacket off. Patient suddenly fell forward and appeared unresponsive; two nurses eased pt down to the floor. Within a few seconds, pt began having tonic clonic seizure and promptly turned onto her right side. EMS, came to pt's side. First seizure lasting 56 seconds; IV access to right AC secured. 2 min postictal/rest followed by 15 second seizure and 5 mg Versed infused to right AC access. Roughly a 60 second postictal/rest followed by 15 second seizure; more paramedics at site at this point. During this time, very little oral secretions, lungs clear, pulse 102; unable to obtain BP. 10 sec seizure began with postictal/rest. Pt remained on right side approx 2 minutes followed by an 8 second seizure. Paramedic directed another 2.5 mg versed. Within approx 60 seconds pt had sixth seizure lasting 31 seconds. Pt placed on stretcher and transferred to care of EMS.
1146011	3/29/2021	CA	30	F	3/29/2021	3/29/2021	Patient got seizure about 5 minutes after received injection. First seizure lasted less than a minute, and 2nd seizure happened about 5 minutes later lasted about 10 seconds. Paramedics arrived and take patient to local hospital.
1145090	3/29/2021	CO	59	F	3/24/2021	3/25/2021	I felt crummy all day. I had a fever of 101.7 Stayed in bed all day. I wound up having a seizure, and going to the emergency room at the hospital. I had EKG, blood work done and fluid.

<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>
1146065	3/29/2021	AZ	25	M	3/29/2021	3/29/2021	Patient had just finished receiving his covid-19 vaccination from vaccinator. At the time of patients fainting I was mixing up covid-19 vaccinations when the technicians said we need you to come out here because a patient is having a seizure. When arriving on the scene I found patient unconscious on the floor face down, while assessing the scene I noticed some blood on floor. I tried to look for any trauma, patient was breathing and I tried to awaken him. I told someone to call 911 and contact a store manager. Then all of a sudden he popped up and sat up like nothing happened. I then noticed the bruising on his nose and asked for an ice pack and a bottle of water. Patient knew his name, was coherent, and seemed to be fine. I stayed with patient until paramedics arrived. Paramedics did a thorough examination and everything checked out. Patient waited for parents to arrive instead of going with paramedics. Vaccinator stayed with patient till his parents arrived.
1144691	3/29/2021	OH	16	F	3/29/2021	3/29/2021	Approximately 15 minutes following vaccination, the patient complained of headache, dizziness, chest pain and throat burning. I asked that she wait an additional 15 minutes so that we could monitor her. Approximately 30 minutes after vaccination, patient appeared to experience syncope or absence seizure (prev. history). we called 911 and paramedics transported her to hospital
1144772	3/29/2021	KY	35	F	3/4/2021	3/4/2021	Patient's husband states pt's seizures have gotten worse since receiving second covid vaccine on 3/4/21. Directly after receiving vaccine pt had seizure and has been having two to four seizures a day since then. Husband also stated seizures changed to where her right side draws up and pt is unable to communicate. Seizure lasts 3-5 minutes and post stage can last up to 30 minutes. Pt states she feels cloudy and that feeling has never went fully away. Pt states she can normally hear what is going on while she is having the seizure but the one she had this morning she could not remember and could not hear during it. Pt had seizure upon arrival to room that lasted 4 minutes with post stage lasting 15 minutes.
1144798	3/29/2021	NE	79	F	3/3/2021	3/28/2021	~~Moderna EUA Requirement" Patient hospitalized for decreased responsiveness and vomiting x2days. Has had approximately a week or so of decline with increase seizures. Acute exacerbation of CHF

<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>
1144895	3/29/2021	MI	25	F	3/29/2021	3/29/2021	Pt at 1014 called RN observer over and stated that she felt like she was going to have a seizure. Pt explained that she has Focal Aware seizures and only has L arm tremors. Pt's L arm was trembling Pt had seizure from 1015-1016. Pt was moved to triage and VS @1019 were 98.6, Hr 93, RR 20, BP 110/76, and sao2 of 98%. Pt was feeling nauseated at 1023 and self medicated with Zofran 8mg po. Pt called FM to come pick her up. Pt C/O headache and felt another seizure starting and took Ativan 1mg po @ 1039. VS at 1043 were 99.6, Hr 92, RR 20, BP 134/92, and sao2 99%. Pt had another seizure @1044 with L arm tremors lasting 1 min. Rapid response team called. Pt transported to ER at 1053
1145016	3/29/2021	KY	18	F	3/6/2021	3/8/2021	48 hours after the vaccine, patient had a drop in glucose down to 40 which triggered grand mal seizure. Admitted to the hospital for 2 days, thought it was possibly due to UTI, however because of how soon it was to the vaccine I wanted to report it just in case it were linked.
1144682	3/29/2021	TX	18	F	3/29/2021	3/29/2021	Two minutes after the vaccine was given, my daughter started to have a seizure.
1145046	3/29/2021	CA	15	M	3/23/2021	3/24/2021	About 10-12 hours after receiving the vaccine, patient had a significant increase in seizures - had seizure clusters (never had them previously). Patient had to be admitted to the hospital. Received rescue anti-seizure medication en-route via EMS, then additional Levetiracetam Bolus after arriving to the ER and subsequently additional dose of IV lacosamide following admission. seizures returned to baseline frequency about 3 days later.
1144677	3/29/2021	AZ	38	M	3/29/2021	3/29/2021	Patient became lightheaded and dizzy. Patient was placed in seated position on floor and passed out. Mild muscle spasm/seizure like activity and pharyngeal gurgling. Patient was unresponsive for approximately 2 minutes and regained consciousness without intervention. EMS was called and attended to patient. Sinus rhythm normal, blood pressure 140/82. Patient placed into an upright seated position, blood pressure remain unchanged. Patient declined transport to hospital, was observed for several minutes and released on his own volition.

<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>
1145121	3/29/2021	OH	25	F	3/29/2021	3/29/2021	Approximately 4 minutes after receiving the vaccine patient appeared to have a absent seizure. We immediately contacted 911. Patient seem to become coherent shortly after. She remained diaphoretic. EMS arrived and further evaluated patent. Spoke to patient at 3:00 pm and she was home doing fine.
1145195	3/29/2021	AL	60	F	3/29/2021	3/29/2021	Patient experienced a seizure after vaccine administration.
1145344	3/29/2021	PA	27	M	3/29/2021	3/29/2021	Immediately after administration of the vaccine, the patient fell onto the ground and experienced tonic clinic seizure activity for approximately one minute and 30 seconds, including eyes rolling to the back of head and jerking motions of all extremities. Patient was taken to hospital via EMS.
1145437	3/29/2021	CO	70	M	3/27/2021	3/27/2021	got chills bad and later in the night felt like was have a sever seizure with the shaking, I was so cold had to put 2 extra blankets on me. also had a hard time getting a full breath. On Sunday when i got up and then had something to eat then went back to bed till 4 pm. Have been drink plenty of water. I still feel light headed on Monday at 2:30 pm.
1145605	3/29/2021	CA	19	F	3/29/2021	3/29/2021	Client was in observation post vaccination. Had seizure and lost consciousness. Not responsive for a few seconds. Regain consciousness and was transported to Hospital via ambulance.
1145831	3/29/2021	WA	24	F	3/20/2021	3/20/2021	Grand mal seizure 23 minutes after receiving 1st dose of vaccine. Managed by parents. (Error on date. It was given on 3/21/21 not 3/20/21. Typo)
1145029	3/29/2021	IL	48	F	3/25/2021	3/25/2021	3 hrs. after my injection I suffered a grand mal seizure. I have a history of seizures but have not had one in 3 years. I was not breathing for 1 minute, hands and face were blue. Unconscious for over 20 minutes. Rushed to ER was given an IV of anti seizure medication.
1144317	3/29/2021	MT	47	M	3/24/2021	3/24/2021	Patient called into clinic to report about two hours after receiving vaccine he passed out and the person that was with him said he had a seizure. Patient reported feeling fine after about an hour, but was very tired and had a headache.

<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>
1145984	3/29/2021	CA	19	M	3/29/2021	3/29/2021	Patient had syncopal episode, possible seizure for 10 seconds. Patient reported by bystander to have hit the back of his head. Blood pressure 148/85, O2 saturation 97%, HR, 103, blood glucose 101 mg/dl. Patient described the event as he "blacked out". Patient c/o thirst. Patient has no complaints of tenderness or pain in back of head. Patient transported to hospital for further evaluation.
1143767	3/29/2021	AZ	31	F	3/27/2021	3/28/2021	I passed out and had convulsions while sitting in a chair at a nail salon. During this event I peed myself. Prior to the event I had some minor body aches, but no fever. Following the event I returned home and began running a fever of 100.5.
1143868	3/29/2021	UT	48	F	3/28/2021	3/28/2021	Seizure, administered patient's own diazepam once able to swallow, husband was familiar with how to care for wife when she has seizures. Aprox 15 min after seizure onset, patient walked with husband to car to go home.
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
1143929	3/29/2021	MN	69	F	2/26/2021	3/23/2021	Patient states that she had numbness in both feet and legs. Several days later these symptoms were getting worse and she went into a seizure, lost control of her use of her legs, arms and her bladder. She called 911 and transported to y Hospital ER. She had MRI w/ negative results and was given fluids. She was released to go home. Pt has appt w PCP and will discuss her symptoms w/ them. Pt is still weak, has fatigue but can use her arms and legs. She is not able to do normal activities. She had her 2nd Covid dose on 3/26/21 @ 9:20 am in her right arm.

<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>
1146036	3/29/2021	CA	76	M	2/17/2021	2/20/2021	2/17 received 1st dose vaccine, Pfizer 2/20-3/9 admitted. Found to have seizures (twitching of upper extremities, aphasia). 2/24 RML pneumonia. Found to have MSSA bacteremia and bacteriuria. Transition from vanco/pip-tazo to cefazolin Mental status improved and he was sent on cefazolin which he was to complete on 3/26/21. Was not sent out on seizure prophylaxis. 3/23 second dose Moderna. Had recurrent seizure on 3/27. Evidence of post central stroke. Expressive and receptive aphasia.
1144215	3/29/2021	MO	61	M	3/26/2021	3/27/2021	UNKNOWN VACCINATION LOCATION. ADMITTED TO CENTER THE DAY AFTER HIS 2ND SHOT FOR CONFUSION, MENTAL STATUS CHANGES, SYNCOPE VS SEIZURE ACTIVITY, LOSS OF CONSCIOUSNESS. NEURO CONSULTED AND THOUGHT POSSIBLE ADVERSE REACTION TO COVID VACCINE #2 AS NO OTHER REASON HAS BEEN FOUND WITH LABS, IMAGING, ETC. NEURO CALLING IT A 2 HOUR FUGUE EVENT.
1143384	3/29/2021	MN	34	F	3/24/2021	3/24/2021	Patient s a 34 y.o. female with PMH of seizure, general anxiety disorder, spells undifferentiated presents to the emergency department chief complaint syncope. Patient reports she received her 1st COVID vaccine shot approximately 1000 hours this morning. Shortly after she started feeling nauseous, reports waking up and seeing EMS and staff standing above her. At the time of ED arrival she reports feeling anxious is requesting her husband and support dog be allowed in the room with her.
1144490	3/29/2021	TX	21	M	3/18/2021	3/18/2021	Patient complained of dizzy spells, and fainted. He bit his tongue while experiencing a possible seizure. No prior history of seizure disorder. Parent was called right after the student experienced adverse reaction. Vital signs taken B/P 128/88, Pulse - 80, Pulse oximetry - 99 %, temperature was 97.4. Patient had not prior history of COVID-19, not taking any medications, no hypertension. Patient became alert 30 seconds afterwards.

<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>
1144495	3/29/2021	NJ	59	F	3/1/2021	3/26/2021	Pt called stating on 3-26-21. She woke up with 102 fever. Had been taking Tylenol since received vaccine Twice that night and continued the next day. Later that day puts husband who is an md said she experienced a seizure for about 10 seconds and wanted to report the adverse effect to someone. The patient did not go to er or md office. Did not call her regular md. She stated she was fine and had no other ill effects
1144560	3/29/2021	MO	68	F	3/8/2021	3/10/2021	passed out on way to bathroom; Maybe it was a seizure; Feeling weak; Fever of 103,Lowest the fever could get is 101; Diverticulitis attack; A spontaneous report was received from a consumer concerning a female patient of 68 years old, who received Moderna's COVID-19 vaccine(mRNA-1273) and experienced Diverticulitis attack, felt weak, passed out, seizure and Fever of 103. The patients medical history included sensitivity to medicines. No relevant Concomitant medications were reported. On 08 Mar 2021,prior to the onset of events, the patient received the first of two planned doses of mRNA-1273(Lot number: 011A21A) vaccine through unknown route for prophylaxis of COVID-19 infection. On 10 Mar 2021, at 1am, she woke up with a fever of 103. The highest was 103 and the lowest she could get it down to was 101. The patient passing out on way to bathroom at one point also and does not know how long she was out for. She believes she could have had a seizure. She also had a diverticulitis attack in this time period which she states being the worse attack and she felt pretty weak . Treatment for the event included Tylenol and used icepacks and was on a liquid diet. Action taken with the mRNA-1273 in response to the event was not provided. The fever resolved on 12 Mar 2021 while the diverticulitis attack and weakness resolved on 16 Mar 2021. The outcome were unknown for other 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.

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1144583	3/29/2021	CO	70	M	3/27/2021	3/27/2021	the night of the 29th got a head ache was very chilled. when I went to be I was so cold ,had to put 2 extra blanks on me to try and stay warm. had the sakes like i was having a seizure. finally went to sleep. woke up 4 time had to go pee. In the morning on Sunday I got up and had some breakfast then went bad to bed, slept till 4pm. felt much better. Today Monday still feel shaky and have headache, not much pep.
1144593	3/29/2021	WA	47	F	1/18/2021	1/28/2021	Headache; Seizure
1144623	3/29/2021	FL	18	F	3/29/2021	3/29/2021	At 1428, patient mother alerted medical staff, stating her daughter had a seizure. Upon arrival, daughter was sitting upright in passenger seat, mother holding her, eyes open, appearing pale. No convulsions , incontinence, or other seizure activity noted. EMS notified and arrived within a minute and evaluated patient. No medications or additional treatment given. Patient ambulated to EMS stretcher with one person assistance. Awake and talking. Patient transported via ambulance at 1437.

<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>
1144171	3/29/2021	CO	32	F	3/24/2021	3/24/2021	Patient was wheeled in on a rolling chair(no wheelchair available at time) from nurse that administered vaccine because of anxiety and a needle phobia that put the patient into a kind of shocked state. Patient was sweating profusely, white to the face, and not speaking very much but would answer questions correctly. EMT was speaking with the PT before walking away to continue other monitor duties when he turned back to see patient limp in chair, head back, eyes rolled back, and some twitching movements of the body. EMT called for rapid response because first thought of seizure and seizure like activity with the twitching movements. EMT got to patient, supported head up straight, and opened jaw to ensure airway was clear. Patient had no response to EMT trying to communicate. Sternum rub was performed where patient came back conscious nearly instantly. PT was unresponsive for roughly 10-15 seconds. Patient was told of what happened and vitals were taken on her, response team was cancelled with most them already on scene. PT was feeling better, sweating stopped, color to the face returned, and PT was speaking and understanding more clearly than before. PT was given a snack and water and was monitored by EMT for an additional 15mins before patient and staff were confident with her leaving.
1141985	3/28/2021	CA	42	M	3/28/2021	3/28/2021	Patient received the vaccination and after he got up from the chair, he passed out and fell to the floor. The intern notified the pharmacist. When I went to see that patient, he was laying on the floor with his eyes rolled in the back of his head and was unresponsive. He was not alert. He started having a mild seizure and I rolled him over on his left side. While I was bracing the patient, pharmacist came in and administered an Epi-pen to his left thigh. Patient stopped seizing so I rolled him back on his back. He became alert and was able to provide me his name, DOB and what he was at the pharmacy for. I rested my hand under his head and monitored his pulse until the paramedics arrived

<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>
1140685	3/28/2021	CT	69	F	3/8/2021	3/9/2021	<p>mild nausea; Syncope (2x) w/mild seizure; Syncope (2x) w/mild seizure; Flu-like symptoms; chills; joint/muscle pain; joint/muscle pain; injection site pain; headache; labored breathing; dry-heaving after second syncope; This is a spontaneous report from a contactable consumer (patient herself). A 69-year-old female patient, not pregnant, received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: LOT 6205 (as reported)), via an unspecified route of administration in the right arm, on 08Mar2021, at a single dose, for covid-19 immunization. The patient has no medical history and has no known allergies. Concomitant medications included sertraline; docusate sodium, ferrous fumarate (FERRO-SEQUELS); and multivitamin - all taken for unspecified indications, start and stop dates were not reported. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EN6201) on 15Feb2021 17:00 in the right arm for covid-19 immunization at 69-years-old. The patient did not have covid prior vaccination. The patient did not receive any other vaccines in four weeks. The vaccine was given at the public health clinic. The following day on 09Mar2021 15:30 after a short walk, the patient experienced flu-like symptoms, chills, joint/muscle pain, injection site pain, headache, syncope (2x) with mild seizure, labored breathing, and dry-heaving after second syncope. The patient was then taken by ambulance to the ER (resulted in an emergency room visit) and was given saline fluids via IV. The vitals and EKG were "ok" on 09Mar2021. The patient recovered relatively quickly and was released. The only symptoms remaining on 11Mar2021 were mild headache and mild nausea. The patient had not recovered from headache and nausea at the time of the report; while recovered outcomes on Mar2021 for all the other remaining adverse events. The patient was not covid-tested post-vaccination.</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>
1141161	3/28/2021	FL	53	F	3/26/2021	3/26/2021	Systemic: Seizure-Severe, Additional Details: around 5:30pm patient was sitting after her covid vaccine. patient fell face first to the ground and begin to have a seizure. 911 was called and patient was taken to the hospital. Before leaving patient's vitals were back to normal, but was taken to the hospital for obseravation. RPh, and ARNP were performing immunizations at the time.
1141148	3/28/2021	CT	51	F	3/27/2021	3/27/2021	Site: Pain at Injection Site-Mild, Systemic: Seizure-Medium, Additional Details: Patient sitting on chair post vaccine (waiting area) she reported (after seizure and fall) that she was feeling dizzy. She doesn't remember after that and was awake on the floor. Customer reported witnessing a seizure for 4-7 seconds BEFORE the fall. She has an abrasion on her left temple post fall. EMS called and patient refused to go to the ED. She said she would go with her friend.
1141462	3/28/2021	IN	49	M	3/25/2021	3/25/2021	Shivers that continued to get stronger almost to a convulsion . Body aches and fever. Body aches and fever lasted until 11 pm 3/26/21.
1141861	3/28/2021	NC	63	F	3/28/2021	3/28/2021	Patient received CoVID vaccine #1 in drive thru lane. Approx 10minutes after vaccine patient driver reported something was wrong with patient. When patient was assessed, it appeared she was having a seizure. Medical alert called. Driver stated patient had history of seizures, but was not a good historian of medical information. EMS transported patient to ED.

<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>
1142002	3/28/2021	CA	27	F	3/27/2021	3/27/2021	27 year old female comes in 3/27/21 at 4:15pm to get Pfizer COVID vaccine. She has no family doctor. On her VAR form she states no seizure or history of seizure but does have reaction to HPV vaccine where her throat swelled up and her MD had to give her oxygen year ago. I asked about any other reactions to any other vaccinations and she said no and was willing to get this vaccine. I told her to wait 30 minutes after vaccination to make sure no reaction. At 4:25pm her sister and mom tell us that patient is feeling weak and dizzy and ask for water, I go out and check and she is pale and is ready to faint. Mother asks for orange juice which she takes a sip. I ask her if she has any health conditions like diabetes, seizures and they say no, then patient has what looks like a petit mal (absence) seizure. While sitting in the chair her eyes flutter, roll back she tenses up and her body freezes for about 20-30 seconds. I tell staff to call 911 and her sister says she's having "another" seizure. We don't move her but make sure she doesn't fall, once the seizure passes we move her to the ground to lie down. She regains consciousness and is coherent but confused. I do not give EpiPen because I witnessed a seizure. The fire and ambulance arrive to assist her and then her family mentions she did have seizures years ago. After 20 minutes or around 4:50pm she feels better and does not want to go to the hospital and walks out assisted by fire/ambulance staff. The next day I call her and she says she feels better and just has a sore arm and will find new doctor check her out.
1142184	3/28/2021		19	F	3/28/2021	3/28/2021	Patient had a seizure, followed by syncope

<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>
1142599	3/28/2021	MA	84	M	3/10/2021	3/17/2021	Became febrile, poorly responsive. Taken to the MGH ED. En route while in ambulance, he experienced a convulsion with rhythmic shaking in all limbs lasting several seconds. He had a second episode requiring midazolam and levetiracetam. On arrival to MGH ED, the patient was afebrile, heart rate 133, blood pressure 173/93, oxygen saturation 99% on a nonrebreather. He was found to be severely encephalopathic, mute, and not answering questions or following commands. He was admitted to the neuroICU and intubated for airway protection given his poor mental status. He was started on broad-spectrum antibiotics for empiric treatment of meningoen­ cephalitis, but these were discontinued after his CSF was not concerning for a bacterial infection herpes simplex encephalitis. Antibiotics were discontinued. He was extubated on hospital day 2. After extubation he had persistent mixed receptive-expressive aphasia that was slowly improving over time. At discharge from the hospital, he was able to occasionally say a simple sentence, could repeat simple phrases, and could follow simple commands. He was discharged to Rehab

<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>
1140660	3/28/2021			F	3/12/2021	3/12/2021	Seizures; Swelling in left arm where she got the vaccine; A spontaneous report was received from a pharmacist concerning a female patient of an unknown age who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced seizures and swelling in left arm where she got the vaccine. The patient's medical history was not provided. No relevant concomitant medications were reported. On 12 Mar 2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (batch number: 044A21A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 12 Mar 2021, the patient experienced swelling in left arm where she got the vaccine. On 15 Mar 2021, the patient had medically significant event of seizures and was hospitalized for less than 24 hours. 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 was not applicable. The outcome of the event swelling in left arm where she got the vaccine was resolved on 12 Mar 2021. The outcome of the event seizure was resolved on 15 Mar 2021.; Reporter's Comments: Based on the current available information which shows a temporal association between the use of the mRNA-1273 and the start date of the reported events and excluding any other etiology, a causal relationship with the events cannot be excluded. Injection site swelling is consistent with the safety profile of the product
1141511	3/28/2021		35	M	3/27/2021	3/27/2021	Patient thought he sat in chair in observation area but he fell on the ground and began to seize. Multiple nurses and EMTs responded and found the patient in tonic-clonic seizure. Pt continued to seize for about 10 seconds and upon exiting the seizure he reported that this happened about 4 years ago The patient repeatedly declined to be transported to the hospital.. He was incontinent and finally he agreed to be transported to a nearby hospital to be checked out.

<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>
1141137	3/28/2021	TX	25	M	3/27/2021	3/27/2021	Systemic: Dizziness / Lightheadness-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: PATIENT RECEIVED MODERNA COVID-19 VACCINE AND IMMUNIZER DESCRIBED HIM AS WANTING TO FAINT OR HAVING A SLIGHT SEIZURE. THE PATIENT WAS RESPONSIVE AND HE DID KNOW HIS DATE OF BIRTH AND TODAY'S DATE. PATIENT DID SAY HE HADN'T EATEN ALL DAY OR ATE A LIGHT SNACK ALL DAY. WE CALLED THE AMBULANCE AND THEY SAID IT COULD OF BEEN DUE TO LOW BLOOD SUGAR OR MAYBE HIS BLOOD PRESSURE DROPPED. WHEN THEY CHECKED HIS BLOOD PRESSURE HE HAD PERFECT BLOOD PRESSURE.

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1139731	3/27/2021	TX	55	F	2/25/2021	2/25/2021	About 45 minutes after the vaccination I felt like my body was buzzing. This eventually rose upward until the buzzing sensation concentrated on the top of my head, at which point I developed an excruciatingly painful headache. About six hours after the vaccine, I started having a fever that eventually was so intense that I felt like my eyelids were going to peel off. Then I started having chills. I was so cold when I had the chills that I shook like someone having convulsions. When I felt hot, I felt like my eyelids would peel off. I drank some water at one point and felt like I'd vomit. Then, a bit later, I felt like I was going to have diarrhea. About eight-ten hours after the shot, it felt some my tendons were being twisted so that my bones were being ground together at the joints. Then I started having muscle pain. I have a very high pain tolerance. This was ungodly. I felt like I was being tortured. This lasted 36 hours. Then my hair started falling out. The week before the vaccine was the snow storm. I had no power for a couple days and no usable water for about five days. I think that my unfortunate telogen effluvium is the result of extreme stress during the storm followed by extreme stress due to the vaccine. However, given that I had beautiful, long, abundant curly hair, this is obviously not a felicitous event. On 3/11, my levator scapula and rhomboid on the left side (shot side) started feeling hot and very hard. Then my posterior and medial deltoid and triceps muscles started rippling (visibly). Then the injection site swelled up so that it looked like I had a large grain of rice sticking out from my arm. Then the anti tragus of my left ear swelled and turned red. I developed floaters in my left eye. This lasted for about 48 hours. My hair, which had stopped falling out, started shedding again. I have lost about 55% of my hair at this point. My arm never really stopped hurting. I have gotten my second shot (3/25) and am at present working through my adverse events after it, but will wait for a couple weeks before reporting them. I don't know if I'll have "Moderna arm" again, so once the two-week mark passes, I'll report. As best I know, I have never been exposed to COVID19, so the idea that I had such a reaction because of that is not relevant.

<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>
1139211	3/27/2021	CA	31	F	3/26/2021	3/26/2021	On Friday, March 26, 2021 client 31 years old female received her second dose of Pfizer COVID vaccine (LOT # ER 8732, EXP 7/2021) at approximately 2:38pm by vaccinator. After vaccine was administered, client complaint of dizziness and brief seizure seating at the vaccination chair in an upright position. Vaccinator lead registered nurse clinician lead, came to assist vaccinator with client's care. (EMT) assumed care of client. Per EMT prior to onset of syncope and brief seizure, patient was alert and oriented to person, time, place, and situation with Glasgow Coma Scale score of 15 (responsive) with all airway, breathing and circulation intact. Client told EMTshe has no prior medical history or reported allergies and had no issues with first Pfizer vaccination on 3.3.21 with Lot #:EN6199.. EMT placed patient on the ground into a recovery position and assessed vitals first time at 2:43 PM: BP 86/60, P 70, R 18. Patient's vitals assessed the second time at 2:48 PM until paramedics arrived: BP 80/66, P 71, R 18. Client remained stable and paramedics arrived at 2:49 PM and they placed client in a supine position on a gurney before transported client to the hospital. No further interventions indicated.
1139273	3/27/2021	CA	25	M	3/25/2021	3/25/2021	Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Additional Details: pt came in for his first covid shot. checked pt health status pt was fine. while pt was at the observation seat his head went back and he started to have minor sshakiness/seizure like/faintness for about 5 sec. paramedic came and pt refused the pramedic he was checkout by paramedic and was responsive. pt then told us he had been fasting for 2 days and had marijuana on his injection day. pt went home and called his primary dr. and is doing well.
1139483	3/27/2021	CO	28	F	3/23/2021	3/25/2021	Likely nocturnal seizure. Woke up and noticed a bitten and bleeding lip and bitten tongue and some confusion and brain fog, and sore muscles.
1140698	3/27/2021	CA	20	M	3/19/2021	3/19/2021	EXPERIENCED A TONIC CLONIC SEIZURE AT APPROXIMATELY 08:45PM THAT LASTED FOR JUST ABOUT 5 MINUTES
1139622	3/27/2021	IA	33	F	3/24/2021	3/27/2021	seizure, resolved

<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>
1139891	3/27/2021	AZ	75	M	3/18/2021	3/19/2021	Friday afternoon my husband experienced chills, then violent shaking and full body seizure. he has never had a seizure before.
1139968	3/27/2021	TN	24	F	3/27/2021	3/27/2021	PATIENT CAME IN ALERT AND ORIENTED. STATED HAD A REACTION IN PAST TO VACCINES AND HAS FAINTED. PREVIOUS VACCINE FOR GOING OUT OF COUNTRY. PATIENT AGREED ALONG WITH MOTHER TO GET VACCINE TODAY. PATIENT RECEIVED VACCINE WITH NO INCIDENT. WE HAD HER SIT THERE AND SHE STARTED FEELING FAINT. SECOND VACCINATOR ALSO NEXT TO PATIENT. PATIENT DID FAINT AND SEEMS TO HAVE A SMALL SEIZURE AS HAD INVOLUNTARY ARM MOVEMENT AND HAD LOST CONSCIOUSNESS. PATIENT BECAME ALERT IN ORIENTED WITHIN 30 SECONDS. PATIENT STATED FELT BETTER BUT CALLED 911 FOR THEM TO COME ACCESS HER. MOM CALLED INTO ROOM AND STATED THIS INCIDENT HAD OCCURRED BEFORE. FIRE DEPARTMENT (EMS) IN STORE AND RESPONDED ALMOST IMMEDIATELY. PATIENT WAS ON FLOOR AT THIS TIME BY DIRECTIONS OF PHARMACY STAFF WITH FEET ELEVATED. BREATHING NORMAL, ALERT AND ORIENTED BUT APPEARS PALE (MOM STATES NORMAL SKIN COLOR). PATIENT ASSESSED BY EMS AND BLOOD PRESSURE LOW. PATIENT AGREED TO GO GET CHECKED OUT BY HOSPITAL DUE TO LOW BLOOD PRESSURE, PALE. LEFT WITH EMS STAFF.
1140116	3/27/2021	TX	33	F	3/27/2021	3/27/2021	client was found having pseudo seizure like symptoms,arrival at site she was found pale and disoriented.assisted to lay down,elevated legs,vs was checked .snacks and water given,ice packs placed on. After 25 mins ,Patient responding well. Assisted onto wheelchair and was wheeled out.
1140265	3/27/2021	OH	54	F	3/23/2021	3/23/2021	On same day of vaccine(5 hours after shot) started to feel disinformation and then pain in my teeth, like an abscess. Body over attacked the vaccine virus and attacked a nerve in my face causing (according to Dr) a Teigeminal Neuralgia reaction Major pain in right side jaw, affecting teeth and ear. On anti seizure medicine to try to calm the nerve.

<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>
1140288	3/27/2021	WI	29	F	3/27/2021	3/27/2021	AFTER 15 MINUTE OBSERVATION, PT WAS UNABLE TO WALK MORE THAN 10-15 FT BEFORE NEEDING TO SIT BACK DOWN AT WHICH TIME SHE SLOWLY SLID OFF THE CHAIR AND ONTO THE FLOOR (GUIDED BY HER FRIEND WHO ACCOMPANIED HER). SHE REMAINED LYING ON THE FLOOR UNTIL MEDICAL PERSONNEL ARRIVED. SHE APPEARED TO HAVE PASSED OUT, HAD VERY BRIEF CONVULSIONS/TREMORS BEFORE COMING TO, AT WHICH TIME SHE WAS ABLE TO RESPOND TO QUESTIONS AND ANSWER THEM. HER PULSE RATE SEEMED WITHIN NORMAL WITH SLIGHTLY ELEVATED RESPIRATORY RATE. MEDICAL PERSONNEL ASSISTED HER FROM THE FLOOR TO THE GURNEY. SHE WAS TAKEN TO THE AMBULANCE IN THE PARKING LOT FOR FURTHER EVALUATION. NO UPDATE ON HER STATUS WAS GIVEN TO US.
1140369	3/27/2021	CO	19	M	3/28/2021	3/28/2021	A few seconds after vaccine was administered the vaccinator turned around to notice patient was unconscious. Vaccinator describes 20-30 seconds of full body shaking. Patient then awoke and was Alert and oriented to people, place and time within 2 minutes. He was nauseas and anxious initially. Onsite EMS was alerted immediately and came to access the patient. 911 was also called quickly under the assumption it may have been a seizure. Patient denied any seizure history. Father arrived a few hours later to pick up patients vehicle and dog. Father informed me that patient was doing better at this point and was being prepared for departure.

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1140386	3/27/2021	MI	48	F	3/23/2021	3/23/2021	03/23/2021 - injection given and within 2-3 minutes after injection I had heart palpitations and flush of heat over my body. After about 3 minutes heartbeat regulated and flush of heat dissipated. About 45 minutes later I got a headache last about 15 minutes. Then came back about an hour later lasting same time before stopping. This occurred again about 3 hours later, same as before. 03/24/2021 - arm was sore and injection site was slightly itchy and hot but stopped by 03/25/2021, no hunger. 03/24/2021 - woke up feeling nauseous and overall crappy feeling (not achy, not in pain). nausea lasted throughout the day, but no vomiting. headache often throughout the day but not lasting more than 10-15 minutes, no hunger. 03/25/2021 - again woke up feeling nauseous lasting off/on thru day, no vomiting, no headache, feeling overall more energetic wanting to eat when nausea went away. 03/26/2021 - woke up NO nausea, not hungry so ate later in afternoon. Within 20 minutes of me eating I became extremely fatigued, dizzy and could barely stand up. I started to feel like I was going to faint and got to a couch and laid down. I started sweating and felt like my body was on fire. My scalp and face were wet with sweat, I felt dizzy and extremely nauseous before I vomited (3) times. After vomiting the dizziness, nausea and weakness dissipated. After about 30 minutes I just felt tired and my chest hurt from the convulsions of vomiting. After about 2 hours I felt better and just tired. 03/27/2021 - woke up no nausea, no headache and slightly fatigued.

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1140921	3/27/2021	MO	62	F	3/27/2021	3/27/2021	<p>Patient arrived to clinic for Covid immunization, received vaccine at 9:39 am in right Deltoid. Called to observation area 9:56 am by clinic case manager for patient report of "feeling funny" post immunization. Patient sitting upright with eye closed at table. Responsive to verbal stimuli and oriented to place and time. Patient complained of the following symptoms: trouble swallowing and "head rush" sensation. Patient was assisted back to exam room with bilateral two person support due to unsteady and slow gait. Eyes remained closed and patient required assistance to lay supine on the exam table. Speech slow and reported extreme feeling of fatigued. Vital signs at 9:58 B/P 118/72 left arm laying, HR 80. Blood Glucose 218. Patient is diabetic and reports she did take morning medications: Victoza 1.8mg, Lantus 60 units and Metformin 1 tab. Pulse ox 96%. 10:03 vital sign recheck 120/70 right arm (supine) with regular pulse in the 90's Complaints of feeling a burning sensation in body and reports very dry mouth with and jaw feeling strange (sensation much like before she has a seizure). 10:15 12-Lead EKG completed and reviewed by Dr who was present in room, no acute changes noted. Dr discussed need for patient to be sent to ER via EMS for further evaluation of vaccine reaction. EMS notified. 10:24 resting with eyes closed, reports ongoing fatigue and dry mouth. States that her "kidney's feel warm" and it "feels like my head is on fire", also states that her tongue has a burning sensation. Reports feeling like throat is "thick" 10:25 clear bilateral lung sounds, oral pharynx with no evidence of swelling. 10:32 Mild non-productive cough, remains with clear lung sounds bilaterally throughout, oral pharynx without swelling. 10:37: continues to report "burning sensation to back of head and neck", lips moistened with wash cloth for ongoing complaints of extremely dry mouth. 10:41: Resting with eyes closed, recheck vital signs, 116/72 right arm (supine), HR 95, 96%. EMS arrival, transported to hospital via EMS for further evaluation.</p>
1140790	3/27/2021	MD	24	F	3/18/2021	3/22/2021	<p>Patient was seizure free for almost 2 years. 3 days after first Pfizer dose, patient began having nocturnal seizures every night for the next 7 days and ongoing. Nights without seizures were due to added dosage of Clonazepam.</p>

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1139570	3/27/2021	IA	61	F	3/23/2021	3/23/2021	<p>Pfizer COVID-19 Vaccine EUA Patient presents 3/23/21 for medical monitoring of syncopal episode s/p COVID - 19 vaccine # 2. Lowered to the floor by vaccine staff. Patient reports symptoms of weakness, other wise states she ~"feels fine~". Two additional syncopal episodes witnessed by myself when patient attempts to change position. Past medical history is significant for mild persistent allergic asthma, pre-diabetes, OSA, obesity and BPPV. Patient reports history of same reaction s/p previous vaccine. At a approximately 0837 patient was noted to have a worsening rash present to her face. EpiPen administered via left lateral thigh at 0838. EMS called to transport patient the ED for further evaluation. Treatment administered: epipen (lot 0FM406, exp 02/22) left lateral thigh at 0838. Upon arrival to the ED, patient's temperature is 98.8° F, heart rate 92-103, respiratory rate 30, saturating 99% on room air with blood pressure 164/91. The patient's laboratory studies were largely unremarkable. While in the ED, the nurse was getting ready to get the patient up to the commode when the patient started to ~"not feel right again.~". She asked her to administer the medications for allergic reaction and reports wall the 2nd medication was being infused, she felt paralyzed and unable to talk, although she was able to hear everything and was aware, she was unable to move or speak for a short amount of time. CT head with completed at this time and showed no acute intracranial findings. Chest x-ray unremarkable. EKG showed normal sinus rhythm with sinus arrhythmia, heart rate 80 and prolonged QT at 470. The patient was administered Solu-Medrol 125 mg IV, Pepcid 20 mg IV, Benadryl 50 mg IV, normal saline 1 L IV. Pt was admitted to hospital for observation. The patient was seen on the unit laying in bed with her husband at the bedside. She reports that she is feeling slightly better and hungry and has never felt at paralyzed/unable to speak feeling before and is very nervous about this. She was wondering if she had a seizure, although she reports feeling aware the entire time and did not lose bowel or bladder function. We discussed that that is not typical for a seizure, but even if we did an EEG at this time, it would not be able to tell us what occurred in the past. We discussed continue the Benadryl, Pepcid, and IV steroids for today and likely decreasing them tomorrow. We discussed the workup of syncopal episodes as well. The</p>

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1138316	3/26/2021	FL	30	M	3/17/2021	3/19/2021	<p>patient and her husband were agreeable to this plan. Patient was discharged from the hospital on 03/24/2021 in a stable medical condition. Patient was instructed to follow-up with her PCP in 1 week.</p> <p>Pfizer-BioNTech COVID-19 Vaccine EUA About a day and a half after receiving the 1st dose of the COVID vaccine I had a grand mal seizure. I was sitting on the couch with my family and my sister said I had only fallen asleep for about 20 minutes. I take seizure prevention medication each night prior to bed. I had not taken the medication yet but I was up to date on taking this medication. I had not had a seizure in 6 years since starting my medication. I did not have a fever before or after this seizure. I was generally feeling normal prior to the seizure ,after receiving the vaccine.</p>
1139024	3/26/2021	MA	27	F	3/19/2021	3/19/2021	<p>At 11:00 pm I had an extremely intense seizure that caused me to convulse on the floor while arching my back. My partner thought I was dying as it was much more intense and extreme then normal. I am still having increased seizures in both pain and severity daily. Typically my seizures last 20 minutes and are from 4-5 in discomfort in pain out of ten. Now they are around 7, even a week later. The first severe seizure was a 10 level pain and diabling. I also got severe swelling in my arm of the site, extreme pain in the my arm lasting four days, and two large cold sores. Typically my cold sores small and last for two days. Mine are still active and gave me a fat lip. I also have extreme fatigue but could be caused by the increased seizures and pain of them. I been unable to perform my normal duties and responsibilities, which my seizures typically do not interfere with.</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>
1138969	3/26/2021	TX	42	F	3/26/2021	3/26/2021	Pt was given the immunization at 4:10pm on 3-26-21 at vaccination site. I asked her to please sit for 15-30 mins during that time period her daughter called on the store line to let us know her mom was having an absence seizure I checked on the patient and asked to please continue sitting down for about 30 more mins (1 hr total). When she left she was alert and I asked her to please give me a call when she arrived at her destination and she called me back and told me she had arrived at her destination and was with her husband. During the time period she was sitting there I called patients' physician and spoke with staff and she confirmed the pt had been seen 3-15-21 and the dr had given the ok for the pt to get the vaccine.
1138968	3/26/2021	CA	19	F	3/26/2021	3/26/2021	Seizure started at 1644, stopped at 1646, emesis, followed by dizziness. Ambulance called, patient taken to hospital, A/Ox4 upon transfer with reported dizziness present still, vitals stable: 122/80, HR: 78, 97% saturation on room air.
1138863	3/26/2021	NY	54	F	3/25/2021	3/25/2021	Patient received covid vaccine around 4pm and reported feeling like she was having a seizure around 4:10. Her eyes starting rolling backwards and she could not verbally respond. 911 was called and she was sat on the floor and monitored by the pharmacist until paramedics arrived. She was responsive when paramedics arrived and took her to ER
1138838	3/26/2021	CA	26	M	3/26/2021	3/26/2021	Patient recived Moderna vaccination and was sitting while being monitored for 15 minutes when he began having seizures. Patient was then taken with paramedics.

<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>
1138639	3/26/2021	ME	45	F	2/17/2021	3/1/2021	1/20/2021: 1st dose. Zero side effects. 2/17/2021: 2nd dose. Mild soreness at vaccine site until about 36 hours after dose. No other symptoms. 3/1/2021: Woke with diarrhea and stomach ache. On & off mild diarrhea until 3/6/2021. 3/6/2021: Severe upper abdominal pain, severe diarrhea, vomiting for 24 hours. 3/7 - 3/24/2021: On & off mild-uncomfortable nausea and diarrhea. Varying levels of intensity but nothing that stopped daily functioning. 3/25/2021: 5 :15 am. Seizure (probably Atonic) lasting approx 7-9 seconds. (Have never experienced seizures of any kind before.) Afternoon, nausea returned. Gone by evening. 3/26/2021: midday nausea returned.
1137390	3/26/2021	MO	20	F	3/26/2021	3/26/2021	Pt received COVID-19 vaccine at 9:57am. Pt went to waiting area in front of pharmacy and sat down. Pt was on her phone when she said she felt like she started dreaming. Her friend said her eyes rolled back and she threw her phone on the floor at 10:02am. When I got to the patient a customer (nurse) was already assisting the patient. EMS and Code White were called at 10:03am. Pt was awake and aware of what was going on. She said she had no history of fainting or seizures. She did say that she normally had a lower blood pressure. Pt was sitting up but laid back down at 10:05am saying that she was having vision issues and feeling dizzy. BP was 112/70 and HR 75 at 10:10am. EMS arrived at 10:12am and took over. BP was still low at that time. Pt denied going to the hospital and EMS left at 10:20am. Pt stayed with friends until 10:40am. Pt left the store with 3 friends who had also received vaccine.

<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>
1135767	3/26/2021	AR	67	F	3/1/2021	3/1/2021	<p> Couldn't get warm- very cold, her skin was very cold; Nausea; Pretty severe headache; Generalized aching; Fibromyalgia flare up; No energy been very tired; No energy been very tired; Felt like she was going to faint; Dizziness; Vision blurred; Loss of appetite; Flu-like symptoms; Hands feel warm to touch, but she still feels cold; She cannot sit or stand without discomfort in her spine; She cannot sit or stand without discomfort in her spine; Sick; Her bones and muscles hurt; Her bones and muscles hurt; Wheezing; This is a spontaneous report from a contactable Other HCP, the patient. A 67-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot Number: EM9809; Expiration Date: 30Jun2021), intramuscularly, on 01Mar2021 at 13:45 (at the age of 67 years old) as a single dose in the left deltoid for COVID-19 immunization. Medical history included having become disabled in 2009, arrhythmia from 2014 and ongoing which was diagnosed after she took a Hep C treatment (Sovaldi, Ribavirin, Olysio). She had to take these medications for five months, where most people have to take it for three, ongoing allergic asthma - allergic to "everything." She has had this her whole life, diagnosed when she was 5. Started treatment with steroids at 16 , Hepatitis C from 1996 to 2014 diagnosed 4 years after blood transfusions Could have already gotten it as a nurse, was much more resistant than the average person 5 weeks to go negative, ongoing hepatic failure from 2013- she went into liver failure from Hep C. An event occurred- exposure of a deadly toxin that came from China, ongoing fibromyalgia from 1992 -Immediately after blood transfusions when her son was born- Gave her the correct blood but her body reacted. Flu shot in Early Oct2020 Fibromyalgia flare up, 4 times the dose (as reported)- Onset Age 66, Seizure disorder which was diagnosed in 2016 after disseminated shingles; after 2.5 months started having black outs where she did things and said things no memory of, the only way she knew it happened is if there were consequences. Doesn't know if she still has those, but she is getting an MRI and EEG. She lost vision in her right eye 2 years ago due to retina surgery macular pucker. She thinks her liver was stealing Vitamin A from her eye. Medical history also includes she ran over herself with her car, blood pressure abnormal, hepatic encephalopathy, autoimmune </p>

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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thyroiditis, and anxiety all from unknown dates and unknown if ongoing. The patient has had cataracts since an unknown date prior to the vaccination. The patient was diagnosed with "Rocky Mountain" in 2009. She also mentioned that when she got the vaccine she did not tell them that she was on steroids and an antibiotic. She commented that she was not in good shape when she took the vaccine to begin with. She is immunosuppressed and thinks that she should not have received the vaccination. But she also stated that she took the vaccine because she is a severe asthmatic and does not have a strong immune system so if she got COVID, she would die. Concomitant medication included benazepril (BENAZEPRIL) for blood pressure abnormal from an unspecified start date and ongoing; amlodipine (AMLODIPINE) for arrhythmia from 2014 and ongoing; rifaximin (XIFAXAN) for hepatic encephalopathy from 2014 and ongoing; lactulose (LACTULOSE) for hepatic failure, ammonia abnormal from 2014 and ongoing; levothyroxine sodium (SYNTHROID) for autoimmune thyroiditis from 1984 and ongoing; omeprazole (PRILOSEC [OMEPRAZOLE]) for reflux gastritis, chronic gastritis from an unspecified start date and ongoing; alprazolam (XANAX) for anxiety, post-traumatic stress disorder from 2009 and ongoing; albuterol [salbutamol] (ALBUTEROL [SALBUTAMOL]) for asthma from an unspecified start date and ongoing; ranitidine (RANITIDINE) for an unspecified indication, start and stop date were not reported. The patient previously took flu vaccine vii, olysio for hepatitis c and experienced histamine level increased, lyrica and experienced weight increased. Ten minutes after the vaccine was administered the patient experienced generalized aching on 01Mar2021 at 13:55 with outcome of not recovered. After twenty minutes she developed a pretty severe headache on 01Mar2021 14:05 with outcome of recovering. After 30 minutes she started to feel nausea on 01Mar2021 at 14:15 with outcome of recovered. She stated that when she stood up to leave felt like started to feel dizzy on 01Mar2021 with outcome of unknown, and felt like she was going to faint on 01Mar2021 with outcome of unknown, her vision blurred on 01Mar2021 with outcome of not recovered and she had trouble getting into the elevator. She also experienced a loss of appetite on 01Mar2021 with outcome of recovering. The

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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patient continued to describe her experiences noting that "things changed daily" and mentioning that she experienced fibromyalgia flare up on 01Mar2021 with outcome of not recovered, no energy been very tired on 01Mar2021 with outcome of not recovered, no energy been very tired on 01Mar2021 with outcome of not recovered, couldn't get warm- very cold, her skin was very cold on 02Mar2021 01:30 with outcome of not recovered, flu-like symptoms on 01Mar2021 with outcome of recovering, hands feel warm to touch, but she still feels cold on 01Mar2021 with outcome of unknown, she cannot sit or stand without discomfort in her spine on 01Mar2021 with outcome of unknown, she cannot sit or stand without discomfort in her spine on 01Mar2021 with outcome of unknown, sick in Mar2021 with outcome of unknown, her bones hurt in Mar2021 with outcome of unknown, her muscles hurt in Mar2021 with outcome of unknown, wheezing on an unspecified date in Mar2021 with outcome of unknown. Lab tests and procedures included cardiac output: over 50 percent, echocardiogram: her heart was good and clear, electroencephalogram with unknown results, magnetic resonance imaging with unknown results, all on unknown dates. Therapeutic measures were taken as a result of pretty severe headache; Sender's Comments: Based on the available information, the company considers that a causal relationship between generalized aching, severe headache, feel dizzy, going to faint, vision blurred, no energy been very tired, very cold, her skin was very cold, wheezing and bnt162b2 vaccine cannot be excluded due to plausible temporal association. The Company considers the reported event fibromyalgia flare up is unrelated to bnt162b2 vaccine but more likely due to underlying medical history of ongoing fibromyalgia. 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.

<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>
1136304	3/26/2021	AZ	20	M	3/25/2021	3/25/2021	Approximately 10 minutes after receiving the Moderna vaccine, this writer was called to the patient room by other staff. The patient was extremely confused and not speaking to anyone. He was gazing to the left and not making eye contact with this writer, who was loudly talking to the patient. Multiple attempts were made to get the patient's attention with no success. The patient then began to involuntarily raise his bent left arm in front of his face and then back down to his side. In this writer's opinion, the patient was having a silent seizure. This writer sat with the patient, who became aware approximately 15 seconds later. He was able to answer questions and was quickly reoriented. At this point this writer had the staff call 911 for further evaluation. After answering basic questions appropriately., this writer gathered vital signs on the patient . The first set of vitals were: bp 88/48, pulse 60, respirations 14/min, oxygen saturation 93% on room air, temp 98.5. After small conversation with the patient, another set of vitals were taken: bp 94/70, pulse 68, respirations 15/min, oxygen saturation 95% on room air, temp 98.8. We then had the patient drink some water, then had him lie down in the patient room until EMS arrived. By the time they arrived, the patient was completed reoriented and laughing with office staff. EMS evaluated the patient and deemed him safe to go home with his friend driving. This writer walked the patient to the car to assess balance and coordination. This writer informed the patient and his friend to call 911 if symptoms returned. The patient agreed.
1136440	3/26/2021	CA	33	M	3/16/2021	3/16/2021	Systemic: Seizure-Mild, Additional Details: Patient had a minor shock lasting briefly within 15 minutes of vaccine administration. 911 was called and the Fire Department arrived, but he had already recovered at that point and refused service. He informed the pharmacy staff that this is a regular occurrence every time he receives a vaccine.

<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>
1136616	3/26/2021	IN	44	F	3/24/2021	3/24/2021	I had long term Covid symptoms from early February 2020 to late February 2021 including, intense concussion like brain fog for months, coughing for months, problems with my fingers seizing up and twitching uncontrollably, and extreme exhaustion for months. I had finally started to feel Covid free, except for some problems with my left hand, by end of February 2021. I got the first dose and about 45 minutes or so later the exhaustion came back suddenly - like someone removed all my batteries - and I started having trouble talking, thinking, remembering. Reading and writing work, but talking is difficult. My hands feel swollen and lacking dexterity and strength. I had an odd headache in the middle of the night (on day 2) with some sharp pain that kind of seeped around my scalp. I thought at first I had been stung by a bee and it went away as quickly as it came. But then the pain would suddenly appear on another part of my scalp. There was a tingling/seeping/spreading out feeling just before it would disappear. I woke up the next morning with a more normal headache, took IBU and CBD gummies, ate breakfast and it's gone. I feel like all I can do is lay in bed and stare at the wall. This is exactly as I felt when I had Covid (though without finger seizures and coughing). I find myself coming to tears with a fear that it won't ever go away or I've brought it on again by getting the vaccine.
1136741	3/26/2021	TX	40	F	2/25/2021	2/26/2021	FiFive (5) seizures over the course of two (2) weeks. The seizures consisted of all of my muscles tensing up and my entire body twitching/ shaking for 1-2 minutes.
1136806	3/26/2021	CA	73	F	3/14/2021	3/14/2021	Ten hours after vaccination I went into convulsions lasting eight hours. Horrible experience!
1136849	3/26/2021	CA	17	F	3/24/2021	3/24/2021	after recieving the vaccine, patient turned very pale and appeared to lose conciousness as well as have convulsions. 911 was called. nurse had patient lie on the floor. o2 was measured to be 96 and bp was 103/74
1136972	3/26/2021	VA	58	F	3/23/2021	3/23/2021	Patient had a seizure the night after getting the shot. She reported that she had been seizure free for almost a year. She had a fever of 101.2 for a couple of days and is still complaining of a sore throat. Patient is going to contact her pcp to follow-up.

<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>
1137019	3/26/2021	NY	22	M	3/26/2021	3/26/2021	Patient passed out and began seizing within 5 minutes of vaccine administration sitting down on chair. Tonic, clonic motions for 5 seconds. No foaming at the mouth. Patient was taken off chair, held on the ground until seizure ended. Patient gained consciousness after a minute. Given water, snacks, air and EMS was called. EMS assessed situation, and allowed patient's girlfriend to pick him up from site and drive back home.
1138487	3/26/2021	TX	73	M	3/22/2021	3/25/2021	Weakness, dizziness, chills and seizure
1137277	3/26/2021	IL	48	F	3/25/2021	3/25/2021	Patient reported to have a seizure approximately 4 hours after receiving the vaccine. The seizure reportedly went on for several minutes with the patient denies any postictal confusion, tongue biting, or incontinence
1138349	3/26/2021	NY	20	M	3/6/2021	3/6/2021	Seizure

<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>
1137538	3/26/2021	FL	47	M	12/16/2020	1/6/2021	47 year old Gynecologist with PMH of severe MDD, GERD, asthma, referred to the ED by his PCP, after 5 days of gait instability, and about 4 weeks of altered mental status, confusion, short term memory deficits and malaise. ADEM suspected and extensive infectious, inflammatory and neoplastic workup was initiated. CT brain - reported NAD MRI brain consistent with Acute Diffused Encephalomyelitis and suspected ADEM. MRI cervical spine with evidence of demyelination involving posterior cord. ICU course complicated by new onset of aphasia, partial left frontotemporal seizures, LGIB due to proximal rectal laceration and central diabetes insipidus. Admitted 3/15/21. On 3/17 he developed aphasia with right sided facial droop and stroke alert was called. Later on 3/17 he developed GI bleeding and was taken for emergent colonoscopy, from which no significant conclusions could be made due to lack of preparation and subsequent poor visualization. No foreign body was reported. After he continued to have ongoing bleeding, the patient had a sigmoidoscopy, during which the migrated clip could be removed and two new hemostatic clips were placed. He subsequently developed large volume urine output and nephrology was consulted; the patient was diagnosed with likely diabetes insipidus. On 3/20 acyclovir was discontinued after HSV PCR was negative. High dose solumedrol for ADEM completed 5 day course 3/21. VDRL was non reactive. There were no oligoclonal bands. Solumedrol 1g daily was started 3/24/21: MRI showed L>R patchy enhancement and diffusion abnormalities consistent with ADEM. Repeat MRI showed new restricted diffusion of the left superior cortex, bilateral medial temporal lobes and hippocampi, genu of the corpus collosum, and pericallosal white matter, with ddx including status epilepticus, autoimmune encephalitis and infectious encephalitis including herpes simplex. Completed 5 day course of high dose steroids, 6 days of IVIG and on ongoing PLEX. Neurological improvement noted 3/25

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1137628	3/26/2021	CA	32	M	3/25/2021	3/25/2021	At approx. 1015 pt began to seize in chair and fell off chair. Pt continued seizing after fall. Another pt sitting next to pt placed pt onto left side during seizure. Nurse assumed care at approx. 1015. Nurse observed tonic-clonic seizure lasting approx. 30 seconds total. After seizure ended, pt had unlabored breathing and appeared foggy for approx. 10 seconds. Patient was then AxO x4. Pt reported 7/10 pain on left side of head and feeling tired. Pt reported no Hx of seizures and no blood thinners. 911 activated at approx. 1016. Pt denied taking any meds and any chronic medical conditions. Paramedics arrived and assumed care at approx. 1024. At approx. 1026, pt left facility via ambulance and transported to ER for further care.
1137915	3/26/2021	FL	20	M	3/23/2021	3/23/2021	20-year-old male with a past medical history of vasovagal episodes, cerebral palsy, dorsal rhizotomy and VP shunt followed by neurology, taking no medications presents to the ED for evaluation of a first-time seizure which occurred 1 hour ago 10 minutes after receiving a Covid vaccine. Mother states that the patient receive the Covid vaccine around 11:15 AM and 10 minutes later he became very pale the e-stim to left lower and patient he had generalized body convulsions lasting less than 1 minute and turned very pale/cyanotic. When he stopped seizing mother states that he was slightly confused as to what had happened and continued to be pale. Patient is completely at baseline at this time answering questions appropriately, however he still complains of having dizziness with sitting up or standing. Patient is answering all questions appropriately. He denies any numbness or tingling. He states he generally feels slightly weak but there is no focal weakness. No headache, nausea, vomiting, diarrhea, recent head trauma, abdominal pain, chest pain or palpitations.
1138074	3/26/2021	MD	24	M	3/26/2021	3/26/2021	customer passed out and or had seizure and EMS was called. customer is alert and fine now.
1138095	3/26/2021	MA	72	F	3/25/2021	3/26/2021	New onset Seizure with acute loss of consciousness. L arm induration and swelling.

<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>
1138131	3/26/2021	CO	44	F	3/18/2021	3/24/2021	On 3/24/21, almost a week after my second vaccine shot, I had a seizure while sleeping in bed. I hadn't had a seizure in over 30 years, and then only with a fever (I had febrile seizures as a child). My husband got some of it on video after being unsuccessful waking me.
1138157	3/26/2021	ME	45	F	2/1/2021	3/10/2021	First it started as retching/vomiting and diarrhea, which lasted about 2 weeks, then subsided. Then a week after that stopped the patient reported having her first seizure that lasted about 5-9 seconds. Patient reports falling to the ground and being unable to control anything.
1138207	3/26/2021	IN	10	F	3/26/2010	3/26/2021	HAD A SEIZURE APPROXIMATELY 3 HOURS AFTERWARDS. SHE DOES HAVE HISTORY.

<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>
1136593	3/26/2021	FL	81	F	2/4/2021	3/8/2021	Headache; Serious convulsion; Slight tenderness at the injection site; A spontaneous report was received from a consumer concerning an 81-years old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced serious convulsion/seizure, slight tenderness at the injection site/vaccination site pain and headache. The patient's medical history included blood pressure high, diabetes and rheumatoid arthritis. Concomitant medications included methotrexate. The patient received their first of two planned doses of mRNA-1273 (lot/batch number: unknown) on 04 Feb 2021. On 08 Mar 2021, prior to the onset of the event, the patient received the second of two planned doses of mRNA-1273 (batch number: 027A21A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 08 Mar 2021, the patient experienced slight tenderness at the injection site. On 09 Mar 2021, at 12.30 and 1.30 AM the patient experienced medically significant event of serious convulsion with no previous history of seizures. Since patient has a disabled husband, she didn't call ER (emergency room) and went to the neurologist next morning who told her to report it. On 10 Mar 2021, the patient experienced headache attributed to migraines. Treatment for the event headache included paracetamol. Treatment information for the events serious convulsion and slight tenderness at the injection site was not reported. 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 event slight tenderness at the injection site was resolved on 08 Mar 2021. The outcome of the event serious convulsion was resolved on 09 Mar 2021. The outcome of the event headache was resolved on 10 Mar 2021.; 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.
1137113	3/26/2021	IN	69	F	3/18/2021	3/19/2021	13 hours after shot, right arm warm and tender, nausea. 22 hours after shot had seizure like activity with staring into space, not responding, right arm twitching. Lasted 2 minutes. Eventually responded to name. A 2nd episode occurred a couple hours later.

<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>
1136411	3/26/2021	TX	41	F	3/25/2021	3/25/2021	Site: Pain at Injection Site-Mild, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild
1135462	3/25/2021	NY	30	M	3/25/2021	3/25/2021	Pt was in waiting area when he started to have a seizure. He went rigid and flipped his chair hitting his head on the cement floor. He was taken to the EMS area.
1136174	3/25/2021	HI	67	F	3/25/2021	3/25/2021	Prior to vaccination, the patient stated that she was nervous, but seemed relieved and okay directly following the vaccination. Following vaccination, patient became restless during the 15 minute post-vaccination window about 2-5 minutes after receiving the vaccine. She initially presented with uncontrollable shaking/bouncing legs, palpitation, sweating, and shortness of breath (though this was very brief. Patient remained coherent and oriented to time/person/place. The shaking and palpitations subsided after a couple minutes and resumed towards the end of the 15 minute waiting period, accompanied by nausea. 25 minutes post-vaccination she appeared to have stabilized, and we assisted the patient to her room nearby at her request to allow her to lie down while being monitored. After returning to her room, she very quickly ran to her sink due to her nausea, then after a minute of attempting to vomit, she collapsed and appeared to have briefly lost consciousness. EMS was called and the patient was rolled onto her side to prevent choking in the event of emesis. Patient remained responsive, but was weak and clammy with a weak pulse and breathing. After the firefighters came, a search of the apartment found the previously listed medications. Additionally, the patient experienced a seizure-like episode lasting 15 seconds in duration. Once the EMT came, they assessed her and monitored her in the ambulance; they reported that her condition appeared stable, her vitals were strong, and transported her to Hospital for observation/testing.

<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>
1134673	3/25/2021	MD	23	M	3/25/2021	3/25/2021	Approximately 10 minutes after vaccination, patient experienced a seizure. EMS was on site and tended to pt immediately. Seizure subsided quickly. Per EMS, patient's blood sugar was "low" and BP was also "low". Ambulance was called. Within a few minutes, patient was awake and able to converse, Was taken to the ED by stretcher.
1134824	3/25/2021	AL	60	M	3/25/2021	3/25/2021	Patient received their vaccine and sat in a chair, within approx. two minutes the patient told another patient they felt hot, I was already walking to the patient to check on them,. The patient's eyes were glazed, Almost immediately the patients eyes rolled back in his head. I shook his arm and shouted to him , he was unresponsive with agonal breaths.. I shouted for help from the other nurses. RNs came immediately. We moved him to the floor, called for an epinephrine injection to be prepared, I began to prepare the site for epinephrine injection to his thigh, nurse checked for pulse... at this time the patient was still unresponsive with agonal breaths... no pulse was felt so compressions were commenced by RN. Nurse gave approx. 15 compressions to the patients chest , the patient spontaneously began to recover. Carotid and radial pulses were felt at this time. Breathing returned to normal. While this was occurring, we called a code blue and 911 was activated. By the time 911 responded the patient was fully conscious , alert and responsive. He could tell us his name and how he felt prior to this incident. The patient was transferred via a stretcher by EMS 911 and RN accompanied him to the ER to give a report. The timeframe for being pulseless and having agonal breaths lasted no more than 30-40 seconds. Patient denied any history of a seizure disorder. No epinephrine or IM Benadryl were administered at the incident site by the responding staff due to the spontaneous recovery.

<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>
1134859	3/25/2021	OR	77	M	3/23/2021	3/24/2021	convulsions. I woke up at about 3:15 with my body shaking and i could not control it. this went on for about 1 hour. I have never had this experience. I literally could not function because of the shkes. the other reactions were, i slept from 4:30 +/- am till 5 pm, when i had Covid i slept for over 5 days. Other symptoms head ache, body aches, fatigue and lose of appetite. I write this at day 3 after the shot, and have tiredness and want to sleep It's like a compressed version of my Covid experience.
1135284	3/25/2021	CA	55	M	1/13/2021	1/28/2021	Seizure; A spontaneous report was received from a consumer concerning a 55-years-old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced seizure. The patient's medical history, as provided by the reporter, included epilepsy. Concomitant medications included lamotrigine and levetiracetam. On 13 Jan 2021, prior to the onset of the event, the patient received their dose of mRNA-1273 (Batch Number: 025L20A) intramuscularly for prophylaxis of COVID-19 infection. On 28 Jan 2021, the patient experienced medically significant event, seizure and was hospitalized. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event seizure was resolved on 28 Jan 2021.; 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>
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.

<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>
1135290	3/25/2021	CA	63	F	1/26/2021	2/22/2021	Seizure; Neurologically confused; A spontaneous report was received from a consumer concerning a 63-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced a seizure and was neurologically confused (confusional state). The patient's current conditions included epilepsy. Concomitant product use was not provided by the reporter. On 26-JAN-2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Batch number not provided) intramuscularly for prophylaxis of COVID-19 infection. On 22-FEB-2021, right before the patient was supposed to get the second dose of vaccine, she had a seizure and was hospitalized. The same day, patient was neurologically confused. The patient underwent different unknown tests including computerized tomography. On 24-FEB-2021, the patient was discharged from hospital. No treatment information was provided by the reporter. Action taken with mRNA-1273 in response to the events was unknown. The outcome of events, seizure and confusional state were resolved/recovered; Reporter's Comments: Based on reporter's causality and the prior history of epilepsy, the events are assessed as unlikely related to mRNA-1273.
1134411	3/25/2021	PA	59	F	3/16/2021	3/16/2021	?Pfizer-BioNTech COVID-19 Vaccine EUA? - Neurological issues - loss of short term memory, tremors, possible seizure, tinnitus, pressure in frontal cortex, brain fog, inability to urinate for 1 day, headache, exhaustion-constant sleeping, rapid heart rate, problems speaking-slow and deliberate, dehydration, motor skills slower, sinus's and whole brain feels dry, time going by really fast, ears hurt, teeth hurt, right and left neck hurt, left arm hurt, right shoulder hurt, hot flashes day and night. MEMORY ISSUES SUBSIDED TODAY, still brain fog, still RAPID HEARTBEAT and shaky. If all of this brain fog/rapid heartbeat doesn't subside by Monday March 29, 2021, an EEG will be ordered to look at the brain. I'm on my 2nd weeks bedrest with no exercise and Tylenol every 6 hours, the tylenol every 6 hours seems to help with some of the brain fog and the rapid heart beat, if I forget to take it I am soon reminded as my heart races and the brain fog reappears.

<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>
1135417	3/25/2021	OR	40	F	3/24/2021	3/24/2021	2.5 hours after vaccination, I was sitting watching tv when I had a sudden neurological event. It was like a seizure. I was unable to talk, my eyes rolled back, and my right shoulder and arm seized up. I was sputtering and unable to make it stop. Lasted for a minute or two then stopped for a minute and happened again. I felt disoriented, confused, scared. I was unable to walk straight or visually focus on anything. I contacted my primary care doctor and she recommended I be seen immediately but advised I call Providence and speak with a nurse. I did that and the nurse said to come in to the ER immediately. I did.
1134314	3/25/2021	OR	69	F	3/9/2021	3/10/2021	seizure in early morning, 6:00am

<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>
1135549	3/25/2021	NJ	24	F	3/11/2021	3/11/2021	left arm is very sore, painful to touch and difficult to move; left arm is very sore, painful to touch and difficult to move; fainted /vasovagal syncope episode; might have convulsed on the floor; out of breath; nausea; dizziness; This is a spontaneous report from a non-contactable consumer (reported for herself). A 24-year-old female patient (not pregnant at the time of vaccination) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 1 intramuscular, administered in Arm Left on 11Mar2021 15:00 (Lot Number: EN6199) at the age of 24 years old as single dose for covid-19 immunisation. The patient's medical history was not reported. Concomitant medication received within 2 weeks of vaccination included levonorgestrel, ethinyl estradiol (reported as "Levonor-E Estrad"). Facility where the most recent COVID-19 vaccine was administered in Pharmacy or Drug Store. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 11Mar2021 15:15, Few minutes after vaccination patient fainted and might have convulsed on the floor. Patient became conscious after a couple min. Patient had spouts of nausea and dizziness. 2 hr after dose (11Mar2021) patient was out of breath and went to a hospital. Doctors suppose that the incident was a vasovagal syncope episode. After 18 hr (12Mar2021) patient's left arm was very sore, painful to touch and difficult to move. The events resulted in Emergency room/department or urgent care. No treatment received for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. No covid prior vaccination. No covid tested post vaccination. The outcome of the events was recovering. No follow-up attempts are possible. 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>
1135558	3/25/2021	NC	70	F	2/20/2021	2/21/2021	Bruising of foot; foot was all messed up/it was all bruised and swollen, but it was not broken. She says this was her right foot; Fatigue; had a low blood sugar episode she supposed; passed out/Unconsciousness; had muscle spasms almost to seizure amount of shaking/full body muscle spasms; had muscle spasms almost to seizure amount of shaking/full body muscle spasms; crashed unconscious to the floor/fell/fell backwards/caught her foot under the vanity; This is a spontaneous report from a contactable consumer (patient) reporting for herself A 70-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 20Feb2021 11:00 (Lot Number: EN6201) as a SINGLE DOSE (at the age of 70 years old) for covid-19 immunisation. Medical history included breast cancer from 1988 to an unknown date , ovarian cancer from 2015 to an unknown date , she has had lymph nodes removed from her right arm "30 years ago" from 1988 to an unknown date, pass out from unknown date to unknown date. Concomitant medication included olaparib (LYNPARZA) taken for ovarian cancer from Feb2020 at 150mg, 2 tablets in the morning and 1-2 tablets at night by mouth.She says she is a little person and couldn't tolerate the side effects of that, so she varies how many she takes based on her side effects. She says she is supposed to take 300mg in the morning and 300mg at night. She says how she takes it is, she takes 150mg or one pill in the morning, then one or two at night depending on how she is doing. Historical vaccine information included BNT162B2 dose 1, lot no: EL9264, route left arm for Covid-19 immunisation. Past drug history included on days of intravenous (IV) chemo when she was being highly treated in the past sometimes she would pass out. The patient reported approximately 15 hours after the shot, on 21Feb2021 she had muscle spasms almost to seizure amount of shaking, full body muscle spasms. She clarifies that her side effects didn't kick in until 02:30AM on 21Feb2021. She says at 07:00AM on 21Feb2021 she got up and went into the bathroom and passed out, and had a low blood sugar episode she supposed. She crashed unconscious to the floor. She said that could be from the shot, but she is also a high risk patient, a cancer patient, and is on a maintenance chemo drug. She says on days of

<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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intravenous (IV) chemo when she was being highly treated in the past sometimes she would pass out, so she doesn't know if that was related to the COVID shot or not. No testing had been done on high risk patients, so she thought maybe this could be a good heads up for something someone else may experience. Her side effects were on and off for several hours, the shaking and spasms would subside and then start again. She says that they went away, and then she got up and passed out, and her foot was all messed up, she doesn't know what she did when she fell, but she had it checked and it was not broken, it was all bruised and swollen, but it was not broken. She says this was her right foot. She says she thinks she fell backwards, and she thinks she caught her foot under the vanity. On unknown date, she experienced bruising of foot, fatigue, foot was all messed up/it was all bruised and swollen, but it was not broken. She says this was her right foot. Outcome of the events was unknown. Information on the lot/batch number 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>
1135574	3/25/2021	CA	43	F	3/16/2021	3/16/2021	Itching; Burning in my throat and chest and arm; Burning in my throat and chest and arm; Throat swelling; Chest pain/burning in her throat and chest; Rapid heart beat; This is a spontaneous report from a contactable consumer (patient). This 43-year-old female patient received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in left arm on 16Mar2021 at 02:00 PM at single dose (lot number: EN6208, expiration date: 30Jun2021) for COVID-19 immunization. Medical history included known allergies to 32 meds and nuts and shellfish, asthma, COPD and seizures and chronic lung disease. Concomitant medications included prednisone and topiramate (TOPAMAX) in two weeks. The patient had no other vaccine in four weeks. The patient was not pregnant when vaccination. The patient was given the covid 19 shot and within mins. The patient tested the shot and started to have itching and burning in her throat and chest and arm and given 50 mgs of Benadryl in her inhaler then a hour later had to go to ER due her throat swelling closed and chest pain, rapid heart beat was given Benadryl n Prednisone. Events started from 16Mar2021 02:15 PM. 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 was recovered with lasting effects. Treatment was received for AE at ER 50 mgs Benadryl and 60 mgs of Prednisone. The patient had no Covid prior vaccination, no Covid tested post vaccination. Outcome of all events was recovered with sequel. Seriousness criteria was reported as life-threatening.

<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>
1135577	3/25/2021	HI	17	F	3/8/2021	3/16/2021	<p>Began having seizures; Presented to the ER on 17 March 2021 for headache with blurry vision; Presented to the ER on 17 March 2021 for headache with blurry vision; Also had persistent nausea and subsequent vomiting; Also had persistent nausea and subsequent vomiting; Fever X1 to 100.4F on day of presentation/no further sz; This is a spontaneous report from a contactable physician. A 17-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) intramuscularly in right arm on 08Mar2021 (lot number: EN6206) at single dose for COVID-19 immunization. Medical history included headache and irregular periods, ongoing hospitalization. No known allergies. Concomitant medications included birth control pills. No other vaccine in four weeks. No COVID prior vaccination. Vaccine received during existing hospitalization. The patient began having seizures (hospitalization prolonged, life threatening) on 16Mar2021 12:00, presented to the ER on 17Mar2021 for headache with blurry vision (hospitalization prolonged, life threatening) on 16Mar2021 12:00, also had persistent nausea and subsequent vomiting (hospitalization prolonged, life threatening) on 16Mar2021 12:00, fever x1 to 100.4F on day of presentation/no further seizure (hospitalization prolonged, life threatening) on 16Mar2021 12:00. Clinical course: Presented to the ER on 17March2021 for headache with blurry vision. Patient reported symptoms for 1 day prior. Also had persistent nausea and subsequent vomiting. Presented to the ED at 23:00. Began having seizures. EEG shows localized to the occipital region. Fever X1 to 100.4F on day of presentation no further sz. LP shows 1 WBC, Gram stain negative. Cultures negative. HSV pending. On ceftriaxone and acyclovir. Continues to have focal sz on EEG now on 3 AEDs. MRI with contrast negative. CBC unremarkable. CRP elevated to 0.8 (normal less than 0.5). Tox screen negative. COVID tested post vaccination: Nasal Swab (SARS-CoV-2 Cepheid) with result of negative on 17Mar2021. Therapeutic measures were taken as a result of all the events which included treatment with IVIG, Antibiotics, Steroids, Antiepileptics. The outcome of the events was not recovered.; Sender's Comments: Based on the information currently available, a possible contributory role of the suspect drug to the</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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reported events cannot be completely excluded based on temporal association and known drug safety profile. 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.

1136000 3/25/2021 MN

34 F

3/24/2021

3/24/2021

Patient has known Severe POTS syndrome with know AV Block Mobitz 1 25 minutes after vaccination the patient had a passing out episode accompanied by petit mal seizure. Patient resumed consciousness after 4 minutes. Patient was transferred to Emergency Room. Vitals were stable.

1136006 3/25/2021 NH

56 F

3/25/2021

3/25/2021

Pt received 2nd dose vaccine, waited her 15 minutes and upon leaving was witnessed by PD to have slumped on the floor, without trauma and began to seize. EMS called to scene and medical OIC called. Upon arrival, 911 called, SpO2 placed. VSS and respirations adequate. Negative for emesis. After 2 seizures, the patient regained consciousness and was able to communicate that her husband was outside, his name was in a blue vehicle. She confirmed she had a history of seizures. Her husband informed us she has a history of these seizures and brain CA. EMS arrived and took control of patient and transported to hospital.

<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>
1136040	3/25/2021	CA	30	F	3/25/2021	3/25/2021	<p>Patient presents to the clinic at about 2:20pm for her 2nd dose of COVID vaccination. She was greeted and asked to fill out another consent form for the 2nd dose and was told it will be reviewed after she completes it. She states she has a history of seizure. State had one small seizure episode yesterday. States her doctor is aware and is running more tests and changing her medications around. States her doctor is aware about her COVID vaccination and made no mention that she should not get the vaccine. She states she is comfortable getting it. She states she received the first dose of the COVID vaccine and did ok. The only symptoms she had was fever for about a week. Again she states her doctor is aware and has not told her not to get the second dose of the COVID vaccine. Consent and history were reviewed and COVID vaccination was given at about 14:27 with LVN. She was told because of her medical history, she will need to be monitored for 30minutes instead of the 15 minutes; she agreed. After vaccination was given, patient sat with another co-worker talking and appeared in no distress. Co-worker left shortly after while she was still there for monitoring. At about 2:30ish pm notice that patient was starting to slide down her chair appearing to have a seizure. Immediately rushed over to her, guided her down to the carpet, supported her head, she was lying to her side. She was not conscious, eyes closed, teeth clenched, no foaming of the mouth were noted. +strong radial pulse. Can hear her loudly breathing through her nose. Pulse oxygen on room air, 92% and heart rate was 67. She was not turning blue. Arms and legs were mild jerking. Called out to have staff called 911 simultaneously while supporting and monitoring patient. About 5 minutes into this, patient started to slowing open her eyes, still altered, teeth still clenching and extremities stopped jerking. Slowly, she started to relax, asked her name and where she is at and why she was there, which she was able to answer slowly. Asked her if she wanted us to call her daughter, she said he because she is a minor. Asked her who she is with and she said her husband is outside. Paramedic arrived and took over care and she was told she will be transported to the ER. Her husband, came into the room. After patient's husband spoke to paramedic, I also introduced myself to him. Per her husband, patient has a history of seizure that has not been controlled. Per husband, he states she</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>
							had 5 episodes on Sunday, 3/21/2021. Her doctor is aware and is doing more testing and changing her medications around. Per patient's husband, he states she was doing an MRA yesterday to further evaluate the seizure and they were not able to complete it because she had 2 episodes. When asked if her doctor mention anything about getting the COVID vaccine, per patient's husband he states they did not say anything. Per husband, she did ok with the 1st dose of the COVID vaccine and only had fevers. Per patient's husband, there was no change in her underlying medical condition with the seizure with getting the vaccine.
1136123	3/25/2021	AZ	24	M	3/25/2021	3/25/2021	Patient was given the 1st dose of the Pfizer- BioNtech vaccine and was told to wait in observation and few minutes later the patient fainted and had what appeared to be a seizure. Pharmacists onsite responded immediately and EMS was called.
1136168	3/25/2021	NC	21	M	3/24/2021	3/24/2021	3 seizures 2 minutes apart lasting a few seconds. EMS called and he was transferred to the hospital. BP:117/72 98% 66 Pulse

<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>
1135293	3/25/2021	AZ	81	F	3/9/2021	3/10/2021	<p>Spasms like seizures; Fidgeting non-stop; Barring their teeth like a grimace; Low-grade fever; A spontaneous report was received on 10 Mar 2021 from a consumer concerning a 81-years old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced spasms like seizures/ seizure, fidgeting non-stop/restlessness, barring their teeth like a grimace/bruxism and low-grade fever/pyrexia. The patient's medical history included COVID-19 and severe Alzheimer's disease. Concomitant product use was not provided. On 09 Mar 2021, approximately 1 day prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 (Batch number: unknown) for prophylaxis of COVID-19 infection. On 10 Mar 2021, the patient experienced low-grade fever, spasms like seizures, fidgeting non-stop and barring their teeth like a grimace. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events, spasms like seizures, fidgeting non-stop, barring their teeth like a grimace, and low-grade fever, 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.</p>

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1133030	3/25/2021	FL	74	F	3/2/2021	3/1/2021	she had low pressure; she passed out at one point; She is very pale in her face.; lightheaded/Dizzy; She felt very bad the second day; She had an allergic reaction; This is a spontaneous report from a contactable consumer. A 74-year-old female patient received second dose of BNT162B2 (BNT162B2), via an unspecified route of administration, administered in Arm Left on 02Mar2021 09:45 (Batch/Lot Number: EL9262) as single dose for covid-19 immunization. Medical history included seizure (she had convulsions as a child). There were no concomitant medications. The patient experienced she passed out at one point on 03Mar2021, she had low pressure on 03Mar2021 at 08:00. The patient also experienced she is very pale in her face, lightheaded/dizzy, she felt very bad the second day and she had an allergic reaction on Mar2021. Reporter states She had an allergic reaction. The first day she felt fine, the second day she had low pressure and she passed out at one point and the rest of the day she had low blood pressure. She felt very bad the second day and Monday was the same and she is still feeling light headed and dizzy today. She says the first dose was given on the 05Feb2021 and her second dose she just had that on 02Mar2021 and that is the dose she is reporting about today. She says it was 03 Mar when she started having low blood pressure and passed out. She says she is still light headed and dizzy today, that is ongoing. She has not checked her blood pressure today but she feels like it is still low. She is very pale in her face. The patient underwent lab tests and procedures which included blood pressure measurement: low pressure on an unspecified date (she had low pressure). Outcome of she had low pressure and lightheaded/Dizzy was not recovered. Outcome of all the other events was unknown.

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1131753	3/25/2021	AK	34	F	3/24/2021	3/24/2021	Patient reported a metallic taste in mouth right after administration of vaccine. She then reported a funny feeling in her throat. Pharmacist gave her Claritin 10mg (5-7 min post vaccination). She has experienced seizures in the past and felt like one was coming on. She had nausea, light headedness, cooling sensations. She was given some water and then asked for pepto bismol, which we gave her (10-15 min) post vaccination. She then started getting hives on neck and eye. She wanted an ambulance called, we did. She started getting tingles on both arms and neck. Felt a sensation like someone sprayed water near her on her neck. Ambulance arrived and by that time she was feeling better and hives were leaving. Paramedics checked her out and she declined going to hospital. Headache started when paramedics were assessing her. She had a friend come pick her up and take her home, to monitor her.
1131771	3/25/2021	IL	86	F	2/4/2021	2/5/2021	She received vaccine #2 on 02/04/2021. In the wee hours of the morning 02/05/2021, she had at least two episodes of seizure. she was found gurgling, hypoxic, jerking of arms.
1131805	3/25/2021	WA	30	F	1/20/2021	1/20/2021	Decerebrate posturing, loss of consciousness for ten seconds, wheezing, atypical seizure, eyes rolled back, EMS called, supplemental oxygen administered Went to ED, given ativan, zofran, 1L LR bolus and neuro assessment by PA-C Severe nausea for 5 days, slept off and on for five days, dizziness for five days, brain fog for 5 days
1131842	3/25/2021	FL	65	F	3/24/2021	3/24/2021	Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Hyperventilation-Severe, Systemic: Seizure-Severe, Systemic: Shakiness-Medium

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1132012	3/25/2021	IL	79	F	3/19/2021	3/24/2021	To er for eval of seizure activity at hospital . Nurse reported that seizure activity lasted 1.5 min and took approx. 30 minutes for her to start " coming around" to her self. Patient was bradycardic en route to hospital. er hpi: "79 y.o. female who presents with seizure activity. Patient is brought to the ER via EMS from nursing home with new onset seizure. Nursing home staff reports patient had tonic-clonic seizure which lasted approximately 1 min. Patient was apneic. Patient is slightly postictal but no urinary incontinence. Patient has no known history of seizure disorder. Patient is resident of nursing home and is a DNR comfort care. Patient with underlying dementia. In speaking with patient she denies any current headache, chest pain, shortness of breath, abdominal pain, nausea, vomiting, diarrhea, fevers, or chills. She is alert only to name." Inpatient admission to hospital 3/24/21 dx acute hepatic encephalopathy, new onset seizure without head trauma
1132118	3/25/2021	OH	40	F	3/24/2021	3/24/2021	Pt began feeling lightheaded after receiving her vaccine. Medical staff was notified and witnessed a syncopal episode where pt was seen with flexed arms and bladder incontinence. Pt was AOx4 after regaining consciousness with SBP in the 80s, diaphoresis, and nausea. Pt did report history of syncopal events associated with needles and SBP around 90s. Pt was monitored and later released by medical staff and EMS after symptoms resolved. PT was instructed to follow up with PCM regarding possible concerns for seizures and hypotension.
1132371	3/25/2021	VA	57	F	3/2/2021	3/7/2021	Seizure - trip to emergency room - follow up MRI, Cardiologist and Neurologist appts
1132443	3/25/2021	IL	29	F	3/20/2021	3/20/2021	103 temperature, seizures, vomiting, feeling like the bones were broken in my neck. I did not make it into the ER

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1134439	3/25/2021	OK	48	F	3/17/2021	3/17/2021	I received the shot at the pharmacy location, they had us sit for about 10min after then we could go, my next appointment happened to be at a dr's office thank goodness because about 10 min after sitting in the waiting room I felt faint and spoke out to the receptionist that I needed to lie down, they laid me down on the couch where I was sitting my blood pressure had shot up to 165/126 or I was unable to stand on my own, I was beginning to convulse and my heart rate shot up, they got a wheel chair, put me in it and took me back to one of their rooms where they I think ran a few test and then they made the decision to take me down to the er, the er which I told repeatedly that I had just received the covid shot, they hooked me up to machines, I think did a EKG, wheeled me to get a mri, and then did a chest xray, all while I was convulsing, they allowed this convulsing to continue for over 3+ hrs before they finally gave me something to calm down the convulsions, I was having sensory issues and could not handle, light, etc, for the next many days my heart rate would jump from the 60's too the top was I think 200BPM, I had to lie in a dark room, no sounds for a few days, I am just now felling a little bit better.

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1133022	3/25/2021	NY	28	F	3/5/2021	3/8/2021	Generalized Tonic-Clonic Seizure; feeling unwell; slightly nauseous; still a little slow in speech and gait; still a little slow in speech and gait; This is a spontaneous report from a contactable consumer (patient). A 28-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6202), via an unspecified route of administration, administered in arm right on 05Mar2021 08:00 as a single dose (at the age of 28-years-old) for Covid-19 immunisation. The patient was not pregnant at the time of vaccination. Medical history included epilepsy, hypopituitarism, central diabetes insipidus, neoplasm of brain, irregular menses, short-term memory loss, elevated LDL, and myopia w/ astigmatism. The patient had known allergies to surgical tape and contrast dyes. Concomitant medications included desmopressin acetate (DDAVP), lamotrigine (LAMICTAL), levetiracetam, and zonisamide; all were taken for an unspecified indication, start and stop date were not reported. The patient previously took amoxicillin and experienced drug allergy. On 08Mar2021 at 06:15 PM, the patient experienced generalized tonic-clonic seizure, feeling unwell, slightly nauseous, still a little slow in speech and gait. Therapeutic measures were taken as a result of generalized tonic-clonic seizure, feeling unwell, slightly nauseous, still a little slow in speech and gait as Nayzilam 5 mg two doses was administered. Clinical course details as reported: the patient finished dinner and evening medications before 6 pm and started feeling unwell and slightly nauseous soon after. Laid on sofa, started to sit up at 6:20 pm, and went into a Generalized Tonic-Clonic Seizure. The patient's father administered Nayzilam 5 mg (2 doses); seizure ended and the patient went into a deep sleep until 8:00 pm. The patient was largely recovered, but still a little slow in speech and gait. The outcome of the events was recovering as reported. Information on the lot/batch number has been requested.

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1134685	3/25/2021	CA	63	F	3/25/2021	3/25/2021	Pt presented today for 1st Pfizer mRNA COVID vaccine. She received the vaccine at 11:06am and proceeded to the check out area and scheduled her second appointment and checked out at 11:10am. She was sitting in the secondary seating area, she looked scared, then she indicated to the APP she felt dizzy, eyes fluttered back, and slumped back into the chair and into APP's arms. With the assistance of another RN, we laid her down on the ground and lifted her legs. She was arousable to sternal rub and complained of dizziness. She was able to report her name and that her husband was outside in the car waiting for her, however, she was slow to answer questions and still appeared distressed. We made several attempts to obtain a BP, however, it would not register on machine, O2 sat 100%, HR 42, manual HR 50 at pericordium. Her bilateral upper extremities were cool to touch and appeared mottled. We attempted to give her apple juice just she was only able to take a few sips. We placed her on 100% non-rebreather. Given low HR, unable to obtain BP, and semi-conscious state, we elected to call 911 at 11:30am. Her husband was retrieved and at patient side when EMS responded. He reported that she has fainted in the past with blood draws and has a past medical history of "leaky valve, low platelets" and later it discovered via her medical records that she has a history of seizures and was on vimpat and lisinoril. EMS arrived, assessed the patient, and moved her to stretcher and transported patient at 11:39am.

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1133286	3/25/2021	GA	68	M	1/18/2021	1/18/2021	1/18 vaccination Within 4 minutes, my husband started with tremors in his hand. Feeling funny. Felt like something was wrong. He was trying to hold hands still but then other extremities started to shake. He passed out. Honked for help. It took both ambulances to tx my husband and onto the stretcher and strapped in. Grand Mal Seizure. It started to fade when he got into but then had another one after he was in the ambulance, worse then the first one. He continued to have seizures for 4 more days. Every couple hours, give him the kepra and topomax to help. 1/20 orthopedist 1/25 PCM 1/26 Neurologist 1/28 home health nurse 2/8 PCM, mental health 2/10 orthopedist 2/12 home health nurse 2/17 home health nurse *Dr Neurologist *Dr. PCM *Dr. **stated he cannot have 2nd vaccine. 'if he has another grand mal seizure it will kill him'
1133317	3/25/2021	AK	19	F	3/24/2021	3/24/2021	Our patient received her shot and stayed in the pharmacy area for 15 minutes and was released. Fifteen minutes late she returned to the pharmacy says she was dizzy and nauseated. We had her sit in the pharmacy for about 20 minutes at whichn time she said she felt better and was ready to go. We had one of our pharmacists walk her but she became dizzy and nauseated again and had to sit down. At this time she said she was hot and very light headed and her vision was starting to get blurry. A minute or so later that she sat up in her chair and stopped breathing and started to fall off. One of our pharmacists caught her and at point she went into convulsions and started gagging and could not breath. 911 was called at this time and an Epi pen was administered. The convulsions stopped 30 seconds afer the Epi and her breathing eazed. The EmT's arrived with in 10 minutes and took her to local emergency room. Our pharmacist called the emergency room about a hour later and they said that She ww as doing well.
1133546	3/25/2021	WA	19	M	3/24/2021	3/24/2021	Client was waiting his shot time when he fell from his chair hitting his left shoulder and face. He appeared to have seizure activity. He became responsive very quickly and was oriented. 911 was called and he was transported to emergency department. He was able to walk to the ambulance.

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1133594	3/25/2021	WI	42	F	3/22/2021	3/23/2021	I began having seizures at night during sleep beginning on 3/23-3/24 overnight. They are simple partial seizures, but wake me up out of sleep. I currently have had 4 seizures all during sleep. I have a history of epilepsy, however I went years without seizures. I did have an occurrence of seizures in February however that was directly related to hormones associated with menstrual cycle.
1133602	3/25/2021	NY	51	F	3/25/2021	3/25/2021	Patient had grand mal seizure following vaccination X 2. Event occurred approximately 10 minutes following vaccination. Patient does report history of "vasovagal episodes". Pulse maintained throughout episode, no medications given. Patient spontaneously returned to orientation. BP 70/50 and HR 59 upon initial assessment. Patient sent to urgent care clinic for further evaluation by provider.
1133741	3/25/2021	IL	65	F	2/25/2021	3/11/2021	After the first dose on 1-29-2021 I was violently vomiting and nausea for several days. I was hesitant to get the 2nd vaccine but I did it anyway. My 2nd dose was on 2/25/2021. Exactly 2 weeks later on 3-11-2021 at 11am I went into a full seizure and my husband called 911. I was not aware of my surroundings until 3/12/2021 at 10am. I spent 4 days in Hospital . MD and several other Neurologists reviewed and tested me for seizures. I had no history and my tests came back with no reason or conclusion for having a seizure. The COVID vaccine had been the single only change in my life. I also had NO pre existing condition to have a seizure. I was so sick after the first vaccine 01/28/2021 that I did not think I should get the 2nd dose but I did. For over 30 years I have gotten my flu vaccine every year with no issues. I will never ever get a COVID vaccine again.
1134107	3/25/2021	CA	50	F	3/22/2021	3/23/2021	While I was asleep my partner saw me having what looked like a seizure on Tuesday 03/23/2021 @11:30pm. I was sleeping on my stomach, my partner describes it like a fish flopping.

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1134111	3/25/2021	NY	30	F	3/25/2021	3/25/2021	Otherwise in normal state of health when she presented to have her first vaccine today. In observation area she developed jerky movement of right upper extremity and called to be taken to first aid bay. As soon as she was transported to the bay she exhibited myoclonic jerks. She reports this has happened in past and that as long as she does not lose consciousness it is normal for her. Jerky movements lasted for about 15minutes and resolved spontaneously. She was not post ictal and was awake and alert and conversive throughout episode. She reports history of seizures but not on any medication. She likely has pseudoseizures. Her vitals were stable. She reports her full blown myoclonic jerky movements have not happened
1134274	3/25/2021		73	F	3/13/2021	3/16/2021	Seizure, aphasia, facial droop 3 days after receiving vaccination.

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1132490	3/25/2021	CA		M	2/10/2021		He was in a hospital now having an emergency due to complications that had something to do with a prostate procedure; he experienced having seizures; This is a spontaneous report received from the Pfizer sponsored program . A contactable consumer (patient himself) reported that a male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number and Expiration date was unknown), via an unspecified route of administration on 10Feb2021 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that, initially, caller wants to cancel his second vaccine dose which according to him was today, 11Mar2021. He said that he was in a hospital now (on an unspecified date in 2021) having an emergency due to complications on an unspecified date in 2021 that had something to do with a prostate procedure he had 2 days ago. He had his first vaccine shot on 10Feb2021. That's more than 21 days if his next schedule was today, 11Mar2021. Consequently, during the call, he experienced having seizures on an unspecified date in 2021. The event "he was in a hospital now having an emergency due to complications that had something to do with a prostate procedure" was considered as serious (hospitalization) by the consumer. The outcome of the event he experienced having seizures was not recovered and unknown for the other event. Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal relationship the causal relationship between BNT162B2 and event, post prostate procedural complications, seizures cannot be completely ruled out.
1134512	3/25/2021	AL	19	M	3/25/2021	3/25/2021	After patient received COVID vaccination, he exhibited seizure like activity. Staff moved patient to floor. 911 was dispatched. Patient complained of nausea. Vomited x2. Skin pale and diaphoretic.
1136251	3/25/2021	TX	51	M	3/22/2021	3/25/2021	New onset seizure 3 days after vaccination

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1131054	3/24/2021	IL	58	F	3/24/2021	3/24/2021	Patient received the Covid-19 vaccine. She reports symptoms of lightlessness, taste in mouth. Pt stated she is unsure if she had a seizure since she has a hx of seizure disorders. Pt did take medications this morning. Pt does not have any facial swelling. Pt started feeling unwell at 11:02am Vitals: B/P: 110/74 HR: 110, 105, 100 02: 87 11:20: Vitals: B/P: 112/74 HR: 98, 86 02: 97 11:32am: BP: 116/76 HR: 86 02: 97 11:45am: B/P:112/72 02: 97 HR: 86 Pt stated she feels ok now, husband is here with pt and is driving her home. Pt aware to mention this to health care provider, pt verbalized understanding
1130530	3/24/2021	VA	61	M	3/18/2021	3/22/2021	Grand mal seizure, wife found patient lying on the ground with eyes fixed and loss of urine. Wife called EMS around 2:22 and patient came to about 15 minutes later.

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1130534	3/24/2021	TX	73	F	3/21/2021	3/21/2021	EMS narrative: EMS WAS DISPATCHED TO A MEDICAL EMERGENCY. EMS ARRIVED ON SCENE TO STAFF STATING THE PATIENT RECEIVED HER 2ND DOSE OF THE COVID VACCINE AND IS HAVING ADVERSE REACTION. STAFF STATED NO SIGNS OF HIVES/SWELLING/AIRWAY COMPROMISE. PER STAFF PATIENT RECEIVED THE VACCINE APPROXIMATELY 5-10 MINUTES PRIOR TO EMS ARRIVAL. EMS ARRIVED AT PATIENT TO FIND A 73-YEAR-OLD FEMALE A&O X4 GCS 15, LYING ON HER RIGHT SIDE ON COT. PATIENT ACTIVELY HAVING FOCAL SEIZURE ACTIVITY. 18 GAUGE IV WAS ESTABLISHED IN THE LEFT AC NOTING FLASH, BLOOD DRAW, AND FLUSHED. NO SIGNS OF IV INFILTRATION NOTED. ALL MEDICATIONS GIVEN AS DOCUMENTED. SEIZURE ACTIVITY STOPPED. BGA/VITALS/EKG WERE OBTAINED AS NOTED. PATIENT MOVED TO STRETCHER VIA 2-PERSON CARRY AND SECURED VIA STRAPS X5 RAILS X2. PATIENT MOVED TO THE AMBULANCE AND SECURED INSIDE. NORMAL SALINE GIVEN THROUGH IV WIDE OPEN. EMS BEGAN TRANSPORT AND CONTINUALLY MONITORED THE PATIENT. DURING TRANSPORT PATIENT STATED, "I'M FEELING A LITTLE BETTER." EMS ARRIVED AT DESTINATION AND MOVED THE PATIENT INSIDE. PATIENT MOVED TO HOSPITAL BED VIA DRAW SHEET. VERBAL REPORT WAS GIVEN NURSE AND CARE WAS TRANSFERRED. EMS CLEARED.
1130637	3/24/2021	TN	40	M	3/24/2021	3/24/2021	Patient had a seizure/convulsion immediately after the vaccination. I did not personally see them have the convulsion, but his wife observed this. By the time I had made it to the vehicle he had come to and was fine. Patient was also extremely anxious about receiving the vaccination. We believe his anxiety may have manifested as a seizure/convulsion in some way. No other issues or allergic reactions.
1130650	3/24/2021	CA	21	F	3/12/2021	3/19/2021	Large, tender, and erythematous rash present on the left shoulder (immunization site), which started on 3/19. Rash is 12 x 12 cm in size, Pt without other symptoms to include fever, chills, cough, SOB, chest pain, seizure, or other neurologic symptoms.

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1130957	3/24/2021	PA	28	M	3/16/2021	3/18/2021	patient had seizures and cellulitis
1130976	3/24/2021	MD	19	F	3/24/2021	3/24/2021	Syncopal with seizure like activity lasting 20 seconds; occurred twice within 2-3 minutes while seated in car
1130511	3/24/2021	CA	23	M	3/24/2021	3/24/2021	5 minutes after shot, pt slid from chair and fell backward; witness said pt suffered from mild seizure; paramedics were called and pt was assessed; pt has no history of epilepsy but did have a fainting episode years ago when giving blood; he also stated he hasn't eaten or drank anything today; he declined transport to hospital but is getting a parent to pick him up; paramedics highly suggested that parent take him to the ER or urgent care
1131034	3/24/2021	CA	21	F	3/1/2021	3/1/2021	Patient was vaccinated on 3/12/2021 with 1st dose Pfizer, lot EN6205 expiration date 6/30/2021. Patient denied medical conditions except adverse reaction of seizure after HPV vaccine. Patient informed RN that she had syncopal episode at 15min and 25min after receiving the 1st dose. Her vital signs were within normal limits after. Patient denied allergies. Medication includes birth control pill. RN relayed information to PHN who texted medical team. Per medical team, patient is to wait until 28 days post 1st Pfizer dose before receiving Janssen vaccine, it is not recommended to receive Pfizer 2nd dose. Patient was advised to consult with her provider.
1130067	3/24/2021	SC	24	F	3/23/2021	3/23/2021	Systemic: Seizure-Medium, Additional Details: Patient had 3 1-minute seizures while in waiting area after the immunization. Patient was conscious between seizures, and is aware of her condition. EMS was called and transported patient from the store. Patient was contacted later in the day. Patient had been discharged from the ER and would follow up with her neurologist. Patient reported that she was doing well.
1131071	3/24/2021		27	F	3/23/2021	3/23/2021	PT HAD A REACTION 10 MINUTES AFTER RECEIVING THE COVID VACCINATION. PT STARTED HAVING SEIZURE LIKE ACTIVITY THAT LAST 30 SECONDS ABOUT 10 MINUTES POST COVID SHOT; PT WAS SENT TO THE ED BY RAPID RESPONSE TEAM. PT WAS CHECKED OUT, DR THOUGHT IT TO BE A BASALGAL RESPONSE, BUT MONITORED HER IN THE ED. SHE WAS GIVEN NS BOLUS. AFTER MONITORING PT SHE WAS DISCHARGED.

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1131085	3/24/2021	TX	44	F	3/23/2021	3/23/2021	Got very dizzy and cold sweats a few minutes after vaccine. Then I had a seizure and thankfully my husband was there and called the paramedics because he thought I was having a stroke and when they came I was waking up but I had very blurry vision and I was very very sleepy and my memory wasn't very good. The paramedics came and checked my vitals and my blood pressure was very very low but I got to feeling better and stayed there for more time. I was very very tired and my memory was kind of bad for the rest of the day. My husband said I was twitching and my eyes were rolled back when I was seizing and he was a little over a minute when I was seizing.
1131114	3/24/2021	CA	20	F	3/24/2021	3/24/2021	Patient lost consciousness for a minute while waiting in the pharmacy after her vaccination. She slid down from the chair she was sitting on and recovered consciousness soon after laying down on the floor. She mentioned she was dizzy but otherwise alright. No signs of allergy, had cold hands. Symptoms indicated syncope but witnesses mentioned they saw her having a small seizure, where she threw her hands and head back before sliding down. 911 was called, they checked her and walked her to her car and let her go with a friend.
1131376	3/24/2021	NJ	58	M	3/9/2021	3/13/2021	Seizures 4 days after the vaccine
1131673	3/24/2021	GA	69	F	3/23/2021	3/24/2021	Just after midnight of the day I received the shot, I started getting the chills although I wasn't cold. The shaking escalated into seizure-like shaking, quivering, jerking. This lasted until approximately 7:00 a.m. My husband had to physically hold me and walk me to the bathroom. He gave me a bottle of water but I wasn't able to unscrew the cap nor hold the bottle and sip from it because my head and hand were shaking uncontrollably
1131674	3/24/2021	NV	43	M	3/23/2021	3/23/2021	No issues immediately following vaccine. About 11am, mild symptoms like 99.4 degree fever, muscle aches, joint pain, very mild nausea, fatigue began. Severe nausea began about 7:15pm. At 7:45pm, severe dizziness resulting in loss of consciousness and fall. Seizure Syncope event lasted 2 1/2 to 4minutes. Slow to wake. Trembling/shaking in extremities, cold sweat. Delayed speech. Paramedics were called. Went to ER at approximately 8:30pm.

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1131688	3/24/2021	NY	57	F	3/11/2021	3/12/2021	started approx 1:30 AM - shakes (felt like a convulsion) vomiting, diarrhea, shortness of breath, chest tightness - no fever
1131023	3/24/2021	OH	68	F	3/12/2021	3/12/2021	She first felt dizzy and light headed about 15-20 mins after shot. An hour later she used the bathroom on herself and was disoriented. The ambulance was called, her oxygen levels were low and she was taken to the hospital. She has seizures at the hospital and she has been sedated ever since.
1129897	3/24/2021	VA	32	M	3/24/2021	3/24/2021	Patient was on his way out of the door and stated that he was feeling dizzy. Patient sat down in the chair and became pale, sweaty, and he loss consciousness for a brief moment. Patient's pupils were dilated and moving rapidly from side to side. Patient quickly regained consciousness. Patient stated that this happens every time that he receives a vaccination or has blood drawn. Denies any history of seizures. It appeared that patient had a focal seizure. Patient's vitals were monitored until WNL and was able to fully regain consciousness. Patient didn't want to go to the ED for treatment. Patient advised not to drive and advised to follow up with PCP ASAP.
1129828	3/24/2021	NY	55	M	3/16/2021	3/16/2021	Arm hurt 1st like bad tetanus shot for 2 days Chills & sweats started the next day or so Left arm lymph node swollen/aching Lightheaded, nauseous, nearly passed out & vomit Thursday night Chills & sweats got worse, very lightheaded, heavy legs, fainted when having seizure Saturday Sunday things seemed to subside * Tinnitus was flaring most of the time **Chronic left jaw ache/pain flaring as well ***Mid back pain spot which has become chronic like jaw wrapped around torso and up/down spine, almost like a cross. This seems to be the lingering issue as of sunday night.

<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>
1129254	3/24/2021	OK	61	F	3/5/2021	3/5/2021	BP dropped to 70/40; seizures; She did fall into a cabinet; bruised up; inflamed; back was on fire; if she moves her head quickly, she can feel like she will have a headache, hangover; could not walk; Trouble walking; Funny taste in mouth; Pain/ felt achy; tingling sensation from head to her to spine/ hands tingling/ it was also in her abdomen area and in her leg; Back pain; Could hardly move; could not stand up; autoimmune response; delayed allergic reaction; tweeky muscle/ pulled a muscle in her back; pain at the top of her head down to her hip; pain at the top of her head down to her hip; having trouble holding her urine; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID19 VACCINE, Solution for injection, lot number: EL9266), via an unspecified route of administration in the left arm, on 05Mar2021 1:45 PM at a single dose for COVID-19 immunization. The patient did not receive any vaccines within 4 weeks prior to receiving the BNT162B2. Medical history included allergic reaction, autoimmune disease, brain barrier fever, epilepsy, encephalitis and meningitis. She had epilepsy as a child. She gets epilepsy when she gets sick. The last 4 times she got sick she had a seizure. The last seizure was 1 year ago (in 2020). She may have had COVID, but she got really sick and had a seizure. She is not sure if it was COVID or not. If it was the flu, she does not want that again. She had ataxia and ended up in hospital two times but did not stay. Prior to this, she did not go to hospital for 30 years. She was unable to walk, her gait was real bad. The neurological disorder messed her up for a while. Concomitant medications were not reported. It was reported that the patient received the PFIZER-BIONTECH COVID19 VACCINE first dose and experienced autoimmune response. After the vaccine, she had pain and tingling sensation from head to her to spine (05Mar2021), BP dropped to 70/40 (06Mar2021), seizures (06Mar2021), and delayed allergic reaction (Mar2021). She wanted to know if she should take the second dose or not. She also wanted to know if that would be considered the anaphylactic reaction. It was also reported that the patient experienced funny taste in mouth, back pain, hands tingling on 05Mar2021. The patient further explained that when she got the shot, she had a funny taste in her mouth. It started immediately

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

after she got the vaccine and it lasted 30 minutes. She mentioned this to the people at the facility, but they said she was crazy and no one else has mentioned this. She thought they would be interested, but they did not care. About 20 minutes later she had a tingly sensation. It was in the back of her head that developed into a stingy, painful, heat, funny type feeling. It was all the way down to her back. She later further explained the back of her head was tingling (05Mar2021). Like were the cerebellum is to spine. This sensation is still there, but better. After she felt this feeling her back then started hurting. She bent over and her back went out. She felt achy. She already had what she called a tweaky muscle (05Mar2021). She had pulled a muscle in her back, but it was nothing that had caused a problem. After getting the COVID vaccine it triggered an immune response in her body. She started to have pain at the top of her head down to her hip (05Mar2021). She bent over and she could not stand up (05Mar2021). Her husband had to help her put her pants on and sit down due to this. She started to have horrible back pain (05Mar2021). She could hardly move (05Mar2021). She was having trouble walking (05Mar2021). She was having trouble holding her urine (05Mar2021). On Saturday evening (06Mar2021), her blood pressure started dropping and she later had a seizure. After the seizure occurred it seems like everything got better and she did not have any trouble since. It was very scary. She mentioned she was in the bathroom and there was a tub full of water. She had a hard time already getting to the bathroom. She was in a lot of pain. The amount of pain she had she thinks affected her blood pressure. She had pain in the back, middle of her back. It started at her head, back of head, down her spine, came down to her back and hips. She was hurting a lot and having a terribly hard time getting around. She could hardly walk. She was going to the bathroom because she felt like she had to go. Her husband was helping her sit on the toilet. When she stood up it was like her blood pressure dropped, she almost went headfirst in the tub full of water, but her husband caught her, laid her down, and had a seizure. This was a very unnerving feeling. The seizure did not last more than a minute, maybe two at the very most. The seizure occurred probably around 6PM or 7PM. It did not last long at all. She woke up on the floor. She had

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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been sitting and she thought she had fallen off the toilet. However, her husband had to remind her that a few things happened in between. She almost fell in the bathtub and she has glass doors. She mentioned she felt as clarified and confirmed sped up. She did fall into a cabinet and is bruised up from that seizure (06Mar2021). She is sore from the pain from that. Still inflamed (06Mar2021) possibly due to the seizure. Like she has ruminants of what occurred to back of head, cerebellum. Before she had the seizure, her blood pressure had started dropping. It started dropping in the evening around 5PM or 5:30PM. Mentioned she is a little confused about the time onset because she was hurting so much and bad all day. She does not take any pain medication. She has an autoimmune disease and it is difficult for her to take medications. On top of that, if she wanted to take an Aspirin she was told she should not take one. She was informed she was trying to promote an auto-immune response to the vaccine. As the day ran on, she was in a lot of pain. She had been in pain since Friday and was trying to deal with that. The patient further stated her blood pressure is back, no illness. After the seizure her blood pressure went back to normal and at this time it is perfectly fine. The back pain she experienced went from the brain down to her backbone. The pain is gone. It started to go away after the seizure and by Sunday 07Mar2021 it was totally gone. At first it was like she could not walk (05Mar2021). It was like she/her back was on fire (05Mar2021). The patient also mentioned if she moves her head quickly, she can feel like she will have a headache, hangover. She feels it in her back. She feels like she is near recovery, and this is a feeling she does not think will stay. She further went on to say her hip where she fell is a different story. However, this is associated to a fall and not a vaccine. She was having this problem when she had the vaccine, but the vaccine caused it to be more and extra aggravating. She later added, when she first got home along with head tingling her hands were tingling as well. When her brain and hands were going through this tingling sensation, she started to notice the back trouble and it was also in her abdomen area and in her legs causing trouble walking (05Mar2021). The events did not require a visit to the emergency room or physician office. Outcome of the events trouble walking, could not walk, tingling

<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>
							sensation and hangover was recovering. Outcome of BP dropped to 70/40 was recovered on Mar2021. Outcome of seizures recovered on 06Mar2021. Outcome of funny taste in mouth was recovered on 05Mar2021. Outcome of back pain was recovered on 07Mar2021. Outcome of bruised up was not recovered. Outcome of the remaining events was unknown. The patient provided an unrelated causality between the vaccine and event fall. No follow-up attempts are needed. No further information is expected.; Sender's Comments: Based on the current available information, the event Fall is most likely related to an intercurrent or underlying condition which is not related to the suspected drug.
1128611	3/24/2021	NY	16	M	3/4/2021	3/14/2021	On day 9 after the first dose, He Had an unprovoked seizure for the first time ever. He never had seizures his entire life. We took him to the emergency room , all tests were normal (including CT scan). Subsequently, he had his first-ever EEG that came back normal as well.
1128370	3/24/2021		29	F	3/23/2021	3/23/2021	Vasovagal Response Confusion, Disorientation, Dizziness, Loss of consciousness, Seizure, Weakness Nausea
1128283	3/24/2021	CA	33	M	3/16/2021	3/16/2021	Systemic: Seizure-Mild, Additional Details: Minor seizure lasted only briefly. Patient seemed unconcerned afterwards and informed pharmacy staff that he goes through this outcome after getting any type of vaccine.
1128206	3/24/2021	TX	49	M	3/12/2021	3/23/2021	DIC, intracerebral hemorrhage, intubation, requiring plts transfusion, seizure

<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>
1130525	3/24/2021	AR	47	M	3/16/2021	3/17/2021	Patient reports receiving first dose of COVID-19 from Hospital (was not given vaccine card as their policy is to wait until after second dose). The day after vaccination, patient was complaining of fatigue with subjective fevers and rigors with associated headache and neck stiffness and on the day of presentation he complained of increased fatigue and general malaise for which he left work early and was ultimately found poorly responsive in his private vehicle with concern for possible seizure activity. He was brought to ER by ambulance. He reported numbness in hands and legs, rigidity, and an episode of urinary incontinence. He was started on empiric antibiotics for possible CNS infection, lumbar puncture completed. Found to have acellular CSF and antibiotics were discontinued. Patient remains in hospital at this time with course complicated by post-LP headache.
1127428	3/23/2021	TX	42	F	1/4/2021	1/13/2021	1st Moderna shot was 1/4/21. Had a syncope episode/potential seizure on 1/13/21 - unwitnessed loss of consciousness for a short period of time with loss of urinary continence. 2nd Moderna COVID shot on 1/29/21 with no reactions. My doctors evaluating me did not consider this as a COVID vaccine reaction, even though it did occur after the first vaccination. I am a nurse with a doctorate degree and do not believe the seizure was the reaction of the COVID vaccine. I was under extreme amounts of stress at work at the time. I also have a prior medical history of syncope episodes when I was a teenager (25+ years ago).
1126125	3/23/2021		41	M	3/20/2021	3/20/2021	Vasovagal event with syncope and seizure activity fir 15 to 20 seconds Client stated he always responds this way to shots. Hx of TBI at age 4 years. Blood pressure 106/68 pulse 84 and O2 saturation 100%. EMS and Dr on site and client released when symptoms resolved. Advised to seek medical attention later if needed. Client verbalized understanding.

<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>
1125834	3/23/2021	VA	73	F	2/25/2021	2/25/2021	seizure; twitches jerks; This is a spontaneous report from a contactable consumer (patient) via Medical Information Team. A 73-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EW6205), via an unspecified route of administration on 25Feb2021 at SINGLE DOSE for COVID-19 immunisation. Medical history included high blood pressure, cholesterol, diabetes, seizure disorder, and was put on continuous positive airway pressure (CPAP) machine. Concomitant medication included unspecified medication for high blood pressures. Patient stated that her blood pressures are normal but she was on medication for it. The patient previously took phenobarbital for seizure. The patient got the first dose of the vaccine on 25Feb2021 and later that day, the patient had a seizure and was in the hospital for days. The patient was put back on seizure medication, Keppra. It was further reported that patient was diagnosed with a seizures disorder when she was 20. She haven't had a seizure probably in 40 years and she was put on a CPAP Machine and she started getting good sleep and she was able to go off all seizure medicines about 10 years ago. The patient got the first shot on the 25Feb, she sit around for 15 minutes and no adverse reactions. She went to lunch with her sister and started having like what she call twitches jerks (not clarified) and she went home and little bit later that afternoon she had a major seizure and had to be taken to the hospital and there she stayed about 4 days. Now she was home and back on her seizure medication (further clarified as Keppra). The patient was hospitalized for seizures on 25Feb2021 and was discharged March 1st or 2nd. Additionally, it was reported that patient had a bunch of laboratory test (unknown results) in the hospital. Electroencephalogram (EEG) and magnetic resonance imaging (MRI) were performed with unknown results. Therapeutic measures were taken as a result of seizure which included Keppra. The outcome of the events was unknown.
1126229	3/23/2021	TX	48	F	3/16/2021	3/17/2021	Seizure the next day plus headaches, tremors and vomiting.

<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>
1126270	3/23/2021	MT	64	F	3/19/2021	3/20/2021	I have fibromyalgia and follow the injection the nerves started firing like crazy. After they calmed down I felt severely drained like post seizure? I was in bed with body aches everywhere I have been injured for 3 days.
1126593	3/23/2021	IN	63	F	3/12/2021	3/13/2021	The following was reported by the patient on 3/23/2021: On 3/13/2021 at 9:10AM, the patient suffered a seizure, she was calm after 5 minutes. At 2:25PM, there was a second episode of seizure. The husband decided to take her to the hospital ER. When they were in the ER, at around 5:50PM, she suffered another seizure and the doctor decided to admit her to the ICU. She stayed in the ICU and was discharged on 3/15/2021. Since then, she was fine already.
1126818	3/23/2021	CA	69	M	3/16/2021	3/16/2021	admitted to the ICU with acute respiratory failure. h/o DM and HL, prior h/o smoking and EtOH and opium abuse (none x 28 yrs, per family). Received second dose of the Pfizer COVID vaccine in AM of 3/16, having had severe adverse reactions (fever up to 104, n/v) to the first dose three weeks earlier. Experienced recurrent fevers (up to 103) beginning by the evening of 3/16, for which he took acetaminophen. Awoke at 3 AM w/ recurrent fevers, for which he took ibuprofen. Felt better in AM, had breakfast, and retired back to bed. Awoke shortly after noon w/ severe n/v and AMS. Was brought to the ED by the EMS. Febrile (T 39.6) w/ rigors, tachycardic, tachypneic, and poorly responsive on arrival. Continued to experience episodes of emesis, and was felt to have possibly had a seizure episode ("looked to the side and was shaking"; no clear tonic-clonic movements noted). Was thus intubated for airway protection. Initial laboratory w/u revealed presence of mild leukocytosis (WBC 12.6, 47p49L0Eo), lactic acidosis (LA 5.2), hyperglycemia (glu 297), elevated lipase level (161) renal insufficiency (Cr 1.23). extubated on 3/19. received antibiotics for positive blood culture (streptococcus parasanguinis). diagnosis: ADVERSE EFFECT OF CORONAVIRUS COVID-19 VACCINE
1126831	3/23/2021	VA	23	M	2/3/2021	2/3/2021	3 to 5 minutes after vaccination patient had nausea and then had a seizure that lasted about 30 seconds. Patient was transported to ER via EMS.

<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>
1126901	3/23/2021	VA	29	F	3/4/2021	3/4/2021	Pt received vaccine, and waited required 15 minutes without incident. While proceeding to registration for 2nd dose appointment, pt exhibited signs/symptoms of seizure activity. Pt became non-responsive and slumped in wheelchair while twitching in extremities, cycling between rigidity and limpness. Mother reported seizure activity (common) controlled by medication taken that AM. O2RA: 94, Pulse: 84, BP: 184/100. RN and Nurse Manager maintained airway (neck position) while awaiting EMS. EMS arrived in 15 minutes, administered IM anticonvulsant, transport to ER with family present.
1127275	3/23/2021	SD	42	M	3/23/2021	3/23/2021	Patient was normal upon administration. Was given instruction to wait 15 minutes in the pharmacy to monitor for adverse reaction, per protocol. Pharmacy staff was alerted by customer that patient was "not looking good". As we walked to patient, we slipped out of his chair and appeared to lose consciousness and/or have seizure-like symptoms. Patient looked very pale, perhaps had some minor foam at the mouth and was extremely hot. We stayed by patient, protected his head, allowed him to come to, took coat off and applied ice packs, took BP/pulse (normal) and patient was oriented x3. EMS arrived and took over.
1125739	3/23/2021	NY	81	M	3/20/2021	3/21/2021	Patient developed a syncopal episode one day following the vaccine. Without warning, he fell to the ground, losing control of bowel and bladder, although no seizure activity noted at the time. He transiently lost consciousness and then woke up confused and combative. Brought to emergency room and admitted with multiple rib fractures. Initial brain imaging was negative but 24 hours later, noted to have small hemorrhagic brain contusion in left frontal/temporal region and a small subdural hematoma. One day later, there was not noted to be any extension of the hemorrhage/hematoma.

<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>
1127544	3/23/2021	CT	23	F	3/23/2021	3/23/2021	The patient received her second dose of the Modern COVID-19 vaccine at approximately 7:20pm on Tuesday, March 23, 2021. Patient stated after receiving the vaccine that she had a "very long time ago passed out after a blood draw". The patient remained in the chair with her nurse for approximately 2 minutes, her color was good, skin was dry and had normal respiration. The patient then stated "I'm not feeling so well". Patient aware, assisted to floor, lying prone, lost consciousness (called EMS), proceeded to have a seizure, bilateral upper arm postured wrists out, lets still, body tremors. Episode lasted approximately 1 minute. During the episode, airway patent, head protected, respirations spontaneous, pulse regular 90-110. Patient awoke spontaneously, stated was somewhat confused, but making sense was able to voice event leading to episode. Patient spoke with her mother, nurse spoke with her mother to advise patient to be evaluated at the hospital due to seizure. Client and mother agreeable, report to paramedic, client transferred to Hospital by Ambulance with wallet, keys, and phone.
1127643	3/23/2021	FL	63	F	3/21/2021	3/22/2021	The day following the vaccine, the above noted patient had a suspected seizure, the first one of her life. Upon investigation at the hospital, there are no signs of any other causation?s of this occurrence. Therefore considering the close proximity of the vaccination, we believe it may be an adverse event that should be reported.

<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>
1127149	3/23/2021	MN	29	M	3/18/2021	3/18/2021	Patient received 1st dose of Moderna at approximately 12:30pm on 3/18/21. He did not stay the recommended 15 minutes on site for observation. He drove himself back to vaccination clinic parking lot at approximately 1:40pm and got out of his car hurriedly to get his mask from the trunk before speaking with EMS on site. He then reported to EMS his wife witnessed him have a seizure (eyes rolled back, unresponsive, stiffening of arms and legs) for 2-3 min approximately 1 hour after receiving his shot. He reported when he regained responsiveness he asked his wife what had happened as he reportedly had no recollection of the seizure, they decided to call the patient's sister and she directed them to return to site of vaccination to report his seizure. EMS who evaluated patient reported he denied (and was not exhibiting) postictal signs/symptoms when he arrived back in parking lot at vaccination site. He denied having a history of seizures or any medical conditions. EMS also reported that neither the patient nor his wife called 911 after the seizure. Patient declined any further medical evaluation/follow up. EMS urged him to call 911 if he had anymore seizure activity to which he replied he thought if he just rested Friday and through the weekend, he'd be fine to return to work on Monday.
1125200	3/23/2021	CA	20	M	2/20/2021	2/20/2021	Patient had vaccination and placed in observation area. Patient had syncopal episode post vaccination. Was seen fall down and hit head and had seizure activity that lasted less than 10 seconds. Patient had brief postictal phase without loss of bladder or bowel control. After a few seconds patient was able to relay his name and was alert and oriented to time and place. Evaluated patient for bodily harm, after finding none moved patient to medical area. Took vital signs and called for transportation to hospital. Medical transport came and after evaluation asked to take patient to hospital patient refused transportation. Patient refused going to hospital and left AMA. Of note, Patient has a history of syncope post injection that was failed to inform us. He mentioned he was afraid to needles like most patients report. Patient said it has happened before after flu shot along with syncope and seizures.

<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>
1125773	3/23/2021	KY	61	M	3/6/2021	3/7/2021	Developed fever to 104 degrees on the morning after vaccination and had a grand mal seizure that lasted about 1 minute followed by generalized tremors that lasted about 10-15 minutes and resolved with administration of rectal Diastat 5mg. Tremors resolved within 5 minutes. Temp treated with Ibuprofen 600mg and cool sponge bath. Temp down to 101 within one hour and afebrile after 8 hours. Temp did not recur. Normal postictal mental status. Somewhat lethargic for a day or two then gradual return to baseline cognitive and physical functioning over 10 days. Wilmer has had this type of seizure with high fever in the past.

<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>
1125833	3/23/2021	IL	69	F	2/24/2021	2/28/2021	seizure like symptoms; she was drooling; Incoherent; was making a bazooka sounding noise; arms and legs shot straight out; This is a spontaneous report from a contactable consumer reporting for their sister (patient). A 69-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) at the age of 69-years-old, via an unspecified route of administration, administered in arm right on 24Feb2021 (lot number: EL1269, expiry date not reported) as single dose for covid-19 immunisation. Medical history included stroke from Sep2020 to an unknown date, cognitive impairment from having stroke, chorea movement of the mouth (she is on medication), blood pressure, cholesterol, anxiety, blood thinner, bones, mouth movements and tooth cleaning from an unknown date and unknown if ongoing. Concomitant medications included ongoing amlodipine at 2.5 mg, daily taken for blood pressure abnormal; ongoing rosuvastatin at 20 mg, daily (has been taking for years) taken for blood cholesterol abnormal; ongoing aspirin [acetylsalicylic acid] from Sep2020 at 81 mg, daily (was on a higher dose but was decreased); ongoing sertraline from Oct2020 at 25 mg, daily taken for anxiety; olanzapine from 20Jan2021 at 2.5 mg, unspecified date at 5 mg, 7 mg, and from 17Feb2021 and ongoing at 7.5 mg, daily taken for mouth movements; ongoing alendronate sodium at 70 mg, weekly (has been taking for years) taken for bone disorder; ongoing apixaban (ELIQUIS) from Sep2020 at 5 mg, daily taken for anticoagulant therapy. It was reported that the patient received the first dose of the Covid-19 vaccine on 24Feb2021. Four days later on 28Feb2021, she had seizure like symptoms. It was not a seizure but it looked like it. She is not sure if this is related. The doctors ruled it out. They said it would be immediate. This could be a coincidence. She is on medication for Chorea movement of the mouth. She was taken to the emergency room and she was admitted to the hospital. Her arm did not even hurt. She was incoherent for about an hour. Things seemed to calm when they gave her IV fluids. Her arms and legs were straight out until she went to the emergency room. She made a noise that sounded like a bazooka. It lasted for a little while. The gave her fluids and took her vital signs. Her arms and legs were no longer stuck out. She was calm when they laid her on the table in the emergency

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

room. It was also reported that the patient was drooling. It was reported that they ran all kinds of tests, MRI, EKG, brain wave thing, unable to find any sign of seizure. Her arms and legs shot out and she sounded like an automatic gun, "ah, ah,ah,ah, us". She told them in the hospital, that she had the covid vaccine, and they said no, it was not that because it was to long after the vaccine. The patient was hospitalized for seizure like symptoms from 28Feb2021 to 03Mar2021. The patient underwent lab tests and procedures which included computerised tomogram: normal, electrocardiogram: normal both on 28Feb2021, magnetic resonance imaging: negative on 02Mar2021, scan brain: normal on 01Mar2021. Therapeutic measures were taken as a result of incoherent and was making a bazooka sounding noise which included IV fluids. The patient recovered from seizure like symptoms, was making a bazooka sounding noise, arms and legs shot straight out on 28Feb2021, from incoherent on 01Mar2021, while the outcome of drooling 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>
1125842	3/23/2021	NY	83	F	2/20/2021	2/20/2021	diagnosis of confusion/ about 2 hours after vaccine she became disoriented, couldn't figure out how to get her seat belt on. the next day she couldn't even dress herself; This is a spontaneous report from a contactable consumer. An 83-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; Lot number was not reported) via an unspecified route of administration, administered in Arm Left, at the age of 83-year-old, on 20Feb2021 13:15 as SINGLE DOSE, for covid-19 immunisation. Medical history included seizure, cardiac disorder, diabetes mellitus, hypertension, blood cholesterol abnormal, and thyroid disorder. Patient is not pregnant at the time of vaccination. The patient did not receive other vaccine in four weeks and was not diagnosed with covid prior vaccination. Concomitant medications included trazodone, potassium chloride (KLOR CON), furosemide, irbesartan, levetiracetam, metformin hydrochloride (MEFORMIN), metoprolol, warfarin sodium (JANTOVEN), nitrofurantoin (NITROFUR), acetylsalicylic acid (BABY ASPIRIN), melatonin, levothyroxine, apoaquorin (PREVAGEN [APOAEQUORIN]), cyanocobalamin (B12 [CYANOCOBALAMIN]). The patient previously took codeine linctus and experienced drug hypersensitivity, hydrochlorothiazide and experienced drug hypersensitivity. On 20Feb2021 13:15, about 2 hours after vaccine, she became disoriented, couldn't figure out how to get her seat belt on. The next day she couldn't even dress herself. this onset was very sudden. The patient was sent to a nursing home with the diagnosis of confusion. The patient was hospitalized for 2 days in response to the event in 2021. The patient did not receive any treatment in response to the event. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 21Feb2021, sars-cov-2 test: negative on 23Feb2021, sars-cov-2 test: negative on 01Mar2021. Outcome was not recovered. Information about lot/batch number has been requested.

<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>
1125095	3/23/2021		20	M	2/26/2021	3/4/2021	Bell's palsy; jaundice looking legs; inability to communicate clearly; Seems to be experiencing numerous seizures; This is a spontaneous report from a non-contactable consumer. A 20-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot and expiry unknown), via an unspecified route of administration on 26Feb2021 as a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced Bell's palsy, jaundice looking legs, inability to communicate clearly and seems to be experiencing numerous seizures on 04Mar2021. The events were considered serious due to hospitalization. The patient was hospitalized on 04Mar2021. It was unknown if patient received treatment for the events. The outcome of the events was not recovered. Information on the lot/batch number has been requested.
1125927	3/23/2021	KY	18	F	3/19/2021	3/19/2021	Within 15 minute waiting period after vaccine administration, patient's mother alerted staff that patient had just had a seizure-like episode after becoming light headed. Patient started flaring with flexion and shaking of upper extremities, nonverbal during event. Staff examined patient and found no signs of a seizure. Patient was sent to the emergency room for further evaluation. Mother states that patient had a similar episode at age 8, but no further details provided. Patient was stable and discharged from the emergency room with a referral to follow-up with primary care physician.
1125333	3/23/2021	GA	31	F	3/22/2021	3/22/2021	Patient reported no allergies to medications, never experienced seizures, Guillian-Barre Syndrome or any other neurological disorder, had not received a vaccination within 2 weeks prior to this vaccine. Patient is currently 20 weeks pregnant. Patient received vaccination around 8:00am and was waiting in pharmacy during 15 minute observation period. Patient was seated and after about 10 minutes, patient became unconscious. Eyes rolled back in head, faint pulse, 911 immediately called. As 911 was called, patient was becoming conscious again. Pulse still faint. EMS arrived within 5 minutes of call. EMS reported patient blood pressure very low and took patient to hospital for further observation.

<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>
1125418	3/23/2021	IL	62	F	3/18/2021	3/18/2021	Patient had a seizure blood pressure and pulse elevated. Known history of seizures. Went to ER
1125498	3/23/2021		47	M	3/22/2021	3/22/2021	Patient stated prior to vaccine he has a history of fainting after vaccination. About 1 minute after vaccination he became pale, clammy, and lightheaded. Spoke with patient while someone else retrieved an ice pack and water. About 2 minutes after vaccination patient became unconscious and upper body had seizure like activity. Patient was moved to the floor immediately regained consciousness. Event lasted approximately 15-20 seconds. After regaining consciousness, stated he felt better. Remained on the floor for about 5 minutes, EMS was called as precaution. EMS stated vital signs and blood sugar were stable. Patient refused transport to hospital. Instructed to follow up with PCP.
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 seemed 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 seemed 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.
1125629	3/23/2021	MA	48	F	1/15/2021	3/12/2021	Non-provoked first time seizure
1125653	3/23/2021	LA	27	F	3/20/2021	3/21/2021	Patient experienced psychomotor symptoms; had one seizure at home and was transported to the hospital where she had another seizure.

<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>
1125699	3/23/2021	WI	22	F	3/20/2021	3/23/2021	After receiving the vaccine, client lost consciousness and collapsed to the floor. EMS was summoned. Client had two separate seizures, regaining consciousness in between and after. Client was taken to local hospital for care via ambulance. Attempts to contact client on 3/21/2021 and 3/23/2021 unsuccessful.
1122323	3/22/2021	SC	67	M	2/15/2021	3/13/2021	Patient developed Gilliam Barre after administration of the second dose of Covid vaccine on 2/15/21; After multiple calls, clinic was where patient received vaccine with LOT #EN6200 (expiration date unavailable in computer system per pharmacist); pt then went to a hospital and was diagnosed as above; treated in the ED for several days per notes at the hospital and was not put in a room due to bed shortages so was transferred to another hospital; patient subsequently developed an NSTEMI, seizures, and was intubated.
1122987	3/22/2021		18	M	3/16/2021	3/17/2021	Patient received vaccine in the AM of 3/16/21. Patient was in his usual state of health when he went to bed the evening of 3/16/21. He ate dinner normally and his PD was started as usual. There were no overnight complications with his PD and he got up shortly before 8 AM. Mom reports the dialysate from his bag was clear and normal and none of his dwell was retained. She heard a loud thud from the bathroom around 8 AM and the patient was found by his mother having generalized convulsions (bilateral upper and lower extremities) and he appeared to be foaming at the mouth. He did not respond to her and she called 911. The seizure stopped by the time EMS arrived and his initial GCS was 12, and 15 by the time they started transport. He had another seizure en route around 9:30 AM and was given 2.5 mg versed and required bagging. Patient was loaded with Keppra and now has been on maintenance Keppra. Patient has not suffered any additional seizures and is currently undergoing an extensive workup by inpatient neurology team. Vaccine adverse effect currently remains on the differential for inciting event leading to seizure however additional labs are pending to rule out other causes (eg. viruses causing PML). Patient was also diagnosed with multifocal pneumonia and started on antibiotics at time of admission.

<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>
1122929	3/22/2021	MI	62	F	3/19/2021	3/19/2021	pt had a seizure while waiting on observation area she reports her family was with her and told her about seizures medical staff alerted and 911 called. pt awoke from seizure and declined to go to ER reports she felt okay. unclear if generalized seizure.
1122700	3/22/2021	NJ	80	M	1/20/2021	2/19/2021	received shot at 1130 am on 2/19. client developed chills/ fever that evening on 2/19. on 2/20, woke up feeling well, was getting dressed to go out to lunch at 12 when he had a seizure, as per his wife, it lasted for about 5 sec. then he recovered and states had lunch and took a nap. no other issues after that.
1123040	3/22/2021	OR	37	F	1/18/2021	1/18/2021	Shortly after my vaccine, I experienced a copper taste in my mouth, felt dizzy and I indicated to a paramedic that I was not feeling well. I continued to feel dizzy and my throat started to swell up and had convulsions and had loss of consciousness. I also began to get hives on my chest, my throat was still swelling up which these symptoms continued over the next few hours. I went to the ER where they gave me an epi shot. I was admitted to the ICU where a kidney panel was performed and I also had another event and they gave me another epi shot which my symptoms step down in intensity and was discharged home. I stayed one night in the hospital. For the next two weeks, I was still having throat swell up, felt disoriented, was having mental foggiess and twitching. Today I still experience some twitching, involuntary spasms but are in mild in intense.
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
1122148	3/22/2021	AR	55	F	3/19/2021	3/21/2021	I can only describe it seizures. I was laying in bed ready to go to sleep when all the hairs on my body stood up and then it felt like an electric shock went through my body. I had a tremendous ringing in my ears through the event and all my muscles tensed up as my head went back into the pillow. it happened 3 times in a row with only about 30 seconds to a minute between each event.
1121904	3/22/2021	NC	25	M	3/21/2021	3/21/2021	Systemic: Seizure-Severe

<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>
1123120	3/22/2021	DE	61	F	1/29/2021	2/6/2021	very large red rash at the injection site; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient received the first dose of BNT162B2 (BNT162B2, Solution for injection, lot number: EL9265), via an unspecified route of administration in the left arm on 29Jan2021 1:00 PM a single dose for COVID-19 immunisation. The vaccine was administered at a hospital. The patient did not receive any other vaccines in four weeks prior to receiving BNT162B2. The patient was not pregnant. Medical history included seizure disorder. The patient did not have covid prior to vaccination. She had no known allergies. On 06Feb2021, the patient had a very large red rash at the injection site 8 days after vaccination. It was not particularly itchy or uncomfortable. It seemed notable only because it was over a week later. The patient did not receive any corrective treatment for the event. Outcome of the event was recovered on an unspecified date. The patient was not tested for covid post vaccination.
1121595	3/22/2021	IL	75	M	2/16/2021	2/19/2021	six small seizures; This is a spontaneous report from a contactable consumer (patient). A 75-year-old male patient received BNT162B2 (Lot Number: EL9264) via unspecified route on left arm single dose for COVID-19 immunization on 16Feb2021, 10:15 AM, at 75-year-old. Medical history included: hypertension, dementia, Lewy body dementia; known allergies: shrimp, coconut. The patient had not had COVID prior vaccination. Concomitant medication included: atorvastatin; donepezil; fish oil; fluticasone. No other vaccine received in four weeks. The patient experienced six small seizures on 19Feb2021, 04:30 PM, emergency room/department or urgent care visited and was reported hospitalized for one day. Treatment received included: a CAT scan, levetiracetam (KEPPRA). Outcome of the event was resolved.

<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>
1121592	3/22/2021			U	3/4/2021	3/5/2021	started shaking and jerking like was having convulsions; started shaking and jerking like was having convulsions; started shaking and jerking like was having convulsions; gets a spasm every once in a while; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received the first dose of BNT162B2 (BNT162B2, lot number and expiry date were not reported), via an unspecified route of administration, on 04Mar2021 (afternoon about 01:05 or 01:15 PM) at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient reported they got the vaccine shot (clarified as Covid-19 Vaccine by Pfizer) on 04Mar2021 afternoon about 01:05 or 01:15 and they were fine all day and all evening. On 05Mar2021, about 03:30 AM in the morning, the patient started shaking and jerking like was having convulsions. The patient was shaking so hard they couldn't get out of bed. They didn't know if that was a reaction to the vaccine or something else. It lasted about 15-20 minutes and then it subsided. The patient then gets a spasm every once in a while, for the next half hour and at the time of report it seems go stopped all together. Outcome of the events was recovered on 05Mar2021. 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>
1121589	3/22/2021	WA	25	F	3/5/2021	3/7/2021	Seizure; This is a spontaneous report from a contactable consumer (patient). A 25-year-old female patient received the first 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 05Mar2021 11:30 at a single dose for COVID-19 immunization. Medical history included epilepsy. Concomitant medication included levetiracetam (KEPPRA). On 07Mar2021 07:00 AM, the patient experienced seizure. The event resulted in Emergency room/department or urgent care. No treatment was received for the event. The facility where the vaccine was administered was in a hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient is not pregnant. Post vaccination, the patient has not been tested for COVID-19. No known allergies. Outcome of the event was recovered with lasting effects. Information about lot/batch number has been requested.
1122642	3/22/2021	MA	66	F	3/5/2021	3/5/2021	Nausea x 4 days, concern that sx was r/t mild seizure activity.
1124364	3/22/2021	MO	30	M	3/16/2021	3/17/2021	Patient received the Janssen COVID -19 Vaccine at the end of a work day on Tuesday March 16, the next day before noon he was experiencing fever, headache and pain in the upper left side of his chest to the side by his left Axillary. He came home at 1:00 pm. Had a headache all evening, fever of 100 and the pain in his upper left side of his chest. At around 12:25 went downstairs to take an Aleve for his head ache, and pain. His pain was so severe in the left upper side that he could not even raise his arm. It was severe pain. He managed to take one pill and collapsed falling on the kitchen floor. We heard the commotion and found him unconscious and unresponsive, we called 9-1-1 and he started to have a Grand Mal Seizure. He has never had a seizure in his life.
1124795	3/22/2021	GA	18	M	3/16/2021	3/17/2021	The NP gave him my vaccine and him mine. No symptoms at time. Headache and seizures, black eye from falling, slow brain. Function

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1124669	3/22/2021	FL	52	F	3/22/2021	3/22/2021	Person had a seizure-like episode requiring intervention from others to help her lie down. Fiance had sublingual Clonazepam available which was administered. EMTs called, arrived and evaluated. VS stable and pt up and walking, declined transport to hospital with EMT. Left for home with fiancé.
1124640	3/22/2021	CA	25	M	3/22/2021	3/22/2021	Patient received 1st dose of Pfizer Vaccine Lot#ER8730 and was sitting in chair at administering station when he lost consciousness. Patient regained consciousness, A/Ox4, skin pale, cold and clammy, pupils dilated. FNP assessed pupils were non reactive to light. Per FNP, patient then had a seizure for approx. 18 sec at 2:55 pm; seizure precautions maintained at all times. Upon regaining consciousness, pt. began projectile emesis. 911 called/patient brought to sick bay. BP 104/51, HR 120, O2 97%, Temp 97.1 Patient remained A/Ox4 and stated he felt "very tired." Patient transferred to paramedics and transported to Hospital. EMS Incident.
1124524	3/22/2021	OH	39	F	3/22/2021	3/22/2021	Patient with PMH of poorly controlled seizures and no regular health care who reported symptoms of feeling warm and lightheaded after receiving her vaccine. Pt had a generalized seizure with postictal symptoms, A/Ox2. She was then observed and evaluated by medical staff and EMS, during which time she had a second witnessed generalized seizure. Pt was sent by EMS to a local hospital.
1124512	3/22/2021	WY	38	M	3/16/2021	3/16/2021	Arm hurt at injection site, upon lifting arm, felt a sensation in arm near injection site and had what appeared to be a seizure that lasted around 10-15 seconds. A few moments later another seizure occurred. Resulted in a hospital visit and a follow-up with a neurologist.
1123807	3/22/2021	NY	57	F	3/22/2021	3/22/2021	About 10 to 15 minutes after receiving vaccine patient complained of tightness in the chest. After a short time she experienced tingling in lips. We moved her to the floor and laid her flat with head raised as she began to experience uncontrolled movements in arms and legs (seizures?) I administered epinephrine for tightness in chest and tingling lips and 911 was called. Rescue squad arrived stabilized her and transported to hospital.

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1124449	3/22/2021	IN	50	F	3/20/2021	3/20/2021	Patient had her vaccine at 1:45pm. By 2:12 patient noted lightheadedness and brain fog and fatigue. Patient requested to go to the bathroom. She was taken by a staff member. Patient reports hx of epilepsy, hx of covid with hospitalization, and kidney disease. 2:22 her bp was 104/63. Her HR was 80 and RR 20 and oxygen 95%. Still reported feeling lightheaded and sensation of head floating similar to when she had seizures. We gave the patient orange juice and crackers. 2:32 bp was 110/72 with HR of 82 oxygen 99%. States feeling better but still slightly foggy in the head. 2:42 bp 118/76 hr 78 and oxygen 98% feels better and is more talkative. She asked to rest with her eyes closed for a few more minutes.
1123370	3/22/2021	PA	60	M	3/16/2021	3/18/2021	On March 16th at roughly 1:30pm, the patient received his first dose of the COVID19 Moderna vaccine. Afterward, the patient experienced no adverse side effects. About 48 hours later, however, at 2pm on March 18th, the patient's spouse attempted to wake him from a nap. The patient seemed much groggier than normal and his expression appeared vacant. When pressed by his spouse, the patient could not say who he was, or who his wife was. He agreed to travel with his wife to the hospital. At the hospital, a healthcare professional asked the patient who he was. He answered with his correct name. He also correctly identified his spouse by name. But when asked where he was, the patient gave a long and incoherent response. After this initial screening, doctors at the hospital evaluated the patient for a stroke. They ruled this out as a possibility. Next, they suspected the patient's MS lesions may have contributed to his "cognitive event." However, after comparing his 2018 scan to a current scan, they determined this was unlikely the cause. After about 24 hours at the hospital, a neurologist hypothesized that the patient had experienced a seizure. Another doctor at the facility concurred with this assessment. By late Friday (more than 24 hours after the episode), the patient had regained most of their cognitive functioning, though he still experienced mild confusion around the week's events (even preceding the "cognitive event"). Prior to now, the patient has never had a seizure before.

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1124224	3/22/2021	FL	58	M	3/20/2021	3/21/2021	chills, fever, muscle contractions/seizures, severe headache, joint pain, sweats, muscle weakness, acid reflux- time course: began approx 8 hrs after shot (12:15am) and continued until 5am,-acetaminophen 1000mg q8h, naproxen 220mg q12h, gaviscon liquid 10ml, the headache, muscle pain has continued at a lower intensity until 12noon on monday 3/22/21
1124036	3/22/2021	MI	60	F	3/22/2021	3/22/2021	Patient was observed, to tilt head back like going to pass out, then slumped forward in chair, extremities convulsed and patient came to. She reported feeling dizziness, chills, nausea and tingling in both hands. I asked her if would like us to call EMS but refused medical attention. She knew date and location when asked. We offered to have family member pick her up but refused.

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1123839	3/22/2021	NJ	75	F	2/25/2021	2/26/2021	seizure / hospitalized for having seizure; trouble talking; biting her lips and as a result was bleeding all over.; feel sluggish.; Fatigue; runny nose; sneezing; A spontaneous report was received from a consumer concerning a 75-year old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced was Seizure, trouble talking, runny nose, sneezing, biting her lips and as a result was bleeding all over, Very upset / frustration, feel sluggish, and fatigue. The patient's medical history was not provided by the reporter. Current history includes stroke. Concomitant medications were carvedilol 12.5 bid, losartan 100mg, rovastatin 20mg, ezetimibe 10mg, levothyroxine 75 mcg, aspirin 81mg On 28-Jan-2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 026L20A) intramuscularly in the unknown location for prophylaxis of COVID-19 infection. On 25-Feb-2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (Lot number: 014M20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 26-Feb-2021, the patient experienced seizure which occurred less than 24 hours after receiving the 2nd dose of the Moderna vaccine. At approximately 10:00 am, the patient wasn't able to formulate a sentence, similar to when she had a stroke. Husband drove her to the ER and she had a seizure in the car. CT Scan showed no stroke, showed a seizure. Patient was admitted, kept overnight, intubated and administered anti-seizure medicine. On 27-Feb-2021, the patient was discharged and developed flu-like symptoms (runny nose, sneezing, fatigue). Flu-like symptoms have cleared. The reporter feels the seizures are related to the prior stroke history. On 10-Mar-2021, a follow-up was received. Patient feel huge disappointment and frustration on reporting serious adverse reaction. New information about the event include that on 26-Feb-2021, her husband noticed she was biting her lips and as a result was bleeding all over. Patient stated she has never had history of seizure but after this incident neurologists put her on high dose anti-seizure medications twice daily. These medications make her feel sluggish. Treatment details provided was Keppra, anti -seizure medications. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the event seizure, fatigue,

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							runny nose, sneezing were recovered on 27-Feb-2021 and 01-Mar-2021 respectively. The outcome of the events trouble talking, biting her lips, feeling upset and frustrated and feeling sluggish were unknown.; Reporter's Comments: Based on reporter's causality and the described prior history of stroke, the event is assessed as unlikely related to mRNA-1273.
1123727	3/22/2021		57	M	3/19/2021	3/19/2021	Following covid 19 vaccine client reported sweating with obvious pallor. He was cold and clammy. He was unresponsive prior for approximately 30 seconds with mild seizure activity with spontaneous movement of eyes with jerking. He was monitored by EMS and evaluated by a Dr. His car seat was reclined, no Epi pen given . Blood Pressure was 82/48 initially with pulse 65 and RR 12. He was transported to EMS vehicle on site and monitored then released home. He was advised to follow up with ER for further treatment if needed.
1123690	3/22/2021	TX	21	F	3/17/2021	3/17/2021	The patient has refractory epilepsy but seizures are generally well controlled (1 seizure every months). Her first seizure followed ~30 minutes after vaccination and she continued to have 6 additional seizures over the course of several hours, requiring admission to the hospital for several days as she recovered from her post-ictal state. She was febrile on admission to 100.5F. Mother of patient noted that she has never had this many seizures in a single day before.

<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>
1123396	3/22/2021	WI	18	F	3/19/2021	3/19/2021	Received first COVID shot on 3/19/21. On 3/20/21 presenting to ER with weakness, achiness, fever, shortness of breath after having coronavirus vaccination yesterday. Patient is sure she had coronavirus back in November. Received the vaccination yesterday about 11 am. Within a couple hours she developed severe myalgias, low-grade fever. Reports she feels a little short of breath from a myalgias. No history of DVT or PE, urinary complaints. Patient has syncopal episode while in triage. No seizure activity. Felt lightheaded with standing. Clinical Impression: 1. Syncope 2. Vaccination reaction, initial encounter Presentation consistent with orthostatic, vasovagal episode from recent vaccination. Patient coronavirus previously stimulating a stronger immune response. doubt infection, PE, worrisome arrhythmia. Advised against second vaccination. return if any problems, worsening
1124450	3/22/2021	TX	44	F	3/13/2021	3/14/2021	Patient reports to the ED w/ 7 days of headache, vomiting, and "seizures." It's difficult for ED staff to determine if these were truly tonic-clonic seizures, generalized, or other. Patient reports being awake for these seizures and that she remembers them. Unsure if patient is describing "chills/shivering" as seizures, but the terminology used by patient/staff/MD/translators is seizures. Patient has no recent history of seizures, and only history (ever) was 21 years ago when she was pregnant w/ 3rd child -- she had 1 seizure, accompanied by nausea/vomiting.
1122304	3/22/2021	CT	56	F	3/18/2021	3/18/2021	Approx. 15min after first dose of Moderna vaccine patient reported feeling dizzy. Patients significant other reported patient feels dizzy prior to a seizure. Patient lowered to the floor and had a seizure lasting about 45 seconds. Paramedics activated @ 3:10pm. Patient alert with intermittent confusion. Blood sugar 94. Patient refused transport to the hospital. Paramedics stayed by, patient had a second seizure lasting about 15 seconds. Post seizure patient agreed to go to hospital for eval. Transported via paramedics to hospital.
1120713	3/21/2021	CA	19	F	3/14/2021	3/19/2021	I had two seizures on 3/19/21 and was admitted into the hospital. Blood tests and MRI were done.

<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>
1121643	3/21/2021	WA	25	F	1/21/2021	2/7/2021	Gran mal seizure 19 days after first dose. First ever seizure I have ever had; it occurred in the middle of the night. All bloodwork, CT, MRI, and EEG studies were WNL.

<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>
1119874	3/21/2021			M	12/18/2020		<p>Took the COVID test has COVID; Took the COVID test has COVID; He has a seizure; Likely a syncopal event; Shoulder in soreness; Felt lightheaded had to sit in chair; This is a spontaneous report from a contactable physician (patient himself), received from the FDA. The regulatory authority report number is 910202. A 39-year-old male patient received the first dose of BNT162B2 (Pfizer-BioNTech Covid-19 vaccine; batch/lot EH9899, expiration date: 31Mar2021) on 18Dec2020 on the right arm, at a single dose, for COVID-19 immunization. Concomitant medication was none. The pediatrician was working in the hospital and was exposed to an office contact who had COVID. The patient had a shoulder in soreness. He was at work on Wednesday and felt lightheaded and had to sit in chair. He had a workup to a CODE team putting oxygen on him. He had a seizure. The patient took the COVID test and had COVID. He was admitted to the hospital for 2 days. It was likely a syncopal event. The onset dates of the events and the hospitalization dates were not reported. The patient was not recovered from the events "took the COVID test and had COVID, seizure, and likely a syncopal event," while the outcome of the events "shoulder in soreness and felt lightheaded" was unknown. The events "took the COVID test and had COVID, seizure, and likely a syncopal event" were reported as serious due to hospitalization, and the other events were reported as non-serious. On 01Mar2021, investigation results from the Product Quality Complaints group was received for the described complaint of "Took the COVID test has COVID" for PFIZER-BIONTECH COVID-19 VACCINE INJECTABLE with lot #: EH9899, batch expiry date: 31Mar2021. Reasonably Suggest Device Malfunction was reported as "No." Severity of Harm was not applicable. No CAPA was previously identified. A full investigation was not required. Root Cause/CAPA: This was not process related; Final Confirmation Status was "Not Confirmed," Vendor Related: No. Conclusion: The complaint for an adverse event requested by Safety with the use of the PFIZER-BIONTECH COVID-19 VACCINE lot EH9899 was investigated. The investigation included reviewing the manufacturing and packaging batch records, retained reference samples, deviation investigations and an analysis of the complaint history for the reported lot and product type. The final scope was expanded to the</p>

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							reported finished goods lot EH9899, fill lot EH9783, and the bulk formulated drug product lot EH9782. A complaint sample or photographs were not received. No related quality issues were identified during the investigation. There is no impact to product quality. The complaint was not confirmed. No reserve sample evaluation was required; this was not a confirmed reserve defect. No lot-specific trend was identified. No expedite trend was identified and no other trend was identified. Complaint sample evaluation: (Parent) Sample Status was not available; site sample status was not received. No follow-up attempts are possible. No further information is expected. Follow-up (01Mar2021): New information received from the Product Quality Complaints Group includes investigational results regarding the previous complaint. No follow-up attempts are possible. No further information is expected.
1120103	3/21/2021	NC	62	F	3/10/2021	3/17/2021	Moderna COVID-19 Vaccine EUA. Red spot at injection site, measuring approximately 2" in diameter appeared on Mar 17. Also at 8:15am on Mar 17 I had a seizure. I had second seizure while lying on the couch at 5:15pm Mar 17. No other assignable cause. Mar18-20 I was often light-headed but no additional seizures.
1120131	3/21/2021	FL	55	F	3/17/2021	3/17/2021	I had awful nausea, loud ringing in the ears, I fainted. The medics provided help, gave me oxygen. I started having convulsions. After some time I felt like the lower part of my face went numb and it took tremendous effort to move my lips to talk. At that point, the medical called the ambulance and sent me to ER, where I was under supervision for some time. I was very weak and nauseated. After I was released, I was very weak could not keep the vertical position. The next day I was very nauseated, with awful tinnitus, lightheadedness, and weakness. Staying vertical for more than 15 minutes brought fainting symptoms. I was not able to get out of the house to work. The next day the fainting symptoms disappeared, everything else continued. Too weak to go to work. I started moving about only on the 4th day after the shot. During this event, I did not have any fever or muscle ache, no virus0tyle symptoms.

<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>
1120526	3/21/2021	PA	35	M	3/21/2021	3/21/2021	Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Systemic: Seizure-Medium, Additional Details: Patient recieved first dose of Pfizer vaccine administered by Staff. Patient appeared confused and lethargic appearing to pass out. Staff administered epinephrine. Patient then started to seize ~2 mins. Patient was then reponsive. Emergency services came and took patient to hospital.
1120727	3/21/2021	NY	21	F	2/23/2021	3/7/2021	On March 7, 2021 my daughter experienced extreme tiredness. I called 911 and paramedics said it may be the effects of vaccine. I was concerned because this symptom came on 2 weeks later. On 3/6/21, I took her to urgent care because I didn't feel comfortable with her extreme tiredness. I was told the same thing. On 2/23/2021, the day that she was supposed to get the second vaccine, she awoke at 12 midnight and was having a full blown psychotic episode. She was make loud noises, hitting the wall, etc. I then took her to the emergency room. My major concern was because my daughter has Down syndrome, a seizure disorder and had heart surgery at three months old (atrio ventricular canal defect).
1120778	3/21/2021	NY	21	F	2/23/2021	3/7/2021	On March 7, 2021 my daughter experienced extreme tiredness. I called 911 and paramedics said it may be the effects of vaccine. I was concerned because this symptom came on 2 weeks later. On 3/6/21, I took her to urgent care because I didn't feel comfortable with her extreme tiredness. I was told the same thing. On 2/23/2021, the day that she was supposed to get the second vaccine, she awoke at 12 midnight and was having a full blown psychotic episode. She was make loud noises, hitting the wall, etc. I then took her to the emergency room. My major concern was because my daughter has Down syndrome, a seizure disorder and had heart surgery at three months old (atrio ventricular canal defect).
1120807	3/21/2021	IN	48	M	3/19/2021	3/20/2021	Seizures

<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>
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.
1120981	3/21/2021	OK	16	M	3/21/2021	3/21/2021	Patient received vaccine and went to sit down in front of pharmacy. He then immediately started feeling lightheaded, his eyes rolled into the back of this head and he had a couple of convulsion. He did not lose consciousness and was immediately aware. He was pale, lips were blue tinged, pulse was 60, sweating and blood pressure was 98/50. Paramedics were called but he had recovered by the time they got there. They said he had a fainting episode due to the vaccination and did not have a seizure. The patient had not eaten anything the whole day and he felt that contributed. Followed up with patient's parent and he is feeling just fine now.
1120987	3/21/2021	FL	19	F	3/21/2021	3/21/2021	Pt had a fainting spell. At first it appeared as if she was potentially having a seizure. After about 3 minutes she came to and was fine. She was examined by EMS and was released to going home own her own with her friends.
1121123	3/21/2021	AZ	30	M	3/21/2021	3/21/2021	Patient got dizzy around 5 minutes after dose; and began shaking a bit 1 minute later and staring into distance. Sweaty, continued dizziness. responsive at 1 minute after side effects began. Patient drank some water as able, and reported ears were ringing. Ambulance was called and reported all vitals looked good and patient likely experience syncopal event rather than seizure.

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1121198	3/21/2021		22	F	3/21/2021	3/21/2021	Patient came in to observation area after receiving the covid vaccination, while she was admitted to the waiting area she started to sit on the floor. Nurse approached her and guided patient to the floor. Patient began to lose consciousness while nurse was guiding her head to the floor. Patient was placed on one side for seizure precaution, vitals were initiated, and EMS was activated. Patient was monitored continuously, legs were elevated, and ice packs were applied to the nape of the neck and the patient extremities. Patient was assisted into a seated position. Pt was provided PO fluids and graham crackers. Patient was ambulated from the floor to the chair by nurses. EMS arrived on site, assessed the patient, and patient was transported to the hospital by the EMS.
1120331	3/21/2021	NY	72	F	3/12/2021	3/14/2021	Patient had one of her typical seizures on 3/14/21. She did not seek care. She managed at home and called 2 days later to notify my office that the seizure had taken place . She was feeling well.
1118589	3/20/2021	WI	26	F	3/20/2021	3/20/2021	Patient was sitting in the observation chair when technician noticed that she appeared to be having an adverse event. Patient had head leaned back, seemed to be unconscious, and had some shaking/convulsions. Shaking occurred for about 45 seconds and patient then vomited. 911 was called. Patient became responsive but was very pale and sweaty though she did not have any breathing issues, so EpiPen was not administered. EMS arrived and patient left with ambulance on a stretcher, though she was conscious and communicating with the EMS team.
1118708	3/20/2021	NY	28	F	3/20/2021	3/20/2021	Patient seemed to have fainted 1 minute after vaccination, then had a seizure, and then had an episode of syncope following the seizure.
1119134	3/20/2021	CA	53	F	3/20/2021	3/20/2021	Pt appeared to have a seizure. Fell to the floor, unresponsive for 15 seconds. Hx Hypertension and seizures.

<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>
1119016	3/20/2021	NY	46	M	3/20/2021	3/20/2021	After receiving first dose of pfizer covid vaccine, patient alerted EMS he didn't fell well. When EMS responded to the patient the patient went unresponsive slumped over in his chair with seizure like activity. Patient was being moved when he regained consciousness. Patient was moved to EMS area. Patient was pale, lightheaded and nauseous. Blood pressure was taken as well as oxygen and heart rate. Blood sugar was checked and an IV was started. Patient was stable and transported.
1118714	3/20/2021	MN	70	F	3/2/2021	3/3/2021	Two Seizures and 5 migraine headaches
1118713	3/20/2021	OH	64	F	3/20/2021	3/20/2021	patient had a seizure within 10 minutes of receiving vaccine.
1118600	3/20/2021	NY	69	F	3/11/2021	3/12/2021	seizures Went to the hospital and they took care of me.
1118328	3/20/2021	MA	57	M	3/14/2021	3/14/2021	Seizure (staring, unresponsive to verbal stimuli) started approx. 5 min post vaccination.
1118182	3/20/2021	IA	58	F	3/19/2021	3/19/2021	She had received her first Covid vaccination this afternoon and following that she became dizzy and had a syncope spell. She tells me that with previous vaccinations this has routinely happened and so it is not different. She was not aware of her surroundings for about 2 minutes after this happened although there was no witnessed jerking or seizure movement. At this point she feels about 90 to 95% back to normal and denies any pain anywhere including in her chest. Initially she had some tingling in her arms although that has resolved.
1118164	3/20/2021	UT	30	M	3/19/2021	3/19/2021	Seizure, nausea, tingling in fingers, stiffness in arms, patient felt hot

<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>
1118087	3/20/2021	NY	78	F	3/20/2021	3/20/2021	9:35 am Daughter stated "she spoke to her mother and she didn't answer her she had a blank stare like she was out for a second then she answered me" Mother pt c/o of "feeling woozy" Assess: When nurse arrived to vehicle pt AAO no SOB, no LOC - N/V VS taken 168/94, HR 80 reg, strong, Resps 18 reg non labored, SpO2 96%. daughter stated "it wasn't like a seizure, her mother doesn't take her medications correctly" No list of meds. Changed monitor to 30 min. gave water for hydration. Pt stated anxious about getting vac. L del vac site benign. - red, - swelling. - facial swelling. Provided reassurance Monitored VS BP elevated 178/96, 80. Advised to call primary to update, V-safe . pt stated "I feel good now, not dizzy" after 30 min OK'd to exit.
1117764	3/20/2021	NC	32	M	3/19/2021	3/19/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Hypotension-Medium, Systemic: Seizure-Severe, Additional Details: Approx. 15 minutes after getting his COVID vaccine pt. notified clinic staff that he was feeling unwell and his heartbeat was irregular. Pt. then started to collapse and after being assisted to the ground had a seizure lasting approx. 10 seconds. After waking back up from seizure pt. had trouble breathing. Clinic staff notified me and I immediately administered 0.3 mg of epinephrine via an auto-injector. 911 was called and Pt. was able to sit back up while he waited for EMS.
1117748	3/20/2021	CA	57	M	3/17/2021	3/17/2021	Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Mild, Systemic: Vomiting-Severe, Additional Details: After couple minutes receiving second dose of covid vaccine, patient passed out and lost consciousness for less than a minute. Patient woke up with brief seizure(jerky movement) and vomited couple times. Patient complained about dizziness. Patient was taken to the emergency room.
1117655	3/20/2021	IL	24	M	3/19/2021	3/19/2021	After getting J&J covid vaccines the patient was having allergy reaction, difficulty breathing and warm. I gave the pt epipen and called 911, he had seizure For 3 minutes as well

<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>
1118671	3/20/2021	CA	38	M	3/20/2021	3/20/2021	Pt. was screened twice about allergic reactions any medical conditions/immunocompromised etc. Pt. responded no to all of the above questions. He was vaccinated IM on left arm. Pt. was educated about post care. Pt. was alert. I moved on to the next two cars and on the third car and about three minutes after his female partner called out for help and said that the Pt. passed out. That's when the other nurse ran to the car to check on him and told me he was having a seizure. I ran to the lead to explain what happened and to call the medical team right away. The other nurse was stabilizing the patient. The patient was going in and out of consciousness for about ten seconds. The medical team arrived and took vitals.
1117524	3/19/2021	NJ	66	M	3/15/2021	3/16/2021	Severe shaking after feeling cold. Nothing like chills, nothing I have ever experienced before. Shaking so bad I had trouble walking. Couldn't open Tylenol bottle, kept dropping it from shaking. Felt like a seizure. Went back to bed and covered up with blankets. Slowly went away. Episode lasted 20 minutes or so. Shook me up as I live alone. Was ready to dial 911...
1116430	3/19/2021	PA	54	M	3/13/2021	3/19/2021	On Friday, March 19 around 9:10am I had seizures - loss of awareness, very pale, shaking (but not quite convulsions). This happened before 25 years ago and is likely unrelated to the vaccine. Expected cold/flu-like symptoms did occur on March 14 and part of March 15 but things have been fine since then. I've followed up with my GCP and am scheduling a Neuro appointment for followup.
1116536	3/19/2021	KS	52	F	3/15/2021	3/16/2021	Fever of 102, Shooting pain in extremities, migraine, red flushed and swollen face, enlarged tongue, increased heart rate, wheezing, joint pain, severe nausea, diarrhea, possible seizure, confusion.

<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>
1116723	3/19/2021	MO	58	M	3/18/2021	3/19/2021	COVID and stroke December 2020. Patient's mother talked to him at 4:30 and he said he was not feeling well. Driving to work when coworkers found pt after he curbed his vehicle with AMS. Right side deficit with aphasia, unknown last normal. Pt had sz upon EMS arrival and 2.5mg versed given. was initially unresponsive while going into the CT suite and apparently had a seizure as soon as he arrived to the ED. but alert by the time he was done with CT head, CTA and CTP. He was followed to the ED assigned room and he was more alert but aphasic and only say 'yep' and did not follow commands. He was able to move his left side initially but not to command. about 2 minutes later he was able to move his right lower extremity to pain followed by right upper extremity. He is febrile with temp >103F. Diagnosed with seizure and Left acute arterial ischemic stroke, MCA.
1116785	3/19/2021	NV	78	F	3/18/2021	3/18/2021	Just like what she felt during her first dose of moderna covid-19 vaccine, she had a seizure about 10-15 minutes after the vaccine was administered. The pt's episode lasted for about 5 min. She was sitting on her wheelchair and her daughter was speaking to her and holding her hand and head. Patient was responding to her daughter when daughter ask if pt can hear her. Patient did say she saw wavy lines while she was having an episode. They left after she felt fine and I spoke to daughter later that evening and daughter said that patient didn't feel tired after they got home and was eating her dinner. Daughter did speak to her mom's neurologist about the seizure that happened with the first shot and md recommended pt get second dose and not sure why she had a seizure.
1116796	3/19/2021	FL	32	F	3/16/2021	3/17/2021	Recvd vaccination on 3/16/21 woke up on 3/17 with mild flu like symptoms nausea, headache low fever began having intense nerve pain/seizure like activity 3/18 and continuing. Used to have nerve pain seizures on daily basis but has not had seizure in over 14 months prior to 2nd vaccination.
1116979	3/19/2021	MI	73	F	3/7/2021	3/8/2021	Had grand mal seizure while driving on 3/8/21. Taken to emergency room and released. Phenobarbital levels were therapeutic. Saw family doctor 3/18/21.

<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>
1117111	3/19/2021	KY	18	F	3/19/2021	3/19/2021	During 15 minute waiting period after receiving vaccine, the mother of the patient called staff over and reported the patient had experienced seizure like activity. When staffed arrived to assess the patient was startled, however was lucid and coherent. Staff then directed the patient to the hospital emergency department for further evaluation.
1117137	3/19/2021	CA	25	F	3/4/2021	3/4/2021	Pt had the pfizer Covid shot. she was sick from the first shot on Feb 4 2021. Fever , headache and chills. She decided to get the second pfizer on March 4. Immediate chest pains then 15 min later, syncope , followed by myoclonic or seizure type activity of both the RT upper and lower extremities. This was seen by me in the emergency room. She was given ativan and the seizure type movement stoped. I called her today on 03-19-2021, She told me she was sick for five days following the second pfizer, Had headaches. body aches and fevers. but today was doing well.
1117423	3/19/2021	CA	54	F	3/13/2021	3/13/2021	I had a seizure where I was involved in a serious car accident because I was driving. I do have a seizure disorder but am on anti seizure medication.
1116387	3/19/2021	VA	66	F	3/19/2021	3/19/2021	12:45 Received Pfizer #2 13:00 Felt dizzy, lightheaded; consumed water and chocolate 13:05 Transported to EMS area of observation area; in wheelchair lost consciousness and had brief 15-20 second seizure 13:10 Repeated bouts of emesis. Patient had marked pallor and diaphoresis 13:35 EMS transport arrived, placed IV, gave phenergan, and transported via ambulance to Hospital Center
1117364	3/19/2021	WA	20	F	3/19/2021	3/19/2021	Delayed vasovagal response with possible seizure. 911 called and arrived minutes later. Pt was sitting in chair and was lowered to the floor when she slumped and started to have a seizure. As soon as she was on the floor she snapped awake. She was disoriented for a moment but was aware. After a few minutes she sat back down in chair and her blood pressure was taken. it was 139/81 with HR of about 79. The fire department came in at this point. Eventually, the fire dept released her as she was with her mother.

<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>
1114271	3/19/2021	NH	51	F	3/10/2021	3/10/2021	Headache; Mild seizure; A spontaneous report was received from a consumer concerning a 51-years-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events mild seizure, headache. The patient's medical history included seizures. Concomitant medications reported were oxcarbazepine 300 mg three tablets twice daily and topiramate 100 mg one tablet twice daily, both were used for an unknown indication. On 10 Mar 2021, prior to the onset of the events the patient received their first of two planned doses of mRNA-1273 (lot/batch: 002A21A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 10 Mar 2021, Patient reported that approximately 30 minutes later after receiving the vaccine, she had a mild seizure that lasted a few seconds. Patient stated she sat still and let it pass. Patient stated she now has a headache. No treatment information was provided. The seriousness criterion for the event mild seizure was medically significant. Action taken with mRNA-1273 in response to the events was not reported. The outcome of events, mild seizure and headache 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.

<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>
1116218	3/19/2021	OH	84	M	1/22/2021	1/28/2021	Mini seizure; Diarrhea; Slight temperature; Vomiting; A spontaneous report was received from a consumer concerning an 84-year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events of slight temperature/fever, vomiting, diarrhea and short seizure early in the morning. The patient's medical history include type 1 diabetic, history of mini seizures and had a pacemaker installed a week ago- did have check up after and was good. Concomitant medications reported were levetiracetam - anti seizure, Insulin 2 times per day taking for type 1 diabetes. On 22 Jan 2021, prior to the onset of the events the patient received the first of two planned doses of mRNA-1273 (lot/batch: 029120A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. He was fine after taking vaccine, but on 28 Jan 2021 started developing symptoms. On 28 Jan 2021, the patient experienced the events of slight temperature, vomiting and diarrhea. On the same day, patient experienced the event of mini seizures for about 5 min in early morning and took levetiracetam. No other treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events 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. Patient's history of seizure was a strong confounder of the event of short seizure early in the morning.
1115799	3/19/2021	AR	82	M	2/26/2021	3/2/2021	On 3/04/2021, patient experienced a seizure. It was an isolated incident and lasted less than a minute. There did not seem to be any residual effects. This was the first and only incidence of a seizure in patient. On 2/27/21 patient experienced fever of 100.8 , exhaustion and delirium. On 2/28/21, temperature was 99.9 and patient slept most of the day. He was restless and cried out in his sleep, speaking to people who were not present. On 3/1/21 temperature was normal and patient was tired but otherwise non symptomatic.

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1113931	3/19/2021	OH	23	F	3/2/2021	3/2/2021	Seizure; Headache; Couldn't feel lower legs; Extreme chest pains and chills; Extreme chest pains and chills; Arm swelling; Pain; Itching; This is a spontaneous report from a contactable healthcare professional (patient). A 23-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 (left arm) on 02Mar2021, 16:15, as single dose for COVID-19 immunisation. Medical history included ongoing epilepsy, covid back in Dec2020, known allergies to flu vaccine and TB test and seizure (have history). Concomitant medications included levetiracetam (KEPPRA), lamotrigine (LAMICTAL), cenobamate (XCOPRI) and magnesium. The patient had no other vaccine in 4 weeks. On 02Mar2021 16:15, the patient experienced arm swelling, pain, itching, couldn't feel lower legs, extreme chest pains and chills. On 02Mar2021, at 17:15, the patient experienced headache an hour later. On 03Mar2021 01:00, the patient experienced seizure at the middle of the night around 01:00. The events resulted in emergency room/department or urgent care. The patient had Covid prior vaccination; and was not Covid tested post vaccination. Outcome of event seizure was not recovered; outcome of the rest of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The patient had underlying epilepsy. However, based on the close temporal association, a possible contributory role of bnt162b2 to the development of seizure 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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1113932	3/19/2021	WA		M	2/24/2021	2/25/2021	hip fracture; atrial fib; could not communicate; everything the patient's wife touched he said "ouch"; rigors or chills; he was limp; loss the use of his legs; convulsion; Still not eating and confused; Still not eating and confused; This is a spontaneous report from a contactable consumer (patient's wife) medical information team. A male patient of an unspecified age (reported as 90, no units provided) 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 24Feb2021 at a single dose for COVID-19 immunisation. Medical history included dialysis receiving dialysis 3x/week; and walker (walking aid user). Concomitant medications were not reported. The patient received his second Pfizer vaccine dose on 24Feb2021. When the patient came home Thursday morning (25Feb2021) from dialysis, he was limp, loss the use of his legs, could not communicate, everything the patient's wife touched he said "ouch". They had to push the patient around on his walker. Her son was helping the patient in the bathroom and he called out and thought the patient was having a convulsion, although she thought it may be rigors or chills. The patient was brought back to the recliner and took his vital signs and he was in atrial fib. The MD was called and medicated him. On Friday (26Feb2021), he was not doing so well, his nephrologist was called and was told to watch him for another day. The patient was admitted to the hospital on Saturday (27Feb2021). The patient was still not eating and confused and he has been diagnosed with a hip fracture. The patient's wife wanted to know if other people had these kinds of side effects. The patient has not recovered from "still not eating and confused". The outcome of the remaining events was unknown.

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1113941	3/19/2021	NV	65	F	2/27/2021	2/27/2021	Seizures; throat swelled up; Troponin level increased; Mild heart attack; arm was hurting; breathing issues; Dry heaves; Mucus to come out; Nauseous; Dizzy; Headache; Ears became hypersensitive; Senses heightened; Threw up; This is a spontaneous report from a contactable other health professional (patient). A 65-year-old female patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration in arm left, on 27Feb2021 (lot# EN6205), as 0.3 ml single, for COVID-19 immunisation. Medical history included seizure from 2017 (she hasn't had a seizure in 8 months), allergy (to a lot of things). Concomitant medications were not reported. The patient did not have other vaccinations in 4 weeks prior. Within 15 minutes from having the vaccination at the center the patient experienced the first seizure that lasted about an hour. The seizure was really bad, she had breathing issues, dry heaving like she was trying to throw up, mucus to come out. The paramedics checked her out, they stayed around until she came out of the seizure. The patient went home and then at 07:50 PM she started heavy shallow breathing, was nauseous, dizzy, had a headache, which also happened at the center. Ears became hypersensitive, it was so noisy like loud, but her husband and the paramedics said it wasn't loud but she could hear it, all of her senses were heightened. She had a second seizure and didn't know how long it lasted. Patient had another seizure at 08:25 PM, at 08:40 PM she had another one, at 09:00 PM patient was coming back around and had another seizure and her throat closed up and that's when she went to the hospital, when her throat started to close up. While the patient was in the emergency room (ER) she had another seizure, she had 6 total seizures, she has never had this many before so she knows it was an adverse event to this vaccination. The seizures also increased the patient's heart enzymes- troponin levels. The patient has an EEG, was given 4 baby chewable Aspirin, as she had a mild heart attack. She thought the seizure increased her troponin. The patient mentioned that during the first event at the center, she was so into the seizures, she remembers grabbing her left shoulder, her arm was hurting. She was so into the seizure and trying to throwing up that it didn't dawn on her. The hospital didn't tell her she had a mild heart attack, it just dawned on her

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1113959	3/19/2021	NH	73	M	2/27/2021	2/28/2021	<p>because her troponin levels were up mildly and she thought the seizures were triggering something in her heart, not just her seizures. The patient got another headache and was dizzy and had shallowing breathing. Seizures recovered on 28Feb2021. The patient underwent lab tests and procedures which included chest x-ray: normal, it didn't show pneumonia or fluid on the lungs on 27Feb2021, electrocardiogram (EKG): normal on unspecified date, electroencephalogram (EEG): normal on 27Feb2021, troponin: increased on 27Feb2021. Follow-up attempts are completed. No further information is expected.; 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> <p>seizure; loss of energy; flu-like symptoms; bouts of nausea; This is a spontaneous report from a contactable consumer (patient). A 73-year-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EL9266), via an unspecified route of administration at the age of 73-year-old at arm left on 27Feb2021 02:45 PM at single dose for COVID-19 immunisation. Medical history included epilepsy. Concomitant medications in two weeks included allopurinol; zonisamide; vitamin D and glutathione. There was no other vaccine in four weeks. There was no covid prior vaccination and no covid tested post vaccination. The patient had Pfizer COVID vaccine Sat, 27Feb2021 afternoon. Then 24 hrs after vaccine had loss of energy with flu-like symptoms and bouts of nausea on 28Feb2021 6:00 PM. Then at 4a.m. early Monday 01Mar2021 morning had seizure. There was no treatment for events. The event seizure was serious for being medically significant. The outcome of events was recovering.</p>

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1114722	3/19/2021	OK	35	F	3/11/2021	3/16/2021	Sore arm for first few days. Woke up on day 5 feeling off. Had an aura start in the left side of vision and thought it was just a migraine. Took migraine medication and 45 minutes later had a seizure. This is the first in my life.
1115077	3/19/2021	MI	26	M	3/12/2021	3/19/2021	Adverse event reported by nurse . Per RN report, early this morning the patient's mother heard him call out. When she entered his bedroom she observed "the tail end of a Grand Mal seizure." RN notes that the mother reported symptoms such as stiffness and flailing which was thought to be consistent with a tonic-clonic seizure. Patient was not incontinent, but did experience a period of confusion following the episode, thought be a post-ictal period. EMS was summoned at 8:10am and transported the patient to the emergency department for assessment. RN reports that the patient has no previous history of seizure. Symptoms have resolved and RN reports that the patient has had no recurrent symptoms or seizures while in the emergency department.

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1115167	3/19/2021	ME	64	F	3/11/2021	3/12/2021	Had COVID in mid-January 2021 Day 3: chills / upper back pain along spine Day 4: am - chills tapered off, significant less upper back pain along spine Day 0: March 10, Wednesday Took Daily Meds and Vit D in am / Copaxone & Clindamycin Phosphate Gel in PM 11am: Donated whole blood at a Church Day 1: March 11, Thursday Took Daily Meds in am / Applied THC/CBD cream to both legs, Clindamycin Phosphate Gel to face in PM 1pm: Received first dose of Moderna Church Medications: took 500mg of Tylenol and 400mg of Ibuprofen after shot PM: Sore arm, swelling and redness 9pm took 500mg of Tylenol and 400mg of Ibuprofen Day 2: March 12, Friday AM Medications: Daily Meds, applied Arnica homeopathic Roll-on to arm, took 400mmg ibuprofen Symptom: sore arm, swelling and redness, slight headache, upper back pain (stinging) along both sides of spine PM Medications: Copaxone & Clindamycin Phosphate Gel; applied Arnica homeopathic Roll-on to arm; applied THC/CBD cream to legs Symptoms: Same symptoms as AM but also had ?the chills? (flu ? like) (no fever) Day 3: March 13 ? Saturday AM Medications: Took Daily Meds , 400 mg Ibuprofen Symptoms: Same symptoms as Friday PM with additional ?jabbing? sensations in my joints as if someone was sticking needles in them (this also happened when I had Covid). Hand and leg cramping. PM Medications: Copaxone & Clindamycin Phosphate Gel and Zaleplon 5mg in PM; applied Arnica homeopathic Roll-on to arm, applied THC/CBD cream to legs Symptoms: Chills worsened by late afternoon. I was awoken at about 11pm by violent and uncontrollable shaking (not minor shivering like with the flu - thought I was having a seizure) and sweating profusely. This lasted about 40 minutes. I was ?shaking /convulsing? to the point that I couldn?t even call for help. I was finally able to grab my phone and call my partner who was downstairs watching television. She tried to help me change out of my wet clothes, but I was unable to stop shaking. She covered me with blankets and held me down. After another 20-30 minutes the shaking subsided and I was able to change my clothes. A shorter episode occurred about 4 hours later (lasting about 20 minutes) Day 4: March 14 ?Sunday AM Medications: Took Daily Meds Symptoms: Chills, fatigue, upper back pain (stinging) along both sides of spine PM Medications:

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							THC/CBD cream to legs Symptoms: Chills, upper back pain (stinging) along both sides of spine Day 5: March 15 ? Monday Back to ?my normal?
1115730	3/19/2021	IL	79	M	3/3/2021	3/12/2021	Patient experienced a witnessed tonic clonic seizure on 3/12 /21 at 5:30am. Seizure lasted for 3 minutes. He was post-ictal for approximately 15-20 minutes afterwards. No prior history of seizure. He was taken for further evaluation.
1113952	3/19/2021			F			Seizure like episodes.; Dizzy spells; High ammonia levels of 267 at the highest; Hit uric acid; She can not walk; Numbness on her right side; Terrible headache; Nausea; This is a spontaneous report from a contactable consumer. A female patient (mother) of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date: unknown), via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The reporter wanted to write because the patient (mother) has been in the hospital almost 18 days with no end in sight. She is going to a rehab facility soon. She had a terrible reaction to the vaccine and the reporter thought it should be noted somewhere. She is an interesting case because lots of things react bad with her. She has dizzy spells, seizure like episodes, high ammonia levels of 267 at the highest, hit uric acid, she can not walk, numbness on her right side, terrible headache, nausea and more from an unspecified date. The outcome of the events was unknown. Information on the lot/batch number has been requested.
1115785	3/19/2021	WA	49	F	3/17/2021	3/17/2021	Blotchy arms and itchy legs within 10 minutes, no breathing issues. At night severe chills (legs, arms, seizure like chills), severe body aches and exhaustion. During the night fever of 100.2. Took Tylenol every 4-6 hours after that, it helped. No appetite and stayed in bed the next day. Day 2 (today) fever has subsided, feeling exhaustion and slight back and neck pain. Taking tylenol still, feeling more alert. Still cannot go out of house or drive.
1115176	3/19/2021	KS	64	M	3/18/2021	3/19/2021	Chills, Leg cramps, Fever 104.1, Nausea, Convulsion

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1115660	3/19/2021	UT	57	F	3/18/2021	3/18/2021	DURING THE 15 MINUTE OBSERVATION PERIOD, ABOUT 5 TO 10 MINUTES POST VACCINE THE PT FAINTED WHILE SITTING IN HER CHAIR AND FELL OUT OF THE CHAIR. I INSTRUCTED A TECH TO 911 WHILE RAN TO THE PT. AS I TOUCHED HER TO FEEL FOR A PULSE SHE REGAINED CONSCIOUSNESS. I EXPLAINED WHAT HAPPENED AND ASKED HER TO STAY WHERE SHE WAS AT UNTIL PARAMEDICS CAME. SHE WAS ALERT AND ABLE TO ANSWER QUESTIONS. THE PARAMEDICS ARRIVED ABOUT 5 MINUTES LATER. THEY GOT HER UP AND SHE HAD A SEIZURE. THE TOOK HER TO AND UNKNOWN HOSPITAL
1115629	3/19/2021	TX	66	F	3/12/2021	3/12/2021	03/12/21 at approx 8 pm I began to have uncontrollable tremors/seizure in both arms, both legs and head. Numbness/weakness in all fingertips and both legs to above the knees. The symptoms continued to increase and at 11:30 pm I was taken to ER. Was transported by ambulance to Hospital. Was admitted to the ICU. Lumbar puncture was done on 03/13/21 to rule out Guillain Barre. Neurologist determined it was a neurological reaction to the COVID vaccine shot. Was released from the hospital 03/15/21. Legs continue to be numb/weak, but I am able to walk carefully unassisted.

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1115599	3/19/2021		42	F	1/19/2021	1/20/2021	Passed Out; Possible Seizure; Swollen Tongue; itches; Headache; shivering; shaking really bad; A spontaneous report was received from a nurse who was a 42- year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced shivering, shaking really bad, had a headache day afterwards, tongue was swollen, passed out and doesn't know if she had a seizure and itchiness. The patient's medical history was not reported by the reporter. Concomitant medications were not provided. On 19-Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 039K20A) intramuscularly for prophylaxis of COVID-19 infection. On 20-Jan-2021, 24 hours after vaccine administration, the patient reported that she was shivering and shaking really bad and had a headache day afterwards. On an unknown date, she reported that her tongue was swollen. She also reported that the she passed out and doesn't know if she had a seizure (date unknown). The patient reported that she took ibuprophen for her headache and diphenhydramine for itchiness. On 28-Jan-2021, she reported that she felt fine. Treatment for events included ibuprophen and diphenhydramine. Action taken with mRNA-1273 in response to the events was unknown. The outcomes of events, experienced some side effects was unknown, shivering, shaking really bad, had a headache day afterwards, tongue was swollen, passed out and doesn't know if she had a seizure and itchiness, were considered recovered/resolved on an unknown date.; Reporter's Comments: Based on the information provided and a strong temporal association between the reported events and administration of mRNA-1273 vaccine, a causal association between the reported events and the product use cannot be excluded. Headache and chills are consistent with the known safety profile of the vaccine
1115499	3/19/2021	PA	28	M	3/10/2021	3/10/2021	Aggressive convulsions, in 5 minute spurts, with pauses between, for roughly 3 hours 11:00pm to 2:00am.

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1115349	3/19/2021	WA	40	F	1/9/2021	1/14/2021	strong seizures; strong pins and needles sensations in left side extremities; A spontaneous report was received from a pediatrician concerning herself, a 40-year old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced strong pins and needles sensations in left side extremities/paraesthesia and seizures. The patient's medical history was not provided. No relevant concomitant medications were reported. On 09 JAN 2021, prior to the onset of events the patient received the first of the two planned doses of mRNA-1273 (Batch Number: 011L20A) intramuscularly in the left arm for prophylaxis of COVID 19 infection. On 14 Jan 2021, the patient experienced strong seizures, and strong pins and needles sensations in her left side extremities, which are still mildly ongoing. She is being evaluated by a specialist. No treatment information was provided. Action taken with mRNA-1273 in response to the events is unknown. The outcomes of events, paraesthesia and seizures, were considered 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 events, a causal relationship cannot be excluded.

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1115268	3/19/2021	IL	16	M	3/2/2021	3/2/2021	seizure like symptoms; Dizziness; lethargy; fatigue; This is a spontaneous report from a contactable pharmacist. A 16-year-old male patient received first dose of intramuscular BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 02Mar2021 at 12:00 at single dose in left arm for COVID-19 immunisation at the age of 16-year-old. Lot number was EN6205. Medical history and concomitant medications were unknown. On 02Mar2021 at 12:00, the patient experienced Dizziness, seizure like symptoms, lethargy, fatigue. It was unknown if the patient was treated due to the events. The patient recovered from the events in Mar2021. It was unknown if the patient had COVID prior vaccination; it was unknown if the patient was tested for COVID post vaccination.; 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 Seizure 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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1111293	3/18/2021	OH	26	M	1/30/2021	1/1/2021	Within the first 24 hours he has had 6 Tonic-Clonic seizures & 3 series of Myoclonic Jerks; Within the first 24 hours he has had 6 Tonic-Clonic seizures & 3 series of Myoclonic Jerks; Within the first 24 hours he has had 6 Tonic-Clonic seizures & 3 series of Myoclonic Jerks; This is a spontaneous report from a contactable consumer. A 26-year-old male patient received the first dose of BNT162B2 (COVID-19 MRNA VACCINE BIONTECH, lot number EN5318) via an unspecified route of administration on 30Jan2021 12:45 into right arm at a single dose for COVID-19 immunisation. The patient medical history included epilepsy and cerebral palsy and known allergies is to amoxicillin. The patient had a seizure disorder, epilepsy (Lennox Gastaut Syndrome). He has an average of 1 Tonic-Clonic (Grand Mal) and 2 Series of Myoclonic Jerks a day. There is no other vaccine was administered in four weeks. There is no COVID prior to vaccination. Concomitant medications in two weeks included topiramate (TOPAMAX), lamotrigine (LAMICTAL), clobazam (ONFI), glycopyrronium bromide (CUVPOSA), potassium citrate, citric acid, calcium carbonate and colecalciferol (VITAMIN D). Within the first 24 hours(PENDING CLARIFICATION, as reported as 30Jan2021 02:45AM) of receiving the vaccine his seizure activity increased. Within the first 24 hours he has had 6 Tonic-Clonic seizures & 3 series of Myoclonic Jerks. The patient received emergency seizure medicine Klonopin. The patient did not test COVID post vaccination. The outcome of the events was recovering.
1112604	3/18/2021	OH	29	F	3/18/2021	3/18/2021	Approximately 5 minutes after receiving first dose of Pfizer COVID vaccine, patient had syncopal episode with brief seizure activity noted
1109959	3/18/2021	GA	40	F	3/9/2021	3/9/2021	focal seizures the afternoon after my first moderna shot- for about 5-6 hours, i experienced very frequent temporal lobe focal seizures. I have never had them in such quick succession or for such an extended period of time.

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1110095	3/18/2021	IL	46	F	3/13/2021	3/13/2021	Chills, uncontrolled shaking (felt like convulsions at times), and tightening of hands and leg muscles for an hour and a half, fever of 104. Had a fever a few times after but not over 101. Headache for 36 hours. Body aches for 24 hours. Arm soreness for 24 hours. Fatigue for 48 hours. (I had a red, itchy rash a week after my first vaccine on 2/13/21 but I didn't think I needed to report it at that time)
1110107	3/18/2021	NY	39	M	3/17/2021	3/17/2021	Patient verbalized he felt he might pass out. Then he had seizure like activity and no response to external stimuli.
1110274	3/18/2021	KS	46	M	3/17/2021	3/18/2021	Violent uncontrollable shaking (convulsions) for about 30 minutes in the middle of the night. Started around 2 am I believe. My wife had the same vaccine the day prior and a similar experience. Can't overemphasize how serious the shaking was and it was scary.
1110351	3/18/2021	KS	48	F	3/16/2021	3/16/2021	Within about six hours, started having violent spasms. Each lasting 45-60 seconds, from neck down. Everything would seize up including jaw. Felt like I was having a seizure but completely conscious. Happened every 2-3 minutes until about 5:00am. Husband had same reaction the next day after his injection.
1110479	3/18/2021	OH	52	F	3/17/2021	3/17/2021	Pt had a tonic clinic seizure in the observation area. Pt was brought to the ground and EMS called. Vital signs stable. Cold compress to forehead . Transported to hospital.
1110578	3/18/2021	KY	65	M	3/17/2021	3/17/2021	Reports shaking episode "like having a seizure but conscious" with spasms in mouth and then unable to move legs. Went to sleep and awoke at 3:30 AM feverish and shaking with temperature of 101.0 F. Headache this morning 03/18/21 at 8:41 AM, feels terrible, and shaky on the inside.
1110652	3/18/2021	PR	25	M	2/11/2021	2/20/2021	Patient had two episodes of seizure 9 days after the covid vaccine (11FEB21) . He didn't had past medical history of seizures. This event happened on the 20th FEB 21. Went to the hospital and is following up with Neurology.
1110087	3/18/2021	IL	27	M	3/17/2021	3/17/2021	Systemic: Seizure-Severe

<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>
1111400	3/18/2021	IN	61	M	2/26/2021	3/3/2021	Seizure occurred on March 3, 2021
1111534	3/18/2021	CA	66	F	3/17/2021	3/17/2021	Scared of needles. Syncope, flushing/sweating. BP 111/51 (pulse 90). Patient placed in supine position - appeared to show signs of convulsion. Taken to the ED.
1111847	3/18/2021	FL	40	F	3/18/2021	3/18/2021	Patient's mother called nurse to vehicle to report daughter was having a seizure. Patient had 2 seizures in the car immediately after receiving Janssen Covid-19 vaccine. Patient then placed on the ground beside the vehicle and patient continued to have 3 more grand mal seizures. Nurses kept patient safe from any injuries. EMS called and responded. Patient transported to medical facility.
1111964	3/18/2021		66	M	3/4/2021	3/5/2021	Went into convulsions approximately 12 hours after receiving the first dose of the vaccine. Thought he was going to die. Attempted to dial 911, could not pick up phone due to convulsions. Is more scared of dying of COVID than of dying of vaccine, so will be going in for 2nd dose and wishes to remain anonymous.
1112032	3/18/2021	TX	51	F	3/18/2021	3/18/2021	Patient describes a seizure episode that occurred this morning. Patient was feeling fine at her usual health, went and got the Johnson & Johnson vaccine. Was monitored for minutes afterwards. Patient stated soon as she got the vaccine, it just made her feel little bit funny but not really able to describe the symptoms further. Went back to work and spoke with her coworker, and walls during the conversation, patient had approximately 2-minute seizure episode in which she became unresponsive, generalized shaking patient did not fall on the floor she was still in the chair. She had a brief cessation of the seizure but then she had a 45-second seizure episode. Patient was post ictal and afterwards became alert and oriented x4 however she had a persistent stuttering which is new.
1112181	3/18/2021	WI	34	F	3/18/2021	3/18/2021	Seizures/ convulsions

<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>
1112230	3/18/2021	MD	21	F	1/8/2021	1/8/2021	Immediately, I had increased heart rate - 194 - I fainted to the ground. I became nauseous, sick and had seizure like episode and then I had tingling sensation in my face and limbs. They gave me shot epi-pen - two doses. I was pretty much paralyzed for hands and legs. I was brought to hospital and they treated me there for about a week and I had muscle weakness. I gained feeling back in my hands but not in my feet. I was at Haywood for a week. Outpatient therapy and a visiting nurse for three weeks. B12; Iron; Gabapentin and that was for anxiety through it all. Test results came up as neuropathy on left side of my body. I have pins and needles pain now. I did gain my walking back. I take Gabapentin for neuropathy pain. I went to hospital - went one day and I didn't get anything back from them. I now use handicap parking for disability.
1112336	3/18/2021	CA	74	F	1/29/2021	1/30/2021	Resident had a seizure on 01/30/2021 at approximately 3:15PM.
1112372	3/18/2021	CA	74	F	3/12/2021	3/13/2021	Patient had a large stroke. Seizure on 01/30/2021 after first dose of Pfizer vaccine on 01/29/2021. Patient was 74 years old at the time she received the vaccine.
1112596	3/18/2021	CA	21	F	3/17/2021	3/17/2021	immediately felt sore on site of injection and within minutes of leaving clinic, i felt sharp pain in my upper left back (still have that discomfort and I looked at my back this a.m. and i have a red bruise like mark) I took advil and laid down, fell asleep and when I tried waking up, I couldn't wake up and when I did wake, I was breathing hard and disoriented. I slept with my mom in fear of having episode again. Around 2:45 am, my mom woke to me shaking like I was having a seizure. it lasted about 30 secs. she called 911 and i was checked out by paramedics, who said my vitals were fine and I should follow up with medical care. My mom and I agreed that perhaps I needed stress dosing of Cortef. I took stress dosage and have been taking stress dosage all day and so far no more episodes. Now waiting for Doctor to call me back and advise.

<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>
1110369	3/18/2021	MN	59	F	2/25/2021	3/15/2021	My reaction after the shot was mild, slight headache and fatigue. 2.5 weeks post vaccine I had a Grand Mal Seizure. I don't know whether or not it is related but I had a seizure 30 years ago and no problems since that time so it made me wonder whether or not it was a result of the vaccine.
1112589	3/18/2021	CA	33	F	3/18/2021	3/18/2021	Client is a 33 y.o. female who received the Covid-19 Vaccine, BNT162b2 (PF) 30 mcg/0.3 mL IM Susp, Lot ER2613 on 3/18/2021. The patient experienced the following reaction(s) during the immediate of observation: 2:35pm Patient with witnessed syncopal episode during observation period. + head strike and loss of consciousness. Patient gained consciousness after about 30 seconds. No seizure activity noted. Denies SOB and difficulty breathing. Patient alert and verbal. Patient was treated/managed as follows: 2:40pm VS BP 144/74, HR 99, RR 20, 99% on room air. Patient alert and oriented. C/o soreness to shoulder. Reports PMH psychogenic nonepileptic seizures induced by anxiety and stress, anxiety, and depression. 2:50pm VS BP 140/82, HR 87, RR 18, O2 sat 97% on room air. Patient reports mild headache and soreness to shoulder. 2:50pm 911 called. Patient given educational material regarding vaccine and advised to continue to self-monitor per the agency guidance. 3:17pm EMT arrived. VS BP 133/83, HR 83, RR 18, O2 sat 97% on room air. Patient reports feeling better. Patient refused transfer to hospital for further evaluation. 3:26pm Patient wheel chaired to car accompanied by mother, grandmother, and RN

<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>
1110344	3/18/2021	NY	57	F	3/18/2021	3/18/2021	Recipient with history of epilepsy induced by stress started seizing approximately 5-6 minutes after receiving her vaccine. Before onset of first seizure pt reported throat tightness and had a mild dry cough. Dr. (Med eval) evaluated patient- lung sounds clear, pulse strong and steady 92 bpm, heart sounds normal. Pt reported that she felt like she was going to seize. Generalized tonic clonic seizure lasting approximately 1 minute. Post ictal period noted with minimal responsiveness but good color and respirations x 1 minute. Second seizure lasted approximately 1 minute, again generalized tonic-clonic with good color and respirations. Post ictal for approximately 3-4 minutes. Pt was transfered from car to stretcher. Sats 97% on room air. lung sounds clear with good respirations. 3rd generalized tonic clonic seizure ensued (lasting approximately 1 minute). EMS gave 5mg IM midazolam in her right deltoid. Transfered into ambulance, 3 lead EKG reviewed by Med Eval and no acute findings were noted. Recipient transferred to emergency department.

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1107207	3/17/2021	NC	71	F	2/27/2021	2/27/2021	A single seizure; Headache; Chills; A spontaneous report was received from a consumer who is a 71 year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced headaches, chills, and seizure. The patient's medical history was not reported. Concomitant medicine reported included metoprolol. The patient received the first of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly for prophylaxis of COVID-19 infection on unknown date. On 27 Feb 2021, prior to the onset of the events, the patient received the second of two planned doses of mRNA-1273 (Batch number: 014M20A) intramuscularly in the right dominant arm for prophylaxis of COVID-19 infection. On 27 Feb 2021, the patient experienced headache and chills. On the morning of 01 March 2021, patient experienced a single seizure and transported to hospital. Emergency department discharged the patient stated that her magnesium levels were low and was given magnesium supplements and advised to follow up with PCP. Later the patient followed up with her PCP and they concluded her magnesium levels were normal then. Treatment for the event included Magnesium Supplements. 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, headaches, chills, and seizure were resolved on 28 Feb 2021.; 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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1107210	3/17/2021	OH		M	1/29/2021	2/26/2021	seizure; shaking; aches and pains; headache; A spontaneous report was received from a consumer concerning a 67-year-old, male patient, who experienced Seizure, aches and pain, headache, and shakes. The patient's medical history, was not provided by the reporter. No Concomitant medications were reported. On 29 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 007MZ0A) in the left arm for prophylaxis of COVID-19 infection. On 26 Feb 2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (Lot number: 006MZ0A) in the left arm for prophylaxis of COVID-19 infection. That night patient had aches/pains and a headache. The next day, on 27 Feb 2021, patient had a seizure. The patient shook so hard he came off the chair, the shaking was unbelievable. He was taken by rescue squad to the local hospital but was transferred immediately to another hospital. Patient was discharged from hospital Wednesday, 3 March 2021. Treatment for the events were not reported. Action taken with mRNA-1273 in response to the events was not applicable as patient received both the doses. The outcome of the events, were Unknown.; Reporter's Comments: The events were consistent with increased risk of complications associated with elderly age of patient. Company assessed the events to be unlikely related to company product.
1108617	3/17/2021	IL	17	M	3/17/2021	3/17/2021	After administering the covid 19 vaccine to patient, patient was observed for 15 minutes for any adverse reaction, then patient was taken back to his room and about 30 minutes after receiving the vaccine patient experienced seizure attack, felt and hit the wall. Seizure attack lasted for less than 1 minute as per staff who was monitoring him, 911 was called. Upon my arrival patient was back to normal and sitting on the chair. 911 arrived and took over. patient was transported to nearest ER.

<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>
1107354	3/17/2021	FL	42	F	3/1/2021	3/1/2021	Patient received the vaccine about 1-2 weeks ago. She became nauseated and fatigued shortly afterward. This worsened until yesterday (3/16/21) when the patient became confused and polydipsic per the patient's mother. In the emergency department the patient had a seizure. CT showed severe brain edema with a sodium of 111. We are unsure if there is any relations to the polydipsia, fatigue, and hyponatremia with the vaccine administration itself. However there is a time relationship with the start of the symptoms.
1107717	3/17/2021	MN	67	F	3/1/2021	3/8/2021	Days after receiving second dose of Moderna COVID vaccination on 3/4/2021, patient experienced increase in her baseline auras and seizures, requiring hospitalization for video EEG monitoring and titration of her anti-seizure medications. I am reporting this due to the temporal correlation. The patient was monitored with EEG while medications were titrated and did not require ICU level care.
1107974	3/17/2021	NM	64	F	3/16/2021	3/16/2021	Per caregiver, pt. had a seizure. Unwitnessed by medical staff. Caregiver did not alert staff. Pt. was not post-ictal and declined medical attention. Pt. ambulated out of clinic.

<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>
1108386	3/17/2021	NV	59	F	3/16/2021	3/16/2021	After the injection the patient grabbed her arm and when she was asked if she was ok she didn't respond and seemed slouched down. It didn't seem like she passed out but she was slouching and not responding. She seemed like she was having convulsion that lasted less than 5 seconds. Then she calmed down and her breathing was fine. I got her to respond to me that she was awake and ok. She responded with head nods. She seemed to come to a little more after a minute and she said she was fine but I wanted to call 911. I called the paramedics. During the wait she seemed to get better, we gave her water and she was slowing starting to move around more. We asked her about any under lying issues or any problems with any vaccine before. She said no to everything. The paramedics came and took all of her vitals and she was cleared that everything was ok. She called her boyfriend and we asked him to come by to help her and give her a ride home and assist. He got here and she still didn't feel totally better. After a few more minutes I took her blood pressure and it was 87/55 and her pulse was around 60. We called 911 again because she stated she wasn't feeling well again. The paramedics came back and she had a 89/41 blood pressure with a pulse of 40. They indicated that she may be having a cardiac issue so they took her to the ER.
1109121	3/17/2021	ID	31	F	3/15/2021	3/15/2021	Pt. had a seizure witnessed by her sister, pt. was able to be kept up right in a chair with no injuries, vital signs WNL, BS 91,
1108455	3/17/2021	CA	88	F	3/17/2021	3/17/2021	Pt. was vaccinated on 3/17/21 at 0924. At 0940, pt. had bounded carotid pulse and decrease level of consciousness. Pt. progressed to having no pulse and chest compressions were given for about 1 minute. Pt. was given 6L of O2 and 9-1-1 was called. Pt. regained consciousness at 0945. BP 140/90, HR 62. Ambulance arrived at 0953 and pt. was assessed by EMT. Pt.'s daughter provided pt.'s medical history. Pt. has history of passing out, atrial fibrillation and seizures. Pt. left via ambulance at 1003.

<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>
1109539	3/17/2021	IN	53	F	3/12/2021	3/13/2021	While lying in bed, I started to experience severe chills that made my entire body convulse violently. My right arm, for instance, was shaking back and forth about 3 inches. M legs were involved, tensing up and shaking as well. The symptoms resolved in about 15 min. as I focused on relaxed breathing and held a heating pad against my body. The following day, my legs felt very weak (as I would have expected.) I did not seek medical treatment, since the episode had ended.
1109433	3/17/2021	NM	76	F	3/12/2021	3/13/2021	3 seizures the next day (3/13/21) and then hospitalization
1109365	3/17/2021	OH	47	F	3/11/2021	3/12/2021	Seizure. Convulsions, lost consciousness, amnesia, high blood pressure, confusion. Numbness of lower lip, tingling in hands and feet, consistent headache, fatigue, memory problems, and filling out of my body are all still occurring five days later.
1109358	3/17/2021	PA	67	F	3/17/2021	3/17/2021	Patient exhibited a forceful cough for a few minutes after receiving vaccine. RN talked with patient through care giver as patient does not speak English, as well as an on site interpreter. Patient described feeling "dizzy" and "sleepy" . patient's care giver described the patients' history of absent seizures brought on by panic attacks. In this anxious state, patient was tachycardia, hypotensive, and tachypneic. RN monitored patient as she lost consciousness for about 7 minutes. in this state, patient was unresponsive with normalized heart rate and respiratory rate. Blood pressure was measured when patient was out of consciousness and was hypotensive. Patient began to regain consciousness after about 7 minutes and was oriented to person, but not place or time. Care giver insisted on not calling for an ambulance and he would take her home. Patient was given 16 ounces of water and vitals monitored for about 20 more minutes until patient was normotensive and orientedx3 and was discharged to home with care giver.
1109150	3/17/2021	IL	21	F	3/17/2021	3/17/2021	Patient lost consciousness seconds after vaccine. This was followed by seizure activity for 20 seconds.

<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>
1108412	3/17/2021	PA	20	F	3/12/2021	3/12/2021	Patient has a history of seizure disorder. Often reacts to injections with seizure. Within seconds of injection, child became unresponsive and went into a 4 minute tonic seizure. Patient has a vagal stimulator implant and mother used the stimulator X 3 every minute after the seizure started. Seizure resolved within 4 minutes.
1107218	3/17/2021	CA	78	M	2/18/2021	2/19/2021	seizures; small stroke; A spontaneous report was received from a consumer (wife of patient) concerning a 78- year-old, male patient who developed seizure and a small stroke. The patient's medical history included seizure 4 years ago, stroke long time ago. Products known to have been used by the patient, within two weeks prior to the event, Cholesterol medicines, Blood pressure medicines and Aspirin. On 18 Feb 2021, prior to the onset of the event, the patient received their first of two planned doses of mRNA-1273 (Lot 031M20A) intramuscularly in the Right arm for prophylaxis of COVID-19 infection. On 18 Feb 2021, the patient developed seizure, small stroke . Treatment for the event was not reported. Doctors are not sure about the causality, but want to report it. They spoke to his doctor about not getting the second vaccine. Action taken with mRNA-1273 in response to the event was unknown. The outcome of the event's, seizure, stroke was considered unknown.; Reporter's Comments: The events were consistent with increased risk of complications associated with history of seizure confounded by elderly age of patient. Company assessed the events to be unlikely related to company product.
1106520	3/16/2021		30	M	3/16/2021	3/16/2021	Seizure about 1 minute after injection, seizure lasted about 1 minute
1106694	3/16/2021	MN	29	F	3/16/2021	3/16/2021	Pt had a reaction to vaccine. Specifically, she fainted and had seizure. It happened within seconds after the immunization delivery. Pt had upper body seizure waist up in the chair. This lasted about 30 seconds at a time. This occurred roughly 3 or 4 times. Emergency services were called. EMTs responded to scene. Pt was well enough not to go to the hospital. Eventually, left with boyfriend feeling better.

<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>
1106722	3/16/2021	CA	33	M	3/16/2021	3/16/2021	After pt received Janssen J&J vaccine, pt was closing his eyes and leaning back. Per LPN, pt had seizure ~15-20sec, foot twitching, PHNs and FNP were called to scene. Pt A&O x4, but then had 2nd seizure <5min later, lasting 15-20sec, not responding to prompts. EMT called 911. Pt then A&O again x4. FNP measured pt pupils: L pupil initially 4mm, then escalated "blown", R pupil 1-2mm. HR 35, pulse ox 99%. Pt Hx of type 1 diabetes, BG 186 per paramedic. Paramedics took pt to ER.
1106774	3/16/2021	CA	26	F	3/16/2021	3/16/2021	Possible seizure, pt shaking, shortness of breath, bluish skin, kept saying "couldn't breathe." Epi-pen autoinjector administered afterwards patient was laid down and raised legs and blood pressure taken which was 118/68, pulse 68. Emergency 911 was called and arrived on scene in 2-3minutes. Paramedics took vitals and deemed it to be a syncopal episode, instructed patient to go to hospital for further monitoring. Husband to drive pt to hospital.
1106788	3/16/2021	GA	78	M	3/3/2021	3/11/2021	Person is having seizures uncontrollable flailing and jerking
1106808	3/16/2021	CA	76	F	3/15/2021	3/15/2021	seizure like activity of upper extremities. slumped over in chair vomited pale in color
1106911	3/16/2021	CA	67	M	3/11/2021	3/12/2021	catatonic seizure in upper left thigh and leg. extreme muscle cramps 1/2 hour Used to get these often but was cured years ago. Extremely painful. After released leg muscle very sore needing of rest so it did not repeat. Felt affects gone by 3/15.
1106430	3/16/2021	KS	70	F	3/12/2021	3/12/2021	Phone call from husband on 3/12/21 at 2:43 pm that after leaving the Health Department around 12:20 pm they drove to restaurant and his wife ate lunch. They drove home and she was resting in living room and he found her at 1:30 pm unresponsive. He called ambulance and she was transported to the emergency department at Center. He reported that the doctor was running tests and he would let me know what they find out. 3/16/21 3:45 pm phone call to, husband and he said patient was sent by flight for life to Center on 3/12/21. He reports that it was determined she had a seizure and then had another in the emergency department and was intubated due to low oxygen levels.

<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>
1106855	3/16/2021	WI	19	M	3/16/2021	3/16/2021	The patient had a seizure and vomited several times post-vaccine. 911 was called and EMS took him to the hospital for further evaluation.
1104671	3/16/2021	MI	39	M	3/12/2021	3/13/2021	Patient has a long history of seizures. He has seizures on a daily basis. He lives with his family, who are his primary caregivers, they family provides all of his activities of daily living. Patient received vaccine on Friday morning, feeling well throughout the day according to the father. Went to bed, during the night in bed he had seizures which is typical for him, and during the episode the father noticed that he had stopped breathing. called 911 who came to the house and the patient died in the house. I do not believe he went to the hospital.
1103742	3/16/2021	MS	64	F	2/19/2021	2/28/2021	Beginning February 28, 2021 stroke, seizure, fever, headache and weakness.
1103779	3/16/2021	NC	55	F	3/15/2021	3/15/2021	Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Seizure-Severe, Additional Details: Event occurred during observation period, roughly 5-10 minutes after administration. Patient was seated and appeared close to fainting (unresponsive, head down, unsteady) which prompted closer observation when she began to have seizure. Patient was moved to cleared floor and EMS contacted immediately; transported offsite soon after. Her husband reported history of epilepsy with drug regimen during event.
1103867	3/16/2021	NY	88	M	2/18/2021	3/1/2021	pt vaccinated with 2nd covid vaccine on feb 18, 2021 and 2 weeks later developed sudden chorea like movements which progressed to where his wife thought he might be having a seizure and he was brought in and hospitalized on 3/13/2021. Pt admitted with acute choreaform movement pattern, possible encephalopathy(having acute mental status changes) and acute functional decline. Pt prior was independent with ADL's, had smooth speech pattern and walked independently with a walker. there have been no recent medication changes or illnesses.

<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>
1104003	3/16/2021	OH	19	M	3/11/2021	3/11/2021	3-11-21 4:26PM CALLED TO VACCINE STATION. PARENT STATES PT HAS BEEN HAVING SEIZURES OFF & ON X ARPOX. 20MIN. SEIZURES STARTED BEFORE VACCINATION. 4:40PM PT POST ICTAL; PINK, W/D, RESP REG WITH EASE - NO RESP DISTRESS. TO EXIT PER W/C TO BE TAKEN HOME PER MOM. NO SEIZURES AT THIS TIME. 3-12-21 9:30AM MOM STATES PT IS '100% BETTER TODAY'.
1104096	3/16/2021	ME	21	M	3/15/2021	3/15/2021	After 11 hours of getting the vaccine I believe I experienced a sleep seizure. I woke up abruptly, shaking uncontrollably with absolutely no control over myself. Since then I've only experienced the normal side effects, muscle fatigue, headaches etc.
1104102	3/16/2021	IN	28	F	3/14/2021	3/15/2021	Around 12:00 a.m. on Monday, March 15, 2021 (which was 12 hours after receiving the vaccination) I started to experience cold chills so severe I thought I was having a seizure. My husband stacked 10+ blankets on top of me trying to get me to warm up. I was running a fever of 103, and my heart rate was at 104 all night long. My fever didn't break until shortly before 8:00 a.m. on Monday, March 15, 2021 but my heart rate stayed between 95 - 102 most of the day. The body aches weren't too terrible, but I did have those. I have bruising, puffiness, and swelling at the injection site.
1104114	3/16/2021	VA	19	F	3/9/2021	3/10/2021	3 Seizures on 3/10 8 Seizures on 3/12 Placed on Ventilator 3/12 Removed on 3/13 5 seizures on 3/13 Placed back on vent 3/13 Removed from vent 3/15 Seizure on 3/15

<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>
1104155	3/16/2021	IN	67	F	2/12/2021	2/17/2021	Five days after the vaccine she was on the phone, sitting in a chair and she lifted her arm up and it felt heavy and it just dropped. She then started to raise the arm and she was not able to do it. She then suddenly lost sensation in her left arm. She then could not control it, would raise when it wanted to but was not able to feel it or control it. (had the feeling that it was not connected to her body and it was just floating around). Then started having involuntary muscle spasms in her mid torso region. The same thing then happened again and the muscle spasms were more intense and she waited around and lasted for minutes. She never lost consciousness, but then it happened again and was spreading on her left side. It then encompassed from her hip up to her shoulder. The involuntary muscle spasms were moving from the side toward her chest to where she felt it would impact her breathing. She then went to the ER and they started doing testing, and she had more spasms, and then started having double vision. In talking with the doctor about all of this she had a CVA with complex partial epilepsy with recurrent seizures and that the double vision was related to the infarct in her brain and that the stroke triggered the seizure that she had. She did not lose any memory, loss of consciousness, no weakness or loss of sensation. These episodes only lasted minutes and a refractory time of minutes and when she got to the ER she the other episode when they were trying to test her. They were not able to do the EKG or EEG due to the involuntary movements and these resolved. She is now completely recovered other than the fatigue with no residual. She saw a neurologist on 2/24/21 who felt like that she had a stroke and put her on Keppra and is going to FU in 3 months at IU. It was ruled out that there was no relationship of her transplant to this reaction. She is now on Keppra, Atorvastatin for the swelling in her brain, and also put on aspirin 81 mg. Her blood tests that were done were all drawn and were all within normal limits except for kidney function, but is only a minor #s for her secondary to the transplant. She then had some titers drawn for CMV and that was also negative. Then she had a COVID test that was negative. Then she had spinal tap that came back normal results.

<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>
1104241	3/16/2021	VA	97	M	3/11/2021	3/11/2021	He suffered a seizure. Shaking (entire body) Labored Breathing, Not responding. Called 911. Taken to Emergency Room.
1104467	3/16/2021	NC	48	F	3/15/2021	3/15/2021	chills, uncontrollable shaking (boby would tense up/hurt every time shake. felt like I was having convulses. my teeth would not stop chattering), body felt cold/hot, unable to sleep, and full body achy/sore, and tired feeling. The chills and uncontrollable body shaking happened twice (around 7:00-8:00 pm and sometime in middle night). I took alieve and probably 15 to 30 min later the body shake would stop.
1106467	3/16/2021	OR	32	M	3/6/2021	3/6/2021	Lightheadedness, nausea, SOB, seizure-like activity - stiffening, arching back, rapid eye mvmt, not following commands.
1104520	3/16/2021	NY	33	M	2/16/2021	2/20/2021	headache, seizures more than usual spent 7 days in hospitals trying to get them under control
1106432	3/16/2021	CA	25	M	3/16/2021	3/16/2021	10:00 am client received his COVID19 vaccination. Immediately the client fainted and fell out of his chair on his left shoulder. He did not hurt his head. Client was lying flat on the floor and then started having seizures and was placed on his left side. Episode lasted 3 seconds. Client was able to answer questions and alert and oriented x 4 and no complaints of pain or discomfort. 10:07 1st vitals taken. 10:09 am client stood up and walked to observation area. Client was under observation for 30 minutes.
1104814	3/16/2021	DC	36	M	3/16/2021	3/16/2021	Pt received the covid vaccine around 12:50 pm. Then as he was walking to schedule his second appointment soon after the vaccine, he fell to his knees (no CHI). I was notified and ran over to see pt was disoriented, pale, diaphoretic. While measuring his left arm BP (80/30), he began to convulse with both elbows flexed. The convulsions lasted about 10 secs, pt did not recall the event, we held him in a seated position on the floor. He felt much better after the convulsion + water/snacks, however we did call EMS during the event. Per EMS, BP was 128/80, and pt was AAOx3. Pt refused to go to the hospital and agreed to f/up with PCP.

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1105044	3/16/2021	CA	39	M	3/16/2021	3/16/2021	39y/o male presents with syncope, head injury and body shaking within 5min of receiving Pfizer vaccine in left arm on 3/16/21. Patient lost consciousness, fell from a seated position and hit the left side of scalp on the floor. Patient then experienced uncontrolled body shaking for <5sec. He had drool from his mouth during episode. Patient regained consciousness after cessation of shaking. He reports associated sweating and head pain. He denies throat enclosing, difficulty speaking, lip/tongue swelling or itching, injection site pain or itching, blurring of vision, light headedness, chest pain, palpitations, or shortness of breath. He reports history of syncope when getting his blood drawn and at site of blood. He denies allergies to medication or vaccinations. He denies any current medical conditions or h/o seizures. On physical exam: Vitals: Heart rate 88, blood pressure 150/100 Skin: his skin is diaphoretic and ~4x2cm skin abrasion to his left scalp is noted. Cardiovascular: Radial Pulse 2+ . Heart regular rate and rhythm. Lungs: clear to auscultation bilaterally Patient was examined by EMS and informed that he could be transported to hospital via ambulance for immediate consultation with provider or can decline services and seek care at a later time. Patient opted to drive on his own to seek care at a later time. He was advised to contact his primary care provider regarding his adverse reaction, seizure and head injury. Note: MA called for PA on site when patient fell and hit head. PA told site manager to call 911 while attending to patient. When PA arrived to patient's side, he had regained consciousness and PA proceeded to provide care and investigate incident.
1105161	3/16/2021	KS	19	F	3/16/2021	3/16/2021	Seizure, grand mal, lasted 10 seconds, postictal up to 10 minutes
1105196	3/16/2021	NJ	85	F	3/14/2021	3/15/2021	3/15 9AM started to have expressive aphasia noticed by family, shaking chills and headache. Brought to ER. CTH completed and negative. Admitted for monitoring. 3/16 early AM (5am) -seizure like activity and right sided facial droop. CTH negative MRI, EEG pending Fever 102 3/16 7AM.

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1105484	3/16/2021	WI	66	M	3/4/2021	3/5/2021	Pt was given first dose Covid vaccine 3/4/2021. then had seizure like activity 3/5/2021. Became unresponsive. Does have a Hx of seizure X1. strong family Hx of seizures. was transported to Hospital Via EMS, Admitted to ICU.

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1105604	3/16/2021	IL	25	F	3/16/2021	3/16/2021	Pt received 2nd COVID vaccination at 1024. Once in observation area, pt became unresponsive shortly after sitting down. This provider was called over by staff to pt, which was noted to have dropped her water bottle and become unresponsive while sitting in the chair. Pt remained in the chair, did not fall or injure self. Upon arrival to patient, she was noted to have moderate pallor, with shallow, slow breathing, no cyanosis noted. Her head was aligned/adjusted to maintain an open airway. Pt noted to have some muscular rigidity and not verbally responsive. Another provider advised to call 911 due to unresponsiveness and seizure-like activity. 911 called @1027, meanwhile pt lifted and placed into a wheelchair and moved to treatment area where vitals were obtained, patient became verbally responsive @1034, responses/speech was clear but slow, pt was oriented to self, place, time and situation. Oxygen applied via facemask @4L. Pt provided staff with phone number to call her mother who was notified of daughter's condition @1032. FD Engine arrival @1033 report given and pt also became more responsive, eyes opened and stated clearly that she was feeling better. Pt color also improved. Pt denied any allergies, PMH or hx of seizure activity. Pt only reported a syncope many years ago. Ambulance arrival @1036, report provided to emergency staff and pt taken to ambulance for further evaluation @1039. Pt returned to vaccine clinic @1052, having declined ambulance transport. When asked about events, pt stated that upon sitting down she felt a sudden onset of moderate nausea and reached for her water bottle in her bookbag, pt states she could not recall or hear anything until she was moved to wheelchair, and did not recall how she came to be in the observation area (based on this information, suspected time unconscious was approx 6-12 seconds). Pt was educated regarding the many causes of syncope and the necessity for further evaluation in the Emergency department. Pt discouraged from driving herself from the clinic and was able to obtain ride from her roommate. Pt urged again to obtain a ride to the hospital for further evaluation, understanding verbalized and agreed with plan of care.

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1105675	3/16/2021	TN	63	F	3/16/2021	3/16/2021	Pt received vaccine at 15:25. At 15:33 pt. reported her lips felt tingly. At 15:38 patient began seizing and was lowered to the ground by 2 staff members. Oxygen was placed on patient at 5L via nonrebreather mask. Initial BP 160/80 manually on right arm, Heart rate 26, oxygen saturation 84%. Oxygen increased to 10L and EPI 0.5 mg administered IM into right anterolateral by, APN at 15:43. 15:44 vitals: BP 182/90 manual R arm, 110 heart rate, 99% O2. Oxygen decreased to 8L. Seizure ended at 15:45. Vitals at 15:45 180/105 BP, 115 heart rate, 98% O2. Vitals at 15:48 185/100, HR 102, oxygen 99%. EMS arrived at 15:50 & 2nd seizure began at 15:50. 15:50 vitals BP 245/110, 131 HR, 99% O2. 15:52 vitals 240/110 BP, 107 HR, 99% O2. Pt. left via ambulance at 15:55.
1105944	3/16/2021	TX	27	M	3/6/2021	3/6/2021	PATIENT HAD A SEIZURE ABOUT 45 MINUTES AFTER GETTING THE VACCINE. PATIENT'S EYES ROLLED BACK AND STARTED FOAMING AT THE MOUTH. PATIENT HAD BEEN SEIZURE-FREE FOR 3 YEARS PRIOR TO GETTING THE VACCINE.
1106306	3/16/2021			F	2/24/2021	2/26/2021	seizure; couldn't move and speak; couldn't move and speak; chills; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age (age: 77, unit: unknown) 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 24Feb2021 at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced seizure, couldn't move and speak and chills on 26Feb2021. The patient received first dose of Pfizer on 24Feb2021, and experienced a seizure 48 hours later. She was experiencing severe chills, then during the night, woke up with a seizure, couldn't move and speak, didn't go to the ER, no history of seizure, already filed safety report. She wants to know if she can receive the second vaccine. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.
1104826	3/16/2021	CA	35	M	3/11/2021	3/14/2021	Small seizure at 1pm on 03/14/2021. Followed by Grand mal seizure at 5:30pm on 03/14/2021.

<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>
1104519	3/16/2021	IN	64	F	2/18/2021	2/23/2021	woke up at 1:30 am to use the bathroom. Started shaking violently, upper torso only. Neck, head, shoulders seemed paralyzed. Arms shaking so badly they were not functioning. Happened a second time 5 days later. Wide awake, getting ready to shower. This wasn't what I would call chills. Seemed more like a seizure to me. It didn't last long, only about 30 seconds, but it was very intense. Only happened two times, but never had that happen before I had the vaccine. Both events happened within 2 weeks of having the vaccine. I am due for my 2nd shot on 3/18, and I'm a little bit concerned about any potential side effects.
1104680	3/16/2021	TX	68	M	2/22/2021	3/12/2021	On 03/12/2021 at 0630 fell out of bed, wife witnessed tonic clonic seizure of 5+ minutes duration, when EMS arrived patient was postictal (confusion).
1103248	3/15/2021	CA	30	F	2/15/2021	2/22/2021	I am currently 22 weeks pregnant with expected date of delivery July 16th 2021. I was diagnosed with epilepsy in January of 2017. In 2019 i began using lamictal and had zero problems with the anti -seizure medication. One week after my second dose of vaccine i developed a significant rash and experienced extreme difficulty breathing. After seeing a dermatologist and getting a biopsy i was told that i had DRESS syndrome which is very uncommon given i had already been on lamictal for such a long period of time. I have been prescribed a topical steroid as well as 40mg prednisone and am titrating off the lamictal to the keppra (1500mg).
1103234	3/15/2021	NM	49	M	3/15/2021	3/15/2021	Patient stared off for a minute or two after receiving the vaccination. The wife stated he frequently has seizures. The patient came-to and waited in a chair for the requested time, then the patient left.
1103073	3/15/2021	GA	74	M	1/16/2021	1/16/2021	i thought i was having a seizure
1103052	3/15/2021	PA	27	F	3/11/2021	3/15/2021	Began feeling sick after injection. Low fever, fatigue for day of injection and day after. Day 3 felt normal, but day 4 began feeling sick again with no appetite, nausea and chills. At 5:30 I passed out and remained unconscious until my mother found me on the floor and then had a seizure lasting about 2 minutes. I was unconscious for at least 30 minutes. I have had seizures in the past, but never anything close to this.

<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>
1103003	3/15/2021	PA	67	M	3/6/2021	3/6/2021	patient received first dose of covid vaccine, she has a history of stroke with an antibiotic and seizure with nsaid. she was instructed to wait 30 minutes in the lobby post vaccine. vaccine was given at 253pm and at 259pm she got lightheaded in her chair and fell to the floor. Patient was alert and oriented x 3, vitals were 171/77, pulse 73 and o2 95% on room air. Vitals were taken again after 2 min and bp was 168/78 and o2 dropped to 85%. patient was placed on 6 liters of o2, code team was called to have her sent to the ER for evaluation due to history of stroke. Code/emergency response team arrived and immediately escorted patient to the ER.
1102917	3/15/2021	MO	18	F	3/15/2021		patient had seizure and hit floor
1102741	3/15/2021	IL	71	F	3/9/2021	3/9/2021	Patient had 2 seizures after receiving the Moderna vaccine for COVID-19. The patient did disclose that she stopped her seizure medication two months prior to the vaccine. Pt also reports that she did have one seizure an hour prior to the vaccination. Pt reports not informing the vaccination team of her seizure. Patient was treated at Hospital ER and was admitted for an observation stay at the hospital to control her seizures.
1102708	3/15/2021	WY	67	M	2/11/2021	2/11/2021	Patient stated he had a seizure four hours after receiving the first dose and fell and hit his head. He was life flighted and was hospitalized for several days. He does not know if this was a reaction to the vaccine and said the hospital was not sure either, but he has never had a seizure before.
1102574	3/15/2021	KS	21	F	3/15/2021	3/15/2021	approximately 5 minutes after receiving vaccination patients boyfriend said that she was filling light headed. I went to the waiting area to check on patient and take her blood pressure. while taking patients blood pressure she had a short (1-2 seconds long) seizure and lost consciousness. Patient quickly regained consciousness and reported no additional symptoms. EMS arrived on the scene quickly and patient left with them.

<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>
1102517	3/15/2021	DE	69	M	3/3/2021	3/10/2021	Received 2nd dose Wednesday, 3/3/21 6:00pm Tues. 3/9/22 late afternoon? fever 101.4 Wednesday 3/10/21? 1:25 or so... while sitting in recliner, starting seeing very bright light? couldn't see anything but bright light.... within seconds starting convulsing/ seizure- for about 30 - 60 seconds- was unaware of what was happening- eyes open but not focused... arms, legs and whole body convulsing? after it stopped within a minute or two? started vomiting uncontrollably? was able to hear me at this point? 911 was called at 1:35.... Taken to Hospital Admitted?

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1103351	3/15/2021	MI	57	M	3/10/2021	3/10/2021	<p>PRESENTING PROBLEM: Syncope and collapse [R55]</p> <p>HOSPITAL COURSE: History of Present Illness: 57-year-old man known to me for bilateral lung transplant for bronchoalveolar cell carcinoma complicated by bilateral pleural effusions of unknown etiology and mild decrease in pulmonary mechanics, DVT on Eliquis who came to the Emergency Room 3/12/21 with a chief complaint of near syncope. Patient and woke up in the early morning hours of 3/12/21 to use the restroom. While urinating, he became very dizzy and nauseated and had a sense like he needed to lay down to rest. Other than nausea he did not have any other symptoms. He returned to his bed and fell upon his wife and had decreased level of consciousness but without total loss of consciousness (he was able to hear his wife talking to him but was unable to respond). This lasted about a minute and slowly he came back to his senses. After this he felt quite cold and did have some shaking but is not clear whether these were true rigors. He did not have any preceding fevers nor did he have any fevers in the emergency room. After about 5-10 minutes he was feeling back to his normal self but want to come into the hospital to get checked out. He has never had anything like this before. The patient has had chest pressure since his COVID vaccine which he had on Wednesday. This is been intermittent, mostly positional and better with laying on his side and leaning forward, worse with recumbency. It is not pleuritic in nature. No associated shortness of breath. No other fevers chills sweats. No sick contacts. Evaluation in the emergency room was done and a CT scan was done and no pulmonary embolus was found. No parenchymal abnormalities. The patient's pleural effusions remain, and her mildly worsened, personally reviewed. Baseline labs were unremarkable for anemia, kidney injury. EKG personally reviewed, normal sinus rhythm. High sensitivity troponin was done and negative. Family otherwise feels well, no sick contacts, eating well no nausea vomiting diarrhea blood in his stool. Pt admitted for observation. Continued to feel well VSS, ekg stable, ECHO without acute findings (see below), UA neg, cardiac monitoring uneventful, orthostatics negative, walking in halls and eating well. Appears to have had vaso vagal episode. Will be getting routine head imaging in the coming month with cancer history See below testing Care plan upon discharge > To call if any return</p>

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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of symptoms > To hold metformin until Monday due to recent dye load > Blood cultures Pending, low clinical suspicion > To change H2 blocker to PPI due to GERD on 3 month esophagram > Follow up in clinic when return from break > Dr discussing with pulmonary team most recent CT (see below) and treatment plan moving forward Brief exam: awake, alert, oriented, not in any distress. PERRL, EMOI, tongue midline. Upper and lower extremities at full strength 5/5 in the arms, hands, dorsi flex and flexion at the ankles, knees and legs. Sensation not tested. Brief history and medical decision making: s/p bilateral lung transplant for bronchoalveolar cell carcinoma complicated by bilateral loculated pleural effusion, DVT on eliquis presenting post syncopal event. Syncopal event without evidence of seizure like activity, fast recovery, and no sudden changes consistent with an acute cardiac event. Thus symptoms were likely due to vasovagal event possibly post COVID_19 related side effect (headache, achy muscles, not feeling well overall). He has no neurologic deficit, CTA thorax without PE, negative EKG, troponin and echocardiogram. He is not on antihypertensives and blood pressures have been normal. Given his initial diagnosis of BAC, there may be concern for metastatic disease, though symptoms have not persisted and he has no focal deficit. He also received contrast for his CTA today, thus will defer further imaging for now. Syncope: - defer 2nd dose of COVID-19 vaccine as its effectiveness in transplant patient is not established and patient potentially had an adverse event. - oral hydration encouraged - monitor for additional ongoing neurologic symptoms such as headaches, vision changes, neck stiffness, fevers, night sweats, weight loss, weakness or paraesthesias - patient advised to avoid driving until further evaluation - consider MRI brain with and without contrast if any symptoms persist or reoccur Complex loculated pleural effusion

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1102083	3/15/2021		68	M	3/12/2021	3/12/2021	Pt seen ER 3/12/2021 Dr for vaccine reaction, initial encounter, evaluation for possible vaccine reaction, pt received first dose COVID vaccine today in clinic, episode where became lightheaded, possibly near syncopal. On arrival to ER back to baseline, monitored on heart monitor with out changed, initially hypertensive but came down, discharged home. Follow up in 1 week with PCP Dr to discuss whether he should receive second dose or not, pt felt just got hot and anxious about the shot, history of CVA which required craniotomy and led to seizure disorder, wife thought he might be having a seizure, blanking out. No other s/s noted.
1102550	3/15/2021	NM	47	F	3/12/2021	3/13/2021	24 HOURS AFTER VACCINE PATIENT REPORTS HAVING FLU LIKE SYMPTOMS IN ADDITION TO INJECTION SITE PAIN AND SWELLING. FLU-LIKE SYMPTOMS CONTINUED UNTIL PATIENT BECAME REALLY NAUSEOUS, WHILE VOMITING (OR SHORTLY AFTER) PATIENT EXPERIENCED A SEIZURE AND FAMILY MEMBERS CALLED 911. PATIENT RECEIVED A CT SCAN WHILE IN THE HOSPITAL TO RULE OUT CONCUSSION OR BLEEDING ON THE BRAIN. AS OF TODAY PATIENT IS FEELING BETTER, BUT STILL HAS INJECTION SITE PAIN.
1102060	3/15/2021	WA	94	F	3/12/2021	3/12/2021	Pt had seizure x2 while in clinic during observation period. Son stated that pt does have seizure disorder and anxiety does exacerbate seizures. Pt denies feeling anxious about vaccine. Initially pt was unresponsive to stimuli, but then opened her eyes and was able to follow commands and answer questions. O2 sats during initial seizure was 86% and BP 190's/80's. Pt with tonic clonic movement during initial seizure. Pt then had subsequent seizure but did not lose consciousness during this one but was unable to respond to stimuli or commands. O2 sats low 90's during this event. Pt's son stated that it was not normal for her to have clusters of seizures like this and so EMS was called.

<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>
1101737	3/15/2021	IN	56	M	3/11/2021	3/11/2021	Pt felt lightheaded once in parking lot after receiving vaccine around noon. Beeped horn at 12:10pm. Fainted and reports possible stiffening of limbs/seizure activity. Hx of fainting with needles. Pt was pale and lightheaded when nurse arrived to car at 12:11pm. 911 called immediately due to possible seizure. BP 90/50, unable to obtain pulse and O2 sats. Ambulance on scene at 12:17pm and patient transported to hospital via ambulance at 12:30pm. Pt was feeling better and responsive when he left scene.
1101502	3/15/2021	TX	26	F	3/12/2021	3/12/2021	10 hours after vaccine administered, body pain, lowered mood, and fever into the night. Hallucinations, fever dreams, night sweats, and possible seizure (unsure, facial twitching was present during suspected hallucination/fever dreaming).
1101470	3/15/2021	LA	61	M	3/11/2021	3/11/2021	PT REPORTED AFTER RECEIVING VACCINE HE WAS A LITTLE FATIGUE & ONCE HE GOT HOME HE REPORT SEIZURE ACTIVITY. HE STATED FOR APPROXIMATELY 40 MINUTES "HE WAS JUST IN A DAZE & STARING" AND AFTERWARDS HE WAS FINE.
1101349	3/15/2021	SC	78	M	3/9/2021	3/11/2021	Admitted with altered mental status, generalized weakness, and fever. Went into cardiac arrest and required intubation. Currently with questionable seizure activity and requiring warming.

<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>
1101154	3/15/2021	FL	87	M	1/26/2021	2/28/2021	Husband experienced seizure lasting 30min. after taking 2nd vaccine. 1st vaccine on 26/01/21 LOT# 00TM20A. 2nd on 23/02/21 LOT# 024M20A, 5 Days after; the Ambulance took husband to hospital & Dr put the patient on a seizure med Levetiracetam 500mg; A spontaneous report was received from a consumer, concerning 87-year-old male patient, who received his second dose of Moderna's COVID-19 vaccine and experienced seizure that lasted about a half an hour. Medical history included: seizure 37 years ago during a stroke. There were no concomitant medications reported. On 26-Jan-2021, the patient received their first of two planned doses of mRNA-1273 (Lot Number: LOT# 00TM20A) and on 23-Feb-2021, he received the second dose of mRNA-1273 (LOT# 024M20A), intramuscularly for prophylaxis of COVID-19 infection. On 28-Feb-2021, five days post receive the vaccine, the patient experienced a seizure which lasted about a half an hour. The patient was taken to hospital and was treated with Levetiracetam 500mg. Action taken with the dose of mRNA-1273 in response to the event was not reported. The outcome for the event was considered as resolved on 28-Feb-2021.; Reporter's Comments: Based on the current available information which show a temporal association between the use of the product and excluding all other etiologies as reported (subject experienced seizure 37 years ago), a causal relationship with the event cannot be excluded.
1101024	3/15/2021	MI	26	M	3/12/2021	3/12/2021	within 5 minutes of getting vaccine patient was sitting in the post vaccination waiting area and fell to the floor hitting head. Staff responded immediately. He quickly became alert and talked to staff stating that he has a history of "passing out." HE was assisted to wheelchair per his request and staff contacted EMS. Unsure if seizure. He postured and fell to floor a second time hitting his head. He immediately awoke and recalled the event again. Staff remained with him on the floor until assisted out with EMS at 10:23. Alert and orientated. Wife returned to the clinic later in the day and stated that he did not go to hospital and refused treatment. He was at home.

<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>
1100945	3/15/2021	MA	28	F	3/12/2021	3/12/2021	Within a few minutes after Jannsen vaccination, in the observation area, patient called attention to staff. A few nurses arrived immediately including this RN. She became dizzy, nauseated. Emesis bag but no vomiting occurred. Vital Signs taken with Systolic BP in the 60's, mild bradycardia, significant clamminess. Patient endorses usually HR higher than this. Patient then developed a period of absence x 2, similar to absent seizure. Patient was laid on a stretcher with slow improvement in S-BP to 111 and clamminess. Given the significant hypotension and suspected absence seizures, staff had already call 911. Patient reported only having some popcorn and coffee all day with no meaningful intake of food or fluids once patient became more alert. This RN provided 2 bags of chips with salt and 2-16 oz. bottles of water. This RN encouraged intake. Fire, EMS, and Police arrived. Patient refused transport to hospital. Patient agreed to wait until significant other arrived to drive patient home. Patient stayed for about an hour extra to eat and drink with moderate effect. Patient stood up and felt moderately dizzy but patient was able to ambulate to her significant other's vehicle. The team encourage patient to contact and see PCP regarding the absent seizure and encourage rest with hydration and intake at home. Incident report was filed with facility.
1100800	3/15/2021	FL	24	M	3/14/2021	3/14/2021	Systemic: Nausea-Medium, Systemic: Seizure-Medium

<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>
1100509	3/15/2021	GA	77	F	2/24/2021	2/27/2021	Seizure; Could not move nor speak; Could not move nor speak; Chills; This is a spontaneous report from a contactable consumer (patient). A 77-year-old female patient received bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 24Feb2021 at 10:00, at single dose, for COVID-19 immunisation. Medical history included mitral valve prolapse and ongoing food allergy (to cantaloupe). Patient did not have COVID-19 prior to vaccination. Concomitant medications included vitamin b complex (B COMPLEX) and calcium carbonate, colecalciferol (CALCIUM + D3). Patient did not receive other vaccine in four weeks. The patient experienced seizure (medically significant) on 27Feb2021 at 02:00 AM with outcome of recovered in 2021, could not move nor speak (non-serious) on 27Feb2021 at 02:00 AM with outcome of recovered in 2021, could not move nor speak (non-serious) on 27Feb2021 at 02:00 AM with outcome of recovered in 2021, chills (non-serious) on 27Feb2021 with outcome of recovered in 2021. No therapeutic measures were administered as a result of the events. Clinical course: the patient reported that she had been having chills for several hours. During the night while sleeping, she believe she had a seizure. She was awakened with her body quivering from head to toe. She had no pain. She was aware of what was happening. She could not move nor speak. The event did not last very long and, when the quivering ceased, she no longer had chills. Patient did not test for COVID-19 post vaccination. The information on the lot/batch number 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>
1100422	3/15/2021	ND	64	F	2/11/2021	2/11/2021	angioedema; Face & tongue tingling; Face & tongue tingling; Itching all over; rash on limbs & chest; swollen lymph nodes; This is a spontaneous report from a contactable nurse (patient). A 64-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN9581), via an unspecified route of administration on 11Feb2021 11:15 (at the age of 64-year-old) at single dose in right arm for covid-19 immunisation. The patient other medical history included seizure disorder, hypertension, obesity, IBS (Irritable bowel syndrome), chronic rhinitis, atrial fibrillation. The patient had known allergies. No other vaccine in four weeks. The patient had received other medications in two weeks. The patient experienced face & tongue tingling. Itching all over, angioedema, rash on limbs & chest, swollen lymph nodes on 11Feb2021 12:00 PM. The patient received the treatment of events included diphenhydramine (BENADRYL). The outcome of the events was recovering.; Sender's Comments: The causal association between the reported event angioedema 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 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.
1102200	3/15/2021		55	F	3/14/2021	3/14/2021	tonic-clonic seizure Patient has a history of seizure disorders, dissociative convulsions, and head trauma.

<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>
1102494	3/15/2021		53	F	3/15/2021	3/15/2021	Patient received 1st dose of Moderna vaccine on 3.15.2021. Approximately 3 minutes after receiving the vaccine, the patient had what appeared to be an epileptic seizure. Patient lowered to the ground with a pillow, provider called, nursing and pharmacy present. O2 sat 99%, pulse 73, and BP 116/42. Patient continued to have seizure, EMS called. Ambulance arrived shortly thereafter, BP 146/58, sats 99%, and pulse 72. Patient quit having epileptic activity at this point. Patient does have a history of non-epileptic seizures from stress, bright flashing lights, etc. Patient assisted to wheelchair and taken to private room with staff. Patient discharged from clinic at 1200, refused transfer via EMS, given warning precautions for when to seek emergency care.
1100607	3/14/2021	NV	55	M	3/12/2021	3/13/2021	Seizure
1099456	3/14/2021	MN	43	F	1/13/2021	1/13/2021	Violent chills (similar to that of a grand mal seizure); fever of 103; severe headache; dizziness; nausea; body aches; fatigue. Lasted 3 days and then just fatigue lingered for an additional 2 days but I was functional to be able to work.
1099356	3/14/2021	WA	22	F	3/14/2021	3/14/2021	Patient had a very short seizure lasting a few seconds. Then was aroused and didn't have a postictal phase. Her skin color was pale, blood pressure was low at 106/70 sitting, and heart rate was slow at 60. She was evaluated by fire department paramedics and transported to ED.
1099337	3/14/2021	MN	42	M	3/14/2021	3/14/2021	Brief seizure, patient came to consciousness within 30 seconds and was coherent and denied ambulance or any further care. Sat in chair for 30 minutes and said he was fine and apologized for event as he said he had seizures before but did not volunteer the information before shot.
1099042	3/14/2021		95	F	2/15/2021	2/20/2021	5 days after injection, had sudden onset of severe back pain, tingling and burning in hands and down legs into feet. Jerking extremities and seizure like activity. Facility staff called for ambulance to transport to ER. No treatment, observed overnight, prescription for Tramadol. Transferred back to facility. Extreme fatigue. Pain manageable with Tramadol. 4 weeks later: extreme fatigue continues.

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1098994	3/14/2021	NC	67	F	3/11/2021	3/12/2021	Seizure and passed out.
1098681	3/14/2021	PA	23	F	3/14/2021	3/14/2021	1305 - pt. found in post vaccination waiting area pale, diaphoretic, and slightly slumped over. RN notified. RN arrived at pt's. side to find her pale and unfocused, staring with pupils slightly dilated. No LOC per medic in waiting area. medic described " 2 minutes of pt. with petite mal seizure activity". RN did not observe any tonic seizure activity but pt. very slow to focus and answer questions. 911 notified and pt. placed in wheelchair and moved to Tx. area. Placed supine, BP 116 palp, HR 100, RR - 28. O2 started @ 6L by NC. 1310- Med Hx reveals pt. stopped oral Cymbalta 3/5/21. 1312 - Pt. more alert , focused and able to answer questions appropriately. 1315 - medics arrived and care transferred. BP - 138 palp Glucose - 95. 1320 - pt. remains stable and able to notify family by phone. 1325 - Pt. transported to Hospital by ambulance in stable condition.
1098642	3/14/2021		28	F	3/14/2021	3/14/2021	dizzy, feeling numb, convulsions per spouse. Evaluated by EMS-Refusal to transport.
1098383	3/14/2021		65	F	3/14/2021	3/14/2021	Headache after vaccine; denied vision changes, trouble breathing, no lightheadedness. Reports headache 3 hours after first vaccine; reported to MD "if severe, seek medical care". Will be following up with MD tomorrow (as is Sunday); Neurologist (seizures, hx stroke) on Wednesday. HA same as when started 8/10; VSS; BP 132/80. Last time, took tylenol for headache; rested in "dark room" (gets migraines). Has BP cuff at home, pulse ox. Will f/u if symptoms worsen.
1098194	3/14/2021	NC	58	F	3/14/2021	3/14/2021	Patient felt flushed feeling which is sometimes a trigger for seizure. Patient observed for 15 mins, no seizure activity or other sx noted.
1098146	3/14/2021	TX	38	F	3/13/2021	3/13/2021	Nauseous, passed put, experienced a seizure
1098752	3/14/2021	NH	68	F	3/2/2021	3/5/2021	3/2/2021 go vaccine - 3/5/2021 had visual issue, bright spinning colorful lights, dizzy. 3/12 had grand mal seizure after same issue. taken away in ambulance. 1st time in my life having a seizure.

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1097433	3/13/2021	CA	57	F	3/8/2021	3/12/2021	I started feeling weird after dinner. I passed out or had a seizure. And then went to the hospital. When I arrived I could barely move my body at all. I had to be undressed by nurses and picked up to get in bed. After three hours I was able to move again and went home.
1097768	3/13/2021	TX	49	M	3/11/2021	3/11/2021	Started feeling really strange, started shaking uncontrollably to the point of almost having seizures , had a high fever from 100-103.6 after receiving vaccine , had severe headache and nausea , started having a cough reflex like throat was swelling . Insides were shaking so bad and couldn?t get it to stop . Went on like this for Thursday night , all day Friday , then Saturday so far . Shaking is better but still having headaches and fever and feeling like something just isn?t right in body .
1096741	3/13/2021	MN	50	M	3/13/2021	3/13/2021	Had seizure in car when leaving the facility, about 1/2 hour after the vaccination.
1096843	3/13/2021	PA	44	M	3/9/2021	3/9/2021	numbness/tingling in left arm after 1 hour, then similar feeling in right arm; then pressure in head after a 2 hours; seizure after 3 hours; I have not had a seizure for 6 years after being treated for it with Keppra starting in 2015
1096897	3/13/2021	MI	46	F	3/12/2021	3/13/2021	vasovagal syncope(faint) at 3 am. that triggered a small seizure (eyes open, arm suspended in bent position mid-air, lasted around 30 seconds). Extreme headache followed for hours after.
1096983	3/13/2021	NC	73	F	3/6/2021	3/8/2021	Nausea, Sudden vomiting, extremely low blood pressure, and then started having a seizure... no previous seizures or seizure disorders.
1097028	3/13/2021		27	F	3/12/2021	3/12/2021	she recieved shot without reaction. she stood up and moved over the waiting area to sit for 15 mintues. after 3 to 4 minutes of talking with her mother (mom left to go get water from front of store). she said out loud "I think I'm going to faint." I rushe out of the pharmacy to help. Her eyes rolled back and she fainted, the she convulsed for 5 top 10 seconds. she woke up 30 seconds later (mom returned by this time). 9-1-1 was called and ambulance came to check vitals and she left on her own accord.

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1097085	3/13/2021	TN	37	M	3/12/2021	3/12/2021	Patient had dark circles under their eyes and did discuss at the drop off window they had a needle phobia. Immediately after the immunization, he said he felt lightheaded. I, pharmacist, sat in the booth and talked to him for a couple minutes then asked if he felt he could finish his observation outside the booth. I notified technician to hand him off to her for observation, sharing by observation that the patient did not look well but he said he was doing a little better. He said he felt better and he did wait in the chairs outside the immunization booth. While I was in the pharmacy discussing this information with my pharmacy technician when I heard yelling and I stepped back out of the pharmacy to observe the patient was sliding out of his chair, stiff straight. My other technician came to my assistance and we both tried to get him to the floor and he was making incoherent noises and his arm was bent behind him and not relaxing to where we could get him to the floor. He then came to and startled a bit, with a bewildered look on his face. He asked what happened and said he felt he was dreaming. A witness waiting on her prescriptions for pickup said that it originally appeared he was having a seizure which was my concern as well. We called code white and 911 and store manager assisted us at the scene. Patient denied the ambulance.
1097095	3/13/2021	MO	28	F	3/10/2021	3/11/2021	Felt absolutely fine after 2nd injection. 10:30AM the next day I started like I had the flu and felt extremely ill out of nowhere. 10:35 am I passed out sitting down at work. I woke up and immediately passed out again. My coworkers said I shook like I was having a seizure as I went down both times. Ems was called and checked vitals. Everything was perfect. Ems wanted me to go to hospital but I refused due to cost
1097713	3/13/2021		26	M	2/26/2021	3/6/2021	2 generalized Tonic Clonic seizures, 6 absence seizure
1097392	3/13/2021	TX	38	M	2/10/2021	3/11/2021	Fainting, possible seizure, unconsciousness, severe chills, nausea, aches/flu like symptoms

<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>
1097534	3/13/2021	TN	22	M	2/3/2021	2/16/2021	had a generalized seizure that lasted about two minutes on February 16th. This was preceded by 5-10 minutes of intense shivering. has a pre-existing seizure disorder, but the shivering was not typical. In addition, he had another generalized seizure on March 11th. In 2019 and 2020, averaged three seizures per year.
1096709	3/13/2021		17	F	3/11/2021	3/12/2021	Fever of 103 F, received Tylenol, then developed tonic-clonic seizure activity for about 20 minutes (received 10mg intranasal midazolam and 0.5mg buccal clonazepam while awaiting EMS)
1097830	3/13/2021	TX	59	F	3/11/2021	3/11/2021	Heart palpitations, shortness of breath, nausea , later extreme tiredness, but could not sleep heart too fast, muscle spasms, jaw pain lack of feeling in arms and legs, @ 10pm I had a seizure in bed w husband, next day feeling exhausted, today still feeling pre seizure
1096664	3/13/2021	AL	57	M	2/25/2021	2/26/2021	I experienced a seizure the next day...broke my foot during seizure
1097192	3/13/2021	AZ	66	F	3/12/2021	3/13/2021	Grand mal seizure. 1st one in 15 years.
1096568	3/13/2021	IN	66	F	3/11/2021	3/11/2021	.Idont know if this is related to the vaccine, but my epileptic seizures increased.. they consist of an aura of smell, taste, and aura , followed by an intense feeling of fear running up and down my body, with tingling. I has three episodes the evening of the vaccine, three the next evening and one during the day. I have not had this in months. My medication controls the.
1096386	3/13/2021	PA	67	F	3/11/2021	3/12/2021	Severe chills (temp was 97.3), uncontrollable shaking (shivering, muscle seizures). I wrapped up in a blanket, made some hot chocolate, sat in a chair to wait it out. Symptoms lasted 45 minutes. After the symptoms improved, I had weak/achy muscles. Even the soles of my feet were achy. A headache followed, so I took 2 aspirin.

<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>
1096311	3/13/2021	SC	27	F	3/12/2021	3/12/2021	Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Additional Details: Patient became rigid, unresponsive, fixed eyes, dilated pupils, shaking (seizure-like movements), when patient was moved to floor, she became alert and oriented. Dizziness, shakiness, body slower to respond than normal...took some time to get back to normal. EMS called for monitoring and support.
1096716	3/13/2021	FL	67	M	3/11/2021	3/11/2021	Seven non epilepsy nocturnal seizures beginning 12 hours after injection and continuing for 18 hours.
1093826	3/12/2021	TX	76	M	3/11/2021	3/11/2021	3 - 4 hours after dose (Dose approx 1030 am reaction 2-230 pm) Light headed then dizzy blood pressure dropped to As low as 85 over 48 then appeared to have a small seizure and passed out. He recovered before ambulance arrived and blood pressure returned to 112 over 68. Then higher when EMT took it after arrival. Today (1day later) he has a bit of a sore neck and is still a little tired. Blood pressure 133 over 70 which is slightly higher than is normal.
1094432	3/12/2021		61	F	3/6/2021	3/6/2021	Patient, reported to EMT #1 tingling in hands and nausea at 0949. EMT #1 reported. At 0950, PHN began to assess patient. Patient started seizing at 0950. Patient observed breathing with minimal shaking and no jerking movements. Patient's family member supported patient in chair and stated she has a history of seizures, takes unknown medication for seizures, and did not have a seizure immediately following the 1st dose of Moderna. Seizure ended at 0953. Patient observed breathing, speaking, and appeared sleepy. Patient advised to wait for further observation. Patient offered 911. Patient declined 911. Patient vitals taken at 0956 by EMT. Blood pressure 100/60 mmHG and pulse 76 beats per minute. Patient and patient's family member reported to PHN wanting to leave facility. Patient offered 911. Patient refused. Patient left facility with family member at 1015 with unlabored breathing. Patient escorted by family member, 2 EMTs and PHN.

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1095026	3/12/2021		61	F	3/12/2021	3/12/2021	patient bring observed for 30 minutes post vaccine. hx of seizures and has service dog hx of anaphylaxis to bee stings and antibiotics. uses epi pen ,not available with patient 10 minutes post vaccine sudden onset cough and c/o itching throat, followed by wheezing nurse stat called. patient stated feels like passing out, within 1 minute started having seizures. was conscious but not responding patient lowered to floor stat team present eejrosepatient lifted to stretched, 100% NRB applied. patient taken to ER. patient conscious and responding
1094404	3/12/2021	KY	19	F	3/11/2021	3/11/2021	The day of the vaccine, Pt had a weird feeling and sat down. She did some breathing exercises but she started breathing faster, leaned over & fell & hit her head slightly. She started jerking for about a minute but she used her magnet and it started to bring her out of it. The very next day, she had 2 more seizures, within a 30 min period, & similar episodes.
1094342	3/12/2021	CO	78	M	2/28/2021	3/11/2021	Seizure
1094138	3/12/2021	MA	82	M	3/10/2021	3/11/2021	D= decedent D received the second dose of the COVID vaccine on 3/10/21 @ 10:45AM. His daughter, *****, transported him to the Pharmacy appointment. She notes that D did not have any complaints before or after the appointment?specifically she denies observing any weakness, dizziness, cough, and fever. D went on to have an uneventful day with normal appetite and bedtime. ***** also mentions that there were no adverse reactions following the first dose either. The next morning (3/11/21) at 6am the decedent?s wife found him in bed ?looking around the room? with gurgling agonal breathing. No seizure activity reported.
1093857	3/12/2021	MS	74	M	2/10/2021	2/12/2021	According to the patient's wife, the patient had flu like symptoms 2/11/2021. Complaints: Thirsty, sweaty and seizure with no prior history. Died at home. Not sent to hospital. Pronounced by coroner

<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>
1094881	3/12/2021	NC	33	M	3/12/2021	3/12/2021	33 yo M with NKA, history of fainting in the past and anxiety about vaccines and needles was in the drive through clinic to receive COVID-19 Janssen vaccine on 3/12. After receiving the vaccine at 0943 (lot # 1802070) in right deltoid, the patient began to feel anxious. He had been or was watching EMS working with another patient who had experienced an ADR. He began to feel "floaty" and noted he was blinking uncontrollably. He reported some tunnel vision/blurred vision. He states he recalled a nurse rubbing on his chest and placing a cold pack on his neck and at this point he began to feel better. He states he was trying to "fight" the feeling and was tensing up his extremities but denied convulsions or any loss
1093698	3/12/2021	LA	64	F	2/25/2021	2/25/2021	Seizure like activity within minutes after vaccine; pt does have history of seizure disorder as well as some non-epileptic spells
1095025	3/12/2021		65	U	1/26/2021	2/19/2021	shortness of breath 3 days after 2nd dose injected. admitted on 2/19 shortness of breath admitted on 2/26 shortness of breath admitted on 3/2 cardiac arrest, neck mass, seizure like activity, acute respiratory failure died on 3/06/2021
1093537	3/12/2021	CA	26	F	3/11/2021	3/11/2021	Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Systemic: Seizure-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Systemic: Vomiting-Mild, Additional Details: Within 10mins of vaccine, pt seem to have a mild seizure for less than 30sec. Pt had no hx of seizures, on no current medication. Pt recovered, and within 1-2mins she passed out. She was warm. She woke up within 1min, then started to vomit. Called emergency services. She felt better after throwing up. When ambulance arrived, she started to have tingling sensation on her finger tips. States she felt better. EMT advised her to go to the ER. Pt decided to go to ER to get checked up. Let with ambulance.
1093971	3/12/2021	WV	65	F	3/6/2021	3/6/2021	Ten minutes after shot I went into a seizure, was taken to hospital admitted over night for observation.

<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>
1094496	3/12/2021	GA	67	F	3/3/2021	3/5/2021	Severe hyponatremia, seizure, vomiting. Required hospitalization, 3% hypertonic saline, consultation with neurology and nephrology. Initial sodium level 114 at discharge sodium was 136. She recovered and is well now.
1094851	3/12/2021	MA	53	M	3/9/2021	3/10/2021	The morning after he received his vaccine he started feeling sick and then started to run a temperature. By evening his temperature was 102.9. Then the seizures started, first his "left" hand up his arm and down his left side. His right hand and arm was shaking rapidly. His left leg stiffened and his toes pointed down and then the seizure traveled to his right side. He remained conscious but somewhat dazed. This went on all night. By 10:00 the next day, Thursday the seizures stopped. His temperature went back to normal Friday morning.
1095334	3/12/2021	TX	48	F	3/12/2021	3/12/2021	She has history of seizures and was given the vaccine and then had a seizure. She was transferred to local ER for further evaluation. She was given Ativan and has been discharged.
1094917	3/12/2021	IL	55	M	3/8/2021	3/9/2021	Patient states they received Vaccine on Monday, became confused at work on Tuesday and then presented to ED after multiple seizures overnight Wednesday and then was having trouble ambulating. also complains of left elbow pain
1094972	3/12/2021	UT	77	F	2/11/2021		A few weeks after receiving the vaccination she felt confused, was going to drive. Ended up having a seizure she said and was taken to Hospital and then to another Hospital. Stated was there for 3 days.
1095568	3/12/2021	NY	25	F	3/11/2021	3/11/2021	I had a seizure about twelve hours after I received my vaccine. I was conscious for it and it involved both my legs and feet.
1095606	3/12/2021	OR	82	M	3/10/2021	3/10/2021	Seizure followed by Acute encephalopathy a few hours after receiving 2nd dose of Pfizer COVID-19 vaccine. COPVID-19 PCR testing positive on admission. Ongoing encephalopathy and patient made Comfort care. EEG showed no overt seizures.

<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>
1095624	3/12/2021	NV	64	M	3/12/2021	3/12/2021	Client had clonic/tonic seizures x2 within one minute of receiving the COVID-19 vaccine, first dose. Within 3-4 minutes of the seizure activity, client was awake, alert, oriented x3. Client was placed on a stretcher by paramedics and transferred via a stretcher to the observation area. Client remained awake, alert, oriented x3. No incontinence noted. Client was transferred to the hospital by the paramedics to the hospital within 10-15 minutes after seizure activity. No other family members were present with client.
1095719	3/12/2021	MT	42	F	3/12/2021	3/12/2021	Seizure
1095835	3/12/2021	WA	65	M	3/5/2021	3/5/2021	Pt had such severe chills the day after vaccine, that he was shivering uncontrollably, seizure-like.
1095965	3/12/2021	UT	50	M	3/4/2021	3/5/2021	Has not had a SZR since april of last year. He was not feeling well after vaccine, (body aches, subjective fever, tiredness) and wife found him having a seizure while lying in bed.
1096097	3/12/2021	IL	66	F	2/24/2021	3/4/2021	Had a Seizure and was transported to hospital by Ambulance, was admitted and kept overnite to run test. Shaking and Unreponsive.

<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>
1094571	3/12/2021	RI	64	F	3/9/2021	3/12/2021	64 yo female with hx bipolar disorder on multiple psych meds, Htn, here for same day visit. Pt reports got her second covid vaccine on 3/9/2021 in the left arm, Pfizer. Yesterday (3/10/21) woke up with severe right knee pain, felt like she could not bear weight/ws going to fall. She went to son's apartment who is in same building and then went to lie down in bedroom. Because she drinks a lot of water, she had to get up to go to bathroom to urinate. She was about to sit down on toilet, when she felt both her legs go numb as well as her arms and her vision was blurred. She tried to grab the tub but fell forward on the floor. She states she urinated on the floor. She was on the floor for about 30 mins until her son got her up and back to bed. Later in the day she needed to urinate again and when she got up, she felt unsteady and fell on the bureau bruising the left arm. Since she feels a bit unsteady with gait and used a walker to come hre today. She denies feeling dizzy before her falls. She denies striking her head. She denies convulsions or hx of seizure disorder. She reports no new meds, only recent change an increase in her alprazolam dose. She does report a headache day after her vaccine.'She denies vomiting or diarrhea or antecedent illness. No longer has headache. She denies positional changes Of note she is on propranolol (prescribed by psych) as well as lisinopril-hydrochlorothiazide for HTN 64 yo female with bipolar disorder on multiple psych meds, htn on propranolol 20 mg bid and lisinopril-hydrochlorothiazide, s/p recent Pfizer covid vaccine, s/p presyncope episode after experiencing severe right knee pain and attempted micturition. Pt felt like her sight was affected and experienced numbness/weakness in legs and arms causing a fall. Did not hit head. The history is most suggestive of a vagovagal episode.
1092435	3/11/2021	CO	26	F	3/11/2021	3/11/2021	Experienced sudden simple onset focal seizure as soon as vaccine was injected into muscle. This was not because of the needle prick but happened afterwards.

<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>
1092857	3/11/2021	FL	76	M	2/10/2021	3/1/2021	Patient was admitted to the Neuro ICU in critical condition. He is there currently on 4 seizure medications AND INTUBATED WITH GENERAL ANESTHESIA TO CONTROL THE SEIZURES. All diagnostic tests including MRI's, CT scans, laboratory tests, Spinal taps are negative. He was presented and they can arrive at no diagnosis!!!! He has no history of a seizure disorder.
1092810	3/11/2021	MN	34	F	1/6/2021	1/25/2021	Seizures starting 1/25/21, transverse myelitis diagnosed 3/1/21 with symptoms of transverse myelitis starting 2/5/21. Now with diagnosis of multiple sclerosis but with atypical initial presentation
1092749	3/11/2021	NE	31	M	2/25/2021	2/25/2021	Patient fell backwards out of chair 3min after administration (later noted was lightheaded right before collapse). Unresponsive, seizure-like behavior initially. EMS administered epinephrine 0.3mg autoinjector into left thigh. By 3:15pm (5min after collapse, 8min after vaccine administration), patient was responsive. Patient eating snack bar by 3:34pm. Patient notes he has exhibited this behavior before with other vaccines and worksite wellness blood draws. Clinic nurse noted patient did not collapse until watching neighbor coworker receive vaccine. Co-workers noted this is a behavior they have witnessed him exhibiting before. Patient called and requested boost dose scheduling the following week; recommended he receive it in a healthcare setting and coordinated local hospital distribution for an appointment.
1092747	3/11/2021	WI	20	F	3/11/2021	3/11/2021	Student received vaccine at approx 4p. At approx 410pm she c/o light headedness. Placed in wheel chair, brought over to cot, drank 2 juice boxes and felt better. No loss of consciousness. Neuro intact, no seizure activity. Denied pain. No facial swelling, rash, difficulty breathing. All extremities with normal movement. Vitals: 4:12 - BP: 103/58, HR 44 (she is a cross country runner), spo2: 99%. Blood glucose: 97 mg/dl. Felt completely back to normal ~425p. Cleared by myself and EMS to go home.

<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>
1092709	3/11/2021	OH	53	F	3/11/2021	3/11/2021	Patient c/o light headedness, diaphoresis, and sweating shortly after receiving vaccine. Symptom onset ~1145a, vaccine time ~1140am. She was incontinent of urine. No loss of consciousness. Neuro intact entire time - no seizure activity. No facial swelling, difficulty breathing, rash. No chest pain. She did complain of left trapezius pain. All extremities with normal movement. Patient was laid flat on cot - no injury sustained. 15L O2 NRB placed. Vitals: 1150: 116/50, HR: 51, Spo2 99%, 1155: 115/65, HR 62, 97%. Blood glucose: 110 mg/dl. ECG SR. Patient did feel better once laying flat. 911 was called at symptom onset. EMS arrived at 12:05p. Reports provided. Patient transported to Hospital ER.
1092685	3/11/2021	NY	68	F	3/9/2021	3/10/2021	Symptoms started at 5:15 PM the next day, about 20 hours after vaccination - Vomiting - High heart rate - Suspected seizure (symptoms differed from the past instances) - Loss of coherence (intermittent for 2 hours) Ambulance brought her to hospital, where she was in ER and later admitted. She is still at hospital under observation at this time, with no discharge date set.
1092628	3/11/2021	NC	26	F	3/11/2021	3/11/2021	Pt. has a history of dizziness/nausea after vaccination. 15 minutes after this vaccination, she had a short 'seizure-like' episode accompanied with slight shortness of breath. Pt. was also very dizzy and nauseous. Sweating came shortly after. EMS was called immediately when first symptoms began. She was responsive the entire time and reported gradually feeling better after about 5-10 minutes. EMS did a prompt check-up and revealed no unusual findings.

<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>
1092582	3/11/2021			F	1/27/2021	2/16/2021	Received 1st dose of Moderna COVID-19 vaccine on 1/27/2021 (patient did receive 2nd dose on 2/24/2021). Patient vacations during winter and was scheduled to come back in April of 2020, however, due to pandemic travel restrictions was unable to return home until October of 2020. Patient was seen in ED on 2/2/21 for UTI. On 2/4/21 patient returned to ED with chief complaint of headache. ED note states patient was fine at previous visit but during this encounter she had an altered mental status. Patient is admitted due to encephalopathy secondary to focal status epilepticus, for which she is discharge with a new prescription for Keppra for seizures, and possible UTI. Test revealed high IgG for virus (IgG is present during prolonged infections, while IgM is present at infection start and little IgM was found). No seizure activity on EEG after initiation of anti-epileptic therapy with gradual improvement in mentation back to baseline. Etiology of seizure disorder unclear. This event followed a COVID-19 vaccine and another case of status epilepticus was seen for another patient who had just previously received the vaccine, prompting the suspicion this could be related to the vaccine.

<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>
1092565	3/11/2021			M	1/26/2021	2/16/2021	Received first dose of Moderna COVID-19 vaccine on 1/26/2021. Patient currently takes Humira for Crohn's Disease (this is a biologic agent that lowers immune response). Patient was started on prednisone 40mg on 1/30/2021 for GI flare. Patient's wife states that he began to have trouble walking and concentrating/focusing. Patient was admitted to the ED four days prior and found to have dehydration and prednisone was stopped completely on 2/13/2021 and patient discharged on 2/14/2021. Morning of 2/16/2021 patient's wife contacted PCP stating patient has gotten worse and can "hardly watch TV due to the stimulation" and wife is unable to get "one word" out of him. RN advised wife to take patient back to hospital for further testing and wife verbalized understanding. Patient presents to the ED on 2/16/2021 and is admitted due to acute encephalopathy. Hospital course was acute encephalopathy secondary to non-convulsive status epilepticus and patient was discharged on 2/24/2021 with new Keppra prescription for new seizure disorder. Etiology of seizures unclear, received Moderna COVID-19 vaccine on 1/26/2021 prior to onset of symptoms on 2/2/2021 but significance unknown. This event followed a COVID-19 vaccine and another case of non-convulsive status epilepticus was seen for another patient who had just previously received the vaccine, prompting the suspicion this could be related to the vaccine. Unknown if PCP aware of vaccine administration.

<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>
1092507	3/11/2021	MA	51	F	3/11/2021	3/11/2021	<p>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</p>

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

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

<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>
							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.
1090864	3/11/2021	OR	64	M	3/6/2021	3/6/2021	I had a Seizure lasting 6 to 7 minutes
1092450	3/11/2021			F	1/11/2021	1/11/2021	Security notified this writer SM was feeling "light headed" post 1st dose of Pfizer covid vaccine. SM seated in auditorium seating. Writer approached SM. SM stated she was light headed. Assessed SM, noted sweating, pale skin and dilated pupils. Patient then went unconscious for approximately 30-60 seconds with seizure like activity. Increased diaphoresis noted. Upon regaining consciousness patient declined any medical history including DM or seizures. Rapid was called, arrived within minutes. VSS were noted to be HR of 43, BP of 68/42. Legs were elevated in seating. When attempted to move SM to gurney SM went unconscious again. Fireman lifted to cart, elevated legs. No seizure activity noted with second unconscious event. SM placed on left side with legs elevated. Return of consciousness noted. Moved to alcove with Rapid team. IV placed, fluids started. Monitored vitals prior to transport to ED. SM's manager made aware and vocera returned to unit.

<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>
1090649	3/11/2021	WV	65	U	3/6/2021	3/6/2021	Pt received #1 moderna vaccine. Immediately after receiving vaccine she had a seizure. EMS took her to the hospital. Pt seizure medicine had been increased in December 2020 when she had her last seizure. Pt was observed in hospital for 24 hours with no seizure activity. Pt has appointment next with her neurologist.
1092402	3/11/2021	LA	16	M	3/10/2021	3/10/2021	Summary: Syncopal episodes x 2 16 yo patient received his Covid-19 vaccine and as he was going to sit down in observation, he leaned on his mom and passed out. His mother gently lowered him to the ground (@ 1804). Patient's mother stated he just passed out and that this was his first injection ever in his life. Patient was immediately assessed by multiple nurses. Patient did not fall or hit his head or injure any part of his body. Patient took less than 60 seconds to respond to verbal commands and comprehend what had happened. Patient's legs were immediately raised and vital signs were obtained. He was diaphoretic and pale but both were dissapating. Patient denied difficulty breathing, pain, discomfort. Patient was moved to a reclined chair. Patient and family at side (mother and father) agreed to be monitored. At 1828, Patient complained of feeling "a star" on the left side of his chest. Patient was unable to describe this further. I asked if he was feeling anxious and he said yes. I instructed patient to take several deep breaths in through his nose and out through his mouth. After doing this 3 times, patient stated he did not feel anything funny in his chest anymore. At 1835, while still seated in a reclined chair, patient passed out again. He was pale and diaphoretic. A few team members saw him jerk/twitch and it was questionable if he was having a seizure. The jerking did not last but a few seconds. 911 was called @ 1826. Patient was transferred to a wheelchair and put in the ambulance @ 1841. Vitals were obtained throughout and charted. Pulse ox saturation levels were not below 96%. Immediately after the patient passed out the second time, his pulse was measured at 38 bpm and his lips displayed slight cyanosis. His pulse quickly rose to 52 bpm, within less than 10 seconds. One minute later his pulse was up to 68 bpm.

<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>
1092279	3/11/2021	MD	26	M	3/10/2021	3/10/2021	About 30 minutes after dose he passed out and had a seizure that lasted 10 -15 seconds. This happened a couple times. He went to hospital had low blood pressure and oxygen. He stabilized and was released. He has a follow up appointment with his primary care doctor.
1092145	3/11/2021	CA	22	F	3/11/2021	3/11/2021	Pt feeling very warm and lightheaded with subsequent loss of consciousness with seizure like activity. After regaining consciousness patient agitated and diaphoretic, vomited.
1091957	3/11/2021	CO	77	M	1/19/2021	2/19/2021	I'm still not sure which COVID19 vaccine my dad received (It made me fill it out--I'm not sure if he got Moderna or Pfizer). Nursing home would know. He received his 2nd shot on Jan 19. On Feb 17 all was fine and they were planning on getting him crowns at the dentist. On Feb. 19 everything went poorly. He started to suddenly have seizures and was not responsive. When I arrived on Feb 21 he didn't say much and had seizures that night. On Feb 22, he responded a little bit and had a big black eye from a seizure the night before. On Feb 22 he had at least 4 seizures and he passed that afternoon around 1:20 pm
1091912	3/11/2021	IN	56	F	3/11/2021	3/11/2021	Pt was given the vaccine in her left arm. pt went unresponsive and began to have seizure like activity . Pt was in a chair and lowered to the floor with the assistance of the nurse on her right side. 911 was called. 02 at 2L was administered. pt then became responsive. EMTs arrived and transported pt to hospital.
1091869	3/11/2021	MN	33	M	2/27/2021	3/9/2021	First time seizure, normal MRI and EEG on workup

<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>
1090224	3/11/2021	OK	70	F	2/24/2021	2/24/2021	Muscle pain; Headache; Having issues breathing; could not swallow; Muscle tightness in right jaw, mouth, neck, shoulder; Muscle type convulsions in neck, shoulder, arms and upper chest; This is a spontaneous report from a contactable consumer reported for self. This 70-year-old female non-pregnant patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number unknown) via intramuscular on 24Feb2021 at 10:00 AM at single dose in left arm in a pharmacy or drug store for COVID-19 immunization. The patient's medical history included high blood pressure. The patient had known allergies: anabolic steroids, many antibiotics. The patient did not have COVID prior vaccination. The patient's concomitant medications included hydrochlorothiazide, triamterene (MAXZIDE) and vitamins. At 24Feb2021 at 10:00 PM, the patient experienced muscles in neck, jaws and throat started clinching up and she could not swallow. The patient began having issues breathing. The patient was advised to go to emergency room (ER). At ER, patient started with muscle type convulsions in neck, shoulder, arms and upper chest. The patient had several episodes. Doctor administered diphenhydramine hydrochloride (BENADRYL) intravenously, did blood and urine workup. After 4 hours the shaking stopped, and the muscle contractions lessened. The patient was sent home. Next day 25Feb2021, she still had some residual muscle tightness in right jaw, mouth, neck, shoulder. On third day 26Feb2021, she had light shaking of hands and arms. The patient was still taking 25 mg diphenhydramine hydrochloride every 8 hours. She added ibuprofen (ADVIL) because she also had muscle pain and headache. The patient was recovering from the events. The patient did not test COVID post vaccination. Information on lot/batch number has been requested.
1091533	3/11/2021	GA	53	F	3/10/2021	3/11/2021	Elevated Temperature Sudden onset of headache Seizure

<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>
1091214	3/11/2021	ND	27	M	3/10/2021	3/10/2021	Immediately after he said he was dizzy. I had him remove his mask and take some deep breaths. He did. I called for help from other nurses in the room. He had seizure activity and fell from the chair to the floor. In the process he hit his head on the table. He had his stocking hat on. The other nurses were there immediately. Talking to him, reassuring the mom, BP, pulse oximeter, ice pack, privacy curtains in place. He was offered food and drink. Other staff removed others from the room. The ambulance was called. And arrived. The ambulance assessed him. Education and instruction were given. They asked him to go to ER. He refused. They advised him to see his Doctor. The ambulance had him sign their needed paperwork. Helped him to his feet, he refused to use their cart provided. He said, I am fine. He was strongly encouraged to follow up with his Doctor. He walked out of the room with ambulance personal and his mom.
1090933	3/11/2021	IL	26	M	3/10/2021	3/11/2021	He began convulsing in his sleep, almost like a seizure except he woke up and became aware of what his body was doing. He could not control his body or limbs to move or stop the shaking. He did not have a fever at the time and could not determine whether or not he felt cold. The uncontrollable shaking was consistent for about ten minutes and then continued sporadically for an hour or so, though it became much more controllable. Hours later, he has more typical symptoms like a bad headache and a fever. The shaking has not come back.
1093002	3/11/2021	CA	37	M	3/5/2021	3/6/2021	Headache, chills, soreness night of vaccine In the morning, lightheadness when standing up resulting in blacking out, hitting head against wall, involuntary incontinence, excessive sweating, shaking, in and out of consciousness, looked like a seizure.
1090813	3/11/2021	MD	71	F	3/1/2021	3/3/2021	Convulsion like shaking but no chills, sweating, throat constriction, no tongue swelling

<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>
1087518	3/10/2021	NC	36	M	3/9/2021	3/9/2021	Patient fell from chair to floor hitting head and sustaining small laceration above left eye. He also experienced mild seizure activity that lasted approx 10 seconds. Patient quickly regained consciousness and was assisted to triage area. BP 140/86, HR 82, O2 sat 97%RA. EMT came and assessed client and cleared him to leave. Client ambulated out of facility without difficulty
1089695	3/10/2021	MA	36	M	3/9/2021	3/9/2021	Violent shaking and a 103 degree fever. The violent shaking made me think I was having a seizure. Nothing would stop the shaking. It stopped on its own between 2:30 and 3 am. The following day I felt like I was hit by a truck and had body aches.
1087665	3/10/2021	CO	51	M	3/7/2021	3/7/2021	3 hours post vaccine, patient passed out and lost consciousness, demonstrating seizure like activity
1086929	3/10/2021	TX	85	M		2/23/2021	Seizure; 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 developed seizure. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On an unknown date, the patient received their second of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 23 Feb 2021, two hours prior to the onset of the event seizure, the patient received their second of two planned doses of mRNA-1273 (Lot 030M20A) intramuscularly for prophylaxis of COVID-19 infection. On 23 Feb 2021, 2 hours post vaccination the patient developed medically significant event of seizure. Treatment for the event included lorazepam. Action taken with mRNA-1273 in response to the event was not applicable. The outcome of the event seizure was not reported.; Reporter's Comments: Very limited information regarding the 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>
1087562	3/10/2021	NC	47	F	3/5/2021	3/6/2021	Received vaccine at 825 am, low grade temp, chills, body aches, temp never over 100.4, at approximately 1:00am woke up to use restroom, felt lightheaded, nauseated. Passed out, hit head and had tonic-clonic seizure. No history of syncope or seizures. Transported to ER by EMS. given fluids, completed labwork and CT head, given concussion protocol. Discharged and arrived home by 5:00am.
1087595	3/10/2021	VA	60	F	3/10/2021	3/10/2021	Patient experienced a seizure lasting 2-3 minutes approximately 1-2 minutes after receiving the vaccine. patient has a history of seizures/epilepsy.
1089335	3/10/2021	MO	51	M	3/10/2021	3/10/2021	patient was sitting in our lobby following covid vaccination when he reported he felt a little dizzy and thought he may faint, (patient was nervous for the vaccine prior to administration), I sent someone to grab a ice pack and a bottle of water for him and while they were retrieving the ice pack he started to seize. Patient was breathing but unresponsive, stiff, and unable to blink, talk, or move for around 2-3 minutes. Once the seizure ended I asked patient if he had a history of seizures, his answer was, "not really". He drank some of the water and sat with the ice pack for a couple minutes and said he felt better. Color returned. Patient stated he felt nerves contributed more than anything and was feeling 100% better when he left. We had dialed 911 while patient was unresponsive but once he was able to talk again he declined 911 and stated feeling much better.
1089226	3/10/2021	IN	64	F	2/26/2021	2/28/2021	During a conversation, I was told I began smacking my lips then proceeded to completely ?zoneout? for 5-7 minutes. My arm was touched and I was asked a couple of questions to which I did not respond. After a few minutes, I became alert and continued conversation where I left off. I was unaware any of this was happening. I was pretty much wiped out for about 5 days. I have never had a seizure before.

<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>
1087769	3/10/2021	NJ	37	F	2/16/2021	2/17/2021	<p>Here is my story. Part 1: I had my second Moderna vaccine on 2/16. 36 hours later I was laying In bed when I all of a sudden felt very strange- sort of faint - like I was going to pass out. Then I started feeling like my Body was going numb. We called 911. I was taken to the ER. What followed was about 15-20 ?neurological? episodes (every ten minutes or so) where my entire body from head to toe became paralyzed- I couldn?t move any of my limbs. I also had no sight. I was not blacked out Bc I could hear everything that was happening. It was also accompanied by extreme chest pain, numbness, contracting of muscles in chest cavity that felt almost like a heart attack. Each individual episode lasted about 3-5 minutes and then slowly the paralysis would undo and I?d regain feeling. And then the full episodes would start over a few minutes later. This went on for a few hours repeatedly while in the ER. I was admitted for testing and monitoring for two days (EEG, EKG, MRI, Catscan) all clear. Once discharged I had lingering neurological symptoms but not the full paralysis episodes. Lingering symptoms included severe chest pain, numbness/weaknesses predominant on the left side as well as other random areas. I was very weak and tired. I started to improve very slowly - by day 10 post hospitalization I was starting to feel like things were turning the corner and maybe I was on my way to recovery. Part 2: I started to finally feel more improved from the lingering neurological issues and then all of a sudden around 5:30PM I was in the kitchen making dinner for my kids on 3/2 and the episodes started again. Called 911. Again, every ten minutes or so they came on (maybe 15-18 episodes) of complete paralysis- this time accompanied by seizure like rapid eye movement from side to side and fluttering of the eyes. I was readmitted to the hospital where the episodes repeated to happen again, maybe 15-20 times. I was admitted. They did a 24 hour video EEG which ?caught? the episodes on video and sound but did not appear negatively on the EEG in terms of abnormal brain activity. I?ve been released as they say there is nothing to do. I have lingering muscle weakness in my eyes- I can?t focus my eyeballs or ?track? on an eye exam and continued muscular chest pain. I also have a lot of PTSD from the trauma of the events.</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>
1088973	3/10/2021	NM	22	F	2/12/2021	3/1/2021	22 year old G2P0 at the time of vaccination. Delivery by cesarean at 40w6d. Female infant with apgars 7 at one minute and 9 at 5 minutes. Weight 7-14. Baby developed seizures on day of life #2. She was found to have a large ischemic injury in her brain.
1088806	3/10/2021	AZ	42	F	3/10/2021	3/10/2021	Patient was given the Janssen vaccine and within 3 minutes the pt complained that she was lightheaded and dizzy. As I walked out of the pharmacy to see what her reaction was her muscles tensed up and she became completely rigid and started sliding out of her chair. By appearances it looked like she was having a mild seizure, with a blank stare. By the time I got her down on the floor and got her coat off to see if there was an allergic reaction to the site the patient came too and asked me why she was in the floor. At that time she was clammy but knew who she was and where she was. Paramedics were called and while they were here she stated that she was dizzy and nauseous so they ended up taking her to a location hospital to be seen. While there they drew blood as a precaution.
1088368	3/10/2021	IN	61	F	3/10/2021	3/10/2021	Patient received vaccination at 12:10. At 12:25, patient complained of tongue thickness. EMS called. Difficulty breathing. Developed seizures. Epinephrine 0.3 administered. Seizures continued on/off for approximately 1234. Tongue swelling did improve. Transferred to hospital setting via EMS at 1245.
1088172	3/10/2021	ME	68	M	3/9/2021	3/9/2021	Patient began to feel short of breath then progressed to shaking and had a seizure. 10mg Versed was administered at the clinic. Once EMS arrived another 5mg of Versed was administered.
1087806	3/10/2021	OK	48	M	3/9/2021	3/9/2021	Within 30 minutes post vaccine administration, patient started having seizure like symptoms (Altered mental status, clenched jaw, non-verbal, right sided headache) - V/S WNL, Ambulance called and patient was taken to ED for evaluation. Responsive during transport to ED. Patient reported back to baseline after 1.5 hours.
1089144	3/10/2021	TX	18	M	3/10/2021	3/10/2021	seizure about 2 hours after event, per mother also with increase in salivation and groaning. Benadryl has helped, is being monitored

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1084212	3/9/2021	OH	23	M	2/23/2021	2/28/2021	First vaccine on 1/26/21 began taking three naps a day and arm pain. Given Ibuprofen. Seemed to resolve after 5 days, but continued to nap three times a day sometimes. No fever, but hot flashes at times. Booster given 2/23/21. Began to nap again three times a day or want to stay in his dark room. Began to have a lot of sinus drainage. Gagging at times. Pain over right eye area. Pain in right flank and stomach area. Severe headaches and possible body aches. No fever, but increased and more severe hot flashes that would wake him. 2/28 had a tonic clonic seizure after presenting with a distressed look throughout the day. Slept and upon waking began vomiting until 3am. Was at the ER and given many tests, pain meds and nausea meds. Ruled out kidney stones with CT scan and urinalysis. No fever, but hot flashing continued. ER visit lasted from 2/28/21 through 3/1/21 ER Physician suspects possible reaction to vaccine. Followed up with Neurologist and General Practitioner and both suspect reaction to vaccine.
1084517	3/9/2021	WA	50	M	3/5/2021	3/6/2021	Friday at 1:30 (3/5 my husband received the first shot. That evening he wasn't feeling well at all. Went to sleep in the morning on 3/6 he still was feeling horrible. Looked gray in color- thought he was getting the flu. At 2AM I woke to him having a seizure. Followed by another seizure at 10AM (3/7) followed by another seizure at 3PM (3/7) followed by another seizure at 3AM (3/8) and another seizure at 6:30 AM on (3/8).
1084709	3/9/2021	NY	71	M	3/6/2021	3/8/2021	atrial fibrillation, hypotension, syncope, possible seizure
1085017	3/9/2021	IL	74	M	3/8/2021	3/9/2021	Seizure
1085560	3/9/2021	CA	44	F	1/19/2021	1/22/2021	I had a visual aura seizure four days after the first vaccine. It started with minor stars/auras in the right side of my right eye and within about 5 minutes, half of my vision was gone. After resting and eating, my vision was restored and the aura stopped. A couple of weeks later I had episodes of minor facial drooping, which lasted for a few hours each.

<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>
1085684	3/9/2021	GA	72	M	3/5/2021	3/7/2021	Developed focal seizures a little less than 2 days later. Had not experienced any seizures since those initial seizures following surgery on 4/19/20. This was first instance. Nothing else in his life was new or different, and he had been on the 500 mg bid dose of levetiracetam for a couple of months, having gradually reduced from 1000 mg bid.
1085765	3/9/2021	NY	68	F	3/5/2021	3/5/2021	Family reported patient had COVID vaccine around 10am. Pt came home at 11am, and was extremely lethargic. They helped her get undressed and in bed, but then patient became very rigid and flailed her arms as if she was having a seizure, only lasted about a minute, she was very lethargic after barely arousable, then again became very lethargic and arms flailed for about one minute. Pt then projectile vomited. Advised calling 911 and patient was taken and admitted into hospital.
1086511	3/9/2021	MD	29	M	3/9/2021	3/9/2021	vasovagal syncope or seizure? After receiving the drive-through vaccine, we drove into a parking space to sit and make sure I was ok. Within 5-10 minutes, I was sitting in the car and sending a text and with no warning whatsoever mid-text lost consciousness, profuse sweating, wheezing, lost color in my skin, was making unintelligible noises, and eventually woke up about a minute later but couldn't speak or comprehend those speaking to me (according to my wife who was terrified). I was not nervous, stressed, or scared of receiving a vaccine. I regained the ability to speak about a minute later and my wife had summoned the staff on the scene who instructed me to lie back and breathe without a mask. I drank some liquids. A nurse was called over and offered to take my vital signs but I decided I felt ok enough not to. Eventually my normal skin color and came back and sweating stopped after about 5 minutes. We sat for a few extra minutes and once I felt it was past me, my wife drove us home.
1086344	3/9/2021	WA	60	F	3/9/2021	3/9/2021	Pt reported have a feeling similar to how she feels prior to a seizure, although she did not progress into a seizure. In addition to an aura, she felt sluggish and felt like she was not thinking clearly. The feeling began "shortly after" her vaccination and has not completely gone away as of several hours later.

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1086454	3/9/2021	PA	31	F	3/8/2021	3/8/2021	Body aches 7pm-10 am chills 7pm-10am body convulsions 9pm-8am vomiting 9pm-3pm headache 9 pm-present (currently 10 pm next day) Treatment- Tylenol, Motrin, fluids, ice pack for head
1083724	3/9/2021		31	F	2/18/2021	2/25/2021	Really bad seizure; A spontaneous report was received from a physician concerning a 31 year old female patient who received Moderna's Covid 19 vaccine(mRNA1273) who developed unusual seizure. The patient's medical history as provided by the reporter included 215Q- 2 copies of a piece of chromosome 15 and the patient was on medications for seizure, sleep disorder and urinary incontinence. Products known to have been used by the patient, within two weeks prior to the event, included daprica, Trazodone, Oxybutynin and Carnitine. On 18-FEB-2021 approximately eight days prior to the onset of symptoms the patient received first of two planned dose of mRNA-1273 (Batch Number 024M20A) for prophylaxis of Covid 19 infection. On25 - FEB-2021 patient had a really bad seizures without the usual triggers. The pulse rate of patient was 89 and came back up.The event was considered as medically significant. The treatment for the event include Valium 5mg. Action taken with mRNA-1273 in response to the event was not provided/unknown. The outcome of the event really bad seizure was 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 event, a causal relationship cannot be excluded.
1086303	3/9/2021	IN	77	F	3/6/2021	3/7/2021	High fever of 102, dizziness, headache, pain in left side of jaw, neck , chest. Nausea, weakness, seizure.,(Never seized before) left eye burning high blood pressure. Symptoms started in bed while asleep 12 hrs after 2 nd vaccine

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1083726	3/9/2021	SD	70	F	2/25/2021	2/25/2021	Loss of consciousness; Could not think straight; Difficulty walking; Having difficulty speaking; Fast heart beat; Dizziness; Gums began tingling; Gums itching; A spontaneous report was received from a consumer concerning a 70-year-old, female patient who received Moderna 's COVID-19 vaccine (mRNA-1273) and experienced events Loss of consciousness, difficulty in walking (difficulty walking), Mental Impairment(couldn't think straight), Dysarthria(difficulty speaking), Tachycardia(fast heart beat), Dizziness, Paraesthesia oral (gum tingling) and Gingival pruritic(gum itching). The patient's medical history was reported as seizure disorder, diabetic, and allergies. Concomitant medications known to have been used by the patient, within two weeks prior to the event included amlodipine, Aspirin, Benadryl, azosemide, fara sulfate, levothyroxine, losartan, magnesium oxide, metformin, meloxicam, Minoxidil, montelukast , omeprazole, potassium chloride er, primidone, propranolol, rosuvastatin, stool softener, Tylenol extra strength, vitamin D3, voltaren topical gel and tramadol On 25 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: 010A21A) intramuscularly for prophylaxis of COVID-19 infection. On 25 Feb 2021, the patient experienced the difficulty walking, couldn't think straight, difficulty speaking, fast heartbeat, dizziness, loss of consciousness, gum tingling and gum itching. Laboratory details were not provided. Treatment details was given as Tylenol and Ativan. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the event Loss of consciousness was reported as resolved. The outcome of the event, Gait inability, Mental Impairment, Dysarthria, Tachycardia, Dizziness, Paraesthesia and Gingival pruritis 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 these events, a causal relationship cannot be excluded.
1083848	3/9/2021	MI	77	F	2/4/2021	2/6/2021	Beginning 2-4(injection date) dull headache on top of head 2-6 vertigo began(room spinning), followed by sinking feeling in head, followed by spasms in center of head felt like seizures. 2-19 hospitalized for CT Scan of Head 2-23 EEG in Doctor Office

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1082260	3/8/2021	NH	57	F	3/6/2021	3/6/2021	Passed out within 10 minutes of getting the shot Went into a seizure An EpiPen was administered within a few minutes Transported to the hospital via ambulance and monitored at the hospital for about an hour after that.
1080336	3/8/2021			F			Borderline seizures; Fever of 104 F; A spontaneous report was received from a consumer (patient), a 67 years-old female patient, unknown race and ethnicity, who was administered Moderna's COVID-19 vaccine (mRNA-1273), and experienced borderline seizures (seizure) and fever of 104 F (pyrexia). The patient's medical history was not provided. Concomitant medication included tofacitinib citrate. On an unknown date, about a month ago, prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 (batch number: unknown), intramuscularly for the prophylaxis of COVID-19 infection. On an unknown date, the patient had a fever of 104 Fahrenheit (F) for 3 days and was very sick with "borderline" seizures. The patient's blood work showed C-reactive protein (CRP) was 31 (unknown units), and white blood cell (WBC) count was low. The patient's physician was very concerned. No treatment medications were reported. Action taken with the second dose of mRNA-1273 in response to the events was not reported. The outcome for the event, borderline seizures was considered as unknown, and that of fever of 104 F was considered as recovered.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.
1080592	3/8/2021	NY	26	F	3/5/2021	3/5/2021	Patient fainted 2 minutes after receiving the Pfizer vaccine and had 10 second witnessed seizure.
1080710	3/8/2021	TX	29	F	2/12/2021	3/4/2021	Syncope episode with convulsions Underwent cardiovascular and brain scanning and imaging Treated with Keppra x 3 days Determined to be a non-seizure event
1080754	3/8/2021	KS	23	F	2/19/2021	2/22/2021	Seizure cluster from 2/22/2021 to 2/28/2021- patient had significant increase in seizure frequency during these days.

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1080868	3/8/2021	DC	27	M	3/6/2021	3/7/2021	I got the shot at 5:30 pm. Starting early the next morning (around 3 or 4am), I began to experience intense fever and headache. I got up to get Advil and had a seizure. I have epilepsy, and had not missed a dose of my medication. My last seizure before this was 2 years ago. After recovering, taking Advil, taking a shower, and going back to sleep for about 4 more hours, I woke up feeling fine.
1080921	3/8/2021	TN	36	M	3/5/2021	3/5/2021	Patient received 2nd dose of Pfizer COVID vaccine approximately 1:00pm. Around 1:15 pm staff were alerted by patient's father that he was having a seizure in the car. Staff went to assess situation, no seizure activity was noted at that time. Patient was lying on his left side in the back of truck, vomit present on truck seat and in patient's nares. Patient has a history of epilepsy. Pulse ox was 78 and HR was 136, and there was concern for aspiration. Pt was placed on oxygen while waiting on ambulance. Oxygen sat improved up to 94% on 4L of oxygen, HR continued in 130s. He was stable when ambulance arrived approximately 15 minutes later, and he was transferred to the hospital.
1080978	3/8/2021	FL	93	F	2/28/2021	3/1/2021	Grand mal tonic-clonic seizure, pt put in bed on 2 l oxygen , postictal sleep x 2 days
1081182	3/8/2021	OH	64	F	2/15/2021	2/21/2021	On 2/15 At 9-10pm she noticed her entire body shaking as if she was having a seizure?. She states this lasted for about 10 seconds. No report of previous seizure disorder. No incontinence, shaking stopped. On Friday night feb 19th, she noted itching in her left eye, eye was swollen , almost shut and then the right eye also became swollen almost shut. Face was very puffy. She then placed cold compress an eyes and took Benadryl. Second dose was not administered today 03/08.

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1081519	3/8/2021	FL	67	M	3/3/2021	3/3/2021	Nothing at all for 14 hours...not even a sore arm. Around eleven that evening, severe headache; nausea; muscle aches arms & legs; and most serious two seizures (spasms??) about 5 seconds apart. I've only had a few muscle cramps in my life so the seizures were unusual to say the least. They started in my lower abdomen (seemed like a small band going full circle around my body) and moved incrementally up towards my shoulders. Rapid movement upward...kinda like squeezing a tube of toothpaste. Each one was only about two seconds long but fairly violent. If I had anything in stomach, it would have been on the floor. Everything was gone (except the sore shoulder) by five in the morning.
1081565	3/8/2021	GA	78	F	2/6/2021	2/6/2021	Chills day Feb 6, Sick feeling & worse tremors Feb 7-Mar 1, Multiple Seizures Feb `13, & F22. Extreme sporadic stuttering started Feb 20 and continues till today Mar mad 2nd shot March 1st. Had multiple seizures Mar 13 preceded by stuttering. Had 3 extreme whole body seizures Mar 7, Today Mar 8.
1081585	3/8/2021	CA	28	F	3/7/2021	3/7/2021	Systemic: Seizure-Medium
1082118	3/8/2021	CA	39	F	2/1/2021	2/1/2021	tremors, questionable seizure like activity

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1082478	3/8/2021	TX	49	F	3/8/2021	3/8/2021	Patient had been sitting in general observation area post vaccine when she began seizing and fell to the floor from chair. Seizure lasted approx 10-15 sec. Patient came to and was oriented x 3. Assisted patient by EMT x 2 to w/c and taken to private observation area. 1421 BP 174/92; HR 108; O2 97%. Patient hands shaking. Patient states she last had therapeutic drug levels done a month ago and her seizure meds were not adjusted. States she took all of her meds, but unable to recall all the names. States she left her list at home. States she did not have an aura prior to seizure, but knows she had a seizure. States she feels too hot in there and offered water. 1435 Refuses transport, refuses further treatment. States she has her friend here and her friend will drive her. Called friend and friend bringing car to exit area. Instructed patient to call physician that is managing her seizures to let them know that this occurred. Instructed to go to ED for further eval. Patient states she is going to go home and agrees to contacting PCP and seeking medical care if seizures persist. Took patient via w/c to awaiting car, assisted to car. Transportation provided in personal vehicle per friend driving.
1082494	3/8/2021	TN	68	F	3/4/2021	3/5/2021	Starting about 12 hours from shot I had excruciating muscle seizures. My entire body's muscle system was pulling and yanking for minutes at a time, as if I were on the rack. I was screaming in agony from the pain. When it stopped, it was only a few minutes before the next seizure. This went on for about 14 hours. Then it tapered off in severity and the time was extended between seizures. I was finally free after about 18 hours. I also experienced extreme fatigue for 5 days.
1082600	3/8/2021	NJ	78	M	3/5/2021	3/5/2021	Pfizer-BioNTech COVID- 19 Vaccine EUA: Vaccine recipient's wife reported that she notice he was slurring his speech and had some confusion prior to getting vaccinated. They contemplated seeking medical care but wanted to get the vaccinated first. After receiving the vaccine, the vaccine recipient was reported to have fell back in his chair and began seizing. EMS responded and treated the patient. They have no history of seizures. They were transported to emergency department at e Regional Medical Center. The patient was admitted to the intensive care unit for further work up and currently present.

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1082635	3/8/2021	NJ	57	M	3/7/2021	3/7/2021	Patient received his first Moderna covid vaccine shot at about 4:00pm on 3/7/2021 and proceedd to the post-vaccination observation area for his 15 minute observation period. About 10 minutes after his shot, patient alerted the an observation staff member that he was starting to feel hot. Staff member alert the pharmacist who had given him his shot and the pharmacist came over. Patient told the pharmacist he feels like he is burning up. Pharmacist took hi temperature an it in the 98 rang (can't remember the exact temp but was 98. something) Patient then then told the pharmacist that he feels like he is getting an aura of a coming seizure. The pharmacist applied an intant ice pack to the back of the patient neck and provided a bottle of cold water. Pharmacist stayed next to him talking to him and asking how he was doing and kept a hand on him in case he had a full blown seizure. Patient was awake but looked pale and seemed like he was going to fainted. Stayed like that for about 10 minutes. after about 10 minutes patient "came back". He looked back to normal and felt fine. During the process he called his wife to come get him and he was fine when she arounds a few minutes later. Patient, wife, and pharmacist chatted for about 15 minutes before wife took him home. Patient said based on his history that it was a petit mal seizure.
1082642	3/8/2021	NC	20	F	3/5/2021	3/5/2021	Syncope or seizure 10 hours after vaccine, preceded about about 1 hour of aches, chills, and feverish feeling. Resulted in fall to floor, hitting head and injuring shoulder. EMTs reported hypertension, tachycardia, trembling, some EKG abnormality, and low-grade fever. Transported to emergency room where CT scan, CBC, and additional labs and monitoring were performed. Released when scans and labs were normal (after monitoring.)
1082751	3/8/2021		63	F	3/8/2021	3/8/2021	Patient finished observation, then suffered a seizure and fall on the way out of the clinic. Paramedics were called and the patient was monitored and transferred to the hospital on site

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1082809	3/8/2021	TX	32	F	3/8/2021	3/8/2021	Client seated in observation. Client lost consciousness (passed out) and fell out of her chair. Client fell onto the floor on the left side hitting the side of her head (left temple area). Witness nearby reports the client had a seizure first prior to falling out of the chair. Seizure activity was not witnessed by the nurse. Client was assisted into a wheelchair and evaluated further in a private area by EMT. EMT was present. EMT assessed client and vitals were taken at 9:36 : O Sat 99%, Pulse 53, BP 112/56. Client was able to report that she felt flushed and hot. Client is visibly sweating. Client states that she felt like her heart was racing and that she was dizzy. Client reports that she has no history of seizures. Client was offered water. Nurse called for an ambulance (EMS) and spoke with dispatch. Client drove herself and has no one with her. The client's status given included details regarding client's vehicle. Client voiced concern about the cost of an ambulance but decides that she would like to be taken to hospital which is in network with her insurance. At 9:43 Client reports that she feels ?heat inside her head? and is feeling very dizzy. A 9:46 EMS arrives on site. At 9:49 Client was transported via stretcher.
1082967	3/8/2021	CA	18	M	2/15/2021	2/17/2021	Two days after receiving the vaccination, experienced two seizures about 2 hours apart; This is a spontaneous report from a contactable consumer(patient). A 18-year-old male patient received the first dose of BNT162B2 (lot number: E13249), via an unspecified route of administration in right arm, on 15Feb2021 11:00 AM at single dose for COVID-19 immunisation. Facility where the most recent COVID-19 vaccine was administered was Adult Residential Facility. The patient's medical history included developmentally disabled, seizures, malaria at birth. Known allergies included Shrimp, Penicillin and Amoxicillin. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient was not tested for COVID-19. Concomitant medications included aripiprazole 5 mg, aripiprazole 10 mg, escitalopram. Two days after receiving the vaccination, the patient experienced two seizures about 2 hours apart on 17Feb2021 14:00. The patient had not had a seizure in 6 months. No treatment was received for the event. The outcome of the event was recovered in Feb2021.

<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>
1082977	3/8/2021			F	1/30/2021	2/4/2021	developed refractory seizures on 04Feb2021 after receiving covid-19 vaccine dose #2; This is a spontaneous report from a contactable physician. A 65-years-old non-pregnant female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiration date unknown), intramuscular on 30Jan2021 at a single dose for COVID-19 immunization. Medical history included diabetes, breast cancer, rheumatoid arthritis and known allergies with penicillin. Concomitant medications included metformin (METFORMIN), hydrochlorothiazide, losartan potassium (LOSARTAN HCTZ), letrozole (FEMARA). The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiration date unknown), intramuscular in Jan2021 at the age of 65 years old for COVID-19 immunization. It was unknown if the patient had other vaccines in four weeks. The patient developed refractory seizures on 04Feb2021, after receiving the second dose of BNT162B2 on approximately 30Jan2021. The patient was hospitalized for 5 days, in the ICU and received anti-seizure meds among others. The patient had no COVID prior vaccination and it was unknown if tested post-vaccination. The event resolved on an unspecified date in 2021. Information on the batch/lot number has been requested.
1083540	3/8/2021	MD	57	F	3/6/2021	3/7/2021	Feels fatigue and like she's about to have a panic attack before fainting....has happened twice and had convulsions once.
1082218	3/8/2021		37	F	2/19/2021	2/22/2021	Vaccine recipient called vaccine clinic on 02/25/2021 stating that she had a grand mal seizure 72 hours after receiving her first dose of COVID-19 vaccine. She did not seek medical treatment at that time. She has a history of seizures & takes Dilantin daily. She has been in contact with her neurologist.

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1082022	3/8/2021	UT	18	M	3/8/2021	3/8/2021	About 3 minutes after patient received immunization, he fainted and had a seizure. Patient was with his parents and he told them he felt like he was going to faint, so his parents stabilized him before it happened. Patient seized for about 10 seconds and then came to alertness. He was made comfortable and given juice and a granola bar after a while because patient had not yet eaten this morning. I monitored patient for about 45 minutes before I felt patient was stable and feeling well enough to leave. Patient left with his parents monitoring him.
1082086	3/8/2021	FL	87	M	2/9/2021	2/25/2021	Patient was vaccinated at pharmacy on 2/9/2021, first dose of Moderna COVID-19 vaccine. Per medical records from hospital: patient developed fever, diarrhea, nausea and abdominal pain on 2/25/2021 and presented to the hospital E.R. on 3/1/2021. Patient was diagnosed with Sepsis and Pneumonia. Cardiac arrest on 3/6/21, renal failure, seizures. Patient tested negative for COVID-19 on 3/1/2021 and 3/8/2021. Patient has declined, was placed intubated and placed on a ventilator. Patient admitted to hospice services on 3/8/2021 and plan is for compassionate removal of life support at hospice. Prognosis is poor.
1078689	3/7/2021	TX	54	F	3/4/2021	3/4/2021	Fainting, shaking all body, difficulty breathing, hyperglycemia, convulsion, pain on shot area. Called 911 to translate at emergency room.
1079841	3/7/2021	TN	21	M	1/6/2021	1/14/2021	Patient experienced a generalized seizure lasting at least two minutes on Jan. 14th, having received the vaccine on Jan. 6th. Patient has no history of seizure disorder. Patient was taken to the ER per his physician's order. CT scan, x-ray and blood work were unremarkable except for an elevated white blood cell count. Patient was released and convalesced at home. There has been no further seizure activity. Patient did not receive the second dose of the COVID19 vaccine.
1079539	3/7/2021	MD	32	M	2/5/2021	2/6/2021	After 23 hours of first dose had a less than ten second seizure. Last seizure over seven years ago. Had a migraine that night before bed. After 53 hours of second dose had migraine headache at that night. Not able to clearly read the number on the CDC card with the EN number.

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1079538	3/7/2021	UT	69	F	2/19/2021	2/19/2021	seizure
1079519	3/7/2021	SC	77	F	2/14/2021	2/14/2021	Started having flu symptoms 3 hours after shot. By following morning had a temp of 105 and was not responsive. Rushed to Hospital by ambulance. Not responsive for 2 days. In hospital for 4 days. Hospital concluded she had a temp induced seizure. Worst response they had seen. Still rests and sleeps more than normal.
1079129	3/7/2021	IL	57	F	3/7/2021	3/7/2021	Person received the Covid vaccine at 9:50 am and within 1 minute after the injections, patient appeared confused and was shanking, had a 2 convulsions while sitting in the chair that lasted 1 second each. Patient stated "I don't know where I am". Patient lowered to the ground, face mask removed. Patient systolic blood pressure was 110 during the episode with HR 56, pulse O2 98% room air. After approximately 4-5 minutes patients stated "I'm feeling ok now" is alert and oriented to self, place and time. Dr. assisted the patient, orange juice given to the patient. At 10:30am patient back to her baseline, no distress noted and discharged home, no distress at the discharge time.
1079015	3/7/2021	NC	23	M	3/5/2021	3/5/2021	While technician finished administering the vaccine , patient had seizure like reaction that lasted for about 15 seconds . Patient immediately gained consciousness and had no recollection of what happened. He waited for 30 minutes and totally fine. Prior to giving the shot, patient checked the box for feeling dizzy after vaccinations, when I inquired about it , he said that was years back and he had no issues with any vaccines that he has taken. He take flu vaccine every year.
1079979	3/7/2021	NY	53	F	3/7/2021	3/7/2021	Patient had seizure 5 min after receiving shot. Lasted 2-3 minutes, given versed IM and started to improve. Monitored through post ictal phase - blood glucose was 186, BP 176/90. Was able to walk after about 20 minutes but taken by ambulance to hospital for further monitoring.
1078566	3/6/2021	WA	68	M	3/5/2021	3/5/2021	sweating seizure like symptom hypotensive

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1077758	3/6/2021	WI	81	M	3/1/2021	3/2/2021	Per neurology consult: "Patient was at his baseline until when he received his 2nd dose of SARS-CoV-2 vaccination. He complained of dyspnea and fear of impending doom after waking up the following morning with some disorientation. He was found to be in AFib with RVR after it was brought to ER the following morning and the rhythm was converted to normal sinus rhythm. Patient continues to have confusion after admission yesterday that seem to get worse today to the point where he did not know his own name or birthdate, and seemed to have global amnesia. Patient has been more drowsy this afternoon after receiving lorazepam 1 mg IV for potential seizure activity so no reliable neurologic exam was obtained. Patient remains afebrile with pulse ox in the low 90s on 4 L of supplemental nasal oxygen in the hospital. He had moderate decrease in kidney function upon admission that has improved. He has baseline anemia with hemoglobin at around 10. Incidentally patient had shingles in the right thoracic dermatome week ago for which he received valacyclovir.
1078470	3/6/2021	CA	23	M	3/6/2021	3/6/2021	Patient administered vaccine - was about to sit down - had syncopal/seizure episode - fell to ground with few seconds of tonic-clonic activity. Patient assisted by medical staff in clinic - ED physician, RN/NP, rolled to side - patient bit lip, mouth bleeding, unresponsive for a few seconds. Woke up - able to respond appropriately, coherent - alert, oriented to person, place and time - patient did not recall falling to floor. Pt denied hx of prior seizures or any allergies or other significant medical history. Taken by wheelchair to emergency dept by staff.
1078209	3/6/2021	IN	30	F	2/18/2021	2/18/2021	Severe pain and swelling joins - felt like they were on fire - recovered in 7 hours Muscle spasms for multiple hours - seizure like lack of control of muscles randomly across body - still suffering back muscles cramping

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1077595	3/6/2021	NJ	33	M	3/6/2021	3/6/2021	History of syncope with injections in the past. 10 min after vaccine, felt dizzy, laid himself on the ground under. Bystander witnessed him lose consciousness for a few seconds. No seizure like activity seen. No confusion after the event and patient recalled when everything that happened. Also states he didn't eat today. Drank Gatorade, stayed recumbent for 30 min and felt better. Ekg sinus rhythm, vital signs stable. Declined to go to the ER. Went home with his fiancée who is a PA.
1077360	3/6/2021	OR	39	F	2/15/2021	2/16/2021	24 hours after the 2nd dose my temperature rose 4 degrees, full body aches and sweating for 24 hours. Followed by dizziness and headache. Within two days my body began having seizures accompanied with ongoing flushing/cold sensations in the occipital region/top of spine, with a feeling of fainting and dizziness, nausea, without loss of consciousness. Sudden jerking movements of the arms, legs and the head/neck range from 2-5 minutes in duration and continue in clusters for 8-20 hours per day. This seizure activity has not subsided since February 17th, and is ongoing to date. MRI confirms no new structural abnormalities in the brain. CBC and metabolic panels are all within normal range. EKG normal. I am not epileptic. No history of drug use. No alcohol use.
1077349	3/6/2021	WA	40	F	2/20/2021	2/20/2021	8 minutes after the administration of the vaccine (while in the observation area) I started to feel really off (dizzy, anxious, ringing in right ear). I ended up becoming unconscious with seizure like activity. They rushed me to the ER and kept me for 6 hours with lots of testing. XRay, blood test, CT of head, EKG, Urine test...all came back normal. Doctor said it was likely a reaction to the vaccine. I am 40 years old with no history of seizures or allergic reactions to vaccines. The week following I experienced confusion, migraines, dizziness, slow cognitive processing, eye strain, word finding difficulties, and exhaustion. I had to take a week off of work to recover. This is the second week and I am still experiencing headaches and occasional dizziness/eye strain.
1078671	3/6/2021	OR	64	M	3/6/2021	3/6/2021	possible seizure a few hours after injection

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1077380	3/6/2021	TX	23	F	3/1/2021	3/2/2021	Had a Grand Mal seizure 22 hours after her shot.
1075679	3/5/2021	OH	47	M	3/1/2021	3/2/2021	Clients mother reports he had a seizure the day following administration of second dose and he developed extreme shaking and thrashing around while she was caring for him and he was lying on his side. The episode lasted for 30 seconds to 1 minute and he slept for about half an hour afterward. He has since been more subdued and listless but is beginning to display more of his typical behaviors again. She said he has had milder seizure like activity in past when his head tilts backward and he has stiffness and staring with last episode of this being 6 months ago. Last grand mal seizure occurred when he was young and related to issues with his shunt.
1077244	3/5/2021	VA	69	F	2/20/2021	3/2/2021	2 seizure back 2 back extreme arm pain
1077148	3/5/2021	TX	64	M	3/5/2021	3/5/2021	It was reported to us that at @1822 the patient sustained a Seizure at home. EMS was called and arrived to initiate CPR. CPR was performed but the patient was declared deceased by EMS at his home.
1076998	3/5/2021	MD	60	M	3/5/2021	3/5/2021	Patient had vaccine and waited the 15 minute waiting period. He felt well after 15 minutes and left the observation waiting area. He went up front to purchase something 5 minutes later and collapsed face first on the floor as observed by a nearby customer. The customer said he started having convulsing seizures and the customer went to aid in keeping the patient safe. the pharmacy manager (myself) was alerted and I immediately ran upfront to the patient with the emergency bag. 911 was already on the cashiers phone. They dispatched an ambulance. The only treatment was keeping the patient on his side and safe. He was having some labored breathing initially which quickly calmed down. The EMT arrived and they called his Dr office off the VAR. They said he had some hx of seizure. He had selected no to question #6 on VAR (Have you had History of seizure for which you are on medication for). He became conscious before transport to the hospital. The EMT stated that he seemed to be covering as expected from seizure. He was then transported to Hospital Center.

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1076133	3/5/2021	IL	31	F	3/4/2021	3/5/2021	Patient presented with possible seizure activity. Patient has a long known history of seizures but when she had the placement of a vagal nerve simulator seizures have subsided for 2 years. Patient also takes THC/CBD gummies for treatment of her epilepsy. Patient states she had the moderna covid vaccine yesterday and has had symptoms of an oncoming seizure today. Patient states she has also had increased anxiety and depression over the last week. Patient currently has tremors and is very anxious and tearful.
1076124	3/5/2021	IL	75	F	2/24/2021	3/5/2021	Patient's son reported that patient had a seizure on 3/5/21 after receiving the second Pfizer-BioNTech vaccine on 2/24/21.
1077288	3/5/2021	TX	25	F	3/5/2021	3/5/2021	Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: shaking (seizure?)-Mild
1075736	3/5/2021	TX	68	F	3/1/2021	3/1/2021	Clinic course: 13:50 patient given covid vaccine #2- Pfizer. 14:10 patient c/o sob and throat closing. 02 sat 94%. Epipen 0.15 mg given IM to lt thigh. 02 at 4l/nc started. 14:15 EMS called to transport patient to UTMB ER. Bp-150/88, p-75. 02 sAT 98% ON 02@4L/NC. Patient Has audible wheezing and unable to talk above slight whisper. 14:20 Patient feeling a little better. Talking in a louder whisper now. Denies sob. States throat still feels like throat is opening a little. 02Sat 98% on 02 at 4l/nc. Patient was evaluated by NP- Employee Health. 14: 25- patient feeling better. I asked her if she has ever had a reaction needing epi pen before and she stated yes. For allergy shot. I asked her if she told MA when asked and she stated no as I didn't think I would be able to get covid vaccine if I said anything about it. She states no reaction to 1st covid vaccine. ED Course: is a 68 year old female with CAD s/p PCI, HLD, OSA, seizures, HTN, asthma who presents after anaphylaxis following 2nd dose of COVID-19 vaccine. Chest tightness and original EKG concerning for STEMI, but on review EKG was artifact and did not evolve. Normal sinus the following day with resolution of symptoms. Epipen also improved symptoms which would be inconsistent with ischemia. Patient respiratory status improved on prednisone and breathing treatments. Patient is now stable for discharge.

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1077051	3/5/2021	CA	46	M	3/5/2021	3/5/2021	Approximately 3 minutes post-vaccination, the patient suffered a witnessed tonic-clonic seizure, which lasted less than a minute.
1075240	3/5/2021	FL	51	F	1/12/2021	1/15/2021	Loss of failing left side stroke like symptoms with seizures
1074998	3/5/2021	OK	66	M	2/28/2021	2/28/2021	Approx 7 hours after receiving the vaccine client says he heard a loud roar and lost consciousness. Wife called EMSA and they met her and was transported to Hospital with seizure like activity for approx. 3 minutes. He has never had a seizure before. They were not sure if the seizure was R/T his stroke or the vaccine.
1074795	3/5/2021	AZ	54	M	3/3/2021	3/4/2021	Seizure 3/4
1074503	3/5/2021	NY	78	M	3/4/2021	3/5/2021	About just after one this morning my whole body began to convulse violently. I am sure it lasted for more than a minute or two. I woke up feeling very tired. I woke up feeling that I ma have had a heart attack.
1074356	3/5/2021	GA	48	F	1/15/2021	1/22/2021	I had epileptic seizures 6 days later and they haven't stopped. Never had seizures in my life
1074341	3/5/2021	CA	52	F	3/4/2021	3/4/2021	Systemic: Seizure-Medium
1076071	3/5/2021	NJ	22	F	3/5/2021	3/5/2021	The vaccine was administered to the patient in the consultation room. Once we left the consultation room, after about 2 minutes, the patient got my attention and complained of feeling dizzy. I went to her side, and she told me that she felt like she was going to pass out. The patient then proceeded to lose consciousness while sitting in a chair in the waiting area. She then exhibited seizure-like movements (muscles contracted, groaning sounds) for about 10 seconds, and she then regained consciousness. I administered no treatment, since this did not exhibit the signs of an anaphylactic reaction. 911 was called, and emergency medical services arrived. The patient was then taken to the hospital. The patient stated that she has had a similar reaction in the past to getting a vaccine, she thinks it is from the stress of getting injected with a needle.
1076291	3/5/2021	TN	46	M	2/9/2021	2/10/2021	Had a seizure while watching TV with my family. I was setting in a chair, not stressed. Family called 911 and ambulance came to take me to office

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1073911	3/4/2021	CA	19	F	3/4/2021	3/4/2021	11A1 19 y old pt received 1 st dose Moderna vaccine, after 5 mins she had episode of syncope, fell from her chair and bump her head. She had seizure for about 10 seconds. After seizure she was A/O x4 , neurologically intact, good PERRLA. Her BP was 95/65, HR 59, O2 sat 98 RA. Pt able to speak and was aware of the situation. 911 was called to take the pt to the hospital for head injury to R/O any abnormality.
1073379	3/4/2021	SD	24	M	3/3/2021	3/3/2021	Patient reports having a grand mal seizure 45 minutes after receiving the vaccine.
1071260	3/4/2021	HI	39	M	2/16/2021	2/16/2021	30 second nonepileptic seizure , loss of blood pressure and extreme dizziness along with nausea
1071484	3/4/2021	IL	71	M	2/25/2021	2/25/2021	Patient with delayed vasovagal likely syncopal episode several hours after vaccine received: "I wanted to let my Dr know that I had an incident on Friday. Sitting at home talking with my wife ant two friends and started feeling "dizzy". They said I started shaking and head rolled back and I was out for a minute. I did not know anything had happened when I opened my eyes. They insisted that I go to the hospital. EMS came and tested me on the way to hospital- all tests good. Same at the hospital- you may have the results. Not a seizure, no high blood pressure, maybe vaccine reaction? they weren't sure what it was, and wanted to keep me overnight and I said no thanks. Home about 5 PM I feel fine. Please let me know if you want to go over.
1071507	3/4/2021		25	F	3/4/2021	3/4/2021	Patient stated he felt dizzy. Then became unresponsive,gasping for air approx 15 seconds. Lowered to the floor head tilt chin lift to open the airway, Seizure began lasting approx 30-45 seconds. b/p166/64 Pso2 99% pulse 80. Patient became responsive, diaphoretic, arms cold, A&Ox3, pupils reactive@0825. 911 had been called. 0835 b/p 140/70 pulse 92 and pso2 99% Patients mother called. Patient taken to ER via ambulance. Patient did report he has had two seizures in the past after a shot and a blood draw.

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1071602	3/4/2021	PA	48	M	3/4/2021	3/4/2021	Patient had two witnessed seizure like episodes with nystagmus and unresponsive each episode lasted less than 20 seconds. Patient had prodrome prior to both events but no memory of either event. Both event happened within 15 minutes of vaccine administration. Patient was transported to the emergency department for further testing and care.
1071624	3/4/2021	MO	43	F	3/3/2021	3/3/2021	Patient states that after waiting for the 15 minutes of observation, within 30 to 40 minutes she had a seizure. Said it resolved and she did not seek medical attention but wanted to know if she should receive the second shot.
1072015	3/4/2021		67	F	2/23/2021	2/24/2021	Fever, seizure lasting about 10-15 seconds
1072129	3/4/2021	ID	33	M	3/3/2021	3/3/2021	03/03/2021 (0720-0735) Immediately following vaccination I experienced 2/10 sharp, constant substernal chest pain lasting for approximately 15 minutes. 03/04/2021 (0200-0400) Awoke with subjective feeling of fever, full-body muscle cramping, and uncontrollable, mild, full-body convulsions without loss of consciousness (not true seizure-like activity). These were not the typical "shivering" symptoms typically experienced by patients with high fever. All other symptoms experienced following severe symptoms more closely resembling flu-like symptoms that are to be expected following second vaccine.

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1072546	3/4/2021	CA	38	M		1/25/2021	seizure 3 days after vaccine; This is a spontaneous report from a contactable other health professional. A 38-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. Medical history included seizure. The patient had known allergies: Risperidone. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient experienced seizure 3 days after vaccine on 25Jan2021. Since the vaccination, the patient has not been tested for COVID-19. The outcome of event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported seizure 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.
1073017	3/4/2021	IL	28	F	3/2/2021	3/2/2021	Patient was seated during her mandatory 30 minute wait, where she stated she began to feel light headed and had a headache. Stated that she has a history of pseudo seizures and that she had one with her first vaccine. Patient then became unresponsive, slumped back in her chair and began to seize. She was lowered to the floor while she was seizing and monitored by paramedics who were on site until the seizure was over. The seizure lasted approximately 4 minutes. Patient was postictal and elected to be transported to the ED for further evaluation. ED discharged her home.
1073036	3/4/2021	TX	32	M	2/20/2021	2/21/2021	Almost exactly 24 hours after receiving the second injection, I had a tonic-clonic seizure. This is my first seizure in >2 years and they have been well-controlled with Lamictal which is prescribed by my neurologist.

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1073047	3/4/2021	WI	79	M	3/3/2021	3/3/2021	Patient recieved 2nd dose COVID vaccine and had unresponsive episode in car after monitoring period, staff assessed in car and patient had recovered, staff encouraged family to take to ED for evaluation. From ER MDs note: EKG was normal sinus rhythm, narrow QRS, delayed transition, minimal lateral st depression V4. Patient IV access on arrival, would Brady down to the 40s 1 time as low as 27 but remained alert, blood pressure is not dip. Troponin was mildly elevated and decision was made to transfer the patient. Prior to transfer is necessary to rule out pulmonary embolism, intracranial injury Patient wished to proceed with CT angio chest and noncontrast CT of head which were without acute findings. Patient given aspirin 81 mg to supplement the 81 mg he had earlier today. Discussed with hospitalist, patient was accepted in transfer. Suspect this is combination of patient's beta blockade with underlying sinus node dysfunction. Patient does have prominent lower extremity swelling and suspect pulmonary hypertension despite treatment with CPAP but cannot exclude valvular heart disease. Patient was went to Hospital. Symptoms thought to be unlikely from seizure. Doubt CVA, ongoing cardiac ischemia.
1073056	3/4/2021	IN	77	M	2/19/2021	2/20/2021	About 24 hours after the injection, I had extreme fatigue and difficulty getting out of bed. along with body aches in both arms and a seizure like blank stare and couldn't move my arms and legs for a short time. Briefly I had shakes in both arms but no fever, chills, or headache. By the next morning the injection arm (left) was achy with no other prominent symptoms.
1073258	3/4/2021	OK	87	F	2/23/2021	2/23/2021	After receiving the vaccine client became flushed, clammy, labored breathing, LOC, and had seizure like activity. After she came to, she c/o not feeling good and lightheaded. She was taken by ambulance to the hospital. Husband said they ran several tests. She continues to sleep a lot and is sore all over.
1074091	3/4/2021	FL	42	F	1/30/2021	1/31/2021	Whole left arm hurt Severe headache 104.5 fever Passed out 2 different times Chills Delirious Lost control of bladder twice Seizure Breathing difficulties-responded to use of inhaler

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1074019	3/4/2021	CA	52	F	3/4/2021	3/4/2021	About 10 mins after vaccination patient stated she wasn't feeling well. When pharmacist went to check on the patient she was seizing. 911 was called. Patient's eyes were fluttering and unresponsive, but breathing. Patient came in and out of seizure a few times. 1 full body seizure about 20 to 30 seconds. Patient was laid on the ground on her side till paramedics arrived. She was then taken by ambulance.
1073905	3/4/2021	TX	33	M	3/4/2021	3/4/2021	lightheadedness after about 5 minutes followed by confusion and loss of consciousness. Brief seizure and short-term aphasia.

<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>
1073821	3/4/2021	GA	36	M	3/4/2021	3/4/2021	Was administered the Pfizer COVID-19 vaccine in our drive-thru clinic on 3/4/21 at approximately 2:15pm. Was in the driver's seat of his SUV with his father in the passenger seat. Nothing in the PQCF gave us any reason to be concerned over this particular administration. After administration, was asked to pull forward and park in a spot on the right in order to sit for his required 15 minutes post-administration. became unresponsive as he was attempting to park and continue to turn the wheel causing him to drive in a U shape into a rock covered median. The SUV was able to clear the median and the car stopped at the APEX. When I saw the car heading towards the median, I started to head toward the site safely. I approached the car slowly asking him to stop. When I did not receive a response, I knew something was wrong. Once I felt the car was safe to approach, I ran to assist the patient. The patient was barely able to communicate but did say he was dizzy. 15 seconds later he was unable to communicate, I called a second pharmacist to run over with an epi pen just in case (this was NOT administered). I immediately called 911 at 2:21 pm. reached into the vehicle and got the vehicle into park, while I assessed his airway, breathing, and pulse from a seated position. The patient began to seize. I continued to hold the patient from outside of the vehicle to maintain the patient's airway and keep him from hurting himself on the steering wheel. The patient regained consciousness approximately 3 minutes later with no memory of what happened. EMS arrived on scene about 2 minutes after he regained the ability to communicate. While EMS assessed the patient, and I reached out to and division one store management per SOP. EMS determined that the patient had a seizure and was able to go home if they wanted. The father moved into the driver seat. We monitored the patient for 30 minutes and allowed them to leave. We followed up with the patient via phone 2 hours later with no concerns noted. No property damage or bodily harm occurred during this incident. If we are given approval to vaccinate this patient with a second dose, we will arrange for this patient to be taken care of in the pharmacy.

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1073443	3/4/2021	KY	35	F	3/4/2021	3/4/2021	Patient has a previous history of seizure disorder. She received the vaccination and proceeded to the waiting area. While there she reported to staff members that she could feel a seizure coming on. She was moved to the floor in a safe location and monitored. She was able to contact her spouse to bring her medication. She began to seize and at one point she did lose consciousness. She regained consciousness and improved rapidly afterwards. EMS was called, but she declined the service. She said that these seizures aren't uncommon and she wanted to go home to recover.
1072923	3/4/2021	AR	29	M	3/2/2021	3/2/2021	During the first day after taking vaccine, started having a fever, headache, and sore throat. By the evening, fever was severe and 102+, with severe headache and sore throat. After sleeping on that night (had disruption of sleep from 2 - 4 in the morning), it was looking normal., just had usual fatigue after a fever. But on Thursday (Took vaccine on Tuesday morning, March 02, 2021), I suddenly started having a seizure, my whole body was shaking, legs were cramping. I thought it was going to go away, but after 10 minutes it was getting worse and I had to call the emergency services. The fire service members first came, they measured my blood oxygen level, it was 98%, but my blood pressure was high (140). I was still shaking and having the seizure. They tried to calm me down by talking, after some time, my blood pressure came to normal and I started getting normal (no seizure at that point). I declined the ambulance service as it is expensive and I was getting normal. I had a 101 fever just after that and went to visit the health care facilities .
1069175	3/3/2021	NC	44	F	3/2/2021	3/2/2021	Symptoms were: general allergic reaction with hives followed by a seizure and spontaneous recovery. Pt relates Seizure was consistent with her normal seizures but slightly worse. She had a seizure 1 week ago and has seizures in clusters, this was consistent with the waning period of the current cluster. Vital signs were (abnormal with tachycardia and hypertension on arrival to the ED). Exam was notable for neck pain. Patient was treated with Benadryl on scene and with Toradol and fluids in the ED and symptoms recovered but multiple shaking episodes characterized by patient as seizure. Patient was observed in the emergency department for an extended period.

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1069214	3/3/2021	CA	26	M	3/1/2021	3/3/2021	He developed a fever and started throwing up the night of his vaccine. He is very small/skinny at 4'10" and 95 pounds. The fever continued the next day, and along with severe fatigue/vomiting, and he wasn't able to swallow/keep down his seizure meds. After giving him Motrin orally and Compazine with suppository, his fever broke in the evening and he was able to eat a little and keep down his seizure meds
1069630	3/3/2021		43	M	1/21/2021	1/21/2021	Patient had a seizure lasting approximately 2 minutes. Pt. has a history of seizures the last one 1 week prior. RN and EMT on site to evaluate the patient. Pt. was stable the mother refused to EMS transfer.

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1070751	3/3/2021			M	2/16/2021	2/1/2021	grand mal seizure; pain in the muscle where the injection was given (sore arm); body aches; fatigue; memory loss; This is a spontaneous report from a contactable nurse reporting on behalf of the husband. A male patient of unspecified age received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 16Feb2021, in arm, for COVID-19 immunisation. The patient was a cancer patient who was taking chemotherapy. On 20Feb2021 the patient experienced grand mal seizure and was hospitalized on the same day. On an unspecified date in Feb2021 the patient also experienced pain in the muscle where the injection was given (sore arm), body aches, fatigue and memory loss. The patient had never had a seizure before and has had memory loss with these seizures as well (had another one in the hospital very early on 22Feb2021 morning). Events outcome was unknown. 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 event Grand mal seizure 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.
1069672	3/3/2021	VA	44	M	3/3/2021	3/3/2021	Patient received a dose of the Pfizer COVID-19 vaccine. Before he could exit the room to begin the observation period, the patient became unconscious and slipped into a seizure. Uncertain if it was hypersensitivity coupled with vasovagal response, an epi pen was primed but not administered. The patient was unresponsive for a minute then came out of his apparent seizure

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1069680	3/3/2021	CA	35	F	3/2/2021	3/2/2021	I received the shot at approximately 11:15am then waited for 15 minutes in an observation area. I was feeling fine and was allowed to leave. I began driving to pick up my husband from work and approximately 5 minutes later, I began to feel woozy and unwell. I wanted to pull the car over, but I was stuck at a red light. The next thing I remember is two men opening the doors to my car and telling me I had had a seizure. While I was unconscious the car had driven into a fire hydrant and water was shooting over the car and street. The men helped me from the car and I laid on the sidewalk until the ambulance arrived. I was transported to the hospital.
1069723	3/3/2021	ME	16	M	3/3/2021	3/3/2021	Given history of anxiety around needles, visual aura, paleness after episode, and quick recovery to baseline presentation most consistent with syncope with myoclonus. Seizure less likely given that this is different than his typical semiology and he has been well controlled on his current AED regimen. Discussed with the Neurology attending of the week who was in agreement. Point of care blood glucose was found to be 111. Per neurology recommendations, Trileptal level was drawn. Patient was observed for 1hr and remained at baseline with no additional events concerning for seizure. Patient and mother were informed about vasovagal syncope and instructed on precautionary measures to take with future shots. Given return precautions.
1069728	3/3/2021	TX	47	M	3/2/2021	3/3/2021	Patient Started having dizziness, feeling faint at around midnight on 3/3/2021. He then lost consciousness, had seizure-like activity and was taken to hospital via EMS. In the hospital patient was unresponsive and received resuscitation attempts unsuccessfully. Per family, after about 45 minutes, code was called and patient expired.

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1069812	3/3/2021	UT	60	F	3/3/2021	3/3/2021	15 minutes after the patient received the vaccine she began feeling light headed. She experienced leg numbness. She said that she felt that if she had to stand up that she would fall over. patient has felt this prior when she over took her seizure medication or when she takes her medication early in the morning. We gave the patient orange juice and water. We checked her blood pressure, oxygen, and heart rate. Patient then stated her throat felt like it was getting tight. We then gave the patient 25 mg of chewable benadryl. Patient did not have difficulty breathing. Patient was monitored for over an hour after vaccine administration
1069888	3/3/2021	MI	86	M	3/3/2021	3/3/2021	Nausea Dizziness Had slight seizure (lasted approximately 5 seconds- arms up and shaking, eyes closed, fell back in chair) Cold sweats (still nauseous 3 1/2 hours after injection, unable to keep anything down (including water)
1069902	3/3/2021	IL	72	F	2/26/2021	2/26/2021	Headaches began later in the afternoon after getting vaccine. Loss of sleep that is abnormal and worrisome due to seizure condition. Sore arm at injection site and general body aches present.
1069904	3/3/2021	TX	20	F	3/3/2021	3/3/2021	post vaccination, pt fainted. bp 132/84, HR 66. pt. aao x 3 almost immediately after fainting episode. Nurses kept patient on the floor, w/ legs elevated above pt.'s chest, and head on pillow. Mom stated, "this is just like when you had the Gardasil." 2n d bp 130/82, HR 62. Mother repeated the statement regarding the Gardasil, and also stated that "it was like she was having a seizure, but it was in the doctor's office so they just took care of everything." Note: Before vaccination, employee reviewed pre-vaccination checklist questions w/ Pt. Pt denied any previous reactions to vaccines.
1069917	3/3/2021		78	M	2/26/2021	2/26/2021	During administration of vaccine, pt. turned head away from vaccinator and did not answer any questions would not respond to his name. A rapid response was called and pt. transported via ambulance to ER. Pt. had a history of seizures. "Not controlled with medications" per pt. Pt. discharged stable.

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1069931	3/3/2021	NY	65	F	1/1/2021	2/4/2021	on 2/4/21, patient developed refractory seizures, requiring hospitalization and antiepileptic medications among others. She had no history of seizures, as well as negative LP studies and negative CNS imaging.
1069565	3/3/2021	WA	53	F	3/2/2021	3/2/2021	Patient experienced tonic clonic seizure within a few minutes of receiving first dose. I was informed at upon arriving at the scene that she had history of seizure but I cannot validate this information. She was evaluated by the emergency department immediately.
1070709	3/3/2021	MO	41	F	2/16/2021	2/16/2021	headache; on and off chills; lethargic; nasal congestion; started feeling run down; This is a spontaneous report from a contactable consumer (patient). A 41-year-old female patient received 2nd dose of bnt162b2 PFIZER-BIONTECH COVID-19 VACCINE, lot number: unknown), via an unspecified route of administration in left arm on 16Feb2021 12:00 at single dose for covid-19 immunisation. Medical history included nocturnal seizures, hypothyroid, sinus infections, seasonal allergies, allergies to sulfa drugs. Concomitant medication included lamotrigine (LAMICTAL), levothyroxine, glucosamine, naproxen sodium (ALEVE), cetirizine hydrochloride (ZYRTEC). The patient previously received 1st dose of bnt162b2 on 26Jan2021 at 11:00 in left arm for covid-19 immunisation. At about 11 pm after the vaccination (16Feb2021 23:00), started feeling run down. Woke up the next morning (17Feb2021) with headache, on and off chills, lethargic, with nasal congestion. No treatment received in response to the events. The outcome of events was recovering. This case was reported as non-serious. 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. Since the vaccination, the patient has not been tested for COVID-19. Information on the lot/batch number has been requested.

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1070802	3/3/2021	WA	56	F	2/7/2021	2/8/2021	On February 8th, 2021 patient came home early from work around noon due to not feeling well. She was feeling tired, slightly nauseous and very low energy. At about 4:50 PM that day, patient got up to walk to the pantry after eating some peanut butter toast. She suddenly stopped and shut her eyes and froze and then she began having a seizure (and she has never had a seizure before and seizures do not run in her family). After the shaking from the seizure ceased, her body tensed up and she fell flat backwards and she hit her head on the refrigerator. She then was going in and out of consciousness, she had a big laceration on her forehead and was bleeding rapidly. I, her daughter, witnessed this and then at 4:54 PM I called emergency services and paramedics arrived and took her to the hospital. Later that evening, the family was notified that the patient had bleeding in her brain, a concussion, a forehead laceration that received 15 stitches and a broken neck (C2 fracture). She was taken to the hospital that evening on February 8, 2021. Patient experienced a second seizure while at the hospital during a CT scan. Patient later was able to come home February 11, 2021 in the afternoon. Patient now has to wear a neck brace for up to 12 weeks, cannot drive, cannot work for up to 12 weeks, and is still recovering cognitively from the concussion.
1071208	3/3/2021	CA	45	F	3/3/2021	3/3/2021	Patient DOB 9/21/75 sustained witnessed tonic/clonic seizure like activity with loss of consciousness lasting <15 seconds with eyes "rolling back" and skin color change from normal for age/race to pale followed by bilateral upper extremity convulsions. Witnessed by monitoring area Registered Nurse. Hx: Seizures, last seizure secondary to codeine ingestion >1 y ago. Anxiety related to injections. Timeline: 1759- Vaccinated with Pfizer Lot # EN6199 1st dose 1805- adverse reaction occurred 1806- mental status: slow to respond, skin: pale/diaphoretic, VS: HR 51 (regular at the radial site), BP 80/palp, RR: 12, T: 36.8, Spo2 100% on RA 1807- 911 activated, placed in position of comfort. 1815- EMS arrived, EKG consistent with sinus bradycardia, HR 58, BP 150/130, RR 15, Spo2 100% on RA 1820- EMS placed patient on gurney. 1825- Departed via EMS gurney

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1067952	3/3/2021	IL	41	F	12/17/2020	12/17/2020	flu-like symptoms; headache; aches; chills; night sweats; more fatigue than normal; This is a spontaneous report from a contactable nurse (patient). A 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not provided), via an unspecified route of administration in the left arm on 17Dec2020 16:30 at a single dose for COVID-19 immunization. Medical history included Seizure disorder, depression, anxiety, mild hyperthyroidism and Penicillin allergy. The patient was not diagnosed with COVID-19 prior to the vaccination. The patient is not pregnant at the time of vaccination. Concomitant medication included carbamazepine, citalopram, buspirone hydrochloride (BUSPAR), and omeprazole. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine. The patient experienced flu-like symptoms, headache, aches, chills, night sweats, and more fatigue than normal on 17Dec2020 19:00. Treatment was not provided in response to the events. The outcome of the events was recovered on an unspecified date. The reporter assessed the events as non-serious. The patient has not been tested for COVID-19 since the vaccination. Information on the lot/batch number has been requested.

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1068132	3/3/2021	IL		F			<p>flu-like symptoms; headache; fatigue; This is a spontaneous report from a contactable nurse (patient). A 41-year-old female patient 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 immunisation. Medical history included seizure disorder, depression, anxiety, mild hyperthyroidism and allergies to penicillin. Concomitant medication included carbamazepine, citalopram, buspirone hydrochloride (BUSPAR) and omeprazole. The patient previously received the first dose of BNT162B2 on 17Dec2020 (Age at vaccination: 41 years) for COVID-19 immunisation and experienced flu-like symptoms, headache, aches, chills, night sweats and more fatigue than normal. The patient experienced flu-like symptoms on an unspecified date. It was reported that with the second shot, the patient took ibuprofen shortly after receiving it and mainly had a headache and fatigue. Just for 24 hours after the shot did the patient have symptoms. The outcome of the events was recovered on an unspecified date. Information on the lot/batch number has been requested.</p>

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							<p>Patient was observed and discharged on 05Feb2021. Per discharging provider the patient had some mild low-grade fever with negative cultures on unknown date. On 03Feb2021, nasal swab resulted negative. Provider unsure if fever due to vaccine or mild case of bronchitis (04Feb2021), patient discharged on a ZITHROMAX pack, antibiotics-one dose of Zosyn, Vancomycin, Rocephin. The patient was treated for the events. The patient recovered from the events. The patient did not have covid-19 prior to vaccination; the patient was tested for covid-19 post vaccination (nasal swab, negative). No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the fever and other 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 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>
1068484	3/3/2021	OH	23	F	3/2/2021	3/3/2021	Patient experienced nausea, vomiting, chest pain and seizures (history of seizures but experienced it more strongly after the shot)
1068697	3/3/2021	NY	56	F	2/14/2021	2/16/2021	Seizure
1068850	3/3/2021	TX	70	F	2/26/2021	2/26/2021	Pfizer-BioNTech COVID- 19 Vaccine EUA: Wife of patient called Primary Care Physician to inform that patient had received dose #2 of Pfizer COVID vaccine, and later that evening experienced a seizure and expired.

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1069614	3/3/2021	WV	59	F	2/18/2021	2/20/2021	48 hours after receiving dose 2 of the Moderna vaccine, patient developed alterations in mental status - cannot recall the events. She was taken to the ED and was found to have a BP of >200/130. Patient had a seizure in the ED - was intubated to protect airway. CT showed some decreased areas of attenuation in the bilateral occipital lobes and cerebellum. MRI showed vasogenic and cytotoxic edema in posterior temporal, parietal and BL occipital and BL cerebellar hemisphere which can be seen with PRES. Patient required inpatient treatment for her elevated BP and neurological evaluation. Was started on Norvasc and Keppra due to concern for PRES. Discharged with follow up in cancer center and with neurology. Hospitalist and neuro teams thought PRES was likely due to her chemo regimen, patient's oncology team though PRES may have been triggered by vaccine due to timing and her dose of Avastin. Pt has extensive oncological history including ovarian cancer w/ metastatic breast cancer in L axilla. Pt recently started on cytoxan, Avastin, pembrolizumab. Also has malignant abdominal ascites.
1069114	3/3/2021	WI	81	F	2/12/2021	2/12/2021	immediately after vaccine injection upper body went into convulsion, uncontrolled jerking and tremor of all extremities. Difficulty Breathing

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1070537	3/3/2021	MO	49	M	3/2/2021	3/2/2021	Administered Moderna vaccination at 1746 and patient stated that he has experienced vagal responses to injections in the past. Patient remained in the vaccination chair for 5 minutes after injection and he reported feeling well and moved to the observation chair without any problems [~10ft]. After being the observation chair patient stood up and took 4-5 steps toward the wall and sat down on the floor. The patient stated he felt dizzy and then became limp & slumped to the right side, eyes remained open with dilation of pupil fixed at 2mm with no blinking noted. Patient's breathing pattern became shallow & snoring sounds noted. Patient did not respond when spoken to nor did he respond to soft shaking of shoulders. Patient began to demonstrate large jerky body movements similar to seizure activity. The seizure like activity continued for 3-4 minutes before the patient was able to become aware of surroundings and answer orientation questions. BP 120/72, HR 64, O2 sats 99%, RR 20. Patient was diaphoretic, pale, shaking of hands and arms, restlessness of lower limbs with frequent repositioning/twitching of legs. EMS arrived to find the patient regaining stability. Patient reported to EMS that his is familiar with this type of response and declined to be taken to
1066295	3/2/2021	FL	58	F	3/1/2021	3/1/2021	58 F with complicated medical history including urostomy, frequent UTI, fibromyalgia, seizures, presenting to the ED for presyncope/seizure following a COVID vaccination today. She reports that after getting the vaccine she felt dizzy. she is able to recount the events, no tongue biting. She was given diazepam via EMS en route. Has not missed any doses of medications. No other complaints. Symptoms started following the COVID vaccination and no other symptoms today.

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1067445	3/2/2021	CA	20	M	3/2/2021	3/2/2021	patient c/o feeling nausea and hot. patient then asked for water. patient then became unresponsive for approximately 30 seconds. seizure like active noted, patient began to have involuntary movement of upper and lower extremities that lasted approximately 10 seconds. Patient accessed for gag reflex and then offered water upon becoming responsive. Patient tolerated water well. Patient offered wet paper towels. Skin noted to be cool and clammy. Vital signs assessed noted to be BP 105/74 and HR 69. Patient alert and oriented x 3, placed in wheelchair for continued observation. Mother stated that syncope activity is normal for patient upon receiving injections or blood draws, seizure like activity is not normal per mother. Patient taken to observation area by paramedic.
1066923	3/2/2021	OH	27	M	3/2/2021	3/2/2021	Patient experienced seizure aura, lost color, began to sweat, eyes rolled back, and was mildly unresponsive within 5 minutes of vaccine administration. Called 911. Placed patient on left side per direction of EMS dispatch. Patient stated the aura had decreased within a few moments of lying down on his left side. EMS assessed the patient's vitals which were normal on arrival. Patient declined transport to hospital and left in care of mother.
1066985	3/2/2021	NJ	35	M	2/4/2021	2/25/2021	New onset headache, seizures, and encephalopathy
1067109	3/2/2021	MI	44	F	12/30/2020	12/30/2020	I experienced palpitations, dizziness and I felt like I was having a panic attack within 5 minutes of the vaccine. I took Advan medication. The following day I felt extreme exhaustion and fatigue. I was unable to do my work because I was so tired and had brain fog. More importantly, panic, heart racing feeling that was concerning to me because I thought it was related due to my seizures. Had a consult to my PCP and neurologist and they are monitoring me due to my symptoms. This has happened to me three times. As far as my second dose I had no reaction to the vaccine.

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1066358	3/2/2021	FL	70	M	1/16/2021	1/19/2021	Three days after receiving dose #1 of COVID-19 vaccine, patient had a first potential seizure event. Patient reports waking up with LLE pain and weakness and a bite mark on the right side of is tongue. He also noticed he had urinated on himself (a small amount). Pt presented to ED on 1/22 where seizure work-up performed. MRI brain showed "non-specific gliosis along the L cerebellar hemisphere along with chronic BG infarcts." Unremarkable EEG. Started on levetiracetam 500 mg BID at discharge and continues to follow with outpatient neurology.
1067275	3/2/2021	IL	29	F	3/2/2021	3/2/2021	Patient was monitored and reported dizziness 10 minutes after receiving vaccine, vitals were within normal limits at that time. After 30 minutes without any other event, patient said she was feeling well and began to leave to go home. About 3 minutes thereafter reported not feeling well. She was taken to an exam room, where she lost consciousness and had a seizure for about 2 minutes, vitals remained normal. Ambulance was called and patient taken to the hospital.
1066741	3/2/2021	LA	57	M	2/1/2021	2/7/2021	Patient got vaccine on 2/3/21. Developed fever of 102 F and malaise on 2/4/21. Reported "low grade fever" on 2/5/21. Had witnessed convulsive seizure on 2/7/21 and went to the ED for evaluation.

<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>
1064665	3/2/2021	CA	30	M	3/1/2021	3/1/2021	COVID19 VACINE CLINIC SHCE: 3/1/2021 4:57 pm: 1st Seizure 20 sec long 30 year old male, had a seizure 10 mins after receiving 1st dosage of pfizer. History of Seizures per parents that are accompanying the patient, every 4 days. Dx of Epilepsy. 3 RN's attending 1. FIRST RN 2. SECOND RN 3. THIRD RN MA attending: 1. ATTENDING MA Note: First Vitals taken, 10 mins after 1st dosage of Pfizer given. 5:00 pm: BP:147/82 HR: 74 O2: 96% Notes: No complaints of pain 5:07 pm: BP: 125/73 HR:76 O2:96 Notes: No complaints of pain Outcome: 30 mins in Observation area, 2nd Dosage for Pfizer appointment made for Hospital. 5:17 pm: 2nd Seizure 10 sec long 5:19pm: EMS called by NP 5:19pm: BP:140/71 P: 69 O2: 96 5:24 pm: EMS Arrived 5:31 pm: Vitals BP:115/72 P:87 O2: 97 Outcome: Family refused EMS. EMS released the patient to the parents due to history of epilepsy at 5:33pm, patient stable. **Instructions were given to the parents by Charge RN and attending RN, advised the family to take the patient to the ER if symptoms worsen. Family understood and agreed. 5:34 pm patient was able to walk out with parent to the exit. Director, & RN on site notified
1066743	3/2/2021	UT	71	F	3/1/2021	3/1/2021	Moderna COVID-19 Vaccine EUA: Approx 12 hours after receiving injection I first got a severe headache, for which I took ASA with some moderate relief. I then noticed body aches & chills. After about 45 minutes I went to bed, still chilled. After lying down the chills became rather violent, more like spasms or seizures and lasted about 15 minutes. Finally they stopped and I had a fitful nights sleep due to body aches & headache. On awakening I still had discomfort, took Ibuprofen, and it is still ongoing at this time (2:30 pm) but seems to be going away. Primary feeling is now weakness & fatigue
1064688	3/2/2021	ID	40	F	2/17/2021	2/17/2021	Severe headache, from back of head to front forehead. Lasting two weeks exactly. Two grand-mal seizures on day 13. Unknown if seizures were related.
1066636	3/2/2021	IL	66	M	2/18/2021	2/27/2021	Seizure around 4:40 am on 2/27/2021. Shaking, eyes drawn in, fists clenched, some foaming at mouth, unresponsive. Ambulance called to the home. Transported to hospital.

<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>
1065747	3/2/2021	OK	33	F	3/1/2021	3/1/2021	Seizure and Allergic reaction
1065771	3/2/2021	FL	78	M	1/16/2021	1/20/2021	Patient's wife reported that he broke both of his shoulders four days after his first vaccine. He had a seizure and fell off the bed breaking his shoulders. No hx of seizures, TBI or stroke. His wife stated they were told by the PCP he could get the second dose of the vaccine. None of these records are accessible by the vaccinating site. No known ED visit or hospitalization related to the event.
1065775	3/2/2021	NJ	69	F	2/27/2021	2/27/2021	SEIZURE SYMPTOMS SOON AFTER. About 15 mins after I had early signs of focal aware seizure (aura) - pins and needles in the face, hands, feet, and very warm face. (RASH AND ITCHING AROUND INJECTION SITE NEXT DAY AND ONGOING.) Slowly, twitching started sporadically lasting 1 - 3 seconds with 5 - 10 minutes in between. Length of twitching stayed the same but slowly became more often. I knew something was going to happen, so I did not want to go home not knowing if it would become more severe or when it would become severe. As time wore on, twitching and body movement increased especially in left thigh where a stronger seizure usually starts. In time, it became almost constant with arm, shoulder and leg movement and then increased to sporadic whole body movement. Took Klonopin. Took about 15 - 20 minutes to take effect I was attended to by doctor and EMS.
1066010	3/2/2021	PA	24	F	2/27/2021	2/27/2021	I had a temp of 102 starting at 10pm and lasting until 9am. I woke up at 1am with a temp of 102.7, drenched in sweat, and shaking so badly my partner thought I was having a seizure. I did not seek treatment, because I was able to sleep after taking Tylenol and having my partner use cold washcloths and ice packs on my neck, forehead, back, and chest. I also attempted to take a shower, but I was so weak I required assistance to walk to the bathroom. I had similar side effects the next night although less intense.
1066093	3/2/2021	TX	63	M	12/30/2020	2/2/2021	No known side effects; however, on 1/20 the decedent suffered lethargy. On 2/12/2021, the decedent had a possible seizure and was transported to emergency department where shortly after arrival, he was pronounced dead.

<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>
1066337	3/2/2021	NC	55	F	2/3/2021	2/8/2021	Grand mal seizure
1064661	3/2/2021	MA	80	F	2/11/2021	2/15/2021	My mother had a seizure on February 15th after receiving the moderna vaccine on February 11th within four days of the vaccine. Doctors at hospital. Staff cannot answer what caused the seizure though they found a 4mm bleed on her brain; believed unrelated to seizure; on an MRI. My mother has never had a seizure and noone in my family have had seizures. I don't know if it's related to the vaccine but felt it should be reported to you.
1067158	3/2/2021	UT	60	F	2/26/2021	2/26/2021	Seizure: Sunday 2/28 @noon Migraines: 2/28 post seizure & 3/1 & 3/2 Pre-seizure symptoms: 3/1 & 3/2 ExtremeMuscle&Joint pain, fatigue, Ubrelvy 100mg 2/28 & 3/2, Ibuprofen 800mg, alt w/Tylenol 2-500mg, Rest/sleep most of days, warm showers, heating pads
1064207	3/1/2021	CA	31	F	3/1/2021	3/1/2021	31 y/o female came in Vaccine clinic for first dose of COVID-19 Moderna vaccine Lot# 013M20A. Patient received vaccine at approx. 3:00pm, walked to observation area to sit for 15 minutes at approx. 3:02pm. At approx. 3:08pm Nurse heard patients cell phone fall to the ground, nurse noticed patient leaning over to her right side and slumped over. Patients head was down and not responding to her name. Nurse heard patient making moaning noises, nurse held patient up and called her name, asked if patient had any disorders, after a couple minutes patient responded, lifted her head up and stated she didn't have any Seizures disorders but does have a history of vasovagal reactions. EMS was called to the scene. Initial BP-90/46 P-51, O2-98%. Patient denies any prescription meds or over the counter meds were taken prior to her vaccine. Per patient No history of any medical conditions. Water was given to patient, was A/O with EMS. Refused to be taken to ER/Hospital and Signed AMA. EMS vitals 107/67, p-73 100%, last V/S bp-125/70, p-79, 100%

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1064057	3/1/2021	NC	37	F	2/24/2021	2/24/2021	Fever (max 105F), generalized tonic clonic seizure lasting >60minutes resulting in rhabdomyolysis , leukocytosis (16k) s/p ceftriaxone x 1 with COVID-19, Flu A/B, RSV all PCR negative followed by transfer to hospital (2/25/2021) with ongoing high fever (Tmax 104F), Admission labs found rhabdomyolysis (CK >100,000 on day 2), elevated lactate (4.4), acute liver injury (AST/ALT >5000), elevated Cr (3.8) requiring CVVHD, DIC, shock, and respiratory failure requiring urgent intubation.
1063461	3/1/2021	NC	73	M	1/16/2021	1/27/2021	Episodes (seizure-like appearance), left arm and leg muscle tension/contraction (clutching of hand, raising of leg), leftward face contortion, extreme pain along entire left side. Periodicity: many events some days (at least 11 events on one day), some days (even a few in a row) no events. Examination for stroke and heart attack were negative. Initial diagnosis of faciobrachial dystonia, followed by negative laboratory blood-test confirmation of diagnosis. No current diagnosis. Several rounds of treatment by IV steroid and oral steroid.
1063449	3/1/2021	NY	31	F	2/26/2021	2/26/2021	Reported trouble breathing , then fainted , was assisted to the floor. epi pen givenx2 Large Tonic Clonic like movements with no loss of consciousness (pseudo seizure) was taken to ED
1062863	3/1/2021	PA	52	F	2/24/2021	2/26/2021	I suffered what seemed to be a seizure on Friday 2/24. It was witnessed by my adult daughter. I was seated on a sofa, my eyes closed and I lost consciousness. My daughter reported that my arms went back and forth as did my head. I woke back up and felt dizzy but fine otherwise. I have never had a seizure or anything like that happen to me on the past. I did have all flu like symptoms (fever, chills, body aches, headache) 12 hours post vaccine which I expected to happen. All of these flu like symptoms occurred 2/23 and were essentially gone by 2/24. I am not reporting the flu like symptoms as ?adverse ?. I am simply reporting the seizure like activity that occurred approximately 1:00 pm on 2/24. I did not seek medical attention but I am following up with my doctor. No more seizures have occurred.

<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>
1062853	3/1/2021	MO	16	F	2/3/2021	2/3/2021	Per MD's note on patient's chart on 2/26/21: Spoke with both the patient's mother and father today. Patient is 16 and received Moderna vaccine. Both state's current guidance and my correspondence with CDC indicate that she should receive 2nd dose of Moderna and not change to Pfizer. Patient does have a history of Rett Syndrome (rare neurologic genetic defect). Parents report 1 week after receiving Moderna vaccination, she experience her first seizure and was transported and treated at Hospital. Seizures can be a feature of this disorder but the patient had not experienced one in the past. Her parents report that her Neurologist does not believe the seizure to be related to vaccination. I informed parents I would search the VAERS system for similar reports. They were not enrolled in V-Safe, but I encouraged them to do so and gave them a link to the CDC site for registration. Correspondence with CDC (via email): "If the Moderna vaccine is inadvertently administered to patients 16 or 17 years old instead of Pfizer-BioNTech as the first dose, CDC currently recommends that the Moderna vaccine may be administered as the second dose (as off-label use). The second dose should be administered as close to the recommended interval as possible, 28 days for the Moderna vaccine. Additional information regarding administration errors and deviations can be found in CDC's current interim clinical considerations regarding mRNA COVID-19 vaccines.
1062650	3/1/2021	NH	74	M	2/21/2021	2/22/2021	At approximately 24 hours after his vaccine, Pt started to have problems with his vision and headache on the right side. It took 2 calls to 911 before I could convince him to go to the ER. While there, he suffered 2 grand mal seizures and he was transferred to another hospital for further treatment.

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1062218	3/1/2021	VA	93	M	2/10/2021	2/12/2021	seizure; unresponsive for 20 minutes; This is a spontaneous report from a contactable physician reporting for himself. A 93-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number/expiration date: not provided), via an unspecified route of administration, on 10Feb2021 at 15:45 (at the age of 93 years old) as a single dose for COVID-19 IMMUNIZATION. Relevant medical history included dementia from an unknown date. The patient previously 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 21Jan2021 (at the age of 93 years old) as a single dose in the deltoid right for COVID-19 IMMUNIZATION. The patient did not have any known allergies. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included atorvastatin and levothyroxine. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 12Feb2021 at 13:30, the patient experienced a seizure and was unresponsive for 20 minutes. Treatment for the events included careful observation and airway protection. The outcome of the events seizure and unresponsive was recovered on an unspecified date in Feb2021. 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.; 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 Seizure and Unresponsive to stimuli 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.

<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>
1064256	3/1/2021	NM	18	F	2/18/2021	2/19/2021	Pt presented by EMS for acute epigastric pain radiating to the back. While waiting for lab results, she was found down in her room and in post-ictal state. She was moved from an urgent care room to an ER bed and returned to near baseline when she had witnessed seizure activity and subsequently required multiple medications to break her status that lasted around 30 minutes
1064325	3/1/2021	OR	30	M	1/28/2021	1/29/2021	Next day unstable 1/26-1/27-1/28 Seizures 1/26- 1/27 - 1/28 Behaviors 1/26-1/27-1/28 Total incontinence 1/26- 1/27-1/28 Eye swelling 1/28-1/29 Red bicep 2/8 - 2/12
1062563	3/1/2021	KS	18	M	2/26/2021	2/27/2021	Fever of 102.5 and seizures

<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>
1064312	3/1/2021	MI	77	M	2/26/2021	2/27/2021	Reported via Nurse Triage / PCP: Fainted earlier, eyes rolled back, mouth was drooping. Nausea, weakness, and chills. BP was 107/75, HR in the 70s. Currently alert and resting. States that patient had his 2nd covid vaccine yesterday AM and then develop chills and clammy skin last night. Symptoms worsened today and patient became weak and fainted. Was unconscious for about 5 minutes and while unconscious, mouth was open and drooling and became incontinent and eyes rolled back in head. Is awake and alert now, but still weak and only able to take 1 or 2 steps. No chest pain or breathing difficulty and no fever. Feeling very nauseous. Caller requesting prescription for zofran. Yesterday AM 2nd vaccine. Last night chills. This AM feeling weak. Today at 11am he felt weak with ambulation. He fainted. Was unconscious for 5 min. Had drooping of the face. He was unresponsive during this time. Had incontinence of urine. Then became awake but very weak still. Only able to walk a few steps. He is communicating. No chest pain. No current fever. No shortness of breath. BP 107/75 with HR 70. He has been very nauseated. He is drinking only small sips of water. Does not seem like a usually COVID-19 vaccine reaction. Given the LOC with urinary incontinence and sustained weakness, I advised ER evaluation to rule out neurological issues. Pt's daughter in agreement. They will go to ER. From Emergency Department: Patient presenting with chief complaint of syncopal episode which was witnessed by his wife. He reported the got dizzy and lightheaded and then passed out while seated. The reported duration of his loss of consciousness was somewhat inconsistent, unclear how long he passed out for, there was however no postictal state. He was not noted have any shaking or seizure activity, he did have an episode of urinary incontinence. He has not been feeling well ever since receiving his 2nd COVID-19 vaccine. By the time of my exam patient states that he is completely asymptomatic, he states he is feeling much better after receiving IV fluids. His lab work is remarkable for a slightly low sodium, compared to his previous levels which were many months ago. Unclear of the acuity of this, although upon further discussion with the patient he has been drinking large amounts of water since his vaccine trying to stay hydrated. I advised him to substitute to some electrolyte balanced fluids and to have his sodium rechecked by his

<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>
							PCP to ensure that this is transient. With negative testing and resolution of his symptoms he is stable for discharge home. Close return precautions were given.
1061233	2/28/2021	CA	64	F	2/18/2021	2/18/2021	With in seconds of receiving vaccine had seizure like effect in head resulting in out of body like experience, muffled hearing, a foul taste in my mouth and altered state of euphoria. Could not report symptoms but if had been asked directly could have. REalised half way driving home that I should not be driving. Euphoria lasted for 24 hours. Was on phone constantly the next day for 7 hours straight without eating. Could not remember what some items were like a drone. Had to ask = that thing that flies with a camera. Short term memory loss that continues. Facial numbness began 48 hours after injection. Facial numbness continues changing in areas of right side of my face. Felt extremely vulnerable. Wore my same clothing for 4 days as I did not remember that I had clean clothing. Did not remember that I should notify medical personal until late 2/20.
1061096	2/28/2021	MA	25	F	2/21/2021	2/21/2021	Seizure after vaccine overnight. Patient has a history of seizures.
1060869	2/28/2021	UT	48	M	2/24/2021	2/28/2021	Aural symptoms and seizure like symptoms. Patient has been seizure free for eight years with Zonegran controlling tonic/clonic seizures. The patient experienced persistent seizure like aural symptoms, ringing in ears for four to five hours post onset and post dictal tiredness.
1060629	2/28/2021	KY	72	M	2/18/2021	2/28/2021	RECEIVED BOTH DOSES OF PFIZER VACCINE ON 01/28/21 & 02/18/21. ON 02/28/21 WENT ER FOR POSSIBLE SEIZURE ACTIVITY. AND DIAGNOSED WITH NEW ONSET SEIZURE AND THROMBOCYTOPENIA AND ADMITTED INPATINET INTO HOSPITAL.
1060569	2/28/2021	OH	29	F	1/4/2021	2/27/2021	Vaccine recieved January 4th and 2nd shot recieved January 26th. Both pfeiffer On 2/27/2021 I became aphasic confused could not remember my name or say anything coherent. Husband called 911. MRI EKG CAT EEG done all negative. Speculating a TIA or seizure.
1060494	2/28/2021	FL	65	M	2/23/2021	2/25/2021	Seizure. Loss of consciousness. 911. Ambulance to ER. Stabilization and release.

<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>
1060429	2/28/2021	PA	42	F	2/24/2021	2/25/2021	Stated with body aches and fever. Body aches became extreme on day 2 after shot. Day three after shot started with motion temors. I move in any way and my body starts to tremor. If I try to walk to far are do too much I shake so much I get dizzy and collapse. Bystanders stated it looked like I was having a seizure
1059220	2/27/2021	NC	35	F	1/26/2021	2/4/2021	??I had a SEIZURE?? -only symptoms I had right before it happened were: 1-headache and 2-Dizziness -lasted almost 4 minutes, it was tonic clinic -911 was called and I went by ambulance to ER
1060299	2/27/2021	CA	30	F	2/23/2021	2/23/2021	Feb 23rd beginning around 8 PM: High fever (102), full-body rash (hives) particularly around abdomen, chest, and neck, pain/swelling around injection site, nausea and vomitting. Feb 24th - fever and rash persisted Feb 25th - rash persisted around chest and throat, spread to under jawline, extreme fatigue, pain/swelling and redness increased at injection site, severe migraine (did not respond to max dosage of ibuprofin). Feb 26th - rash persisted just around throat/jawline, extreme fatigue persisted, pain/swelling, redness and itchiness around injection site increased, migraine persisted, large sheets of dead skin peeling off the inside of mouth (e.g., cheeks, tongue, roof of mouth) Feb 27th - rash around throat faded, pain/swelling/redness around injection site faded, increased itchiness around injection site, extreme fatigue persisted, migraine persisted, increased amounts of dead skin peeling off inside of mouth (e.g., cheeks, tongue, roof of mouth). *The skin peeling off of the inside of my mouth (e.g., cheeks, tongue, roof of mouth) happened to me once before several years ago after a week of taking a new anti-epileptic medication (Topamax), which my neurologist prescribed to me to treat seizures following a traumatic brain injury. After a week on Topamax, the inside of my mouth began to peel uncontrollably, and so my neurologist instructed that I stop the medication immediately as I appeared to be having an allergic reaction to it. Perhaps there are similar compounds in the Moderna vaccination to Topamax, to which I may be allergic.
1060238	2/27/2021	FL	72	F	2/1/2021	2/27/2021	Uncontrollable shaking and twitching in entire body. Looks like an all day seizure. Symptoms began at approx 2pm, 27 hours after second Moderna injection

<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>
1060204	2/27/2021	TX	68	F	2/27/2021	2/27/2021	Pfizer-BioNTech COVID- 19 Vaccine EUA Approx 5 minute post vaccination, patient began reporting itching. Shortly after, developed a dry cough and reported that her throat "felt funny." Patient began vomiting and having difficulty breathing, speaking in 1-2 word sentences. Pt received epi pen to left thigh, with some resolution of symptoms. Pt continued to have cough and nausea, chest pain. Gave 25 mg benadryl IM at 08:27 am. Patient received 2nd dose of Epi for increased SOB, difficulty breathing, and increasing cough, with some resolution of symptoms. Patient reported increased chest pressure. Began having seizure like activity at 08:30, lasting approx 20 seconds with no post ictal period noted. EMS arrived after 2nd dose of epi. Second "seizure like" activity after EMS arrival, lasting approx 20 seconds. During transport to ambulance, patient had 2 more episodes of seizure like activity with no post ictal phase. ED note states low suspicion for true seizure since patient was awake during episodes of tonic clonic movements, answering questions during, and did not have post ictal state.
1059487	2/27/2021	NY	31	F	2/26/2021	2/26/2021	Injection into left deltoid. 1min later felt "aura" (muscle weakening, light headed). Took two pumps of rescue inhaler and took out Epi Pen. 2 Mins later: called for help, nurse gave patient provided EpiPen (I was shaking too much to inject myself), additional Epi from crash cart, non rebreather O2. Symptoms included: convulsions; dizziness; bronchospasms; throat closure; difficulty breathing; dry heaving.

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1059437	2/27/2021	IL	37	F	2/27/2021	2/27/2021	Patient states 30 seconds after the injection, she began to feel nauseated. She stated the following symptoms came on "Like a wave": Dizziness, light headedness, ears ringing, sound pulsing, and her vision began to go black. She described the field of vision closing like that of a loony toons show ending (coming from the outside in). Patient was found to have her eyes closed, hyperventilating at a rate of 28 breaths per minute. Ice pack placed on her neck. She was coached to slow her breathing, instructed to hold her breath for 10 seconds, then to release it slowly. She did this for 3 minutes. She related her body felt tingly all over. Encouraged patient to continue the slow breathing. As patient began to feel better, she related that she has a known needle phobia. She expressed that she becomes anxious even when she is not the one receiving a shot, and this fear stems from a traumatic experience of her son having a seizure after a shot. She works at a school and when they do first aid training and cover the diabetes section, the pictures of needles make her anxious. Patient provided with therapeutic communication, encouraged to discuss fears with her counselor. Patient remained seated in clinic until she felt well enough for her husband to drive her home.
1059263	2/27/2021	MA	67	M	2/26/2021	2/26/2021	Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe, Systemic: Shakiness-Severe, Additional Details: Patient was sitting in observation and his head and eyes rolled back. He was observed to go into a shock state, possibly seizure for a few minutes. After a few minutes, patient regain orientation and was alert and was able to answer questions before the ambulance arrived. Patient left with the ambulance to the emergency room.
1059264	2/27/2021	MA	67	M	2/26/2021	2/26/2021	Systemic: Fainting / Unresponsive-Severe, Systemic: shortness of breath-Severe, Systemic: Seizure-Severe, Systemic: Shakiness-Severe, Additional Details: Patient was sitting in observation when he suddenly had his head and eyes rolled back. Patient's daughter alerted the pharmacist on duty that he felt like he couldn't breathe. Patient went into a possible seizure. His eyes rolled back and his body went stiff. After a few minutes, patient was alert and oriented enough to answer questions coherently before the ambulance arrived. Patient went on the ambulance.

<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>
1057974	2/26/2021	PA	70	F	2/25/2021	2/26/2021	Patient reported having 2 seizures at 7:30am and another around 9:15-9:30am the day after vaccination. She has had seizures in the past and is not on any maintenance medication for this condition. She did not require immediate medical attention.
1056449	2/26/2021			F			Convulsions due to pain; Severe pain; A spontaneous report was received via voicemail from daughter, concerning her mother, a female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced convulsions due to pain and severe pain. The patient's medical history was not provided. No relevant concomitant medications were reported. On an unknown date, the patient received their first of two planned doses of mRNA-1273 (Lot: unknown) intramuscularly for prophylaxis of COVID-19 infection. On unknown date, the reported stated her mother experienced severe pain to the point of convulsing. She mentioned her mother was at the doctor. No treatment information provided. The outcome for the event, convulsions due to pain and severe pain, were unknown.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.

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1056476	2/26/2021	WV	73	M	1/14/2021	2/10/2021	Seizures; Mini stroke; Tired; A spontaneous report was received from a consumer concerning a 73-year-old male who received Moderna Covid-19 vaccine and experienced seizures, mini stroke, confused, agitated, eyes were abnormal, memory impairment, and tired. The patient's medical history included heart attack and stent placement in 2011. His relevant concomitant medications include acetylsalicylic acid, candesartan cilexetil, clopidogrel bisulfate, diltiazem hydrochloride, ezetimibe, adenosine, gabapentin, metoprolol tartrate and rosuvastatin calcium. The patient received their first of two planned doses of mRNA-1273 on 14 Jan 2021. On 10 Feb 2021, 30 minutes prior to the onset of the events, the patient received his second of two planned doses of mRNA-1273 (Lot#010M20A) intramuscularly in left deltoid for the prophylaxis of COVID-19 infection. On 10 Feb 2021, With in 30 minutes of receiving the vaccination, the patient had a seizure. They took him to the hospital, where he had a computerized tomography (CT) scan, blood work and had a consult. After consult, they said, it's a mini stroke. They released him and told her if it happens again call 911. He felt so tired and went to sleep at home. Around 17:00 dinner time, he woke up looked very blankly, and his wife reported knowing he had another seizure. She reported he ran to his keys saying, "I have to go", seemed confused, agitated and didn't know where he was. She called 911 and he was transported to the hospital in an ambulance. Around 19:00 the same day, he was admitted to do scans overnight. Around 21:00, patient's eyes were abnormal, he became agitated again and nurses confirmed he was having another seizure. 30 minutes later, he was talking to his wife and daughter as if he didn't remember anything. He mentioned some metallic taste in his mouth. On 11 Feb 2021, they did an electroencephalogram (EEG) and confirmed that he was having seizure. He was prescribed seizure medication and released him from hospital. However, the patient and his wife reported not wanting him to take the medication as they believe the events were due to the vaccine. Treatment information was not provided. Action taken with vaccine is not applicable as the patient received both the doses. The outcomes of the events, seizures, mini stroke, and tired, were recovered.; Reporter's Comments: Very limited information regarding this event

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							has been provided at this time. The patient's medical history of heart attack and concomitant medication use can be confounding factor. Further information has been requested.
1056611	2/26/2021	TN	78	F	1/22/2021	1/1/2021	Swelling, which is hard like an egg, at the injection site; Redness at the injection site; Very lethargic; This is a spontaneous report from a contactable consumer. A 78-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot and expiry date unknown), via an unspecified route of administration at the age of 78 years, on 22Jan2021 at a SINGLE DOSE for covid-19 immunisation. Medical history included ongoing type 2 diabetes mellitus, ongoing urinary tract infection, hyperparathyroidism from 21Jan2021 and ongoing, ongoing osteopenia, ongoing meningioma, seizure from an unknown date and unknown if ongoing. The patient received the first dose on 02Jan2021. On 23Jan2021, the patient experienced swelling, which was hard like an egg, at the injection site and redness at the injection site. The patient was also very lethargic on an unspecified date. No treatment was received for the events. The outcome of the event lethargic was unknown while other events were not recovered. Information on the Lot/Batch number has been requested.

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1056657	2/26/2021	CA	71	M	1/23/2021	2/2/2021	10 days after 1st dose patient suffers ischemic stroke 4 days later the patient suffered a seizure; 10 days after 1st dose patient suffers ischemic stroke 4 days later the patient suffered a seizure; This is a spontaneous report from a contactable consumer. A 71-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) on 23Jan2021 at 08:00 at single dose via an unspecified route of administration on left arm for COVID-19 immunization. Relevant medical history included Parkinson's disease, dementia, Post-traumatic stress disorder, high blood pressure and high cholesterol. Concomitant medication were not reported. It was mentioned other vaccine on 28Jan2021, but no further information provided. On 02Feb2021 at 12:00 am, 10 days after 1st dose of BNT162B2 patient experienced ischemic stroke and 4 days later the patient suffered a seizure. The events resulted in 6 days of hospitalization. At the time of the reporting the patient was recovering from events. Information about lot/ batch number has been requested
1056844	2/26/2021	CT	43	F	2/23/2021	2/24/2021	Seizure
1056850	2/26/2021	NY	51	M	2/5/2021	2/10/2021	At about 2am on 2/10/21, Patient got up from bed and fell down a flight of stairs. He was initially bleeding and unconscious and was brought by EMS to the hospital. Upon arrival at the hospital he had a temperature of 40 C. He was found to have 2 small left temporal hemmorrhagic contusions on CT scan. He had a seizure during the hospitalization. He was initially treated for HSV encephalitis but it is not clear if that was confirmed. The hospital team may not have known of the recent vaccination. He improved during the hospitalization, but remained with a very unsteady gait. He could not return to the group home. He was transferred to a rehab facility to receive PT on 02/16/2021. He remains at rehab. Prior to the fall, on the 3rd day after vaccination, on 2/8/21 at about 10 am, the patient coughed and had a small blood on the inside of his face mask while at his day program. He was seen by his PCP and had no abnormal findings. He had a CBC, BMP and CXR and all were unremarkable.

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1057237	2/26/2021	TX	43	M	2/26/2021	2/26/2021	I have a video showing a tonic seizure less than 10 minutes after injection.
1057260	2/26/2021	TX	74	M	2/1/2021	2/1/2021	Patient returned for there second dose and when stated that when he arrived home from his 1st vaccine he had 2 seizures that his wife witnessed and 1 while he was alone. Patient did not report the reaction to anyone at the office or the via the VSafe app. The provider was consulted and 2nd dose was not given. Patient is to follow up with his PCP as he does not have a history of seizures.
1057774	2/26/2021	IN	70	M	2/26/2021	2/26/2021	Pt had seizure like activity-- head back, eyes rolled back, face red Lasted about 1 minute PT was lowered to the ground by staff out of chair No other injuries Pt then had nausea and vomiting -- was observed for about 1 hour-- more nausea and vomiting as he was taken to the car Pt agreed to be seen in the ED-- was given zofran and released Later wife stated he has similar reactions to other immunizations
1058800	2/26/2021	WI	41	F	2/9/2021	2/19/2021	ON FEBRUARY 19,2021, PATIENT HAD A GRAND MAL SEIZURE IN THE EVENING. SHE REPORTED TO THE EMERGENCY DEPARTMENT AND THE CASE WAS DISMISSED AND SHE WAS SENT HOME. ON FEBRUARY 21, 2021, PATIENT HAD ANOTHER GRAND MAL SEIZURE AND WAS HOSPITALIZED. SHE WAS DISCHARGED ON KEPPRA 1000 MG TWICE DAILY. SHE REPORTS SHE HAS SWELLING ON THE LEFT SIDE OF HER BRAIN AND CONTINUES TO HAVE SMALLER SEIZURES WHERE SHE IS AWAKE BUT NOT RESPONSIVE.
1057997	2/26/2021	SC	69	M	2/25/2021	2/26/2021	~~Feeling Hot" without fever and nausea 10 hours post vaccine and resolved within 1 hour. Seizure, Hypotension, Unresponsive followed shortly by cardiac arrest and pulseless electrical activity 21 hours post vaccine. Pronounced dead 22 hours post vaccine
1058049	2/26/2021	OH	48	F	2/23/2021	2/24/2021	She developed new onset acute psychosis. Was admitted to hospital for management and monitored overnight with head imaging, labs and an EEG that did not show any seizure activity. Psychosis appears to have resolved over past 24 h (several days after injection) - d/c from hospital last night 2/25.

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1058147	2/26/2021	FL	88	M	2/6/2021	2/10/2021	Two complex seizures; An 88-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; Lot number: UNKNOWN) via an unspecified route of administration on 06Feb2021 (at the age of 88-years-old) as a single dose for COVID-19 immunization. Medical history included atrial flutter from an unspecified date and unspecified if ongoing. It was reported that the patient was not diagnosed with COVID-19 prior to vaccination. Concomitant medications (within two weeks) included warfarin sodium (COUMADIN). It was reported that the patient did not receive any other vaccine within four weeks prior to the COVID-19 vaccination. The patient experienced two complex seizures, serious for hospitalization, on 10Feb2021. The clinical course was reported as follows: "Two complex seizures confirmed by ED (emergency department) physician. No history of seizures. Negative CT head and labs. Unclear if seizure was related to COVID vaccine 5 days prior." It was reported that treatment was not received for the event. The clinical outcome of the event two complex seizures was recovered/resolved on an unspecified date. It was also reported that the patient had not tested positive for COVID-19 post vaccination. No follow-up attempts are possible; information about lot number cannot be obtained.; 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 Seizures 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.
1058255	2/26/2021	NC	56	M	1/27/2021	1/27/2021	Patient developed seizure 30 minutes after receiving injection. This was witnessed so EMS was called and taken to ED and had another seizure which was witnessed by our staff. I examined patient post ictal.

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1056624	2/26/2021	MI	69	F	1/22/2021		The pressure across my chest and like under my ribs about 6 inch hold away across; I did feel like vomiting; This is a spontaneous report from a contactable consumer (patient). A 69-year-old female patient received the first dose of bnt162b2 (Pfizer-Biontech Covid-19 Vaccine), Batch/lot number: EL9261, via an unspecified route of administration on 22Jan2021 at single dose in left arm for COVID-19 immunisation. Medical history included bypass surgery in Mar, diabetic and seizures from an unknown date and unknown if ongoing. The patient was taking several medications. Patient stated she had the first vaccine (Covid-19 Vaccine by Pfizer) on last Friday and done okay but then she had 10 O'clock in the morning and about 1 O'clock in the morning she woke up with all the pressure across her chest and like under her ribs about 6 inch hold away across and she did feel like vomiting and she was wondering if that was a reaction to that shot and if she should get the second one, she was just kind of concern what she should do it. No treatment was received for the events. The events didn't require Physician Office/ Emergency Room visit. The patient didn't perform any test. The outcome of the events was unknown.
1058650	2/26/2021	KS	65	M	2/24/2021	2/24/2021	Started with coughing, about 4 hours after the vaccination, then chills and fever, I visited the ER about 31 hours after the shot. They gave me an IV to reduce my fever. I slept well the second night , other than my muscles ache. Then on Friday morning which was about 47 hours after the vaccination, I had a seizure.
1058959	2/26/2021	NV	59	M	2/24/2021	2/25/2021	About 8 hours after my second injection I had alot of muscle aches, felt hot with no fever, and was very tired. At about the 13 hour mark I had a seizure, was unconscious and unresponsive. My wife called an ambulance and I was taken to the ER.
1058874	2/26/2021	TN	66	F	2/25/2021	2/25/2021	Patient had seizures like symptoms after receving Pzifer Covid vaccine. EMS was called but patient was not transported. Patient was released to home
1057706	2/26/2021	IL	78	F	2/4/2021	2/5/2021	Patient has episode of amnesia possibly cause by seizure. Patient also had headache, chills, fatigue.

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1055536	2/25/2021	NC	42	F	2/25/2021	2/25/2021	The staff member was given a Covid-19 vaccination as part of the LTCF Covid-19 clinic scheduled on 2/25/2021. During the 20 minute observation period the patient lost consciousness and begin to have seizure-like shaking. An 0.3mg epi-pen was administered in the lateral thigh. The patient then experienced cardiac arrest at which point nurses from the LTCF began and completed 2 cycles of CPR before the staff member was resuscitated. EMS arrived and assessed the patient. Patient was taken to the hospital for further evaluation.
1055962	2/25/2021	IN	73	M	2/3/2021	2/17/2021	Seizures, with bad head pain, followed with loss of speech. High with blood cell count, indicating infection, but none found. Was on a breathing, and feeding tube. Was in hospital for one weeks time. Now in a Rehab facility, with loss of memory and balance.
1054253	2/25/2021	WI	70	F	2/8/2021	2/8/2021	PT WAS GIVEN VACCINEE. WITHIN 3 TO 5 MINUTES, SHE APPEARED TO BE HAVING A SEIZURE. AID WAS ADMINISTERED. RPH HELD HER UPRIGHT (PT WAS FALLING OUT OF HER SCOOTER). 911 WAS CALLED AND ICE PACK APPLIED TO CHEST TO HELP WITH FIGHT OR FLIGHT FEELING. SHE WAS NAUSEOUS, LIGHT-HEADED, AND FAINTED. PT WAS HELD UNTIL EMT'S ARRIVE, AT WHICH POITN SHE WAS COHERENT. STAFF AT FACILITY BROUGHT THE PATIENT ORANGE JUICE. SHE WAS OK WITH SITTING AND STANDING BP O F96/62. SHE FELT BETTER AND REFUSED TO GO TO THE HOSPITAL.
1055645	2/25/2021	FL	41	F	2/5/2021	2/18/2021	Seizure 2 weeks later with overnight hospitalization after not having seizure since 10/2016
1053753	2/25/2021	TN	40	M	2/23/2021	2/25/2021	Seizure lasting about 1 1/2 minutes with vomiting afterwards off and on for 30 minutes. He was very tired on the 24th.

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1053781	2/25/2021	IL	81	F	2/23/2021	2/23/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Seizure-Severe, Additional Details: The incident happened at COVID clinic. Patient was receiving the 2nd dose of the vaccine. The first time we administered the vaccine to the patient, she informed the immunizer that she had a bad cough for 3 days. The patient did mention that she suffers from seizures often. The 2nd dose was administered by the RPH immunizer and was directed to the waiting area for 15 minutes. During that time in the waiting area, she was talking to the.
1055799	2/25/2021	AZ	54	F	2/9/2021	2/10/2021	I have auras/warning signs when my brain is unstable or close to having a grand mal seizure. I had about 10 of these episodes in the following 60 hours post vaccination. They DID NOT progress to grand mal seizure. Last from 5-15 minutes. Having this many is as odd for me as for a general person.
1054196	2/25/2021	CT	64	M	2/24/2021	2/24/2021	Seizure like activity 2 hours following vaccine
1054557	2/25/2021	HI	38	M	2/23/2021	2/23/2021	Flu like symptoms followed by two episodes of fainting and convulsions requiring ambulance 15 hours after vaccine.
1054564	2/25/2021	CA	34	M	2/18/2021	2/19/2021	Blacked out: I was attempting to put on a sweater to go to the bathroom. I had my arms up and felt a lot of pain in my arm, and blacked out and fainted. I don't recall the events for the next 60 seconds. My wife said that I fell on the bed, was unresponsive, saw foaming at the mouth, had seizure, and urinated in my pants. She adjusted the bed so that my head is up, and threw cold water at my face, mouth and teeth, which made me responsive, and then walked me to the bathroom. During the night, I had fever, Chill, pain at injection site, vomit, nausea, headache, light-headed. I didn't have appetite in the morning and had nausea and headache. I felt better ~3pm when I could finally eat rice, yogurt and chicken. I am feeling well now, but worry that the seizure had caused any long term damage.
1054627	2/25/2021	SC	57	M	2/19/2021	2/20/2021	Febrile Seizure - treated at the hospital, happened the following day

<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>
1054867	2/25/2021	CA	67	F	2/17/2021	2/18/2021	I had a seizure after second shot
1054991	2/25/2021		38	M	2/13/2021	2/23/2021	Per Dr.'s admit note: "Etiology unclear though favor meningitis/encephalitis given 2 days of viral symptoms, headache, questionable neck pain, and low-grade fever of 100.6. Had first COVID-19 vaccination on 2/13. Cannot exclude paraneoplastic syndrome; possible hilar mass noted on CXR will need further work-up to rule out sarcoid/malignancy. Concern for viral meningitis. No known sick contacts. Another tonic-clonic seizure occurred around 08:00 on 2/24 AM with vomiting; no overt aspiration though certainly high risk given situation.~~

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1055535	2/25/2021	WI	70	F	2/25/2021	2/25/2021	<p>Patient was alert and conversational throughout first COVID-19 Pfizer vaccination. During post vaccination waiting period, patient became unresponsive and exhibited convulsion like movements in her waiting chair. Pharmacist quickly evaluated patient and patient was only minimally responsive to painful stimuli only. Breathing was rapid, shallow, and irregular with an expiratory wheeze heard upon auscultation. Patient was slouched in chair but supporting self and had a strong grip with her left hand. Skin condition was warm but diaphoretic. Ambulance 911 service was called. No swelling of the throat, mouth, face, nor lips was seen. Patient continued to be non-responsive, with non-comprehensible sounds, and was not opening eyes or following commands. Due to worsening ability to breathe and wheezing on expiration, epinephrine 0.3 mg was administered intramuscularly into the left thigh at 1230 on 2/25/2021. Approximately 5 minutes after epinephrine administration, the patient's work of breathing improved, wheezing was diminished upon expiration, and respiratory rate had slowed to 16 breaths per minutes. BP was 160s/80s and HR 98 (after epinephrine administration). Patient began opening eyes spontaneously but was still not following commands. Ambulance service then arrived, report was given, and patient was transported to Hospital Emergency Department. Patient was under the care of Doctor at the emergency department and received albuterol/ipratropium nebulization, dexamethasone 10 mg IV, famotidine 20 mg IV, and magnesium sulfate 2 g IV. After the physician evaluated the patient and talked with family, the patient's family stated that the patient has a history of anxiety related reactions such as this with convulsion like activity. Doctor then determined that the patient did not have an anaphylactic/allergic reaction and instead had a anxiety related vasovagal type reaction. Doctor stated that the patient could receive the second COVID-19 vaccine dose in 3 weeks without issue. Patient then discharged from Emergency Department (unsure if AMA). Patient then presented to the pharmacy with her daughter after discharge to fill in staff on the outcome of the reaction. Patient appeared to be at baseline mentally and physically. Pharmacist contacted Emergency Department to discuss case with patient's nurse to obtain information about medications</p>

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							received in the emergency department. Patient daughter stated that she would like to be present for second dose of vaccine to help avoid a similar anxiety related reaction from occurring.
1054160	2/25/2021	IL	36	M	2/11/2021	2/12/2021	2/12/2021 woke up with sore arm and back. 2/13/2021 woke up with headache around 1am. Headache and nausea all morning. Mid-late afternoon started having seizures. Admitted to Hospital 2/15/2021 expired. Reported per wife on 2/25/2021.
1052032	2/24/2021	NC	44	M	2/19/2021	2/19/2021	Patient had seizure, provider could not find pulse, administered 2 rounds CPR and applied AED, EMS notified. Patient alert and awake after 2 rounds CPR and was admitted to hospital.

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1051263	2/24/2021	PA	71	F	1/27/2021	2/1/2021	<p>Passed away; Found unconscious; Coma; Lack of oxygen to the brain; A spontaneous report was received from a consumer, concerning his mother, a 71-year-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and passed away, prior to death, patient experienced lack of oxygen to the brain and was found unconscious and went to coma. The patient's medical history reported included seizures. Concomitant medications included phenobarbital, lamotrigine and levetiracetam. On 27 Jan 2021, approximately six days prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 (lot number: 030L20A) intramuscularly for prophylaxis of COVID-19 infection. On 01 Feb 2021 at 4 am, the patient was found to be unconscious on the couch, hence she was rushed to the hospital with lack of oxygen to the brain. Later, she went into a coma, hence she was in hospital for 30 hours and then was transferred to a different hospital for a second opinion on 06-Feb-2021, where she was passed away at 02:20 PM. Treatment information was not provided. Action taken with mRNA-1273 in response to the events were not applicable. The outcome of events, lack of oxygen to the brain, found unconscious and coma were considered unknown. The outcome of event passed away was fatal as she died on 06 Feb 2021 at 2:20 pm. The cause of death was not provided. Plans for an autopsy were unknown.; Reporter's Comments: This is a case of 71-year-old female subject with a history of seizures who died 6 days after receiving first dose of vaccine. Very limited information has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Passed away</p>

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1051301	2/24/2021	NC	51	F	1/25/2021	1/26/2021	Exhausted; Night terrors; This is a spontaneous report from a contactable consumer, the patient. This 51-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EL3248), DOSE 1, single dose via unknown route of administration in the left arm on 25Jan2021 about 3:45pm (at the age of 51 years-old) for COVID-19 vaccination. Medical history included ongoing severe asthmatic onset date unknown, probably during childhood but worsened with age and became really bad after hurricane, ongoing irregular heartbeat, ongoing menopause, ongoing food allergies includes banana peppers, jalepenos and nuts; anything spicy; these cause anaphylactic reactions where her throat is itching and swells, ongoing Hashimoto's disease, thyroid, endocrine abnormality and compromises immune system, to keep her brain going through menopause, seizure disorder and high blood pressure. Past drug events included Demerol-Vistaril: ate part of her leg away, top layer of her leg just fell off; she had all the skin done and had plastic surgery to repair this in 1988; Lot/NDC/Expiry: Unknown, does not have product, anaphylactic reactions to: penicillin: Lot/NDC/Expiry: Unknown, does not have product; clindamycin: Lot/NDC/Expiry: Unknown, does not have product; sulfa: Lot/NDC/Expiry: Unknown, does not have product; Darvocet: Lot/NDC/Expiry: Unknown, does not have product; Ceclor: Lot/NDC/Expiry: Unknown, does not have product. There was no family medical history relevant to events, night terrors and exhausted. Concomitant medications included atenolol 12.5mg taken once daily (1/2 of 25mg tablet) for irregular heartbeat, levothyroxine 125mcg taken once daily for thyroid, bupropion (WELLBUTRIN) 300mg taken once daily for menopause, amphetamine aspartate, amphetamine sulfate, dexamphetamine saccharate, dexamphetamine sulfate (ADDERALL) 20mg extended release taken once daily to keep her brain going through menopause, topiramate (TOPAMATE) 25mg taken once daily for seizure disorder and lisinopril 10mg taken daily for high blood pressure. On 26Jan2021, the patient had night terrors where she started screaming in her sleep at midnight and was exhausted at 05:00 and ongoing. There were no relevant tests. The night terrors and exhausted did not require a visit to the physician's office or emergency room. The clinical outcome of night terrors

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1051522	2/24/2021	WI	88	M	2/22/2021	2/23/2021	was recovered with sequel and not recovered for exhausted. 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): None.
1051604	2/24/2021	PR	66	F	2/18/2021	2/24/2021	Patient brought to emergency department at 2210 with concern for stroke d/t left sided weakness. Upon arrival patient appeared to have seizure like activity and was given 2mg of ativan and keppra 1000mg. Patient remained able to converse with providers during episode. Seizure activity/muscle twitching resolved after ativan/keppra administration. At the time of filing this report the patient is being admitted to the hospital.
							The next day of vaccination, early in the morning wake up having convulsions.

<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>
1050997	2/24/2021	AL	77	M	1/30/2021	1/31/2021	seizure; hospital staff "couldn't wake him up"; A spontaneous report was received from a consumer who was also a 77-year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced a seizure. He was hospitalized for one night and the staff had a difficult time waking him up. The patient's medical history included prostate cancer last year. Patient provided that he takes 8 or 10 different medications daily but did not list them out. No other medical history was shared and patient has no known drug or food allergies. On 30-Jan-2021, prior to the onset of the events, the patient received one of two planned doses of mRNA-1273 (Lot number: 042L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 31-Jan-2021, the day after the mRNA-1273 vaccine was given, the patient had a seizure and was hospitalized for one night. He stated that the hospital staff had a hard time waking him up. He spent one night in the hospital and was released on 01-Feb-2021. It was not reported what caused the seizure and the patient was unsure if the hospital knew that he had the vaccination the day prior. He was discharged with Keppra. Consent to contact was given by the patient to contact him and the hospital. No further treatment information was not provided. Action taken with mRNA-1273 was not reported. The events, seizure and depressed consciousness level, were considered resolved on 01 Feb 2021.; Reporter's Comments: Very limited information regarding these events have been provided at this time. Further information has been requested.
1052249	2/24/2021	NY	55	F	2/24/2021	2/24/2021	Patient had a Petit Mal Seizure SP vaccine administration . Seizure lasted 25 seconds , followed by somnolence. Patient fully recovered from the seizure. Her vitals were taken , BP found to be extremely elevated. Patient has an existing hx of seizure , stated that she took her BP and seizure medication this AM . Patient refused to go to the ER for further evaluation . Patient was informed of all possible outcomes including stroke and / or death. Patient signed AMA and patient states she will call the ambulance from home of she continues to feel ill. Patient left the clinic after 1 hour.

<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>
1052665	2/24/2021	AZ	70	F	2/23/2021	2/24/2021	A little after midnight, I woke up shaking because I was so very cold. It felt almost like a seizure because my lack of control was evident in my movements. With my heaviest PJs on, it took 8 blankets to finally warm me up. I am on a CPAP machine but I was having a hard time getting my breath. I was also nauseous but never threw up. I finally got back asleep a little after 3 am but woke several times after that. This morning, I had a terrible headache and can't get rid of it. Although I feel better than last night, I feel lousy. It is now 2 pm and I just want this to be over. On the first shot, I didn't have any reaction at all.
1053044	2/24/2021	CA	35	M	2/24/2021	2/24/2021	35 yo male, aprox 510 minutes post vaccination pt fell to floor. Immediately had seizure activity. Impact was on forehead area with a moderate size hematoma noted and abrasion. Pt is able to answer questions but not remember conversation prior to fall. VS initially were 99% o2 sat, hr-68, 82/43, hr 51. o2 via nc applied @ 2l per nc. o2 sat 99-100%. Skin cold, clammy, ashen, post seizure activity noted. EMS called. Father called was in car waiting and came into building. Pt transported to medical center via ambulance. Last VS 108/76, 100%, hr-87, r-20@1456. 1445 b/p 60/44, hr44, o2 sat-99%, r-18.
1053233	2/24/2021	SC	94	M	2/22/2021	2/23/2021	tonic clonic seizure hospitalized for observation
1051938	2/24/2021	WA	40	F	2/20/2021	2/20/2021	Patient had witnessed seizure like activity for 30 seconds. Patient transported to ER on Gurney with RN All extremities contracted with grunting Airway maintained After activity was alert pale diaphoretic
1051935	2/24/2021	KY	83	M	2/16/2021	2/17/2021	Patient fell 12 hours post shot and then had a seizure.
1050126	2/23/2021	IL	31	M	2/18/2021	2/18/2021	1145 vaccine administered 1147 patient stood up from chair and then had syncopal episode. Fell face first onto floor. Hit head on wall trim on the floor. Eyes dilated, fists clinched, arms and legs shaking, not responding to verbal cues. Seizure like activity last approximately 1.5 minutes 1150 called 911 1200 ambulance arrived on scene. patient c/o lightheadedness and needing to continue to lay down 1210 transported patient to ER at Hospital

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1048195	2/23/2021	CO		M	1/11/2021	1/26/2021	Seizures; Seizure; A spontaneous report was received from a physician assistant concerning a patient of unknown age who experienced seizures. The patient's medical history was not provided. Concomitant product use was not provided/unknown by the reporter. On 11JAN2021, approximately 16 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 for prophylaxis of COVID-19 infection. On 26JAN2021 and 29JAN2021, the patient experienced seizures. The patient does not have history of seizures. The patient was transported to the ER for treatment and they had a consult with a neurologist on 08FEB2021. The neurologist advised the patient that it would be ok to get the second dose of the vaccine. The events seizures, was considered resolved on 26 Jan 2021 and 29 Jan 2021.; Reporter's Comments: This case concerns a male patient, who experienced a serious unexpected event of seizure (twice) after receiving first dose of mRNA-1273 (Lot# unknown). Very limited information has been provided at this time. Further information has been requested.
1048835	2/23/2021	MD	74	M	2/3/2021	2/5/2021	Multiple Seizures: no long term side effects
1049109	2/23/2021	MN	23	F	1/27/2021	2/23/2021	Patient had a first time seizure and she has no other risk factors for seizure. Of note, the patient had COVID-19 infection three months ago and received her first dose of the Moderna vaccine three weeks ago
1049496	2/23/2021	OH	19	F	2/8/2021	2/23/2021	Bells Pals half of face, numbness, weakness, headache, fever, diarrhea, nausea, chills, body aches, fatigue., tics and then a few days later had a gran mal seizure, forgetfulness

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1049699	2/23/2021	VT	55	M	2/6/2021	2/7/2021	Per H&P and physician notes, patient was admitted to hospital on 2/7/21 with status epilepticus from home. He had received his second dose of COVID19 vaccine on 2/6/21 per Emergency Department note. Patient was febrile on admission (40.7 Celsius) and was intubated. Patient had issues with hypotension, neurologic impairment, and metabolic issues. Received pressors, IV fluids, Keppra, IV antibiotics to cover for possible CNS infection. Lumbar puncture performed. Abnormal EEG on 2/9/21. Recurrent seizure on 2/10/21. Pt extubated on 2/12/21. Blood cultures, urine culture, and CSF culture all no growth. Sputum culture mixed oral flora. As of 2/22/2021, patient tolerating tube feeds, shakes head yes and no responding to questions.
1049869	2/23/2021	NY	46	F	2/23/2021	2/23/2021	While Pt was sitting in the waiting area she began to has partial upper body "seizure" also breathing problem that included tightness in her throat, husband alerted staff who then alerted EMS, upon arrival to the Pt she was saying under her breath "EPI" Pt quickly moved to the back of the tent to the EMS area where EPI .3 administered in the left thigh, lung sounds where having wheezes in both sides. within minutes she stated she felt much better. As we obtained Pt demographic she again stated her throat was feeling tight, second dose of EPI .3 given, within minutes it happened again a total of three EPI .3 given and 50mg of Benadryl given, ambulance arrived to transport.
1049902	2/23/2021	VA	17	F	2/13/2021	2/13/2021	Patient is 17yo here for COVID 19 Pfizer Vaccine; Within 15 minutes of the shot, she developed unresponsiveness. She has snoring, seizure disorders, OSA, hypertension, developmental delay, elective mutism. Her mother called us to the room Per mother , She was unresponsive, her lips were blue and she was pale She has had no recent seizure; compliant with Keppra She was very anxious prior to the vaccine. She was at baseline this am per mom prior to the shot.

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1050464	2/23/2021		23	F	2/23/2021	2/23/2021	10 minutes post vaccination during observation, patient fainted and did not rouse immediately. I administered ammonia inhalant was used within 1-2 minutes of her LOC, and patient gained consciousness but was diaphoretic and pale. Within 2 minutes of the ammonia inhalant, she began convulsing (full body convulsions, eyes rolled) For 30-45 seconds. She had continued LOC for 1-2 minutes, 15L O2 mask was administered, and patient slowly came in and out of consciousness for the next 5-10 minutes, bradycardic 35-45 bpm, BP 72/50, HR irregular, RR 16 BS clear. At the time of observed convulsions, 911 was called and arrived within 10-12 minutes. When EMS arrived, she remained pale but with some improved pallor, HR 45 bpm, and more alert. Transported by EMS to hospital for eval.
1050500	2/23/2021	WV	18	F	2/20/2021	2/20/2021	Around 7 o'clock I woke up shaking and sweating, I felt like I was having a seizure. My arm also felt like it had been stabbed over and over again. This lasted for three hours
1048874	2/23/2021	IL	86	M	2/11/2021	2/11/2021	Approximately 30 minutes after receiving the vaccination dad had a seizure, and he continued having seizures for 24 hours. He developed a low grade fever of 99.4 for 24 hours. He was very ill for 8 days and has been continuing to recover slowly.
1049873	2/23/2021		76	M	2/19/2021	2/23/2021	Patient had the Moderna vaccine 1st dose roughly 5 days ago. Overnight, his wife woke to him having an episode of what appeared to be a tonic clonic seizure around 5 am on 2/23/21, followed by a period of disorientation and unresponsiveness consistent with a post ictal state. The patient has no history of seizures. It is unclear if this had anything to do with the Moderna vaccine, but I am reporting it due to the timing of the episode in conjunction with the vaccine.
1048746	2/23/2021	TN	76	F	2/22/2021	2/22/2021	Systemic: Seizure-Medium
1047200	2/22/2021	OR	40	M	1/13/2021	2/5/2021	Patient had breakthrough seizure on 2/5/2021. Last prior seizure was 5/2020 before starting Keppra. It is not clear if seizure was related to vaccine.

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1047596	2/22/2021	CA	78	M	2/18/2021	2/19/2021	Stroke and seizure (In the past he had a stroke and seizure) So this is not his first time and we are not sure if this is related to the vaccine.
1047391	2/22/2021	NY	32	F	2/15/2021	2/15/2021	Lightheaded. Skin was clammy, convulsions started, Epi pen administered, she had tongue swelling, came around then eyes rolled back in head, nausea, blood pressure high.
1047328	2/22/2021	AZ	26	F	2/19/2021	2/19/2021	Individual comes to mass vaccine administration clinic .Consent form and risks were reviewed with the individual prior to receiving vaccination. Individual received 1st dose of Moderna Vaccine, Lot # 015M20A, NDC 80777-273-10, 7/29/21 expiration. Individual was given 0.5ml of Moderna Vaccine IM and then escorted to waiting room for monitoring for 30 minutes. Individual had no reactions to the vaccine or complaints but after 13 minutes at 3:53 pm she started with a seizure and was unconscious. 911 was called and her vitals monitored. 3:59 pm pulse 62, O2 98%, BP 125/77 blood sugar 77.Smelling stick was used and individual slowly woke up. Staff from the center she came from came over and states that individual does have a history of seizures. Paramedics on the scene asses individuals vitals and share that she had a seizure and left since individual signed not to go to the hospital 4:05 individual took a clonazepam 0.125 from her purse and took it po. Individual remained stable and alert 4:14 individual was assessed again vital 110/83, pulse 60, O2 96% Patient was stable the rest of her 30 minutes post vaccine administration individual left stable with staff. Individual motioned that she was feeling better since she does not speak Individual was given follow up vaccine appointment in 30 days but was told she needed to get a note from her provider that she is able to have a second vaccine.
1047276	2/22/2021	LA	57	M	2/3/2021	2/7/2021	For two days after the second injection, which I received on Wednesday, February 3, I had fever and chills. I did not feel myself that Saturday or Sunday. Sunday evening, February 7, at 8:00pm, I had a Grand Mal seizure. I was transported to the emergency room by EMS, treated and released.

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1047607	2/22/2021	MA	81	F	2/3/2021	2/12/2021	Received 1st dose Feb 3 @ 7am. Felt minor soreness for 2 days. Felt fine afterwards. Feb 12 developed flu like symptoms, headache mild fever, tiredness. Symptoms progressed Sat & Sun. Monday she was speaking with her brother who said she wasnt making sense. Called ambulance & brought her to hospital. Ran CT scan, multiple MRIs and did spinal tap. Diagnosed with HSE enciphilitis. Has had multiple seizures. Very confused, can barely speak, doesnt recognize or understand who people are. Troubling motor skills.
1046597	2/22/2021	OR	36	F	2/20/2021	2/20/2021	muscle pain, fatigue, seizures
1045926	2/22/2021	RI	79	M	2/16/2021	2/16/2021	Site: Pain at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: slurred speech, confusion, possible seizure, minimal right side of body function-Severe, Systemic: Numbness (specify: facial area, extremities)-Severe, Systemic: Seizure-Severe
1045819	2/22/2021	WV	74	F	2/4/2021	2/5/2021	Had seizure 2/5/21 . Does have dx of seizures disorder
1045809	2/22/2021	OK	41	M	2/15/2021	2/15/2021	Approximately 14 hours of shot I suffered 3 partial seizures (20-30 second duration) in short succession with 5-10 minutes of each other. I was awake and aware during all 3 events. After 3rd, I had a severe headache lasting 24-36 hours.

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1045735	2/22/2021	MA	29	F	2/20/2021	2/20/2021	Around 5:30 PM I began experiencing normal symptoms like headache and muscle ache. At 8:15 PM I began to feel light headed, nauseous, and short of breath. Around 8:20 I needed to lay on the floor to prevent myself from fainting. My eyes were rolling back because I was borderline unconscious. I felt like I had no control of my body and had to go to the bathroom. For around 15 minutes I was on the floor convulsing, shaking as if I had chills and my muscles were involuntarily tensing. My pulse was extremely low. After the convulsions stopped I remained on the floor an additional 15 minutes. Around 8:45 PM I was able to return into my bed with assistance. My nauseous remained and I began experiencing chills. I slept on an off the entire night. At about 1 AM what I suspect was a fever began to break and I was extremely sweaty. For the following day I experienced exhaustion and muscle soreness. I am still experiencing exhaustion. I recognize a bulk of my symptoms were normal but the convulsions, losing consciousness, and inability to control my body seemed worth reporting.
1047278	2/22/2021	OR	58	F	2/18/2021	2/21/2021	Initially, sore arm and some upper trunk muscle soreness on the day after vaccine. 3 days later, admitted to the hospital after witnessed fall by husband - cardiac arrest. Seizures seen today. Unsure if directly related to the vaccine, as there are several days between vaccination and the arrest, but no new medications or issues since vaccination.
1261998	2/21/2021		57	M	1/28/2021	1/29/2021	Narrative: 56 y/o male with history of seizure disorder received second dose of COVID-19 vaccine on 1/28/21 while inpatient. The following morning, he told nurses he felt like he had a seizure in his sleep. The nocturnist witnessed an active seizure later that morning, and the patient was transferred to the ICU. A total of 5-6 seizures were documented that morning. According to his chart, he also has a seizure following his first COVID-19 vaccine. Of noted, the patient has had multiple intermittent breakthrough seizures during his hospitalization since being admitted back in 9/2020.
1042986	2/20/2021	DC	73	F	2/20/2021	2/20/2021	Patient began to experience seizure activity(shaking and verbalized didn't feel well and sensed seizure coming on) during the 15 min observation period after her 2nd vaccine.

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1042821	2/20/2021	TN	18	M	2/15/2021	2/18/2021	Hypothermia. Four days after second dose body temp dropped to 94 degrees F. Evaluation for sepsis was unremarkable. CBC was normal, blood cultures were negative. Hypothermia was treated with warming devices. Increased seizure activity was noted. Keppra was started for increased seizure activity. Hypothermia resolved with resolution of the seizures.
1042868	2/20/2021	CO	52	M	2/15/2021	2/15/2021	Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Severe, Systemic: Seizure-Medium, Systemic: Shakiness-Severe, Additional Details: About 5 minutes after receiving vaccine, patient was seated in observation area and notified facility staff member who was in charge of observing patients that he felt faint. Staff member reported patient quickly turned extremely red and was showing seizure-like activity, unconscious. She alerted the pharmacists to come over I came over and patient appeared bright red, pupils extremely dilated and was not conscious, grabbed pt arm he woke up and then showed typical vasovagal symptoms thereafter.
1043158	2/20/2021	ME	78	F	2/10/2021	2/10/2021	Potential Absence Seizure duration 5-10minutes, vomiting at conclusion. Episode occurred roughly 40 minutes post vaccination. Patient returned to her baseline following episode. EMS called and patient evaluated in ED and returned to facility with no lasting effects.
1043880	2/20/2021	IN	59	F	2/19/2021	2/20/2021	Pt received second Moderna COVID-19 vaccination administered in left arm at her assisted living facility by Pharmacist at 1153 on 2/19/2021. Pt was monitored for vaccine reaction with no known adverse reaction. Approximately 18 hours post-vaccine, she was found deceased in her sleep at 0540 on 2/20/21. Per circumstances/pt history, it is presumed that the patient aspirated while sleeping, perhaps secondary to a seizure. Coroner was notified and declined as coroner's case. VAERS notification being made due to pt death within 24 hours of receiving a vaccine.

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1043776	2/20/2021	NY	92	M	2/13/2021	2/20/2021	Patient with severe muscle weakness with tremulousness 3 days post-vaccination, and subsequently patient developed new onset seizure like activity on 2/20/2021 around 3:30 pm requiring admission to the hospital for further evaluation and monitoring. All events occurred within the 14-day period post vaccination.
1043475	2/20/2021	OH	63	F	2/17/2021	2/17/2021	Patient had seizure of clonic tonic activity was post-ictal. Non verbal and did not respond to questions.. Transferred to ER via squad.
1042578	2/19/2021	NY	37	F	2/18/2021	2/19/2021	After 12 hours, extreme shakes and shivers, hot and cold, fainted and possible seizure for approximately 30-45 seconds- could not move or speak- was unresponsive and panting- cognitively aware but unresponsive.
1040594	2/19/2021	NY	25	M	2/17/2021	2/18/2021	Grand mal seizure. Lasting 4 minutes , unconscious for 10/12 minutes. Transported to hospital via ambulance. Vomiting and loss of bladder.
1042346	2/19/2021			F			Seizures; This is a spontaneous report from a contactable consumer (parent). A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date were unknown), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunisation. Medical history included epilepsy. The patient's concomitant medications were not reported. The patient hadn't had seizures in 3 years but 36 hours later from receiving her first dose, she had her first seizure after 3 years. Outcome of the event was unknown. Information on the lot/batch number has been requested.

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1042340	2/19/2021	NC		F	1/21/2021	1/1/2021	Seizure; AFib; Terrible chills; Muscle pain where every muscle in her body hurt; shaking like crazy and could not stop; This is a spontaneous report from a contactable consumer (patient). This female patient of unspecified gender received the 1st dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 21Jan2021 at single dose for covid-19 immunisation. Medical history and concomitant medications were unknown. On Sunday night, the patient had to go to ER because she was having terrible chills and was shaking like crazy and could not stop. It lasted 45 minutes. She went to the hospital. They kept her in emergency room. She had AFIB and had a seizure from it. She thought she was dying. After she had this and finally thought it might be a side effect from the injection. She did not know it was in the muscle and she had muscle pain. Thought she was getting beaten by a stick. All evens were in Jan2021. They also called 3 times for her to come back in to get the second dose. She was sure this was what caused it. Every muscle in her body hurt. At the time she did not know it was injected into the muscle. She did not want to go through this again. She wanted to know if she should get the second dose. Outcome of the event shaking like crazy and could not stop, Terrible chills was recovered on Jan2021. Outcome of the events Muscle pain where every muscle in her body hurt, AFib, Seizure was unknown. Information on the lot/batch number has been requested.
1042142	2/19/2021	UT	23	M	2/5/2021	2/6/2021	Seizure-like episodes. No treatment at this time.
1041767	2/19/2021	MI	80	F	2/17/2021	2/19/2021	This resident sustained 2 seizures, 45 minutes apart, and an elevated temperature of 101 F on 2-19-21. The first seizure occurred at approximately 8:45 am and the second at approximately 9:30 am. The resident does not have a seizure disorder or history of seizure activity other than 1 day after receiving the first dose of the same vaccine on 1-20-21.
1041474	2/19/2021	WI	88	F	2/14/2021	2/15/2021	unresponsive, possible seizure, flushed skin, clammy, slight foamy mouth

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1041424	2/19/2021	NC	24	F	2/18/2021	2/18/2021	Eyelids blinking/ Not Responding BP 164/106, EMS called In a few minutes she was responsive, anxious had a tremor, but according to caregiver at facility the tremor was normal. EMS took her to hospital as a precaution, thought she had a seizure due to anxiety. She is treated for anxiety and seizures.
1040564	2/19/2021	MD	41	M	2/1/2021	2/1/2021	Tonic clonic seizure; This is a spontaneous report from a contactable physician. A 41-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date unknown), via an unspecified route of administration on 01Feb2021 14:00 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced tonic clonic seizure on 01Feb2021, the same day. The patient received the dose at 14:00 and had the seizure around 19:00. Patient has recovered from the event on an unspecified date. No treatment was received for the event. Information about lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported tonic clonic seizure and the administration of the COVID-19 vaccine, BNT162B2, based on the reasonable temporal association and lacking alternative explanations. 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.

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1040563	2/19/2021	NY		M			<p>Lost consciousness; possibly had a seizure; tingling in his hands; unable to speak; felt dizzy; was tired afterwards; felt sick; This is a spontaneous report from a contactable physician. A 27-year-old male patient started to received dose 2 bnt162b2 (UNSPECIFIED TRADE NAME), via an unspecified route of administration from an unspecified date to an unspecified date at SINGLE DOSE for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient received BNT162B2 first dose on unspecified date with unspecified lot and expiration date. The patient reported at 4:30 after second dose of vaccine lost consciousness for 15 seconds on an unspecified date, possibly had a seizure on an unspecified date, tingling in his hands on an unspecified date at 9:00 in the evening, unable to speak on an unspecified date for 15 seconds, felt dizzy on an unspecified date, was tired afterwards for about 2 hours on an unspecified date, and felt sick on an unspecified date. Outcome of event Lost consciousness was recovered, possibly had a seizure was unknown, tingling in his hands recovered, unable to speak was recovered, felt dizzy was unknown, was tired afterwards recovered, and felt sick 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 seizure, LOC and other 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 including Head CT/MRI, serum toxicology screen, chemistry panel and EEG, 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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1040547	2/19/2021	TX	21	F	2/6/2021	2/7/2021	Mini seizures; Body chills; A spontaneous report was received from a consumer, concerning herself, a 21-year-old female patient, who received Moderna's COVID-19 vaccine and experienced mini seizures and some chills. The patient's medical history reported includes seizures. Concomitant product use was not provided by the reporter. On 06-FEB-2021, prior to the onset of events, the patient received her second of two planned doses of mRNA-1273 (lot number unknown) intramuscularly for the prophylaxis of covid-19 infection. On an unspecified date in Jan-2021, the patient received her first dose of vaccine and on 07-FEB-2021, a day after the second dose of vaccine, patient experienced some chills and mini seizures. Treatment information was not provided Action taken with mRNA-1273 in response to the events were not reported. The outcome of the events, mini seizures and some chills were considered unknown at the time of this report.; Reporter's Comments: Based on temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded, however, patient's history of seizure is a confounding factor that may a possible contributory role. Further information has been requested.
1041110	2/19/2021	ME	52	F	2/18/2021	2/18/2021	Around 10 minutes after vaccination patient alerted pharmacy staff members at the clinic that she had a "weird taste in her mouth like she has when she has seizures". Employees of her congregate-care facility came over and told pharmacy staff that she does not have true seizures, but rather "pseudo-seizures" as part of her mental health condition. The pharmacy staff has the patient immediately sit back down. She appeared to have lost consciousness one time. Staff reported her eyes seemed glazed over. The patient denied any feeling of throat closing or tingly of lips or tongue. The pharmacy staff was able to obtain a carotid pulse but due to obesity was unable to take a blood pressure even with a large cuff. At that point pharmacy staff called 911 to get patient further evaluation. EMS evaluated the patient and declined transport and instead returned her to her apartment. Congregate-care staff reported that patient has a history of this type of reaction when being around groups of people.

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1041385	2/19/2021	IL	70	F	1/15/2021	1/16/2021	Recieved vaccine on 1/15/21, seizure activity noted on 1/16/21 at 2pm. Transferred to hospital. Cause of seizure unclear. Admitted to Hospital returned to facility on 1/22/21. Recieved 2nd COVID-19 dose with no side effects noted.
1038368	2/18/2021	MD	45	F	2/14/2021	2/14/2021	Got at the mass vaccination site, is a drive through site. Husband was driving. Pt herself was in passenger seat Reports she had her first covid vaccine 2/14/21 (pfizer) around 10:30am Placed in left upper arm about 10 min after the injection + pain at the site, and then felt tight in shoulder Then became nausea and her husband woke her up; and was about 15 seconds per her husbands report No seizure activity No rashes No throat swelling No swelling No n/v The vaccine staff then came over to her parked car Took her BP and reports was low, cannot recall how low Was starting to feel okay when the vaccine staff came over, reports was a national guard MD, who said he advised an epi pen due to her reaction, then to call 911. And then was given epinephrine and then called the ambulance Pt was feeling better when the EMT arrived, and was taken into the ambulance, she declined the ER Went home, husband drove home, and she rested on the couch the rest of the afternoon Has been feeling fine every since Feels well, eating drinking like normal, no syncope, no rash, no changes to skin, no arm pain
1038711	2/18/2021	CA	38	M	2/12/2021	2/12/2021	Received dose around 5pm, by between 7-8pm I had body aches, and severe chills - almost to the point of convulsion. Woke up with a fever in morning, fever off and on the following day, fatigue the following two days. By day two I was having difficulty breathing while laying down, shallow breaths. I went to urgent care by the fourth day because the breathing difficulty increased, to the point where it was hard to breathe sitting up. Dr. at the urgent care did chest Xray and EKH, which were both normal. He tested me for COVID-19 and the results were negative. It is now day 7 and I am still having shallow breathing, with what feels like an unclearable chest congestion, and cough.

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1038625	2/18/2021	MI	54	M	2/15/2021	2/16/2021	Pt resides at an facility, normally communicative and interactive. Received his second dose of the Moderna COVID-19 vaccine 2/15 and complained of a head ache after. The morning of 2/16 he was found to have a fever of 104.8, altered mental status, possible seizure like activity and taken to ED. ID consulted due to high fever, AMS, LP recommended to rule out meningitis. Due to the patient being on warfarin he needed to be reversed first which was done. The following day he was back to his baseline and afebrile. LP was canceled at that time.
1038617	2/18/2021	CA	29	F	2/5/2021	2/10/2021	Symptoms reported: headache grand mal seizure. Was transferred to ER on 2/10/21. Per staff report ? I was sitting on the couch, and my partner noticed I have having a seizure, he lowered to me to the ground and called the ambulance. My seizure lasted for 1 minute. When I was in the ER, they gave me 2 bags of fluids, they did an X-ray, CT scan, blood work, and UA, they reported to me that all the result were normal. They did not send me home with any medications. However, they did not clear me to drive. They said that I need to get cleared by a neurologist before I can drive, so that?s why I have not been back to work?
1038560	2/18/2021	NC	78	M	2/12/2021	2/13/2021	PT WAS VACCINATED ON FRIDAY. ON SATURDAY HE HAD A SEIZURE. HE WAS HOSPITALIZED AND LATER PUT ON A VENTILATOR. PT WAS DISCHARGED SUNDAY
1038383	2/18/2021	MI	60	F	2/15/2021	2/16/2021	Pt received Moderna vaccine, 2nd dose on 2/15/2021. She was subsequently admitted to the hospital for fever and Seizure on 2/16. Pt also noted to have fever ~104F. She does have a history of seizure disorder and is maintained on anti seizure medication. Suspect the seizure related to high fever ~104F possibly from her vaccination.

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1039952	2/18/2021			U			Two report of death related to the vaccine were reported in a young premature baby and 25-year-old young person who dies 15 minutes after receiving the vaccine.; a young premature baby received BNT162B2; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer reported similar event for 2 patients. This is 1st of 2 reports. A patient of unspecified age and gender (reported as a young premature baby) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. The consumer stated his main concern was even though the vaccine had been authorized. The vaccine was only given vaccine on the side of the road. People were dying from the vaccine more than from the virus. He gave out some percentage of people that could die from the virus vs from the vaccine. The percentage of death rate was 0.00045% from the virus. The percentage of death from the vaccine was 6.6%. There were many people reporting side effects such as bell's palsy, whole body convulsion. Two report of death related to the vaccine were reported in a young premature baby and 25-year-old young person who died 15 minutes after receiving the vaccine. He said it's sad these were front line worker who were facing all these side effects. The outcome of the event was fatal. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021157531 same reporter, drug, event, different patient; Reported Cause(s) of Death: Two report of death related to the vaccine were reported in a young premature baby and 25-year-old young person who dies 15 minutes after receiving the vaccine.
1038263	2/18/2021	NH	29	F	2/13/2021	2/13/2021	concerned about some focal bruising, erythema and soreness at the site of injection (L deltoid). Patient states she did not have any reaction to the first dose aside from some muscle tenderness. Denies fever, chills, seizure, headache, arthralgias, N/V, abdominal pain, diarrhea, urticaria, dyspnea, wheezing.

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1038252	2/18/2021	IN		F	1/4/2021	1/7/2021	<p>Nervous system disorder NOS; Severe uncontrollable body movements, my tongue was also affected; Allegedly having an adverse reaction with seizures; A spontaneous report was received from a consumer who was a 42-year-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced attack on nervous system, severe uncontrollable body movements, and allegedly having an adverse reaction with seizures. The patient's medical history, as provided by the reporter, included hysterectomy. No concomitant medications were provided. On 04 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot Number: 011L20A) for prophylaxis of COVID-19 infection. On 07 Jan 2021, the patient's tongue began to spasm. On 08 Jan 2021, the patient's whole body had been convulsing all day. The patient reported that it was attacking her nervous system on an undisclosed date. She visited four hospitals in two days; all blood work was normal. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, attack on nervous system, severe uncontrollable body movements, and allegedly having an adverse reaction with seizures, was considered not recovered/not resolved.; Reporter's Comments: This case concerns a 42-year-old, female patient with medical history of hysterectomy, who experienced serious, unexpected event of seizures and non-serious, unexpected event of dyskinesia and nervous system disorder NOS. The events occurred 4 days after the first dose of mRNA-1273 (Lot Number: 011L20A) 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.</p>

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1038190	2/18/2021	MD	70	F	2/17/2021	2/17/2021	Patient is prone to seizures. She received the Covid shot. At about 4:00 pm that afternoon she began to have a seizure. I was very atypical of her previous seizures. She began the seizure at a very low level (no outward signs other than total confusion and unable to speak. This condition lasted until about 8:pm. Now and again she would do her normal "shake". The seizure eventually stopped. Additional dose of Keppra was given as well as a few drops of Lorazepam.
1038427	2/18/2021	IL	40	F	2/16/2021	2/16/2021	Heart palpitations immediately (2/16 at 6:15pm) but subsided within 10 minutes. Nausea started about 8pm night of vaccine along with extremely sore arm. Nausea persisted all night and at 5am felt like I was going to be sick so went to bathroom. Sat down on toilet and don't remember anything until I woke up on bathroom floor with two knots on my head. Unsure if syncopal episode or seizure as I have multiple knots on head and my belongings from my pockets were strewn about the floor. Body aches began around noon day after shot along with low grade temps and chills. Nausea and headache persists today (2/18) but I am unsure if that is from vaccine or head injury.
1038828	2/18/2021	FL	69	F	2/15/2021	2/15/2021	Within 15-minutes of vaccination, EMS evaluated the patient for "focal seizure like activity". No other information was given and no EMS report was submitted for the incident. There have been no hospital visits identified for the patient's condition.

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1039430	2/18/2021	CT	83	M	2/4/2021	2/4/2021	VAMS ID 100781798. On the day following vaccine administration, the wife of named individual called to report non-allergic symptoms that occurred approximately 7 hours after vaccine administration. Wife reports that after husband awoke from a nap that lasted about 2 hours she observed him to have bilateral "whole body" muscle stiffness including "legs crossed and could not uncross them" and stiff jaw like a "lock jaw". Lasted 20 minutes and then he was well the following day and beyond. He has a known but unspecified, well controlled seizure disorder but symptoms did not resemble usual seizure activity. Reporter notified usual health care office, and patient was seen by Dr. on 2/8/21. I spoke with his wife who reported symptoms to our office. Wife advised that per Dr. he classified it as a post-vaccination "adverse neurological event". Wife further advised that per Dr., patient can proceed with getting his second dose of Moderna COVID-19 vaccine.

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1039954	2/18/2021			U			Two report of death related to the vaccine were reported in a young premature baby and 25-year-old young person who dies 15 minutes after receiving the vaccine.; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer reported similar event for 2 patients. This is 2nd of 2 reports. A 25-year-old patient of unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. The consumer stated his main concern was even though the vaccine had been authorized. The vaccine was only given vaccine on the side of the road. People were dying from the vaccine more than from the virus. He gave out some percentage of people that could die from the virus vs from the vaccine. The percentage of death rate was 0.00045% from the virus. The percentage of death from the vaccine was 6.6%. There were many people reporting side effects such as bell's palsy, whole body convulsion. Two report of death related to the vaccine were reported in a young premature baby and 25-year-old young person who died 15 minutes after receiving the vaccine. He said it's sad these were front line worker who were facing all these side effects. The outcome of the event was fatal. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021155151 same reporter, drug, event, different patient; Reported Cause(s) of Death: Two report of death related to the vaccine were reported in a young premature baby and 25-year-old young person who dies 15 minutes after receiving the vaccine.
1040063	2/18/2021	FL	71	M	2/18/2021	2/18/2021	Patient had a mild seizure and passed out for about a minute

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1040157	2/18/2021	WI	16	F	2/18/2021	2/18/2021	A minute after receiving vaccine, client lost consciousness for approximately 30 seconds paired with facial twitching. No history of seizures and history of syncope due to holding breath and anxiety with medical procedures and vaccinations in the past.EMS was called, client was evaluated by EMS upon arrival, parent was called and history verified. It was discussed with parent that PCP and client have a plan in place for these kinds of reactions to go home and continue monitoring, so client was driven home by friend.
1040163	2/18/2021	OH	52	F	2/18/2021	2/18/2021	patient was waiting in vaccine observation area. patient reported to us not feeling well. instructed patient to sit down, as she was going back to her seat, she began to have what appeared to be seizure. Bystander and I held patient to prevent her from hitting head on ground until seizure stopped and put patient in recovery position. paramedics called by pharmacy staff and dispatched. paramedics took patient for further medical care
1040170	2/18/2021	OR	37	F	2/6/2021	2/13/2021	Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.

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1040233	2/18/2021	NV	77	F	2/18/2021	2/18/2021	PATIENT STARTED TO HAVE SEIZURE WHILE SHE WAS IN HER WHEELCHAIR ABOUT 10 MINUTES AFTER HER VACCINATION. PATIENT'S DAUGHTER AND I WERE WITH HER WHILE SHE WAS HAVING SEIZURE. SHE WAS AWARE WHAT WAS GOING ON BUT HER BODY WAS SPASMING. SHE DID NOT HIT HER HEAD AS SHE WAS IN HER CHAIR AND DAUGHTER ASKED US NOT TO CALL AMBULANCE (OFFERED TO CALL RIGHT AWAY) AS HER SEIZURES USUALLY PASS AFTER A FEW MINUTES. AFTER A FEW MINUTES (PATIENT WAS SITTING WHOLE TIME), SEIZURE PASSED AND HER BODY WAS NOT SPASMING, PATIENT STAYED FOR ADDITIONAL 20 MINUTES TO BE MONITORED IN CASE ANYTHING HAPPENED. NO TREATMENT WAS GIVEN EXCEPT GIVING PATIENT WATER (PATIENT HAS HISTORY OF LYMPHOMA, SEIZURES (ON MEDICATION FOR IT PER DAUGHTER)). AFTER 30 MINUTES, PATIENT RECOVERED AND WAS BACK TO NON-SEIZURE STATE. DAUGHTER STATED IT WAS FINE TO LEAVE AND NO ADDITIONAL HELP WAS NEEDED AND PATIENT WITH DAUGHTER LEFT.

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1040300	2/18/2021	CT	41	M	1/26/2021	1/31/2021	<p>Patient is a 41 y.o. male on no AC/AP with no pmhx reported presents 1/31 PM initially to Hospital for acute onset 10/10 headache refractory to 800mg motrin which started in occipital region then spread to whole head and neck, nausea and vomiting x 3. Symptoms started around 5pm when he was on a conference call and reports he got bad news so was stressed out. Denies any recent trauma. Pt received toradol 30mg, dexamethasone 10mg, benadryl 25mg and reglan 10mg at hospital prior to transfer. CT showed diffuse SAH and CTA showed no signs of obvious aneurysms. He then received 1g IV keppra and was started on Cardene for BP goal <140. He was transferred to NICU for further monitoring. While in the NICU, his exam and imaging remained stable. He underwent CTA which was unrevealing, and DSA which showed evidence of vasculopathy. BPs came down to <160 and he came off of cardene, did not require additional meds. He was transferred to the floor. Upon transfer, he had another thunderclap HA, accompanied by HTN to the 200s systolic, tachycardia to the 120s, diaphoresis, and blotchy macular rash over the anterior shoulders. Imaging was negative for vasospasm or recurrent bleed, and it was felt that patient's presentation was most c/w RCVS. Trigger felt either 2/2 caffeine intake (patient reported drinking 60 oz coffee daily) vs. Sympathetic discharge syndrome such as pheochromocytoma or carcinoid syndrome. LP was performed, which revealed no nucleated cells and protein elevated in proportion to blood, which confirmed the diagnosis of RCVS. Studies were sent off to diagnose carcinoid syndrome and pheo. Patient was started on nimodipine/gabapentin with standing tylenol and PRN oxycodone for breakthrough pain. Within days, the HAs had markedly decreased in intensity. He was taken off of keppra after 1 week with stable exam and no e/o seizures. He was briefly switched from nimodipine to verapamil but switched back prior to discharge. He was discharged with outpatient followup.</p>

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1086048	2/18/2021	IN	77	F	2/11/2021	2/11/2021	Patient received vaccine @ 1315. At approx 1325 patient showed signs of seizure activity and possible anaph. Patient was laid down flat At 1335 patient was given Epi in (L) thigh and 911 was called. Ambulance showed up at 1345 and patient was taken to hospital. Epi lot# 0FM498 Exp. 05/2022
1040343	2/18/2021	NY	70	F	2/9/2021	2/12/2021	2/9: Received vaccine 2/12: Brain fog - actions disassociated from thoughts 2/14: Altered mental status - in a "fog"; transported to ER via ambulance; neuro exam , diagnostics (CT with & w/o contrast, CTA, CT perfusion, MRI, EEG), COVID -19 PCR, blood work/urine - all negative for intracranial bleed/stroke/tumor, ischemic changes, perfusion issues, seizures, COVID, etc. Diagnosis: Transient Global Amnesia (TGA). Admitted overnight. Amnesia event lasted 7hrs from onset and mental status returned to baseline with no residual effects. The 7hr amnesia period is unable to be recalled.
1039289	2/18/2021	AZ	46	F	2/13/2021	2/13/2021	Pharmacy District Manager: Patient had what was presumed to be a seizure. No epinephrine or any medication was administered on site. Paramedics and Fire Dept was called. She did come to within a couple minutes but was unaware of where she was. She was transported to Hospital. (head school nurse) confirmed with me that she was released from the hospital later that same afternoon.
1040236	2/18/2021	AK	75	M	2/4/2021	2/8/2021	Initial inset of the event was extreme flushing of the face, confusion and with no resulting memory of the almost hour long event. Extreme confusion and some memory loss continued for almost 24 hours. He was taken to Emergency Room because of the fear that it was a TIA or seizure. All test preformed at hospital came back normal (CT Scan, Extensive Labs, EEG, Echocardiogram). He was kept overnight to make sure the event was not a precursor to a stroke. He was released on 2/9/21 and told to make an appointment with his family physician and seek a neurological consult.
1036187	2/17/2021	MI	60	M	1/29/2021	1/29/2021	Patient had a Seizures Without Status Epilepticus after the vaccine. Onsite EMS was called vitals were taken BP 164/100 BG 154 HR 93. Patient Treated and Transported by the EMS to the hospital.

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1037202	2/17/2021	WA	21	M	2/17/2021	2/17/2021	Patient had seizure about 45 minutes after receiving Covid 19 vaccine. Dr at ER confirmed this seizure was not related to Covid vaccine. Patient didn't take Depakote for 2 days. His Depakote level was low. Patient has history of brain tumor and seizure.
1036974	2/17/2021	FL	77	M	2/17/2021	2/17/2021	Mini seizure, jerking limbs , eyes rolling in back of head, choking.
1036956	2/17/2021	IL	75	M	2/11/2021	2/12/2021	I had a seizure. My wife found me on the bathroom floor convulsing. I was unconscious for over an hour and a half. I was taken to hospital by ambulance. I have short term memory lost. All of the scans were normal and all my vitals signs were normal . I never had a seizure before and it was not signs of a stroke on the cat scan.
1036832	2/17/2021	NY	61	F	1/9/2021	1/12/2021	Achy sore/heavy muscles (current to date) , fatigue that grew worse daily (and current to date) , whole body chills that lasted 2-3 hours (until 1/25 and now on occasion) , night sweats (1/12-1/25) , diarrhea (1/23 - 1/25), headache (1/25 to current date), dizziness (1/25). On Jan. 25: Went to bathroom around 3:15 p.m. with diarrhea and became woozy so decided to get off of the toilet and sit down on the floor. Husband found me semi conscious on the floor with drool at about 4:10 p.m. He tried to awaken me and found me not lucid, speech was garbled, fragmented responsiveness and could not keep upright position, could not give details to the situation. Husband called 911. Ambulance transported to hospital ER during hospital exams and tests patient was not lucid and this continued for the next 32 hours. EKG, EEG, CT scan, MRI, Blood/Lab work; all tests were negative indicating no seizure , healthy heart, clear brain scan, no stroke, white blood count normal, dehydrated. All tests negative with all doctors unable to find a reason for this situation other than the Moderna vaccine considered highly for the situation. Advised patient not to take the second dose of Moderna.
1036767	2/17/2021	CA	79	F	1/28/2021	1/28/2021	4 seizure type episodes (including shaking, eyes rolling back for about 15-30 seconds long) after being moved out of bed - lasted 4 days Fever up to 102.5 - lasted 5 days Could not stand - 8 days Body aches - 8 days Could not walk - 9 days Weakness - on going since vaccine Shaking - on going since vaccine

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1036585	2/17/2021	RI	63	F	2/13/2021	2/15/2021	Patient called EMS approximately 1pm on 2/15 with complaints of generalized weakness. Upon arrival EMS found her to be diaphoretic and she had a witnessed syncopal episode with question of v-fib and seizures. She became unresponsive and had no pulse. CPR was begun and she was transported to ED. She remained asystole throughout. CPR was initially continued in the ED for approximately 30 minutes and then stopped with Time of Death noted at 13:27. ED notes noted "suspect given history that patient experienced massive MI, PE or ruptured AAA". Death certificate notes indicate "significant conditions contributing to death after cardiac arrest; ASCVD".
1036455	2/17/2021	OH	38	F	2/12/2021	2/14/2021	On February 14th our dayshift staff arrived at work and upon approach to Patient's room approximately 0700 noted her to very warm and flush. Her temp was taken. She was at 103F. On-call nurse was called. Tylenol was advised and recheck. Prior to recheck Patient's roommate came out stating Patient's was shaking. Staff immediately went to her room to find her actively in a seizure of unknown duration. 911 was called d/t the seizure not ceasing/fever. Squad arrived and Patient was still having tremors. Staff followed to the ER. Patient was intubated and placed on a ventilator. Covid test negative. She is currently at Hospital x3 days.
1038544	2/17/2021	FL	67	F	2/11/2021	2/13/2021	Vaccinated 2/11 and symptoms started 2/13 at noon. Sudden bronchial spasms, obstructive apnea, cyanosis. EMS gave a breathing tx, O2 sats WNL. Declined transfer to hospital at that time for fear of Covid. Client exhibited confusion, oriented x 0, short term memory loss. Bronchial spasms resumed, EMS again called, transported via EMS to MC. Diagnosed with transient global amnesia and hypercapnia. Client was transported to MC for CT and MRI for r/o stroke. Stroke was ruled out. Client with c/o severe H/A, nausea, dizziness, myoclonic seizures. Severe h/a which lasted 4 days. Still experiences mild memory loss, confusion, and h/a are becoming less severe. Client states that sensory processing is slowed
1036286	2/17/2021	WA	44	M	2/12/2021	2/12/2021	Seizure

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1036807	2/17/2021	AZ	37	M	2/16/2021	2/16/2021	immediately following inoculation the individual complained of left arm soreness with alternating cold and hot sensation; he also told the observation nurse that during his 15 minute observation he had "3 seizures." none of the seizures were observed by any of the clinic staff. The individual requested to be taken to the emergency department. The rapid response team assisted him to the ED.
1036087	2/17/2021	NJ	29	F	2/16/2021	2/16/2021	Difficulty breathing- received EpiPen dose, patient was able to breath normally again Shortly thereafter patient was witnessed to have seizure like activity, EMS was called and administered Ativan and Benadryl in route to ED
1036060	2/17/2021	TX	94	F	1/26/2021	1/26/2021	New onset seizure
1036049	2/17/2021	IL	68	M	2/7/2021	2/11/2021	while sleeping experienced what was described as a seizure taken to hospital by ambulance CT scan on arrival showed no indication for the seizure later in day EEG and MRI performed, no abnormalities found keppra (500 mg, twice per day prescribed) waiting for follow up appointment

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1036047	2/17/2021	NY	74	M	1/16/2021	1/24/2021	Short version The patient has long-standing health issues. The patient received the first dose of Moderna COVID-19 vaccine on 1/16/2021 (unknown location). The patient suffered an event in his home on 1/24/2021. CPR and treatment was begun and he was transported to the ED. He was pronounced dead in the ED at 0846. Long version 70-year-old male with past medical history of CAD with pacemaker, A. fib, COPD, hypertension/hyperlipidemia presenting in cardiac arrest. 911 call at 0724. Per EMS, patient was witnessed by family to have seizure-like activity and then collapsed and became unresponsive. Patient was noted by family to be pulseless and CPR was started right away. Patient received two doses of epi by police were on scene first (AED defibrillation x2) and six doses of epi (plus 6 more AED shocks) by EMS when they arrived. Patient had CPR performed for 45 minutes prior to arriving at the hospital. On route, patient had episodes of paced rhythm and V. fib. Patient received one amp of bicarb and one amp of calcium en route. Patient also received 300 mg of amiodarone en route. Arrived in ED at 0810 Patient received ongoing compressions, shocks and additional medications (epinephrine x6, lidocaine IV, sodium bicarbonate) until time of death called at 0846 in the ED.
1035865	2/17/2021	MD	48	M	2/17/2021	2/17/2021	PT received 1st dose 0.5. ML Moderna IM Left Arm at 0900 HRS. PT did not present with any significant medical history or preexisting symptoms before vaccination. PT ambulated under his own power to observation area. Approx 5 minutes into observation patient walked back to vaccination table, asked for water, then postured and fell to the ground. Patient appeared to have a vasovagal or seizure event. PT did not hit their head when falling. PT regained consciousness, recalled the vents leading to the altered level of consciousness, but does not remember losing consciousness. PT evaluated by EMS and transported to local ED for evaluation and treatment.
1035663	2/17/2021	MI	52	F	2/16/2021	2/16/2021	not feeling well , seizure like activity. I ER itch feeling. treated with Benadryl.

<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>
1035522	2/17/2021	DE	75	M	1/30/2021	1/31/2021	First time seizure occurred 12 hr after injection; This is a spontaneous report from a contactable consumer (patient). A 75-year-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EL9265), via an unspecified route of administration on left arm on 30Jan2021 13:30 at single dose for COVID-19 immunization. Medical history reported as none. There were no concomitant medications. First time seizure occurred 12 hr after injection (AE resulted in: Emergency room/department or urgent care, Hospitalization for 3 days) on 31Jan2021 02:00. Therapeutic measures (LEVETIRACETAM TABLETS - (KEPPRA)) were taken as a result of event. The outcome of event was recovering.

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1035519	2/17/2021	TN	37	F	2/1/2021	2/2/2021	At 4 Am the morning after my second vaccine I had a seizure.; I was found non responsive; blood pressure of 227/153; This is a spontaneous report from a contactable Other Health Professional (patient). A 37-year-old female patient received 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular on 01Feb2021 10:00 at single dose on right arm for COVID-19 immunisation. Medical history included high blood pressure. Historical vaccine included 1st dose of BNT162B2 on 11Jan2021 08:00 am via intramuscular on right arm for COVID-19 immunisation. Patient was not pregnant. Concomitant medication included labetalol and HCTZ. At 04:00 am of 02Feb2021, after second vaccine patient had a seizure. Patient was found non-responsive with a blood pressure of 227/153. Emergency room was visited. Patient have no history of seizures and it was concluded by PCP that this was an adverse response to the vaccine. Treatment was received. Outcome of the events was recovered/resolved with sequel. Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events seizure, loss of consciousness and hypertension 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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1035006	2/17/2021	NC	74	F	2/1/2021	2/2/2021	Passed out and fell to the floor before daylight; Passed out and fell to the floor before daylight; Dizziness; This is a spontaneous report from a contactable consumer (patient's spouse). A 74-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EL9265) on 01Feb2021 at 13:15 at single dose intramuscular COVID-19 immunization. Relevant medical history included Alzheimer's disease diagnosed about 5-6 years ago, seizure (diagnosed 40 years ago) and ongoing high blood pressure. Concomitant medications were not reported. On 02Feb2021 patient passed out and fell before daylight morning, it may be around 06:00-07:00 (as reported). Patient's spouse informed that got up early and was already up when she called him to tell him she had fallen. She sleeps a lot anyway, so she was just put back to bed. Reporter didn't know exactly when she was up again. It was also informed that several of the medications that she took have side effects like dizziness (as reported). At the time of the reporting event outcome was unknown.
1036450	2/17/2021	CA	28	M	2/17/2021	2/17/2021	15 second whole body seizure witnessed by father. Patient vomited for about 15 minutes. Father stated that his seizure probably due to being constipated and not reacting to treatment this morning.
1036591	2/17/2021	PA	81	M	2/8/2021	2/9/2021	Patient received vaccine on 2/8 at 2:50pm. On 2/9 at 10am, patient was found unresponsive. EMS noted R gaze preference and L sided contracture. Patient was intubated and symptoms resolved when given Versed. Concern for seizure activity.
1033422	2/16/2021	FL	70	F	2/11/2021	2/11/2021	PT RECEIVED VACCINE AT 0921 AND IMMEDIATELY APPEARED TO BE HAVING A SEIZURE. EMS CALLED. APRN ON SITE AS WELL AS PARAMEDICS ASSESSED PATIENT, VITALS WNL. PATIENT BEGAN BECOMING RESPONSIVE AT 0927. EMS ARRIVED ON SCENE AND PT REFUSED ANY CARE FROM EMS AS WELL AS TRANSPORT. PT SIGNED AMA FORM.
1033398	2/16/2021	TN	47	M	2/11/2021	2/12/2021	Two severe seizures 23 hours after injection, fever of 101.4. First seizures in more than a year. Oral thrush two days after injection, fever blisters on lips three days after injection.

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1033453	2/16/2021	NJ	34	F	2/5/2021	2/5/2021	~~...noted she had back, neck & four extremity rigidity with tonic / clonic seizure movements. It appeared like a petit grand mal seizure with facial pallor, loss of consciousness, some saliva foaming formation on lips. ...The patients pallor and bradycardia (48 bpm) was evident, the patient was breathing on her own and able to respond to direction and pain stimuli.(2 minutes from initial evaluation.) The seizure like signs and symptoms resolved quickly She was able to place her head between her knees after 30 seconds with her feet on the floor. Her mentation improved rapidly..." Evaluated by EMS, refused transport to ED. PMD followup unknown
1033599	2/16/2021	TX	61	F	2/13/2021	2/13/2021	1500 FELT "PALPIATATIONS" AND FACIAL FLUSHING EPISODE IN IN HE LAST 10 MINUTES, RESOLVED SPONTANEOUSLY 1504 BLOOD PRESSURE 75/86, HR 105 O2 100%; HEART RATE REGULAR AND RAPID, FEELS FLUSHED HEART RACING. PATIENT REPORTS SEIZURE EPISODE LAST NIGHT 1511 BP 54/87 HR 99 O2 99%, PATIENT STATES SHES FEELING BETTER 1530 PATIENT FEELING MUCH BETTER. INSTRUSTED TO SEEK EMERGENCY MEDICAL ASSISTANCE IF SYMPTOMS RETURN
1034074	2/16/2021	CA	75	F	2/16/2021	2/16/2021	Patient came in for COVID vaccine accompanied by son. She was a little anxious about getting the vaccine but son was here to support her. About two minutes after injection she said she felt dizzy. We brought water to her. We tried to get a BP could not get a reading. We attached pulse oximeter and her HR was 41 BPM and she was 96% SpO2 on RA. Within two minutes she was in and out of consciousness and could not hold herself up in chair. We notified the IC and brought a wheelchair so that we could transport her down. Son said she was hydrated today and that she took all of her medications. Son did say she was recently put on Paroxetine and Aldactone. Son stated that she has hx of seizure and this is how she acts when it happens.

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1034094	2/16/2021	CA	70	F	2/13/2021	2/14/2021	First thing in the morning could only stand for a few seconds without feeling I was going to faint. Symptom lasted for about 4 hours. At 1:00 p.m. took temp which was 102. Approximately 5 minutes later I had a seizure. My partner who witnessed the event stated I laid back on our sofa, my head turned and my eyes rolled to the right and I was shaking . I was unresponsive. It lasted about 15 to 20 seconds. Immediately after coming out of it I lost my bowels.
1034187	2/16/2021	CO	28	M	2/16/2021	2/16/2021	Patient was sitting in the 15 minute waiting area after receiving the vaccine. After sitting in the waiting area for roughly 5 minutes it looked like the patient was starting to fall asleep. He slid off of his chair and onto the floor where it looked like he was having mini seizures. He was unconscious for about 30 seconds to one minute. The paramedics were called.
1034307	2/16/2021	NJ	42	F	2/16/2021	2/16/2021	Patients experienced a mild seizure during observation period following vaccine. EMS was called and patient came to immediately after. RN took vitals on Patient while we waited for EMS to arrive. Patient has history of seizure disorder but had no issue with 1st dose. EMS evaluated at scene and Patient returned to residence facility.
1030648	2/15/2021	FL	21	F	2/14/2021	2/14/2021	Patient stated she was feeling dizzy. As I started asking more questions, her head slowly tilted back and eyes became wide and had a distant look, like a mild seizure . She was talking slowly but clearly, During the event. She was sweating, even though it seemed chilly. Her BP was low and my monitor wouldn't register result. EMTs quickly arrived and their monitor took a while to register a result . She came out of it after a few moments feeling weak. We have her some OJ and she seemed to steadily improve. The whole event from start to when she was ok to walk out on her own was about a half hour. She had a relative Come pick her up and take her home.

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1030523	2/15/2021	OH	93	M	2/13/2021	2/13/2021	<p>Patient received his second dose of the Pfizer vaccine. He was accompanied by his daughter. Per daughter prior to receiving his vaccine he was his "normal" self. He was sitting in a chair next to the vaccinator. He did walk in with a walker and minimal assistance from his daughter. He did have a gait belt on around his waist. When I came to patient he was looking straight ahead with his left eye open - right eye s/p surgery to his right eye per daughter. He did not respond to questions asked. His daughter stated mentally he is normally intact. His pulse was faint but palpable. His color was pale with slight dusky skin to hands. 911 was called. Undetectable blood pressure initially with his faint pulse. Initially his heart rate was 105. He was shallow breathing. BP was undetectable sitting - with oxygenation low 80's on room air. He was lifted to a bed/cart with legs elevated. He was given supplemental oxygen. After laying down with legs up he started to look around. He was able to tell me his name and respond to questions. His blood pressure was 117/68 with heart rate 55 and oxygenation on 6L nasal cannula 87-88%. Patient's daughter stated that patient was recently at hospital with low blood pressure and questionable seizure activity. No obvious seizure activity noted today. Paramedics - updated with patient history and events. Blood sugar checked at 183. Patient neurologically improved with ability to state name, his daughters name and his age. No injury noted. Dr phoned and updated on patient condition and events. Patient transported without injury on oxygen. Two daughters with patient to emergency room. Pt being evaluated by cardio on admission for syncope/possible seizure. Still admitted</p>

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1032141	2/15/2021	NC	67	M	2/2/2021	2/3/2021	Patient received 2nd dose on 2/2 at 0733. Patient missed work on 2/3/21 due to "effects from COVID vaccine". Patient was unable to go to work due to disorientation, confusion, headache, and chills. The patient's employee health department advised the patient's family to send patient to be seen by ED. Per ED note patient had complaint of intermittent confusion and disorientation, and fever. Symptoms started after he received his second Covid vaccine. Patient was alert and oriented when seen by ED physician. Patient described symptoms as coming and going, have been worse when he first wakes up. Patient has a past history of seizures and TIA. Provider admitted to make sure he was not having further seizures or TIA. Patient was observed and discharged on feb 5. Per discharging provider the patient had some mild low-grade fever with negative cultures. Provider unsure if fever due to vaccine or mild case of bronchitis-patient discharged on a Zithromax pack.
1031998	2/15/2021	ME	22	M	1/28/2021	1/28/2021	After about 15 minutes the subject asked to use a pulse oximeter, reading normal. Then said it was like looking in a tunnel. We asked him to sit and applied an ice pack to the back of the neck. At the time this provider did not know the patient had a seizure disorder. He slid to the floor with full tonic clonic involvement. His head and neck were protected. 911 was called and an ambulance. After about 3 minutes the subject regained consciousness. He did not wish to be checked out at the hospital. He signed a release and his mother picked him up

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1031487	2/15/2021	PA	33	M	1/25/2021	1/26/2021	<p>spiked a fever of 101.3; spiked a fever of 101.3 which cause a 20 minute seizure; spiked a fever of 101.3 which cause a 20 minute seizure; headache; This is a spontaneous report from a contactable consumer reported for himself. A 33-years-old male patient received the 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3302), via an unspecified route of administration at right arm on 25Jan2021 11:00 at single dose for COVID-19 immunization. Medical history included seizure disorder and other neurological issues, allergy to latex. Concomitant medication included levothyroxine sodium (SYNTHROID), fluoxetine hydrochloride (PROZAC), omeprazole, lacosamide (VIMPAT), lamotrigine (LAMOTRIGINE). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Historical vaccine included 1st dose of BNT162B2 (lot number: EK9231) on 04Jan2021 12:00 PM at left arm for COVID-19 immunization when he was 32-years-old. The patient had a headache throughout the following day and evening on 26Jan2021. On 27Jan2021 spiked a fever of 101.3 which cause a 20 minute seizure. He was hospitalized for 2 days. Events resulted in emergency room/department or urgent care, hospitalization. Treatment was received for the adverse event in hospital. The events outcome was recovering. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, it was unknown if the patient had been tested for COVID-19. The report was reported as serious with seriousness criteria-caused hospitalization.</p>

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1031465	2/15/2021			F		1/29/2021	seizure; signs of confusion; Fever; shoulder pain; A spontaneous report was received from a husband, concerning a 26-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced shoulder pain, fever, signs of confusion and a seizure. The patient's medical history was not provided. No relevant concomitant medications were reported. On an unknown date, the patient received the first of two planned doses of mRNA-1273 intramuscularly (lot number: unknown). On 29 Jan 2021, the patient received the second of two planned doses of mRNA-1273 intramuscularly (lot number: unknown) for prophylaxis of COVID-19 infection. On 29 Jan 2021, the patient's husband reported that patient experienced shoulder pain, 10-12 hours later the patient started to have a fever. On 30 Jan 2021, the patient had signs of confusion and then suffered a seizure and was taken to the hospital. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome for the events, shoulder pain, fever, signs of confusion and a seizure, were unknown.; Reporter's Comments: This case concerns a 26-year-old, female patient, who experienced a serious unexpected event of Seizure, non-serious unexpected event of Confusional state, and non-serious expected events of Pyrexia and Arthralgia. The events of Pyrexia and Arthralgia occurred on the same day after second of two planned doses of mRNA-1273, lot # unknown. The events of Seizure and Confusional state occurred approximately 2 days after second of two planned doses of mRNA-1273, lot # unknown. Treatment information is not provided. 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.

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1030797	2/15/2021	AZ	48	F	2/12/2021	2/12/2021	Fevers to 104 degrees with delirium, severe muscle contractures of neck, upper back, and left arm. Severe rigors. Involuntary spasms of back and neck lasting 1-3 minutes. Severe headache -frontal location and behind eyes. Possible febrile seizures per husband (temp 104.5, not responsive, repeated jerking of neck- resolved after placing in ice bath) . Fevers refractory to ibuprofen/tylenol. Initially continued for duration of 12 hours, remitted for 2 hours, then resumed for additional 24 hours. Intermittent muscle spasms with chills continued for another 12 hours, along with muscle soreness.
1032223	2/15/2021	NY	89	F	2/12/2021	2/12/2021	One hour after vaccination, pt reports "feeling out of it" and confused. Diarrhea began the following day. ON day 3, Monday, pt to ED c/o focal tremors intermittently in each arm and leg. Pt has no history of seizure disorder. On arrival to ED, pt having tremors in right arm, improved after benzodiazepine administration (ativan IV 1mg once). CT head negative for acute illness.
1030351	2/15/2021		25	F	2/13/2021	2/13/2021	Sudden LOC, possible seizure (rigidity) for 5 sec, no post-ictal state, but some disorientation. 99 on RA, 118/76, 99-103 HR, tachypnea to 26. Assessed by EMS, pt refused transport- paramedic got AMA signed. Vasovagal response, Confusion, Disorientation, Loss of consciousness

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1031460	2/15/2021	CA	77	F	1/15/2021	1/15/2021	<p>Convulsing; Mild diarrhea; Fatigue; Mild bladder infection; Sweating; Pain; Fever; Nausea; Chills; A spontaneous report was received from a consumer concerning a 77-years-old, female patient who received Moderna's COVID-19 Vaccine, and who experienced pain, fever, nausea, chills, convulsing, uncontrollable body jerking, sweating, full body ache, fatigue, and mild diarrhea. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 15 Jan 2021, approximately the night of prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Lot number 011L20A) intramuscularly for prophylaxis of COVID-19 infection. On 15 Jan 2021, the patient developed pain, fever, nausea and chills. On 16 Jan 2021, the patient entire body started convulsing and sweating. She developed pain; entire body ached with uncontrollable body jerking. Patient was taken to the hospital, where she received intravenous fluid and paracetamol and was diagnosed with a very mild bladder infection. On an unknown date, the patient had mild diarrhea and fatigue. Action taken with mRNA-1273 in response to the events was unknown. The outcome of the events pain, fever, nausea, chills, convulsing, uncontrollable body jerking, sweating, full body ache, diarrhea, and fatigue was not reported.; Reporter's Comments: This case concerns a 77 year old, female patient, who experienced serious unexpected event of seizure, and non-serious unexpected event of hyperhidrosis and cystitis, and non-serious expected events of nausea, pyrexia, chills, diarrhea and fatigue. The event of pain, pyrexia, nausea, chills occurred 1 day (same day) date after mRNA-1273 (Lot# 011L20A), while the event of seizure, hyperhidrosis, and cystitis occurred 2 day (same day) date after mRNA-1273 (Lot# 011L20A). The event of diarrhea and fatigue occurred on an unspecified date after mRNA-1273 (Lot# 011L20A). Treatment included IV fluids and Tylenol. 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 events, a causal relationship cannot be excluded. Additional information has been requested.</p>

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1029660	2/14/2021	CO	71	M	2/11/2021	5/11/2021	Absolute ZERO side effects from first dose, not even a sore spot on injection location. Migraine intensity headaches started 4 hours after injection of the second dose and lasted for approx. 40 hours. Went to sleep at 10:30 PM the night of the second dose and woke up in a startled state every half hour until I got out of bed at 5:30 AM. From 5:30 AM until approx. 10 PM the day after my second dose I experienced seizure-like symptoms where I would seem to fall asleep while in a sitting position and awake just a minute(s) later in a confused state of mind. This would happen frequently and stopped its frequency slowly and stopped entirely late that same night. I experienced eye pain to the point I had to apply ice bags to my face the entire day after the second dose. Body pain was so severe I cannot compare it to any other flu-like symptoms I've ever had. Totally recovered after 48 hours.
1029499	2/14/2021	CO	56	F	1/26/2020	1/27/2020	I got up at 3:00 a.m. (11 hours after receiving the vaccination) to get a drink of water. I lost consciousness suddenly, resulting in a face plant on tile floor, which caused serious facial and dental injuries. While attending to my injuries, my husband also experienced loss of consciousness and convulsions (three times). He has submitted his own paperwork.
1029484	2/14/2021	CO	67	M	1/26/2021	1/27/2021	Spouse woke at 3am got up for a drink of water and fainted - fell on a tile floor damaging lips and teeth. I got up to help, cleaning up blood and checking injury. After a while I got dizzy and fainted, got up too soon and fainted again. I fainted a third time, had convulsions and lost bladder control. Visited my PCP a week later. Now have a neurologist appt scheduled, a month out. Currently, I have no apparent issues.
1029005	2/14/2021	NJ	28	M	2/3/2021	2/3/2021	patient became syncopal and fell onto floor with subsequent seizure activity

<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>
1028923	2/14/2021	KY	46	U	2/13/2021	2/13/2021	Patient is a 46-year-old female who has known history of previous reactions to immunizations with anaphylaxis as well as seizures who presented to the emergency department with some symptoms after receiving Covid vaccination. She reported onset of some mild headache and dizziness as well as ringing in her ears. She states that these are symptoms sometimes that precede a seizure episode. She has managed on Keppra 750 mg twice daily and has been on this regimen for some time. Here in the emergency department she had no significant concerning findings on exam. Vital signs were fairly unremarkable, there was no rash, there is no stridor or throat swelling, lungs were clear. There is no seizure activity or any other neurological findings. I spoke at length with the patient and her significant other regarding this symptomatology but I do not see any reason at this time that she would need to be admitted to this hospital. She could still potentially develop a seizure-like episode although I do not anticipate this to be the case. There is definitely nothing at this time that would point towards anaphylaxis. There was a Keppra level that was drawn and is pending at this time. I have sent a letter to neurology to let them know that it is still pending at this time.
1028905	2/14/2021	NY	67	F	2/14/2021	2/14/2021	onset of vaccine 0854 0900 onset of symptoms of "head spinning, headache, heart beating a million miles an hour" she started to go into a pseudoseizure, unresponsive to name, responsive to pain she was taken for evaluation: BP 200/100 at 0912 BP 160/90 0920 HR at 84-90 given 25 mg Benadryl po at 0916 tolerated well at 0927, "feel fine, no headaches, no dizziness, no lightheadedness, ready to go home" She refused transportation to hospital, signed refusal form discharged to home at 0935 with husband driving
1031032	2/13/2021		64	M	2/11/2021	2/11/2021	Narrative: Patient with history of seizures was given his 1st dose of Moderna COVID- 19 vaccine toward the end of a stable dialysis treatment. 15 minutes post immunization, patient experienced hypotension and grand mal seizures. Hypotension resolved with saline administration. Oxygen via NC administered. EMS called due to ongoing seizure activity. Transported to hospital where he was admitted for an undisclosed diagnosis.

<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>
1027545	2/13/2021	VA	93	M	2/10/2021	2/12/2021	seizure at 1:30 pm on 2/12/21; patient unresponsive x 20 min then somnolent x 3 hours
1027563	2/13/2021	CT	24	M	2/1/2021	2/3/2021	Migraine, Seizures.
1027570	2/13/2021	PA	59	F	2/10/2021	2/11/2021	Received 2nd Moderna 2/10/21. Later that evening felt feverish. Next morning 2/11/21 had a syncopal event in her bathroom. Presented to the ER and was observed overnight and was seen by urology. Was thought to possibly have had a seizure. MRI, EEG was unremarkable. Was not initiated on any meds.
1027780	2/13/2021	OH	34	M	2/13/2021	2/13/2021	Passed out in his chair and hit the floor. Possible seizure for 5 seconds. He was the conscious over the next hour but would get light headed and need to lay down.
1027959	2/13/2021		35	M	2/11/2021	2/12/2021	Fatigue, fever (101+), joint pain, muscle aches, migraine, tonic-clonic seizure
1031036	2/13/2021		60	M	2/5/2021	2/8/2021	Seizures Narrative: Hospital employee found aphasic & altered gaze, then tonic-clonic seizure witnessed. Employee intubated in internal ED. Employee drank 1/2-1 gallon Vodka, last drink 24 hours prior to onset. Employee has history alcohol-induced seizure.
1027840	2/13/2021	NY	78	F	2/4/2021	2/4/2021	Severe leg cramps. It felt like many muscles in my legs and toes were cramping at once. Legs were painfully bending and twisting Could barely walk. Very difficult to try to relieve them as motion to relieve one cramp made others worse. Lasted about 45 minutes. After about 15 minutes I took a cyclobenziprene I'd had for a back spasm about a year ago. After seeing a report of a woman with severe seizure-like leg spasms I decided to report my experience. I am concerned about taking dose #2 scheduled for March 4.
1026188	2/12/2021	GA	68	F	2/8/2021	2/10/2021	Convulsions/Mini Seizure

<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>
1342700	2/12/2021	MI	39	F	2/12/2021	2/12/2021	on 2/12/21 at an offsite COVID 19 vaccine clinic between 1-3 pm pt was administered second dose of COVID19 Moderna vaccine and shortly after experienced what seemed to be a catatonic seizure. EMS was called by a staff member immediately. Rph's on site tended to pt immediately monitoring pulse and breathing . seizure lasted approximately 1-2 minutes. Was resolved upon EMS arrival, EMS encouraged/recommended to take pt to hospital . Patient refused to go to hospital . EMS asked pt a few questions that she answered correctly then EMS had pt sign- waiver declining to go to hospital even if it resulted in death. At end of clinic 3pm., when we were leaving pt was very aware and talkative. Patient does have history of seizure disorder that is controlled with medication. Per the pt, she is currently taking depabote. Pt did not have any reaction with first dose on COVID 19 moderna vaccine administered on 1/15/21.
1026752	2/12/2021	OH	77	F	2/3/2021	2/6/2021	Developed vomiting, seizure and cardiac arrest, V Fib
1026617	2/12/2021	NJ	52	M	1/22/2021	2/12/2021	*Please note it is not known if event was related to vaccine* On 2/10/2021, at approximately 5:30 AM, patient began to experience dizziness and shortness of breath. Per witnesses, he then began to have seizure activity followed by cardiac arrest. He was treated with CPR and 1 shock from the AED, which resulted in spontaneous return of circulation. He was awake and confused after return of pulse and sent to Hospital Emergency Room. This event occurred 19 days post first vaccine. He was scheduled to get his second dose on 2/12/2021, but did not receive it due to event.
1027039	2/12/2021	CT	49	F	2/11/2021	2/11/2021	I am the patient and within five minutes I got extremely hot my hearing started to leave me and then I passed out I don't know how long I was out for but staff that were there said I was having a seizure shaking and making gurgling sounds in my throat when I came to I could see people but my hearing took longer to come back. I was then brought to Midstate hospital via ambulance at Midstate I had an EKG and blood work done as well as blood pressure monitored and blood oxygen levels

<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>
1025365	2/12/2021	NJ	21	F	2/2/2021	2/2/2021	Patient fainted after injection, possible seizure (she had rapid eye movement) lasted approximately 1 minute. Patient woke up saying she was ok then fainted again lasted approximately 2 minutes . After she woke up she wanted and received ice pack behind her neck . We asked her to stay 30 minutes for observation. She stated she was fine after the 30 minutes.
1026405	2/12/2021	MD	42	M	2/10/2021	2/10/2021	Severe chills starting at bedtime; no amount of layers could fix. Felt like I was in the arctic without any protection. Shivering was like I was having a seizure for about 3 hours. Severe nausea to the point where I can hardly eat. I'm down almost 5 pounds since Wed morning. Severe headache since Wed night that feels like I have an ice pick in my forehead. Excessive fatigue, sleeping about 16 hours Thur and today (Friday). Severe dizziness when standing from a chair or bed; need to brace on wall for about five minutes before episode passes. Loss of taste and smell. Severe neck pain. Photo sensitivity. Runny nose and sever sinus pressure. Maintaining a temperature of about 100 and 101. Had to take off work Thur and half day off today, teleworking the other half.
1026583	2/12/2021	MD	33	F	1/15/2021	1/15/2021	Patient felt faint and moved her self to the floor. She was unconscious and began to have witnessed seizure activity, which lasted approximately 3 minutes. When she did become conscious again, she was disoriented and urinated on herself. 911 was called but when the ambulance arrived, they asked her if she was okay, and she said she was ok . Information relayed to the drivers of what was witnessed but they declined to take her to the hospital. Her husband came and took her home about an hour later. No further seizure activity. Vitals were stable

<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>
1025007	2/12/2021	NJ	21	F	2/2/2021	2/2/2021	Rapid eye movement like "having a mini-seizure"; Fainted; Feeling warm; A spontaneous report (United States) was received from a pharmacist concerning a 21-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and fainted and experienced to have rapid eye movement like "having a mini-seizure" and feeling of warmth. The patient's medical history included historical seizures. Concomitant product use was not provided by the reporter. On 02 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (Batch number:026L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 02 Feb 2021, a few minutes after the injection, the patient fainted then recovered but again fainted and was noted to have rapid eye movement like "having a mini-seizure". HCP managed her with ice pack as patient complained of feeling warm and she recovered in less than 30 minutes. Treatment information was not provided. The outcome for events fainted, rapid eye movement like "having a mini-seizure~~" and feeling warm were resolved.; Reporter's Comments: This spontaneous report concerns a 21-year-old, female patient with historical seizures. who received experienced the patient fainted then recovered but again fainted and was noted to have rapid eye movement like "having a mini-seizure." The event occurred a few minutes after the administration of mRNA-1273 vaccine (Batch number: 026L20A, expiration date: unknown). Treatment administered include Icepack and outcome is resolved. Based on the information provided which includes a strong temporal onset between the vaccine administration and the event, a causal association cannot be excluded. However, event is confounded by the subject's history of seizures. Feeling warm is consistent with the safety profile of the product.
1025228	2/12/2021	KS	83	M	2/2/2021	2/3/2021	Seizure

<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>
1026764	2/12/2021	IL	76	M	2/12/2021	2/12/2021	Potential allergic reaction - epinephrine administered PT had seizure activity at 11:45am, within 30 minutes after administration of first COVID vaccine (Moderna) Epinephrine (0.3mg) administered by provider at 11:47am PT had audible and palpable pulse, approximately 180 bpm that declined to 107 at time of arrival of the fire/ambulance department, respirations and heart rate did not cease during event PT in postictal state after seizure however able to dictate to Fire Department his name, date of birth and his last seizure which he states was "a month ago" Patient was transported to Hospital in stable condition Fire Department
1025368	2/12/2021	CA	81	F	2/11/2021	2/11/2021	Systemic: Seizure-Mild
1025375	2/12/2021	CA	81	F	2/11/2021	2/11/2021	Systemic: Seizure-Mild
1025458	2/12/2021	ME	27	F	2/11/2021	2/11/2021	Please note, vaccine was not administered at doctors office. Not clear what was being asked in previous page for address - of doctor or vaccination site. I had vaccine at 730-740am and by 430pm, I had heavy onset symptoms of body aches, chills, fever etc. I took 1000mg of Tylenol and began feeling better. Still exhausted so I went to bed around 630pm but because I was pushing so much fluid, I kept getting up to pee. I was still freezing. Around 940pm, I woke up to pee and again freezing still. I sat on the toilet and started having full body convulsions and the next thing I remember is waking up on the floor. My husband found me passed out, face first on the tile floor with my pants still down. I hit the left side of my face very hard. My husband helped me to bed where I took more ibuprofen and tremored for the next hour before I fell asleep. I woke up completely drenched and sweat and with a headache.

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1025481	2/12/2021	WV	73	M	2/10/2021	2/10/2021	After receiving the vaccination her husband met with his son. He reported that his dad did not know anything. His wife told the son to bring him to Hospital. They brought him to the hospital and got there and his son said that he had called the daughter and he did not know the day, month, his grandson's name, like he wasn't there. He had a funny look on his face that he was "out of it". Asked simple questions about pet at home, favorite and could not remember the name of the cat. He then came out and said that he was fine. They ran tests for a mini-stroke, CT scan, blood work. They had a consult with Neurology, virtual. The neurologist did some questioning, and by 3:00 they felt that it was like a mini-stroke, and she said that she felt it was from the vaccination as it occurred right after the vaccine. She took him home, and told him to take a nap. By 4:30 PM she woke him up and said that they were going to eat, she was getting things ready. He was sitting on the couch about 5:00 PM and had that blank stare again. He went walking through the house walking aimlessly and started fumbling through papers. She called 9-1-1 and within 10 minutes they took him to the ER. It took her an hour to get to the hospital, his daughter met them at the ER. He told them that he was fine, and they knew that he was not. By 7:00 PM they were going to do an MRI and wanted to admit him to the hospital. All of a sudden at 9:00 he was having another episode. She got the nurse and they watched him and decided that he was having a seizure, (agitation, not making sense.). The entire episode lasts for about 30 minutes. They did an MRI and an EEG, which she does not have the results of. On 2/11/21 she talked to the neurologist who insisted it was due to the vaccine. He has now settled down and has not had another seizure since 9:00 PM the night before. He was discharged yesterday at around 1:00 PM, he slept, got up and is fine this morning. He was diagnosed with seizures, and to FU with Dr. in Epilepsy clinic, and prescribed Keppra, which he has not taken as he feels it was due to the vaccination.. He does not remember the events that took place.

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1025542	2/12/2021	NV	82	M	2/11/2021	2/11/2021	I was in bed when it happened and it was very sudden. I had a sudden constriction of all of the muscles in my body to where I was frozen and my mind kept saying I have to get lose. This lasted about 30 seconds to a minute and a half and then it went away. I looked on google and decided it sounded like I had an awake seizure so I went to bed. It didn't hurt, there was no pain, it just constricted my whole body, I was alert and I knew I was being constricted and my mind was fighting to try to loosen and finally it loosened. I have never had anything like that happen to me in my whole life, so that is why I assumed it would be considered and after effect of the vaccine.
1027371	2/12/2021	FL	73	M	2/9/2021	2/9/2021	SEIZURE at exactly 28 minutes post-injection. Unconscious for 34 minutes. Observed at clinic until ambulance transportation to Medical Center
1025219	2/12/2021	GA	63	F	2/3/2021	2/4/2021	Left side swelling to include face, arm, hand, trunk, legs and feet. Noted to be +3 pitting edema. On 2/5 @ 1307 start having seizure activity that lasted for over 20 minutes. Per hospital policy code blue was called. This resulted in an ER send out.
1024111	2/11/2021	MA	55	F	2/3/2021	2/8/2021	Sore arm first injection as expected. 2nd more sore. Some fatigue. Felt totally fine prior to until my husband turned onto our home street and I started to verbalize that this is not our neighborhood nor our house. I then started to have a seizure which I was told lasted 5 minutes and was turning blue. I was buckled at the time. I have compression fractures of T12 to L2 He called an ambulance and I had a second one. I had ct , mri, mra, eeg, ekg, labs. Treated with muscle relaxants, toradol. Put on keppra. Cannot drive for 6 months. All new onset. Having a lot of back spasms especially in the night My mouth and tongue are sore from biting on it During seizure Foggy thinking and decreased memory

<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>
1024048	2/11/2021	SC	78	M	2/2/2021	2/3/2021	The next two days following the vaccination, the patient was lethargic and not getting out of bed. His caregiver had to make him eat and bathe. On the third day his caregiver had woken him up and found that he had wet himself (this has never happened before). He had altered mental status and was not able to recognize any of his family members. He was taken to the emergency room on 2/6/2021 where he had a seizure and found to have a subarachnoid hemorrhage. He is still hospitalized.
1024718	2/11/2021	TN	76	M	1/26/2021	1/26/2021	Seizure followed by loss of speech, weakness, confusion
1024066	2/11/2021	NY	52	M	2/11/2021	2/11/2021	Patient had a 2 seizures lasting 1 minute each approximately 2 hours and 4 and 1/2 hours post vaccination.
1024416	2/11/2021	ND	79	F	2/8/2021	2/9/2021	At 1207, resident was noted having facial twitching and seizures and crackles , Vitals: BP 199/95, O2 Sats 89% on RA, PR 88, Temp 97.3, RR was hardly counted because of body movement. Blood sugar was 172 mg/dL. Hooked on O2 at 4L per NC. Informed MD and ordered to send to ER. Family - were updated. Ambulance was called. Family clarified resident's status is DNR. Report was given to ER nurse. Updated ER that INR today is 5.5 and MD ordered to HOLD Coumadin till 02-11-21.
1024529	2/11/2021	CA	18	F	2/9/2021	2/9/2021	patient starting shaking and fell down to the ground from chair. No LOC or confusion. Also felt light headed with VSS. EMS called. no known history of seizures. Transported to the ED
1024549	2/11/2021	FL	45	F	2/10/2021	2/11/2021	Fever over 103 Seizure
1023814	2/11/2021	TN	40	M	1/25/2021	2/3/2021	Moderately severe tonic/clonic seizure of approximately 60 second duration observed by nursing staff at approximately 7:00am on 2/3/21. Patient was awake sitting at the dining table. Patient has no previous history of seizures. The only immediate treatment was continued observation, with no further seizures noticed to date. Patient visited his PCP later that day for follow-up, no treatment advised.

<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>
1024710	2/11/2021	IN	68	F	2/8/2021	2/11/2021	I woke up at 3:30 a.m. February 11. I noticed I had wet the bed (which I haven't done for 60+ years) and felt very weak--afraid to move for fear I would pass out. I had no pain and no indication of heart attack or stroke. After 5-10 minutes I walked to the bathroom where I had diarrhea and vomited a small amount. I stayed on the stool for some time because I felt too weak to safely get up. I did go back to bed after 15 minutes or so. I got up again with diarrhea an hour or so later. I got up at 9 a.m. feeling a lot better but still weak. Took it easy the rest of the day and had regained most of my energy by evening. I think I may have suffered a seizure of some kind resulting in the wet bed and extreme weakness.

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1021987	2/11/2021	WI	81	M	1/22/2021	1/24/2021	<p>non responsive to verbal stimuli, unable to hold trunk upright, eyes not focused; non responsive to verbal stimuli, unable to hold trunk upright, eyes not focused; This is a spontaneous report from a contactable other health professional. An 81-years-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EL3249), intramuscular in left arm on 22Jan2021 10:00 at single dose for covid-19 immunisation. Medical history included Parkinson's disease, post polio syndrome, Alzheimer's disease, atrial fibrillation, benign prostatic hyperplasia, right knee replacement, sleep apnoea, restless legs syndrome, covid-19 prior to vaccination. Concomitant medication included carbidopa monohydrate, levodopa (CARB/LEVO), cephalexin (unknown manufacturer), cetirizine (unknown manufacturer), citalopram (unknown manufacturer), donepezil (unknown manufacturer), etodolac (unknown manufacturer), finasteride (unknown manufacturer), furosemide (unknown manufacturer), metoprolol (unknown manufacturer), omeprazole (unknown manufacturer), oxybutynin (unknown manufacturer), senna alexandrina leaf (unknown manufacturer), tamsulosin (unknown manufacturer). The patient experienced had vaccine on friday and on sunday had neurological symptoms, non responsive to verbal stimuli, unable to hold trunk upright, eyes not focused on 24Jan2021 14:00 with outcome of recovered in Jan2021. The patient was sent to ER and CVA/TIA were ruled out. Has no history of seizure disorder. Returned and had 1 more episode later in the day. Vitals were all within his normal limits. ER physician felt was possible reaction to vaccine. The patient was not treated due to the events. The patient had not been tested for COVID-19 since the vaccination.; 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.</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>
1024732	2/11/2021	CA	40	F	2/10/2021	2/11/2021	Less than 24 hours after the patient received her first dose, she had what appeared to be a partial seizure. During the episode, the patient acknowledged that she has had seizures in the past and takes Lamictal to control it. She stated that she has not had a seizure in over a year prior to getting the vaccine.
1024618	2/11/2021	MS	41	F	12/14/1979	2/11/2021	Patient started having seizures after 15 minutes of receiving the vaccine. The EMS was called. The pt was place on oxygen due to O2 dropping. The EMS took the pt to hospital
1023790	2/11/2021	TX	59	F	2/9/2021	2/9/2021	Per patient had a seizure
1023770	2/11/2021	TN	56	F	1/25/2021	2/2/2021	Severe tonic/clonic seizure of approximately 60 second duration observed by nursing staff at home at approximately 6:30am on 2/2/21. Patient was awake and lying in bed. Patient has no previous history of seizures. The only treatment was continued observation, with no further seizures noticed to date. Patient is on hospice due to her diagnosis of dementia, and both Hospice and her PCP were notified. On 2/9/21, patient was diagnosed with a fractured hip, unknown if that occurred secondary to the seizure mentioned above.
1023598	2/11/2021	FL	62	F	2/10/2021	2/11/2021	I had a mild seizure this morning that lasted about a minute.

<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>
1023375	2/11/2021	IA	35	F	1/29/2021	1/29/2021	Became unresponsive; Looked like having a seizure; Felt light headed; BP extremely low; Profusely sweating; Heart rate extremely low; A spontaneous report was received from a pharmacist, concerning a 35-year-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced felt light headed, became unresponsive, looked like having a seizure, BP extremely low, heart rate extremely low, and profusely sweating. The patient's medical history, as provided by the reporter, included high blood pressure. Products known to have been used by the patient, within two weeks prior to the event, included hydrochlorothiazide/lisinopril. On 29 Jan 2021, five minutes prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot Number: 025L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 29 Jan 2021, the patient felt light-headed five minutes after receiving the vaccine. He then became unresponsive but was breathing and had a pulse. The reporter stated it looked like the patient was having a seizure; his eyes rolled upward, his left arm shook, and he did not respond to touch or voice. It was reported that 911 was immediately called and responded within a couple of minutes. The patient's blood pressure and heart rate were extremely low, and he was profusely sweating. The reporter stated that the patient came to and still felt very light-headed. The patient was then taken to the emergency department. Medical tests and laboratory results were unknown, but the reporter stated that a magnetic resonance imaging (MRI) was possibly performed. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome for the events, became unresponsive and looked like having a seizure, were resolved on 29 Jan 2021. The outcome for the events, felt light headed, BP extremely low, heart rate extremely low, and profusely sweating, was unknown.; Reporter's Comments: This case concerns a 35-year-old, female, with medical history of high blood pressure, who experienced a serious unexpected event of syncope, seizure, and non-serious unexpected events of dizziness, hypotension, hyperhidrosis, and heart rate decreased. The events occurred 1 day (5 min) after mRNA-1273 (Lot# 025L20A). Treatment information was not provided.

<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>
							Concomitant medications included: hydrochlorothiazide/lisinopril. Based on temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Additional information has been requested.
1023359	2/11/2021	OK		F	1/28/2021	1/28/2021	Seizure; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number/expiration date not reported), via an unspecified route of administration on 28Jan2021 at a single dose for COVID-19 immunization. Medical history included being immunocompromised from an unknown date and was taking a lot of medications. Concomitant medication includes a lot of medications (unspecified). The patient was previously vaccinated with the first dose of BNT162B2 on an unspecified date. It was reported that the patient received the second dose of COVID-19 vaccine on the afternoon of 28Jan2021 and experienced seizure. The reporter wanted to know if he needed to seek a doctor early this morning for the patient. The outcome of the event was unknown. No follow-up attempts are possible. Information about batch/lot number cannot be obtained. No further information is expected.
1022330	2/11/2021	SC	69	F	2/10/2021	2/10/2021	patient had a seizure, no medical intervention needed, patient returned to baseline after 10 minutes

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1024817	2/11/2021	GU	68	M	2/11/2021	2/12/2021	Patient was coded and expired Code Blue: Patient was in dialysis, after 30 minutes his sbp dropped to 60s he was given 4 albumin. Patient who was responsive before that became unresponsive, had seizure like activity, lost pulse and spontaneous breathing. HD stopped. Code called. Cpr started. A few minutes into cpr patient started to profusely bleed - gi bleed and ventilation became very hard., intubation was very difficult and ventilation hard as we suctioned large amounts of aspirated blood. Patient was eventually intubated. More than 8 doses of epi ws given, sodium bicarbonate * 2 given with continuous cpr. It was mostly PEA with one shockable rhythm. And shock delivered for vfib. patient continued to profusely bleed, og insertion was not successful and effective ventilation was very tough due to massive aspiration,. Possible variceal rupture with cpr from his cirrhosis is likely scenario. After 30 minutes of unsuccessful ventilation and acls protocol. Code was stopped.
1021768	2/11/2021	PA	22	M	2/10/2021	2/10/2021	Patient had increased frequency of seizures (6 in the same day of vaccination), treated with Clorazepate bridge
1024824	2/11/2021	NV	51	F	2/11/2021	2/11/2021	Patient began to have a seizure within 6 minutes of vaccination. She also had symptoms of shortness of breath and tachycardia
1026337	2/11/2021	GA	32	M	1/27/2021		Had back to back seizures 2 days after getting the vaccine (1/27/21). Hospitalized for 48 hours. came back and had another seizure after discharging from ICU.
1284984	2/11/2021	GA	32	M	1/27/2021		Had back to back seizures 2 days after getting the vaccine (1/27/21). Hospitalized for 48 Hours. Came back and had another seizure after discharging from ICU.
1284986	2/11/2021	AZ	83	F	2/11/2021	2/11/2021	Care taker reported that patient vomited and started convulsing. She also reported that patient history of seizures. Care taker reported that was given rectal valium and was stable after administration.

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1024760	2/11/2021	NE	51	F	2/10/2021	2/10/2021	2nd Vaccine I had, severe uncontrollable shaking, similar to a seizure, severe chills, nausea, throbbing headache, entire body aches/pain and loss of grip in my hands, couldn't move either of my arms-shot was in left arm-104 temperature, I couldn't get out of bed and I missed an entire day of work. I'm still dizzy, lightheaded and nauseous and it's 9 pm!
1022456	2/11/2021	SC	72	F	1/22/2021	1/23/2021	2:00 am seizure, dizzy, weak, diarrhea, nausea, head pain, rapid heart beat. This got better. 3:30 am bad seizure with foaming at nose and mouth, convulsions, dizzy, unable to move, terrible head pain, nausea, rapid heart beat, extreme hot and cold spells; freezing from bones out. The seizure got better after about an hour, but the tremors did not stop until around 6:00 am. The morning of the shot, I ate a banana for breakfast. Only thing I ate after the shot was late lunch was rice with tomatoes in it, green beans, fried squash (all out of my garden).
1024685	2/11/2021	PR	33	F	1/20/2021	1/24/2021	Seizure events for three consecutive times in one week. Urticaria, vomiting, diarrhea, hands and feet cramps and intense headaches. I actually still have headaches as of today. On January 24th I went to the Emergency Room for the events that I just mentioned. Also, I am currently going for treatment with a Neurologist

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1018771	2/10/2021	TX	78	M	1/22/2021	1/24/2021	chills; body aches; fever of 102.9; extreme weakness; dizzy; This is a spontaneous report from a contactable consumer reported for himself. This 78-year-old male patient received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration at right arm on 22Jan2021 12:00 PM at single dose for covid-19 immunisation. Medical history included Seizures, low white cell count, enlarged prostate and COVID-19. Prior to vaccination, the patient was diagnosed with COVID-19. The patient had no allergies to medications, food, or other products. Concomitant medications included any other medications the patient received within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 24Jan2021 08:00 AM (reported as 18 hours after injection), the patient experienced chills, body aches, fever of 102.9, extreme weakness, dizzy. At 4 am on 25Jan2021 the fever broke and now he was ok. No treatment received for the adverse event. Outcome of the events chills, body aches, extreme weakness and dizzy was recovered on an unspecified date, of the event fever of 102.9 was recovered on 25Jan2021. Since the vaccination, the patient had not been tested for COVID-19. Seriousness criteria was reported as non-serious. Information on the lot/batch number has been requested.
1019445	2/10/2021	VA	55	M	1/1/2021	1/27/2021	gran mal seizure
1018381	2/10/2021	NY	30	F	12/30/2020		Injection sight tenderness; Fatigue; Severe headache; This is a spontaneous report from a contactable other HCP report for self. This 30-year-old not pregnant female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140) intramuscular at left arm on 30Dec2020 at single dose for COVID-19 immunization. Medical history included Asthma, anxiety, allergies to Acetaminophen (seizure like activity and fainting). No COVID prior vaccination. No other vaccine in four weeks. Concomitant medications include Fluoxetine, lorazepam, and Ibuprofen. Patient experienced injection sight tenderness, severe headache for 5 days, fatigue for 7-10 days after first dose. The outcome of events was unknown.

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1021319	2/10/2021	IA	33	M	2/3/2021	2/3/2021	Patient received vaccine in AM, had seizure in PM at work with typical post-ictal picture. Has epilepsy but no seizure since 2014. Also has history EtOH misuse but history not consistent with withdrawal. Patient had some waxing and waning altered mental status, worsening slowly over next 2-3 days. Presented to ER with AMS. Initially thought to be EtOH withdrawal, but due to atypical clinical appearance, LP performed and HSV encephalopathy diagnosed.
1021270	2/10/2021	MO	28	M	1/28/2021	1/28/2021	Immediately after I administered the vaccine, the patient passed out. He fell onto the floor and we witnessed some oral seizure like type movement. The patient was unconscious for approximately 1.5-2 minutes. Our Chief Medical Officer was on site and walking into the room as the patient fell. We immediately placed him on his left side, protected his head, and stayed with him. We called 911 immediately due to the uncertainty of health issues. Once conscious, the patient explained to us that he experiences such every time he receives a vaccine. He was assessed by the CMO as well as the EMTs that arrived on scene. His vitals were taken. He was moved into a comfortable position and monitored. He was alert and orientated x 3. We requested he have someone pick him up instead of him driving himself home which he did. This gentleman is also an employee and we were able to see him and verify all was well in the following days. We also recommended he tell all vaccinators that he experiences LOC post vaccination. When he receives his second dose we plan to have him lying down and our CMO will be present. We recommended he follow-up with his PCP.
1020859	2/10/2021	MO	84	F	1/19/2021	1/24/2021	Started on Jan 24 or 25-Extreme fatigue, sleeping til late in afternoon,, unable to get out of bed,, headache, just didn't feel right. Went to primary doctor office on 29th. Ran every blood test, ekg and chest xray-mostly normal except orthostatic hypertension. Told to increase fluids. Felt a little better over the next week then same symptoms again Feb 4 and 5th. Took to ER had a seizure and vomiting. CT showed a Stoke and am currently in hospital.
1020784	2/10/2021	UT	89	F	1/21/2021	1/23/2021	Paralysis swelling. Seizure, lost eye sight, partial speech ! And is bed riding and loss of balance

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1020684	2/10/2021	MI	73	M	1/13/2021	1/16/2021	Patient received vaccine at Public Health Clinic. Patient ended up having a seizure 3 days later and ended up in the hospital. Found to have right lobe pneumonia and low depakote level. Patient noted to have multiple seizures at hospital, issues with stabilizing HR and BP, and passed away on 1/20/21.
1020631	2/10/2021	IN	22	F	2/5/2021	2/6/2021	pt had a seizure that lasted 20 second the morning after receiving the second dose of her vaccine. No further symptoms or abnormalities noted after this event
1020577	2/10/2021	AL	81	F	1/13/2021	1/13/2021	PFIZER-BIONTECH COVID-19 VACCINE EUA. Vaccination occurred between 6:30am to 10am. Adverse event noted at 5:30pm included seizure activity followed by lethargy/unresponsiveness lasting a few minutes (approx 15 min unresponsive). VS 138/82, 76,16. Blood sugar 105. O2 sat 98% on room air. MD visited and ordered labs. Subsequently treated for UTI with Rocephin IM x 5days.
1020515	2/10/2021	IN	88	F	1/13/2021	1/14/2021	Daughter of client reported that her mother had 2 "seizures" with loss of consciousness 24 hours post vaccination. No history of seizures. Patient reportedly had COVID with significant "brain fog" 1 month prior to 1st dose of vaccine.
1020276	2/10/2021	OH	78	F	2/5/2021	2/6/2021	Began having seizures on 2/6/2021 a day after having vaccination. Husband of patient reports patient having 2 seizures on 2/6/2021. Pt transported to ER for testing. Husband denies pt receiving any treatments. Pt underwent various tests. Pt sent home. Husband reported pt having altered mental status from seizures. Pt then had 4 more seizures on 2/7/2021. Husband states pt had altered mental status but her condition began improving after seizures. Pt has not returned to baseline cognitive function as stated by husband. Husband states pt has a history of seizures and is prone to having seizures. Pt also in early stages of dementia.

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1019827	2/10/2021	AZ	90	M	1/25/2021	1/31/2021	Vaccine on Jan 25, 2021 Minor seizure on Jan 31. 2021- 4:35pm talking, then staring, "blank stare", didn't recognize either daughter for about 10 minutes. Daughter did stroke tests, all normal. called 911, they saw no stroke symptoms, EKG normal. Within 15 minutes, he was coherent but lethargic. Could not remember 15 minutes prior. Did NOT take to ER. Saw cardiologist next day and then had head CT later that week.

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1020733	2/10/2021		80	F	1/27/2021	1/28/2021	The night after receiving dose 1 of the vaccine, she didn't want to eat dinner, was starting to spit up saliva, and noted a new headache, and asked her daughter to sleep with her that night considering she was feeling poorly. She was restless all night, and then at ~5am her L arm began to twitch; she was still alert at this time but didn't realize her arm was moving. Shortly after this she lost consciousness, her eyes rolled back in her head, and she developed a frank GTC seizure. Her daughter called an ambulance, and by the time she was on the way to the hospital, she was awake and alert again. At the hospital, she was initially talking and able to answer most questions appropriately. She was noted to be afebrile, hemodynamically stable, without an O2 requirement, though with tachycardia to the 110s. She was found to have a leukocytosis to ~16, thrombocytosis to ~550, and LDH elevated in the 600s. Over the following day, her mental status declined and she became agitated and disoriented to place/time. CT chest revealed b/l multifocal pneumonia, for which she was started on pip-tazo. She underwent MRI brain (DWI sequence only) which did not reveal any obvious CVA. LP was performed on 1/29 at ~10PM; as far as we can tell, she had only received pip-tazo for antibiotics at this point. CSF studies revealed 220 WBCs (14% PMNs, 76% lymphs, 10% monos), 14 RBCs, Glu 59, Prot 145; GS 2+ WBCs, no orgs; india ink stain negative; Cx pending at time of transfer. Given concern for bacterial or viral meningoencephalitis she was transitioned to vancomycin/ceftriaxone/acyclovir. Patient was then transferred to another Hospital for further management. Micro was all negative or pending at the time of transfer. Shortly after admission to hospital she was intubated. Spine MRI was notable for longitudinally extensive transverse myelitis. All infectious workup has been negative with just two more pending studies for tuberculosis; autoantibody panel pending. She is now able to follow commands with eyes and mouth, but has not been able to move her arms or legs. We do not have high suspicion that this syndrome is related to the vaccine, given that progressive neurological symptoms started the week before vaccine, but thought it prudent to report given the time course.

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1018108	2/9/2021	TX	39	F	2/9/2021	2/9/2021	While PT was waiting during her 15 minutes observation period post covid-19 vaccine administration PT began to experience seizure like activity lasting about 5 minutes. PT has a PMH of seizures, is compliant with her prescribed medications, and suffered a seizure a week prior. An IV was established and PT VS were monitored while PT was transported to the hospital. Prior to transport PT was COAX4 and remained stable through out transport. Run # 21-0766
1017079	2/9/2021	CA		U	1/23/2021	1/23/2021	Fainted; Had a seizure; A spontaneous report was received from a physician concerning a patient who received Moderna's COVID-19 vaccine (mRNA-1273) and fainted and had a seizure. The patient's medical history was not provided. No relevant concomitant medications were reported. On 23 Jan 2021, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 23 Jan 2021, after vaccine administration, the patient fainted and had a seizure. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the events, fainted and seizure, were unknown.; Reporter's Comments: This case concerns a patient, who experienced events of fainted and seizure. 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.
1017190	2/9/2021	NC	66	M	2/5/2021	2/5/2021	CLIENT STATES 3 HOURS AFTER RECIEVING VACCINE HE HAD A SEIZURE, WIFE IN ATTENDANCE AND LASTED ABOUT 30 MINUTES, HAS O2 SAT FINGER PROBE AT HOME AND SAT WAS 96 % BUT HEART RATE VIA MACHINE WAS IN 30 RANGE. HAD CHEST PAIN NON RADIATING. DID NOT SEEK MEDICAL ATTENTION UNTIL MONDAY, 3 DAYS AFTER VACCINE,THIS IS WHEN HE SAW HIS CARDIOLOGIST AND HAS ECHO ORDERED FOR 1 WEEK. HE ALSO HAS A MD APPOINTMENT WITH UROLOGIST FOR KIDNEY STONES. PULSE RATE WAS BACK TO 60 RANGE WITHIN 1 HOUR.

<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>
1017560	2/9/2021	CA	37	M	2/5/2021	2/6/2021	Severe chills with shivering thermogenesis for only ~10 minutes (1 episode only). I was unable to speak for a few minutes due to the uncontrolled muscle contractions and was just generally too uncomfortable to move. It was not a seizure, but it was temporarily debilitating. Once I got myself wrapped in a warm blanket, it only took about 10 minutes to pass (and never returned). The rest of the day I did feel generally ill, but the day after I felt completely back to normal.
1017732	2/9/2021	CA	71	M	1/28/2021	2/4/2021	On 2/4/21 had a seizure which he has not had in 16 years. He then started to get really tired, and still having that today 2/9/21. Had the feeling of having a heavy flu. No treatment, no other seizures.
1017813	2/9/2021	FL	27	F	2/4/2021	2/4/2021	After the vaccine I was in the waiting room, then I had seizure-like tremors full body and complete energy loss, was taken to the triage for CBC and EKG testing. Full body tremors subsided after 1 hrs and was left with extreme arm tremors. Given Ativan for tremors stopped momentarily but after 20 minutes tremors in arms began. Moved to the Health ER where was given a CT scan and Benadryl. Calmed the tremors. Left hospital at 1:30AM and the following day (02/05/2021) ran a fever of 101 for almost 16hrs, treated with fever reducers.
1017874	2/9/2021	NY	68	F	2/6/2021	2/6/2021	Patient had multiple seizures that were treated with 5 mg Versed intranasally and 5 mg IVP. Seizures broke and was transferred to Hospital
1017893	2/9/2021	IL	43	M	1/29/2021	1/30/2021	My brother has epilepsy. His seizures can be triggered by low grade fever and exhaustion. He had covid in early October. His seizures are generally well controlled but he had several after the vaccine. I understand that the vaccine did not cause the seizures. The fever caused the seizure. I just think it's important to neurologists to have this info to see how we can go about mitigating the seizures and if the 2nd dose is necessary. Keeping him hydrated may have helped and also giving him something immediately for the low grade fever. Just knowing these things may help others.

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1018650	2/9/2021	NM	43	F	1/29/2021	1/30/2021	Woke up at 1:30 am with fever. Muscles spasming, took an Advil, didn't help. Took another Advil 30 min later, restless, can't stay still, moaning. Muscle cramping getting worse in abdomen. Get up to get more water and urinate, starting to salivate as if going to throw up. Lean over toilet for 20 min, burning hot, weak, throw cold water around face and neck. Take another Advil, lay back down in bed, muscle convulsions for next 20 min, slowly dissipating. Entire episode took 3 hours. Felt like worst period cramping with fever on top of food poisoning. Next day was mildly nausea and sore, tired.
1018094	2/9/2021	UT	63	M	2/5/2021	2/5/2021	Patient experienced a grand mal seizure approximately 4 hours after receiving his first dose of the Moderna vaccine.
1018112	2/9/2021	NY	35	F	2/8/2021	2/9/2021	Fever of up to 102.5 F, convulsions (with absolutely no control over my muscles), migraine, chills, extreme fatigue, stomach cramps and nausea.
1016007	2/9/2021	IA	28	F	2/8/2021	2/8/2021	Approximately 2 hours after vaccination, she complained to co-workers about being dizzy and then she had a syncopal episode where she lost consciousness and had seizure like activity lasting approximately 1 minute. She was taken by EMS to the Emergency Department and evaluated, here it was discovered that she has a history of nonepileptic seizure episodes and the Physician Assistant providing care did not think this episode was "measurable allergic reaction to her vaccination however perhaps the stress and worry of having this shot just prior to her symptoms". Followed up with the employee today and she is having expected side effects from vaccine administration (body aches, fever up to 102-103, and headache), no further seizure like activity.
1018030	2/9/2021	OR	82	F	2/6/2021	2/8/2021	Pt with seizure-like activity noted x2 by her husband, with symmetric jerking of legs, loss of responsiveness, loss of bowel/bladder function.

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1016658	2/9/2021	FL	72	F	2/7/2021	2/7/2021	I found her unresponsive in her room, she had some white stuff on her mouth. I called 911. while waiting I placed ice on the back of her neck and she began to respond, as she began to become more responsive she defecate all over herself. I checked her blood sugar it was 159. The ambulance arrived, they checked her vitals said they were ok, they gave me the option of monitoring her at home or going to the ER. I chose to monitor her at home. Monday all day she still had a fever complaining of headache, joint pain and pain in the arm she received the vaccine, at times she became very delirious, nothing she said made sense. . Her doctor said she had a seizure and offer to place her on seizure medication. I gave her two 500mg Tylenol she has an appointment on March 7th for the second dose but I am afraid to give her the second dose.
1015673	2/9/2021	NC	71	M	1/27/2021	1/30/2021	Confusion; General "Don't feel right"; Seizure; Low Sodium level; This is a spontaneous report from a contactable consumer (reported for himself). A 71-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number: EL3247), via an unspecified route of administration on 27Jan2021 11:15 at single dose in left arm for COVID-19 immunization. Medical history included High Cholesterol; No known allergies. Concomitant medication in two weeks included atorvastatin. Facility type vaccine was Hospital. No other vaccine in four weeks. On 30Jan2021 23:00, the patient experienced Seizure, Low Sodium level, Confusion, General "Don't feel right". The events resulted in Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). The number of days hospitalization was 3 (from unspecified date in 2021 to an unspecified date in 2021). It was unknown if treatment received. No covid prior vaccination. Covid tested post vaccination: Nasal Swab tested on 01Feb2021 with the result of Negative. The outcome of the events was recovered on an unspecified date in 2021.

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1015667	2/9/2021	NY	30	F	1/20/2021	1/20/2021	diarrhea (7+ loose stools each day starting on this day); headache; severe nausea; worsened muscle pain; new joint pain morning after (Included in aforementioned, but significant stiff neck.); new joint pain morning after (Included in aforementioned, but significant stiff neck.); fatigue/malaise; fatigue/malaise; This is a spontaneous report from a contactable other HCP report for self. This 30-year-old not pregnant female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3302) Intramuscular at left arm on 20Jan2021 at single dose for COVID-19 immunization. Medical history included Asthma, anxiety, allergies to Acetaminophen (seizure like activity and fainting). No COVID prior vaccination. No other vaccine in four weeks. Other medications in two weeks includes fluoxetine, lorazepam, and Ibuprofen. Patient received first dose of bnt162b2 (lot number: EL0140) on 30Dec2020 and experienced injection sight tenderness, severe headache and fatigue. On 20Jan2021 5:00 PM after the second dose, patient experience headache, severe nausea, diarrhea (7+ loose stools each day starting on this day), worsened muscle pain several hours later, new joint pain morning after (Included in aforementioned, but significant stiff neck), fatigue/malaise. Patient received Ibuprofen and rest, supportive care due to events. The outcome of event was not recovered. Rapid Nasal Swab tested Negative on 21Jan2021.; Sender's Comments: The reported event diarrhea was likely causally related to the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) due to temporal relationship, and considering no alternative cause reported currently. 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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1016233	2/9/2021	CA	78	M	2/5/2021	2/6/2021	About 4 hours after his vaccine, the injection site starting hurting, but not bad. He could not sleep on it at night as he felt like he was sleeping on a red hot pocker. On Saturday he was extremely tired in the afternoon. Had to come in from yard work as he could not function. He also had pain in his neck and shoulders. On Sunday he the feelings were going away, but his muscles started aching. On Monday he felt really strange, felt like he was in a fog, and his muscles ached. He could not get relaxed, did his normal Monday chores, laundry and house cleaning. He then tried to relax but his muscles and nerves were very tense. He went to bed around 9:30 on Monday, fell asleep and awoke at 2:00 AM and could not go back to sleep his muscles in his arms and legs were in spasm and his arm would jump like a shock reaction and jump off of the mattress, as well as his leg. It was worse on the left side than the right arm. This went on every 10-15 minutes for about 3-4 hours. Around 4:00 AM this morning it eased off to sleep and woke up at 10 and felt better today. He hasn't had any more of the seizure type feelings in his arms or legs. He did speak with Moderna who told him that he was the 4th one with this reaction and to report this to us.

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1011490	2/8/2021	WI	25	F	2/5/2021	2/5/2021	ED COURSE & MEDICAL DECISION MAKING Patient is a 25-year-old female who presents as a first responder to the emergency department today. On my initial evaluation she is awake, alert, and in no acute distress, she does appear drowsy. She is fully oriented and able to answer questions. She has a normal neurologic exam. Her labs show negative pregnancy, mild anemia, no leukocytosis, unremarkable CMP, normal CK. A CT scan of her head shows no acute abnormalities. The evaluation she appeared back to baseline. On chart review it appears that she has previously been diagnosed with psychogenic nonepileptiform seizure and so no medication been previously recommended by her neurologist. It is possible that her Covid vaccine triggered a recurrence of these versus this episode represents a true seizure. Therefore I did recommend against driving, working at heights, swimming alone, and recommended things to help avoid seizures. I recommended she follow-up with her primary care doctor as well as her neurologist. I do not think she requires any medication today. She is ambulating with a stable gait in the emergency department. She will be discharged home, she was provided with reasons return to the emergency department.
1010548	2/8/2021	CA	36	M	1/19/2021	1/19/2021	sciatica with pain radiating from lower back to glute and then down to the left foot; This is a spontaneous report from a contactable healthcare professional (patient). A 36-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EL3247), intramuscular in the left arm on 19Jan2021 at 13:15 at a single dose in the Nursing Home/Senior Living Facility for COVID-19 immunization. Medical history included stroke, hodgkin's lymphoma, cerebral vasculitis, seizures, chronic venous insufficiency, and had COVID prior to vaccination. Concomitant medication included levetiracetam (KEPPRA), apixaban (ELIQUIS), and levothyroxine sodium (SYNTHROID). The patient experienced sciatica with pain radiating from lower back to glute and then down to the left foot on 19Jan2021. Leg feels like it is going to give out. The patient did not receive treatment for the event. The patient was not tested for COVID post vaccination. The patient was recovering from the event.

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1012782	2/8/2021	NY	52	M	1/19/2021	1/20/2021	Vaccine administered on 1/19/21 at 2:15pm and patient began having seizure activity on 1/20/21 at approximately 4pm. Patient sent to ER for evaluation. Temperature of 102 was noted at ER. Seizure eventually resolved and he returned to his residence. He has a prior history of seizures.
1012842	2/8/2021	NY	74	F	2/4/2021	2/4/2021	74 yo woman living in a group home for people with developmental disabilities. She has longstanding difficult-to-control seizure disorder, on valproate, lamotrigine, and levetiracetam. She had asymptomatic COVID-19 infection in November 2020, probably discovered in the course of surveillance testing of residents/staff, perhaps in relation to an outbreak in the residence. Sometime during the night following her vaccination earlier that morning, she developed a fever, and then was found to be having a generalized tonic-clonic seizure. Estimates of duration in the records range from 20 to 40 minutes. She was brought by ambulance to Hospital ED, and then admitted. Her temperature was said to be 103 F. She received midazolam, and at least one dose of IV antibiotics. By the evening of admission on 5 February 2021, she was still unresponsive. On arrival, her COVID-19 PCR was again/still positive. She had no prodromal symptoms suggesting COVID-19 reinfection, nor did anyone in the group home, staff or residents. Her initial WBC was normal but with a slight left shift. UA was normal. Head CT showed her known cerebral atrophy and chronic microvascular disease. Admitting valproate serum level was subtherapeutic; levetiracetam and lamotrigine levels were therapeutic. Blood cultures are no growth at 2 days. Urine culture negative. By hospital day 2, her transaminases had bumped to over 1000.

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1012896	2/8/2021	IA	51	F	2/6/2021	2/6/2021	RN was called over to case, upon arrival, case was pale, diaphoretic, nauseated. Attempted to ask case name twice, she did not respond, case was began ?snoring? for roughly 3 breaths, then began dry heaving, which produced minute amount of blood tinged phlegm. At this time, case was able to tell me her name and was able to remember that she had just received her vaccine. Per her mother and guardian, case has history of mental disabilities and allergy to oral penicillin. Case also has history of childhood seizures that were so mild, she is not on medication. Case requested to be taken to ED for evaluation.
1013143	2/8/2021	CA	83	M	2/6/2021	2/8/2021	Pt is on hospice services for 5 months for CVD/CVA. On 2/8/21 pts dtr called to report new onset seizure (no hx of seizures). Per dtr report only change in pts condition is that he rcvd the COVID vaccine on Saturday 2/6/21. Dtr called 911 due to severity of seizure.
1013202	2/8/2021	CO	71	F	2/3/2021	2/4/2021	Had COVID vaccine on Wed Feb 3, had seizure-like symptoms last night, her body mostly went stiff, happened at least 3 times during the night. Was very limp afterwards; has not had any issues since waking up this AM, has headache and body aches.
1013233	2/8/2021	FL	66	F	2/2/2021	2/3/2021	24 hours after second Pfizer dose, multiple Seizure activity occurred. Client was transported to the hospital for a 3 day stay. During that visit client was sedated and has little recall of hospitalization. Medication upon discharge - Keppra 750mg BID. First dose Pfizer 1/12/21 no reaction, not even sore arm

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1014817	2/8/2021	ID	44	F	2/5/2021	2/5/2021	I felt fine after the vaccination at 11AM. Between 1-3:30PM, I got a pedicure and drank two 5.4% alcohol beverages. I drove home, made dinner, and ate. Shortly after eating, around 7:00PM, the soreness in my arm got intense, I began feeling nauseous and disoriented. I went to the bathroom and got on my hands and knees because I thought I was going to vomit. My boyfriend helped me get up on the edge of the bathtub, but I quickly passed out and fell forward. He said I was out for approximately 30 seconds. I came to long enough to tell him to call my mom then passed out again. for about 15 seconds Within minutes my mom, sister and daughter arrived, followed by first responders. First responders had to keep me from passing out for about 10 minutes, during which time I broke into a cold, soaking sweat, had involuntary muscle convulsions, extreme nausea, disorientation, slurred speech, and loss of ability to get up or walk on my own. I was admitted to the emergency room around 7:45. It took another hour for me to regain muscle control, speech and total coherency. I was released and went home. My arm was severely sore until Monday morning, but I also experienced severe fatigue, nausea, headache and muscle aches until late Sunday.
1013035	2/8/2021	HI	87	F	2/4/2021	2/5/2021	Moderna COVID 19 vaccine #1 given 2/4/21 at 130pm. Patient had malaise, confusion on 2/5. She then had 3 generalized seizures- status epilepticus- on 2/5 around 4-5pm. MRI brain and labs unremarkable. She recovered 36 hr later - on Keppra.
1009402	2/7/2021	NY	57	M	2/1/2021	2/6/2021	Fainted twice. During the second faint had a mild shaking (seizure) he was out for about about 10 seconds then came awake. Sweating and hot. He slept for an hour, then was able to stand, and take the stairs up to bed. I'm calling his doctor tomorrow (Monday).
1010172	2/7/2021		41	F	2/4/2021	2/4/2021	1350 Feeling anxious and weird, HX seizures as a child, 1413 Zyrtec given laid down Semi Fowlers position 1444 Report feeling nasal congestion throat swelling has improved. Vitals 124/84, P-79 SPO 97 % Exited and in stable condition.

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1009831	2/7/2021	MO	33	M	2/4/2021	2/4/2021	10 hours after receiving injection, spontaneously began feeling cold, shivering to rigors, rapid heart rate increased respiratory rate, lips and nail bed dusky, T37C. Took to ER, Temp 101 F and experienced a grandmal seizure, lasting approximately 1 minute of vigorous movement. frothing and flaying . Temp up to 103F. tachycardia and SOB, PO2 in 90's blood pressure low 78/45 88/50 after 3 liters of fluid up to 100/50. Chest Xray, EKG, multiple labs blood and one urine text.

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1020134	2/7/2021		61	M	1/28/2021	1/29/2021	<p>anxious, restless, weak, dizzy, felt "horrible". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, "shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease." No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got "that shot" he hasn't felt well. When asked what shot pt replied "COVID shot." Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above</p>

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information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped.

1007638 2/6/2021 OH

39 F

2/3/2021

2/3/2021 Patient experienced seizure activity and respiratory distress approximately 1 hour after receiving the vaccination. Patient does have a history of seizure activity and physician on site was skeptical as to whether this was due to the vaccination or the patients history. Could also have been a result of change in environment or stress of vaccination clinic day.

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1007846	2/6/2021	MO	22	F	2/6/2021	2/6/2021	Patient collapsed to the ground when walking to leave the post vaccine clinic observation area. She collapsed and had a 60second seizure followed by 4 minutes of post ictal activity. She did not vocalize answers during the time but nodded yes when asked if she had a seizure disorder. Patient had another 60 second seizure and then EMS arrived. Her seizure was generalized twitching and patient was unconscious. Vitals remained stable.
1007848	2/6/2021	MA	77	F	2/6/2021	2/6/2021	Patient complained of dizziness and said she was going to pass out. Observation nurse called site clinical lead over, at that time the patient was responding to verbal cues. Mask was taken down and she was guided to take slow deep breaths, continued to report feeling as though she was going to pass out. Site clinical lead then noted patient with fixed gaze to the size, clenching hands and rigid posture. Observation nurse called for EMS assistance. Patient breathing slowed, mouth open, eyes remain fixed to the size with rigid posture for 5-10 seconds. Patient did not respond to any verbal cues. Site clinical lead and observation nurse lowered patient to the floor, at which point patient became responsive. Responded correctly to reason for visit to site, location and how she was feeling. Denied history of seizures or stroke. Reported feeling anxious and needing to use the bathroom. Did not appear to lose bowel control at any point. Patient was very diaphoretic and pale, but alert overall. Cold compresses applied to forehead and back of neck while patient remained supine. EMS arrived and had patient sit up, at which point she again became very pale and reported feeling as through she was going to pass out. EMS transported to hospital for further evaluation.
1008282	2/6/2021	NM	43	F	2/6/2021	2/6/2021	Patient was reported to have possible seizure. She reportedly went to floor on her own. Seizure had ended and had gotten back to her feet by the time pharmacy personnel arrived. Patient seemed not to want to stay in store and left with a family member about 5 minutes after event was reported.
1008329	2/6/2021	MO	65	F	2/3/2021	2/4/2021	Vomiting Nausea Dizzy Possible seizure while sleeping
1008509	2/6/2021	IN	54	M	2/3/2021	2/3/2021	Normal chills, weakness, sore body, dry mouth. Had a seizure around 7PM

<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>
1015840	2/6/2021	OH	56	F	2/3/2021	2/3/2021	Approximately 12 hours post injection - There were great tremors inability to control extremities, complete weakness, unable to move bed sheets or stand, seizure like activity with lack of ability to walk to commode or reach toilet paper could not walk back to bed. Following night - complete drenched but manic in morning when awoken.
1007754	2/6/2021	PA	20	M	2/5/2021	2/5/2021	Following second vaccine, about 12 hours after vaccine. Sever levels of fatigue, nerve pain, joint and muscle throbbing, convulsions, fever of 102.4
1008756	2/6/2021	IN	38	F	2/4/2021	2/5/2021	Nausea, seizure
1005639	2/5/2021	CA	71	F	1/29/2021	1/30/2021	hospitalization, intermittent drooling, difficulty finding words (like a broca's aphasia), slurring of words, and absent seizure

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1004266	2/5/2021	TX	26	F	1/5/2021	1/1/2021	hard large lump that hurts at the injection site /Left arm has a knot in it from injection site; hard large lump that hurts at the injection site; chest pain; shortness of breath; This is a spontaneous report from contactable consumer (patient). A 26-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231), via an unspecified route of administration into the upper left arm on 05Jan2021 at single dose as a precaution because she works in nursing home (COVID-19 immunisation). Medical history included Covid positive back in Oct2020. Concomitant medication included biotin and one a day women's vitamin. Family members have medical issues. Dad has heart tumors, seizure, sleep apnea and osteoporosis. Mom has asthma, diabetes, has had cancer, neuropathy and macular degeneration. The patient received first dose of the covid vaccine on 05Jan2021 and had some symptoms after the vaccine. On unspecified date in Jan2021, the patient hard large lump that hurts at the injection site, chest pain and shortness of breath; similar to when she had Covid positive back in October. She still has a lump at the injection side which has gotten smaller in size but still hurts to touch. Left arm has a knot in it from injection site; does not reured ER or visit to physician's office. It feels like a bump with something in her arm. She doubts that is the case. She wanted to see if that was normal and when it might go away, especially since she should be getting second dose on 26Jan2021. She is a speech therapist. There is no prescriber. They came and gave to everyone all at once. It was really big at first. It felt like someone punched her. It was a big giant lump, but it is getting better. The injection was given in the upper left arm and it felt like it went into the muscle. The outcome of the event vaccination site mass was recovering, and the outcome of the remaining events was unknown.
1004913	2/5/2021	VT	21	F	2/4/2021	2/4/2021	After receiving vaccine, Employee complained of tachycardia (P=100), some dizziness. Employee drank water and juice. Employee appeared like she might vomit and started shaking, employee was lifted from her chair to the floor. Employee was turned to her right side and was having a seizure. CODE Team was called and Employee was taken to Emergency room via stretcher.

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1005098	2/5/2021	VA	88	F	2/2/2021	2/2/2021	Systemic: Seizure-Severe
1005290	2/5/2021	ND	40	F	12/22/2020	1/1/2021	On Jan 1st-3rd felt so tired I couldn't get out of bed. Slept almost 24 hours a day. Morning of Jan 3rd I had a seizure. I have no memory following the next 36 hours. Spent 3 days in the hospital. Cause as yet I know. EEG during hospital stay and again on Jan 29th showed no unusual activity. Mri and CAT showed nothing abnormal.
1006791	2/5/2021	MN	79	M	1/28/2021	1/28/2021	Seizure Activity: Nursing assessment: 1/28/2021 17:55 Staff asked writer to check on resident, stating that there was something wrong with him. Resident found sitting up in wheelchair. Resident noted to be nonverbal, making small jerking movements with upper extremities and head articulated to the left. As writer attempted to assess pupils, resident squeezed eyes shut and grimaced. Resident did squeeze with both hands, equal strength. VS: 94, 16, 138/86, 97% on RA. Resident put into bed with assist of two staff and hooyer lift. MD notified: 1/28/2021 18:10 Return phone call received from Physician. Advised to continue to monitor and OK to send to ED if resident representative wants further evaluation done. Nursing assessment: 1/28/2021 18:35 Resident found to be alert and smiling at this time. Resident speech is garbled per baseline. VS: 111, 20, 129/77, 100% on RA. Resident able to follow commands. ROM equal with strength at baseline. No incontinence noted. Resident noted to be fatigued. Start of episode of seizure-like activity not witnessed. The time between first found by staff to noted resolution was approximately 40 minutes. No further seizure episodes noted. No previous hx of seizure activity.

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1007072	2/5/2021	AZ	32	M	1/27/2021	1/27/2021	Patient received his vaccine and was waiting in the post-vaccination waiting space. Within 5-10 minutes he slumped in his chair and became unresponsive. Became responsive to voice but was slurring his words. Patient was diaphoretic. HR in 90s, O2 98%. His eyes rolled back in his head suspecting vasovagal episode, we moved patient to the floor and raised his legs. He became more responsive. Was fully oriented although did not seem incredibly alert. Cycled multiple BPs with 100s-110s/60s-70s. HR 70s-80s supine, O2 sat 96-98%. EMS was called for transport to ED given patient's lack of prompt recovery. We attempted to sit patient up and he again became lightheaded and had to lie back down. While in supine position, remained with normal and stable VS. At no time did he manifest any rash, respiratory symptoms, throat or chest tightness, abdominal discomfort, or other overt signs of anaphylaxis. Patient was transported to the ED where ROS was reported as: - CONST: +fatigue, denies fevers or chills - EYES: Denies vision changes - ENT: Denies rhinorrhea, sore throat - CV: Denies new chest pain - RESP: Denies SOB or cough - GI: Denies abd pain, n/v, diarrhea - GU: Denies dysuria - MSK: Denies new joint swelling or pain - SKIN: Denies new lesions or rash - NEURO: Denies new HA, numbness, or weakness - PSYCH: Denies suicidal ideation Vitals: BP 116/67, O2 99% on RA, Temp: 97.7F, Pulse 79. ED provider felt this was most likely vasovagal episode given occurrence following vaccine administration and associated sx's. EKG without evidence of dysrhythmia. No PE risk factors, SOB or CP. Pt with HA that was not thunderclap nor severe in nature and was consistent with prior migranes, thus do not suspect SAH. No hx to suggest anemia and no anemia on blood work today. No report of seizure. Pt is alert without report of post-ictal period.
1005641	2/5/2021	MO	21	F	2/3/2021	2/4/2021	Patient reported having a seizure that was non convulsive. Patient was no conscious, racing heart beat. Seizure lasted 17 minutes. Patient reported no vomiting or urinating during the seizure.

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1005734	2/5/2021	PA	44	F	2/4/2021	2/4/2021	15 min after vaccine administered patient stated she had a frontal headache radiating to her right side of head and tingling around her lips. She was instructed to stay for an additional 15 min for observation. She was placed on a stretcher to lie down. She was conversing and her S/S went unchanged. At approx 1 pm she became unresponsive, she did not wake with touch or verbal command Her eyelids were fluttering as if she was experiencing a seizure. A condition was called. Pulse ox 100 % blood sugar 90. Monitor NSR. She remained unresponsive and was taken to the ED. Upon arrival to the ED at approx 1:17 pm, the ED nurse stated she was awake. Evaluated by physician, labs and CT head ordered. Patient stated all lab work and CT scan was normal. Employee was discharged with a diagnosis of vasovagal near syncope.

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1006005	2/5/2021	FL		M	1/16/2021		seizure; This is a spontaneous report from a contactable consumer (patient's wife). A 70-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot: EH9899, expiry: 31Mar2021), via an unspecified route of administration on 16Jan2021 09:00 at a single dose for COVID-19 immunization. Medical history included diabetes, cholesterol (abnormal), kidney (disorder), heart (disorder) and thyroid (disorder). Concomitant medications included insulin aspart (NOVOLOG) for diabetes, insulin glargine (LANTUS) for diabetes, atorvastatin for cholesterol, tamsulosin, valsartan (DIOVAN) for the kidneys, levothyroxine for thyroid, diltiazem for heart, metformin hcl, macrogol 3350 (MIRALAX) from 01Feb2013, aspirin [acetylsalicylic acid], vitamin D3 and cyanocobalamin (VITAMIN B12 [CYANOCOBALAMIN]). It was reported that the patient had seizures between his first and second dose of the COVID vaccine on an unspecified date. He has never had a seizure in his life, and he had the Covid shot last Saturday a week ago, not yesterday but the week before (16Jan2021). The patient's wife was asking if they are suggesting that a seizure could have been an allergic reaction and if there has been any other call with someone having a seizure after having the COVID 19 vaccine. The patient was admitted in a hospital from 22Jan2021 to 23Jan2021. Friday of this week (Jan2021), they did a CT scan, blood work, and an MRI. The doctor gave him a pill, anti-seizure pill to start taking. It is Keppra low dose, one in the morning and one in the evening. The patient's wife was not stating that the seizure is caused by Pfizer, but her husband has no history or family history of seizures and is wondering if her husband should take his second shot on 06Feb2021. The outcome of the event was unknown.
1006485	2/5/2021	OH	34	F	1/4/2021	1/7/2021	Had a seizure on 1/7/2021 at home - fell to floor face first and became unconscious - seizure activity two different times a few minutes apart Very nauseated and a severe headache all day prior to seizure

<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>
1006562	2/5/2021	CA	65	F	2/4/2021	2/4/2021	Patient receive COVID vaccine 1, went to observation area and "jerking upper and lower extremities" after sitting. Code Assist called, patient was hypertensive at 182/108, with saturations of 100% on RA. Was transported to Urgent Care in same facility. By that time, she was alert, appropriate, seemed to have a left facial droop. Secondary to apparent seizure and hypertension, decision to transport by 911 was made. Patient did leave the Urgent Care area with paramedics but later decided to go home instead. She spoke with her primary care provider today, 2/5/21.. At that time patient revealed that she was taking zonisamide but not keppra, as prescribed
1006583	2/5/2021		46	F	2/4/2021	2/4/2021	During the 15 minute observation period post-vaccination, patient was noted to have hives on her neck. Patient was taken to ER. Arrival Vital Signs were WNL. Patient c/o itching, erythema, swollen tongue, changed voice, breathing "a little tight". Epinephrine and DuoNeb ordered. Seizure like episode at 02.04.21 at 1240 BP 209/81, HR 111, RR 24, Pulse Ox 100% on 15% Non-rebreather mask, Rectal temp 98.4 ED MD wrote: "At approximately 12:40pm this afternoon the patient was having what appeared to be a seizure versus severe rigors. She was not verbally responsive and appeared to be apneic with her head shaking in her arms flailing rigidly in an up and down motion. Symptoms lasted approximately less than 2 minutes and patient was not postictal. She was not incontinent. Blood sugar is in the 180s and her rectal temp is normal. I believe this patient is having a severe reaction to her moderna vaccine that she received earlier today. Her 1st vaccine was January 7th and today was her 2nd vaccine for COVID." Teleneurology consult conducted, no documented recommendations. Patient was transferred to higher level of care.

<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>
1006640	2/5/2021	NM	45	F	2/3/2021	2/4/2021	In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some "pressure in her head" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM.

<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>
1005565	2/5/2021	PA	56	F	2/4/2021	2/5/2021	Woke up suddenly at 1am on 2/5/2021 with increasing neurological symptoms similar to a migraine aura. There was a no obvious pain, but a sense of deep heaviness/pressure/sinking/dizziness in my head and body. Bilateral tingling/numbness, but still was able to move legs and arms. Did not lose consciousness. My first thought was seizure or stroke. I later spoke to an infectious disease doctor that thought it may be brain vessel spasm due to inflammatory response from vaccine. I had no side effects from first COVID shot other than arm pain.
1002888	2/4/2021	OR	42	F	2/4/2021	2/4/2021	(This RN was not direct observer of initial incident. Initial events as reported by initial responding RNs). Pt had just received Pfizer vaccination and was seated in observation area. Was observed to be "not looking well" and approached by staff. Pt began to hyperventilate, exhibit repetitive jerking motions to upper body/"pseudo seizure-like activity", and reported feeling nauseated. Began to slide out of chair, x2 RNs assisted pt to floor. Pt then placed in wheelchair and taken to Triage tent A. Pt remained alert and oriented throughout duration of event. VS @0915- BP 128/77 HR 131 Sats 100% on RA. 0.3mg IM epinephrine given at 0919. VS @ 0920 HR 108 0938 O2 sats 87% on RA, applied 0.5L O2 via nonrebreather mask. Sats back up to 100% @ 0939. Pt remains alert, intermittently exhibits periods of jerking actions and hyperventilation between periods of calm. With staff assist, called husband who was en route. VS @ 0940- HR 101, Sats 100% on 0.5L via nonrebreather. 50mg IM Benadryl given at 0940. VS @ 0950 HR 109 sats 100% on RA. Husband, to bedside. Pt remains alert. 1007 EMS arrives for transport to Emergency Department
1003434	2/4/2021	OR	44	F	1/29/2021	1/30/2021	24 hours later. Pain that radiated from injection site in left breast and into back and entire arm. A red 2 inch circle about an inch over injection site. Swelling in left arm pit and itching in arm put for 5 days. Fever of 103 degrees Ferenhite. Body chills. Back of head during fever would shake as if about to have a seizure. Woke up next morning in a sweats but flu like symptoms gone. Very scary with the feeling of almost have seizures.

<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>
1003382	2/4/2021	AL	83	F	2/2/2021	2/3/2021	Began with vomiting and diarrhea. C/O chest pain. Bradycardia. Hypotension. 2 seizures in 45 minutes after not having one in years. We gave fluids. Gave Zofran. Comfort measures. Pt passed at midnight. Was completely fine one day before. Had minimal issues with COVID though did have a pneumonia that was treated w ATB early on and resolved.
1002484	2/4/2021	MI	77	F	2/4/2021	2/4/2021	Pt has a hx of seizure disorder. Vaccine given at 0942. Seizure started at approximately 0944 and lasted until 0948. Patient was unable to converse- was attempting. It lasted approximately 4-5 minutes. Her partner was with us and assured us she was okay and did not need medical tx. She states vaccines can "sometimes shock system" but it had been a long time since she had a seizure. Second seizure occurred at 10:10 and occurred for approximately 3 minutes. Patient states she took her medication: Lamictal 150mg BID for her seizures. Partner states that seizures can be normal for her and declined need for ambulance.

<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>
999881	2/4/2021			F	12/30/2020	1/4/2021	after having the COVID-19 vaccine, she mentioned that she was very sick in the hospital and is now getting well; She had seizures after receiving the MMR vaccine; She described her adverse reaction by having stroke like symptoms which she described as she cannot speak; She described her adverse reaction by having stroke like symptoms which she described as having numbness in her hands, face and lips; She described her adverse reaction by having stroke like symptoms which she described as having numbness in her hands, face and lips; She also felt exhausted; she also has pain in her arm; She mentioned that she also has her vision affected/She couldn't drive/There were wavy lines all through her eyes; She described her adverse reaction by having intense headaches/She described her adverse reaction by having stroke like symptoms which she described as having headaches; She described her adverse reaction by having stroke like symptoms; She started to have hallucinations such as seeing people that weren't there, seeing snowstorms, and seeing things shipping throughout the wind.; This spontaneous report has been received from Pfizer Inc, and a nurse, referring to a 65-year-old female patient. The patient's pertinent medical history, previous drug reactions or allergies, and concomitant medications were not provided. On unspecified date (reported as when the patient was younger), the patient was vaccinated with measles, mumps, and rubella virus vaccine (manufacturer unknown) (dose, vaccine scheme, route of administration, anatomical location, lot number and expiration date were not provided), as prophylaxis. On an unknown date, after received the measles, mumps, and rubella virus vaccine (manufacturer unknown), the patient had seizures. She mentioned that she did not have adverse event (AEs) with other immunizations but the measles, mumps, and rubella virus vaccine (manufacturer unknown). On 30-DEC-2020, the patient was vaccinated with the first dose of included SARS-CoV-2 spike protein mRNA vaccine (PFIZER BIONTECH COVID-19 VACCINE) (dose, route of administration and anatomical location were not provided), as prophylaxis. On an unknown date, after SARS-CoV-2 spike protein mRNA vaccine (PFIZER BIONTECH COVID-19 VACCINE) vaccination, she was very sick in the hospital. On 04-JAN-2021, she stated to experience an adverse

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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reaction described as having intense headaches, having stroke-like symptoms (cerebrovascular accident), as she could not speak (speech disorder), having headaches, having numbness in her hands, face, and lips (hypoaesthesia and hypoaesthesia oral). The patient also felt exhausted (fatigue), had pain in her arm (but for that event she reported that she was not very concerned). Additionally, she mentioned that her vision was affected, she could not drive, and there were wavy lines all through her eyes (visual impairment). She also started to have hallucinations, such seeing people that weren't there, snowstorms, and things shipping throughout the wind. It was reported that the patient wanted to know recommendations about the second shot of the SARS-CoV-2 spike protein mRNA vaccine (PFIZER BIONTECH COVID-19 VACCINE) because with her experience, she was not comfortable having the second shot of that vaccine. At the reporting time, the patient was getting well from the event illness. The outcome of the cerebrovascular accident, headache, visual impairment, pain in extremity, fatigue, hypoaesthesia oral, hypoaesthesia, speech disorder, seizure and hallucination was not reported. The causality assessment between the event seizure and measles, mumps, and rubella virus vaccine (manufacturer unknown) was not provided. The causality assessment between the events illness, cerebrovascular accident, headache, visual impairment, pain in extremity, fatigue, hypoaesthesia oral, hypoaesthesia, speech disorder, seizure and hallucination and the suspect vaccine was not provided. Upon internal review, the events cerebrovascular accident, hallucination and seizure were determined to be medically significant.

<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>
999944	2/4/2021			M	12/28/2020		fatigue; drops in his blood sugar; This is a spontaneous report from a contactable consumer (patient). This consumer reported similar events for two patients. This is the first of two reports. A male patient of an unspecified age (age reported as under 55/under 56 years old) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on 28Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced some fatigue and drops in his blood sugar after his first vaccine. The patient asked about any information about seizures or Pancreatic (low Blood sugar) issues and fatigue after receiving the vaccine, and wanted to know the additive/ingredients in the Covid 19 vaccine. The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021071679 same reporter/drug, similar event, different patients

<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>
1000556	2/4/2021	PA	71	F	1/19/2021	1/20/2021	Fever 103.6F with chills; Fever 103.6F with chills; Vomiting; This is a spontaneous report from a contactable other healthcare professional reporting for a patient. A 71-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), lot number: EH9899, via an unspecified route of administration on 19Jan2021 at 11:15 (at the age of 71 years old) as a single dose in the right arm for COVID-19 vaccination. Medical history included hypertension, seizures, hypothyroid, and attention deficit disorder all from an unknown date. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medication names were not reported, but it was reported that she used other medications in two weeks. The patient did not receive any other vaccines within four weeks prior to the vaccination, The vaccine was given at a Nursing Home/Senior Living Facility. On 20Jan2021 at 12:00AM, the patient experienced fever 103.6F with chills, and vomiting. The patient received treatment of Tylenol 1gm once only for fever and chills. The clinical outcome of fever 103.6F with chills, and vomiting was recovered on an unspecified date in Jan2021. It was also reported that since the vaccination, the patient had not been tested for COVID-19.
1000739	2/4/2021	PA	78	F	1/5/2021	1/5/2021	Approximately 10 minutes after receiving the COVID- 19 vaccine resident displayed seizure activity, staring straight ahead and strong allover muscle jerking of both the up and lower extremities, color became gray, activity lasted approximately 3 minutes, resident then became relaxed, color returned to normal, BP-140/80, 97.8, 60, 16, sleeping the remainder of the shift,. Resident continued to decline until resident CTB on 1/19/21
1000859	2/4/2021	OH	35	F	2/2/2021	2/2/2021	Chills/convulsions, fever, body aches, headache
1000873	2/4/2021	FL	49	F	2/1/2021	2/1/2021	Systemic: Anaphylaxis-Severe, Systemic: Fainting-Severe, Systemic: Seizure-Severe

<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>
1003229	2/4/2021	MO	67	F	1/25/2021	2/1/2021	The vaccine is metabolized through CYP450 same as the topiramate. On day 7 after the second vaccination, my migraines returned. They have been under complete control for over 5 years. I have had to increase the dose of topiramate in order to stop the migraines somewhat. My main concern is that topiramate is also used for seizures. If a person taking this for seizures has the same reaction as I did, they may have seizures shortly after their second dose of the MRNa vaccination (either Pfizer or Moderna).

<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>
1001419	2/4/2021	TX		F	1/13/2021	1/13/2021	Seizures; bumps on her right arm; red big spots on her right arm; Fever; A spontaneous report was received from a caregiver concerning a 55-years old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced seizures, fever, and red spots and bumps on her arm. The patient's medical history, as provided by the reporter, included being non-verbal, unable to walk, and seizures that last 1-2 seconds. No relevant concomitant medications were reported. On 13 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number 041L20A) intramuscularly in the right deltoid for prophylaxis of COVID-19 infection. The reporter was a consumer who holds a foster care for older patients. This patient was under her care at the time of the report. The patient received the Moderna Covid-19 vaccine on 13 Jan 2021 at 10 A.M. at the foster care location. She did not notice any reaction after administration. That evening, she saw two big red spots and bumps on her right arm. She iced the patient's arm, but the redness was still visible and bumps were present. That night, the patient started a fever of 102 degrees Fahrenheit. The reporter iced her body down and gave her paracetamol, which helped. She reported that there was no vomiting. On 14 Jan 2021, in the morning the patient had a seizure that lasted 30 mins. The reporter stated that she usually does not call 911 because she is familiar with the patient's seizures that last between 1-2 seconds, but this led her to call emergency services. The seizure was gone when they arrived, and she continued to care for the patient at the home. On 16 Jan 2021, the seizure returned. She had another seizure on 18 Jan 2021, which was concerning, per the reporter because of their frequency. She contacted the patient's health care provider who did not advise anything. She scheduled an appointment with a neurologist. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, seizures, fever, and red spots and bumps on her arm, was not reported.; Reporter's Comments: This case concerns a 55-year-old female patient with a significant medical history of seizures who experienced a medically significant and unexpected event of Seizure and non-serious unexpected event of Injection site papule along with non-serious expected events of Injection site erythema and Pyrexia. The event of Seizure occurred

<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>
							approximately one day after receiving their first of two planned doses of mRNA-1273 (041L20A), which returned on day 3 and 5 after vaccination. The events of Injection site erythema, Injection site papule and Pyrexia occurred on the same day after receiving their first of two planned doses of mRNA-1273 (041L20A). Treatment for pyrexia included iced her body down and Tylenol. Based on the current available information and temporal association between the use of the product and the onset of the events, a causal relationship cannot be excluded and the events are considered possibly related to the vaccine. Of note, patient's prior history of seizures is considered a confounding factor for the event of seizure.
1002948	2/4/2021	WI	64	M	2/3/2021	2/3/2021	Resident had chest pains and rapid heart rate and felt like he was going to have a seizure. Laid back down for a few hours, then EMT called at 6:19 am and transported to hospital. Hospital update that he does have a fever and have him on IV fluids. Tests came back that his cumin levels were high. Patient is back home.
1002604	2/4/2021	MD	28	F	1/22/2021	1/22/2021	Rash (scaly spots appeared over the left upper extremity and back - this isn't an uncommon autoimmune response for this patient) Brain fog Word finding difficulties Suspected decreased seizure threshold - unclear if partial seizure was elicited Intense fatigue Increased sleep Treatment: monitored for 30 minutes status post vaccine injection without any notable concerns; routine observation and monitoring given seizure history Time course: Rash lasted for 1 week; Brain fog/word finding difficulties last fully for 10 days, then started to dissipate; Fatigue and increased sleep lasted 1 week

<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>
1002630	2/4/2021	TX	41	F	1/20/2021	1/22/2021	Pt. stated that she received the COVID vaccine on 1/20/21. On 1/21/21 she felt tired, had loss of appetite. She reported that she went to a store, and apparently "passed out." Employees of the store told her that she had a seizure. Pt. was transported to local ER, where she states that she had a CT of brain, blood work and was told "everything is normal." Stated that she had COVID testing both in the ER and at work, both reportedly negative. This clinic, has thus far been unable to obtain the individuals medical records from the ER. When seen in our clinic on 2/3/21, pt. stated that she is feeling better, but fatigued. No other loss of consciousness reported by pt.
1002643	2/4/2021	CT	75	F	2/3/2021	2/4/2021	Patient had seizure
1002755	2/4/2021	WA	21	F	1/28/2021	1/28/2021	shortly after receiving vaccine client began to have seizure, RN and MD responded to car, family stated this was a normal petit mal seizure for client, family attempted to give client ativan but was unable, EMS called, arrived, MD suggested glucose level, Seizure improving, starting to listen to mother, EMS took over patient, stable, and transported
1002849	2/4/2021	NC	63	M	2/3/2021	2/3/2021	Arrived to the hospital with questionable stroke, 2 seizures in route to hospital (witnessed by EMS personnel) approximately 8 hours after injection.
1002531	2/4/2021	VA	54	F	2/4/2021	2/4/2021	Patient had a seizure about 1 hour following vaccination. Pt has hx of seizure disorder.
1001227	2/4/2021	OH	45	M	2/2/2021	2/3/2021	On 2-3-21 at 8:30a, he had a 1 minute seizure. He also had a fever of 101.3F. The temp responded to Tylenol. He did have another seizure at 12:05p for 1 minute. He continued to require medication for fever thru 12:15am on 2-4-21.

<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>
1001587	2/4/2021	WA	46	M	1/30/2021	1/31/2021	I have never had a seizure in my life before or since, but that morning I had five partial focal seizures in y right arm, over the course of six minutes. As I was on the phone (to report the first one to my caregiver) when the second hit, I inadvertently punched myself rapidly and repeatedly in the right side of my head, with the phone handset functioning as an impromptu bludgeon, leaving bruises reminiscent of the victim of a fist fight. Also at the time I had a strong headache, cold chills, a 102 degree Fahrenheit fever and body aches. None of which persisted beyond noon.
998018	2/3/2021	WI	59	F	1/11/2021	1/22/2021	Reports she suddenly felt ill the morning of January 22, chills, weak, fatigue. Followed by what appeared to be a Grand Mal Seizure. Reports she has not had a seizure in 20 years. However writer found documentation of a seizure in 2014. Patient feels it was related to the vaccine.

<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>
996592	2/3/2021	UT	89	M	1/19/2021	1/19/2021	I received a Moderna vaccine injection on January 19, 2021 at approximately 3:15 p.m. Later that evening at about 7:40 p.m, I was suddenly hit with pain in my back like someone had hit me with a board. The pain continued to surround the midsection in a swath of about 15 inches. I felt like my muscles were failing me. I made it to my bed where I started shivering and shaking uncontrollably feeling like I was having a seizure. The shaking was sporadic, lasting about an hour. I was covered with a blanket and continued with liquids for dehydration and was given an Xanax to calm nerves. Later that night while attempting to sleep, I was perspiring and my heart was beating 90 to 100 beats hindering sleep. Through the night I attempted to go to the bathroom but with absolutely no control over my arms and legs I was unable to stand. Rolling off the bed and unable to pull myself back, I lay on the floor and pulled a cover over me. At about 4:30 a.m. (Wednesday morning.) I was covered with another blanket and a pillow was put under my head. I slept until awakened at about 11 a.m My heart rate and oxygen level was checked and appeared to be within normal range. I was greatly fatigued, and light-headed. Continuing a regimen of liquids, I was fed a small amount of soup and some fruit. I ate nothing the rest of the day. I slept most of the day. In the evening, I was fatigued and nauseated and spent 2-3 hours through the night on my knees in the bathroom attempting to vomit. Thursday morning I was awakened around 11.a.m. and was barely able to lift my head. I slept more until needing to use the bathroom and receiving more liquids. Two hours later I was able to eat only a half a piece of toast ? the first and only thing I was able to eat that day. Early evening having no control of my legs, I attempted to walk. It was difficult getting legs out of the covers, but I got up and walked a few feet with the help of a walker. However, an hour later (about 8:30) I went to the bathroom and was unable to pull myself up from the toilet and fell to the floor and crawl flat on my stomach to my bed. I had no strength in my legs and arms and needed assistance from two people to put me on my bed. Periodic rapid heartbeat and fatigue caused restless sleep. Some strength began to return on Friday and with caution over the weekend, and support from a loving family, I appear to be making a slow recovery. Checking with several family medical people working in

<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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hospitals, my experience with the serum seemed more extreme than most. Therefore, it was felt that I should report some information on how the Moderna injection affected me that it may be of help to others. (Some of the above information was related to me as I was not always cognizant of conditions at particular times.) I am still puzzled, as members of my family are, as to what happened to me. We would be grateful for any information that might be helpful for us to understand my situation as it relates to others that may have had similar experiences with the Moderna serum.

<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>
996739	2/3/2021	CA	75	F	1/18/2021	1/19/2021	<p>Approximately 22 hours after vaccination had a seizure. Felt fine up until the seizure occurred. Never had a seizure in past. No other illness or symptoms. No fever or change in blood sugar.; This is a spontaneous report from a contactable Physician. A 75-year-female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Intramuscular on 18Jan2021 19:30 at single dose on left arm for COVID-19 immunization. Medical history included Stroke, diabetes, hypertension, anaphylaxis to bee stings. The patient had no covid prior vaccination. The patient had no covid tested post vaccination. The patient was not diagnosed with COVID-19 prior to vaccination. Concomitant medications included sitagliptin phosphate (JANUVIA), hydrochlorothiazide, telmisartan, rivaroxaban (XARELTO), gabapentin and baclofen. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously had allergy to Morphine and experienced Hives. Approximately 22 hours after vaccination the patient had a seizure on 19Jan2021 17:15. She felt fine up until the seizure occurred. She never had a seizure in past. No other illness or symptoms. No fever or change in blood sugar. No treatment was received for the event. The patient had not been tested for COVID-19 since the vaccination. The outcome of the event was resolved. Information on the lot/Batch number has been requested.; Sender's Comments: Based on the time association and previously allergic reactions to bee stings and other drugs, the possible contribution of suspect BNT162B2 to the event seizure cannot be excluded in this elderly patient with multiple medical histories including stroke, diabetes 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.</p>

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996907	2/3/2021	TN		F	1/2/2021	1/2/2021	<p>Felt like she was having a seizure, her head kept moving back and forth; Tremendous amount of mucous in her nasal cavity; Didn't feel good; Got really hot; A spontaneous report was received from a consumer who was a 76-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced really hot, didn't feel good, felt like she was having a seizure, head kept moving back and forth, and tremendous amount of mucus from her nasal cavity. The patient's medical history included vagus nerve problems. No relevant concomitant medications were provided. On 02 Jan 2021, at 11: 30 am, the patient received their first of two planned doses of mRNA-1273 (Lot: unknown) intramuscularly for prophylaxis of COVID-19. On 02 Jan 2021, about 8:30 pm, the patient stated she got really hot and didn't feel good. She mentioned she had a history of vagus nerve problems, and this reminded her of that experience when she felt like she would pass out. The patient said she felt like she was having a seizure and her head kept moving back and forth. She mentioned having a tremendous amount of mucus in her nasal cavity. She stated she still didn't feel like herself at the time. On 19 Jan 2021 the patient stated she felt a bit better. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome for the events, really hot, didn't feel good, felt like she was having a seizure, head kept moving back and forth, and tremendous amount of mucus from her nasal cavity, were resolving.; Reporter's Comments: This case concerns a 76-year-old, female patient with medical history of vagus nerve problems, who experienced serious, unexpected event of seizure like phenomenon and non serious, unexpected event of hot flush, malaise and mucus discharge. The event occurred 9 hours after the first dose of mRNA-1273. 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.</p>

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997303	2/3/2021	FL	34	F	1/5/2021	1/6/2021	Patient reported on 2-2-21 that she had a "seizure" during the night following the vaccine. Patient reports that around 12 hours after the injection (which would have been around 2 am on 1-6-21) that she woke up with her arm sore and with nausea. Reports that she went to the bathroom because she thought she was going to be sick but husband reports she passed out and had "seizure like" activity. Husband reports that she "was out" for about 1 minute. Patient was evaluated by ER staff with labs, CT, urine specimen. Per the patient everything came back ok except wbc and tsh were slightly elevated. She is establishing care with primary MD and he is desiring MRI. Patient has not had MRI to date due to insurance requirements. Patients stated that she had COVID in September 2020 and since October 2020 she has been having dizziness and that it has been increasing over the last few months.
997349	2/3/2021	MN	35	F	2/2/2021	2/3/2021	Seizure occurred about 22 hours after vaccine. Unclear if related to the vaccine or recent changes in medications. Patient does not typically have generalized clonic-tonic seizures but had a 2.5 minute GTC seizure the day after vaccination.
997905	2/3/2021	TX	68	M	1/27/2021	1/27/2021	Loss of consciousness, seizure, Fatigue, body aches, soreness at injection site, fever

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998394	2/3/2021	KY	41	F	1/14/2021	1/16/2021	Will call back later this week with lot number. Two days later my body started tingling, I ended up leaving work early. I called the doctor who said and take some Benadryl and rest it off. I was nausea all weekend and slept most of the weekend. I went to work on Monday and worked through Thursday. Friday 1/22/2021 afternoon my body began tingling again, I became so weak that I couldn't walk. I had to leave work early and they made my husband come pick up because the staff at my job did not think I was safe to drive. I was nauseous again. I had major diarrhea and vomiting about a week after receiving the vaccine. This lasted around 3 days. I finally went into the ER on 1/24/2021. They treated me Magnesium and Potassium and 2 bags of IV fluid and said I was dehydrated and sent me home. I went from the ER and I could not sleep that night, the ER gave me so much Zofran it was just to much. I still continued to throw up at home. Went back to ER this time in on 1/25/2021 around 5AM I was losing feeling in my fingers and toes, they were completely numb. I was also still vomiting. They said I my electrolytes were still out of balance and gave more nausea medicine, medicine to help with the cramping and more IV fluids. I was sent home later that afternoon. I went to work on the 26th, I felt slow to react, trouble concentrating, very lethargic, and off balance. I was still nauseous but it was getting better with medicine. My eyes yellows turn straight yellow, I thought I had jaundice. I was able to work all day. I left work and when I pulled into driveway at home 7:01 PM and EMS was in front of my house 7:14 PM. I went inside and went to bathroom and my husband found me and I was having a full blown seizure, foaming at the mouth. EMS took my to ER and I was treated for a seizure and an elbow injury and went home. I have seen the neurologist and my physician since being discharged. They did more blood work. I have been having high blood pressure since then. I am trying to get an MRI scheduled that my neurologist ordered. They started Keppra 500 MG to control the seizures. I have been taking Tizanadine for muscle spasms from the elbow injury when I feel during the seizure. I did have an MRI 6 months ago.

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998412	2/3/2021	NJ	54	M	1/8/2021	1/20/2021	Patient is noticed to have generalized weakness, holding his head towards right side, mild right facial puffiness with mild left facial droop, and sent to ER, on 1/22/21. Patient also had mild fever for the last two days and was on Tylenol, blood pressure also remained elevated moderately than the usual readings. Patient was admitted through ER for 2 days and was discharged on 1/24/21, with a diagnosis of possible TIA, Todd's paresis post seizure. Patient's CT head and MRI of brain was negative for acute stroke. Patient's left facial droop and right side facial puffiness resolved over a week but noticed to have right sided pronounced weakness with moderate swelling on right arm. Patient used to eat by himself, but now not able to do so and not able to hold cup in the right hand. Patient was again sent to ER for repeat CAT scan of head, further evaluation and management. Not sure if patient had an adverse reaction to Covid-19 vaccination, but definitely these symptoms were developed after 2 weeks of receiving Pfizer vaccination, which may be coincidental. Patient was followed up by the neurologist a week after the discharge from hospital who couldn't rule out adverse reaction of vaccination. Patient is awaiting for an EEG, carotid ultrasound and Echo as an out patient.
998416	2/3/2021	ND	39	F	1/8/2021	1/12/2021	Two tonic clonic seizures experienced 6&12 hours post chemotherapy (4 days post vaccine) regimen, cycle 2 of adriamycin and cytoxan

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998549	2/3/2021	VA	23	M	2/3/2021	2/3/2021	Patient presented with a no health hx except for hives to PCN as a child and "passed out" with a childhood vaccine x 7 years ago. Vaccine given without incident, doctor present to distract patient while I gave vaccine. 3-5 min post vaccine patient c/o of nausea and trash can provided. Patient became silent while talking, head fell forward and clonic tonic posturing noted in upper extremities. Called to doctor and patient lowered to floor and placed in recovery position, MSE lasted approximately 30 seconds, EMS called. Post seizure: Patient very pale and diaphoretic, oriented to person quickly, no signs of facial swelling, resp distress or symptoms of a severe allergic reaction. B/P 134/50 HR 80 and regular, patient at this time shares that he had a MSE 3 or 4 years ago with friends. States came around after eating and drinking. States he did not share this information with his health care provider. Patient was AA&O x3 but with dismissed LOC from pre-vaccine state. 1200-EMS arrived, B/P 110/7, glucose 88/EMS, attempted to sit patient up/EMS, became dizzy and pale. Lowered to recovery position and waited for second team. Attempted to sit patient up again when second team arrived and again he became pale and dizzy. 1212- patient consented to be transported to hospital at this time/EMS.
998787	2/3/2021	NC	50	M	2/3/2021	2/3/2021	Seizure unilateral right side, less than 2 mins. 2 times post injection.
998825	2/3/2021	OH	23	M	1/21/2021	1/23/2021	Grand Mal seizure. 55 hours post vaccine. Lasted 15 minutes and required emergency rescue medication Nayzilam. He has seizure disorder but his seizures are well controlled. Typically only has one post op brain surgery or due to illness/infection. Has less than 10 in his life. Phoned one of his physicians to report the seizure and discuss situation. Was told to just watch for other symptoms or side effects. He recovered from seizure and rescue med. Notified two other doctors of the event the next work day.

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999299	2/3/2021	TX	27	F	2/3/2021	2/3/2021	After receiving moderna vaccine administration, we requested pt to wait at least 30 minutes prior to leaving the pharmacy. After 30 minutes, we came back to give the pt her vaccination card and as soon as she stood up, she fell slowly onto the floor and started having seizure (pt didn't hit her head per technician on scene) around 3:50 pm and became unconscious for a few seconds. She was able to answer our questions when she woke up, but was confused of where she at. She continued to call out random names. We called the ambulance and assisted her while she was on the floor. She had another seizure 5 minutes after the first seizure and became unconscious again for a few more seconds. After she woke up, we placed her on her side and monitored her pulse rates and her breathing while on the phone with 911 personnel. The paramedic came 10 mins after the call. Pt had a history of seizure (she wore epileptic tag around her neck). Pt was taken by paramedic to the nearest hospital for further observation.
997849	2/3/2021	VA	40	M	1/28/2021	1/29/2021	Seizure activity, tx with ativan IM and sent to local ED. Febrile to 102.9, status epilepticus, given Fentanyl, Versed, and Keppra. RSI and intubation performed. Intubated and transferred for neurology care. History of similar events; had similar event when infected with COVID-19. Was extubated uneventfully and is recovering well. Currently on azithromycin and augmentin for aspiration PNA>

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994577	2/2/2021	FL	60	F	1/30/2021	1/31/2021	2:00am. Chills started first. Then chills got so bad I started shaking uncontrollably almost like seizures. I used slow breathing methods to try to reduce my shaking. I used an extra large heating pad with 4 blankets but could not get my body warm. I felt like i was suffering from hypothermia. I moved my heating pad around to large body parts to try to warm individual body parts to slow my severe shaking. My severe shaking and extreme chills went on for at least 4 hours. I felt nauseous and felt like I might vomit. I got in shower at 6:30 am to get into a hot shower. I could not lift my left leg without extreme pain in my lower left back. The pain in my back then moved to my hips, then my upper right side. I had diarrhea for 2 days and indigestion after eating small bits of food. I took Tylenol gel caps on Sunday morning with a full glass of water and went to sleep at 10:00 am. I woke up with my hip joints and left ear pain.
996134	2/2/2021	OR	23	F	2/2/2021	2/2/2021	Vaccination administered at 5PM (4:45 appointment) Patient has history of fainting with injections. Patient asked to lie on gurney for vaccination in Medical tent B. Immediately post vaccination eyes rolled back in head. Brief tonic seizure lasting 1-1.5 minutes. Patient unresponsive @ 40 seconds then eyes open and responsive to voice. Vitals stable during episode. BP 135/77 P 103-82 R 14-16 O2 sat 94% on room air improving to 99% after 1 minute. Vital signs repeated at 17:10 and 17:25 (stable). Patient asked to remain supine on gurney for 30 minutes post injection. Patient conversing with staff 2-3 minutes post incident. Patient able to drink juice and light snack prior to DC. DC home with mother after 35 minute observation. Patient assisted to schedule next appointment. Patient asked to request to lie on medical gurney in medical tent for second injection.
995889	2/2/2021	NY	59	F	1/26/2021	1/26/2021	Resident had seizure activity
995563	2/2/2021	TX	85	F	2/2/2021	2/2/2021	Seizure - onset approximately 1 hour after vaccination administration. No medical history of seizures. Duration estimated 3 min - myoclonic head jerking, eyes rolled back, cyanosis

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995462	2/2/2021	NC	71	M	1/27/2021	1/30/2021	Seizure, low sodium, confusion
996158	2/2/2021	AZ	85	F	1/27/2021	1/27/2021	Seizure like activity, nausea
995142	2/2/2021	NY	66	F	1/14/2021	1/19/2021	Short fainting spell; This is a spontaneous report from a contactable consumer (patient). A 66-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/lot number: EJ1686), intramuscularly on 14Jan2021 after 15:00 (her appointment was at 1510 but she had to wait past her appointment time before she received it) in upper right arm at single dose for Prevent Covid in hospital. No history of all previous immunization with bnt162b2 considered as suspect. No additional vaccines administered on same date of bnt162b2. Medical history included breast cancer from 9 years before 19Jan2021 (2012) and she has been Anastrozole since, she was only supposed to take Anastrozole for 5 years and when she was one month away from being done with it she had a Seizure and she was found to have a Tumor in her brain, she had had Srs surgery on her brain on 13Apr2016, she was prescribed Levetiracetam, a seizure medication, for two years and had not had any problem since. Concomitant medication included ongoing anastrozole taking for about 9 years for Post breast cancer. No prior vaccinations within 4 weeks. The patient previously took levetiracetam for seizure, she stopped taking Levetiracetam 750mg about 2 or 3 years before 19Jan2021, flu shot on 05Dec2020 for immunization at the age of 66-year-old. The patient reported that she had a short fainting spell around 8:30am on 19Jan2021 and she was not sure if it was related to the Covid vaccine. She described that she had been sitting for a while and when she got up she felt like this black curtain coming down which she has felt before in the past but she usually recovered and never lost control to where she fainted. Her husband was there to catch her. She clarified that she never passed out. She did not have any reactions in the past few days since she received the covid vaccine, she did not even have soreness at injection site. The event was not required a visit to Emergency Room nor Physician Office. Relevant Tests was none. The outcome of the event was unknown.

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996409	2/2/2021	GA	71	F	1/16/2021	1/17/2021	PATEINT FELT FINE ON THE HOME FROM PHARMACY, STARTED FILLING ILL (NOT QUITE HERSELF) BEFORE BED. SHE AWAKENED AT 5:45 AM. FELT AS IF SHE WAS GOING TO FAINT. SAT DOWN AND PASSED OUT AND HAD A SEIZURE. SLID OUT OF THE CHAIR AND URINATED ON HERSELF AND THE FLOOR. WAS TRANSPORTED BY AMBULANCE TO HOSPITAL.
994502	2/2/2021	FL	78	M	1/19/2021	1/20/2021	Change in gait followed by seizure like bilateral movements. Transported to hospital and admitted. 2 days of testing and consults. Symptoms gradually decreased and released 2 days later.
994265	2/2/2021	AR	82	F	1/20/2021	1/20/2021	got the 2nd vaccine on Thursday and already had symptoms from 1st vaccine but became weaker, vomiting, diarrhea. headache went to the ER Sunday . She was coherent just weak. Did Xray of stomach found out she had colitis , started her on antibiotics and admitted her and by the next morning She started having delusions, almost like having a seizure. on blood work her magnesium was low. She started retaining fluid. Thought maybe she had stroke but CT showed nothing. Now she doesn't know who she is and just repeating numbers. Pt is currently in the ICU. She has a feeding tube now do to not eating.

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993606	2/2/2021		65	F	12/30/2020	1/4/2021	<p>hallucinations; having stroke like symptoms; having intense headaches; felt exhausted; has pain in her arm; her vision affected/wavy lines throughout her eyes; numbness in her face, hands, and lips; This is a spontaneous report from contactable Nurse reporting for herself. A 65-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 30Dec2020 at single dose for COVID-19 immunisation. Patient age at time of vaccination was 65 years. The patient did not have reactions with other immunizations except a severe reaction with the measles, mumps, and rubella (MMR) vaccine when she was younger. She had seizures after receiving the MMR vaccine. The patient's concomitant medications were not reported. The patient mentioned she had a severe reaction. She described her adverse reaction by having intense headaches, having stroke-like symptoms in which she described as she cannot speak, having headaches, having numbness in her hands, face, and lips. She also felt exhausted. She also had some pain in her arm that she is not concerned about. She mentioned that she also has her vision affected, she couldn't drive, there were wavy lines all though her eyes. She started to have hallucinations such as seeing people that weren't there, seeing snow storms, and seeing things whipping throughout the wind. All the events started on 04Jan2021. She reported she was very sick in the hospital and is now getting well. However it was unknown if she was admitted to hospital (clarification pending). She wanted to know recommendations about the second shot of the COVID-19 vaccine because with her experience, she is not comfortable having the second shot of the COVID-19 vaccine. Information about 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 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</p>

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993562	2/2/2021	GA	62	F	1/15/2021	1/18/2021	<p>appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> <p>rash in the top of right hand/rash on the left hand; looks like dryness; This is a spontaneous report from a contactable consumer (patient). A 62-year-old female patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number: EN9899), via an unspecified route of administration on 15Jan2021 at 13:30 on the left arm at a single dose for COVID-19 immunization. Medical history included partial seizures complex, asthma, beginning of heart disease and high cholesterol all from an unknown date and unknown if ongoing. There were no concomitant medications. The patient had no prior vaccination within four weeks. The patient stated she has a rash on the top of her hand right hand and rash on the left hand; it is real dry, it looks like dryness, on 18Jan2021. The patient stated that she doesn't know if it is allergic reaction. She needs help to figure it out. She is asking if she needs to see her doctor. The patient stated that otherwise, the vaccine was healing her and helping her. She stated that she knows you can have a rash all over your body and she wants to know if that is going to happen. She clarified she noticed the rash on the top of her right hand - not the palm. She isn't sure if it came from taking out the trash or cleaning stuff or some other reason. She stated that it is now trying to get on the other left hand too. She said you can't really tell it on her left hand but she noticed it on the night of 18Jan2021. She is unsure if when she washes her hands it is getting from the right hand onto the left hand. She just needs to know if it is from the vaccine or if she needs to stop taking out the trash or maybe wearing gloves. She is scheduled to receive the next dose on 5Feb2021. She lives in a senior facility building. One of the staff members got COVID so they had to get the vaccine. The adverse event did not require a visit to the physician or emergency department (ER). The outcome of the events was not recovered.</p>

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993536	2/2/2021	SC	28	F	1/15/2021	1/15/2021	Seizure; muscle spasm; weakness; hard to breathe at time; can't stay awake; This is a spontaneous report from a contactable nurse (patient). A 28-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot number: EL3346), via an unspecified route of administration at Left arm on 15Jan2021 08:00 at single dose for covid-19 immunization. Medical history included seizure, asthma, known allergies to penicillins and NSAIDs. Concomitant medication included levetiracetam, escitalopram, phenytoin, lamotrigine. The patient previously took naproxen, azithromycin, clindamycin; all experienced drug hypersensitivity. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 15Jan2021 at time of 08:30, the patient experienced seizure, muscle spasm and weakness, hard to breathe at time, can't stay awake. Events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care. 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 not recovered.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the seizure and other reported events due to temporal relationship. Of note, the patient has a medical history of seizure disorder. 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 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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993496	2/2/2021	MA	22	M	12/28/2020	12/28/2020	Low count platelets; Convulsions after vaccination without loss of consciousness; A spontaneous report was received from a pharmacist concerning a 22-year-old male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced convulsions without loss of consciousness and low platelet count. The patient's medical history was not reported. Concomitant medications were not provided. On 28 Dec 2020, the patient received their first of two planned doses of mRNA-1273 for the prophylaxis of COVID-19 infection. On 28 Dec 2020, after getting vaccinated, the patient immediately started to experience tremors and shaking all over his body which was described as convulsions without losing consciousness. On 05 Jan 2021, the patient had a blood test that showed a low platelet count. No treatment information was provided. Action taken for the event was not reported. The outcome of the events, convulsions without loss of consciousness and low platelet count, was considered unknown.; Reporter's Comments: This case concerns a 22-year old male patient. The medical history is not provided. The patient experienced a medically significant and unexpected medically significant event of Convulsions without losing consciousness immediately after receiving their first of two planned doses of mRNA-1273 (Lot unknown). Additionally, the patient experienced an unexpected non-serious event of Platelet count decreased. Based on the current available information and temporal association between the use of the product and the onset of the events, a causal relationship cannot be excluded and the events are considered possibly related to the vaccine.
995335	2/2/2021	VA	49	F	1/31/2021	2/1/2021	About 19 1/2 hours after receiving 2nd dose of Moderna vaccine I had a seizure. I had been asleep, but woke up feeling nauseous, got out of bed to get to the bathroom and my husband said I collapsed, stiffened and had spasms, when I regained consciousness, I had buzzing in my ears, and couldn't feel my extremities for a few minutes.
991651	2/1/2021	VA	24	F	1/25/2021	1/31/2021	Experienced 20 second tonic seizure w/ loss of consciousness. No prior history of seizures.

<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>
993103	2/1/2021	TX	59	F	1/28/2021	1/28/2021	0910 PATIENT FEELS LIKE HER HEART IS POUNDING DUE TO SIMPLE PARTIAL SEIZURES. PATIENT IS AWAKE, ALERT, AND ORIENTED X3 0930 PATIENT FEELING BETTER. "CALMING DOWN". PATIENT STATES NEUROLOGIST AND RHEUMATOLOGIST HAD CLEARED HER FOR COVID VACCINE. PATIENT ATE BREAKFAST, TOOK ALL SCHEDULED MEDS PRIOR TO VACCINE. PATIENT STATES SHE IS NOT SURE IF IT WAS VACCINE OR JUST ANXIETY. "ANXIEY CAN BE A BREAKTHROUGH FOR SEIZURE" PER PATENT 0945 PATIENT STATES SHE FEELS GOOD TO GO HOME. DENIES INCREASED HEARTRATE.
990444	2/1/2021	FL	40	F	1/14/2021	1/15/2021	left auxiliary Lymphadenopathy and lymphadenitis; left auxiliary Lymphadenopathy and lymphadenitis; eyelid swelling; left eye swelling; left eye swelling and tenderness; This is a spontaneous report from a contactable physician (patient). A 40-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date: unknown), via an unspecified route of administration on the left arm, on 14Jan2021 07:30 at a single dose for COVID-19 immunization. Medical history included seizure, COVID prior to vaccination and penicillin allergy. Patient was not pregnant at the time of vaccination. Concomitant medication included levetiracetam (KEPPRA) and lacosamide (VIMPAT). No additional vaccines administered within 4 weeks before the vaccination. The patient previously took LAMICTAL and experienced allergy. The patient experienced Left auxiliary lymphadenopathy and lymphadenitis, eyelid swelling, and left eye swelling and tenderness on 15Jan2021 15:00. Patient took BENADRYL as treatment for the events and was recovering. Patient had not been tested since the vaccination. Information on the lot/batch number 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>
990497	2/1/2021	FL	71	F	1/9/2021	1/11/2021	nauseous; threw up all day; heart races a little bit in the middle of the night/her heart also went racing a few times in the night; sinus pain; dizziness/like she was not dizzy today like she was yesterday, but today she was just more like lightheaded; Low grade fever; feeling sick/doesn't feel good; head hurts really bad/terrible headache; This is a spontaneous report from a contactable consumer (patient). A 71-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; lot number EH9899, expiration date Mar2021) via an unspecified route of administration on 09Jan2021 at a 0.3mL via injection into the left arm for covid-19 immunization. The patient stated that she had Type 2 diabetes which diagnosed about 10 years ago and high blood pressure diagnosed about 20 years ago, so her providers office sent her a text saying the doctor wanted her to have the vaccine. She confirmed that she had no other vaccines on the same day as the COVID vaccine. The patient stated that she had high cholesterol about 5 years ago and her doctor initially put her on Lipitor, but she got to a point where she could not walk, so her doctor put her on something else, but she could not tolerate that either, so then she was switched to the Pitavastatin Calcium. The patient stated that she also had a very sensitive stomach, but she cannot think of the name of what she was diagnosed with because since she had her a couple of seizures started about two years ago this upcoming Aug, she can't think straight. The patient also had GERD about 5 years ago, macular degenerative disease a couple of months ago. All medical condition was still ongoing. Current concomitant medications included levetiracetam (KEPPRA, Tablet) 500mg, once daily, by mouth started from about two years ago, this upcoming Aug for seizures; metformin 1000mg, two tablets daily, by mouth started from about 10 years ago for Type 2 diabetes; allopurinol Tablet 300mg, once daily, by mouth started from probably 2 or 3 years ago for her kidney; metoprolol tartrate (LOPRESSOR, Tablet) 50mg, once daily, by mouth started from 2 years ago for high blood pressure; empagliflozin (Jardiance, Tablet) 25mg, once daily, by mouth has been on this product about 6 months for Type 2 diabetes; lisinopril Tablet 40mg, once daily, by mouth started from probably about 10 years ago for high blood pressure; diltiazem hydrochloride (CARDIZEM CD,

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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24 hour Capsule) 180mg, once daily, by mouth started from a couple years ago; omeprazole magnesium (Prilosec, Capsule) 20mg, once daily, by mouth started from probably about 4 years ago for GERD; hydrochlorothiazide Tablet 25mg, once daily, by mouth started probably about 10 years ago for high blood pressure; Vitamin D 125mcg or 5000unit Tablet, once daily, by mouth as Vitamin supplementation started taking this about a year ago. The patient had a blood test where her Vitamin D was a little low. Vitamin C was got it over the counter; PreserVision OTC medication, with Vitamin A, E, C, zinc and copper Two capsules by mouth daily started from about two months ago for macular degenerative disease; pitavastatin calcium Tablet 2mg, once nightly, by mouth for High cholesterol; it was on it before, but started back on it a couple months ago. The patient reported she doesn't feel good and got headache on 11Jan2021, had dizziness and low grade fever on 15Jan2021, had nausea and threw up, sinus pain and heart races a little bit on 17Jan2021. She did not want to go through this again. The patient stated that she had the first shot of the Pfizer COVID Vaccine on 09Jan2021. She felt for a day and a half by Monday, 11Jan2021, she has been sick ever since, she did not feel good at all. She had a terrible headache, and for probably one or two days, she ran a low-grade fever. Her headache was still ongoing, but it had eased up because she was taking Tylenol. The patient stated that the dizziness she had, caused her to be nauseous and she threw up all day yesterday. She tried to eat something today and she was just having bad problems with feeling sick all the time. She asked if there are recommendations for getting the second shot after having symptoms like this. Today is the third day that she had been feeling the dizziness and it had improved a little, like she was not dizzy today like she was yesterday, but today she was just more like lightheaded. The patient reported that the nausea was ongoing, she felt like she was going to get like today like she did yesterday. She did not think she still has a low grade fever, she probably had the low grade fever on 15 and 16Jan2021. She just can't seem to shake not feeling good. At first that it was her sinuses because that was where her head was hurting, but then the sinus pain went away but she still had a headache. The patient stated that her heart also went racing a few times in the night.

<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>
							Yesterday was a bad day, but today she was a little bit lightheaded. She tried to eat some toast today, so she will see if she can keep that down. The outcome of the events headache, dizziness, heart rate increased and sinus pain was recovering and the low grade fever was recovered on 17Jan2021 and other events was not recovered.
991579	2/1/2021	KS	39	F	1/29/2021	1/29/2021	Systemic: Anaphylaxis-Severe, Systemic: Seizure-Severe
992018	2/1/2021	ND	30	F	1/29/2021	1/30/2021	First vaccine dose was given on 12/29/2020. Patient had moderate swelling to injection site on first dose and was treated with prednisone. Patient was placed on prednisone as pretreatment for second dose. She took the first dose of prednisone on 1/28/2021. Received the second vaccination on 12/29/2021. Patient called ED nursing station one day after (1/30/21) receiving the second vaccine dose stating she had a fever of 102 and did not feel well. She treated it at home with ibuprofen and Tylenol. Her last dose of prednisone was on 01/30/2021. She went to work on 02/01/2021. Staff said they tried talking to her but it was like she was not hearing them. Shortly after she was found unresponsive in the bathroom. She was brought to the ED. She was responsive to voice but was aphasic and had left sided deficits. In past records, she has had episodes of neurological symptoms that were unexplainable. Unable to obtain an accurate history on her due to aphasia so it is unknown what this could have actually started from. Reporting due to previous reaction to vaccine and recentness of second dose in relation to this incident. Did try Keppra to cover for possible seizure. Consulted with transferring physician and she is not a candidate for TPA. She was transferred out to a facility with higher level of care. During time in this ED, neurological symptoms did not improve.

<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>
992308	2/1/2021	WI	25	F	1/28/2021	1/28/2021	: 10 minutes after vaccination to left deltoid, patient approached medical assistant in observation area and reported left neck discomfort and difficulty breathing ?with mask on?; patient taken immediately to exam room for evaluation by nurse practitioner, including full set of vital signs and clinical eval (physical exam and subjective interview); performed continuous monitoring in exam room (including vital signs and physical exam) with 2nd nurse practitioner joining at times to assist; after several minutes, patient reported vision problems at which point patient was placed in supine position on exam table; after laying supine for several minutes, patient exhibited seizure like activity; at onset of seizure activity, notified COVID-19 RN to activate EMS via 911; Epinephrine via autoinjector was then administered to left vastus lateralis; continued clinical evaluation and vital signs monitoring until EMS arrived at scene to assume care; patient alert and accompanied by staff for transport to Hospital via EMS
992407	2/1/2021	NY	67	F	1/22/2021	1/31/2021	Seizure, 60 sec generalized clonic-tonic

<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>
992411	2/1/2021	TX	43	F	1/28/2021	1/29/2021	<p>01/29/2021 930 noticed an itch on left thigh, like I wanted to hive - on various spots throughout the day.</p> <p>01/30/2021 very tired (to be expected), noticed I had burning in what feels like my gall bladder and developed an ?odd? stomach ache later in the day. Thought it had to do with something I ate, but consumed nothing out of the ordinary. Went to bed early, felt like I wanted to fever but never did. decided to take a tsp of children?s Allegra because I still felt ? itchy? at times. 01/31/2021 woke up to what felt like pressure on my chest, like someone was squeezing me. Thought that was odd and thought it was perhaps the way I slept. Was still tired (4AM) went back to sleep. Woke up again feeling more rested and the same feeling. It was an awful feeling. Grabbed my pulse oximeter and my oxygen was about 96 laying down. Called an. ER, thought maybe I had Covid or something as I have never felt that way before. Receptionist told me she felt the same way after she got the shot. I ate, felt better but then developed a horrific headache akin to a migraine that was so sensitive to any movement I made. Felt like someone was shaking my head, it was so painful and I became disoriented. Like. I would get confused in my thoughts. Became very sensitive to light and movement. Looking at Facebook, I had to stop because I felt like I was going to seizure. Had to really rest. Ate lunch and took a multivitamin to see if that helped. Eventually I felt better but had to be careful, take it easy. 02/01/2021 woke up this morning still tired, like my body is fighting something. And I could feel the headache coming on and noticed I was getting confused in my thoughts. I decided to stay home from work. The morning was very bad as I felt as though I wanted to seizure. Could not get a hold of my doctor. My head still hurts, not as bad, but after I eat, I get confused and can?t hold two thoughts at once if that makes sense. Head seems very sensitive to eye movement like yesterday. It?s a gross feeling, even in absence of the pain.</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>
992451	2/1/2021	GA	63	F	1/29/2021	1/30/2021	PT COMPLAINED OF CHILLS, MUSCLE ACHES THE NEXT DAY. SATURDAY AFTER 12, HUSBAND (WHO IS A PHYSICIAN) REPORTED SHE HAD A SEIZURE. SHE NEVER LOST CONSCIOUSNESS. HE APPROXIMATES THAT IT LASTED ABOUT 15 MINUTES. SHE RECOVERED AND HAS NOT HAD A REPEAT EPISODE.
992701	2/1/2021	WV	22	F	2/1/2021	2/1/2021	SYNCOPE. PT STATED THEY WERE GOING TO PASS OUT, BUT NEVER DID. SHE LATER REPORTED THAT MY VOICE GOT SOFTER AND HAD TUNNEL VISION. DURING THE EVENT SHE STOPPED COMMUNICATING AND HAD A SLIGHT CONVULSION THAT LASTED ABOUT 20 SECONDS. PT THEN FELT HOT, CLAMMY, AND "NOT GOOD". PT FELT THIS WAY FOR ABOUT 5 MINUTES AND THEN FELT FINE.
993106	2/1/2021	GA	52	M	1/14/2021	1/28/2021	Experienced a witnessed seizure at work (Paramedic) then became combative. (No hx of seizures). Subdued by use of versed and transported to. Received fluids. CT scan, labs, chest xray, and drug screen all normal. Remained in ER for observation for approximately 6 hrs then discharged.
991417	2/1/2021	FL	65	F	1/31/2021	2/1/2021	Severe chills almost seizure like for at least 2 hours no fever until the morning 100.9
989508	1/31/2021	CO	75	F	1/3/2021	1/3/2021	All information per patient's husband: patient started experiencing severe headache on the day of vaccination. Headache continued for three days during which no medical attention was sought. Confirmed that patient never took any NSAIDs to treat headache during this time. On day 4, patient had a subdural hematoma accompanied by two seizures upon which she was flown to a hospital to receive treatment. Husband did state that patient is on warfarin due to factor V deficiency and that treating physician thought that this was most likely caused by the warfarin, however that the vaccine could not be ruled out completely. Husband also said INR has always been within normal limits.
989664	1/31/2021	OR	18	F	1/15/2021	1/16/2021	seizure

<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>
990048	1/31/2021	CO	67	M	1/27/2021	1/27/2021	Two hours post vaccination it was reported by nursing staff that patient had difficulty breathing. Pt shortly afterwards had a seizure
989940	1/31/2021	TN	30	F	1/19/2021	1/19/2021	Profuse vomiting and diarrhea, syncope, chills, seizures. ER visit received 3 bags of lactated ringers, 12 mg of IV zofran, 12.5 mg of IV phenergan, 2 CT scans.
989922	1/31/2021	TX	38	M	1/30/2021	1/31/2021	Initial symptoms: Body aches, fatigue, sore arm This morning: Same as above with the addition of dizziness, nausea, vomiting, diaphoresis, Temp was 99.9 Around noon: Seizure that lasted about 2 minutes with vomiting. My wife witnessed the event. After the event, I had no recollection of what happened but I was oriented to place and time. 17:00- Addition of headache
989888	1/31/2021	FL	67	F	1/22/2021	1/22/2021	Shot administered 6:08pm. About 6:18pm I felt very tired and wanted to close my eyes. I told my husband 'I don't feel well'. Immediately my eyes rolled back and convulsions started. Then I passed out. EMTs were called over to car and started to administer oxygen. I woke up about 6:30pm cognizant of surroundings. BP was normal. No fever, no rash, no chills. I was just tired. Then 2 hours of vomiting started. Last vomit about 8:15pm in ambulance. EMT unable to administer IV. After waiting in ER waiting room for 45+ minutes, a bed was available (around 9pm). ER doctor gave me ondansetron ODT 4mg Once. Released at 10:12pm to go home. Next 3 days symptoms of lightheadedness and dull headache.
989738	1/31/2021	AR	79	F	1/28/2021	1/29/2021	Seated playing cards. Sudden onset extreme dizziness, short seizure, blacked out X 1-2 seconds Other player called 911. One fire truck followed shortly by one ambulance both with two very cute EMTs. All vital signs normal. Very similar to dehydration attacks but worse and that always followed rising and walking. This attack worse and was not set off ambulating. Worried about a worse effect after second vaccine.

<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>
988888	1/31/2021	IN	70	M	1/30/2021	1/30/2021	HE received his vaccine and was in the post vaccine area for approximately 10 min. The paramedic and I looked up and noticed a sudden change in mental status- dropped his phone and started making slight grunting noises as well as turning pale. We rescued the patient, got the stretcher and he became lucid. His activity was seizure like (petit mal). I called the ED charge nurse, provided report, and the patient was transported via paramedic X 2 to the ED for an evaluation.
987605	1/30/2021	WI	55	F	1/1/2021	1/21/2021	Hives, seizure like spasms, triggered migraine, lost ability to speak, unable to hold pen and unable to write my name, sweats but had cold skin, racing heart rate, difficulty breathing, unable to track what was happening around me, burning and itching skin
988837	1/30/2021	KY	19	F	1/29/2021	1/30/2021	Nocturnal seizure, pain around injection site, fatigue, chills, diarrhea
988771	1/30/2021	IL	32	M	1/26/2021	1/26/2021	PATIENT HAD A SEIZURE, NO TREATMENT WAS SOUGHT, PATIENT STATES HE WAS EXHAUSTED AND SLEPT AFTERWARDS

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987977	1/30/2021	FL	59	M	1/19/2021	1/22/2021	Approximately 60 seconds prior to emergency, patient felt a sense of panic (first time ever). Stated to me (wife) "I feel like I am having a panic attack" as we walked on to a parking garage elevator at 12:30 pm on 1.22.21. As I turned to push the button to go down, leaned against the wall of the elevator. His eyes fluttered and back, he was a little pale. When I turned around, again, he fainted and fell face down on the elevator floor. He never stopped breathing and had no convulsions. He was out for less than 30 seconds. When he came to, he got up by himself with minimal assist from me (911 was already on their way). He did not remember saying that he felt like he was having a panic attack; but he remember the fear/panic he felt just prior to. He was oriented x3. I had him smile, stick his tongue out and speak to make sure it was not a TIA or stroke and there were no symptoms of that. His bladder did release. He went by ambulance to the ER (we were on a mini vacation to celebrate his birthday). They did a CAT scan, checked his blood sugar twice, EKG twice, complete blood work panels and urinalysis. All tests were either normal or negative. They found nothing. His BP was normal for the first 30 minutes at the hospital, then increased. But has been normal ever since (he checks it daily). Absolutely no other symptoms since that episode. He met with our PCP on 1.29.21 as a follow-up and she directed us to complete this form. She has ordered a consult with a Neurologist and that is scheduled for 3.10.21. His second shot for the vaccine is due on 2.9.21.
987737	1/30/2021	MI	65	M	1/22/2021	1/23/2021	On 1-23-21, less than 24 hours after the vaccine was administered, the person developed facial numbness, slurred speech, memory difficulty. BP: 200/100. This occurred again on day 3. Hospitalized a total of 6 days. Discharged home on 1-29-21. Diagnosis: TIA, possible seizures. No history of either. Positive history for controlled hypertension.
985948	1/29/2021	VT	68	M	1/23/2021	1/25/2021	He had a generalized seizure just over 48 hours from the administration of the second dose in the series. He has a longstanding seizure history with periodic seizures. He was hospitalized for two days which infection was ruled out and he had returned to baseline. There was no attribution of the seizure to the vaccine by the hospital team.

<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>
985772	1/29/2021	LA	35	F	1/28/2021	1/28/2021	Nurse 1/28/2021 09:07:30 AM > 0855: Patient c/o blurred vision and dizziness, BP 170/80, P 108, O2 98. Upon assessment patient states she felt like "I'm going to have a seizure", patient completed 15 minute observation and nurse extended observation for additional 10 minutes. 0927: BP 120/78, P78, patient states "feeling much better" and has a doctors appointment tomorrow, nurse suggested that she should visit ER for further observation. Nurse 1/29/2021 08:19:42 AM > Contacted patient for f/u, message left Nurse /29/2021 08:45:01 AM > Spoke with patient, says that her heart rate seemed to be elevated most of the night and that she had to sleep sitting up, concerned about receiving s

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985635	1/29/2021	TX	72	F	1/13/2021	1/13/2021	<p>awful burning in the chest/pain in her chest; horrible pressure and pain in her chest; nausea; felt woozy; 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 EL3246), via an unspecified route of administration in the right arm on 13Jan2021 at 17:39 at a single dose in the hospital for covid-19 immunisation. Medical history included anxiety, seizures, and high cholesterol. She passed out last summer and they put her in the hospital from 31Aug2020 and ran all kinds of tests. In the end, they said she only had a few PVCs (premature ventricular contractions) and she doesn't need to see the doctor for a year. Mentioned she also has chronic bronchitis and this is related to having low platelet count and low immunity. All of these events predate treatment with Pfizer COVID 19 vaccine. Concomitant medication included amlodipine, atorvastatin for high cholesterol, clonazepam for seizures, escitalopram for anxiety, levothyroxine sodium for thyroid, and mirtazapine for sleep; all were ongoing. Stated that she had something weird happen after her injection about four hours after the shot. She received the first dose of the Pfizer COVID 19 vaccine on 13Jan2021 at 17:39 in the right arm. About three or four hours later on 13Jan2021, she was getting ready for bed and when she sat down and leaned over she had a god awful burning in her chest and nausea. She was going to take baking soda but when she sat up she had horrible pressure and pain in her chest and felt woozy so she sat on the floor and then the pain started to radiate through her arm and into her neck. The horrible pain and pressure in her chest felt like something was sitting on her chest and the bad pain in her chest was going into her arm and a little into her neck. She laid real still on the floor, and did a lot of praying, and then 20 minutes later it totally stopped. She got up slowly and finished getting ready for bed and was fine. She was just hoping they will still let her get the second shot. The whole event only lasted 20 minutes and when it was over it was completely gone. She did tell her husband when he came home. She was alone when this happened. The patient wanted to know if she can receive second dose of vaccine. She stated it almost felt like a heart attack. She was planning to get the second dose on 03Feb2021. Wanted to know if</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>
							her effect will preclude her from getting the second dose of the vaccine. Outcome of the events was recovered on 13Jan2021.
986003	1/29/2021	OK	25	M	1/29/2021	1/29/2021	About 5 minutes after the vaccine, I felt my vision going dark and blurry. I then lost consciousness and was told my eyes rolled back and slightly convulsed. I regained consciousness after a short time frame.
984810	1/29/2021	TN	33	F	1/25/2021	1/25/2021	Multiple Seizures unable to breathe still continuing at times still taking normal seizure meds along with Ativan when needed
987301	1/29/2021	NC	87	F	12/28/2020	12/28/2020	My Mother was given the Covid Vaccine (1st Dose) on 12/28/2020. Later that night we received a call from the nursing facility that my Mother was having uncontrollable seizures and had to be transported to the nearby hospital. The ER doctor confirmed that my Mother had tested positive to Covid. She was treated for Covid and was on life support. A few days later we received a call that my Mother had a major stroke. She passed away on January 4, 2021
984800	1/29/2021	TN	32	F	1/4/2021	1/5/2021	Multiple Seizures 24 hrs after event unable to breathe lasted for over one week.
986845	1/29/2021	NH	32	M	1/29/2021	1/29/2021	VR passed out several minutes after injection. He had brief seizure like activity and quickly regained consciousness within approximately a minute. His BP , HR, RR and O2 saturation were within normal limits afterward. He notes that he stayed up all night working the night shift as a police officer and then had caffeine this morning. He had an identical episode years ago after being sleep deprived and receiving a dental injection. EMS was summoned, but he declined transport to the hospital and elected to go home. He was driven home by his wife.
984853	1/29/2021		29	F	1/29/2021	1/29/2021	Syncope versus seizure with urinary incontinence and shaking. Transported to ED via EMS.

<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>
984594	1/29/2021	NY	79	M	1/14/2021	1/15/2021	Threw up 4 times; Had diarrhea 3 times; Tired; This is a spontaneous report from a contactable consumer (patient). An 80-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection (lot number and expiry date unknown) at 79-year-old via an unspecified route of administration in the left arm on 14Jan2021, 9:03 AM at a single dose for COVID-19 immunization/ because people are dying. The patient's medical history was not reported. Patient however stated he is familiar with cancer, epileptic seizures, and heart attacks (pending confirmation if referring to medical history). The patient lives alone and has nobody. Concomitant medications were not reported. On 15Jan2021, from 2:00AM, the patient threw up 4 times, had diarrhea 3 times, and was tired. The patient recovered from the events "threw up" and "diarrhea" on 15Jan2021 (time unspecified). Outcome of the event "tired" was not recovered. It was reported that the patient was scheduled for his second dose on 04Feb2021 at 3:30 PM. Information on the lot/batch number has been requested.
986068	1/29/2021	UT	46	F	1/15/2021	1/16/2021	This is a spontaneous report from a contactable consumer (patient). A 46-years-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), via an unspecified route of administration at left arm on 15Jan2021 02:30 at single dose for COVID-19 immunization. Medical history included complex regional pain syndrome (reported as CRPS) and seizure disorder. No known allergy. Concomitant medication included lamotrigine (LAMICTAL) and birth control, multi-vit. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced headache and fatigue approx. 24 hours following vaccine, headache worsened overnight and felt "un-well", achy on 16Jan2021 15:00 with outcome of not recovered. Therapeutic measures were taken as a result of events included Tylenol/advil. No COVID prior vaccination, since the vaccination the patient hadn't been tested for COVID-19.
986319	1/29/2021	MA	37	M	1/28/2021	1/29/2021	Seizure- labored breathing, tonic clonic, altered consciousness/ unresponsive- duration 4 min, followed by post-ictal state, transported to hospital

<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>
987400	1/29/2021	NY	90	M	1/26/2021	1/26/2021	Patient left the pharmacy and was at his table eating. He dropped his bowl and appeared to be shaking and his eyes rolled back. He was unresponsive so his wife called 911 and an ambulance came and transported him to the Hospital. Concern at the time was either a seizure or stroke.
984389	1/29/2021			F			Seizures; A spontaneous report was received from a consumer concerning a female patient who received Moderna's Covid-19 vaccine (mRNA-1273) and experienced seizures. The patient's medical history was not provided. Concomitant product use was not provided. On an undisclosed date, the patient received their first of two planned doses of mRNA-1273 (Lot number: not provided) for prophylaxis of COVID-19 infection. A social media message was received from a consumer concerning a female patient who developed seizures after receiving the Moderna COVID-19 vaccine. The report stated that the patient was still in this condition more than a week after receiving the vaccine and that she was sent home from the hospital. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the event, seizures, was considered unknown.; Reporter's Comments: This case concerns a female patient, who experienced a serious unexpected event of seizure. The event occurred on an unspecified date after first dose of mRNA-1273, lot # unknown. Treatment details were not provided. 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.

<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>
984404	1/29/2021	IL	41	F	1/13/2021	1/13/2021	Full body rash; trouble clearing throat; felt like there was something stuck in throat; This is a spontaneous report from a contactable nurse (patient). A 41-year-old female patient (not pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number EL3249), intramuscular (right arm), on 13Jan2021 09:45, at single dose, for covid-19 immunization. Medical history included allergies: sea salt, hypothyroidism, anemia, asthma, and seizures (when younger). Concomitant medications were not reported. The patient previously took tramadol and hydrocodone and experienced allergies to both drugs. The patient experienced full body rash on 13Jan2021 10:15 (also reported as about 30 mins after vaccination). On 13Jan2021 10:15 (also reported as about an hour after receiving vaccination), the patient had trouble clearing throat and felt like there was something stuck in throat. The patient has been taking Benadryl and Motrin for these adverse events. The patient had no other vaccine in four weeks, had no other medications in two weeks, had no Covid prior vaccination and, had not been Covid-tested post vaccination. The outcome of the events was recovering.
987047	1/29/2021	WI	30	F	1/28/2021	1/28/2021	Pt has hx of epilepsy but did not inform staff of this. Pt received vaccine. Approximately 12 minutes in to 15 minute observation period, pt expressed she began to feel an aura. RN tended to pt. Pt was safely lowered to the ground where she was placed on her right side. Pt was alert but not responding to RN questions, thus EMS was called as a precautionary. Seizure activity described as full body movements began and lasted approximately 30-40 seconds. EMS arrived post seizure. Post seizure, pt alert and answering questions appropriately. Declined going to hospital via EMS. RN placed call to pt boyfriend who came and picked up pt from the West Allis health department.

<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>
986259	1/29/2021	IA	35	F	1/29/2021	1/29/2021	Patient felt light headed within 5 minutes of having Moderna Covid-19 vaccination. Consumer then became unresponsive after receiving vaccination. He was breathing and had a pulse. . It looked like he was having a seizure; his eyes rolled upward, his left arm shook and he did not respond to touch or voice. . 911 was immediately called and responded within a couple minutes. After a minute he came to and still felt very lightheaded Upon arrival of 911 his BP and heart rate were extremely low and he was profusely sweating. He was then taken to the emergency department.
982529	1/28/2021	MO	52	F	1/28/2021	1/28/2021	Petite mal seizure blank stare with poor respond to staff. Has not experienced this effect under current med regimen in 3 years according to caregiver.
983159	1/28/2021	TX	64	F	1/28/2021	1/28/2021	Patient had left to walk around the store. When patient returned she was not speaking. Patient stumbled into the counter then into the wall. We then caught patient before she could fall on the floor. We placed patient in a chair. Tried to talk to patient but was not responding . Called 911, and which point EMS said patient was having a seizure. EMS then transported patient to the hospital.
982268	1/28/2021	MI	55	F	1/25/2021	1/25/2021	I have longstanding epilepsy but have not had a grand mal seizure in many years until the night I received my second Covid vaccination.
983478	1/28/2021	TX	40	F	1/28/2021	1/28/2021	employee became light headed, dizzy and nauseous. 10-15 min after vaccine. 0956 vitals were taken and employee was asked to lay down on cot (vitals 143/83 p 90) 1003 employee began to have seizure like activity a rapid response was called at 1008. Employee refused to go to ED , husband notified. 1020 Benadryl was given per MD continued monitoring until 1135 employee was recommended to go to ED by MD , she refused stated she was ok just tired. Assisted to vehicle with husband at 1140

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983269	1/28/2021	CA	36	F	1/28/2021	1/28/2021	At checkout post observation period, recipient fell to floor from standing position, seizure observed, series of seizures observed, occurring every 1-3 min, 15-20 second duration, with increasing intensity. BP 144/80 P 87 R 20. O2 Via NC at 6 liters initiated. EMS arrived 1:07 pm. EMS left to transfer to hospital at 1:14 pm. Recipient responding appropriately to commands before and after each seizure. Reported by caregiver that recipient has history of recurrent seizures.
982978	1/28/2021	UT	58	F	1/19/2021	1/20/2021	on Jan 20th, I took my dogs to their grooming appt and stopped at store for a few things. I woke up in store to EMS putting me in ambulance. I asked them what was going on and they said I had a seizure. I had no pre-warning, hit head, right shoulder, and bit lip. EMS took me to Emergency Department. Had labs and head CT, all normal. MD felt seizure was due to vaccine.
982414	1/28/2021	CA	33	F	1/20/2021	1/20/2021	Approximately 10 mins post Pfizer vaccine patient notified EMT she was going to have a seizure. She was placed in a safe position, seizure lasted about 30 seconds. Mild body movement, patient urinated, no physical injury. Mother was present, primary historian. Described course of seizure as regular and last seizure 6months ago. As EMT began taking vitals, she expressed feeling nauseous, and vomited. Afterwards patient stated feeling very tired and wanted to leave. Refused paramedics to be called. Patient wanted to rest, left at 3:00PM. Alert and oriented, no complaints besides feeling tired, able to walk with steady gate. Counseled patient to follow up with provider as soon as possible.
981781	1/28/2021	OK	28	F	1/27/2021	1/27/2021	States was feeling bad that afternoon when left work with achiness, pain in arm, and chills. States fever went to 102.4 and had two witnessed seizures. Had vomiting also.

<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>
981577	1/28/2021	MA	37	F	1/27/2021	1/27/2021	I receive the injection at 7:30 in the morning. At 10:30 in the evening I awoke to having severe Rigors . Shaking uncontrollably. I then became very nauseous. I walked to my bathroom but then felt very dizzy so I had ole my husband up and got myself to the floor . I then passed out and lost consciousness. My husband almost called 911 as he said I was convulsing and he thought I was having a seizure. When I came to I started vomiting . Today I have a headache , body aches , body chills and exhaustion .
981463	1/28/2021	NY	65	F	1/22/2021	1/23/2021	Severe nausea and vomiting,chills, fever,body aches...I had to stay in the bathroom all day sat., nothing would stay down...my body has never ever convulsed so hard to try and get something out of it... Sun .morn. still aches ,fever 101.6 my normal is 97.5...diarrhea all morning...very weak my injection site is sore...my nose has what looks like blisters all around both nostrils and lips have blisters...very tender...very swollen. ..I was able to keep water and food down...mon. still have fever until tues. Still ache all over...my nose seems very inflamed..mon more it was like a pocket of pus came out the left sinus...I had been putting Abreva on and into my nose.and switched to bacitracin...the swelling in my nose has gone down but the blisters are very noticeable...it is Thursday and I am finding myself out of breath on exerting myself and my whole body feels very drained, tired even though I have been getting more sleep...my left arm where the injection was feels like it has been punched .not sore ,not red.just Tha after effects of a punch...I am still putting Bacitracin on and in nose...my O2 stats have not been low at all

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981430	1/28/2021	AL	36	F	1/26/2021	1/26/2021	Around 6PM the evening after receiving the vaccine my arm became noticeably sore and I began to feel achy all over. I became noticeably more tired than usual around 8PM and went to bed about 8:30. At around midnight I woke up hurting all over, joints and muscle aches. I felt suddenly very nauseated and got up to go to the bathroom toilet. Once crouched down over the toilet I became very lightheaded and dizzy. My vision went white and starry and remained this way for my guess is around 5 minutes. My husband says I was showing seizure like activity, moaning and "clenching up." Once my vision cleared up I still felt awful, lightheaded, weak, dizzy. I sat up with a cold cloth on my head. My husband during the course of this was terrified and called an ambulance. The EMT's arrived and informed me the episode had occurred because I was hyperventilating. My chest was uncomfortable at this time and my fingers were tingling. They calmed me down and check my vitals which were stable. I went back to bed and slept after that. I had another feeling of dizziness and nausea about 7AM the next day which resolved. I felt very tired, weak, and achy all day the next day.
983432	1/28/2021	IL	48	F	1/27/2021	1/28/2021	I received a phone call from the persons work place. They reported that she had a seizure at 2:00 PM this afternoon. Prior to the seizure they said that she was "feeling off", "jittery", and "misfiring". The RN that notified me said that they were checking on her every hour and the last check in was at 1:00 PM. She went to check on her at 2:00 PM when she found her in the hallway very pale/gray, bradycardic, and hypotensive. The nurse said she appeared to be postictal and hallucinating. They immediately called 911 -and she was transferred to the hospital and to my knowledge she is still there. RN will keep me updated.
980111	1/27/2021		40	F	1/26/2021	1/26/2021	Constant Fever despite taking Tylenol around the clock, 103.1. Chills, syncope, seizure, extreme fatigue, nausea, headache, loss of appetite.

<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>
980197	1/27/2021	AZ	33	F	1/15/2021	1/15/2021	Approximately an hour after receiving he shot I began experiencing early signs of a headache, and slight fatigue which slowly increased throughout the evening. I woke at 1am (approx. 10 hours after receiving the second Pfizer vaccine) shaking and shivering uncontrollably, freezing and at times convulsing. I was experiencing mild nausea and was unsure if I was having a seizure due to level of shaking and convulsing. Through approx. 4pm the next day I was running a high fever, was almost incapable of speaking or moving due to level of fatigue and weakness. After my fever broke i remained feeling sick through the following day. I needed to take advil for the following 3 or 4 days to manage continual headache, and mild body aches.
979064	1/27/2021	TX	24	F	1/26/2021	1/27/2021	No hx of seizures. Woke up with severe abdominal pain and need to have bowel movement. Diarrhea 1x wth nausea. Severe ear ringing, headache, confusion, and out of body feeling. Loss of control over large muscles, shuffling gait, unable to open eyes or speak, impaired LOC, anxiety and emotions, diaphoresis and hyperventilation.
980074	1/27/2021	IL	36	F	1/27/2021	1/27/2021	patient had her jaw clenched and her upper body contracted, with partial seizure of the upper body, with difficulty breathing. her pulse ox was 86 %. she was given a shot of epinephrine and immediately recovered with pulse ox up to 98%. She was taken to the ER by EMS

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979724	1/27/2021	NM	34	M	1/27/2021	1/27/2021	Patient had vaccine administered by PA and was walking to do his observation period and stopped to get water from a fountain and leaned forward then fell to the floor was unresponsive and had an approximate 20 sec GTC seizure when the seizure was over he came to and was very confused and diaphoretic for approximately 15 minutes after the seizure. 911 was called by RN, and EMS came to assess the patient while waiting patient was placed into a wheelchair by multiple staff and taken to a cot where oxygen was applied. Vitals were taken and vitals were stable. EMS took blood sugar upon arrival that was stable. Patients sister has significant history of seizures but patient has never had a seizure before. Once patient was no longer sweating, pale and confused he was observed for half and hour. His parents came to get him and drove him home from the event. Patient was stable talking and no confusion or SOB or other symptoms after the half hour and patient was released to his father to drive him home and to monitor him for other symptoms.
979422	1/27/2021	NY	73	F	1/26/2021	1/26/2021	Systemic: Seizure-Severe
979227	1/27/2021	ME	57	M	1/24/2021	1/24/2021	Systemic: Exhaustion, Systemic: described by the EMT as a vasovagal reaction. patient passed out and had seizure like reactions. was unresponsive and given epi pen. after EMT arrived, patient was monitored and allowed to leave; symptoms lasted 1 day
979211	1/27/2021	CA	33	F	1/20/2021	1/20/2021	seizure after vaccine
978894	1/27/2021		27	F	1/21/2021	1/21/2021	Patient had a syncopal episode after receiving dose of vaccine and after asking for some water stating she felt dizzy and faint, pale, stiff, unaware of surroundings, nonverbal for approximately 1 minute. Hx of getting anxious at times and hx of seizures. EMS activated - and patient went with EMS for further evaluation.

<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>
976811	1/27/2021	AZ	7	M	1/12/2021	1/12/2021	temperature 101; vaccine was administered to 7-year-old son; This is a spontaneous report from a Pfizer sponsored program, received from a contactable nurse. This nurse reported similar events for two patients. This is the first of two reports. A 7-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided) solution for injection, via an unspecified route of administration on 12Jan2021 at a single dose for Covid-19 immunization. Medical history included respiratory distress (at birth had persistent respiratory distress requiring oxygen for 10-12 days), Febrile seizure in Jan2017, and pneumonia in Jan2017. The patient's concomitant medications were not reported. A mother went to get vaccinated for Covid-19. She took her kids ages 7 and 15. The kids were also vaccinated. The vaccine was administered to the 7-year-old son on 12Jan2021. Her son (patient) had a temperature of 101 on 13Jan2021. The mother was concerned because the vaccine was not recommended for his age. She was wondering if he should be in the ER. The reporter does not know if the child still has a fever. She said that the vaccination providers went ahead and gave the vaccine to the children as well even if they were not scheduled to get them. Outcome of the event was unknown. Information of lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021041926 Same reporter, product, and event, different patient
979461	1/27/2021	NY	54	M	1/22/2021	1/24/2021	The patient lives in a group home. He has a history of seizures with occasional breakthrough. On 1/24/22 at ~4 am he had a cluster of seizures and a fever of 102.0F. The staff called 911 and he was taken to the Hospital and admitted for observation. All the details of the hospitalization and treatment are not known now. His group home staff person who was at the hospital with him reported that he was back to his baseline after 1 day. He remained in the hospital for video EEG monitoring. The studies will be reviewed by neurology to determine if medication changes are needed. His discharge is planned for tomorrow (1/28/2021).

<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>
977426	1/27/2021	GA	70	M	1/20/2021	1/20/2021	Patient has a history of advanced melanoma with brain metastasis. He developed seizure disorder as well and had some mild seizures at home over the prior month. He received the vaccine at 4pm and was monitored in the office for 15 minutes. He then went home with his daughter whom he lives with. He ate dinner with her and read until 8pm when he went to his room. She found him in his room at 9pm unresponsive with seizures. Hospice was alerted and recommend oral valium. He continued to be unresponsive and expired the following day at 7:30 pm.
977903	1/27/2021	WA	27	M	1/21/2021	1/22/2021	Got him up in the morning after he had gotten the vaccine the day before. Sa t him down on the toilet and he immediately had a major seizure. Came out of it, let him sit for 5 minutes, got him up and sat on the chair, gave some juice and water, and he was back to normal. He had diarrhea the day of the vaccination and the day before.
981003	1/27/2021		35	F	12/30/2020	1/1/2021	Patient is a 35yof with a PMH of migraines and anemia who presents for first seizure. Given description of an ictal cry followed by whole body shaking and soreness, it sounds like a GTC. Seizure was in the setting of sleep deprivation for >30 hours and 2 days after first COVID 19 vaccine. She has no other history concerning for subclinical seizure activity.
978123	1/27/2021	CO	76	F	1/26/2021	1/27/2021	Pt states she got her second Moderna COVID19 vaccine in her LUE yesterday 1/26/21. She developed a low grade fever and nausea last night. Today, 1/27/21, around 0800, pt states that she fainted, fell on her left side and injured her L elbow. She states that her husband found her and said it appeared as if she was having a "mini seizure". Husband states pts fainting/seizure episode lasted for 15-20 seconds. Pt states that her L elbow pain was 7/10, but is currently 2/10 and she is now experiencing some tingling in her L third and fourth fingers. Pt denies any hx of a seizure and is currently able to get up and walk around. Pt speaking in full and coherent sentences while on call. Pt advised by triage RN and PCP to go to ER for an evaluation

<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>
977631	1/27/2021	MA	37	F	1/26/2021	1/26/2021	I had the Moderna shot at 3:15pm and it took five hours for it to get into my bloodstream. I ended up having one seizure at around 7:30pm at home and then another one at the hospital around ten pm. I was discharged from the hospital at 11:33 pm. The hospital said that I had a seizure and that's what they treated me for.
979263	1/27/2021	VA	55	F	1/26/2021	1/27/2021	Awoke with body aches, muscle spasms to the point my body felt like it was having a seizures. Chills, pain in joints and muscles. I constantly felt like I had to stretch my body out. Jerking movements for close to two hours. Husband gave me ibuprofen, which did help. Nausea close to the end of the second hour, but never vomited. No HA. Started approx. 12:22 am and started to feel better approx 2:00 am. Did not go to work today as I was tired and sore. Slept most of day. Seem better now, 3:30 pm.
975796	1/26/2021	CA	47	M	1/23/2021	1/23/2021	Uncontrollable shivering shaking almost like a seizure type. Severe headache, pain muscles, close throat dry throat. Tiredness fatigue.

<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>
973185	1/26/2021	AK	41	F	1/11/2021	1/11/2021	headache; feeling unwell; received the first dose on 18Dec2020 injection in left arm at 07:00am/ second dose on 11Jan2021 at 15:30; This is a spontaneous report from a contactable consumer. A 41-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date: unknown) via an unspecified route of administration, in the left arm on 11Jan2021 at 15:30, at a single dose, for COVID-19 immunisation (prevent COVID). Relevant medical history included seizures diagnosed in 2014. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) injection on 18Dec2020 at 07:00 A.M. in the left arm for COVID-19 immunisation (prevent COVID). She was ok on 19Dec2020. After mid-day around noon she did not feel well, and it was hard for her to work on the 19th. She missed two days of work. On 20Dec2020, she could not get up from the bed. Concomitant medications included topiramate for seizures and levetiracetam (KEPPRA). The patient did not receive other vaccines within four weeks prior to and on the same day of COVID vaccination. The vaccine was administered in the hospital. The patient received the COVID vaccine yesterday (11Jan2021). She missed work today (12Jan2021) since she was feeling unwell and having a headache. She works in housekeeping. She started feeling unwell and her headache started after 3 in the morning. She wanted to stay home. Last night she was quite unwell, but she was better after taking second dose of Tylenol. She may need to take more medicine in 2 hours. The events did not require emergency room or physician visit. She does not have lot, NDC, or expiration date to provide for either dose. Outcome of the events headache and feeling unwell was recovering. Information about lot/batch number 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>
973521	1/26/2021	AK	41	F	12/18/2020	12/19/2020	could not get up from the bed; she did not feel well; This is a spontaneous report from a contactable consumer (patient). A 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route in left arm single dose for prevent COVID on 18Dec2020 at 07:00am, at 41-year-old. Medical history included: seizures from 2014. Concomitant medication included: ongoing topiramate oral 50mg one tablet in the morning and two tablets in the evening for seizures; levetiracetam (KEPPRA). No additional vaccines administered on same date of BNT162B2. She was okay on 19Dec2020. After mid-day around noon (19Dec2020) she did not feel well, and it was hard for her to work on the 19th. She missed two days of work. On 20Dec2020 she could not get up from the bed. Emergency Room or Physician Office not visited. No relevant tests done. Action taken for BNT162B2 was not applicable. Outcome of the event was unknown. Information about lot/batch number has been requested.
973571	1/26/2021	MD	57	F	1/14/2021	1/15/2021	Diarrhea; This is a spontaneous report from a contactable health professional (reported for herself). A 57-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: unknown), via an unspecified route of administration on 14Jan2021 (07:30 AM) at single dose for Covid-19 immunization. The patient's medical history included psoriatic arthritis, seizure disorder, and allergy to latex. Concomitant medication included esomeprazole sodium (NEXIUM). 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 diarrhea on 15Jan2021 (06:00 AM). There was no treatment received for the adverse event. The outcome of event was not recovered. The patient has not been tested for COVID-19 since the vaccination. This case is non-serious. No follow-up attempts are possible; information about lot/batch number cannot be obtained.
973673	1/26/2021	NY	30	F	1/20/2021	1/21/2021	Fever of 104, causing febrile seizure. Symptoms began approx. 12 hours after vaccination. Patient was hospitalized for observation for 15 hours.

<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>
974341	1/26/2021	FL	50	F	1/23/2021	1/24/2021	Fever 104F and hallucinations prompting ED visit. While in CT, rigors observed which raised concern for seizure. Patient was admitted for workup. Subsequent EEG did not reveal epileptiform activity.
974823	1/26/2021	OH	55	F	1/11/2021	1/11/2021	When i first got the shot I didn't think it was bad at all I actually hardly felt the needle. around 5 o'clock I started feeling ill and then i started about quarter to 6 I started getting cold and shaking bad but it wasn't like a seizure. So really severe chills. When i got home i got under heated blanket then I started getting itchy and noticed hives all over body. then I started getting blisters on palms of my hands and they were like water blisters. I was uncontrollably itchy. I started looking up online what to do and asked friends and family and started taking Benadryl. I had to take it for 4-4.5 days so then the hives finally went away but I was still itchy. I've just been very very exhausted and been having to push myself to get up. I had anxiety about getting the vaccine but I decided to get it. I still don't feel like myself, I don't have much of an appetite but not losing weight because I've been forcing myself to eat. I'm taking vitamins and praying I feel better but I just don't feel like myself. I don't have as much energy and exhaustion is the big thing. My joints started hurting really bad.
974833	1/26/2021	ND	85	M	1/19/2021	1/24/2021	1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.

<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>
975148	1/26/2021	IL	59	M	1/2/2021	1/4/2021	On 1/4/21 Client had what appeared to be a seizure and went unresponsive. He foamed from the mouth and turned blue. O2 Sat was in the 60's, O2 was applied previous to paramedics arrival. BP was high. Unresponsive for 30 minutes. When he woke he did not recognize anyone, did not know where he was at or what day of the week it was. He was transported to the Hospital. Multiple tests were ran and nothing out of the ordinary was found. Started seizure medication.
975673	1/26/2021	FL	27	F	1/20/2021	1/20/2021	Within 1.5 hours, I started getting a bad headache. She was not hungry, was nauseated and was becoming clammy. She tried to eat but it did not make it better. When she got home, she continued to feel "really bad like she was getting over the flu." She slept for over 10 hours. When she got up, she could not move her arm and her arm was sore at the injection (it was hard, a little swelling but was not red). Then she started feeling worse with bad pain (like she had a stroke). This was around 12 noon to 1 PM on 1/21/21. Around 7 PM that night, she presented to the ER. The ER doctor said he thought she was having a migraine but she has never had one before. Her blood pressure was high at 127/110. Her supervisor walked into the room and said her face was pulling and it looked like a stroke to her. She reported severe pain from her ear to her neck on the right side of her head. She left due to having to provide care to her newborn. She went to hospital on 1/21/21 about 2100. Her blood pressure was still high and she had a heart rate of 120 bpm. She did lab work and CT scan. ER doctor believed she was experience Bell's Palsy and that she had had a mini-seizure. She provided prednisone 60 mg X 1 dose, Valtrex tid and shot of Toradol. She prescribed Toradol for outpatient pain relief.
972145	1/25/2021	TN	76	F	1/22/2021	1/22/2021	Systemic: Seizure
974317	1/25/2021	TX	27	M	1/22/2021	1/22/2021	Pt complained of developing an "aura" that he associates with pre seizure sxm initially followed by shaking. He took an additional dose of Keppra 1000mg & then stated that his throat felt like it was closing. Epipen SQ injection given R thigh @ 6:07 pm. (VS 99% RA P 78 BP 158/90) 6:13pm pt walked to chair verbalized he felt better. 6:17p O2 Sat 99% P83 6:19 BP 160/98 P78 O2 sat 99%

<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>
974105	1/25/2021	CO	22	F	12/31/2020	12/31/2020	Seizure after returning home from getting vaccination (Grand mal) 2 hours post vaccination She had an stressful episode with elevated HR and normal SPO2 5 minute after the shot which was controlled with clonazepam
972956	1/25/2021	AZ	59	F	1/25/2021	1/25/2021	On Jan 25th, 2021 patient went to the Covid clinic to get the first dose of covid vaccine at 5:50 pm. After receiving the vaccine , patient was advised to wait at the waiting room to watch for any adverse reactions. Around 6:05 pm patient had a seizure and was around by the hospital staffs. The rapid response team came and took the patient to the Emergency Department on a wheelchair. Patient was alert when she left the Covid clinic.
972563	1/25/2021	TX	30	F	1/25/2021	1/25/2021	Patient has history of seizures under control with medication. After administration of vaccination, patient had seizure episode within 10 minutes. Patient said while waiting during observation period she got very hot and heat can be a trigger for her seizures. Patient's head and body was secure. Patient claims no injuries from seizure. With ice and water patient cooled down. Checked on patient frequently, Patient felt hot again after 2 hours, however patient was working at this time. Patient again sat and ate some ice and water. Checked patient's blood pressure and heart rate at 2 and half hours after administration. BP was 130s/70s and HR was 64. Patient was recommended to take Tylenol whenever she gets a chance or when she gets warm and was advised to contact her PCP or specialist as soon as possible. Patient felt good enough to continue working according to patient.

<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>
972540	1/25/2021	MN	51	M	1/19/2021	1/22/2021	1/22/2021 this resident was found on his kitchen floor having severe Grand Mal seizures and was profusely foaming from the mouth. RN (writer) responded to the emergency. Resident had 8 seizures between the time of calling 911 and them arriving. They had been IV pushing Ativan and Versed. The seizures did not stop. He was rushed to Hospital, intubated, placed on life support and admitted to the ICU. Resident had an emergency craniotomy and they did not find any infection or cause of the seizures. Many other tests were done and nothing was determined to be the cause at this time. Reported to ICU nurse on 1/23/2021 that resident had received the Moderna vaccine a couple days prior.
972488	1/25/2021	OR	36	F	1/25/2021	1/25/2021	pt experienced seizure and brought responsive to medical tent. Pt has hx of seizures and autism. Also had an itchy rash to chest. Epi 0.3 and 50mg Benadryl given.
972341	1/25/2021	OH	81	M	1/25/2021	1/25/2021	Patient came in to receive his first COVID-19 vaccination at 2:00pm on 1/25/2021. Patient received his vaccine at 2:08pm intramuscularly in his left arm. Patient was asked to remain in the waiting area to be observed. At around 2:34pm, patient started feeling light headed and started yawning. Patient's wife noticed the yawning and said that he does that before experiencing a seizure. After a couple minutes of slow steady breathing, patient started having a seizure and his eyes started rolling back. Patients pulse was steady at the time and soon came out of the seizure. About 45 seconds-1 minute later he started experiencing a second similar seizure that lasted roughly 15 seconds. EMS was called and they came to help him. Patient experienced 1 more quick seizure in the time it took the EMT to get to the store. Patient started having a stronger pulse, breathing better, and looked a lot better. Patient also is a diabetic at the time and his blood sugar was slightly low. EMT assisted patient the rest of the way and they patient and wife left the store to go home.
972254	1/25/2021	MA	21	F	1/25/2021	1/25/2021	Patient suffered from seizure right after vaccine administration.

<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>
972130	1/25/2021	MO	41	F	1/22/2021	1/23/2021	The patient woke up Saturday (1/23/21) with a sore arm and also woke up a little late (for her) with a headache. The patient also felt like she wanted to throw up. The patient went to the bathroom, then started seeing light spots. Shortly after the patient went to the floor. Her husband said that she had a seizure. Said she went stiff, arms were pinned down, eyes open and fixed for 20-30 seconds. and then went limp and sweaty. When she came to, she was nauseated and weak. She took Zofran and slept most of the day. She woke up Sunday and felt fine.
971969	1/25/2021	LA	72	F	1/15/2021	1/21/2021	brought by EMS to ED; seizures at home in bed; 6 Epi and 1 bicarb; no hx of seizure
971949	1/25/2021	MI	49	F	1/14/2021	1/15/2021	I received my second Pfizer covid vaccine at 4:00 p.m. on 1/14/2021 from a co-worker. At 2:30 a.m. on 1/15/2021 I woke up with severe rigors that lasted 2 hours. Over the course of the day 1/15/2021 I had a second 2 hour episode of rigors. They were almost violent and seizure-like. In addition, I had severe nausea, dizziness, decreased vision, fever, myalgia, and exhaustion. My temperature reached 103.4 and lasted over 24 hours. Ibuprofen would bring the fever down 1 degree and helped decrease rigors, but did not help the headache. On 1/16/2021 I developed redness and swelling of entire upper left arm, and edema in arm pit. I spent three days unable to work or sit up in a chair. Symptoms began to decrease after three days, but I was unable to resume full work days until 1/22/2021. Vision returned to 100%, and nausea resolved, on 1/23/2021. Decreased appetite and fatigue are still an issue as of 1/25/2021.

<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>
971552	1/25/2021	PA	30	F	1/11/2021	1/11/2021	Passed out; Chest tightness; Dizziness; Trouble breathing; Itching throat; This is a spontaneous report from a non-contactable consumer (patient). A 30-year-old female patient (no pregnancy) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140), via an unspecified route of administration at site of left arm at 17:15 on 11Jan2021 at single dose for COVID-19 immunization. Medical history included migraine and seizure. Concomitant medication included lamotrigine (LAMICTAL) and zonisamide (ZONEGRAN). Both received within two weeks of vaccination. The patient experienced passed out, chest tightness, dizziness, trouble breathing, and itching throat, all at 17:30 on 11Jan2021. No other vaccines received in four weeks. Facility type vaccine was in hospital. Adverse events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care. The patient received salbutamol (ALBUTEROL), steroids, diphenhydramine hydrochloride (BENADRYL), lansoprazole (PREVACID) and IV fluids for treatment. No covid prior vaccination. No covid tested post vaccination. No known allergies. The outcome of events was recovering. No follow-up attempts are possible. No further information is expected.
970850	1/25/2021	NC	28	F	1/22/2021	1/23/2021	Severe shaking about 12 hours after injection. Started as shivering and turned into full body convulsions lasting just over an hour. Bundling up in blankets did not help as shaking intensified. Only other side effect was a sore arm at injection site.
972263	1/25/2021	MI	77	F	1/21/2021	1/21/2021	Symptoms started to show after 6 hours from having vaccine administered. Patient had stiffness (unable to sit back down from standing position), blank stare, depressed breathing and fever. Transferred to ER, seizures were witnessed. IV Keppra was initiated. Patient was discharged after 2 days and followed up with primary care provider in clinic. Primary provider documented that cellulitis is noted in right arm and antibiotic has been initiated.

<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>
969665	1/25/2021	IN		F	1/4/2021	1/4/2021	Seizure x 10 with pain internally; Shaking uncontrollably from head to toe; Joint pain; Body aches/Crying in pain; Tongue started having spasms like crazy jumping like heartbeat; A spontaneous report was received from a consumer concerning a female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced body aches, tongue spasms, joint pains, seizures, and tremors. The patient's medical history was not provided. Concomitant medications were not reported. On 04 JAN 2021, the patient received their first of two planned doses of mRNA-1273 (Batch number: unknown) intramuscularly in left arm for prophylaxis of COVID-19 infection. On 04 Jan 2021, the patient experienced body aches and tongue started having spasms that was explained as like crazy jumping like heartbeat. On 06 Jan 2021, she experienced joint pain. On 07 Jan 2021 at 8:00 AM, she experienced seizure times 10 with pain internally and convulsion, and she shook uncontrollably from head to toe and cried in pain. Her husband reported that her seizure-like symptoms were lessened during sleep. He took his wife to emergency room where blood test and urinalysis were performed but no significant findings were found. The patient was transferred to a different hospital's emergency room and was given lorazepam in the ambulance. At the hospital, the same tests were repeated with the same results. The patient was notified that there were no findings from the blood test, and no viruses were evident. The patient was given diphenhydramine at the hospital. The patient was advised to see a neurologist. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the events, body aches, tongue spasms, joint pains, seizures, and tremors, were not recovered.; Reporter's Comments: This case concerns a female patient who experienced serious unexpected events of Seizure, Pain, and Tremor, a non-serious unexpected event of Tongue spasm, and a non-serious expected event of Arthralgia. The events of Pain and Tongue spasm occurred on the same day when the patient received their first of two planned doses of mRNA-1273 (Batch number: unknown). The event of Arthralgia occurred 3 days after the administration of mRNA-1273. The events of Seizure and Tremor occurred 4 days after the administration of mRNA-1273. Very limited

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							information regarding the events has been provided at this time. Based on temporal association between the use of the product and the onset of the events, a causal relationship cannot be excluded.
971555	1/25/2021	NC	85	M	1/11/2021	1/12/2021	Passed out; massive diarrhea; fell and hit his face; fell and hit his face; This is a spontaneous report from a contactable consumer. An 85-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 11Jan2021 at single dose for covid-19 immunisation. Medical history included epilepsy from an unknown date and unknown if ongoing (Caller says her father in law hasn't had seizure in years, it was diagnosed when he was a kid, 60-70 years ago). There were no concomitant medications. The reporter is calling on behalf of her father in law. She said he had his first dose of the COVID vaccine recently, she pulled this number off of the paperwork today. She says that she believes he had a side effect for it, and also he was rescheduled for his second dose. She says his second dose was supposed to be in 21 days but they rescheduled him for it at 18 days instead. She says he got the first dose on 11Jan, and they rescheduled his next for the 29th. She says she wanted to know if this was correct or ok. The reporter says that the following day he ended up having massive diarrhea, that it caused him while he was on the commode to pass out and he fell and hit his face, the best she can tell he was alone at the time. She says he did not go to the hospital for that, he got up and cleaned himself off and took a nap, and the nurse next door checked on him later on. The outcome of the events was unknown. Information on the lot/batch number has been requested.
969152	1/24/2021	KS	30	F	1/16/2021	1/16/2021	Patient had 4 seizures within 72 hours after receiving the vaccination. This is increased frequency compared to regular amount of seizures.
968973	1/24/2021	PA	57	M	1/22/2021	1/23/2021	Chills lead to severe shaking / seizure-like activity for approximately 1 hour. Condition abated after taking 1000 mg apap, 200 mg Motrin and 10 mg prednisone. This occurred about 12 hours post vaccine. Reaction preceded by brain fog.

<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>
969186	1/24/2021	WA	77	F	1/23/2021	1/23/2021	1/23. Seizure 1/24. Seizure
969260	1/24/2021	MA	25	F	1/23/2021	1/23/2021	came on 1/23/2021 to vaccinate at Facility. She vaccinated patient. This patient was very apprehensive about receiving the Pfizer vaccine. She held her hand to calm down. gave her the vaccination and 5 mins later the patient said she has a headache, was upset, and started crying. She covered her eyes with her hands and started to shake. She also went to her bed and was rolling in it. The facility called 911 and they came within 5 mins. They did confirm that the patient wasn't having a seizure. Patient was calmed down but still went with the paramedics to be checked out. When I followed up with the facility, they said it was an anxiety event and the patient is back at the facility doing well. Let me know if you have any additional questions.
969381	1/24/2021	MO	34	F	1/21/2021	1/21/2021	COVID-19 vaccination - 2/2 in series. Reportedly, patient fainted following first dose. Approximately 5-6 minutes after patient received second dose, she become lethargic, progressing to non-responsive. A rapid response was called and patient was transferred to the emergency department. She was protecting her airway. En route to the ED, patient's eyes rolled backwards and she began having generalized tonic-clonic movement indicative of a seizure. Patient was turned onto her side until seizure activity subsided. Post-ictal state lasted approximately 5-10 minutes after seizure activity ceased and patient became alert and oriented and able to answer all questions. All lab tests and imaging were normal.
968115	1/23/2021	IA		M	3/24/1950	1/23/2021	Patient experienced a seizure 2 hours post his second COVID 19 vaccination. Patient has a history of seizures but had been seizure free for greater than 12 months according to the nursing staff.

<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>
967899	1/23/2021	VT	20	F	1/22/2021	1/22/2021	My fever was through the roof. My body ached so bad I couldn't walk. I was on fire all over. Then came the adverse event- uncontrollable shaking. This was not a side effect written on the moderna sheet of risks. I was shaking so bad I thought I may have a seizure. I finally settled down and fell asleep. About an hour later, I woke up shaking out of control. I was going to call 911 but my partner was able to grab some NyQuil for me and knocked me out. It was the most terrifying experience of my life and I will not be getting the second shot because of it.
967836	1/23/2021	MA	32	F	1/21/2021	1/21/2021	I passed out/minor seizure? Was transported to the ER and given fluids. All test results came back OK and I was released. Nothing like this has ever happened in my life.
968007	1/23/2021	VA	68	M	1/23/2021	1/23/2021	Patient given covid shot. Around an hour after the patient started having a seizure . Nurse gave oxygen and called rescue squad. Patient take to hospital

<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>
968320	1/23/2021	CA	74	F	1/23/2021	1/23/2021	<p>Result type: ED Note Result date: February 13, 2019 20:29 PST Result status: Auth (Verified) Result Title/Subject: ED Note Performed By/Author: MD on February 13, 2019 20:37 PST Verified By: MD on February 13, 2019 20:37 PST Patient Age: 72 Years Gender: Female Date/Time: 02/06/19 13:25 Time of my initial contact with patient: Patient was seen at 1327 Mode of Arrival: POV/Walk-in Triage Narrative: PT BROUGHT TO ED FROM PT SESSION VIA GURNEY WITH C/O SPASTIC MOVEMENTS OF ARMS LEGS. PER EMPLOYEE IN PT; THIS EPISODE LASTED 1 HR 15 MINUTES.. PT'S SPOUSE AT BEDSIDE. SEIZURE PADS PLACED ON BED RAILS, PT AWAKE, ALERT, ORIENTED, DR AT BEDSIDE. PT STATES SHE HAD A COLONOSCOPY YESTERDAY. Chief Complaint: Involuntary movement History of Present Illness: This is a 72-year-old unfortunate female who has been suffering a series of episodes of movement disorder like choreoathetoid spastic events she was being evaluated in the hospital and started having 1 of these episodes and was brought into the emergency room with concerns of a possible seizure certainly patient was quite awake and alert knowing that she could not inhibit these upper and lower extremity spastic type of movements she can that the rectum patient did not seem to be too upset by them and seemed to be some events that she has suffered through multiple times her husband is at the bedside patient has already been evaluated by neuro neurology and has been referred to a motor disorder department. Both the patient and his and her husband do not want to initiate a complete workup has been done several times in the emergency room just wanted to see if we could help her with some Ativan and they are already pending a scheduled appointment this is a sick specifically patient denies any headache any chest pain any palpitations no history of trauma or fever Problem List & Past Medical/Surgical History: Acid reflux Asthma aneurysm pain smoker Movement disorder Thyroid disease Family History: Family history is significant for the</p>

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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absence of any motor disorders Social History: Patient states no history of tobacco use Patient specifically denies any previous use of Drugs or previous trauma Allergies: Dilantin (Rash) codeine (Acute vomiting, Rash, ITCHING) fentaNYL (Shortness of breath) morphine (vomiting, itching) opioid-like analgesics (Rash) tetanus toxoids (Edema, fever) traMADol (itchy) Medications: Available Med List Reviewed Review of Systems: All other systems reviewed and are negative except per HPI Physical Exam: Vital Signs BP: 177/85 mmHg Temp (Temporal): 36.3 DegC (97.3 DegF) HR: 80 bpm Resp: 18 br/min SpO2: 100 % [Patient is alert, cooperative, no acute distress] Vital signs as noted HEENT: [Normocephalic, atraumatic, pupils were equal and reactive to light, extraocular movements movements are intact, neck is supple, no thyromegaly] RESP: [Respiratory rate normal is noted, patient is breathing comfortably in no acute distress, with no adventitious breath sounds. specifically no wheezing no rhonchi no rales] CV: [Regular rate and heart rate noted, patient has no S3, no gallop, perfusion confirmed normal] GI: [Patient's abdomen is soft nontender, no rebound, no guarding] Neuro: [GCS of 15, mentation is normal, thought content and processes intact, motor and sensory both upper and lower extremities normal.] Skin: [Good color and normal capillary refill, no rash] MS:[Patient exhibits a spastic type of upper and lower extremity movements which seem to be having no rhythmical sequence she continues being alert and oriented throughout these episodes they seem to subside after a few minutes and with no obvious precipitant begin again Test Results: Labs Results Laboratory and workup and imaging was refused by the patient as they have had that several times Diagnostic Results Imaging Studies Reviewed Emergency Department Course and Procedures: Medications, IV's and Blood Products Ordered LORazepam (Ativan) 1 mg = 1 tab once PO Critical care patient underwent a critical care observation irrespective of any procedures during her stay in the emergency room a total duration of approximately 42 minutes with concerns of her safety and her neurological status to protected from injury and to monitor her cardiovascular respiratory and neurological organs Medical Decision Making: And reexaminations patient spastic events seem to subside

<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>
							only slightly this is a 72-year-old female presents with a motor disorder of unclear etiology already extensive ER and internal medicine workups has already seen neurology I did speak with the neurologist of the patient tonight to ascertain if there was anything other than Ativan that I could attempt and to also ascertain that she did have a follow-up with her referral motor disorder specialist Impression: Choreoathetotic movements of unclear etiology Plan: Discharge Discharge Follow Up Follow up with primary care provider Within: 3-5 days Comments: Return to ER for any concern Referral for suspected pre-hypertension or hypertension was given. MD Please note: Unless specifically stated, all procedures mentioned, tests done and medications given were performed/interpreted by the emergency physician, or were under the direct supervision of the emergency physician.
965835	1/22/2021	FL	42	F	1/4/2021	1/5/2021	Vaccine 1/4 Left arm, ED visit 1/5 due to dizziness, light headed, chills, HA, fever went up to 102.0, almost passed out; oxygen given, HR rate went up to 230, started to have convulsions, o2 sats down, RR 70, given ativan for convulsions; Follow up with Care Spot 1/; MMI 1/13
965979	1/22/2021	NM	55	F	1/6/2021	1/7/2021	High fever 102 started at 2:30AM on the 7th . I had riggers, my whole body was out of control shaking like a seizure. I was extremely confused I had a 8/10 headache. I had serve fatigue. This last about 24 hours then went away I finally got out of bed the next day about 4:30PM.
965648	1/22/2021	TN	27	M	1/21/2021	1/21/2021	Patient was at his residence. self reported sore arm muscle from injection. was in hot tub, unknown amount of time. got out to check his temperature and fell and hit head on floor. unknown amount of time unresponsive. witnessed seizure activity/ severe muscle cramping post fall en route to ED and also in ED. Possible diagnosis: new onset seizures, rule out rhabdomyolysis
966670	1/22/2021	WI	83	F	1/21/2021	1/21/2021	Moderna COVID-19 Vaccine EUA Pt found unresponsive with seizure at her skilled nursing facility. Pt had first dose of vaccine earlier in the afternoon prior to being found unresponsive and seizing.

<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>
966667	1/22/2021	GA	44	F	1/20/2021	1/21/2021	I believe that I had a seizure lasting about 30 seconds or so
966530	1/22/2021	TX	95	F	1/21/2021	1/21/2021	She began exhibiting seizure like activity, admitted to hospital and observation and since has returned to the facility.
964886	1/22/2021	MO	30	F	12/29/2020	12/30/2020	Fever, intense seizure for 10 min causing blackout, lost feeling in face and three toes, still can't feel 3 toes, lost consciousness.
964082	1/22/2021	CA	44	F	1/13/2021	1/14/2021	Two grand mal seizures and went unconscious. Prior to seizures felt very lethargic.
964202	1/22/2021	OH	24	F	1/13/2021	1/20/2021	1 week later I had a severe Gran Mal seizure
964456	1/22/2021	OH	31	M	1/12/2021	1/12/2021	Moderna COVID-19 Vaccine EUA Fever, Headache, Chills, body convulsions, delirium, confusion, severe fatigue, dyspnea on exertion. Symptoms persisted for about 30 hours. Following recovery of acute symptoms, persistent chest pain is present and is worsened with exertion. Mild soreness is present at the injection site over 1 week later, but is mild and has no significant erythema indicative of allergic response.
966167	1/22/2021	RI	49	F	1/21/2021	1/21/2021	Very sudden severe tremors of face and limbs. I hesitate to refer to it as chills, it was closer to a seizure (of which I have no history). It ended as suddenly as it began, approx 5-10 minutes later. I fell asleep for 12 hours. Today have severe malaise and mild confusion consistent with post-ictal response. Had difficulty organizing routine task (how to make coffee) then slept 4 hrs afterwards from the effort (despite it being caffeinated).
964591	1/22/2021	RI	66	F	12/28/2020	12/29/2020	Patient recieved dose of pfizer COVID-19 vaccine and at some point during the week after had a seizure that lasted 10 seconds. Patient is being monitored.
964909	1/22/2021	CT	36	M	1/20/2021	1/20/2021	Arm throbbing, chills, uncontrollably shaking and convulsions, migrane headache, body aches, muscle aches, hurts to breathe, walk, eat, etc. numbing of limbs, unable to open and close hands, extremely tired and lethargic

<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>
964931	1/22/2021	PA	50	F	1/21/2021	1/21/2021	Systemic: Anaphylaxis-Severe, Systemic: Seizure-Medium, Systemic: Tingling, tremors, convulsions, numbness and difficulty breathing -Medium
965049	1/22/2021	IL	85	F	1/18/2021	1/20/2021	I had a seizure in the early morning 2 days later. I have had seizures for several years and am on anti seizure medication (Vimpat) but have not had any for at least a year. I recovered quickly and am fine now.
965563	1/22/2021	NJ	43	M	1/11/2021	1/1/2021	coughing quite a bit; seizure; his whole body feels sore; This is a spontaneous report from a contactable consumer (patient's mother). A 43-year-old male patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EL3248) in right deltoid, on 11Jan2021 around 10:30, for COVID-19 immunisation. The patient was in high risk group, was living in senior facility and was disabled. Medical history included also ongoing hydrocephalus diagnosed when he was less than a year old, ongoing shunt (the first one when he was 11 months old, has had multiple revisions since then, the last in 2017), vagal nerve stimulator implantation ongoing from 2003 (for epilepsy; has had multiple since then, last one in 2015), ongoing hemiparesis since he was a baby and epilepsy (he was taking epilepsy drugs but it was well controlled). Concomitant medications included oxcarbazepine (TRILEPTAL) ongoing from 2000, at 1800 mg daily (600 mg in the morning and 1200 mg at night), for epilepsy and levetiracetam (KEPPRA XR) ongoing from 2000, at 1500 mg twice daily (in the morning and at night), for epilepsy. He was on prior medications to these, since he was young. Over the years he has changed to newer and better medications. On 11Jan2021 around 8-9 PM the patient experienced seizure. The patient has not had a grand mal seizure in over 5 years. On an unspecified date in Jan2021, after the vaccine, his whole body felt sore. He was unsure if it was from the seizure or the vaccine. The reporter also noticed that the patient had been coughing quite a bit on 12Jan2021 morning. Events outcomes were 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>
965837	1/22/2021	NY	69	M	1/22/2021	1/22/2021	Received vaccine without complication. Has a known seizure disorder secondary to brain injury. Seizures often triggered by stress. During observation period, RN was made aware that patient had decreased responsiveness. States this is common activity for absent seizures which he has several per week. First set of vitals: HR 70, RR 20, SpO2 95% on RA. He was taken to tent where he became more alert and was A&O x 3 and recovered quickly. Second vital set taken 10 mins after first: HR 70, RR 16, BP 140/96, 97% on RA. Evaluated by provider: clear lung sounds, no signs of stridor or difficulty breathing denied any rash, SOB, CP, swelling of mouth or throat. Returned to baseline within 10 mins. Recommended to be evaluated at the ER though left AMA.
964495	1/22/2021	NC	90	F	1/14/2021	1/18/2021	Seizure-like activity. Started on Keppra
962517	1/21/2021	MI	80	F	1/20/2021	1/21/2021	grand mal seizure and temperature of 101.3
960925	1/21/2021	VA	67	F	1/12/2021	1/13/2021	She began to have twitching on the day of vaccine 1/12/2021 but does have a history of seizures secondary to cancer, low grade temp of 99.4 for which she was given tylenol. After the tylenol her fever broke but the lip twitch persisted and her body began to twitch intermittently. She continued to have the twitching throughout the evening and then became unresponsive. She was sent out EMS to our local hospital. She was admitted and returned from the hospital on 1/19/2021 and state she feels fine. New Diagnosis of Metabolic Encephalopathy
961128	1/21/2021	UT	33	F	1/20/2021	1/20/2021	Patient experience a 3 seizures following administration of vaccine. Vaccine was administered at 10:35am, seizures started at 10:40am, EMS arrived at the 10:52am.

<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>
961179	1/21/2021	TX	82	F	1/5/2021	1/12/2021	Seizure like episode on 1/12/21, one week after vaccine, last 1.5 hours, consisting of both eyes twitching and clenching/spasm of right hand and arm. EMS called. BP normal. Continuing weakness of right arm and right leg, which was side weakened by stroke. Could no longer stand or walk on right leg. Some slurring of speech. Some confusion. Went to hospital 1/14. No evidence of stroke or current seizure. Considered problem to be mild UTI, started antibiotics, rapid improvement. Discharged 1/17. Woke up 1/18 with aphasia. Went to urgent care, sent immediately to hospital. Doctors found no evidence of stroke or seizure. Consider problem to be due to inflammation, caused by mild UTI (which was cleared by antibiotics) or perhaps due to inflammation caused by Covid vaccination. The inflammation reinitiated the symptoms of her stroke, although she never had expressive aphasia prior to this, only word-finding problems, which had been resolved.
961399	1/21/2021	CA	75	F	1/18/2021	1/19/2021	Grand Mal Seizure lasting about 10 seconds. Recovered without sequela. No h/o any seizures prior to vaccine.
962591	1/21/2021	IN	68	F	1/21/2021	1/21/2021	Patient was sitting in chair waiting for the 15 minute observation time, about 3 minutes after injection patient started convulsing, patients husband lowered patient to floor and myself and another nurse rolled patient to her left side, seizure lasted approximately 2 minutes , patient awakened and was disoriented and approximately a minute later had another seizure lasting one minute. EMS was called and arrived but patient and husband refused transport to ER.
962722	1/21/2021	KS	61	M	1/18/2021	1/19/2021	Hypoxia, left sided weakness, seizures, transferred to Emergency Room.
964017	1/21/2021	TX	40	F	1/18/2021	1/19/2021	Passing out with seizure like activity 14 hours after dose 2 vaccination

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962111	1/21/2021	NY	45	F	1/7/2021	1/9/2021	I had severe nerve pain in the arm I received the injection in/the pain is intermittent and severe and starts from upper arm to my fingers; This is a spontaneous report from a contactable nurse. A 45-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; lot number: EL0142), via an unspecified route of administration on 07Jan2021 10:30 at single dose at left arm for COVID-19 immunization. Medical history included seizure, meningioma, and asthma. Known allergies: Latex, reglan, and Bactrim. Concomitant medications included lamotrigine (LAMICTAL), mirabegron (MYRBETRIQ). The patient previously took reglan [metoclopramide], and bactrim and experienced allergies. On day 2, 09Jan2021 21:00 post vaccine the patient reported "I had severe nerve pain in the arm I received the injection in. the pain is intermittent and severe and starts from upper arm to my fingers." It was unknown if the patient received treatment for the event. The patient underwent lab tests and procedures which included Nasal Swab: negative, and PCR: negative covid test name post vaccination PCR; both on 04Jan2021. The outcome of the event was not recovered.
961624	1/21/2021	OH	67	M	1/20/2021	1/20/2021	Systemic: Seizure-Mild
959657	1/20/2021	VA	29	M	1/20/2021	1/20/2021	Patient had seizure like activity- Has seizure disorder meds were stopped 1-6-2021
958470	1/20/2021	LA	45	F	1/5/2021	1/5/2021	Started with HA/fever/fatigue and body aches on date of vaccine on 1/5/21. Also had shakes, and had numbness loss of feeling to leg leg. Was admitted to Hospital for 5days. Had intermittet seizure type episodes. Has had labs and imaging tests that have been neg Under the care of the A Neuro Group. MRI scheduled for 1/20/21. As of 1/20/21 feeling better but still weak.
958576	1/20/2021	VA	44	F	1/19/2021	1/19/2021	Systemic: Anaphylaxis, Systemic: Seizure-Severe
958649	1/20/2021	TX	64	F	1/20/2021	1/20/2021	Pt passed out & shaking (possible seizure) shortly after injection. 911 called. Pt conscious after 1-2 minutes. Declined transport to ER. Monitored by RN and pharmacist for 45 min. Pt's husband drove her home when status returned to normal

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958843	1/20/2021	WA	58	F	1/9/2021	1/10/2021	I began to pass out and yelled for my husband, he said when he came in I was sitting on the toilet with my head back, eyes rolling back not responsive.; I had my 2nd vaccine at work early Sat the 9th and felt increasingly worse all day; I woke up at midnight and felt extreme malaise; I was covered in sweat; vomited; I checked my temp and it was 99.7°F; sore; I think I had either a seizure or a vasovagal response.; This is a spontaneous report from a contactable nurse (patient). This 58-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot EJ1685 or FJ1685), intramuscular at single dose in the left arm on 09Jan2021 06:00 for Covid-19 immunisation. Medical history included atrial fibrillation on unknown date (1 episode), allergic to Keflex. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot EJ1685 or FJ1685), intramuscular in the left arm on 22Dec2020 for Covid-19 immunisation. On 10Jan2021 01:00 AM, the patient experienced: I began to pass out and yelled for my husband, he said when he came in i was sitting on the toilet with my head back, eyes rolling back not responsive (loss of consciousness) (medically significant), I had my 2nd vaccine at work early sat the 9th and felt increasingly worse all day (feeling abnormal), I woke up at midnight and felt extreme malaise (malaise), I was covered in sweat (hyperhidrosis), vomited (vomiting), I checked my temp and it was 99.7°F (pyrexia), sore (pain), I think I had either a seizure or a vasovagal response (seizure). No treatment required. The outcome of the events was recovered. The events were described as follows: I am healthy RN with no active medical problems. I had my 2nd vaccine at work early Sat the 9th and felt increasingly worse all day, I expected this so was not alarmed and went to bed around 10pm. I woke up at midnight and felt extreme malaise and went to the bathroom in case I might vomit, etc. and I tried to have a BM. I began to pass out and yelled for my husband, he said when he came in I was sitting on the toilet with my head back, eyes rolling back not responsive. He yelled at me for about 10 seconds and I came to, I was covered in sweat. I asked him to walk me back to the bedroom where I again passed out, fell to the floor and hit the bed, then was unresponsive

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again for about 10 seconds then came to again and vomited. After this I felt completely relieved of my malaise. I checked my temp and it was 99.7°F. After this I was sore but otherwise completely okay, the next day I had a temp of 99.5°F. Today I am back to normal. I think I had either a seizure or a vasovagal response. The vaccine was administered at Hospital Facility. 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. The patient had not been tested for COVID-19 since the vaccination. The patient was not pregnant at the time of vaccination.; Sender's Comments: Based on the close temporal relationship, the association between the event "began to pass out" 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.

<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>
958921	1/20/2021	CO	48	F	1/13/2021	1/13/2021	This may be a duplicate report, as primary care notes state the process has been initiated. However, out of an abundance of caution, and as the facility the event was reported to, I wanted to enter this report for completeness due to the unusual events. Patient received 1st dose of moderna covid vaccine at an outside facility and (per patient) had a seizure at that site immediately following the injection (history of seizures due to past meningitis, no seizures in past 3 months per patient). No medications were given, 911 was not called, patient not instructed to go to ED (per patient). Patient went home. Once home, patient reported "stroke like symptoms" on her right side (weakness and inability to close right eye for 30 minutes, numbness in R thigh and heel). Then weakness moved to left side (numbness/tingling in L hand and eye, numbness in L lower leg) along with some swelling to face/tongue. Had back pain but no chest pain or difficulty breathing. Extreme dizziness. No additional seizures. The next day she called our nursing line to report these symptoms and was instructed to go to the ED and also scheduled a visit with primary care provider the next morning. Patient stated she was feeling better and apparently did not go to the ED, instead choosing to see PCP next morning. On presentation to PCP, injection site was red and swollen, itching and swelling in hands, itching in bottom of feet, widespread joint pain. No visible rash, no dysphagia, no difficulty breathing. Other symptoms had largely resolved. Patient was prescribed benadryl (no steroids due to allergy to prednisone), cold compresses for injection site and sent home with instructions to go to ED if symptoms reappeared. Also recommended making an appointment with a neurologist for additional follow up as patient currently does not see a neurologist for seizures and is treating with CBD/THC only.
959081	1/20/2021	PA	98	F	1/12/2021	1/14/2021	Increased confusion on 1/13/21 with delusions. Seen in ER. No fever. CT found mass in amdomen. Upon returnning to personal care home had a seizure. Patient on pain meds.
959260	1/20/2021	KY	58	F	1/19/2021	1/20/2021	Chills, seizure like activity, body aches, injection site soreness

<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>
959683	1/20/2021	MD	26	F	1/19/2021	1/20/2021	I had a tonic clonic seizure for the first time 12 hours after receiving the vaccine.
958369	1/20/2021	NJ	45	F	1/20/2021	1/20/2021	Pt received vaccine. She was being observed for 15 min after injection. About 5 minutes into her observation time, she alerted the nurse that she was not feeling well. Nurse went over to talk to her and pt started to seem wobbly in seat. Pt then fainted and once on the ground, she started having a seizure. Epipen 0.3mg was administered and 911 was called. Pt stopped seizing upon receiving epinephrine. Paramedics and ambulance arrived and pt was taken to the ED.
959087	1/20/2021	TX	58	F	1/14/2021	1/15/2021	Patient states when she woke up the next morning and went to the bathroom she got a feeling like she was about to pass out so she states that she sat down on the bathroom floor to avoid passing out. She then states that her husband told her that her head slowly fell back and she started shaking and her eyes remained open. She also states that her husband said he was shaking her and lightly tapping her face until she gained back consciousness but shortly after she did it again. She states her husband said it didn't last long but she does not remember passing out or what she believes was a small seizure episode. She states that after her reactions resided she went to see her doctor and he took her vitals, did some blood work, and tested her for COVID and the Flu. Patient also states that having the reaction she developed a bad headache while waiting in the doctors office. States that on Saturday her headache wasn't as bad as on Friday and on Sunday she developed sharp, stabbing pains to the right side of her head that is not constant but comes and goes every now and then. Patient states her and her husband came across a news article that stated the vaccine she received is in question and believes that could be part of the reason for her adverse reactions. Patient states that she still doesn't feel normal but her doctor told her to give it a few more days for symptoms to subside.

<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>
956352	1/19/2021	AK	51	M	12/18/2020	12/18/2020	ABOUT 5 MINUTES AFTER RECEIVING VACCINE, PATIENT BEGAN SEIZURE. PATIENT FELL TO FLOOR FROM CHAIR. OBSERVING RN'S PROVIDED IMMEDIATE CARE. A CODE WAS CALLED. CODE TEAM TREATED PATIENT, THEN TOOK TO EMERGENCY DEPARTMENT.
954509	1/19/2021	UT	52	F	1/14/2021	1/15/2021	Chills really bad, had 10 blankets on me, just to get warm. Shivered so bad I looked like I was having a seizure. Lasted about 5 hours. Dull headache for 2 days.
955491	1/19/2021	NC	48	F	1/15/2021	1/15/2021	Systemic: Anaphylaxis-Severe, Systemic: Seizure-Severe
956313	1/19/2021	AK	51	M	1/8/2021	1/8/2021	APPROXIMATELY 5 MIN AFTER RECEIVING VACCINE, IN OBSERVATION, BEGAN TO HAVE A SEIZURE. FELL ONTO STAIRS IN THEATER-LIKE SEATING. CARE WAS IMMEDIATELY REDERED BY RNS, A CODE BLUE WAS CALLED. CODE TEAM ATTENDED TO PATIENT AND SUBSEQUENTLY TOOK TO THE EMERGENCY DEPARTMENT.
957137	1/19/2021	NJ	89	F	1/13/2021	1/13/2021	Emesis, LBM, Grand Mal seizure activity
957152	1/19/2021	OR	64	F	1/10/2021	1/10/2021	ER/URGENT CARE VISIT: Opening Alert charting for RETURN FROM ER (DX SEIZURE HISTORY OF). resident was sent out to the ER @ 11:54 AM after having trouble breathing following her COVID vaccination. RN administered EPIPEN, emergency services was called and resident was sent out VIA ambulance
957227	1/19/2021	CA	63	M	1/8/2021	1/9/2021	Hypotension, Prolonged seizure with bowel incontinence, cough, weakness and delirium, resulting in 911 transport and admission to hospital for intubation and mechanical ventilation for acute respiratory hypoxia.

<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>
957277	1/19/2021	AZ	49	F	1/15/2021	1/16/2021	Woke up shivering at 1 A.M. Saturday so bad that my husband thought I was having a seizure, took my temp it was 104. Took Tylenol, held cool compress on my forehead, the next day had bad chills, throbbing headache, and temp never dropped below 100. I was very weak, every muscle in my body ached, couldn't eat, yet my blood sugar was high all day. Kept checking my temp. It was avg. 102 . Read about the side effects, seemed like I just had it worse than others. Then into Monday morning, still felt awful, but had woke up in a pool of sweat, temp finally fell to 99 . Seemed like the worst was past, was able to eat a little breakfast, but then the diahrea started! I called in sick again, and went to Urgent care. The Dr. said I had a severe adverse reaction to the second vaccine. I asked for a Covid test just in case. Now Tuesday, felt better today, still a bit tired, temp has been avg. of 98 today, got results from test, negative.
955450	1/19/2021	IN	29	F	1/16/2021	1/17/2021	Approximately 12/13 hours post-vaccine dose #2 I was woken from my sleep with severe body aches. Extremely uncomfortable, from neck to back to calves, without improvement with Tylenol or ibuprofen, causing me to be unable to sleep. Around hour 20 post-vaccine, I started to get chills. It wasn't just feeling cold or shivering, it was full body convulsions that lasted approximately 15 minutes. I became nauseas and dizzy after that for about an hour, unable to stand or walk anywhere. The severe body aches continued, with no improvement from Tylenol or ibuprofen or heating pad. Aches resolved around hour 30 post-vaccine and the only symptom left was pain at the injection site.
955540	1/19/2021	NV	66	M	1/15/2021	1/15/2021	Systemic: Seizure-Mild
953249	1/18/2021	TN	37	F	1/12/2021	1/14/2021	injection site became red & swollen, the size of a softball. Employee started having seizure like symptoms on 1/14/21 and was admitted to hospital. DC from hospital on 1/16/21 and on 1/17/21 started having seizures again and readmitted back to hospital. Employee has no history of seizures.

<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>
953286	1/18/2021	FL	72	F	1/6/2021	1/12/2021	Patient had vaccine on 1/6/21 and have three grand mal seizure on 1/12/21. She was hospitalized and return to facility on 1/15/21. Patient does has history of seizure but the last one was three years ago.
953316	1/18/2021	PA	38	F	1/16/2021	1/17/2021	14 hours after vaccine, woke up with significant myalgias, urge to defecate (moved bowels twice, second time was diarrhea), nausea (no vomiting), severe dizziness. Syncopal event in bathroom, witnessed by husband. Went to ED due to husbands concern for possible seizure-like activity while unconscious (~30 seconds).
953357	1/18/2021	IA	86	F	1/16/2021	1/16/2021	Resident had seizure like activity that was about 30 minutes in duration where her upper/lower extremities were shaking uncontrollably. Resident had to be admitted into hospital for observation.
953401	1/18/2021	VA	38	F	1/7/2021	1/9/2021	Patient is a 38 y/o female physician with ADHD and depression presenting with concern for involuntary choreiform movements that began 1/9. Patient has never had this problem before. She does not note any associated symptoms. She denies extremity weakness, paresthesias, seizures, headache, chest pain, abdominal pain, nausea, vomiting, fevers, and other symptoms. She cannot think of any inciting injury or event that led to this. She did receive the second dose of the Pfizer COVID vaccine on 1/7, and is unsure if this is related.
953681	1/18/2021	CA	59	F	1/18/2021	1/18/2021	20-30 min post injection, patient experienced tachycardia, palpitations, shortness of breath, syncope, loss of consciousness. 911 contacted by nursing home staff. Patient was placed in nursing home bed, 1 EpiPen dose administered by clinic nurse (RN. Nursing home staff began supportive care, supplemental oxygen given. patient experienced petit mal seizure and was non-responsive for a few minutes. Eventually came to but was still unstable. Paramedics took over at this point and patient was evaluated and transferred to hospital.

<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>
953793	1/18/2021	UT	21	F	1/13/2021	1/14/2021	Next day after the 2nd dose of the COVID vaccine patient began feeling fatigued and nauseous. Then at urgent care, patient experienced difficulty breathing, tachycardia, and chest tightness. Patient also had a seizure and brief LOC. Patient went to urgent care, rapid response called and then transported to EMS to nearby hospital.
953926	1/18/2021	NC	74	M	1/7/2021	1/12/2021	Seizure
952419	1/18/2021	TX	42	F	1/16/2021	1/16/2021	Seizure
954055	1/18/2021	UT	53	F	1/18/2021	1/18/2021	pt started having seizures and was given ativan. EMTs were called and patient was taken to the ER
952888	1/18/2021	AR	53	M	1/13/2021	1/14/2021	Lower arm sore after 12 hours, fever severe convulsions, high fever, nausea, vomiting, shortness of breath, body aches after 15 hours that lasted about 2 hours in severity. Today is 4 days post incident and still have weakness, body aches and fever are subsiding.
951744	1/17/2021	IA	19	F	1/16/2021	1/16/2021	usually experience very brief loss of consciousness but upon injection i lost consciousness immediately and proceeded to have a mild seizure lasting approximately 10 seconds followed by numbness in my legs for 10 minutes after injection.
950754	1/16/2021	NH	29	F	1/16/2021	1/16/2021	0820 Covid Vaccination given 0842 Pt honks horn in in distress 0843 Pt is extricated from her vehicle 0843 Medical Provider called 0844 Pt noted to have four separate tonic-clonic events without incontinence, oral injury or post ictal period 0854 ambulance arrives 0859 pt loaded into ambulance 0907 ambulance left for ER, the patient has a H/O of such events and did mention she was taken off anti-convuls. medications and had a possible diagnosis of pseudo-seizures. -
950531	1/16/2021	AR	54	F	1/15/2021	1/16/2021	Fever vomiting chills seizure (the injection triggered it) fell bad since the injection.

<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>
950067	1/16/2021	WV		F	1/7/2021	1/7/2021	<p>She did not have any problems immediately after the shot or waiting period. She went back to work and all was normal until she went to meeting. It was a little less than 4 hours after the shot. She asked to have her temperature checked, then fell on the floor and collapsed. Her BP was 190/110, and her HR was very high, beating out of her throat and throat swelled up – she could barely breathe. Normally, her BP is 120/80 and HR is usually around 68 BPM. She could not move her legs or arms, but she could move fingers. This is an anaphylactic seizure that acts like a stroke – severe slurring of speech, cannot close eyes (but vision blurred), throat swells up and constricts airway, and she yells out uncontrollably. She shivered like she was very cold, but she did not have any convulsions. It lasted around 20 minutes. EMT who took care of her. She could hear everything going on, but her vision was very blurry (could not see). She was taken to Hospital. They checked her for stroke, did a CAT scan, and took her blood. Everything came out normal. She felt fine after it was over. She was released at 8 pm to go home, and she walked out on her own. She feels that the 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC] in the vaccine may be what triggered her reaction as she thinks it may be closely related to steroids. She will NOT take the 2nd shot on advice of doctor. Dr. has been her physician for 10 years. Previous History: Seizure reaction to steroids – happened 4 hours after took the steroid – this same anaphylactic like seizure happened with the steroid, exactly. Present at that event were several people. Patient says that this is the exact same reaction she had both when she took the steroid and following the COVID vaccine.</p>
946153	1/15/2021	CO	36	F	12/30/2020	1/1/2021	<p>Woke up with sore left arm and headache. As day progressed headache continued and had several episodes of feeling hot, sweaty, and nauseous. At approximately 8 pm I had another episode of feeling unwell. I sat down on couch and had a seizure. Arms went straight out from body, legs got tense, loud noise from mouth, then was slumped over on couch. Husband got me to the pickup and drove me to the emergency room.</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>
949610	1/15/2021	GA	54	F	1/15/2021	1/15/2021	A few minutes after receiving the vaccine, patient complained of dizziness and sat down. Within just a couple of minutes she was losing consciousness. 911 was called and EMT came within 5-8 minutes and patient was on floor. EMT assessed patient and transported to local hospital (Medical Center). Patient was seen and discharged and the physician at the hospital did not feel the seizure was a result of the vaccination but her medical condition and history of seizures.
948471	1/15/2021	WA	50	F	1/8/2021	1/8/2021	5-6 HOURS AFTER VACCINATION. CONVULSIONS/SEIZURE, HIGH BLOOD PRESSURE, INCREASED HEART RATE,
948414	1/15/2021			F	1/11/2021	1/11/2021	Security notified this writer patient was feeling "light headed" post 1st dose of Pfizer covid vaccine. Patient seated in auditorium seating. Writer approached patient. Patient stated she was light headed. Assessed patient, noted sweating, pale skin and dilated pupils. Patient then went unconscious for approximately 30-60 seconds with seizure like activity. Increased diaphoresis noted. Upon regaining consciousness patient declined any medical history including DM or seizures. Rapid was called, arrived within minutes. VSS were noted to be HR of 43, BP of 68/42. Legs were elevated in seating. When attempted to move patient to gurney patient went unconscious again. Fireman lifted to cart, elevated legs. No seizure activity noted with second unconscious event. patient placed on left side with legs elevated. Return of consciousness noted. Moved to alcove with Rapid team. IV placed, fluids started. Monitored vitals prior to transport to ED. Patient's manager made aware and returned to unit. --Hospital
948243	1/15/2021		64	F	1/12/2021	1/13/2021	Observed in her room having seizure activity and unresponsive to stimuli. BP of 200/120, oxygen level dropped to 86%, HR was 116. She was transferred from Hospital A and later transferred to Hospital B and placed on a ventilator. This remains her current status
948026	1/15/2021	KS	47	M	1/6/2021	1/6/2021	Day of the vaccination, patient went home and developed a bilateral nosebleed and had a seizure. Patient continues to feel poorly as of 1/15/2021 but has returned part time to work.

<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>
947963	1/15/2021	NJ	24	M	1/15/2021	1/15/2021	I had Syncope and possible seizure 5 minutes after getting the shot.
947831	1/15/2021	WI	27	F	1/15/2021	1/15/2021	Seizure like reaction after COVID-19 vaccine, experienced weakness and shortness of breath.

<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>
947549	1/15/2021	CA	40	F	12/30/2020	12/31/2020	partial complex seizure; I lost muscle tone and collapsed; severe LUE weakness; severe pain; aura; I lost muscle tone and collapsed; This is a spontaneous report from a contactable other health care professional (HCP) reporting for herself. A 40-year-old female not pregnant patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in the Left arm on 30Dec2020 h 05:00 PM at single dose for COVID-19 immunisation, lot number: EH9899. Patient did not receive any other vaccines within four weeks prior to the vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Medical history included epilepsy (well controlled with medications) and she was allergic to phenytoin (DILANTIN). Concomitant medications in two weeks prior to the vaccination included carbamazepine, lamotrigine (LAMICTAL) and fluoxetine. It was reported that on 31Dec2020 h 14:00 (also reported as approximately 22 hours after vaccine) patient experienced severe left upper extremity (LUE) weakness and severe pain. She then experienced an aura and had a partial complex seizure. Patient lost muscle tone and collapsed. The episode lasted approximately 1.5 minutes, no treatment was given. Patient was tested for Covid post vaccination, she underwent Covid-19 PCR Test (Nasal Swab) on 04Jan2021 and on 07Jan2021, both with negative results. She also underwent a Covid-19 PCR Test on unknown unknown date in Jan2021 with unknown results. Patient recovered on 31Dec2020 from the events.; Sender's Comments: There is not a reasonable possibility that the reported events were related to the suspect product event most likely due to patient underlying contributory factors. 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.

<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>
947216	1/15/2021	NY	69	F	1/13/2021	1/14/2021	No immediate adverse effects noted on 1/13/21. Patient was tired on the morning of 1-14-21. Her pulse was noted to be 106 at approx. 7:30am. She had a 10 minute tonic clonic seizure at approx. 8:15am. She was post ictal until 10:30 am. After the seizure, her O2 was 90% and she was noted to have a temp of 100.4. She was also very tired and confused. She went to ER by ambulance approx. 8:45am and they did a CT, Labs and a urine analysis. No significant findings reported. She returned to the residence at 4:37pm on 1-14-21 and was on vitals every 4 hours. Her vitals have returned to baseline.
946732	1/15/2021	NY	51	F	1/14/2021	1/14/2021	Rash, swollen tongue and 2 seizures. Admitted to hospital with diagnosis of seizure and allergic reaction.,
945935	1/15/2021	NM	40	F	1/6/2021	1/6/2021	Anxiety; Headache; Seeing stars; Chest tightness; Hand tremor; SOB; This is a spontaneous report from a contactable pharmacist. A 40-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EL1284; Expiration date was not reported), intramuscularly on the left arm on 06Jan2021 (10:15) at a single dose for COVID-19 immunization at the hospital. Medical history included migraines; heart murmur with surgery; grand mal seizure that has resolved; and contrast dye allergy. Concomitant medications included sumatriptan and norethindrone [norethisterone]. The patient previously took phenytoin, iodine, terconazole, tramadol and cetirizine; and had allergies with these medications. On 06Jan2021 (10:15), the patient was seeing stars; had chest tightness; hand tremor; and shortness of breath (SOB). The patient was referred to the Urgent Care Clinic due to these events. On 06Jan2021 (12:30), at the Urgent Care Clinic, the patient had anxiety and headache. The patient had received acetaminophen, diphenhydramine, ibuprofen and water as treatment for the events, 'seeing stars', 'chest tightness', 'hand tremor' and 'shortness of breath'; and was provided with education on managing anxiety. The outcome of the events was recovered in Jan2021 for 'seeing stars', 'chest tightness', 'hand tremor' and 'shortness of breath'; and was unknown for 'headache' and 'anxiety'. The patient did not have COVID-19 prior to vaccination, and was not tested post-vaccination.

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946258	1/15/2021	NC	52	F	12/31/2020	12/31/2020	THAT EVENING BETWEEN 10-11 PM HAD A GRAND MAL SEIZURE AND WAS UNRESPONSIVE. TAKEN TO ER WHERE BLOOD WORK WAS DONE AND CT SCAN. SENT HOME AROUND 6:30 AM ON JAN 1ST. (I DO NOT REMEMBER MUCH JUST WHAT MY FAMILY HAD TOLD ME) . I DO REMEMBER BEING SEVERLY SICK WITH VOMITING IN THE ER. CURRENTLY FOLLOWING UP WITH MY FAMILY MD AND HAVE MRI AND EEG TESTS SCHECULED WITHIN THE NEXT COUPLE OF WEEKS.
946300	1/15/2021	MO	28	F	12/23/2020	12/23/2020	PLEASE NOTE: The patient verbally reported this event to me on 01/14/2021. The event occurred 12/23/2020. Seizure approximately 5-6 hours after receiving the vaccine. Repeat seizures approximately 30 and 54 hours post vaccination. Please note, the patient states she is a newly diagnosed epileptic. She claimed her neurologist recently adjusted her seizure medications as well prior to the vaccination.
944477	1/14/2021	NJ	75	F	1/14/2021	1/14/2021	Patient given vaccine. Within 5 minutes husband said she?s having another spasm. She was being monitored for 15 minutes after the injection. After the spasm it appeared to. become a seizure and passed out for 5 minutes . Husband said she missed her medicine and needed her carbidopa/levodopa. 911 arrived and administered oxygen and took to the hospital.

<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>
942580	1/14/2021	AZ		F	12/28/2020	12/28/2020	<p>Rigidity all over; All muscles were clenched up; BP was 170; Heart rate elevated; A spontaneous report was received from a pharmacist concerning a patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced rigidity all over, all muscles were clenched up, BP was 170, and heart rate elevated. The patient's medical history, as provided by the reporter, was unremarkable with no history of allergies or seizures/epilepsy. No relevant concomitant medications were reported. On 28 Dec 2020, ten minutes prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the left deltoid for prophylaxis of COVID-19 infection. On 28 Dec 2020, ten minutes after vaccination, the patient had rigidity all over and all her muscles were noted to be clenched up. There was no loss of consciousness and the patient claimed that she was still able to hear the people around her. Her blood pressure at the time was 170 and her heart rate was noted to be elevated. Her temperature was 98 degree Fahrenheit. Treatment for the event included oral diphenhydramine which caused her condition to subside. After an unspecified period of time, the rigidity recurred and the patient was taken to the emergency room. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, rigidity all over, all muscles were clenched up, BP was 170, and heart rate elevated were not reported.; Reporter's Comments: This case concerns a female patient who received their first of two planned doses of mRNA-1273 (Lot unknown), and who experienced the serious unlisted events of Muscle rigidity and Muscle tightness and the non-serious unlisted events of BP was 170 and heart rate elevated. The events occurred 10 minutes after vaccination and treatment with oral diphenhydramine was administered. Based on temporal association between the use of the product and the onset of events, a causal relationship cannot be excluded and the events are considered possibly related to the vaccine.</p>

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942818	1/14/2021	FL	53	F	12/30/2020	12/30/2020	Left arm soreness for 24 hours and low grade fever of 100 F; Left arm soreness for 24 hours and low grade fever of 100 F; This is a spontaneous report from a contactable nurse. A 53-year-old non-pregnant female received bnt162b2 (lot: EK9231), intramuscular in the left arm on 30Dec2020 14:30 at a single dose for covid-19 immunization. The patient's medical history included migraine, seizure (resolved x2years) from an unknown date and unknown if ongoing , and allergy to penicillin. There were no concomitant medications. On 30Dec2020 20:00, the patient experienced left arm soreness for 24 hours and low grade fever of 100 f. The outcome of the event was recovered on an unknown date. No treatment was given to the patient for the event. The vaccine was administered in a hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient did not have Covid prior to vaccination and has not been tested post vaccination.
943127	1/14/2021	MA	21	F	1/8/2021	1/8/2021	Systemic: Chills-Mild, Systemic: Generalized Body Aches -Mild, Systemic: Joint Pain-Mild, Systemic: Nausea-Mild, Systemic: Vomiting-Mild, Systemic: Seizure-Mild, Systemic: hand spasms-Mild; symptoms lasted 1 day
943240	1/14/2021	MA	21	F	1/8/2021	1/8/2021	Systemic: Chills-Mild, Systemic: Generalized Body Aches -Mild, Systemic: Joint Pain-Mild, Systemic: Nausea-Mild, Systemic: Vomiting-Mild, Systemic: Seizure-Mild, Systemic: hand spasms-Mild; symptoms lasted 1 days
943306	1/14/2021	IL	27	M	1/10/2021	1/11/2021	Fever, uncontrolled convulsions, rapid cycling of body temperature for roughly 48 hours, migraine, intense body pain and lethargy, inability to sleep, no appetite
943307	1/14/2021	KY	17	F	1/4/2021	1/4/2021	Systemic: Seizure-Severe
943359	1/14/2021	KS	38	F	12/30/2020	1/12/2021	Unprovoked seizure (clonic tonic) 13 days later, requiring hospitalization and testing
943416	1/14/2021	SD	40	F	1/8/2021	1/8/2021	Became pale, clammy, uncontrolled shaking (seizure like)

<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>
943636	1/14/2021	CO	25	F	1/13/2021	1/13/2021	Vasovagal syncope (loss of consciousness) Tonic seizure (tensing and twitching of arms) Irregular heartbeat (per EKG) Extremely low blood pressure I received the vaccine at a public health pop-up, drive through clinic for first responders - I accessed the vaccine through my employer as a first responder. The vaccine was administered to my left arm without complication at approximately 1:00pm (my scheduled appointment). I proceeded to the area designated for patients to be observed after receiving the vaccine and was asked to wait 15 minutes. I recall getting to the observation area then telling my spouse I felt unwell - after the event he notified me that I told him I was about to pass out and asked him to get medical help. I lost consciousness approximately 5-10 minutes following the vaccine. My husband reported that after losing consciousness I seemed to have a minor seizure, as evidenced by my head jerking and my arms and fingers "tensing and curling up". I was sitting in the passenger seat of my car at this time, so I suffered no fall or fall related injury. Public health officials and EMT responded. They indicated to my spouse that I had experienced a vasovagal syncope episode and that I had "gone tonic"/ had a "tonic seizure". They took my blood pressure, which was very low (I don't recall exactly but it was 80 over something). They also took my blood sugar among other things that I do not recall. I was given oxygen and put into an ambulance. I was shaking, so they wrapped me in blankets. I believe they may have done an EKG and placed a blood pressure cuff while I was in the ambulance, but I do not recall any specifics about this. The EMT also drew my blood, placed an IV, and administered IV fluids while I was in the ambulance. I was taken by ambulance to the emergency department

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943866	1/14/2021	CO	77	M	1/8/2021	1/8/2021	Within 30 sec post injection, patient moved his head back and closed his eyes as the NP was putting syringe into sharps. Another RN also witnessed this as well as his wife who said "he does this". NP rubbed his arm and called out his name twice while the RN got the EMS from another room. As EMS arrived (2:36?), pt opened his eyes, was oriented to PPT, had vitals at 159/102, and was offered to be taken to hospital to be further evaluated but declined. Pt was talking and walking with cane into the observation wait area within 10 min. He waited for at least 45' where EMS monitored him and retook vitals before being sent home with wife and driver. Wife and Pt stated he had a visit with a new PCP Monday 1/11/21 thus was instructed to follow-up about this event of possible Petite Mal seizure at that visit.
944236	1/14/2021	MI	43	M	12/27/2020	12/27/2020	New onset seizure approximately 20 hours post vaccination
944517	1/14/2021		44	F	12/23/2020	12/25/2020	Myalgia chills, fatigue, syncope vs seizure 43 yo employee falt fatigue on 12/24 and again on 12/25/20. The patients husband reports she was walking down the stairs, seemed "off" and missed the step/slid on step injuring both feet/ankles. Pt got up and was able to stand for a few minutes. Husband reports that he than sat her on the steps-few minutes later she had syncope with convulsions vs seizure. Per his report this lasted over a minute, she stopped breathing and was unresponsive. He reports she was confused while he was on the phone with 911 operator (3 minutes). Patient was taken to Health Center for work up. The head CT, labs, X-rays, EKG were unremarkable. Followed up her physician Dr. and was referred to neurologist. She had a MRI without contrast which was unremarkable and is scheduled to undergo a sleep deprived EEG. She is undergoing physical therapy at this time for injury to bilateral feet/ankles.

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944649	1/14/2021	TX	33	F	1/6/2021	1/7/2021	1/7/2021 @ 5:00 a.m. patient woke up and couldn't move her right side (neck, arm and leg). Sister helped dress her and drove her to the hospital. During the ride the hospital the patient had 2 seizures and a 3rd seizure in the ER at the hospital. Patient states she has never had multiple, back to back seizures before. States she hasn't had a seizure for 2 years. EEG was done. Was released from the hospital on 1/9/2021 and to have outpatient MRI of head, shoulder, c-spine. Does not have full range of motion of right neck, and arm, hand and fingers and is painful. 1/14/2021 - full release back to work on 1/14/2021.
944663	1/14/2021	KY	67	F	1/12/2021	1/14/2021	Resident had been monitored and had shown no signs or symptoms of any kind until 2 pm on 1/14/2021. Resident was found in the floor of her room. She had fallen and was having a seizure, temperature was 99.7F and Oxygen saturation was 82%.
944710	1/14/2021	TN	21	M	1/13/2021	1/13/2021	per report via email - patient receive COVID vaccine during staff clinic in the AM. During the evening patient started to feel sick. symptoms included: nausea/vomiting, uncontrollable jerk like seizures, very disoriented, respirations ragged and rapid. Family called 911 taken via ambulance to local ER. per report patient received IV fluids, medicine to treat nausea/vomiting and meds to "get his respirations under control". patient sent home and is now resting.
944868	1/14/2021	IL	23	F	1/14/2021	1/14/2021	Before injection patient was very nervous and did not eat breakfast. 3 minutes after injection patient complained of blurred vision and dizziness. BP 88/50, HR 54, O2 92%, pale in color, patient started to shake and have seizure activity only lasting a few seconds. 3 person assist to lie flat on the floor, rolled to left side. Patient was non-verbal at this time. 911 was called. At 9:11 AM EMS arrived and patient was responding at that time, patient transferred to the hospital. After hospital visit staff reported back the doctor felt it was an anxiety response rather than a vaccine reaction.
944949	1/14/2021	CO	48	F	1/13/2021	1/13/2021	Seizure,numbness on whole right side,back pain, face droop,extreme fatigue,dizziness,headache,pain in shoulder

<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>
945561	1/14/2021	CO	48	F	1/13/2021	1/13/2021	Post injection x 5 min. sitting in chair, friend stated pt. was having a reaction, nurse was notified, pt. stated "I am having a seizure", pt. was placed on floor, MD on site for clinic examined pt. Pt. responded to base line and placed on chair. Water provided. After observation, MD stated pt. to call her PCP and was able to go home with friend.
946899	1/14/2021	MO	32	U	1/14/2021	1/14/2021	Client was sitted in the chair and started rolling his eyes stretching his feet and twitching like he was having a seizure. Was helped on the floor gained consciousness. Stood up and sat on the wheelchair wheeled to the cot area and was place on the cot. V/P 133/96 HR - 54 - 78 O2Sat 97% B/S - 111 glucose gel EMS was called Client was stable Had lost conciousness and disoriented when he woke up. Client started he felt light headed and had vision event
963168	1/14/2021		80	M	1/5/2021	1/6/2021	shaking, altered consciousness Narrative: One day after pt received his first covid vaccine, pt experienced upper extremity shaking leading to ED visit and subsequent hospitalization with concern for seizure. Examination and labs were not consistent with seizure. He had features of lewy body disease and parkinsonism. Labs were significant for leukocytosis, but pt had no other signs/symptoms of infection or findings to indicate a source of infection. Pt referred to Neurology.
943992	1/14/2021	NC	28	F	1/11/2021	1/11/2021	Systemic: Fainting-Medium, Systemic: Seizure-Medium; symptoms lasted 0 days
944212	1/14/2021	NY	76	M	1/13/2021	1/14/2021	Two seizures of Left arm shaking and non-responsiveness with urinary voiding and post-ictal state the day after vaccination

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943752	1/14/2021	KS	59	F	1/5/2021	1/13/2021	Day 1 very slight swelling of arm and immediate bruising. Day 2 faint nausea and mild headache with bruising much darker. Day 6 migraine headache and bruising starting to fade. Day 7 still had migraine headache. Axillary of same side of body as shot became mildly tender starting in the a.m. Day 8 still had migraine, axillary still tender, by evening arm began to swell, become bright red and itchy. Redness was located just below bruise and was 2 inches across and 3 inches down. Later that night I began to have seizures without warning interspersed with waves of dizziness. Day9 (today) I have fatigue and dizziness. As the day progresses the dizziness is getting better. The fatigue is exhausting.
939400	1/13/2021			F			nervous; very cold; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiration date not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history included seizure. The patient's concomitant medications were not reported. The caller reported having seizures once in awhile and asked if this vaccine was meant for everyone or if there is a different one that people with seizures are supposed to get. The caller stated the seizures are a pre-existing condition and she has not had a seizure since receiving the vaccine. The caller stated that she did speak with her doctor and he said it was fine for her to receive the vaccine and she received the first dose on an unspecified date on Saturday but she got nervous and very cold. The reporter wondered if she should get the second dose as normal then. The reporter wanted to know the answer soon because of the nerves. She has calmed down a bit and wanted to hear what someone has to say right away. The outcome of the events was unknown. This case reported as non-serious. Information on the lot/batch number 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>
941639	1/13/2021	MO	33	M	1/13/2021	1/13/2021	first seizure onset about 23 minutes after vaccination and lasted for 2 minutes, pt recovered then went into another seizure at 11:03 for 2 minutes. pt was given epi-pen and Benadryl following second seizure and recovered afterwards
941576	1/13/2021	KY	23	F	1/12/2021	1/13/2021	Employee was awoken at 5:30 am on 1/13/2021 by chills and a feverish feeling. She then became nauseous and faint. She passed out and was noted by her mother who is a RN to have a seizure. She remained out for several minutes and then aroused. She has remained groggy the rest of today but has improved. She has a history of non-epileptic seizures since she was 14 and has been on medications for this. Employee stated she has not has any seizure activity in over a year. She did not see medical attention due to recovering quickly from this.
941490	1/13/2021	NY	89	F	1/13/2021	1/13/2021	The nursing home resident received the vaccine at 11:00 am. At 11:45 am she had an episode of non-bloody, non-bilious vomiting. At 12:00 pm she had an episode of loose stool. At 12:15 pm she was noted with generalized tonic-clonic seizure-like activity. Oxygen was applied via non-rebreather mask and resident was transferred to the Hospital Emergency Department for further evaluation. At the time of this report, she is stable in the ED and awaiting imaging studies. (head CT)
941179	1/13/2021	NJ	70	M	1/7/2021	1/11/2021	Approximately 5 days after receiving vaccine patient presented to office complaining of worsening resting hand tremors and had a temperature of 101 F. No other source of infection found including negative chest x ray and urine studies. CBC was within normal limits. Patient with seizure history however never had symptoms similar to this. Neurological exam normal in office. Fever resolved the next day.
941046	1/13/2021	MO	82	F	1/11/2021	1/12/2021	Altered mental status and seizure like tremors, slurring her speech, could not state day, time, place, or situation, salad like statements, increased weakness.

<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>
940708	1/13/2021	NY	79	F	12/30/2020	1/1/2021	Jan 1st, patient had a seizure after breakfast. Temperature was 98.5 Pulse 95. B.P. 160/70 Two hours later another seizure at the home, with emesis, Sent to hospital at 2pm. Focal Status epilepticus. Seizure activity along with continuous persistent activity with emesis throughout the 12 hour time in the ED. Seizure during the CT scan.
941728	1/13/2021	GA	88	F	12/29/2020	12/29/2020	Resident undergoing wound care. Vaccine given and approximately 5 minutes after administration, this resident noted to have rapid jerking eye movement determined to be seizure activity. After the seizure, resident stabilized. Resident was asked if she was feeling ok and she nodded her head yes in agreement. Resident has a history of seizures and is being treated with Dilantin and Keppra.
939506	1/13/2021	CA	46	F	12/23/2020	12/23/2020	Palpitations; Chest pressure; Lightheadedness; Nausea; This is a spontaneous report from a contactable nurse (patient). A 46-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly on 23Dec2020 14:15 at left arm, at single dose for covid-19 immunization. Medical history included history of seizure, known allergies: topical Sulfa. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included (ascorbic acid) (VITAMIN C), (sambucus nigra) (ELDERBERRY), (linum usitatissimum seed oil) (FLAXSEED OIL), (allium sativum) (GARLIC). The patient previously took lamotrigine (LAMICTAL) and known allergies: LAMICTAL. The patient was not pregnant at the time of vaccination. The patient experienced palpitations, chest pressure, lightheadedness and nausea on 23Dec2020 14:15. The patient received Zofran and Meclizine given. Event resulted in: Emergency room. The outcome of the events was recovered on an unspecified date. 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. No seriousness criteria: no Results in death, no Life threatening, no Caused/prolonged hospitalization, no Disabling/Incapacitating, no Congenital anomaly/birth defect. Information on the lot/batch number 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>
940448	1/13/2021	OK	88	F	12/28/2020	12/28/2020	Systemic: Seizure-Severe
938114	1/12/2021		30	F	1/12/2021	1/12/2021	Syncope and seizure
938484	1/12/2021	NY	39	F	1/12/2021	1/12/2021	patient fainted, 10 sec seizure, diaphoretic
938413	1/12/2021	IN	48	F	1/6/2021	1/12/2021	Pt had a strong seizure
938318	1/12/2021	NE	34	F	1/12/2021	1/12/2021	The employer called and stated that she had a grand mal seizure 1 hour after having her vaccine. Her employer stated that she has a history of seizures and that her neurologist had told her she could receive the vaccine but that it could trigger a seizure. Patient was taken by ambulance to the hospital.
938222	1/12/2021	NY	75	F	1/4/2021	1/8/2021	At 11:40am on 1/8/21, resident appeared catatonic and was just staring at the wall. When on unit, observed resident seated in a chair, blankly staring at the wall with no loss of consciousness. Blank stare accompanied with mild jerky movement. Resident was safely assisted to bed. Oxygen at 3lpm was administered. Petit mal- like seizure lasted for 5 minutes. Resident regained prior level of alertness and doesn't recall what had happened. Resident with no known history of seizure disorder.

<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>
938055	1/12/2021			F			Seizure; This is a spontaneous report from a contactable physician (patient). A female patient of an unspecified age received BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) on an unspecified date, at single dose, for COVID-19 immunisation. Relevant medical history and concomitant medications were unknown. On an unspecified date, after the vaccination, the patient had a seizure. Clinical outcome of the adverse event was unknown at time of this report. The information on the lot number has been requested.; Sender's Comments: A possible causal relationship between seizure and BNT162B2 cannot be completely ruled out considering the temporal relationship. However, more information would allow for a full medically meaningful assessment, especially medical history, concomitant medications, concurrent illness and event details description including time lag between the onset of the event and vaccination date 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.
937282	1/12/2021	TN	42	F	1/11/2021	1/12/2021	Grandma seizure last 30 seconds then she came too and started throwing up. Little blood in stool. Now 7 hrs. later she has a headache and is nauseous with occasional stomach cramps and diarrhea. Kept at home didn't seem to need hospital.
937625	1/12/2021	FL	70	F	1/12/2021	1/12/2021	PT COMPLAINED OF NUMBNESS IN HER ARM AND COMPARED TO THE SENSATION TO BEING SIMILAR TO FEELING SHE HAD EXPERIENCED WHEN HAVING A SEIZURE. TAKEN TO ER, NO SEIZURE. ELEVATED B/P 210/90

<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>
933806	1/11/2021	NH	29	F	1/9/2021	1/9/2021	Patient was in the passenger seat with a male driver. Patient stated "no" when asked if any medical issues. Stated "no" when asked if had any adverse reactions in the past to vaccinations. Vaccine administered, pt within seconds lost consciousness. Few seconds later pt had a seizure. 911 called. Help called for pt to be moved to cot. Pt started coming to and feeling better. Male driver later stated something to the effect of "this happens to her every time". BP 110/60. HR 78. SPO2 96%
933755	1/11/2021	MD	26	F	1/3/2021	1/4/2021	Numbness and tingling bil upper extremities, seizure, temporary paralysis R arm. Started day after vaccine given, was observed overnight in hospital.
934193	1/11/2021	OH	35	F	1/8/2021	1/10/2021	Received the vaccine 1/8/21 at 4:45pm, the next day had a sore arm and was tired. Woke up Sunday at 4:37am to take some ibuprofen for my arm pain and didn't get to take the meds, I had a seizure the meds and my glass were all over the floor. I never even felt it coming on, I just remember waking up. I looked at the clock at 4:46am. It seemed like a very long time to be out. When I woke up I felt very nauseas and had a hard time getting up to go to the bathroom. I never did get sick but laid down and fell asleep immediately. I slept all day Sunday. Today, Monday 1/11/21, I am still exhausted and light headed but not as nauseas.
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.
935736	1/11/2021	CA	23	F	1/8/2021	1/8/2021	Patient has seizure a couple hours after vaccine. Patient was transported to hospital via ambulance.
935960	1/11/2021	IA	58	F	1/11/2021	1/11/2021	Patient had a "psychiatric seizure" apparently has a history of these. Became agitated and aggressive. 911 was called and medics took the staff member to the hospital.

<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>
936047	1/11/2021	TX	47	F	1/9/2021	1/9/2021	Patient had headache, diaphoresis, low blood pressure and seizure. Patient got Tylenol for her headache and was observed for a few minutes. She was offered Benadryl but patient was allergic to Benadryl. She exhibited grand mal seizure twice. The ambulance was called after the second grand mal seizure.
932836	1/10/2021	MA	67	M	1/7/2021	1/10/2021	1/8/20 Around noon got very cold and around 430 broke into seizure like chills and tempeture and fever took two tylenol(650)mg went to bed and woke at at 2;00 fine
932992	1/10/2021	IN	42	F	1/4/2021	1/5/2021	1-5 2:30am stomach pain, diarrhea. Injection site discomfort. As the day went on severe body aches, legs more so. 1-6 body aches, felt feverish without fever, 10:30am tongue began to spasm while in relaxed state. Top of tongue was raw from rubbing my top teeth. That continued through Thursday. Thursday morning I woke up feeling pretty good then approx 8:30 am spasm started in my right hand then right arm, both arms too full body convulsions. I was taken by ambulance and have since visited 5 hospitals with no answers. It?s now Sunday 1/10 and my body continues to have uncontrollable body movements.
932558	1/10/2021	PA	45	M	12/30/2020	1/4/2021	Patient developed chills/shivering/tingling day 4 post-injection. The episodes are occurring every 10 minutes and last 30-45 seconds. Symptoms continue at day 11 post injection. Symptoms are similar to the patients pre-ictal aura. However, no generalized seizures have occurred.
932920	1/10/2021	UT	66	M	1/6/2021	1/7/2021	Seizure occurring at 0700 in dining room, 1 episode, unresponsive for 2 minutes, after episode experienced general weakness then shortly was able to walk after, vitals stable after

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932270	1/10/2021	IN	25	F	1/8/2021	1/9/2021	Almost exactly 12 hours after receiving the second dose of COVID vaccine, I woke up from sleep curled into a ball, covered in sweat, absolutely freezing, teeth chattering, and all my muscles were shaking violently. I tried to roll over in bed and all of my muscles locked up and I began to convulse even stronger. This made me feel extremely nauseous and then I began to vomit. I know I had a high fever but I was unable to keep down any medications as I kept vomiting. I felt ill like this for the next 24 hours, with a 100.1 fever even after rounds of ibuprofen and tylenol, and severe muscle soreness and achiness, and headache. I also have intermittent nausea and will occasionally vomit bile. I finally woke up on 1/10/2020 and don?t have a fever, but my body feels very beat up and sore.
990775	1/9/2021		34	M	12/29/2020	12/29/2020	Headache, Seizures, UrticariaPruritus & NauseaVomiting Narrative: NORMALLY HAVE SEIZURES EVERY EVENING, BUT THIS SEIZURE ABOUT 5.5 HRS POST VACCINE WAS MUCH MORE SEVERE WITH "EYES ROLLING IN BACK OF HEAD" AND FELT "IN A DAZE". TOOK AN EXTRA DOSE OF CLONAZIPAM 1 MG
931441	1/9/2021	PR	88	F	1/8/2021	1/8/2021	Seizure

<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>
931546	1/9/2021	IL	44	F	1/9/2021	1/9/2021	<p>Patient was extremely anxious prior to vaccine. She told me she did get seizures but she took medication for it and I informed her that it would still be recommended to get the vaccine. She was visibly anxious even after vaccine. Immediately after she began crying to her friend and said she "was just SO afraid of needles". I told her to take some deep breaths and after a minute or two she went to the observation room. Approximately 15 minutes later she rushed back into the room looking like she might hyperventilate or have hypoglycemia (shaking, cold sweats). She sat down and I tried to calm her down. I asked someone to get her orange juice. During the next couple minutes she did not seem to be getting any better and started shaking. I requested someone call 911. Another staff was helping so I moved to get and administer an epi-pen injection. By this time the patient was not responsive, but was still breathing. I instructed staff to help move her to the floor for monitoring and if needed, cpr. She regain partial consciousness. Her breath and pulse were always present, so there was no need to begin cpr. After a few minutes EMT arrived and transported patient to local hospital. During all of this, other employees at the facility were attempting to contact family members, which they were eventually able to do. About 30 minutes later the staff informed me they had spoken to family members who were at the hospital and that she was improving, but they had not seen her yet.</p>
931628	1/9/2021	MD	24	F	1/8/2021	1/9/2021	<p>awoke at 2 am with nausea, chills, generalized pain. Immediately felt myself start to pass out or have a seizure- I am not sure which. Family member reports my eyes were open with absent stare however I lost consciousness, <60s. My right calf was in a severe muscle spasm as soon as I became conscious which leads me to believe I had some convulsions. Nausea chills and generalized pain persisted throughout the rest of the morning. Stopped around 10 am and turned into pounding headache and fatigue. Additionally my left arm is in moderate to severe pain (not like the typical soreness I get with the flu shot). I am in significant pain moving my arm, but also changing body positions while keeping my shoulder still and close to my body (bending over, scooting over in bed).</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>
931806	1/9/2021	MD	34	M	1/7/2021	1/8/2021	Spastic convulsions that occurred in every muscle in my body lasting for more than 4 hours. Hands now tingle and spasm from time to time.
931927	1/9/2021	NJ	52	F	1/5/2021	1/5/2021	Seizure/focal approximately 10 minutes after injection lasted 1-1.5 minutes....
964641	1/9/2021		57	F	1/6/2021	1/6/2021	Narrative: Temporary restriction on driving until further evaluation due to symptoms of seizures.
978083	1/9/2021		47	M	1/5/2021	1/5/2021	Dizziness, Seizures, Syncope, Bradycardia, cold, clammy Narrative: 10 mins after administration, Employee began expressing lightheadedness, Employee assessed, employee was cold and clammy. Employee then began to have a seizure which last approx 30 sec. Vital signs assessed BP 110/80 HR 87 then dropped to 50 which is unusual for employee. o2 sat 94% on room. Employee regained consciousness and was able to state name, time and place. Reported no previous history of seizures. Employee handed off to ER staff for further eval.
929300	1/8/2021	WI	70	F	1/7/2021	1/7/2021	Allergic reaction / Syncope and collapse Patient reports feeling dizzy, hot, and that her eyes felt funny. Patient was sweaty, heart rate within normal rhythm . Patient lost consciousness and began seizure-like activity and was assisted to the ground. Patient regained consciousness about 20 seconds later. At 12:48: BP was 91/44 upper right arm, HR 78, O2 sat 100%. At 12:50 BP was 76/50 and patient report shortness of breath and the sensation that her throat was closing up. She was assisted to supine position again. at 12:54 Epinephrine 0.3ml was administered IM. At 12:56 NS administered wide open with pressure. Blood glucose 109. at 12:59 BP was 133/67. Taken to Emergency Department where she received famotidin 20mg IV, Methylprednisolone 80mg IV and KCL 20mEq po due to Potassium level of 3.4.
930670	1/8/2021	NY	48	F	12/30/2020	12/31/2020	The patient reported shortness of breast and difficulty breathing. The patient's husband stated that he witnessed the patient having a seizure. Patient advised to call EMS. EMS took the patient to hospital. The patient was stabilized after receiving emergency treatment.

<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>
930600	1/8/2021	SD	39	F	12/18/2020	12/24/2020	8:45 am 12/24 - severe rash on my left hand; and wrist; a mild rash went to my arm, chest and back hairline and on my forehead. Benydryl - 25 mg. Went to ER after it spread at 11:00 am. Had another 25 mg benydryl and a pepsid 20 mg at ER. Rash lasted two days. Ended Dec. 26. It was also after I increased my seizure medicine on Monday 12/21. Received at 8:30 am today/8th - second dose of vaccine.
930348	1/8/2021	NJ	33	F	12/28/2020	1/1/2021	I am breastfeeding. My daughter had seizure like episodes starting on Saturday 1/2, Sunday 1/3, Monday, 1/4 and 2 times on Tuesday 1/5.
930297	1/8/2021	RI	29	F	1/7/2021	1/7/2021	29-year-old previously healthy female presenting today with difficulty sleeping, sore throat, and nausea after receiving the second Pfizer COVID-19 vaccine around 10 AM. Patient says that after her first dose of the vaccine she had mild sore throat and hoarse voice that resolved spontaneously. She had her vaccine around 10, several hours later before coming to the emergency department between 2--230 she had the sudden onset of difficulty speaking with associated sore throat and nausea. She has had dry heaving but no large amounts of vomiting. She has not had stridor, wheezing, shortness of breath, syncope, or the development of a rash or hives. She has not had a reaction to her prior vaccines she does not have any other allergies in general. She has otherwise been well recently without infectious symptoms including fevers, chills, cough, and has not been exposed to Covid to her knowledge. Medications administered in ED included diphenhydramine 50 mg IV once, dexamethasone 10 mg IV once, famotidine 40 mg IV once, ondansetron 4 mg IV once. Had brief episode of shaking and R arm rigidity in the ED. Patient denies LOC during the episode, did not have a post ictal state, no tongue biting or episodes of incontinence. Given single event without LOC, less concern about episode being a seizure. Patient has had no further episodes of shaking since admission. CT brain was wnl, no FNDs noted on exam.
930233	1/8/2021	TX	25	M	1/7/2021	1/7/2021	Patient reported fever of 101 degrees and went to the ER due to previous history of seizures due to fever. Received Tylenol in the ER and fever subsided.

<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>
930187	1/8/2021	WA	18	F	1/8/2021	1/8/2021	Patient had seizure 10 minutes after injection. No history of seizures, but brain tumor resection about a year ago. 911 was called; EMS evaluated and had patient transported to hospital
929859	1/8/2021	IL	50	F	1/7/2021	1/8/2021	seizure activity, sent to the hospital for low blood pressure
928104	1/8/2021	CO	50	F	1/5/2021	1/5/2021	approx 20 after injection 1420, started getting chills, cold sweat, elevated heart rate, shortness of breath and blocky red rash on neck and torso. immediately drove to urgent care, was not allowed in for treatment due to did not have phone on med to call for appointment. went home, took 50 mg benadryl and pepcid po. had tachypnea and continued blocky rash on neck and torso with chest tightness. took albuterol inhaler. approx 0200 had rigors/ seizure. with continued prior symptoms. took additional 50 mg benadryl and albuterol inhaler. temp 99.0. in am 1/6 called urgent care to make appointment thought needed steroid. they said to go to ED. was afraid to go to ED in fear would be intubated as had before for allergic reaction. took additonal 50 mg benadryl, pepcid and zyrtec along with a shot of epi pen. within minutes, all symptoms resolved. will be calling place where I got vaccinated today to report. 1/8/21
928051	1/8/2021	CO	50	F	1/5/2021	1/5/2021	20 minutes after vaccine, cold chills sweat. 30 minutes after shortness of breath blocky rash neck/ torso. went to urgent care, wouldnt let me enter becuase didnt have a phone on to call. Went home, took 50 mg benadryl pepcid PO. took albuterol inhaler due to tachypnea. tried to wait it out at home. apporox 0200, rigors/ seizure tachypnea continued with respirations ranging 32-38/min. took 600 mg ibuprofen and albuterol inhaler, additional 50 mg benadryl. continued blocky rash. next day, called urgent care asking for appointment, thought needed steroid, they instructed to go to ED to check for covid. explained to them not covid, but allergic reaction. afraid to go to ED in thinking may need to get intubated. approx 1030 am, had 2 additional episodes of rigors/ seizure. temp never above 99.0 F. found epi pen in house and used it. no further rigors, no further tachypnea, rash disappeared.
927426	1/8/2021		60	F	1/6/2021	1/6/2021	Chest pain Abdominal pain Fever, severe chills, diaphoresis Seizure like activity for two night

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930012	1/8/2021	KS	27	F	1/8/2021	1/8/2021	Pt had several seizures about 15 minutes after receiving the vaccine. EMS was called/evaluated the patient. The patient planned to contact her primary care provider.
925925	1/7/2021	NY	52	M	12/28/2020	1/4/2021	1 day after the vaccine he had a low grade fever... 1 week later he had a seizure and then multiple ones in the ER...
927041	1/7/2021	PA	27	M	1/6/2021	1/6/2021	Fever as high as 101.6, body aches, severe pain at injection site, convulsions/chills, nausea, cough, migraine
926934	1/7/2021	MT	37	M	1/6/2021	1/7/2021	Pt awoke and had seizure like activity, went to hospital in neighboring county.

<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>
926787	1/7/2021	MN	53	F	12/30/2020	12/31/2020	<p>Resident had the COVID vaccine 12/30/2020. 12/31/20, resident has been in bed all shift. Staff became concerned when resident was not easily aroused. Resident displayed signs of tremors, twitching, confusion, in and out of consciousness, low O2 sats, elevated pulse and fever, fatigue and weakness. Writer called NP. NP stated this is most likely a reaction d/t the COVID vaccine. She gave orders for Benadryl 25mg IM x1 now and Tylenol 1000 mg now. NP also stated resident will not be getting the second dose of vaccine. Will continue to monitor and update NP if worsening symptoms. After receiving Benadryl and Tylenol at 145pm, resident began to appear as though she was feeling better and was talking to talk, fever had gone down. Tonight resident is not easily aroused, lethargic, continues to have tremors and twitches, almost appearing as convulsions. When asked if she knows where she is or what day it is, resident can properly answer. Resident denies SOB but staff has noted loud squeals while breathing. NP was updated and gave new orders to give Benadryl 25 mg IM x1 if needed and Ok to send resident to ED. Resident currently refuses to go to the hospital. Will continue to monitor. BP 152/112, P 116, T 99.1, O2 87-91. Resident's O2 at 1205am was 80% on 3LPM. Resident unable to be aroused from sleep by writer. NAR called to assist. NAR could not arouse resident. Writer and NAR attempted to reposition resident and resident's breathing became more labored. Resident turned back to previous position and writer called on call MD at approx. 1220am. MD returned call approx. 1235am with orders to send resident to ED. 911 called and ambulance arrived about 1245am. History of present condition given to EMTs and they stated resident would be going to Hospital. Writer has attempted to contact Hospital ED x3 but have been unable to get through. An EMT did just call to clarify when vaccine was given, what symptoms have been present and when they started. She said she has everything she should need and she will let Hospital ED staff know to call if they need anything else. Writer will again attempt to contact them though. Resident's temp was 97.5 and BG 128. When EMTs arrived they got an O2 reading of 60%. Resident did open her eyes a couple times during transfer from bed to stretcher and while stretcher was going outside but no responses from resident were made.</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>
926755	1/7/2021	NM	70	F	1/5/2021	1/5/2021	Vaccine Candidate received vaccine approxat 2:30pm, was monitored for 15 min no complications at the time, went home. Around 5:30pm while walking into her home she became unresponsive, was assisted in a siting position, became incoherent, mumbling and started to convulse to the right side of her r upper extremity. Foaming at the mouth and stopped breathing, CPR was initiated for 1-2 min, EMS arrived was transported to Medical Center. She was admitted and is currently hospitalized. MD reports this event is highly unlikely related to the vaccine given her medical history but suggested to report being its a new vaccine. Current status: stable.
926360	1/7/2021	OK	26	M	12/31/2020	1/3/2021	Marked increase in seizure activity. I seizure on 1/2/21, then a cluster of about 20 e\seizures on 1/3/21, followed by 3 seizures on 1/5 and 2 on 1/6. He was seizure free for approximately 10 months prior to vaccination.. Treated on 1/3 with Nayzilam nasal spray X2 to stop seizures per doctor's order.

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926220	1/7/2021	WA	52	M	1/3/2021	1/3/2021	<p>Patient is a 52 y.o. male. Chief Complaint Patient presents with ? Allergic reaction Reaction to Covid Vaccine Is patient concerned about a specific cause for the current symptoms? Yes Covid Vaccine Onset of symptoms: 0830. Symptoms include: difficulty breathing and/or wheezing, rapid heart rate or palpitations and generalized redness. Rash distribution: Face. How are symptoms changing over time? improving. Patient describes symptoms as moderate. Has patient tried any treatment for these symptoms?No What makes the symptoms better? Rest and time What makes the symptoms worse? Nothing Patient states that the shortness of breath and the increased heart rate started after about 4 minutes - then went away but came back much stronger at 10 minutes post vaccination No itching, wheezing, cough - just flushed and chilled Increased HR and jittery Did have surgery recently Did have Moh's procedure in the fall and had a reaction to the lidocaine - increased heart rate, increased blood pressure Associated symptoms: o Fever No o Sore throat No o Recent illness No o Exposure to person(s) with similar rash No Patient has flu vaccine documented this season. Patient Active Problem List Diagnosis ? Migraine ? Obstructive sleep apnea syndrome ? Calculus of gallbladder without cholecystitis without obstruction ? Hemiplegic migraine without status migrainosus, not intractable ? Low HDL (under 40) ? History of nonmelanoma skin cancer ? Encounter for screening colonoscopy ? Essential tremor Medical History Past Medical History: Diagnosis Date ? Acquired hypothyroidism ? Chronic kidney disease Stage 2 ? Chronic migraine with aura 01/04/2013 ? Colon polyps ? Color blind ? Enlarged prostate ? GERD (gastroesophageal reflux disease) ? Hemiplegic migraine ? Hx of febrile seizure ? Kidney stones x 1 - 2001 ? Nodular basal cell carcinoma (BCC) 09/08/2020 bcc nod, rt cheek and rt medial cheek ? Obstructive sleep apnea syndrome 11/04/2013 Home sleep testing on 10/31/13 with apnea/hypopnea index = 9 and low oxygen saturation = 90%. Auto-PAP titration pending. Surgical History Past Surgical History: Procedure Laterality Date ? Colonoscopy 04/10/2020 ksc ? Hx lap cholecystectomy N/A 12/23/2020 LAPAROSCOPIC CHOLECYSTECTOMY ? Hx of mohs/skin cancer surgery and repair 09/08/2020 bcc</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>
							nod, rt cheek ? Hx of mohs/skin cancer surgery and repair 09/08/2020 bcc nod, rt medial cheek ? Hx wisdom teeth extraction ? Upper gi endoscopy 04/10/2020 ksc Objective: BP 116/74 Pulse 84 Temp 97.9 °F (36.6 °C) (Oral) Resp 18 SpO2 97% General:well-hydrated, well nourished, no acute distress HEENT: ENT exam normal, no neck nodes or sinus tenderness Lung: clear to auscultation bilaterally Heart: regular rhythm, tachycardia noted and no murmurs, clicks, or gallops. Extremities: extremities normal, atraumatic, no cyanosis or edema Skin: flushed (face and neck and chest primarily) , no hives Neuro: alert, orientation normal, speech normal 9:30 AM Improving symptoms Decreased HR, although patient states if feels like it is cycling, flushing is almost resolved No hives or shortness of breath Mild jittery feeling
927096	1/7/2021	MA	60	M	12/28/2020	12/29/2020	Day 2 (12/29/20): Fever (<100 degrees), Mild muscle aches, Fatigue Day 3 (12/30/20): Fatigue, Muscle aches Day 4 (12/31/20): Alternating chills and profuse sweating starting at 8am, Full body flushing, Grand Mal Seizure at 4:30pm
922682	1/6/2021	NC	23	F	12/28/2020	12/28/2020	Patient experienced seizure-like symptoms. No limb movement, but eye fluttering and unconscious.
924131	1/6/2021	PA	79	M	1/5/2021	1/5/2021	Hypoxia, epilepsy seizures
922934	1/6/2021	TX	40	F	1/5/2021	1/5/2021	Pfizer-BioNTech COVID-19 Vaccine. Patient received COVID vaccination on 1/5/2021 and began feeling dizzy, light-headed and then had a witnessed syncopal episode with seizure-like activity, vomiting and loss of consciousness. Onset of symptoms were almost immediately following receipt of the vaccine. Patient demonstrated seizure-like activity again while in the ED. Patient received lorazepam 1 mg IV, diphenhydramine 50 mg IV, Lactated Ringers 500 ml IV bolus, NS 1000 ml bolus, potassium bicarbonate 25 mEq. Patient ED visit 0852 until 1404. Patient responded well to treatment and was discharged in stable condition.

<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>
921631	1/5/2021	MI	83	F	1/3/2021	1/5/2021	~~Patient with seizure this am during 1 assist transfer, resident passed out, lowered to shower chair next resident with incontinent episode and was sent to Emergency Department emergently and currently under evaluation with possible admission. ~~
921151	1/5/2021	NY	43	F	12/28/2020	12/29/2020	The resident who was known to have seizures, and under control for many yeas with Keppra 1000 mg twice a day, on the second day after vaccination developed recurrent seizures requiring hospitalization to an intensive care unit, with intubation and mechanical ventilation until 1/5/21 (to be extubated today). She is still at the hospital.

<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>
921037	1/5/2021	AZ	21	F	12/28/2020	12/28/2020	<p>nauseous; weak; no appetite; numbness on the skin of my arms and legs; I was post lctal for 2+ hours; seizures/having 2 non epileptic seizures; dizzy and lightheaded; This is a spontaneous report from a contactable nurse (patient). A 21-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE. Batch/lot number: EK5730), intramuscularly on 28Dec2020 07:45 AM at right arm, at single dose for covid-19 immunization. Medical history was none. There were no concomitant medications. The patient was not pregnant at the time of vaccination. The patient received vaccine around 7:45 AM. Within 2 minutes she felt extremely dizzy and lightheaded on 28Dec2020. She sat down and drank some Gatorade and took deep breaths. The feelings persisted 5 minutes later. She then woke up after having 2 non epileptic seizures while still in 15m waiting period, (This included posturing and color change) a rapid response was called and she was taken to the ER. She was post lctal for 2+ hours. Dizzy and nauseous, weak and no appetite for the rest of the day. She had no history of epilepsy. She also have numbness on the skin of my arms and legs within 24 hours of the vaccine. Onset date of all events (except dizzy and lightheaded) was reported as 28Dec2020 08:00AM. Treatment fluids, Zofran was received for all events. All event resulted in emergency room. 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. The outcome of the events was recovered with sequel.; Sender's Comments: A possible contributory effect of suspect BNT162BW on reported seizures 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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920711	1/5/2021	UT	31	M	12/31/2020	12/31/2020	I am the patient's neurologist. The patient has very well controlled epilepsy without a seizure in over a year. He is compliant with medication and did not have another provoking factor. Approximately 6 hours after receiving the vaccine he had a generalized seizure, which was witnessed by his wife. He had an aura, behavioral arrest, tonic-clonic activity for 1 minute followed by a post-ictal period of several hours. This is consistent with his known seizures, but the provocation appears to be the vaccine he received earlier in the day.
919991	1/5/2021	FL	59	M	12/17/2020	12/21/2020	Periorbital edema more on the right than the left; Herpes labials; This is a spontaneous report from a contactable Physician (patient). A 59-years-old male patient received the 1st dose BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot EH9899) via an unspecified route of administration on 17Dec2020 18:45 at single dose in left arm for COVID-19 immunisation. Medical history included Hypertension, Hyperlipidemia, nocturnal seizures and known allergies: Quinolones. Concomitant medications included Atorvastatin, Gabapentin, magnesium chloride (MAG), Telmisartan and riboflavin (VIT B2). The patient experienced Periorbital edema more on the right than the left at 25Dec2020 08:00, herpes labials on 21Dec2020. The patient did not receive any treatment. Outcome of events was not recovered.
921914	1/5/2021	PA	79	M	1/5/2021	1/5/2021	Episode of vomiting, change in mental status, hypoxia and seizure activity.

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918969	1/4/2021	IL	48	F	12/21/2020	12/21/2020	<p>Within a couple hours severe pain in left arm at injection site and deltoid; burning in left scapula to left side of chest, by midnight was unable to lift arm away from body more than 25 degrees; burning in left scapula to left side of chest, by midnight was unable to lift arm away from body more than 25 degrees; Pain remains 7/10 in shoulder blade and arm; Still do not have full AROM 23+ hours after injection; muscle spasms around left shoulder blade 4-5 hours later; 130 resting heart rate 6 hours after; burning in left scapula to left side of chest, by midnight was unable to lift arm away from body more than 25 degrees/ Pain remains 7/10 in shoulder blade and arm; This is a spontaneous report from a contactable other healthcare professional (patient). A 48-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: Unknown), intramuscular in the left arm on 21Dec2020 13:15 at a single dose for COVID-19 immunization. Medical history included partial motor seizures face. Prior to vaccination, the patient was diagnosed with COVID-19. Concomitant medication included lisdexamfetamine mesilate (VYVANSE 40 mg), escitalopram oxalate (LEXAPRO 10 mg), brivaracetam (BRIVIACT, 100 mg). On 21Dec2020 4pm, within a couple hours severe pain in left arm at injection site and deltoid, muscle spasms around left shoulder blade 4-5 hours later, 130 resting heart rate 6 hours after, burning in left scapula to left side of chest, by midnight was unable to lift arm away from body more than 25 degrees. On 22Dec2020, by 9 am this morning back to 90 degrees shoulder flexion and abduction with pain. Pain remains 7/10 in shoulder blade and arm. Still do not have full AROM 23+ hours after injection. The patient was not hospitalized for the events and did not receive any treatment for the events. The events were reported as non-serious. The vaccine was administered in a workplace clinic. The patient has not received any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was recovered on an unspecified date in Dec2020 with sequel. Information regarding lot/batch number has been requested.</p>

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918776	1/4/2021	OK	40	F	12/24/2020		I had seizure like 3 times; Vasovagal reaction; Fever; Headache; Weakness; It's just little bit shaky and breathless; It's just little bit shaky and breathless; allergic reaction; This is a spontaneous report from a contactable consumer. A 40-year-old female patient received bnt162b2 (BNT162B2, lot number: EK5730), via an unspecified route of administration on 24Dec2020 at a single dose for covid-19 vaccination. There were no relevant medical history and concomitant medications. The patient reported that on an unspecified date, she had an allergic reaction. She had vasovagal reaction and seizures. Vasovagal was an allergic reaction that happened, and added that basically it's an allergic reaction. The patient experienced fever, headache, and weakness like right now. It was just little bit shaky, ever since yesterday and she had been way off like she take it as instruction yesterday, weakness, headache and breathless did not stopped from yesterday. The patient had been taking Tylenol for fever and headache. The patient reported that the events persisted. On 24Dec2020, lab work was done at the hospital, and she was told that the lab work was okay and they did CT scan of head because she developed seizure. She had seizure like 3 times so they scanned her brain. The outcome of the events was not recovered.

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919275	1/4/2021	WY	43	F	12/23/2020	12/25/2020	I started with fatigue on 12/24/20 and on 12/25/20 developed fatigue and chills (could not get warm). On 12/25/20 I was walking downstairs when my husband felt I didn't look normal. I fell off the bottom two stairs sustaining injury to both feet. I was able to get myself up to standing position and then sat down. My husband reports that a few minutes later I had what he described was seizure activity for about one minute/stopped breathing and he called 911. Due to COVID visitor restrictions my husband was not allowed to go to the ER with me the night of the incident. I had full work-up with labs, EKG and head CT that were unremarkable at Medical Center. I had an appointment with my primary care physician on 12/28/20 and was referred to neurologist. He did an exam, ordered MRI and sleep deprived EEG. My MRI was completed and reported as no abnormalities. I have the sleep deprived EEG scheduled on 1/11/21. I have continued pain/physical therapy on both feet/ankles from the date of the incident.
917475	1/2/2021	WI	22	M	1/2/2021	1/2/2021	Pt had grand mal seizure approximately 10 minutes post vaccination. Seizure lasted about 3 minutes, then another seizure resulted approximately 2 minutes later lasting about 3 minutes, then ambulance arrived. Pts blood sugar was checked and was slightly low as well according to EMS. Pt seemed to stabilize. as being brought away, but in post-ictal phase.
917539	1/2/2021	IA	68	M	12/29/2020	12/29/2020	Seizure
917042	1/1/2021	MI	43	M	12/27/2020	12/28/2020	I received the vaccine at 6:30pm on 12/27. I worked at 7pm and took lunch at 2:00am. After lunch, I immediately felt sick to my stomach and threw up. I went home after my shift and went to bed. After 5 hours, I woke up and went to the couch to lay down while kids watched TV. Next, I woke to several people in my house. I had a seizure and my son had called 911. I was taken to emergency department. I was admitted and stayed 2 nights in the hospital.

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916785	1/1/2021	TX	35	F	12/28/2020	12/28/2020	After receiving the vaccine I began to feel lightheaded and short of breath. I felt tachycardiac and felt like passing out. I got transferred to the er where I received the epipen along with oxygen and antiseizure meds for my seizure. I was then transferred to Medical Center for further care where I was later discharged.
915616	12/31/2020	OR	41	F	12/28/2020	12/29/2020	I woke up Tuesday, the morning following injection, to get ready for work. I got my coffee, and felt very lightheaded and fuzzy. I sat down on the bed. Everything began to get dark and fuzzy, I felt like I was going to throw up. I tried to call out for my husband, but I didn't think I got his name out. The next thing I remember my husband was holding my and yelling at me, trying to get me to respond. He reports that he heard me call his name, he came into the bedroom to find me stretched out, stiff as a board, with my head cocked all the way back, tongue sticking out of my mouth, and unresponsive. He picked me up and my body remained rigid. After a minute and a half, I came out of it extremely confused. I did not know where I was or if it was real or a dream. He ran me to the hospital across the street from our house. I was admitted to the ED where I received IV fluids, an EKG, CT scan, and blood work. They do not know why it happened to me, but agreed it was possible I had experienced a seizure in reaction the the vaccine I received less that 24 hours prior.
915587	12/31/2020	TN	48	M	12/19/2020	12/23/2020	Seizure

<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>
916400	12/31/2020	WI	45	F	12/31/2020	12/31/2020	7:40a- before receiving the vaccine, patient was observed high level of anxiety, asking for friend to be there for the support. When she saw a needle, she moved away and ran out of the room. She came back after a few minutes, still looked nervous but still consented to receive the vaccine. 7:49a- Onset of dizziness, light headed, increase BP = 152/103. She was closely monitored by RNs for ~ 40 mins, reported feeling better and denied any further symptoms. She was released from observation room leaving for home 8:35 - while waiting for elevator, she screamed while lying down on the floor stating she was not feeling well. A rapid response was called, suspecting seizure-like reaction. BP = 150/106, P=80, repeated BP = 154/88 8:43 - blood glucose = 64, gave her glucose gel 5g, then was transported by EMS to closest ER. Patient did loose conscious ness or have injury related to falling and being on the floor.
916294	12/31/2020	MN	86	F	12/30/2020	12/30/2020	Hypoglycemia with seizure like activity. Blood Sugar 44. Glucose gel was give and was sent to our emergency room.
916473	12/31/2020	AZ	54	F	12/31/2020	12/31/2020	Patient complained of a headache, then patient was losing consciousness and gasp for air. EpiPen was utilized due to being unresponsive then began to seizing. Patient started to flatline and an AED was used while a paramedic came. Patient was put on her side then facility gave something for seizures. Lastly, ,ambulance took her to the hospital.
916324	12/31/2020	TN	55	F	12/29/2020	12/31/2020	Moderna COVID-19 Vaccine EUA This morning at 11A patient was getting changed which requires her wheelchair to be leaned back so she can raise up as nurse pulls up pants. After raising chair back to sitting position, patient did not raise her head back to resting but instead kept it thrown back which is highly unusual. Her eyes stayed rolled to top of head and body stiffened. She was unresponsive. Signs suggesting seizure which patient does not have. It lasted approx. five seconds. Patient blinked and began to laugh. She said she blacked out but knew where she was and who everyone around was. All vitals are in normal range and she has not shown any other symptoms since injection. She also has been all normal since episode.

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915265	12/31/2020	NY	30	U	12/30/2020	12/30/2020	Five minutes after the Moderna COVID vaccine was administered via IM route patient began to have seizure like activity, bilateral pupil dilation, bounding pulse and uncontrollable body movements. EpiPen administered by nursing.
914033	12/30/2020	IL	60	F	12/29/2020	12/29/2020	Patient received the Pfizer-BioNTech vaccine at around 1:30pm on 12/29/20. After about 15 minutes, she complaints of headache, lightheadedness, weakness, shivering , shaking. and want to lie down. she was taken into a room where she lay down and then had seizures which lasted about 20 seconds. After she was stabilized and received supplemental oxygen, she was transfered to the ER by the EMT at approximately around 2:05pm
913350	12/30/2020	NY	44	F	12/29/2020	12/31/2020	I woke up from sleep and developed tachycardia, tachypnea, feeling cannot breathe, excessive sweating, pain and numbness on the left arm where I received the vaccine, then I lost consciousness for unknown time. When I woke up I felt my legs and arm were shaking not sure if it is seizure or not as there is no witness. I walked a couple steps to the next room to wake up my husband and then I lost consciousness again after I heard ringing sound in my ears and black in front of my eyes. My husband found me on the floor and I fell on my left hand with small injury on the dorsum of my left hand that I am not sure how it happened. After drinking fluid I felt little bit better. I received 600 mg of Motrin and continues to have headache and muscle ache but no other symptoms at this time.
913554	12/30/2020	NC	83	F	12/28/2020	12/30/2020	Seizure activity in absence of known seizure disorder while eating breakfast. Seizure lasted about 2.5 minutes. Post-ictal period about 40 minutes.
913644	12/30/2020	ID	39	F	12/29/2020	12/30/2020	Pfizer-BioNTech COVID-19 Vaccine I experienced a seizure like nightmare. There was a flash of bright light and then I started shaking and moaning/gurgling. I could only move my right leg to try to get my husbands attention but my arms and upper body were in paralysis. I have never experienced anything close to this, but since I was sleeping, I am not sure exactly what it was. I believe it only lasted for about 30 seconds, and afterwards, I feel okay.

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913794	12/30/2020		32	F	12/23/2020	12/23/2020	patient in the monitoring facility post vaccination with possible allergic reaction with reported tongue swelling. Monitoring team called. Patient then had seizure. Transported to ED.
913984	12/30/2020	TN	38	M	12/22/2020	12/24/2020	his thighs are getting tossed to the right; This is a spontaneous report from a contactable consumer (patient). A 38-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EK5730, expiry date: unknown), via an unspecified route of administration at the right deltoid on 22Dec2020 18:40 at 0.3 mL, single for covid-19 immunization. Medical history included mini strokes and master strokes, connective tissue disorder from 2018 (diagnosed 2 years ago), seizure and brain issues. The patient experienced "his thighs are getting tossed to the right" on 24Dec2020 05:00. The morning of 24Dec2020, patient woke up and he felt like everything was getting switched to the right on his thighs. Below his calf and his torso are fine. He feels fine though, it was just his hips and thighs. His sister reminded him that this is how he felt when he had mini strokes and master strokes in the past. She reminded him that his left leg would go to the right. He was not falling or anything though. He feels fine, it just has that feeling. He would like to know if he should be seen for this. He was just asking because his sister is freaking out and asked if he should be seen. Patient takes epilepsy medication, blood thinners and thyroid medication. He will receive 2nd dose on 08Jan2020. Outcome of the event was not recovered.

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914521	12/30/2020	ID	39	F	12/28/2020	12/29/2020	<p>Patient presents with ? Altered Mental Status ? Headache HPI Patient presents to ER by EMS ambulance after family called 911 as patient was incomprehensible with slurred speech and moaning on the phone this evening. On arrival of EMS patient was asleep in bed and reportedly unresponsive other than to localize to pain. EMS transferred patient to ER. On arrival to ER patient had GCS 7. Reportedly patient is locum nurse who works in a Nursing Home and patient reportedly received COVID vaccination 2 days ago and that night reportedly began complaining to family on the phone of headache, nasal congestion, sore throat, cough, fever, chills, nausea, emesis, myalgias, and lethargy. Per the medical record patient has history of seizures, migraines, and sciatica. No other information is known on patient arrival to ER. 1. Peripheral IV right dorsal hand placed by EMS in route to ER. 2. On arrival to ER GCS 7 (E1M5V1) and roving eye movements with episodic lateral conjugate and at times disconjugate gaze concerning for seizure activity. Arms and legs with moderately increased tone but no clonic movements and patient able to localize bilaterally. 3. Ativan 1 mg IVP for seizure, then further 2 mg IVP for persistent seizure. 4. Fosphenytoin 1,000 mg IVPB in ER for loading dose of antiseizure medication. 5. Patient had significant improvement following completion of Ativan 3 mg IVP and GCS improved to 14 (E3M6V5) from GCS of 7 (E1M5V1). 6. Patient able to communicate after improvement as above and reports she has had headache or migraine for past several days as well as dysuria with bilateral CVA pain and has significant pain on percussion of bilateral CVA and moderate pain on palpation of bilateral flanks. No nuchal rigidity or pain with ROM of neck. Additionally, she complains of severe headache and diffuse pain of back and abdomen/pelvis. She reports a history of seizures in the past and reports she had one last month and was treated at a hospital in her home state. She denies antiseizure medications. Additionally, patient reports nonproductive cough, sore throat, nasal congestion, fever, chills, myalgias, lethargy, nausea, and episodic emesis over the past 2 days. She has anterograde amnesia following seizure and does not recall events. 7. Normal saline 1,000 mL IV bolus, then 100 mL/hour in ER. 8. CT of head with and without contrast performed and negative for intracranial</p>

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915428	12/30/2020	FL	62	F	12/22/2020	12/22/2020	<p>hemorrhage, lesions, stroke, or other acute pathology. 9. CT of chest/abdomen/pelvis with IV contrast shows no acute pathology or notable abnormalities. 10. Lactic acid drawn and normal. 11. UA and urine microscopy collected by straight catheterization and culture collected and pending. 12. Blood cultures x 2 collected and pending. 12. Rocephin 2 mg IVPB in ER after blood cultures collected. 13. Vancomycin 20 mg/kg (1,500 mg) IVPB following Rocephin. 14. Dexamethasone 10 mg IVP in ER. 15. Duoneb nebulizer in ER. 16. Called to discuss with patient's daughter and the family's preferred contact who is 23 years old. She reports patient had COVID vaccination 2 days ago and beginning that night patient has complained of headache, fever, chills, nonproductive cough, sore throat, nasal congestion, myalgias, and lethargy. Additionally, she reports patient has history of seizures on at least 1 occasion in the past a few months ago but is not on antiseizure medications. She reports patient had MRI and MRA of her brain at that time and reportedly an intracranial aneurysm was identified at that time. 17. Called to request transfer to another facility and spoke with hospitalist who states there is no neurologist there and suggests transfer to larger tertiary care facility with neurology. 18. Called to request transfer and accepted by ER provider. 19. Transfer by ALS ground ambulance with telemetry, pulse oximetry, O2 to keep > 02%, vitals every 30 minutes, normal saline at 100 mL/hour, Rocephin 2 grams IVPB, vancomycin 20 mg/kg (1,500 mg) IVPB in ER. DISPOSITION Patient Stabilized and Transferred Data Unavailable Wed Dec 30, 2020 2:12 AM CST</p> <p>Required code to be called and short MICU admission for observation, including neurology and psychiatry services. Seizures & PNEA (Psychogenic Non-Epileptic Attack)</p>

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913929	12/30/2020	KY	63	F	12/22/2020	12/1/2020	migraine; off-balance/loss of balance; dizziness/woozy like symptoms; Mild headache; didn't feel very good; sensitive to light; she might have body pain; her brain was over sensitive/brain wasn't right; felt stiff; This is a spontaneous report from a contactable other healthcare professional (patient herself). A 63-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), via an unspecified route of administration on 22Dec2020 at single dose at left arm for immunization. Medical history included migraine (had migraines probably all of her life, the official diagnosis was 12- 15 years ago), fibromyalgia, subclinical seizures, asthma, chronic lung disease, allergies, paralyzed vocal cord, trach, hum hum flu epidemic, infection and sick. The patient's concomitant medications included fremanezumab (AJOVY) every month and a couple of other things, like zonisamide (ZONEGRAN) which was a seizure med that she took daily that also helped manage her migraines, both of those are old and have been on board and being used for a long time. Patient got the COVID vaccine, clarified later to Pfizer COVID vaccine, on 22Dec2020 and was reporting a mild headache on same day. Patient had dizziness, a loss of balance, and migraine with woozy like symptoms on 23Dec2020. Patient was not doing much, she didn't feel very good. Patient said this was just a regular headache, no big deal. She said she came home and felt stiff and took Acetaminophen and was fine it was no big deal. She said she went to sleep. She said she sometimes had migraines without headache, body migraines, with dizziness, or she might have body pain, more like she is woozy or dizzy. Patient said she was sensory sensitive, her brain was over sensitive. She said she stood up from bed to get up for the day and said her brain wasn't right. She said she decided to have some tea and was getting started for the day, after about an hour and a half to two hours she took her migraine medicine, it usually resolved in about an hour or two. She said having the vaccine triggered a migraine, gone full blown, how it felt when she was sensitive to light, sounds are too much, she was off balance. Treatment medication for headache was acetaminophen, reporter said she didn't have it with her right now and if she went to get it she wouldn't feel good. She said she took the regular high dose acetaminophen,

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911356	12/29/2020	NM		F			<p>the extra strength, one dose by mouth last night. She said she took the migraine medicine today, 2.5mg, about half an hour ago. She said the name brand for it is called naratriptan hydrochloride (AMERGE), she took the generic named naratriptan. Naratriptan NDC: 0054-027903, LOT/EXP covered over with a pharmacy label. She says this is a new medication for her, it was prescribed 20Oct2020. Patient got the Pfizer COVID vaccine on 22Dec2020 at ten minutes until 04:00PM eastern time, and she received no other vaccinations. She said since she had allergy issues previously they had her wait a little longer. Patient had her second vaccine dose scheduled in three weeks. For medical history, patient said her migraines, fibromyalgia, and subclinical seizures were diagnosed all at once by the neurologist, diagnosis was 12-15 years ago, diagnosis for asthma it was hard to say when, she has been treated more specifically for it the last 10 years. She said she had a paralyzed vocal cord after she had a trach when she was 11 and had an infection and ended up paralyzing her vocal cord, and they also started treating the chronic lung disease and asthma at that point, about ten years ago. Patient had a history of allergies. She said something about a location having had a hum hum flu epidemic, and she was in ICU very sick at some point in the past. Unable to clarify these statements. Patient labs had been great in 2020. Patient asked if she should go ahead and have the second dose after having this reaction this time or if there was information on how to prepare for that. Outcome of all events was unknown.</p> <p>Headache; Chills; Body ache and little bit congested; Body ache and little bit congested; This is a spontaneous report from a contactable consumer (patient). A 50-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for immunization. Medical history included high blood pressure, seizure disorder. Concomitant medication included metoprolol, aripiprazole (ABILIFY). The patient experienced headache, chills, body ache and little bit congested on an unspecified date with outcome of unknown. No treatment was received for events. Information about Lot/Batch number has been requested.</p>

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913071	12/29/2020		45	F	12/29/2020	12/29/2020	patient had an episode of syncope/seizure, certainly not clear that is related to the vaccine, admitted for further work-up
911880	12/29/2020	PA	46	M	12/21/2020	12/24/2020	dejavu symptoms throughout the week after the dose. On Thursday Morning approximately 2.5 days after the dose, I had a seizure in my sleep at approximately 4am.
911170	12/29/2020	PA	58	F	12/18/2020	12/1/2020	Caller states she cant focus/She just can't focus; this is horrible/I have a hard time focusing; I'm like you know fogged; I just want to sleep/I have been sleeping all weekend that was horrible; I have some headache; I just don't feel right this is terrible; This is a spontaneous report from a contactable consumer (Patient). A 58-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), intramuscular in the arm on 18Dec2020 at single dose for covid-19 immunization. Medical history included seizure. Concomitant medication included celecoxib (CELEXA), levothyroxine sodium (SYNTHROID), phenobarbitone [PHENOBARBITAL] for seizure. The patient stated that she could not focus, this was horrible and had a hard time focusing on 18Dec2020, the patient also stated that "like you know fogged" on 18Dec2020, the patient just wanted to sleep and she had been sleeping all weekend that was horrible on an unspecified date in Dec2020, the patient had some headache on an unspecified date Dec2020, she just took some Ibuprofen for the headache, the patient just didn't feel right this was terrible on an unspecified date in Dec2020. The outcome of 'could not focus' was not recovered and the outcome of the other events was unknown.
911064	12/28/2020	WA	60	F	12/28/2020	12/28/2020	patient started having dizziness when she got up to leave from the waiting room 15 minutes post vaccination, she also mentioned headache behind her right eye. She was taken to an exam room in a wheel chair as she was unsteady on her feet. She was laid down on an exam table and vitals checked. She states no previous vaccine reactions, has history of seizures and has had them with increased frequency recently. Patient was released to her friend to be driven back to work 1 hour and 27 minutes post vaccination

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910202	12/28/2020	NJ	39	M	12/18/2020	12/23/2020	Pediatrician working in the hospital. Was exposed the an office contact wo had covid. Shoulder in soreness. At work on Wednesday. Felt lightheaded had to sit in chair. That's all he reminders. He workup to a CODE team putting oxygen on him. He has a seizure. Took the COVID test has COVID. Admitted to hospital for 2 days. Likely a syncopal event.
911050	12/28/2020	TX	43	F	12/28/2020	12/28/2020	SHORTNESS OF BREATH, TROUBLE BREATHING, CATATONIC STATE, POTENTIAL SEIZURE
911035	12/28/2020	AL	47	F	12/22/2020	12/22/2020	Approximately 7 hours after receiving the vaccine patient who is a L&D Nurse return to work in her area. She describes that after finishing with a C-section she felt burning in both of her eyes (she thought this feels like an allergic reaction, but I am not sweating and haven't rubbed my eyes). She went to the restroom to get a cloth to wash her eyes; afterwards she reports her vision went totally black in both eyes. She reports feeling frustrated that no one came to help and some panic in trying to figure out how to get out of the restroom. She did make it out of the bathroom. Her Staff reports she postured and turned arms inward, head going to one side and passed out. They also report ~ 10 minutes of incoherent conversation and stating "I got the vaccine, maybe I was given the wrong thing and now I'm blind". Upon waking, patient vision fully restored and patient does not remember incoherent conversation. Differential diagnosis- TIA vs. CVA > seizure disorder>>> complex migraine

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910959	12/28/2020	CA	33	M	12/23/2020	12/23/2020	33 y.o. male with no significant past medical history except for obesity who has been working as a nurse in the emergency room department in our hospital and today he received COVID-19 vaccine and 30 minutes later patient started having increased saliva, cold hands and feet, left-sided pressure-like headache and some numbness in his legs at the same time he suddenly started talking only in first language and lost his ability to speak in second language. He understand second language but replying first language stating that he is talking in second language. On exam he was alert oriented confused by people not understanding his second language stating that his numbness and cold feeling in the hands and feet have improved. Initially patient received 10 mg of Decadron for possible allergic reaction he had a head CT scan that was negative and his labs were remarkable only for hypokalemia. Patient had no prior history of any neurological symptoms he was advised admission to the hospital for observation Patient symptoms resolved next day,he is alert oriented able to communicate in second language he had a head MRI and head neck MRA that came back negative and had an EEG that showed no seizure activities. Patient was seen in neurology consultation who felt that patient most likely had an episode of migraine headache. Patient is going to be discharged home and to have a follow-up with his primary care physician next week
909778	12/27/2020	VA	20	F	12/26/2020	12/26/2020	8:27 Hives, itching all over chest and on tongue, tongue swelling, slight difficulty swallowing. 8:30 epi administered/ benedrlr 8:32 pseudo seizures begin off and on till the 27th
908342	12/24/2020	TN	48	M	12/19/2020	12/23/2020	Seizure witness by wife who is a physician. Bit tongue. No history of seizure or other neurologic disease.
908603	12/24/2020	TX	61	F	12/19/2020	12/20/2020	Headache: 2/10, global/ diffuse, responds to excedrin & getting, worse in the morning. +R Foot went numb and the resolved. No tingling, weakness, or numbness, dysphagia, slurred speech, seizures, blurry vision. Thirst: Very thirsty. ALtered Mentation: Slower in responding, Having to really think before she speaks Muscle Spasms +hot flashes no fever, chills, chest pain, or sob. hyper-emotional (Spontaneous crying).

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908293	12/24/2020	AZ	47	F	12/20/2020	12/20/2020	Left arm start swelling at the injection site and down to the elbow around 5:30pm; This is a spontaneous report from a contactable consumer reporting for herself. A 47-years-old female patient received bnt162b2 (BNT162B2; Lot #Eh9899) vaccine, via an unspecified route of administration in the left arm on 20Dec2020 10:00 at single dose for covid-19 immunisation. Medical history included hypertension from an unknown date, migraine from an unknown date, partial seizures from an unknown date, intracranial aneurysm from an unknown date. Concomitant medication included spironolactone (SPIRONOLACTONE), hydrochlorothiazide, triamterene (TRIAMTERENE & HCTZ), estradiol (ESTRADIOL). The patient was allergic to lisinopril, amlodipine, gentamicin sulfate; methylmethacrylate; polymethylmethacrylate; zirconium dioxide, zonisamide. The patient left arm start swelling at the injection site and down to the elbow around 5:30pm with outcome of recovering.
908609	12/24/2020	FL	28	M	12/23/2020	12/23/2020	Patient was in the 15 minute post-observation window and was scheduling his appt for second dose. Patient noted that he has a fear of needles and mentioned that he was feeling light-headed and experiencing tunnel vision.. He subsequently became diaphoretic and syncopal. He spontaneously recovered and was helped back into the chair. Did not fall to ground or hit his head. A SWAT was called. During SWAT evaluation, patient was given cool compress for neck and mentioned that this has happened before with injections. Subsequently had another syncopal episode and witnessed clonic seizure of roughly 25 seconds in duration. Patient again spontaneously recovered and was brought to the ED. the patient was unable to recall the events and has no history of seizure activity. Patient was given crackers and juice in ED and monitored for approximately 3 hours. Patient was discharged to home.
907478	12/23/2020	IN	67	M	12/18/2020	12/20/2020	Seizure (Grand mal)

<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>
908009	12/23/2020	NY	57	M	12/23/2020	12/23/2020	Resident noted to be experiencing a full body tonic/clonic seizure approximately one hour and forty-five minutes post receiving the vaccine. Supplemental oxygen via nasal cannula provided, vital sign monitoring, solu-medrol IM provided, epinephrine IM provided, clonidine tablet provided PO, stat labs ordered: CBC, BMP, depakene level, UA. Resident exhibited positive reaction to interventions. Seizure lasted approximately 5 minutes, afterwards resident presented at baseline: alert and oriented x3 and communicative. Oral intake tolerated approximately an hour and a half post seizure. Enhanced monitoring in place.
906532	12/22/2020	FL	40	F	12/19/2020	12/20/2020	seizure, resident sent to er and in CCU
905503	12/21/2020		43	F	12/21/2020	12/21/2020	During the 15-minute observation period the patient became flushed and began complaining of a headache. She then went unconscious and had tonic-like activity for approximately 2 minutes. The patient subsequently stopped the seizure-like activity and woke up but was confused and was acting in a postictal fashion. She was evaluated emergently upon arrival in the ED and noted to have an altered mental status. Physician noted that this does not appear to be an allergic or anaphylactic reaction. There was no evidence of rash and lung sounds were clear with no wheezing. Subsequent CT showed a diffuse subarachnoid hemorrhage and patient was transferred to the Medical Center for further treatment.
905183	12/21/2020	NC	51	M	12/17/2020	12/18/2020	12/21@11:50-Caller stated that he had vaccine at 9am and had a seizure about 4am the next morning. Patient also had slight head. Caller stated that he is feeling better no medications were given .Caller had Cat scan and EEG. Caller has follow up 12/22.

<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>
904555	12/20/2020	NY	63	M	12/15/2020	12/17/2020	I had no reaction following the vaccination. The next day I had very mild soreness at the injection site. The next morning (about 36 hours after the vaccination) I woke up with fatigue and a sore throat. I had breakfast and about 10 minutes later I vomited everything (projectile vomiting, no nausea or abdominal pain). An hour later I had episode of severe watery diarrhea (just one episode). Felt very weak so I decided to sit down, stumbled to a chair, and then proceeded to have a syncopal episode with about 4 minutes of seizure like activity (witnessed, I don't remember that part). Decided to go to the ER, where I had labs, EKG, CXR, head CT scan, MRI and EEG. I was admitted for 24 hour observation, all the tests were normal.
904359	12/20/2020	WV	19	M	12/19/2020	12/19/2020	Within 5 minutes, started feeling very tired and dizzy, leaned head back trying to relax. Approximately 15 minutes after vaccine had seizure lasting up to 15 seconds possibly. Brought to floor carefully. Then had small second seizure (about 5 seconds in duration). Difficulty Breathing immediately. Then extreme trouble breathing/stopped breathing , given 0.3 mg EpiPen in right thigh, gasped and began breathing again. Checked pulse (80 b/pm) then waited about 3 minutes and EMTs arrived. BP was 140/90 ish. Both higher but not terribly high.
904052	12/19/2020	IL	41	F	12/18/2020	12/18/2020	nausea, elevated blood pressure, syncopal episode x3, ?? seizure
903332	12/18/2020	NC	51	M	12/17/2020	12/18/2020	Seizure approximately 24 hours after vaccination

<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>
903014	12/17/2020	WV	86	M	12/15/2020	12/16/2020	<p>Patient reported to CNA that they felt like they soiled their pants. CNA confirmed that patient did not soil themselves and transferred patient to the restroom. While the patient was on the toilet attempting to have a bowel movement the CNA reported patient had 10 seconds of tonic clonic behavior and then went unresponsive and then back to tonic clonic behavior. This happened 3 times prior to getting patient put back into his bed. Patient went unconscious after last episode while on bed for a more extended period of time while a STAT page was called. Physical Therapist and Aid sternal rubbed him and he had gasp and woke up. Prior to and immediately following the episode his vitals were within normal limits. Neuro exam was unremarkable after patient came to. When he woke up he knew his name, date, and day of the week. He was only confused to where he was. Patient was agreeable to be transported out. EMS was called and transported the patient to Hospital. Patient displayed no seizure activity or neurological deficits in ER. Patient had a CT scan, which came back normal. Virals remained within normal limits and laboratory values were noncontributory. He was diagnosed with a UTI due to the presence of hematuria associated with a syncopal episode. Patient had a Foley catheter upon admission to the nursing home. Patient was administered Ceftriaxone at the hospital and discharged back to Nursing Home on Omnicef the same day. Patient is back at nursing home facility and has not displayed any additional signs of seizure. He is stable and Foley catheter has been removed. Facility spoke to wife who reported that patient did not have a seizure history.</p>
902790	12/16/2020	KY	31	F	12/16/2020	12/16/2020	<p>11 minutes after first dose of Covid Pfizer vaccine, patient became unresponsive, pale, diaphoretic with possible seizure activity. Patient dropped all belongings, leaned to the left side, with eyes rolling back in her head. Episode lasted about a minute. Patient could not remember what had happened. Vitals were BP 110/60, HR 64, RR 22. Patient was advised to go to ED for further evaluation but she refused. Patient was given a snack and an RN stayed with her for about 20 more minutes to monitor.</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>
902811	12/16/2020	KS	39	F	12/16/2020	12/16/2020	Associate received vaccine at 12:15 pm and was monitored for 15 minutes. After 15 minutes, associate went to check out table. While at check out table, associate fell to ground and was experiencing seizure like activity. Supportive treatment was administered and associate was transferred to ED.