

The Vaccine Adverse Event Reporting System (VAERS) Results

NJ Covid Life Threatening Report

Data current as of 01/27/2023

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VAERS ID	Adverse Event Description
<u>0904436-1</u>	The patient was well prior to vaccination (12/17). The day after, he felt mildly unwell and had a low grade fever. The following day, he had a fever of 102. He received 1L of fluid at Urgent Care and had a BP ion the 80s. Shortly thereafter, he felt palpitations and developed AF. He came to the hospital where he was tachycardia to 200 bpm and hypotensive to SBP70s. He received aggressive fluid resuscitation (4L), IV metoprolol and was started on empiric Abx. Within several hours, the HR lowered, BP increased, and AF spontaneously converted to sinus. He had no dysuria. Cutures so far have not shown growth at our hospital. Urinary culture from urgent care has reportedly shows 20k gram positive cocci.
<u>0940813-1</u>	she was dying as her blood pressure dropped to 70/40 and to come for a last visit; This is a spontaneous report from a contactable consumer. A 100-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 02Jan2021 at single dose for COVID-19 immunization. Medical history included COVID in Dec2020, urinary tract infection (UTI), dehydration and Covid sickness (vomiting) (was treated earlier in month for UTI and dehydration from the Covid sickness (vomiting)). Known allergies: no. The patient's concomitant medications were not reported. After testing positive in mid December to COVID and being declared Covid free on 30Dec by the nursing staff and in good health, with normal vitals and oxygen levels, the patient was given a vaccination on 02Jan2021. In the early evening the patient's blood pressure dropped to 70/40 and the reporter was told to come for a last visit. The patient was sleeping comfortably. She did not wake up when spoke with her. No one expected her to make it through the night. The next morning she work up, ate breakfast, watched TV, got IVs and oxygen and her vitals improved significantly. Lab tests and procedures included blood pressure: 70/40 on 02Jan2021, oxygen levels: normal, COVID test: positive in Dec2020 (testing positive in mid December to COVID and being declare Covid free on 30Dec), vitals: normal; improved significantly. Facility where the most recent COVID-19 vaccine was administered: Nursing Home/Senior Living Facility. If the patient received any other vaccines within 4 weeks prior to the COVID vaccine: No. Prior to vaccination, was the patient diagnosed with COVID-19: Yes. Since the vaccination, has the patient been tested for COVID-19: No. AE resulted in: Life threatening illness (immediate risk of death from the event). Serious: Yes. Seriousness criteria-Results in death: No. Seriousness criteria-Life threatening: Yes. Seriousness criteria-Caused/prolonged hospitalization: No. Seriousness criteria-Disabling/Incapacitating: No. Seriousness criteria-Congenital anomaly/birth defect: No. Information about lot/batch number has been requested.
<u>0943220-1</u>	Began with tingling/itching to tongue and roof of mouth approx 15 minutes after administration, progressed to tingling of lips, was sent to the ED for observation. Within 20-30 minutes developed cough, throat tightness, difficulty swallowing, breathing, vomiting, shortness of breath. Noted to have uvular swelling and wheezing on examination. Given Benadryl, Pepcid, Solumedrol, Zofran, Albuterol MDI, Epi IM. within a few minutes symptoms returned and were worse where I felt like I could not breathe, throat was closing, could not talk. Noted to be pale, HR in 140's. Given second dose of epi IM and symptoms improved. Was transferred to Obs Unit., within 2 hours (approx 6 hours after administration), developed SOB, throat tightness, cough, vomiting, difficulty breathing. Again noted to have swelling of uvula, wheezing on exam. Given Solumedrol, Benadryl, SQ epi, Albuterol, Racemic Epi nebulizer. Was transferred to ICU, all meds held except Pepcid. Day #2 ~10 am (25 hours from administration) developed throat tightness, diffuse red rash to arms, difficulty breathing, vomiting. Again noted to have uvular swelling and wheezing. Given Solumedrol, Benadryl, Pepcid, Albuterol MDI, Racemic Epi neb. Solumedrol started q12hour dosing. Strange feeling/fullness in throat continued all day, got additional racemic epi neb that night with improvement of symptoms. Following morning (day#2 after vaccine) noted to have diffuse red rash to chest and face, spread to arms, then began coughing. Given Solumedrol, Pepcid, Benadryl, Advair, Racemic Epi nebulizer. Solumedrol changed to q8 dosing. Approx 4 hrs later nurse noted rash worse on face, associated with itching, throat tightness. Given additional Benadryl, Racemic Epi neb with improvement. Rash continued that night with throat tightness, got additional Benadryl and Racemic Neb that night (total of 3 Racemic nebulizer on Day#2 post vaccine). Transferred to telemetry floor. Day#3 post vaccine rash improved, but still present to chest and face. Throat fullness present, especially after drinking. Am still hospitalized while writing this report
<u>0946096-1</u>	started with left sided lower back pain; This is a spontaneous report from a contactable Nurse (patient). A 22-year-old female patient received the first dose of BNT162B2 (lot number: EH9899), via an unspecified route of administration at left arm on 16Dec2020 13:45 at single dose for covid-19 immunization. Medical history included allergies for All fish. The patient's concomitant medications were not reported. The patient had the first covid vaccine on 16Dec2020 and on 20Dec2020 started with left sided lower back pain. The event resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization (2 days), Life threatening illness (immediate risk of death from the event). The patient received the Heparin drip and xarelto at home for the event. The patient was not pregnant. The patient received the covid test post vaccination on 09Jan2021. Test type was Nasal Swab. The result was negative. The outcome of the event was recovered with sequel on unspecified date.; Sender's Comments: From the information provided it is unclear what is the nature of the reported event and what are the reasons that have put the subject at immediate risk of death. The event is considered possibly related to the suspect product based on the positive temporal association.
<u>0976973-1</u>	Elevated blood pressure (180/116 highest recorded); dizziness; weakness lasting several hours; This is a spontaneous report from a contactable consumer (patient). A 44-years-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in the left arm on 20Jan2021 14:15 at single dose for COVID-19 immunisation at Public Health Clinic/Veterans Administration facility. The patient medical history was not reported. Concomitant medication included atorvastatin (LIPITOR), 40 mg daily, butalbital, caffeine, paracetamol (FIORICET). The patient experienced elevated blood pressure (180/116 highest recorded), dizziness and weakness lasting several hours on 20Jan2021 14:30 with outcome of recovering. The events were considered life-threatening (immediate risk of death from the event) and resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care visit. No treatment was performed. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination the patient had not been tested for COVID-19. Information on the lot/batch number has been requested.
<u>0982472-1</u>	Worsening respiratory failure 1/20/2021 death 1/27/2021
<u>0989541-1</u>	Other than sore arm after vaccine, developed weakness and melena 2 days later on Friday the 22nd and intermittent for next 3 days. He saw cardiologist the following Friday (29th) who advised blood work. The next day sent to ER as hgb was only 5.2. EGD. He received 3 units of PRBC and a gastric AVM was cauterized. He has had a Type 2 MI and is still hospitalized.

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<u>0994455-1</u>	cardiac arrest; This is a spontaneous report from a contactable consumer. An elderly (older than 65-years-old) male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number unknown), via an unspecified route of administration on 20Jan2021 as the second single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. He was reported as with unspecified health issues, and no known allergies. The patient previously received BNT162B2 for immunization, on an unspecified date. The patient experienced cardiac arrest on 23Jan2021, at 20:30, which was serious as it was life-threatening and involved hospitalization (in the intensive care unit (ICU)). Details were as follows: after the patient received the 2nd dose of the vaccine on 20Jan2021. The reporter indicated that he was released to go on 23Jan2021. The patient went into cardiac arrest. Therapeutic measures were taken as a result of cardiac arrest. The patient was reported as in the ICU, and critical on life support. There was no note of COVID prior to vaccination. It was unknown if the patient has had a COVID tested post vaccination. The outcome of cardiac arrest was not recovered. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.
<u>1000754-1</u>	on 2/1/2021 Resident Reported Back pain given Tylenol Medication orally For Relief. APPROXimately 30 Min Later. complaint of & Noted Diarrhea, Shivering, and vomiting SeNT To ER 2/1 And Admitted Diagnosis: Sepsis
<u>1000775-1</u>	on 1/26/21 Found laying on Bathroom Floor in Bedroom Apt. Complaint of Right Shoulder pain bleeding (unknown origin) then discovered origin HANd/FINgers. (Head on Floor toWArDs WALL) SeNT TO ER 1/26/21, Admitted 1/26/21 Diagnosis: AoRtic STENOSIS
<u>1001424-1</u>	Anaphylactic reaction; Had severe itching in the whole body; chills; A spontaneous report was received from a physician concerning a 80-year old, male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced anaphylactic reaction, severe itching in the whole body and chills. The patient's medical history was not provided. Concomitant medications reported included tamsulosin, omeprazole, simvastatin, amlodipine and finasteride all for unknown indications. On an unknown date, approximately 2 days prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Batch number 01120A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On an unknown date, the patient experienced severe itching and chills for about a day following vaccination. 2 days following vaccination, the subject experienced an anaphylactic reaction. He sought medical attention from his dermatologist who gave him the diagnosis. Treatment for the event included sertac at night, claritin in the morning, and betamethasone 0.05% cream. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events anaphylactic reaction, severe itching in the whole body and chills were unknown.; Reporter's Comments: This case concerns a 80-year old, male patient, who experienced a serious unexpected event of anaphylactic reaction and pruritus (had severe itching in the whole body), and a non-serious expected event of chills. The event of anaphylactic reaction occurred 2 days after first dose of mRNA-1273, lot # 011L20A. The event of, pruritus and chills occurred on an unspecified date after first dose of mRNA-1273, lot # 011L20A. Treatment included Sertac-one pill at night, Claritin- one pill in the morning and Betamethasone dipropionate 0.05% cream. 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.
<u>1012079-1</u>	My platelets dropped from 382k to under 10k 2 days after receiving Moderna Covid-19 Vaccine. I experienced bloody nose, Petechia, oral blood blisters, bruising, bleeding gums and was bedridden with fatigue.
<u>1023722-1</u>	Pt without h/o hematologic disease. Admitted to hospital <2 weeks after vaccination with acute severe thrombocytopenia (platelets 17) without otherwise normal CBC/diff. No symptoms other than bruising and minor bleeding (epistaxis). Pt treated as ITP with oral dexamethasone bolus (40mg PO qd x 4). Immediate improvement of thrombocytopenia. February 11, 2021 06:10 94 L 10 3/cumm February 10, 2021 06:50 36 L 10 3/cumm February 9, 2021 13:55 17 CL 10 3/cumm Will be discharged on to complete steroids on 2/12 and then labs/CBC will be monitored every few days as outpt. Pt to continue to hold BASA until at least confirm stability of platelets off Rx.
<u>1028508-1</u>	moderately high fever, headache for two days, then three days later (Tuesday morning) Signs of TIA - slurred speech, central vision blurry, word recall difficulty
<u>1039951-1</u>	Severe Headache; eye pain; earache on side of shot; itching both arms; severe jaw pain; severe chest pain; body ache; high fever; fatigue; profuse sweating; belabored breathing; hot; butterfly rash of face; This is a spontaneous report from a contactable physician (patient). A 66-year-old female (Not pregnant) patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration at right arm on 11Feb2021 14:30 at single dose for covid-19 immunization. Medical history included hypothyroidism, hypertension, hypercholesterolemia, breast cancer, osteoporosis, ligamentous RA, degenerative joint disease (DJD). The patient had known allergies to cilantro, cephalosporins, all morphine and morphine derivatives, Herceptin, astralogous mushrooms, gadolinium dye, fentanyl. The patient's concomitant medications reported as other medications in two weeks was yes. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced severe headache, eye pain, earache on side of shot, itching both arms, severe jaw pain, severe chest pain, body ache and high fever & fatigue - profuse sweating, belabored breathing hot butterfly rash of face on 12Feb2021 at time of 06:00 AM. AEs resulted in Doctor or other healthcare professional office/clinic visit, Life threatening illness (immediate risk of death from the event). The patient received Prednisone 80 mg and Benadryl 50 mg as treatment. Prior to vaccination, the patient was diagnosed with COVID-19. Covid was tested post vaccination. The patient underwent lab tests and procedures which included Nasal Swab and PCR test: negative on 09Feb2021. The outcome of events was recovering. Information on Lot/Batch has been requested.; Sender's Comments: Based on the compatible temporal association, there was a reasonable possibility that the vaccination with BNT162B2 played a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
<u>1047007-1</u>	Acute diverticulitis (first ever episode) and peritonitis
<u>1047298-1</u>	Symptoms : sensation that your throat was closing, that I could not breath, I could not swallow, flushed face, increased heart rate, pain down left arm, weakness Treatment:Epinephrine given at 12:00 PM, Epinephrine given at 12:15 PM, MethylPrednisone sodium succinate (solumedrol) given at 12:00PM, Diphenhydramine given at 12:02 PM, Ondansetron given at 12:20,Famotidine given at 12:01PM, Sodium Chloride 0.9% Stopped at 3:00PM EKG Discharge 4:45
<u>1059857-1</u>	Headache and syncope with head injury.
<u>1060242-1</u>	The patient developed back pain one month after the first injection on February 24 she was diagnosed with pericardial effusion?s and 750 mL was drained from the pericardium. The work up is on going but it seems to be Pericarditis which occurred after the vaccination
<u>1060459-1</u>	The following day would not get out of bed. It was clear by @ 6pm he was in shock - called ambulances; hospitalize 3-4 days
<u>1063711-1</u>	2-3 asthma attacks per day
<u>1068818-1</u>	Within minutes, Xavier felt burning sensation but did not report it while she was in the observation room because she thought it will go away just like it did with first dose. She then started to have rashes, low grade fever, and felt weak same day, and went on the following day. On 2/21/21 she had generalized swelling and rashes, difficulty breathing and went to the hospital.
<u>1071382-1</u>	On February 15, 2021, had fever and MASSIVE HEADACHE. Got worse each day. Went to ER on 2/19/21, was treated and release. Found unconscious in home on 2/20/21. Was hospitalized on 2/20/2021. Was diagnosed with varicella meningitis on 2/22/2021. Hospitalized till 2/25/2021. Still not well

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<u>1073431-1</u>	"According to NJIIS registry, patient received Moderna dose 1 at ""Rite Aid 00994"" on 3/3/2021. Patient arrived in ED on 3/4/21 at approx 9AM via ambulance. ED physician note: ""56-year-old male brought in by EMS intubated with CPR in progress. It was reported that he arrived to work and then passed out. CPR was initiated almost immediately. BLS determined that he was pulseless and AED was applied. He was defibrillated twice. He was then intubated by ALS and administered epinephrine twice with return of spontaneous circulation. He maintained a pulse for approximately 20 minutes when he again developed cardiac arrest. ACLS guidelines were again initiated and there was no return of pulse for approximately 20-25 minutes until he arrived in the emergency department. Emergency department CPR was continued and he was administered an additional epinephrine with return of a pulse. Is reported that he had no complaints prior to the event."" Patient was intubated and ventilated, started on norepinephrine drip in ED. Twelve-lead EKG demonstrated right bundle branch block with left posterior fascicular block and diffuse QRS widening and diffuse repolarization abnormalities. Family consented to Cath Lab. Per Interventional Cardiologist note: ""1. Angiography demonstrated proximal to mid LAD hazy 90-95% lesion likely culprit for cardiac arrest. 1 stent placed. 2. Diffuse distal right coronary disease that is likely nonculprit for cardiac arrest. 3. Left ventriculography demonstrated severe anterior wall hypokinesis with overall left ventricular ejection fraction of 40%. 4. Patient electrically and hemodynamically stable. Levophed has been stopped. Amiodarone bolus given in the Cath Lab for frequent ventricular ectopy. No drip was continued due to resolution of ectopy. 5. Dyslipidemia he will be on high-dose statin therapy. 6. Diabetic management as per primary team. 7. Quad-Lumen placed by me. Hypothermia protocol to be initiated in the ICU given GCS score less than 8 with no purposeful movements. Head CT scan completed before cardiac catheterization that demonstrated diffuse cerebral edema. 8. Prognosis guarded and likely poor. The next 24 to 40 hours will be critical. Family was updated in detail."" Patient transferred to ICU post Cath Lab. Remains intubated, ventilated in ICU."
<u>1077351-1</u>	Heart Attacks
<u>1079120-1</u>	Got pneumonia both lungs couldn't breathe was hospitalized six days. Not around many people after injection and always wore a mask.
<u>1081604-1</u>	Possible PEA arrest unclear etiology ~1 hour after receiving first dose COVID-19 moderna vaccine, s/p ROSC in field after 3 minutes CPR, no meds given. Intubated in field, extubated after 2 days.
<u>1087526-1</u>	I received my second vaccination in the morning on 02-04-21. I visited my OBGYN that afternoon learned that I was approximately seven weeks pregnant, and that my baby was healthy with a heartbeat, I returned to the OBGYN four weeks later for my routine visit and learned that the fetus had died around week 8, which was approximately one week after receiving the vaccine. I had no other issues or complications that would have contributed to my miscarriage.
<u>1102151-1</u>	Developed R calf pain on 1/16/21, progressively worsening over 3-4 weeks. Diagnosed with R posterior tibial DVT on 2/6/21 and started on apixaban.
<u>1110659-1</u>	Less than 5 minutes after receiving the vaccine, I experienced tingling in my left fingers. Less than 15 minutes of receiving the Covid-19 Pfizer vaccine, I experienced chest tightness and shortness of breath. I thought I was having an asthma attack, so I proceeded to use my inhaler. After using the inhaler, I started coughing while trying to breathe. Next my tongue started swelling, followed by my throat and back of the tongue. The nurses / EMT reported that my face turned red and my heart-rate was elevated. The EMT proceeded to give me EpiPen, which almost instantly caused the swelling in my tongue to go down. While being monitored for 3 more hours at the emergency room, the swelling went down even more and breathing became more normal. The following day, I visited my allergist doctor, and I was still experiencing some swelling in my neck and chest tightness. I was given a steroid shot, which seemed to clear the rest of the allergic reaction.
<u>1110935-1</u>	Chest pain Myocarditis. Admitted to hospital. Diagnosis confirmed by cardiac mri.
<u>1113967-1</u>	He was having trouble breathing; His heart is working at 25% capacity; This is a spontaneous report from a contactable consumer. A 77-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 08Mar2021 (Lot number: was not reported) (at the age of 77-year-old) as single dose for COVID-19 immunisation. Medical history included wears a heart pacemaker and cholesterol issue, both from an unknown date and unknown if ongoing. On 09Mar2021, the patient experienced trouble breathing, it was reported that his heart was working at 25%. The patient was admitted to emergency room and subsequently he was hospitalized for 3 days, the events were life-threatening. The patient outcome of the events was not recovered. Information about lot/batch number has been requested.
<u>1116221-1</u>	Woke up with pain in left leg lower calf on February 26 one week after my second vaccine. Had pain and throbbing in leg couldn't sleep with pain so on the evening of March 3rd I went to urgent care . Doctor didn't think it was blood clot because I had no swelling or redness in my leg but gave me a script for ultrasound. I couldn't get an appointment until the morning of March 5th . Was diagnosed with a very large blood clot in lower leg going up past my knee. I am now in Eliquis blood thinner for 3 months while they run tests
<u>1122581-1</u>	itching, breathing short and quick, weakness all over light headness
<u>1128585-1</u>	15 minutes after shot, numbness in lips, itchy mouth and throat, within about 5 more minutes throat tightness, sensation of difficulty swallowing. Then abdominal pain, nausea, then feeling of something really wrong, I didn't feel well, then got weaker and weaker, couldn't lift arms, and felt extremely fatigued, trouble staying awake. Taken by ambulance to medical center. On route, ambulance stopped and another team came in. I was given epinephrine, zofran, Benadryl, and maybe a steroid? Not sure. When I arrived at hospital, I think I was given dexamethasone and famotidine. I was barely awake but could speak. Could not hold anything. After several hours, they woke me up, I felt myself again, and I was discharged. Following days I felt exhausted and dizzy, and had a headache. Took prednisone for five days.
<u>1130383-1</u>	3/16/2021 Reaction from Pfizer second shot: I received the second Pfizer vaccine on Tuesday, February 23rd, 2021 around 1PM. Early Wednesday morning I developed Gastric reflux which I never had before. As the day progressed I had severe abdominal pain that lasted throughout the day, also something I never had before. Nausea set in late that evening. Although Thursday was fairly stable, on Friday I developed black diarrhea that continued all day. By Sunday I was so weak that a nurse came and sent me to hospital via ambulance. After 4 days of blood tests, transfusions, a chest x-ray, heart monitor, endoscopy and colonoscopy etc. , the only diagnosis for the significant blood loss was a bleeding ulcer. This must have been developing on Wednesday when the severe pain began. After release from the 4 day hospital stay, I was sent to our health clinic for 6 days to regain some strength. Since I never had ulcers, I firmly believe that everything was activated on Tuesday when I received the second Pfizer vaccine shot. Please advise on your perspective of my situation. Is what I have described similar to others who have reported vaccine side-effects? Thanks and be well.
<u>1130730-1</u>	Received vaccine at 9:30am on 3/19. That same afternoon at 2:00pm, I experienced intense pain in the jaw, shortness of breath, sweating, pressure/squeezing in chest, and uncontrollable shaking all throughout my body. Went to ER. EKG showed arrhythmia. Troponin tests did not show evidence of a heart attack. Admitted to the hospital for observation, but many symptoms subsided.
<u>1132349-1</u>	Cardiac Arrest due to vfib
<u>1141367-1</u>	Difficulty breathing, ambulance ride to hospital, 2 day stay in hospital for bilateral pneumonia

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<u>1147061-1</u>	pt states that immediately after taking the vax she got light headed and her limbs felt very very heavy. Her BP was up to 192/90. They had her sit to monitor her BP and she became nauseas. She went to the ER. They continued to monitor her BP and she was given IV Benadryl. The heaviness in her limbs lasted many hours. Once her dizziness, heaviness in limbs, and her BP was 141/67 and still coming down she went home. Walking to her vehicle she had the dizziness, heaviness and was light headed again. When she got home she went to bed. Pt woke up having heart palpitations. No chest pain or SOB. These palpitations lasted about 15 minutes. On 3/30/2021 she has some fatigue and a tightness around the top of her head. Pt has a FU appt w/ PCP on 3/31/2021.
<u>1151156-1</u>	Inability to walk, effectively communicate, raise my arms, suffered sustained premature ventricular tachycardia for a number of hours, life saving procedures enacted, no blood flow to extremities, severe pain, vomiting's, periods of unconsciousness
<u>1162136-1</u>	"Had I expected LAD heart attack on 15Feb after cardiologist said that heart is clear and risk is low; This is a spontaneous report from a contactable consumer (patient). A 72-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration, administered in Arm Right on 12Feb2021 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation, at 72 years old. Medical history included diabetes mellitus, high blood pressure, hypothyroidism, and Known allergy: Sulfa from an unknown date and unknown if ongoing. Patient did not have COVID prior vaccination. Patient is not pregnant. Concomitant medication included metformin; metoprolol; amlodipine besilate (AMLOD); insulin degludec (TRESIBA); and clonidine hydrochloride (CLONIDIN) taken for an unspecified indication, start and stop date were not reported (other medications in two weeks). The patient experienced ""had i expected lad heart attack on 15feb after cardiologist said that heart is clear and risk is low"" on 15Feb2021 05:00. The patient was hospitalized due to the event for 7 days on an unspecified date in 2021. The event required emergency room visit and physician office visit. Treatment was given for the event which includes Emergency Stent placement and update to medication. The patient underwent lab tests and procedures which included sars-cov-2 test (blood test): negative on 15Feb2021. Therapeutic measures were taken as a result of had i expected lad heart attack on 15feb after cardiologist said that heart is clear and risk is low (myocardial infarction). Outcome of the event was recovered with sequelae on 2021. Seriousness criteria was reported as hospitalization, medically significant, and life threatening. Information on lot number/batch number has been requested."
<u>1162861-1</u>	Heart Attack (NSTEMI) and 3 strokes
<u>1166586-1</u>	Pericardial Effusion Bilateral Pulmonary Embolism
<u>1167114-1</u>	After a few minutes, I started to feel chest pains which started to intensify, then my breathing started to get shallow. Next, I was feeling tingling in my extremities. Then like the flick of a switch, I went into anaphylactic shock. I couldn't breathe and struggled to get the words out to get an epi pen. I was then injected with 3 epi pens while the ambulance was called. I also felt tingling in my tongue and mouth. The following day at home, I had another reaction. It started with tingling in my throat then the shallow breathing again. Chest pains again, then anaphylactic shock again. The next day, allergy symptoms came back, but not anaphylactic shock. This time, the addition of burning in my biceps on both sides, which traveled down to my forearms. Later on, the burning traveled down my torso to my legs. There is also some burning in my ears and scalp. My breathing is shallow, and it seems like when the allergy meds start to wear off, the symptoms keep coming back. They're happening now as I write this
<u>1174362-1</u>	STEMI; This is a spontaneous report from a contactable healthcare professional. An 80-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date were not reported), intramuscularly, administered in the left arm on 29Mar2021 13:30 (at the age of 80 years old) at a single dose for COVID-19 immunization. Medical history included hypertension, hyperlipidemia, asthma, chronic kidney disease (CKD) 3, all from an unknown date and unknown if ongoing. Concomitant medications included tamsulosin, amlodipine, doxazosin mesilate (CARDURA), albuterol [salbutamol], umedidinium bromide (INCRUSE ELLIPTA) atorvastatin (LIPITOR) and montelukast sodium (SINGULAIR), all taken for an unspecified indication, start and stop date were not reported. The patient previously took enalapril and augmentin [amoxicillin; clavulanic acid] and experienced allergies with both. The patient previously received first dose of BNT162B2 (lot number and expiry date were not reported), intramuscularly, administered in the left arm on 05Mar2021 13:00 (at the age of 80 years old) at a single dose for COVID-19 immunization. The patient experienced ST-elevation myocardial infarction (STEMI) on 31Mar2021. The event was reported to have resulted in doctor or other healthcare professional office/clinic visit, emergency room/departement or urgent care, hospitalization (also reported as number of days hospitalization: 0; pending clarification) and was reported as life threatening. Treatment included cardiac catheterization. There was no other vaccine in four weeks. It was unknown if the patient had COVID prior vaccination and was not COVID tested post vaccination. The outcome of the event was recovering. Information on the batch/lot number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported event cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
<u>1177518-1</u>	Heart suddenly lost electrical current requiring pace maker to be implanted
<u>1178250-1</u>	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 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) 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.

VAERS ID	Adverse Event Description
<u>1189624-1</u>	Pulmonary embolism; This spontaneous case was reported by a physician (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Pulmonary embolism) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event (No reported medical history). In March 2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Apr-2021, the patient experienced PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criteria hospitalization prolonged and life threatening). The patient was hospitalized on sometime in April 2021 due to PULMONARY EMBOLISM. At the time of the report, PULMONARY EMBOLISM (Pulmonary embolism) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment information was not provided. This case refers to a 67 year-old elderly female patient who developed pulmonary embolism about two weeks after receiving the second dose of mRNA-1273 vaccine. Very limited information has been provided at this time.; Sender's Comments: This case refers to a 67 year-old elderly female patient who developed pulmonary embolism about two weeks after receiving the second dose of mRNA-1273 vaccine. Very limited information has been provided at this time.
<u>1190069-1</u>	Dizziness for days after shot leading up to 4/6/21 , on 4/6/21 passed out unconscious in the shower. 911 called taken by ambulance to ER. Admitted for 4 days, all testing was negative.
<u>1192802-1</u>	Blood Clots, Stroke
<u>1199984-1</u>	I started having pain in my left calf on Sunday 4/11/2021. I went to the doctor on the next day, Monday, April 12 at 9am. He sent me to the center where they did an Ultrasound which was positive . I was advised to go to the Hospital for a CT scan of my lungs and brain. I went to medical center on Monday at 6pm. There I was given an Iodine CT scan. They noticed a small spot of pneumonia. They repeated the Ultrasound of my leg and took a swab for Covid-19. I was given a prescription for Xarelto and an antibiotic , Levaquin, 500mg.. I came home.
<u>1201055-1</u>	Shortness of breath and rushed to ER - they found massive blood clot in both lobes of my lungs. No sign of Deep Vein Thrombosis - seems a mystery. Almost fatal if not gotten to ER so quickly they said. I was in the ICU from 4/7 - 4/10
<u>1201157-1</u>	No adverse events for 1st dose, 2nd dose was temporally correlated with autoimmune hemolytic anemia
<u>1201181-1</u>	Leg blood clot that traveled to my lungs leading to A Pulmonary Embolism
<u>1202573-1</u>	Stroke after first dose of vaccine
<u>1205627-1</u>	Janssen shot on Mar 12, 2021. On Mar 25,2021 at 10 AM, I woke up with a headache, sore joints, nausea. Also blurry vision and inability to read words on a page. Sensing something wrong, my sister drove me to emergency room at Hospital where I was admitted. I was later told I suffered a stroke. I was in the hospital for 5 days, receiving various tests. (Hospital has all info on record). I am awaiting surgery to remove blockage from carotid artery. Doctor has all my information and should be reporting the event also to VAERS.
<u>1206182-1</u>	Severe headache, Numbness, and migraine, nausea for 9 days
<u>1206779-1</u>	Pt received vaccination. Pt reports that she started feeling more fatigued and short of breath the week following injection. However, on 09Apr2021 pt had increased SOB and chest pain while shower, went into the doctor. After scan discovered Massive PE. Pt decompensated quickly and required intubation. Upon transfer to medical center, there were complications with ET tube and pt coded and required resuscitation for 6 minutes. Pt recovered and was transferred. Pt had Chest Xray, doppler of Bilateral lower extremities. Confirming PE and also left Popliteal DVT. Pt was on heparin drip which was switched to lovenox for proper anticoagulation. Pt was extubated on the 11th, is recovering. .
<u>1207498-1</u>	blood clots in the both lungs
<u>1208891-1</u>	Hemmoraged and passed many clots from my reared. Lost a lot of blood. Fainted and threw up. Was in ICU for 2 nights. Had 2 blood transfusions. They damped area where polyp was removed on March 30th.
<u>1209551-1</u>	My mom had called saying she's feeling nausea, dizziness, drowsiness and vomiting. We called the emergency services when they arrived she had collapsed. They broke the window and took her to the hospital, upon arrival we were informed that she has got a hemorrhage possible clotting due to high blood pressure. I now know the term is Cerebral Hemorrhage, she has been in ICU on a ventilation machine while they tried to drain the blood and clots. She's currently out of ICU however still complains about headache and back pain. We are informed that she has now developed some blood pressure and diabetes however it could be cleared in the short term. She's at the hospital and unknown how long she would have to stay there.
<u>1210122-1</u>	My mother received doses of the Pfizer vaccine. She received the first shot on Friday March 5, 2021 at 12:15 PM and the second vaccine on Friday March 26, 2021 at 11:45 AM. Both vaccines were administered at the pharmacy. Early Tuesday Morning she was incoherent and suffered a stroke. She was taken to the hospital and spent the entire week at the hospital. Her primary doctor, was out of town and Dr was the covering doctor. While in the hospital she was under the care of another Dr
<u>1210966-1</u>	My mother was found unconscious on the kitchen floor. She was taken to the hospital. She had different test including a Cardiac stress test and it was found to be okay. However, my mother developed a blood clot in her left leg. She still been under medical observation in the hospital.
<u>1211289-1</u>	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.
<u>1214074-1</u>	STROKE OCCURRED AT 11:30 ON TUESDAY NIGHT. WE DIDN'T RECOGNIZE SYMPTOMS UNTIL 3:00 AM WEDNESDAY MORNING WHEN HE WAS TAKEN TO HOSPITAL . SLURRED SPEECH, UNABLE TO GET UP, DROOPING MOUTH.
<u>1218763-1</u>	14 hours after vaccination patient experienced signs and symptoms of a stroke: aphasia, left arm weakness, clumsy, could not text. Called 911
<u>1219739-1</u>	ventricular tachycardia
<u>1222132-1</u>	Pulmonary embolisms. Shortness of breath starting about 36 hours after injection. Treated with oxygen, Eliquis and Metropolol
<u>1226348-1</u>	Shortness of breath, pulmonary emboli, deep vein thrombosis (DVT) in leg
<u>1226480-1</u>	development of severe neck pain leading to acute quadriplegia over the course of 24 hours Patient was intubated, started on high dose steroids and had an emergent C3-C7 decompressive laminectomy, medial facetectomy Extubated in ICU and now recovering.

VAERS ID	Adverse Event Description
<u>1227278-1</u>	heart attack; stroke; This is a spontaneous report from a contactable consumer. A 67-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration on 24Jan2021 13:00 (at the age of 67-years-old) (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. Medical history included hypothyroid, sleep apnea, known allergies: Shellfish, Sulfa, Possible Tree Nut allergy. Concomitant medications included levothyroxine sodium (SYNTHROID); ascorbic acid, ergocalciferol, nicotinamide, retinol, riboflavin, thiamine hydrochloride (VITAMINS [ASCORBIC ACID;ERGOCALCIFEROL;NICOTINAMIDE;RETINOL;RIBOFLAVIN;THIAMINE HYDROCHLORIDE]); clarithromycin (CLARITIN [CLARITHROMYCIN]). In Feb2021, Exactly 3 weeks after the first dose, the patient had a heart attack and stroke. The events were assessed as serious (hospitalized, life-threatening, disability). The event resulted in emergency room and physician visit. The patient was hospitalized for 10 days. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on an unspecified date. The outcome of the events was unknown. Information about lot/batch number has been requested.
<u>1227279-1</u>	heart attack; stopped breathing; This is a spontaneous report from a contactable consumer. A 67-year-old female patient (mother) received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date: unknown), via an unspecified route of administration on 14Mar2021 (67-year-old) as single dose for COVID-19 immunization. Medical history included Hypothyroid, Sleep Apnea, Known allergies: Shellfish, Sulfa, Possible Tree Nut allergy. Patient is not pregnant. Concomitant medications included levothyroxine sodium (SYNTHROID); apixaban (ELIQUIS); senna [senna alexandrina]; valsartan; clopidogrel; metoprolol; atorvastatin; macrogol 3350 (MIRALAX). The patient previously took vitamins, Claritin , first dose of bnt162b2 on 24Jan2021 01:00 PM (67-year-old) for COVID-19 immunization and exactly 3 weeks after the first dose, the patient had a heart attack and stroke. Exactly 3 weeks after the second dose (04Apr2021), the patient stopped breathing and died. It was reported that death cause was unknown but also likely heart attack (unspecified date). Ae resulted in: [Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event), Disability or permanent damage, Patient died]. Number of days hospitalization is 10. Patient had no covid prior vaccination. The patient was covid tested post vaccination. The patient underwent lab tests and procedures which included covid test (Nasal Swab): negative on an unspecified date. The patient died on 04Apr2021. An autopsy was not performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: stopped breathing; death cause: likely heart attack
<u>1229945-1</u>	3 days after receiving my 2nd Moderna vaccine I went into anaphylaxis. My throat felt like it was closing, tongue swelled up and could barely speak. My hands swelled and very extremely itchy. I developed hives all over my upper body including my head. This has Never happened before.
<u>1231560-1</u>	On 4/17/21 (ie within 48 hours of receiving COVID 19 Pfizer Shot #2 (4/15/21), my daughter began experiencing chest pain in the PM (PM of 4/17). It was initially mild so we did a watch and wait overnight but when it did not go away by morning of 4/18/21 we went to Urgent Care . Upon presentation at urgent care, she had an irregular EKG, we were advised to immediately do to a Hospital ER , upon arrival she presented with same EKG findings from urgent care, BW was run and her troponin level was a 7, this hospital recommended (after consultation with their cardiologist) that based on her age and urgency of the heart condition, we should be transported to a pediatric hospital with cardiology expertise. She was transported by ambulance to another Hospital, Cardiology Unit. . After a scary 24 hour overnight stay at the hospital she was released on 4/19/21.
<u>1235833-1</u>	Brain Aneurysm; This is a spontaneous report from a contactable consumer. A 50-year-old female patient (non-pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in arm right on 08Apr2021 16:00 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included asthma from an unknown date and unknown if ongoing, no known allergies. Concomitant medication in two weeks included fluticasone propionate, salmeterol xinafoate (ADVAIR), and patient had birth control. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient previously received first dose of bnt162b2 on 18Mar2021 04:00 pm at the age of 50-year-old at right arm as single dose for covid-19 immunisation. The patient was not diagnosed with COVID-19 prior to vaccination. The patient experienced brain aneurysm on 11Apr2021 13:00 with outcome of recovering. Patient received aneurysm coil as treatment. The adverse events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event). Information about lot/batch number has been requested.
<u>1236597-1</u>	Bleeding aneurysm.
<u>1237637-1</u>	Transient Ischemic Attack on April 14, 2021 and Transient Ischemic Attack on April 18, 2021.
<u>1241351-1</u>	10 days after the shot, my blood pressure rose to 198/112 and my pulse went to 161. and i called 911 and went to hospital. i had a severe headache for 3 days leading up to calling 911. finally on the April 1st, i went to hospital. i had a lump on my right shoulder never there before and i felt like the lump was causing my right side of my face to be numb. The hospital refused to believe me that i had some blood clot, they downplay the incident and instead gave me a brain CT SACN and brain MRA which was negative, they kept me for observation overnight and let me go noon the next day. since i have had follow ups with my regular doctor, a cardiologist and my nephrologist. I know that reaction was due to medication, either way glad i got the shot. BUT Since this time, I am retaining water, i know this because my rings do not fit anymore, rings i had for 20 years, never ever once had a hard time to put on or remove. I know my body, thats not the worse of it. i test my blood pressure every day at requesting of my kidney doctor, since the incident of my pressure 198/112 my diastolic on average is raised 20 points. I log this daily. here are some examples from before the medication 111/67 , 109/63 , 129/64 , 105/62 120/81. now my pressure is totally different for example, 155/88 150/91 157/90 , 134/88. nothing else changed in my life, I am exactly the same as before only now i have covid shot.. yesterday i saw the 4th doctor since i am shot up and she gave me a new pill olmesartan medoxomil, only on it one day but my diastolic pressure is still much higher than before. i dont want to die, i dont want a stroke, or a heart attach, i have a lot to live for still. nobody is helping me, doctors are just throwing pills at me and not treating root cause which i feel strongly to beleive it is from covid shot.
<u>1242325-1</u>	pt reports she became itchy and noticed red bumps on arm then went into rest room and saw it was all over her whole body she returned to her car where her husband was during trip home she developed headache and began having difficulty breathing they went to hospital where she reports she spent two days received two doses of epinephrine and three doses benydryl she reports she would have flare ups of the rash during hospitalization
<u>1242632-1</u>	extensive bilateral PE
<u>1244816-1</u>	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.
<u>1248162-1</u>	Very sick for three days as reported through CDC checking site. On 4/18 I began feeling extremely nauseous and had diarrhea and then began vomiting blood for over twelve hours. I went to the ER on 4/19 where they did an MRI and found two hemorrhaging lesions on the right side of my brain.
<u>1249046-1</u>	Stroke

VAERS ID	Adverse Event Description
<u>1255603-1</u>	platelets were tested and had dropped from 296 in Fe to 18 by 01Apr; sick; inflammation response wherein all of new/ old scars swelled up and looked fresh (including an old bee sting, csection scar, etc.); inflammation response wherein all of new/ old scars swelled up and looked fresh (including an old bee sting, csection scar, etc.); petichiae; badly bruising; This is a spontaneous report from a contactable consumer (patient). A 33-years-old female patient (not pregnant) received bnt162b2 ((PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in arm left on 01Mar2021 09:45 at the age of 33-year-old (Lot Number: EM6203) as single dose for covid-19 immunisation. Medical history included ulcerative colitis (remission), beta thal minor, allergies to aspirin and humira; Idiopathic thrombocytopenic purpura (ITP), delivery on28Jan2021. The patient had ITP during pregnancy (delivered 28Jan2021) and had been well in the normal platelet range at/after delivery. Concomitant medications included vedolizumab (ENTYVIO) taken for colitis ulcerative; folic acid; diphtheria vaccine toxoid, pertussis vaccine acellular, tetanus vaccine toxoid (TDAP) taken for an unspecified indication on 30Jan2021. The patient previously received the dose 1 bnt162b2 (Lot number: em9809) for covid-19 immunisation on 08Feb2021 09:30 AM. When the patient had the second dose (01Mar2021), she had an inflammation response wherein all of new/old scars swelled up and looked fresh (including an old bee sting, csection scar, etc). The patient also started badly bruising and having petichiae on 01Mar2021. Her platelets were tested and had dropped from 296 in Feb2021 to 18 by 01Apr2021, it continued to drop. This was the lowest they have ever been. She've been very sick on and off since having the second dose (01Mar2021) and recently finished high dose steroid treatment. The adverse event resulted in doctor or other healthcare professional office/clinic visit, life threatening illness (immediate risk of death from the event). Therapeutic measures were taken as a result of events and included treatment with high dose dexamethasone and blood monitoring. The events outcome was not recovered. No COVID 19 diagnosed prior vaccination, since the vaccination the patient hadn't been tested for COVID-19.
<u>1256081-1</u>	April 14, my sister was transported to hospital feeling faint and numbness in her left leg. As a result, she was admitted and treated for: ? blood pressure readings as low as 82/43, 76/50 while standing ? blood clots on her heart that traveled to her brain that were causing multiple mini strokes ? 95% blockage in her right heart vessel which required a stent ? 50% and 60% blockage in other chambers that will require attention She was given heparin and then switched to a different blood thinner to dissolve the clots. she was discharged on April 23rd with instructions to followup with her cardiologist and neurologist.
<u>1264109-1</u>	Patient reports receiving second dose of COVID vaccine on Saturday (Pfizer) and that night experienced fever and chills. When patient awoke in the morning he reports neck stiffness and left sided chest pain. The neck stiffness has since mostly resolved although chest pain has been getting worse. Patient reports it is localized, sharp, non radiating, constant, 6/10 in severity and exertional. pt admitted at Hospital ++ marked troponin leak and cardiac cath which revealed non obstructive CAD, elevated LVEDP (30) and transferred to another facility . Pt started on milrinone drip and had a endomyocardial biopsy on 4/22/21 : no lymphocytic myocarditis pt discharged on 4/23 with outpatient fu and metoprolol succinate and spironolactone for 3 months if tolerated to minimize myocardial injury from resultant inflammation + cats at home
<u>1270463-1</u>	Hospitalized on April 27, 2021 with blood clots in my lungs.
<u>1271104-1</u>	Immediately after the injection patient felt a pressure like and felt a ball on the back of his head left side that resolved within a day. Within a week from vaccine patient started having a headache on and off with feeling of like his brain is swelling on the left side. Within another week patient experienced abdominal pain and chest pressure. went to a hospital CT abdomen was negative. On 4/28 patient had a severe headache followed by numbness to left face and left facial droop. 911 was called patient was code stroke in ED.
<u>1272975-1</u>	Sharp chest and shoulder pains (heart attack like symptoms) started on Sunday evening and I went to the emergency room. The emergency room cardiologist did an EKG and echocardiogram and determined there was something abnormal. The cardiologist then did a cardiac catheterization and the diagnosis was pericarditis and myocarditis, which is inflammation of the heart and damage to the muscle. I spent two days in the hospital and upon discharge I was sent home with three different medications that I will have to take for the next couple of months.
<u>1273829-1</u>	Transient Ischemic Attic T.I.A.
<u>1274325-1</u>	Ischemic CVA
<u>1276790-1</u>	having a blood clot down whole right leg / up right side into right chest / under right breast / several clots in her lower abdomen; she almost died; urinary tract infection; right leg is very swollen; Kept losing consciousness/Passed out; hard time walking; had to use a walker; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (having a blood clot down whole right leg / up right side into right chest / under right breast / several dots in her lower abdomen), LOSS OF CONSCIOUSNESS (Kept losing consciousness/Passed out) and FEELING ABNORMAL (she almost died) in a 56-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002b21a and 004m20a) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included LEVOFLOXACIN, RIVAROXABAN (XARELTO), LISINAPRIL, HYDROCHLOROTHIAZIDE, OXYCODONE and LEVOTHYROXINE SODIUM (SYNTHROID) for an unknown indication. On 12-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 29-Mar-2021, the patient experienced GAIT DISTURBANCE (hard time walking) and WALKING AID USER (had to use a walker). On 12-Apr-2021, the patient experienced THROMBOSIS (having a blood clot down whole right leg / up right side into right chest / under right breast / several clots in her lower abdomen) (seriousness criteria hospitalization prolonged, medically significant, life threatening and intervention required) and LOSS OF CONSCIOUSNESS (Kept losing consciousness/Passed out) (seriousness criterion medically significant). 12-Apr-2021, the patient experienced FEELING ABNORMAL (she almost died) (seriousness criteria hospitalization and medically significant). On 26-Apr-2021, the patient experienced PERIPHERAL SWELLING (right leg is very swollen). On an unknown date, the patient experienced URINARY TRACT INFECTION (urinary tract infection). The patient was hospitalized from 12-Apr-2021 to 19-Apr-2021 due to FEELING ABNORMAL and THROMBOSIS. On 12-Apr-2021, LOSS OF CONSCIOUSNESS (Kept losing consciousness/Passed out) had resolved. At the time of the report, THROMBOSIS (having a blood clot down whole right leg / up right side into right chest / under right breast / several dots in her lower abdomen) was resolving and FEELING ABNORMAL (she almost died), URINARY TRACT INFECTION (urinary tract infection), GAIT DISTURBANCE (hard time walking), PERIPHERAL SWELLING (right leg is very swollen) and WALKING AID USER (had to use a walker) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 12-Apr-2021, Computerised tomogram: blood clots (abnormal) blood clot. On 12-Apr-2021, Ultrasound scan: blood clots (abnormal) blood clots. Action taken with mRNA-1273 in response to the events was not applicable. Patient stated she was in the ICU24-48 hours then transferred to another area of the hospital where she spent another 5-6days. She is still having to use a walker. Her right leg is very swollen. She has to walk and keep her right leg elevated. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Further information has been requested. This case was linked to MOD-2021-090647 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Further information has been requested.
<u>1277146-1</u>	Patient presented to the emergency department with right-sided pleuritic chest pain-she has a pulmonary embolism on CT angiogram. She was started on heparin and admitted to the medical center. She received her Johnson and Johnson vaccine on 03/04/2021.
<u>1280884-1</u>	Within 12 hrs of vaccine, marked confusion and then ischemic colitis the following day.

VAERS ID	Adverse Event Description
<u>1281337-1</u>	pt says she started having trouble breathing so went to an Urgent Care where she was told she had allergies and prescribed some allergy medication. She continued to decline so on 4/28/21 she went ER. They did Chest X-Rays and other test and was diagnosed w/ blood clots in both lungs. She was admitted and stayed overnight. She was released and told to FU w/ Pulmonologist on 5/4/2021 @ 1 PM.
<u>1282009-1</u>	progressive generalized weakness including of cranial nerves diagnosed as acute demyelinating encephalomyelitis (ADEM)
<u>1283201-1</u>	Severe allergic reaction Suffocating and not being able to swallow Had to go to emergency room Injected with steroid anti inflammatory, Benadryl and pepsid
<u>1283498-1</u>	CEREBRAL SINUS THROMBOSES
<u>1284853-1</u>	I had a Stroke; Blood clot travelled to my brain; effected left side of my body; ability to speak; This is a spontaneous report from a contactable consumer (patient). A 46-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot: ER 8729), via an unspecified route of administration in left arm on 10Apr2021 (at the age of 46-years-old) as single dose for covid-19 immunisation. The vaccination facility type was a pharmacy/drug store. The patient's medical history and concomitant medications were not reported. The patient had no known allergies. The patient did not have covid prior vaccination. The patient had no other vaccine in four weeks and no other medications in two weeks. The patient had a stroke. Blood dot travelled to his brain and effected left side of his body and ability to speak on 15Apr2021 at 17:30. The events resulted to emergency room/department or urgent care, hospitalization for 3 days, life threatening illness (immediate risk of death from the event), disability or permanent damage. The patient received unspecified treatments for the event. Covid test post vaccination on 15Apr2021 with result of negative. The outcome of the events was recovering.
<u>1285794-1</u>	Dural venous sinus thrombosis complicated by intracranial hemorrhage and seizure
<u>1288455-1</u>	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.
<u>1289372-1</u>	stroke
<u>1292046-1</u>	Same day as when patient received the 2nd vaccine, she was overcome with generalized fatigue and nausea. By the 4th day, her legs would not hold her when she tried to stand getting out of bed. She was nauseous to the point of not being able to eat or drink. Infact, she did not have the strength or desire to eat or drink. By the 5th day post vaccine (02/20/21), I took her to the Emergency room because she was so fatigued, she just slept, and couldn't stay awake to eat or drink. She was able to get to the car with a walker, but that was the last time she walked. After time at hospital and then Skilled nursing, she passed away on 03/21/21. She never regained the ability to toilet herself, eat on her own, failed to eat and drink, and eventually was put on hospice because she lost 30 pounds over the month from failure to eat or drink, even though I was there or the nurse was there to feed her every meal, and try to get her to take fluids. Her fatigue was just overwhelming. When she first arrived at the emergency room, she: ? Presented with 2 days of weakness and AMS; fever, nausea and generalized fatigue ? Word finding difficulty; without stroke or acute abnormal on CT or MRI; according to the Hospital
<u>1294490-1</u>	blood clot in left leg calf
<u>1294828-1</u>	very tired, slept all day; slept all day; She had trouble breathing; pain in back of right shoulder; found two blood clots on lungs and two in legs; found two blood clots on lungs and two in legs; there was damaged to his wife's heart too; weighed165 pounds initially and then went down to 145; This spontaneous case was reported by a consumer and describes the occurrence of DYSPNOEA (She had trouble breathing), ARTHRALGIA (pain in back of right shoulder), FATIGUE (very tired, slept all day), HYPERSOMNIA (slept all day), PULMONARY EMBOLISM (found two blood clots on lungs and two in legs), DEEP VEIN THROMBOSIS (found two blood clots on lungs and two in legs) and CARDIAC DISORDER (there was damaged to his wife's heart too) in a 79-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 028A2 or 078A2 and 028A2 or 078A2) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 31-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced DYSPNOEA (She had trouble breathing) (seriousness criterion hospitalization), ARTHRALGIA (pain in back of right shoulder) (seriousness criteria medically significant and life threatening), FATIGUE (very tired, slept all day) (seriousness criteria hospitalization, medically significant and life threatening), HYPERSOMNIA (slept all day) (seriousness criteria hospitalization, medically significant and life threatening), PULMONARY EMBOLISM (found two blood clots on lungs and two in legs) (seriousness criteria hospitalization and medically significant), DEEP VEIN THROMBOSIS (found two blood clots on lungs and two in legs) (seriousness criteria hospitalization and medically significant), CARDIAC DISORDER (there was damaged to his wife's heart too) (seriousness criterion hospitalization) and WEIGHT DECREASED (weighed165 pounds initially and then went down to 145). At the time of the report, DYSPNOEA (She had trouble breathing), ARTHRALGIA (pain in back of right shoulder), FATIGUE (very tired, slept all day), HYPERSOMNIA (slept all day), PULMONARY EMBOLISM (found two blood clots on lungs and two in legs), DEEP VEIN THROMBOSIS (found two blood clots on lungs and two in legs), CARDIAC DISORDER (there was damaged to his wife's heart too) and WEIGHT DECREASED (weighed165 pounds initially and then went down to 145) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Computerised tomogram: two blood dots on lungs and two (abnormal) two blood dots on lungs and two in legs. On an unknown date, Weight: 145 (Low) weighed 165 pounds initially and then went down to 145. The patient was hospitalized for around four days. The patient size of clots as 10 cm and 9cm in the lungs. The reporter stated that Heparin was used in the hospital and after the discharge the patient was put on Eliquis for the next 6 months. The reporter reported that the patient weighed165 pounds initially and then went down to 145 afterwards. Action taken with the mRNA-1273 is considered as not applicable. Company comment: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine, the onset of the reported events, a causal relationship cannot be excluded.
<u>1295164-1</u>	Patient's wife called today to inform us that her husband passed away on 04/17/2021. Patient experienced some side effects after receiving both doses of Moderna vaccine such as body ache and feeling of lethargy. Patient was taken to the hospital around 04/16/2021. Exact cause of the death is not known as wife did not want to get autopsy done.
<u>1300544-1</u>	"8 days 9.5 hours after 1st moderna vaccine. emergency room visit for a ""thunderclap"" headache. diagnosed with a subarachnoid hemorrhage. (brain bleed). no avm, no aneurysm found after 7 days hospitalized with a multitude of scans performed. zero reason for this to have happened?!"
<u>1301800-1</u>	STEMI that occurred 24 hours after vaccination. Suspect coincidental but temporally related.
<u>1303248-1</u>	FIRST DOSE ADMINISTERED 3/22/21. SECOND DOSE ADMINISTERED 4/9/21. DIAGNOSED WITH APPENDICITIS 5/6/21 WITH ONSET OF SYMPTOMS 5/2/21. LAPAROSCOPIC APPENDECTOMY PERFORMED 5/6/21.

VAERS ID	Adverse Event Description
<u>1306915-1</u>	"Client rec'd her vaccination on 04/09/2021. Approximately 2 weeks later, family states client started to not "feel well." Patient had leg pains and fatigue, as per family. On Saturday, May 8th, client drove her self to the ER, due to worsening symptoms of cough, leg pain, and shortness of breath. Client was evaluated in the ER and evaluation showed clots in bi-lateral lungs and lower legs. Surgery was performed to remove clots in lungs. Client was admitted. On 5/9/2021 client was intubated, and had an ECMO procedure. Client i remains in the hospital."
<u>1313725-1</u>	"The next day I started to feel strange and had a racing heart and some leg pain. Slowly over the course of four days (Friday to Monday) I continually felt "off" but differently than others explained post-vaccine (not necessarily flu like). This was an extremely high heart rate (up to 130+) and palpitations, chest pains, and calf discomfort. Finally on Monday, March 1, I went to my primary doctor because I felt so off and I knew something was wrong. My doctor sent me to the ER where they found a new DVT in my upper leg. This time it was deemed unprovoked, though it was right after the second vaccine."
<u>1317002-1</u>	A blood clot (DVT)
<u>1317656-1</u>	early morning after vaccine felt chest congestion and crackling sound in chest. felt congestion for the next 6 days. on tuesday 5/4 i could not breath. went to the emergency room in an ambulance. ER gave me oxygen and increased my lasix to double the dose. chest xray showed fluid build up in the lungs. that night breathing retuned to normal. spent two nights in the hospital with double doses of lasix each day. discharged on 5/6/2021
<u>1318440-1</u>	Had the feeling of a weight on my chest & trouble breathing 4/22/2021. Went to Dr who sent me to Hospital. Later transferred to Hospital to have a Pacemaker implanted by Dr. Just 3 months before I had a perfectly normal EKG. Now I had complete Left Bundle Branch Block of the heart.
<u>1319844-1</u>	Heart had stopped for 4 minutes; Some coronary incident; went to emergency room because wasn't feeling well; Fractured ribs; This spontaneous case was reported by a pharmacist (subsequently medically confirmed) and describes the occurrence of CARDIAC ARREST (Heart had stopped for 4 minutes), CORONARY ARTERY DISEASE (Some coronary incident), MALAISE (went to emergency room because wasn't feeling well) and RIB FRACTURE (Fractured ribs) in a 90-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 036B21A) for COVID-19 vaccination. The patient's past medical history included Multiple myeloma (Had multiple myeloma treatments in past 13 years and I'm in remission. Had multiple chemotherapies for them throughout since the year 2008.) in 2008. On 09-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 24-Apr-2021, the patient experienced CARDIAC ARREST (Heart had stopped for 4 minutes) (seriousness criteria hospitalization, medically significant and life threatening), CORONARY ARTERY DISEASE (Some coronary incident) (seriousness criteria hospitalization, medically significant and life threatening), MALAISE (went to emergency room because wasn't feeling well) (seriousness criteria hospitalization, medically significant and life threatening) and RIB FRACTURE (Fractured ribs) (seriousness criteria hospitalization, medically significant and life threatening). The patient was hospitalized on 24-Apr-2021 due to CARDIAC ARREST, CORONARY ARTERY DISEASE, MALAISE and RIB FRACTURE. The patient was treated with Manual therapy (CPR) for Cardiac arrest and Rehabilitation therapy for Rib fracture. At the time of the report, CARDIAC ARREST (Heart had stopped for 4 minutes), CORONARY ARTERY DISEASE (Some coronary incident), MALAISE (went to emergency room because wasn't feeling well) and RIB FRACTURE (Fractured ribs) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No relevant concomitant medications were provided. The patient went to emergency room because he wasn't feeling well. The patient was treated (details not provided) for 6-7 hours and assigned him the room. According to the patient, he did not remember anything after that. He woke up next day with all the tubes in him. Reportedly, his heart had stopped for 4 minutes and he had some coronary incident. The patient was given CPR to bring him back and due to that, he had fractured ribs. He was discharged after 5 days to a rehabilitation facility. No other information provided. Action taken with mRNA-1273 in response to the events was not Applicable. Concomitant information 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.
<u>1320197-1</u>	pericardial effusion tamponade; This is a spontaneous report from a contactable consumer (patient). A 67-year-old female patient received bnt162b2 (Pfizer-BioNTech COVID-19 vaccine), dose 2 via an unspecified route of administration, administered in Arm Right on 23Feb2021 (Batch/Lot Number: EN8208) at the age f 66 years old as 2nd dose, single for covid-19 immunisation. Medical history was not reported. The patient's concomitant medications were not reported. The patient previously received first dose of BNT162B2 on 31Jan2021, (Lot Number: EL9264) in the right arm at the age of 66 for COVID-19 vaccination. The patient reported that she began having signs and symptoms on 29Mar2021; heavy weight in throat like there was a softball in her throat; pressure in that area when she bent over; chest tightness; difficulty breathing; a lot of chest pain; chest stiffness; sharp stabbing pain in upper left chest. The patient stated that it took 13 days and 2 trips to the ER and multiple Doctor calls before they could diagnose what was wrong. She had visited her general doctor who thought she had an embolism and sent her to the Emergency Room on her second visit. They did a D-Dimer test, which they hadn't done on her first Emergency Room visit. The patient was diagnosed with pericardial effusion tamponade on 08Apr2021 as confirmed with the echocardiogram performed on 09Apr2021. On 09Apr2021 they removed the fluid, 700cc of blood, surrounding her heart. The patient was in the ICU from 08Apr2021 to 16Apr2021. The patient stated that she was hoping she would be able to transfer to a hospital but she was in too bad of shape to be transferred. The patient reported that she has some mild symptoms, residual symptoms, some pain in chest and some tightness, but it was much better now. She had an echocardiogram a week after getting out of the hospital which showed no fluid now. The patient was placed on medication. The outcome of the event was recovering. Follow-up attempts are needed. No further information is expected.
<u>1320405-1</u>	Itchy throat body Body flushed Chest tightness Throat tightness Tachycardia Hypertension Nausea SOB
<u>1321373-1</u>	Diagnosed with Myocarditis. Severe chest pain began at 2:30am. Went to hospital ER at 4am. Was given an ekg and blood test which showed a potential heart attack and was treated with Nitroglycerin at 4:30 am. Was given a cardiac catheterization at 6am that showed no heart attack and no arterial obstructions but showed one wall of the heart was not functioning properly. Heart issue was confirmed later in the day by an echocardiogram study. Was admitted to the hospital. Had an additional attack of chest pains at approximately 2:30pm the next day which was treated with 3 tablets of Nitroglycerin. Blood tests showed markers for inflammation.
<u>1321826-1</u>	Blood Clot in my lower right leg. Which can be life threatening if it were to dislodge and travel to the lungs and or Heart. Treatment: 30 day starter pack Eliquis 5mg tabs blood thinner, Methylprednisone 4mg dospak 21s, Acetaminophen 325mg 2@-6hrs or as needed
<u>1322889-1</u>	om 5/8/21 at 9:00 PM, felt light headed, stepped outside for air, returned to closest chair, calling to significant other, I feel dizzy. Sat in chair, staring blankly, not responding to calling, or physical touch. breathing shallow, facial and lip color pale, pasty white gray. weak pulse. 911 called, and responded 8-9 minutes later. By the time they arrived, patient had aroused and aware of his surroundings,. Although color was slow on returning to normal. EMS arrived, BP 120/80. Patient refused to go to ER . On 5/10/21 at 2:00am, patient woke up and had a nosebleed lasting 2 hours, pouring from nose. 911 called and transported to medical center for cauterization, nasal packing and observation. 5/11/21 developed a reddened rash on right hand, lasted 5 days. Nasal packing removed on 5/13/21. No further complaints at this time.
<u>1322955-1</u>	2 weeks later developed DVT (leg pain, also found to have ACL tear of unknown duration), loss of appetite, and bilateral stiffness in hands. Hospitalized for DVT on blood thinners since Diagnosis: Acute embolism and thrombosis of unspecified deep veins of right lower extremity ; Unspecified abdominal pain ; Nausea with vomiting, unspecified ; Strain of muscle, fascia and tendon of the posterior muscle group at thigh level, left thigh, initial encounter ; Essential (primary) hypertension

VAERS ID	Adverse Event Description
<u>1323456-1</u>	Within 24 hours pain in left side of left chest, in 48 hours pain on full left side of chest, within 72 hours pain through entire chest. Hospitalized within 72 hours, chest pains, catheterized within 120 hours, had a blood clotting issue, put into medically induced coma for three and a half days, followed by a pulmonary embolism and four (4) clogs, two (2) in either leg, within two weeks. Hospitalized twice, currently on three blood thinners, a beta blocker, pepcid, a statin, and one other. Expected to be on three blood thinners for at least three (3), most likely six (6) months. Start cardiac rehab on 5/19/21. Have chronic cough and chest discomfort. Expected recovery time: six (6) months.
<u>1327214-1</u>	developed lethargy 3 days later and found to have acute brainstem infarct on MRI
<u>1327810-1</u>	5 weeks and 6 days later I suffered a PE with Infarct. was hospitalized 6 days. anticoagulants, IV antibiotics, s/s pain, fever, shortness of breath.
<u>1329590-1</u>	ectopic pregnancy; This is a spontaneous report from a contactable consumer (patient). A 30-years-old female patient (not pregnant at the vaccination) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Mar2021 (Batch/Lot number was not reported) as UNKNOWN, SINGLE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient previously took biacin and experienced allergies. It was reported the Pfizer covid shot caused the patient to have an ectopic pregnancy. She ovulated the day before her shot while trying to get pregnant and just found out due to the shot she had an ectopic pregnancy on 04May2021. Event resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). No treatment received. Since the vaccination, the patient has not been tested for COVID-19. The outcome was recovering. Information on batch number has been requested
<u>1330247-1</u>	IMMUNE THROMBOCYTOPENIA
<u>1331799-1</u>	Patient had second Covid vaccine one day prior and presented to urgent care complaining of rash, easy bruising
<u>1331836-1</u>	Received first vaccine 4/21/21. Within two days started having tightness in chest, but no other adverse reactions, happened a couple times a day. 5/13/21 received second vaccine....had tightness two more times, then 5/14:22 evening had a heart attack....ambulance to Hospital. 99% blockage in LAD. Hospital inserted stent. Spoke with all of the Cardiologists about my concerns as Heart problems ?Do not? run in my family. I have always had excellent blood pressure and low cholesterol....my father is 86 and was a smoker, and never been on blood pressure medication, same with my late Grandfather. I've never? had any type of chest pains in my life. Also, I am retired and have had numerous vaccines, with no issues. The hospital cardiologists said that I could report this, but they believe the Heart attack is due to the fact that I smoke....I just don't believe that....the Heart Attack occurred 36 hours after my second vaccine!!!
<u>1332422-1</u>	High blood pressure, over 180; Pulse rate over 115, Sweating, Dizziness, Chest pressure, Difficulty Breathing
<u>1336701-1</u>	"4 days after first shot, she called me complaining of bad back pain. She was going to her family doctor the next day for her 21 yr old well visit and was going to get it checked out then. She had a complete physical and was cleared even her lungs were clear and she was good. Tuesday night April 13th at 10pm, she told me she had "air bubbles" in her chest. I said you mean indigestion, take tums I said. She said not mom, actual air bubbles and they are popping in my chest. I said you just got your physical, you are fine. They Thursday night April 15th she started having difficulty breathing and was out of breath. She went to urgent care on April 16th because she felt awful and they saw in an X-ray that she had a "cyst" in her upper right part of her lung and her lung was about to collapse. Sent her home on bed rest with a steroids and 2 inhalers. We got her Friday night from college because the pain in her back and now her chest was worse. Took her to ER and she had a collared lung and pneumothorax. She was admitted to the hospital and they tried to see if the lung would heal itself. It did not. They had to do surgery to repair the hole. When they were in there they saw a cobblestone texture where the hole was and they removed that texture and repaired the hole. She has never had a lung issue. Ever. She is also the 3rd person in my family to have had an adverse reaction to the shot. 6 of us vaccinated and 3 with injuries."
<u>1338628-1</u>	Although I have heart disease, and had triple bypass surgery three years ago, I consistently take my blood pressure. My blood pressure has been in a normal range since the operation, and following receiving the first dose of the vaccine it became elevated and I needed to go back on an old medication. Even then, my blood pressure was erratic. Two weeks after my 2nd COVID shot I had a heart attack due to a blood clot. This dot was able to be removed by a heart cath-lab. This could be a coincidental flare up due to an old issue, but the timing aligns with both doses of the vaccine.
<u>1340276-1</u>	This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (blood clot in each lung) in a 67-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 039K20A and 029L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included CALCIUM FRUCTOBORATE, CHONDROITIN SULFATE SODIUM, GLUCOSAMINE HYDROCHLORIDE, HYALURONIC ACID (MOVE FREE JOINT HEALTH) for Joint disorder NOS, MINERALS NOS, VITAMINS NOS (ONE A DAY [MINERALS NOS; VITAMINS NOS]) for an unknown indication. On 21-Jan-2021 at 11:00 AM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 18-Feb-2021 at 9:30 AM, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 28-Feb-2021, the patient experienced THROMBOSIS (blood clot in each lung) (seriousness criteria medically significant and life threatening). On 28-Feb-2021 at 6:00 PM, the patient experienced DYSPNOEA (shortness of breath). At the time of the report, THROMBOSIS (blood clot in each lung) outcome was unknown and DYSPNOEA (shortness of breath) had resolved with sequelae. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-Feb-2021, Computerised tomogram: blood clot (abnormal) Blood clot in both lung. On 21Jan2021, patient had received the first dose of Moderna Covid-19 vaccine and about 4-5 days later, he began to noticed that his breathing was labored. At the time of the report, the patient did not think much about the labored breathing since he was older in age and thought it was due to exercise. Patient received second dose of Moderna COVID-19 Vaccine on 18-Feb-2021 and he reported that his breathing became more laboring where he needed to stop walking to catch his breath. He had 2 scan which revealed that he have a blood clot at each lung and he was prescribed Xarelto 15 mg twice a day, then he will begin Xarelto 20mg once a day on 20-MAY-2021. Patient is on Kirkland C 500mg as a concomitant medication as well. Most recent FOLLOW-UP information incorporated above includes: On 13-May-2021: Significant FU- outcome of the event.
<u>1340745-1</u>	Patient had previous history of ITP in October 2020. Patient received Pfizer COVID-19 vaccine on 05/04/2021. She had documented normal CBC on 05/05/2021 with platelet count of 220 K. patient then developed oral mucosal bleeding and hemorrhagic blisters on 05/20/2021. Also increase spontaneous ecchymosis that started 2 days prior. Patient presented to my Hematology office on 05/21/2021 and was found to have platelet count of 2 K. repeat labs in the emergency room showed platelet count of 0. Patient currently undergoing treatment with high-dose steroids, IVIG and potential rituximab. Platelet count 1 K today on 05/22/2021
<u>1341471-1</u>	The same day I took vaccine on April 6, 2021, I had pelvic pain and cramping that increase over the next two weeks. I made an appointment with my physician. On 4/29/2021 I was examined by my physician and was told to go to the ER. I had my appendix removed and the pathology report showed that I had a blood clot.
<u>1341714-1</u>	4 days later suffered Acute Myocardial Infarction involving the left anterior descending (LAD) coronary artery
<u>1342932-1</u>	experienced acute pericarditis
<u>1345409-1</u>	Convulsions, unable to walk, Uncontrolled.

VAERS ID	Adverse Event Description
<u>1346757-1</u>	The patient is a pleasant 36 year-old female with no significant medical history, no significant surgical history, no history of COVID-19. She said she received her second dose of COVID-19 vaccine on May 9th, 2021 . Three days after her second dose she started noticing fevers all last week and all this week. She saw her primary care physician, was noted with hypoxia, decreased O2 saturations on room air and subjective shortness of breath; came into the emergency room. CT angiogram was negative for pulmonary embolism but shows ground glass infiltrates. She is noted with elevated B-natriuretic peptide, elevated troponin-I. Being worked up for myocarditis.
<u>1347518-1</u>	the patient had an acute Myocardial infarction within 48 hours of modern vaccination no prior history of coronary artery disease
<u>1353632-1</u>	My daughter started to experience headaches 2 days after her first dose. On May 13th the headache had become so bad that she would cry and then suddenly became unable to speak or grab. She could not formulate actual words and was unable to smile . This lasted 15 minutes. A trip to the nearest Emergency room was inconclusive and resulted in discharge. 24 hours later , we had the same incident only this time magnified times 10. Where she remained in a catatonic like state for 7 hours only to snap out of it independently without medical treatment. After multiple test she was diagnosed with viral encephalitis. All major causes of encephalitis were ruled out and we were told it was possible a side affect of her first Moderna Covid Vaccine dose. We are still seeing doctors and testing but she seems to have improved without medication which is even more alarming .
<u>1354936-1</u>	Heart attack (complete blockage in LAD artery). Symptoms began Wednesday 5/12 with elevated heart rate/chest tightness. Went to ER on Friday 5/14 and received two stents via cardiac catheterization.
<u>1355338-1</u>	10 days after receiving the Janssen vaccination I was driving and experienced blurred vision. Pulled over, waited a while then continued driving when vision improved. Arrived home and family member noticed facial drooping on right side as well as slurred speech. Immediately called 911 and was transported to hospital within 30-45 minutes.
<u>1355533-1</u>	Post the Second Dose Following symptoms started to show-up - Tiredness, Confused state of mind, Loss of appetite - Lack of Sleep - Fluid accumulation and swelling in legs, face/eyes - Increased Creatinine, Reduced Hemoglobin, Vitamin and Iron Deficiency

VAERS ID	Adverse Event Description
1360614-1	<p>thought he was having a heart attack; It was all over his body and his left side, the pain/ left side hurts/ spread up his arm and down his hand and shoulders; left side hurts because that was where he got the shot; the first shot almost killed him, he has a defibrillator attached to his heart; This is a spontaneous report from a contactable consumer (patient himself). A 69-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; Batch/Lot Number: ER8732) via an unspecified route of administration, administered in left arm, on 23Mar2021 (at the age of 69 years old), as 1st dose, single, for COVID-19 immunisation. The patient's medical history included stroke, weak heart, defibrillator/pacemaker insertion, impaired eyesight/ half-blind, pneumonia, headache, and ongoing prostate. The patient had a defibrillator attached to his heart, staples in his chest, and stitches. He got a weak heart from pneumonia which gave him a stroke and led to impaired sight. Patient stated everything else was working. The reason he's blind was because pneumonia hit his heart and caused a stroke along with the medication he was being given, and it happened before getting the COVID vaccine and has nothing to do with the shot. The stroke caused blindness, and they needed to add a defibrillator to his heart because the pneumonia weakened his heart even more than it was already weak. He had a defibrillator attached to his heart 14 years ago and it got took out about 7 years ago because his heart was better. He reported he had to get another defibrillator due a problem from pneumonia. The patient missed his first appointment for the first dose as he had back trouble and a headache. He called the hospital, and they listed off if you're feeling this or this don't come. The patient wasn't feeling well, so he didn't go; he did not seek medical treatment. The patient has compromising conditions; he has a defibrillator and he take blood pressure and heart medications. Every time they tested him, he was negative for COVID and he did not test positive. Concomitant medications included tamsulosin taken for prostate, start and stop date were not reported. The patient was also taking nearly 15 pills a day; 6 in morning, 2 in the afternoon/lunch, 6 at evening time and some at night before bed. He reported that he was pill popping because of his condition and he could sell and still have more than enough for himself to take, that is how bad it is for him. The patient reported about number one and number two shots of COVID vaccine. The number one shot scared him, so he was scared of getting shot number two. He didn't know what the deal of it. He received it at the hospital on 23Mar2021 (Tuesday), and it woke him up on Wednesday morning around 2 A.M (24Mar2021) and he thought he was having a heart attack. The patient wanted the second shot, but he didn't want to get it. He wanted to know whether you have to take the first shot over again or can you take the second; he heard the second shot was worse. He missed his appointment on 15Apr2021 because the first shot scared him, and he panicked. The patient stated that the first shot almost killed him, he has a defibrillator attached to his heart, and he was scared to get the second. The patient wanted to know what the deal was, if he can take second dose safely. He stated no big deal, and he's leery after the first shot woke him up. He had a pain from Wednesday morning to Sunday afternoon, stated he had a pain grade of 6-12. The patient also stated that he has been going crazy with other things, staying away from other things, with the condition he's in, he's blind, and he stayed in the house. When he went out, he was covered. The pain lasted Wednesday through Sunday, he didn't go anywhere and makes precaution to make sure not to catch something, he's always masked and always home. The patient reported that he was having pain at times when he touches his side. When he goes to bed, he sleeps on his right side with his arm across his body laying on a foam block because that side hurts. He clarified that his left side hurts because that was where he got the shot. He was surprised, the pain was so sharp, he thought he was having a heart attack. It came from his elbow, started there and spread up his arm and down his hand and shoulders. His left side hurt when he touched and pressed down, it was a pain of 12. He thought he was having a heart attack, and it scared him, that's why he didn't get the second shot. He heard the second one was worse than the first one. If the first one made him feel he was having a heart attack, the second one would surely kill him. He was worried so he decided to stay home. He felt like a kid staying home from school. The pain went away, it just scared him for how he woke up. If he had a pain grade face in the hospital, it was off the chart. He knew how he felt and how he looked, it would be off the chart. He thought in his mind he was dying, felt like he was having a heart attack, like he was dying. It took a little bit of time, he had to calm down and find where the pain was coming from, and where it was going. Pain was coming from his elbow, across his chest and hitting his defibrillator. Patient stated this was the reason he felt he was having a heart attack. The defibrillator woke him up, it had an effect on it, it woke him up and scared him. They had to put the defibrillator in because he needed it for his heart. He thought he was having a heart attack after all this, he was bugging. His son came in, and he told his son that he was in pain. His son told him not to get the shot and believed this was why the patient was hurting. His son said the vaccine and the defibrillator caused him to feel like he's having a heart attack, the shot did something to his elbow which caused the pain and when it hit, it hit everything and he had a pain grade of 20. It woke him up and scared him. He won't say what he wanted to say, it is personal, but it scared him that much he wanted to go there. The patient was supposed to get his second dose 15Apr2021 because the first shot scared him, and he panicked, he did not because he was scared to death. The patient reported that everything began on Wednesday, the pain was gone, and he has recovered completely. Patient stated his pain grade was a 6-12. The pain in his elbow has recovered completely. He stated his elbow showed pain when it gets cold or rains, when it gets wet. Patient wanted to make sure if he gets the second shot, does he have to get the first shot again since he missed the second shot appointment. Everybody was saying to get the COVID vaccine, to prevent him from getting COVID, they wanted everyone to get vaccinated. He was unable to read his vaccine card because he was half-blind and will have someone else look at it. The patient missed his second dose appointment due to the effect of the first dose of the vaccine; he had a bad reaction from the number 1 shot and that was why he did not get the number 2 shot because of him being compromised due to his condition and the medications he takes. He had the first dose on 23Mar2021 and scheduled to get the second dose on 25Apr2021 (more than 21 days). He believed the ingredients combined this caused it, when he had the event he thought that it did bother his defibrillator, he had pain that made him think he was having a heart attack. That with the meds it may have added to the pressure he received when he got the shot, where he got the shot. His left side was bothering him, he thought he had a heart attack; his defibrillator was thumping, and he had pain that hit his elbow and his defibrillator woke him up. He knew it had to do with COVID shot. It was all over his body and his left side, the pain. His heart medication and blood pressure medication were nothing different. He had pain in his side, that he does not normally have which branched out from the elbow, to the hand, to the defibrillator. His left side was sore and he could not lay on it and could not touch it since it was so painful. Patient confirmed the pain was all down the left side and he got the vaccine in his left arm. The only last effect he was having is that he was afraid to get that second shot, he was afraid to go to sleep as he won't wake up after getting the 2nd shot or how he will going to react to it. He was paranoid in his mind to get the second shot. He reported that everything was wrong with him and that the shot had to fight with his medications and his body pain for it. He reported his body is paying the price. He felt like he was having a heart attack, pain going up and down arm, his fingers felt like needles going into his hand, like life was going back through his hand. His pain went to his chest his face was nowhere on the pain chart, his pain was like a 16 on a scale of 1 to 10. When he woke up that night it was like a 20, then if he touched his arm the pain was like a 14-16. The patient could not sleep, he could not sleep on his left side. Patient had to put a foam pad on his left side he got from his friend or sleep on his right side. That started Wednesday morning at 2 A.M to Sunday morning, he was surprised when he woke up that Sunday, he was not in pain when he woke up on his back. Patient reported he was half blind and can't find his medications. He reported he put his medications down earlier and was not sure where they were. nAround that time he went to the hospital due to breathing issues, problems breathing. He went in twice and they discharged him on their own but, he had more problems breathing. What he did not know at the time he had because he did not look at the discharge paper and no one explained them to him was that he had Pneumonia when he went to the hospital. The outcome of the events vaccination site pain, heart attack was recovered on unspecified date in 2021; while for the remaining events was unknown. Information on Lot/Batch number was available. Additional information has been requested.</p>
1361894-1	ST Elevation Myocardial infarction (I21.3 - STEMI)
1362438-1	Tachycardia, high blood pressure, elevated levels of troponin. I was hospitalized with these conditions

VAERS ID	Adverse Event Description
<u>1362608-1</u>	On 1/27/21, Patient took the 1st Moderna vaccine. She had flu like symptoms after for 3 days and then she broke out in hives. She continued to have flu like symptoms, and she felt very week. On 2/3/21 we took her to Hospital where the doctors indicated that she had a heart attached They released her from the hospital on 2/4/21. When she came home she was very tired and was disoriented. The following morning, she was running a fever and her eyes rolled back in her head. We called the ambulance who took her back to Hospital. The doctors indicated that had a stroke. They indicated that blood clots ?showered? her brain. She has lost her peripheral vision on the right ride. She has issues with her memory and executive decision making and reasoning.
<u>1371496-1</u>	i had a stroke
<u>1374169-1</u>	became unresponsive, intubated in the field with CT images revealing a diffuse SAH, IVH, cerebral edema, brain compression, possible aspiration pneumonia o Admit to NICU s/o Doctor o Consult Doctor for CC o Neuro checks q1h o SBP < 110 o Mannitol 50g IV x1 stat than 3% HTS for NA goal 145-155 o EVD placement ASAP o Amicar 5g stat o COVID PCR negative o Labs/ medications as ordered o SAH protocol o Plan for cerebral angiogram and possible coiling in am with Doctor.
<u>1376895-1</u>	Had stomach pain about a week after the second shot went to the emergency room on may 5th and was admitted with a blood clot in the portal vein of my liver. Spent 6 days on heparin iv and I'm now on elequis for at least 6 months
<u>1382560-1</u>	Pt complained of heart palpitations and chest pain approximately 4 days after receiving dose.
<u>1383096-1</u>	6/6-fever (102 temporal) and headache, these resolved, followed later by chest pain, went to medical center and evaluated, negative troponins. 6/7-chest pain began again, returned to medical center, found to have elevated troponin of 3.19. 6/8 at 1am-Transferred to another medical center PICU where he had sensation of numbness in left arm, a squeezing sensation of left arm, and severe chest pain. EKG showing ST elevation and troponin of 3.75. Given dose of 30mg Toradol and pain resolved. Started on Motrin q6h, trending troponins. In the morning pain much improved, but still with pain on deep inspiration relieved with leaning forward. Repeat EKG shows diffuse ST elevation, consistent with presumptive diagnosis of myopericarditis. Repeat troponin at 9am of 9.3, BNP of 197. Echo done wnl. Scheduled for cardiac MRI with contrast per cardiology recommendation to r/o myocardial edema. Viral panel sent to r/o viral etiology despite no prior symptoms.
<u>1384683-1</u>	major seizure within minutes of receiving shot; This is a spontaneous report from a contactable consumer. A 78-year-old male patient received the second single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 05Mar2021 at 14:00 (at the age of 78 years), in left arm, for COVID-19 immunization. The first dose of BNT162B2 was given on 12Feb2021 at 12:00 PM in left arm (at the age of 78 years). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Medical history was not reported. The patient did not have COVID prior vaccination and was not tested for COVID post vaccination. Concomitant medications included unspecified statin drug and blood pressure medicine. On 05Mar2021 the patient experienced major seizure within minutes of receiving shot. The event required Emergency room/department or urgent care and ended up on ventilator in ICU. Treatment received included lorazepam (ATIVAN), intubation, ventilator, CT scan, MRI, EEG. The event was reported as serious as required hospitalization for 6 days and was life-threatening. Event outcome was unknown. Information on the lot/batch number has been requested.
<u>1385378-1</u>	ANAPHYLAXIS: Pt received his second Moderna COVID19 shot on 12Apr2021 at approximately 2:30pm. He waited the required 20 minutes to check for any adverse reaction and then left the facility to drive home. On his drive home, at approximately 3:30pm, he started feeling light headed and lost consciousness, striking a telephone pole. He was gasping and struggling to breathe, so the ambulance treated him with oxygen. When he arrived at the ER , the doctor assessed his condition and confirmed that he was experiencing an anaphylactic reaction related to the COVID vaccine and treated him with an epinephrine injection, steroids, benadryl, and nebulized albuterol.to open his airways. He remained at the ER for ~ 6 hours for observation until his blood oxygen levels increased and he was stable to be released. The car accident resulted in PT suffering a fractured sternum as confirmed via Chest CT Scan by his primary doctor. PT has no history of any allergic reaction to any medication or vaccine. Although he does have well-regulated asthma, this incident was not characteristic of any asthma-related reaction he has ever experienced.
<u>1385879-1</u>	Myasthenia gravis exacerbation causing respiratory failure and intubation. Today is day 12 of symptoms. She also has profound weakness from her myasthenia gravis. Treated with intubation, high dose steroids, and increased pyridostigmine.
<u>1388162-1</u>	myocarditis. elevated troponin, ECG changes, good function on echo. treated with NSAIDs

VAERS ID	Adverse Event Description
1390327-1	<p>The Moderna covid vaccine was the first vaccine I ever had. On the evening of the 18th, I was sitting alone after work, scrolling my phone when my heart started beating very fast, hard, and irregularly. I felt pressure in my chest and a wave of tingling wash over my head. My vision went funny and grey around the edges as if I was about to pass out. It felt like something was squeezing my heart. I sat on the floor, put my head between my knees and took deep breaths. The heart rate spikes seemed to come in waves with a feeling of pressure every few minutes. I called someone to take me to the ER and they arrived about 45 minutes after initial symptom onset. My heart rate had slowed slightly and the spikes were coming farther apart by then. It was cold in the car and it gave me chills, but I felt that it made me feel a little better. At the ER, they kept me from about 9:30 pm to after 3:00 am. My symptoms slowly abated, with heart rate spikes coming about every 15 to 30 minutes, but shorter, and not going as high. I sat there and watched the pulse monitor for about 5 hours, varying between the 60s and 108. I was discharged after several tests without a diagnosis and told to follow up with a cardiologist in 2 days. The attending physician verbally told me the tests were normal and I was fine, but when I viewed my test results online, it said I had an abnormal ECG, left atrial inflammation, and a possible heart attack. I was uninsured at the time, so they declined to run expensive tests. I also did not have a primary care provider. Around midnight on the evening of the 20th/morning of the 21st, a similar thing occurred while I had a late night snack and watched a TV show. I did not feel as if I was going to pass out, but had regular heart rate spikes, and a rapid, irregular heartbeat with pressure in my chest. This time I also had nausea and burning in my stomach. I did deep breathing all night. Managed to doze for about an hour. This episode lasted until 6 am. I felt better then and tried to find a cardiologist, but was referred to the ER. By the time a friend took me there (around 7-7:30 am, I think), my symptoms had largely abated, but I was very fatigued and short of breath just standing. I was again discharged after testing with no diagnosis, but told to follow-up with a cardiologist. Again, I was verbally told again that the tests were normal and I was fine, but the notes said possible biatrial inflammation. By this point, my chest ached constantly. A close friend came to help take care of me on the evening of the 22nd, and I got so excited to see her that my heart rate spiked again. I lay down and did deep breathing and couldn't talk to her or look at her until the next day without intense heart rate spikes, nausea, chest pain, and chest pressure. I saw Dr. on the 23rd. He diagnosed me with orthostatic hypotension and tachycardia. He took my pulse while sitting (about 80, which is high for me, because my average resting pulse is usually in the high 40s/low 50s), and when standing. When I stood up, my pulse went to 120 and I became short of breath. He told me to drink pedialyte, ingest a lot of salt (he declined to recommend a specific amount), wear compression stockings, exercise while lying down, and ease myself back into activity. I should also keep my feet up as much as possible. I immediately started drinking a lot of pedialyte (a gallon to a gallon and a half a day), eating salty foods, and keeping my feet elevated. I continued to be very fatigued with episodes of rapid heartbeat (though not as bad as I went to the ER for). I frequently got a squeezing feeling in my chest as if my heartbeat was irregular. I took my blood pressure regularly and it was usually low (90s/?). Anything that was remotely exciting spiked my heart rate. I could not watch TV, listen to music, game, talk on the phone, or even sit upright. All I could do was lie flat and play boring, unexciting games on my phone. This continued for weeks. I could only sleep on my back because sleeping on my side gave me a feeling that my heart was compressed and increased my heart rate. When I got out of bed, after a few seconds I would get black spots in my vision and a wave of tingling over my scalp and feel as if I were about to pass out. Bending over and leaning on the counter for about 5-10 seconds makes this abate. My friend had made me an appointment on April 28th, so I went to this appointment because I was not feeling better and wanted a second opinion. Dr. did not communicate as well, but seemed to agree with Dr. assessment. He prescribed fludrocortisone, metoprolol, and sertraline. He told me to take the fludrocortisone for two days before starting the metoprolol. The metoprolol seemed to help. It started keeping my heart beat irregularity/spike episodes from getting as high or lasting as long. Those have slowly diminished, though I still have a lesser version of them. The metoprolol also seemed to mostly end the squeezing feeling to my heart and irregular beat. On the evening of the May 6th, my heart started beating very hard and fast. My blood pressure was 140/?. I stopped taking the fludrocortisone and ingesting salt. I also had a squeezing feeling at the bottom of my sternum. On the 7th, I was unable to take a full breath. Whenever I tried to inflate my lungs, the squeezing feeling at the bottom of my sternum would worsen and keep my lungs from expanding. If I lay flat and only took shallow breaths, I didn't notice anything, but as soon as I sat up or tried to stand, I could barely breathe. Dr. office referred me to the ER. At the ER, my blood pressure was 160/?. I was admitted to the hospital on the evening of the 7th and discharged on the 10th. During my stay, I was able to get temporary Medicaid to cover my hospital bills. Insurance through get covered would start on the first of June. During my hospital stay, I lay flat constantly so I could breathe, and that symptom slowly lessened, though did not go away completely. I also started experiencing tension in my throat and jaw while lying flat on my back and could not find a comfortable sleeping position. I was seen by a cardiologist who ordered tests for me on the 8th and the tests were administered on the 10th. I was briefly seen by a cardiologist, that morning and he said it was possible I had a hiatal hernia that was physically irritating my heart. At that time, my admitting doctor, told me nothing matched my symptoms and maybe it was anxiety. The discharge paper listed anxiety, depression, increased risk of falls, decreased cardiac output, high risk of bleeding, and orthostatic hypotension. Verbally, I was told I was a clot risk, but it was not on my discharge papers. I was not referred to psych or prescribed medication, or referred for an endoscopy, but discharged with the exact same symptoms I had been admitted for and told to follow up with a cardiologist in a couple weeks. Over the course of the next couple weeks, without treatment, the tension in my chest slowly eased until I could breathe almost normally. Taking a deep breath still gives me a weird feeling of uncomfortableness and pressure in my chest, but only a deep one. I still get winded easily, but not from standing up or walking around my apartment. Bending over is hard. I started being able to carry things as long as they weren't heavy. On May 18th and June 8th, I saw a primary care provider, who ordered more tests and referred me to a pulmonologist, endocrinologist (next week and the week after), psychiatrist and psychologist (but I am having trouble finding ones who will work with my insurance). I also saw a gastroenterologist, on the 21st, was prescribed Prilosec, and scheduled an endoscopy in early July. I still have a lot of the same symptoms, some of them have lessened a little, and some are mostly gone. Fatigue is constant, shortness of breath, tightness in my throat, tightness at the bottom of my esophagus, and increased heartbeat are common. Nausea and stomach burning only occur occasionally, but I still have nearly constant discomfort at the bottom of my esophagus/top of my stomach. I constantly feel as if something is squeezing my throat. The very rapid heartbeat spikes seem to be almost entirely gone, thanks to the metoprolol, but there are still mild ones. Chest pressure occurs frequently, but usually goes away when I change position. Tightness at my jaw occurs concurrently with the chest pressure. I can sleep on my side again, though it is still feels as if it increases my heart rate sometimes. I consider it an accomplishment that I can now sit upright most of the time most days. I sometimes have a few good hours in a day where I feel almost normal. I can walk on a flat surface for a short period of time, but going up even a slight incline causes heartbeat spikes and a feeling of my heart being squeezed and I have to stop immediately. Harder work like carrying heavy groceries or an extended period walking around a store would be impossible for me. I still get black spots in my vision when I stand up, but only sometimes and have just kind of gotten used to it and expect to have to stop and bend over. Sitting upright without back support is uncomfortable and slumping at all increases the pressure at the bottom of my esophagus. I am a massage therapist, but have been unable to work since this started. I can't even take care of myself without the assistance of friends. I still don't have a diagnosis that explains my symptoms.</p>
1395209-1	<p>10 days after second vaccine I had trouble breathing when walking or climbing stairs. I never had this before even though I have a preexisting condition of hypertrophic cardiomyopathy. In fact, I wore a heart monitor for one week and had an EKG and saw my physician prior to receiving any vaccine and was in stable condition. I started to improve after the 10 day, but the shortness of breath came back in the beginning of May. I finally took a stress test on Friday, May 28th and was told by my physician that I had AV Block and needed a pacemaker and defibrillator on an emergency basis. I asked my physician if this could have been from the vaccine and he said he wasn't sure because he didn't have enough data. He said it was possible because it may have caused inflammation in the heart.</p>
1399481-1	<p>Anaphylaxis (difficulty swallowing, tingling tongue and throat, difficulty breathing, rash, increased heart rate) - transported to ER at Medical Center, treated with IV steroids/antihistamines, sent home with scripts for continued steroids/antihistamines</p>

VAERS ID	Adverse Event Description
<u>1400077-1</u>	fever, chest pain, elevated troponin, and EKG changes consistent with myocarditis.
<u>1407749-1</u>	Adverse Events: Severe Loss of Breath; Numbness in Extremities; Chest Pain; Heart Palpitations; Fainting; Dizziness Treated with Oxygen and High Dose of Benadryl at hospital. Returned home roughly 4 to 5 hours after treatment.
<u>1407874-1</u>	New Onset Cardiomyopathy with low ejection fraction, CHF, new onset AFIB
<u>1408662-1</u>	3 days after the first dose, pain in stomach that stopped after a few hours. 3 days after the second dose, appendicitis was diagnosed and surgery done.
<u>1409700-1</u>	broke out into hives; throat began to swell; breathing became difficult; anaphylaxis; patient age: 15; This is a spontaneous report from a contactable consumer (patient). A 15-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0217), dose 2 via an unspecified route of administration, administered in left arm on 03Jun2021 14:30 (at 15-year-old) as 2nd dose, single dose for COVID-19 immunization. Medical history included low growth hormone production, and known allergies: many foods. Concomitant medications included somatropin (NORDITROPIN); anastrozole (ANASTRAZOLE DENK); olopatadine; levocetirizine dihydrochloride (XYZAL); didlofenac sodium, heparin sodium (ALLE). 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 previously received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0173), via an unspecified route of administration, administered in left arm on 13May2021 17:30 (at 15-year-old) as 1st dose, single dose for COVID-19 immunization. On 03Jun2021 at 17:30, the patient experienced 3-4 hours after dose, broke out into hives. He took benadryl. Throat began to swell and breathing became difficult. He used epi-pen to stop anaphylaxis. The seriousness criteria of the events was reported as life threatening. The events resulted in doctor or other healthcare professional office/clinic visit. The outcome of the events hives, throat began to swell, breathing became difficult, anaphylaxis was recovering. Since the vaccination, the patient had not been tested for COVID-19.
<u>1411022-1</u>	I got headaches and a pretty normal response from the first shot. But my headaches were pretty bad and started a week after the first shot. I had my second shot on the 29th of April. A week after that in may I had a weekend of the worst headaches of my life. I thought I had a brain tumor. But because I got headaches after the first shot I shrugged it off as a rough vaccine reaction. In the following two weeks (early may) I got bad leg cramping at night and had trouble swallowing. On may 20th I went to the hospital because the entire right side of my body went numb after a particularly bad headache. I had an mri and it showed a lesion on my brain. It appears that I developed CIS or clinically isolated syndrome, the precursor to MS following my vaccine shot.
<u>1413138-1</u>	acute cardiac angina, angioplast
<u>1415382-1</u>	After first vaccine administered on April 30, 2021, patient developed severe headaches, photophobia, stiff neck, fever and chills that lasted 3 days. Second vaccine was administered 3 weeks later on May 21, 2021, fever, chills, rigors, photophobia, stiff neck, severe headache continued for 2 weeks. Patient went to an urgent care center and requested COVID rapid and PCR tests. During the visit, a flu test and Lyme Disease test were done. Tests were negative. Patient continued to be symptomatic and sought medical care at medical center on June 8, 2021. Patient received care in the ER and was admitted with a r/o diagnosis of meningitis. Empirical meningitis protocol was started. Spinal tap, blood cultures, urine cultures, tic borne infections were all negative. Patient improved with prednisone therapy. Patient discharged from hospital on June 11, 2021. Negative tic and bacterial tests and rheumatoid panel were discussed during the post discharge visit on June 21, 2021. It appears that the patient exhibited a severe adverse event reaction to the Pfizer Covid second vaccine dose.
<u>1417103-1</u>	Was April 23 and I felt strong chest pain, my primary doctor made an EKG showed PRE INFART, they sent me to emergency room There, I was in observation 24 hours and they made me a NUCLEAR TEST, it showed LEFT VENTRICULAR OBSTRUCTION HYPERTROPHY, POSSIBLE ISCHEMIA, and sent me home follow cardiology, I got Cardiology, he made me a Catheterization, and told me I just have 30% blocked arteries and gave me treatment of Lipitor checking every three months. FROM APRIL 23RD, I experiencing chest pain , presi=n around my breast, pain on my middle center back and discomfort on my upper stomach, I can?t do exercises for more than five minutes when before pre infart I was doing for 30 or 45 mnts without any complain on my heart. IF , BEFORE COVID VACCINE PHEIZER, I never had any complain about my heart, why AFTER EIGHT DAYS (I GOT THE SECOND DOSE PHEIZER 03-15-21) CAME ALL THESE SERIOUS PROBLEMS WIYH MY HEART!
<u>1422332-1</u>	Subarachnoid hemorrhage - bleed day 5/24 - rushed to ER and was seen immediately on first CAT scan. Admitted to Neuro ICU for 14 days. Then transferred to rehabilitation hospital and is now going to outpatient PT. Symptoms were extreme headache and then inability to walk. Rushed to ER via ambulance.
<u>1423878-1</u>	Patient had a left sided segmental and subsegmental pulmonary embolism, severe back pain, dyspnea, tachycardia and tachypnea, started on 6/24.
<u>1427232-1</u>	Guillian Barre-was totally paralyzed; Guillian Barre-was totally paralyzed; This is a spontaneous report from a contactable consumer (patient). An 80-year-old patient of unspecified gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EM9809) at the age of 79-years, via an unspecified route of administration, administered in left arm on 09Feb2021 at 12:00 at single dose for COVID-19 immunisation; second dose of other vaccine (unspecified, lot number: ENG205) at the age of 79-years, via an unspecified route of administration in left arm on 09Feb2021 for immunization. Medical history included esophagus cancer. No known allergies. 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. Other medications in two weeks were none. On 31May2021 at 12:00, the patient experienced Guillian Barre-was totally paralyzed. The events were reported as life threatening illness (immediate risk of death from the event). The patient received oxygen and medicines as treatment. On 03May2021, COVID-19 virus test (nasal swab) was negative. Outcome of the events was unknown. Follow-up actions are needed. Further information has been requested.

VAERS ID	Adverse Event Description
<u>1430036-1</u>	<p>Received the first Pfizer COVID vaccine (ew0161) injected at 4:30PM on 29 April 2021 at the Pharmacy. He became weaker, more tired and sleep afterwards, He developed decreased oral intake. He was unable to recall his name, so family brought him to the ER. In the ER he was noted with significant anemia Hgb 6.5 and thrombocytopenia with platelet of 6. There is question of hemolysis with reticulocyte 8, LDH 1757, total bill 3.8. There is elevated D-dimer and renal function. Hematology consultation was placed for possible TTP versus COVID vaccine induced thrombocytopenia. PT was placed on plasmapheresis and found to have ADAMST13 def. PT received S/p plasmapheresis 11 times PT was placed on plasmapheresis and found to have ADAMST13 def. PT received S/p plasmapheresis 11 times on 4, 5, 6, 8, 9, 10, 11, 12, 13, 17, 19 May 2021. Received Rituximab 375 mg/m² = 731 mg IV weekly X 4 on 5, 13, 19, 26 May 2021. Completed high dose steroids 1000 mg x 3 days AMS and seizures 2/2 TTP related metabolic encephalopathy (improved), Small R parietal subdural hematoma likely related to TTP. No focal deficits. Treated for TTP with plasmapheresis. Initially alert but not oriented. Had an episode of seizure, intubated for airway protection Patient was hospitalized for 15 days 4-19 May 2021. He was in ICU for 1 week and 8 days in general ward. He was unconscious for the first week experienced 2 episodes of seizure. He has been comatose since he developed the first episode of seizure on 5/5/21. He developed another episode of seizure after the brain MRI on 5/5/21. PT discharged on 19/5/21 and continued blood works and Rituximab therapy as out patient. Assessment: TTP, based on his clinical features including altered mental status, fe1er, hemolytic anemia and thrombocytopenia, renal insufficiency, and peripheral smear with 7-8 schistocytes per HPF (5/4/2021). Adam Ts 13 activity <3 Hemolytic anemia, severe thrombocytopenia 212 TTP with AdamTs13 deficiency In setting of hemolytic anemia, thrombocytopenia, AKI and AMS Hgb 6.5, Billi 3.8, LOH 1757, ARC 3.6 significant for hemolytic anemia on adm Peripheral smear showed anisocytosis, microspherocytosis and possible 1 schistocytes Platelet 6, multiple petechiae, no active bleeding, gualac negative. Received 1U PRBC. Direct Coombs test -ve, Tbili elevated Plasmic score 6 Acute kidney injury 212 TTP vis Prerenal (Resolved), Hyponatremia (resolved) FENA 0.5 Hematology followup: TTP (THROMBOTIC THROMBOCYTOPENIC PURPURA) 5/14/21 He developed a new ulcer in the mid of tongue. He coughs and sputum is clear. He feels better. Sip plasmapheresis and rituximab infusion yesterday. 5/13/21 He continues improving. Good appetite. He still coughs with blood streak, slightly pinkish sputum. 5/12/21 His mental status is back to baseline. He is able to eat regular food and walk inside his room. Clo cough with blood streak, slightly pinkish sputum. 5/10/21 Fully alert and awake, but reported confusion and forgetful episodes. Eating better. Clo tightness in arms 5/9/21 More alert and awake. Started eating. Feeling tired. Clo mild pain at shoulders. Sip 1 unit PRBCs 5/8/2021 Mild improvement. Wife is at bedside. No acute overnight events. Still has intermittent confusion. Surgery re-placed left IJ Shiley for PEX 5/7/2021 He has intermittent confusion and irritation, mixed with short-term of AAO x 3. He pulled out his PEX line and has urinary incontinence. He is NPO and remains sleeping most of time. 5/6/2021 Sip extubated. He appears tired, but arousable, follows commands and carries normal communication with b/I symmetric strength with no motor deficits. Afebrile since last night. 5/5/2021 He developed 1 episode of seizure. Sip Ativan and 1 dose of propofol for intubation. He has been in comatose since then. Brain MRI was performed this afternoon. He developed another episode of seizure after the brain MRI. Sip 1 unit packed RBC 5/4/2021 and 1 unit packed RBC 5/5/2021. He developed mild bleeding from the bronchial suction and Foley catheter. He developed fe1er temperature 101 during the first plasmapheresis. Temperature was 104 about 2 hours after the first plasmapheresis. He has had persistent high fe1er since then. 5/4/2021 Lab showed WBC 7.1, Hb 6.5, pit 6, MCB 92.1, neut 68%, re18%, PT 14, PTT 30. 5, D-dimer 2.19, fibrinogen 490, CMP normal except Ca 8.1, Glu 189, BUN 47, Cr 1.57, T bili 3.9, direc10.9, and AST 56. LOH 1757, TSH 4.828, serum HIV and hepatitis panel negative. COVID-19 Ag, SARS-CoV2 Rapid and Flu Ag negative. 5/5/2021 WBC 21,500, hemoglobin 6.2, platelets 17,000, neutrophils 69%, PT 14.9, PTT 28.3, D-dimer 5.5, glucose of 296, BUN 63, creatinine 2.18, total bilirubin 2.5, albumin 3.6, LOH 891, AST 57, ALT 32, alkaline phosphatase 51. Laboratory results: WBC H 13.2 (MAY 14) H 11.6 (MAY 13) H 13.4 (MAY 12) H 16.8 (MAY 11) ? Hgb L 9.9 (MAY 14) L 11.3 (MAY 13) L 10.8 (MAY 12) L 10.4 (MAY 11) Hct L 30.2 (MAY 14) L 33.3 (MAY 13) L 31.5 (MAY 12) L 31.2 (MAY 11) Pit L 92 (MAY 14) L 58 (MAY 13) L 63 (MAY 12) L 74 (MAY 11) Risk Assessment: Denies Alcohol Use Substance Abuse Risk As sessment: Denies Substance Abuse Tobacco Risk Assessment: Denies Tobacco Use</p>
<u>1430631-1</u>	<p>Severe blood clotting in the bladder 2 days following 2nd injection. Led to my dad fainting and being sent to hospital by ambulance. He was in the hospital from 2/23/21 - 3/2/21. While there they flushed his bladder and removed the blood clots. Was diagnosed with bladder cancer, but the cancer in the bladder was now found to be prostate cancer. My dad was treated with low dose chemo therapy and targeted radiation therapy following these events.</p>
<u>1435912-1</u>	<p>Stroke; This spontaneous case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (Stroke) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006B21A) for COVID-19 vaccination. Concurrent medical conditions included Blood pressure high (had been put on hypertension medication). Concomitant products included LOSARTAN for Hypertension. On 19-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 10-Jun-2021, the patient experienced CEREBROVASCULAR ACCIDENT (Stroke) (seriousness criteria hospitalization, medically significant and life threatening). The patient was hospitalized for 2 days due to CEREBROVASCULAR ACCIDENT. At the time of the report, CEREBROVASCULAR ACCIDENT (Stroke) outcome was unknown. Concomitant medications were not reported. Treatment medications were not provided. This case concerns a 71-year-old female hospitalized with a serious unexpected event of cerebrovascular accident. Event latency 55 days after second 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. This case was linked to MOD-2021-066369 (Patient Link).; Sender's Comments: This case concerns a 71-year-old female hospitalized with a serious unexpected event of cerebrovascular accident. Event latency 55 days after second 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.</p>
<u>1437280-1</u>	<p>Developed blood clots in left calf leg</p>
<u>1437553-1</u>	<p>Patient developed atrial tachycardia requiring emergency room treatment. He does have a bicuspid aortic valve but had not previously had cardiac issues. Required adenosine then cardioversion that failed. Now on tikosyn.</p>
<u>1437862-1</u>	<p>Acute pericarditis</p>
<u>1442334-1</u>	<p>PATIENT ON VENTILATOR; SUSPECTED CLINICAL VACCINE FAILURE; DELTA VARIANT COVID INFECTION; This spontaneous report received from a consumer via social media (news report) concerned a patient of unspecified age and sex. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) frequency one total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient got infected with the delta variant of covid while the patient was in the hospital (suspected clinical vaccine failure) and was using ventilator. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the delta variant covid infection, suspected clinical vaccine failure and patient on ventilator was not reported. This report was serious (Hospitalization Caused / Prolonged, and Life Threatening). The suspected product quality complaint has been confirmed to be not voided based on the PQC evaluation/investigation performed. This case is associated with product quality complaint (PQC) number 90000184361.; Sender's Comments: V0: 20210664408-COVID-19 VACCINE AD26.COVID-19-Patient on Ventilator, Delta Variant COVID Infection. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). 20210664408-COVID-19 VACCINE AD26.COVID-19-Suspected Clinical Vaccine Failure. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: SPECIAL SITUATIONS.</p>

VAERS ID	Adverse Event Description
<u>1445735-1</u>	Possible Kidney Infection; Possible Pneumonia; Passed away; Low Iron Levels; Lack of appetite continued after first shot; Nauseous; Felt Cold (Chills); This spontaneous case was reported by an other caregiver and describes the occurrence of KIDNEY INFECTION (Possible Kidney Infection), PNEUMONIA (Possible Pneumonia) and DEATH (Passed away) in a 90-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 022N20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Aspiration pneumonia (Had Aspiration Pneumonia prior to vaccination and was hospitalized.), Stent placement (Received a heart stent 7 years ago.), Heart valve replacement on 12-Jan-2021 and Intubation. Concomitant products included AMIODARONE and HYDROCHLOROTHIAZIDE (DIURETIC [HYDROCHLOROTHIAZIDE]) for an unknown indication. 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 CHILLS (Felt Cold (Chills)). On 14-Mar-2021, the patient experienced KIDNEY INFECTION (Possible Kidney Infection) (seriousness criteria death, hospitalization, medically significant and life threatening), PNEUMONIA (Possible Pneumonia) (seriousness criteria death, hospitalization, medically significant and life threatening), DECREASED APPETITE (Lack of appetite continued after first shot), NAUSEA (Nauseous) and BLOOD IRON DECREASED (Low Iron Levels). On 23-Mar-2021, DECREASED APPETITE (Lack of appetite continued after first shot) and BLOOD IRON DECREASED (Low Iron Levels) outcome was unknown and CHILLS (Felt Cold (Chills)) and NAUSEA (Nauseous) had resolved. The patient died on 23-Mar-2021. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Mar-2021, Blood iron: (Low) Had very low Iron levels.. On an unknown date, Polymerase chain reaction: (Negative) Had several Negative PCR tests every time he was hospitalized. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Reporter states that her Husband passed away on 23MAR2021 but his death was not vaccine related. Had damaged his esophagus while intubating him. He was not doing great but he was functional prior to vaccination. On 14MAR2021 he was hospitalized. Doctors did not know what was wrong with him. His doctor stated that he had Kidney infection or pneumonia but all tests were normal. Reporter stated that the Doctors do not know what was happening to him but it was not vaccine related. Concomitant medications included Defibrillator along with above mentioned medications.; Sender's Comments: This fatal case concerns a 90-year-old male hospitalized with serious unexpected events of kidney infection, pneumonia, death and nonserious decreased appetite, blood iron decreased, chills and nausea. Event latency 11 days 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.; Reported Cause(s) of Death: Possible Kidney Infection; Possible Pneumonia; Passed away
<u>1446649-1</u>	high fever 102, strange body aches on around ribs and back Chest ache. shortness of breath climbing stairs very tired Began on 3/23/21. went to urgent care on 3/26 did ekg all ok. went to regular doctor on 3/30 did EKG ok 4/5/21. another doctor visit EKG. showed AFIB. sent to ER. Afib - water in lungs and around heart many test given. released from hospital on 4/09/2021. now on eliquis, cartizam proton
<u>1446789-1</u>	"7/4/2021: 15 year old male with autism and ADHD that presents to PICU from another hospital status post cardiac arrest times two. Mom states that patient has been having coughing for the past 2 weeks. Went to PMD on 6/25 who noticed wheezing on his exam. Ordered a CXR for 6/29. The next day, told mother of the results which showed pneumonia, "fluid in lungs." Started on albuterol q4, cefdinir, and OTC cough medicine with no improvement of symptoms. Began having decreased appetite, urine output. Had a couple episodes of post tussive emesis with blood tinged secretions. Abdominal pain started the day before admission. Patient continued having increased coughing and shortness of breath. On day of admission, patient was walking up the stairs to take a shower. He then fell and hit his head on the wall. Denies LOC at that time. Stated that he could not breath. Patient brought to ER. Patient went into cardiac arrest at 1840 until 1910. CPR was done, given epinephrine, and intubated. Then went into cardiac rest again. Placed on Vent, TV 450, PEEP 6, Rate 15, Peak pressure high 30s. Given ceftriaxone, vancomycin, toradol, 40mg lasix, 4mg zofran and 2L NS bolus. CBC, CMP, blood gas, troponin, pro BNP, RVP/COVID ordered. Started on versed (6.5), epinephrine (20) and norepinephrine (10) drips. Was then flown by helicopter to our PICU. Of note, patient had second dose of Pfizer vaccine on 6/19. Mom believes symptoms started just before his vaccine dose."
<u>1446986-1</u>	Started feeling sick, feverish, night sweats, cough, heavy phlegm. Got worse & worse. Went to urgent care on 6/17. Immediately taken to ER and was admitted to hospital for 8 days. Discharged 6/25. Diagnosis was pneumonia. Almost died because my lungs were so full of infection. I was perfectly prior to vaccine. No illnesses, lung problems, etc. hadn't even been to a dr for being sick? for a few years.
<u>1454123-1</u>	Blood work done on 06/21/2021 came back with Platelet level @9. Blood repeated 2-3 times on 06/22/2021 and platelet level came back being at 6 -8. Dr. advised to give IVIG INFUSION with Steroid to avoid immediate risk of Internal bleeding. Patient was showing signs of Petechiae on her lower legs when at the hospital. Subsequent blood work on 06/25/2021 after IVIG showed a boost in platelet to 138. Weekly blood work has been ordered to check platelet levels and impact activities have been restricted.
<u>1454478-1</u>	I felt like my throat was closing up and I had a lot of pressure in my throat and chest and felt like I couldn't breathe. I used my mother's albuterol asthma inhaler and took allergy medication, which didn't help much. Then I feel asleep (passed out?) and didn't wake up until the next day. My throat still felt tight but I was able to breathe the next day.
<u>1457266-1</u>	On July 6, 2021 I went to Family Practice for first shot of Moderna Covid-19 vaccine at 1pm. Within approximately 12 minutes of receiving the vaccine, I started to feel my tongue swell and had difficulty swallowing my own saliva. I alerted the nurse and was given an oximeter. Oxygen levels ranged between 97-99 but heart rate went up to 143. As tongue became enlarged I was unable to close my mouth and it became dry so they gave me water to try to sip on as well as liquid Benadryl. EMTs were called and upon their arrival, it was determined that I needed to get epinephrine shot. I was given epinephrine .03mg and IV was started and another round of Benadryl (50mg) was administered. By 1:40pm pulse rate had gone down to approximately 115. Wheezing was noted by the EMTs. On the way to hospital, I was given 125mg of Solumedrol. Upon arrival at the hospital I was also given famotidine. I was monitored for approximately 3 hours and discharged feeling stable with swelling of tongue and throat resolved. No prescriptions given. On July 7th at approximately 1am, I started to feel the swelling of the tongue and narrowing of the throat re-appear as well as chest pressure and pain and went to Medical Center. Treatment there included a second round of IV Benadryl and another epinephrine shot. Symptoms improved and I was in observation for approximately 4 hours and discharged with symptoms having been resolved. Prescription for prednisone, famotidine, and epinephrine pen given. Instructions to also continue Benadryl every 3-4 hours given as well as follow-up with allergist and primary care doctor.
<u>1459890-1</u>	Elevated blood pressure, swelling and redness in upper arm, warm to touch, rash on entire left arm, extreme pain radiating down arm including some tightness, pain radiating up to shoulder and neck, stiffness in neck and shoulder, numb/tingly feeling in just above the elbow down to my fingertips, redness to face. Went to hospital May 29th diagnosed with allergic reaction and infection. Placed on Benadryl, steroid and doxycycline for 7 days. Returned to urgent care per doctors office on June 25th and was told infection still existed. Placed on Benadryl, steroid and doxycycline again. Admitted to hospital June 28th for IV treatment for the infection. referred to dr/neurologist for the numb/tingly feeling in arm/hand. Dr believes the needle struck/knicked my nerve. Believe there is additional inflammation to the nerve and needs to be further evaluated.

VAERS ID	Adverse Event Description
<u>1461744-1</u>	MODERNA COVID-19 VACCINE EUA May 27, 2021 @ 1:00PM: Right flank pain, profuse sweating, near syncope. ER visit #1 at Medical Center. Diagnosed with a probable kidney stone. Treated with abx empirically. CT Scan Abd and Pelvis without contrast did not demonstrate kidney stone. However, bilateral lower lobe ground-glass opacities were seen on CT Scan and CXR. Biofire swab negative. WBC and blood in the urine. Discharged home on antibiotics. May 28, 2021, @ 2:00 AM: Persistence of the right flank pain, unchanged after starting antibiotics. Onset of nausea/vomiting, loss of appetite, constipation. Tolerating only clear liquids. ER Visit #2: Pain control with Toradol, given IV fluids, Reglan, and Zofran. Labs repeated. ER doctor did not repeat the CT Scan due to concern about radiation. May 29, 2021, @ 4:00 AM Persistence of the right flank pain, vomiting, as above. ER Visit #3: Pain control, IV fluids, Reglan was given. CT Scan Abdomen and Pelvis repeated with PO and IV Contrast revealed probable right renal infarct affecting approximately 60% of the right kidney. CT Chest done: unsure of findings. CXR done before admission. Ground-glass opacities at the bilateral lower lobes were seen again. Biofire still negative. ADMITTED to Medical Center on May 29, 2021, until June 2, 2021. During the hospital course, IV antibiotics were given for several days. Started on anticoagulation with Lovenox during hospitalization. Also started on Toprol for HTN. Hematology workup was done, including hypercoagulable workup. Multiple consults called: nephrology, infectious disease, pulmonology, surgical team, cardiology. CTA of the kidneys was done: unsure of findings. BLE Doppler done: negative. Observed in telemetry x1 day - severe aortic regurgitation. Discharged home on antibiotics, Eliquis, Toprol, Amlodipine on June 2, 2021 with diagnosis of right renal infarct.
<u>1465997-1</u>	Tachycardia, sweating, confusion, itching, nausea and hypotension beginning approximately 3 minutes after vaccination. Epi-pen used as well as Allegra given. Transported to hospital and given steroids and IV Benadryl. Released after 4 hours but approximately 30 minutes later began experiencing tachycardia and sweating along with nausea again. Returned to ER and admitted. Released after 2 days.
<u>1470534-1</u>	suffered a stroke
<u>1471070-1</u>	Two days after vaccine I was having trouble breathing, irregular heart beat, congestion, bloating, swelling. Went to hospital and nothing was found in tests. A month and a half later I was having similar symptoms and went to the hospital where they found I was having heart failure. My heart was performing 10-15%.
<u>1475423-1</u>	Two days after COVID vaccine, patient suddenly lost a tooth, despite having no prior dental issues. Then her face ended up developing a long last swelling and rash episode that lasted for 1.5-2 months. Patient thinks it was a reaction to the amoxicillin she was given, but it persisted despite not being on the medicine, being given steroids, and antihistamines. Patient was in the ED twice for the facial swelling. Also saw Dermatology. Pt later saw an allergist and she is not allergic to amoxicillin, only other new thing had been the vaccine when it all started. Then the patient suddenly develops severe bradycardia to the point of syncope and episodes of sinus arrest. Patient then ended up requiring a pacemaker to be placed.
<u>1478029-1</u>	Patient was hospitalized for Guillain Barre Syndrome
<u>1481440-1</u>	Nausea, vomiting, difficulty walking, unable to eat or drink; unable to clear secretions, difficulty breathing
<u>1481759-1</u>	"Anaphylactic Reaction; Rapid Heart rate; Narrowing of throat; swelling of tongue; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of ANAPHYLACTIC REACTION (Anaphylactic Reaction), HEART RATE INCREASED (Rapid Heart rate), THROAT TIGHTNESS (Narrowing of throat) and SWOLLEN TONGUE (swelling of tongue) in a 49-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 008B21A) for COVID-19 vaccination. No medical history was provided by the reporter. Concomitant products included LEVOTHYROXINE for an unknown indication. On 06-Jul-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Jul-2021, the patient experienced ANAPHYLACTIC REACTION (Anaphylactic Reaction) (seriousness criteria medically significant and life threatening). 06-Jul-2021, the patient experienced HEART RATE INCREASED (Rapid Heart rate) (seriousness criterion medically significant), THROAT TIGHTNESS (Narrowing of throat) (seriousness criterion medically significant) and SWOLLEN TONGUE (swelling of tongue) (seriousness criterion medically significant). The patient was treated with DIPHENHYDRAMINE HYDROCHLORIDE (BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]) (oral) for Adverse event, at a dose of 50 mg; EPINEPHRINE for Adverse event, at a dose of 0.3 mg; METHYLPREDNISOLONE SODIUM SUCCINATE (SOLUMEDROL) for Adverse event, at a dose of 125 mg; FAMOTIDINE (PEPCID [FAMOTIDINE]) for Adverse event, at an unspecified dose and frequency and PREDNISONE for Adverse event, at an unspecified dose and frequency. On 08-Jul-2021, ANAPHYLACTIC REACTION (Anaphylactic Reaction), HEART RATE INCREASED (Rapid Heart rate), THROAT TIGHTNESS (Narrowing of throat) and SWOLLEN TONGUE (swelling of tongue) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Additional concomitant medication included ""MP thyroid."" Within 12 minutes of receiving the vaccine, the patient developed an anaphylactic reaction, with swelling of tongue, narrowing of the throat and a rapid heart rate. Oral diphenhydramine 50 mg and epinephrine injection 0.3mg was given to the patient by emergency medical technicians. The patient was taken in an ambulance where she received methylprednisolone sodium succinate 125 mg. She was taken to a local emergency room for treatment. In the emergency room, she was given famotidine and then discharged after observation. Approximately 12 hours later, the patient began to experience the same anaphylactic reaction again and was taken to another emergency room. The patient was treated with intravenous diphenhydramine and an epinephrine injection. She was observed in the emergency room then discharged with prescription medicine. 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."
<u>1485044-1</u>	Stroke with three blood clots to the brain.
<u>1485102-1</u>	After getting the shot, I was monitored at the hospital clinic for 15 minutes at the facility. I did not have the reaction right away not until I got home. I got the vaccine around 9 am for my pre employment requirement and and I got home at 11 am on July 12,2021. Around 11:30am my left arm where I had the injection is sore, which was expected but the worst was experiencing hives/pruritus for the first time and it was bad. Thankfully we had some benadryl home medication and calamine lotion and I took bed rest and hydrated myself and helped by family members who are nurses. I also experienced body malaise, the symptoms eventually improved after day 3. Currently I feel some heaviness when I take deep breaths and still monitoring.
<u>1485638-1</u>	Adverse effects started approximately 12:00am the night of the second vaccine. The AE's included cough, temperature of 101.2F, total body aches and required best rest for approximately 36 hours. This was followed by the development of a chronic, persistent and deep cough. Previous to receiving the vaccine I was being treated for diverticulitis in January of 2021 and it was noticed that I had slightly elevated eosinophils (~1000). After the second vaccine dose the cough continued to worsen and get deeper and more persistent. At the end of March I was referred to a pulmonologist and it was found my absolute eosinophil count was 130000 and I was sent to ER for treatment. After admission, I was referred to the Cancer center for further outpatient treatment. During my outpatient treatment (March 24- April 30) I slowly developed paraplegia to the state where I could no longer walk After numerous tests including bone marrow biopsy, thoracic and abdominal CT scans, 3 brain MRI's several parasite tests no specific cause of the high eosinophils was determined. Additionally, multiple organs were effected including infarctions in the brain, high troponin levels (pericarditis/myocarditis?) requiring echo cardiogram , TEE, and angiogram, as well as bowel resection resulting in an ostomy (May 1, 2021). All together, I required major surgery for a life threatening condition, spent 7 days in ICU, 7 days in the hospital surgical unit, 20 days in a rehab facility, and an additional 3 weeks in a nursing and rehab unit. I am still recovering and receiving home care and rehab. As there was no discoverable cause of the hyper-eosiniphilia, it is my strong belief that the Moderna Covid vaccine (2nd dose) was a significant contributing factor, an accelerant and/or the root cause of the hyper-eosiniphilia and the subsequent events unfolding. It seems highly probable that the vaccine is the cause and further investigation should be conducted.

VAERS ID	Adverse Event Description
<u>1498647-1</u>	Patient presented on 6/19/2021 with cardiogenic shock that quickly progressed and ultimately required heart transplant. Pathology from explanted heart showed lymphocytic myocarditis
<u>1498900-1</u>	I, patient was vaccinated on March 30, 2021 at the time mentioned above in the form with the Janssen COVID-19 vaccine at a Medical Center hospital, for 24 hours after the vaccination, I am unwell general: (headache, body ache, diarrhea, stomach ache, chills, fever and discouragement), at the hospital they recommended taking tylenol, after 24 hours all symptoms started to improve, then I was able to go back to my work. As the days passed, I began to present discomfort in my legs: (extreme fatigue, pain, swelling, redness and a lot of itching) being the symptoms more severe in the right leg, I also had a headache, chest pain and back. By April 15, 2021, I could no longer bear the By April 15, 2021, I could no longer bear the discomfort and pain so strong and decided to go for emergencies to the Bergen New Bridge Medical Center hospital, where I was hospitalized for two days, on April 15 and 16, 2021, there too. I was diagnosed with venous thrombosis in my right leg due to the Janssen COVID-19 vaccine. After leaving the hospital, I was prescribed a medicine of (Xarelto) 20 milligrams, for 3 months and 10 days of disability, being able to return to work on April 28, 2021. After 3 months and I finished my medication on July 9, 2021, after 7 days I returned to present the same symptoms that I had presented on April 15, 2021, seeing myself in the obligation to return to the emergency center of the Medical Center hospital, there they gave me medications until July 21, 2021 where I had my follow-up appointment with my general practitioner MD, that day my doctor told me that I had not had any improvement and would have to send me medications again for another month until next month where I will have a follow-up appointment for my illness. Personally I feel that I am not evolving for the better, I feel more and more tired in my legs and the pains and swelling are getting stronger. In advance, I thank you very much for your attention.
<u>1508960-1</u>	anaphylaxis/allergic reaction; Mast Cell Activation Syndrome; Drug Hypersensitivity Syndrome; Intolerances to medications which has now expanded to food, exertion, scents, and temperature changes; Intolerances to medications which has now expanded to food, exertion, scents, and temperature changes; Intolerances to medications which has now expanded to food, exertion, scents, and temperature changes; This is a spontaneous report from a contactable consumer (patient). A 47-years-old female patient (not pregnant) received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in arm left at age of 47 years, not pregnant on 19Mar2021 14:00 (Lot Number: Pfizer7534) as single dose for covid-19 immunisation. Medical history included allergies to penicillin prior to vaccine and traumatic brain injury from near fatal accident. Concomitant medications included ethinylestradiol, ferrous fumarate, norethisterone acetate (LO LOESTRIN FE) taken for birth control; fluticasone propionate (XHAANCE). The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient had an anaphylaxis/allergic reaction to the first Covid Pfizer vaccine shot, (her only shot) on 19Mar2021 and since then things had spiraled out of control with her body; many medications to treat had caused more anaphylaxis allergic reactions like Benadryl, Cromolyn and Famotidine/Pepcid (7meds in total as she had been on no new meds since). She presented with Mast Cell Activation Syndrome and Drug Hypersensitivity Syndrome. 5 ER visits, 2 hospital stays and no improvements. The only medications that seem to provide any relief. Hydroxyzine, Singular and Prednisone and even with these medications she continue to have allergic reactions or intolerances to medications which has now expanded to food, exertion, scents, and temperature changes. Not sure why this was happening, as prior to 19Mar2021 no food allergies and never had anaphylaxis until then. Patient in need of treatment by a vaccine expert. Her body saw everything as a toxin. Adverse event started at 19Mar2021, 14:00, and resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). Hospitalization for 7 days. This case was serious with seriousness criteria reported as life threatening and caused hospitalization. Prior to vaccination, the patient was not diagnosed with COVID-19. Covid test via nasal swab on 12May2021 was negative. The outcome of the events was not recovered.
<u>1510147-1</u>	Pericarditis, perimyocarditis, pulmonary embolism
<u>1519135-1</u>	Shortly after the second shot I had terrible body pain and chills. Later that night stabbing pain vomiting and diarrhea. I waited one more day the pain as unbearable and when to the hospital and appendix had to be removed.
<u>1519993-1</u>	Patient reported experiencing slurred speech on July 17, 2021 (5 days after initial dose). Patient felt extremely dizzy and called 911. While on call, patient had slurred speech and emergency was dispatched. Patient was admitted same day to Hospital in city.
<u>1522915-1</u>	I was a healthy and active 48- year old with no medical conditions and no medications. Fulfilling my civic duty, I received the recommended Covid 19 vaccine, on May 11, 2021 and second dose on June 2, 2021. On June 10, 2021, I had a stroke. I now have to maintain 3-4 different medications to prevent another clotting event, and I am unable to fully use my left arm and left hand/fingers. This damage has impacted my ability to work and my left arm/hand function could be limited for the rest of my life.
<u>1523170-1</u>	1)2 hrs after vaccine, lightheaded, vomited light brown vomitus 2)4 hrs after vaccine large black tarry stools 3)overnight large black tarry stools total to may be 4 4)3/04/21-0400 took BP-> SBP 88 lightheaded, feeling dizzy 5)around 0500 decided to call ambulance, not allowing spouse to drive me as I started to be symptomatic 6)at Medical Center (where PCP is), Hgb on this admission was 8 (prior was 11)->given 2 unks PRBC right away 7)since had nothing to eat midnight of 3/04->upper endoscopy was done-> (-) result 8)colonoscopy done (still with black tarry stools, occasionally bloody->(-) result 9)H&H trended, Hgb went down to as low as 6.5-> total units PRBC received=6 10)Bleeding scan-> (-) result 11) was on Protonix IVP and IVF; ice chips on this admission 12)PRAYERS in JESUS' NAME & claimed Mark 5:29 by faith (plus family/friends' intercession), 3/07 bleeding stopped 13)3/08 discharged home 14)3/15 capsule endoscopy as out patient -> (-) result 7
<u>1529305-1</u>	26 y.o. male with no PMHx presented 7/29/21 w/ 4 days of intractable nausea and vomiting and decreased PO intake, found to have a systemic inflammatory response and liver dysfunction. Labs that were of particular concern on admission were WBC 14, ALT > AST and Direct hyperbilirubinemia, D-dimer (severely elevated), but notably NOT anemia and thrombocytopenia. CT Abdomen/Pelvis found distended gallbladder with wall thickening and diffuse decrease in hepatic attenuation. CTA Chest found number small PE and pulmonary infarcts. MRI abdomen showed Fatty liver with distended GB and mild thickening but no gallstone or CBD dilatation. Differential includes Sepsis (source still unknown), antiphospholipid syndrome vs some other inflammatory condition like an autoimmune condition or vasculitis. I think we also need to consider a vaccine adverse effect like multisystem inflammatory syndrome. Patient received Pfizer Vaccine, Lot #EW0151 on 4/12/21 and then Lot #EW0172 on 5/3/21. He first at symptoms of shortness of breath and exercise intolerance starting 5/25/21. By 7/5/21 he was unable to walk up stairs without dyspnea and increased effort, and was hospitalized on 7/29/21. Transjugular liver biopsy was heavily considered but not performed after he clinically improved on anticoagulation. By 8/2/21 he was starting to have some gross hematuria, vs concentrated urine. Nephrology was consulted in his care. His urine eventually cleared.
<u>1535431-1</u>	Pt admitted on 07/23 w/ hx of headache for 5 days and GTC on day of admission, found to have L vein of Labbe thrombosis complicated by L temporal lobe infarct extending into the left inferior parietal lobe w/ minor hemorrhage in infarct. Pt started on heparin gtt but still developed midline shift and bradycardia, so was sent for decompressive L. hemisrani w/ subglaleal hemovac placement on 07/24. After sx, patient had persistent R hemiparesis w/ R tongue deviation and profound expressive aphasia w/ some evidence of apraxia. Pt then managed w/ lovenox for AC, keppra for seizure ppx as well as PT/OT/ST for improving strength and language. Pt expected discharge to acute rehab on 08/11.
<u>1541817-1</u>	Rapid fluttering heartbeat over course of 3 months. Attacks increased in frequency and intensity as time went on.
<u>1544926-1</u>	I don't believe this is repeated by staff called and said i shld report it. I took Bactrim antibiotic for an ear piercing infection and had allergic reaction with full body hives. I have never had any problems with medications prior to this. I was given a steroid and benedryl injection and prescribed 6 days of steroids as treatment, with continued oral antihistamines.

VAERS ID	Adverse Event Description
1546328-1	evening of 3 Apr 21 woke up from sleep with sense that I could not breath; something wrong. i drove to local ER where I was admitted to ICU fo2 days, with numerous blood clots in both lungs and one on my right upper leg. I was not in any vehicle accident nor suffered any fall or injury prior to this diagnosis. I was in complete shock. No family history of blood clots.
1550644-1	I suffered a Cardio Myopathy on 2/24/2021, four days after received my second dose of the vaccine..
1554070-1	brain aneurysm/thunderclap headache on 3/1/21. Intense pain in head for 3-4 minutes, body immobilized, followed by continued more general pain in head, dizziness, ringing in ears for several weeks afterwards.
1602811-1	1st dose very sleepy 2 day then felt fine. Second shot had a fever for 2 days.
1627938-1	DAY AFTER SECOND COVID VACCINE HAD A ISCHEMIC CVA, WITH TOTAL LEFT SIDED PARALYSIS NOT RESPONSIVE TO MEDICAL INTERVENTION, HAS BEEN IN HOSPITAL SINCE 4-17-2021, IS NOT EXSPECTED TO EVER LEAVE HOSPITAL
1628054-1	3-4 days after receiving the vaccine, patient developed shortness of breath, loss of appetite, and fatigue. Patient believed that symptoms were a result of seasonal allergies and contacted PCP for treatment. PCP prescribed prednisone and albuterol. Patient took medication for 4 days without change in symptoms. Follow-up appointment with PCP found patient with low blood oxygen levels and low blood pressure, possible mild fever. patient was sent to ER on 5/21. Patient was admitted with pneumonia of unknown origin. Patient spent 1 week on general care floor with worsening conditions, possible ARDS. Patient was admitted to ICU and put on a ventilator on 5/28. Patient continued to worsen until MRI lead to a diagnosis of Myositis with ILD. Patient was transferred on 6/4 and put on ECMO. Patient health continued to decline (kidney failure) and was pronounced brain dead on morning of 6/7 and family decided to remove patient from life support.
1628151-1	Immediate and unexplained bruising, extreme exhaustion
1628350-1	Fainting and seizure at about 3:30 on August 18. Fainted from sitting on stool, fell to ground and hit head face-on. Seizure movements and unresponsive to coworkers for 4-5 minutes. Paramedics arrived afteri awoke slightly and took me to emergency room where I stayed from Wednesday afternoon until Friday afternoon for tests and observation.
1637853-1	The adverse advents occurred as follows: 1. Around 1am, the patient felt like he was burning inside and that it was going form his chest to his stomach and then pain all over 2. Then he felt dizzy like he was going to fall down and sat down instead, moaning 3. He then felt like he was going to pass out 4. He went to the toilet and threw up violently and went to sit on the bed and then went back to the toilet again to throw up but didn't and then was so dizzy he couldn't get off the toilet for about 10-15 minutes. 5. Then he went back to the bed, still dizzy. His wife said his eyes were glazed over and then rolled in the back of his head. He then fell backwards on the bed and started shaking/convulsing and gurgling. His wife had to pull him to the floor in a upright position just to get him breathing because he seemed like he was choking. She said he was going in and out of consciousness. She talked to him but he wasn't able to speak. His wife then called 911. 6. When the ambulance arrived he said he was temporarily blind and this lasted off and on for 2 days
1646823-1	congestive heart failure; Myocardia; I went into afib; Experienced chest pain minutes after shot was administered.; Shortness of breath; Coughing started hours after the dose; High heart rate/heart right went to about 180 bpm; This is a spontaneous report from a contactable consumer (patient). A 31-years-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in right arm on 17Jul2021 at the age of 31 years as single dose for covid-19 immunisation. Medical history included high blood pressure which he was medicated for and was under control, patient had recent tests done and had no issues with his heart, hypothyroidism, covid-19 prior vaccination. Concomitant medications included metoprolol; amlodipine; hydrochlorothiazide; levothyroxine sodium (LEVOTHYROX). Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient experienced chest pain minutes after shot was administered. Chest pain, shortness of breath, and coughing started hours after the dose. Patient was admitted 2 days later to the emergency room with chest pain and high heart rate. Patient went into afib, at the hospital where his heart right went to about 180 bpm. Patient was diagnosed with myocardia and congestive heart failure. Adverse event start time was 17Jul2021 05:00 PM. Duration of hospitalization was 1 day. Treatment received included pill to slow heart rate 3 times, medication change. Adverse events resulted in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event), disability or permanent damage. Since the vaccination, the patient had not been tested for COVID-19. Outcome of events were not recovered. The lot number for BNT162B2 was not provided and will be requested during follow up.
1653563-1	Ruptured Appendix. I was hospitalized and given IV antibiotics then sent home with 2 weeks of oral antibiotics, when the abscess clears up I will need surgery.
1662316-1	Only able to get pregnant through IVF/FET. I received the vaccine at 11 weeks pregnant. And the next day I was bleeding and miscarried.
1662396-1	I am the epidemiologist reporting on behalf of 61-year-old female patient. The patient received an initial vaccine series with two doses of the Moderna vaccine on 1/15/21 and 2/12/21. They later received a third dose of the Moderna vaccine on 8/19/21. The individual reports to contact tracers that they began experiencing COVID-19 symptoms 8/20/21, the day after their third dose. On 8/23/21 (four days post third dose), this person experienced a heart attack and tested positive for COVID-19 via a rapid test the same day. They subsequently tested negative via a PCR test on 8/25/21. This is a probable vaccination breakthrough infection post Dose 3. I do not have further information regarding immunodeficiency status or underlying health conditions that may have contributed to the heart attack/positive test.
1666098-1	Appendicitis.
1670306-1	ACCUTE CHEST PAIN/ HEART ATTACK -PAIN DOWN BOTH ARMS, NAUSEA, EMT ADMIN NITROGLYSERIN & BABY ASPIRIN ADMITTED TO HOSPITAL - CHEST XRAY -BLOOD WORK ENZYME LEVEL 4.6 - HAD CATHERIZATION, NO BLOCKED ARTERIES, NO HEART DAMAGE
1670860-1	Feeling very unwell starting on Saturday morning. Could not do usual activities like picking up sticks in the yard. Heart Attack very late Sunday night. Went to the Emergency room and had stents placed late Monday.
1673455-1	getting allergy attacks and severe breathing difficulties from peanuts, sesame, charcoal, coaltar which didn't happen earlier before taking Pfizer vaccine; getting allergy attacks and severe breathing difficulties from peanuts, sesame, charcoal, coaltar which didn't happen earlier before taking Pfizer vaccine; getting allergy attacks and severe breathing difficulties from peanuts, sesame, charcoal, coaltar which didn't happen earlier before taking Pfizer vaccine; This is a spontaneous report from a contactable consumer (patient). This female consumer reported that a 41 years old female (no pregnant) patient received BNT162B2 (lot number=EL3302), at the age of 41-year-old, on 17Apr2021 vaccine location in Left arm at single dose for covid-19 immunization. Medical history was Gastroesophageal reflux disease (GERD), Arthritis. Known allergies to Peanut, Soya, Sesame. No covid prior vaccination. No covid tested post vaccination. No other vaccine in four weeks. Other medications in two weeks included Omeprazole, Desloratadine. Adverse event on 18Apr2021 was getting allergy attacks and severe breathing difficulties from peanuts, sesame, charcoal, coaltar which didn't happen earlier before taking Pfizer vaccine. I never had any allergies from peanuts and sesame. Also these came (-) on Food Allergy test done on 23Dec2020 at ENT and Allergy facilities. Event resulted in Doctor or other healthcare professional office/dinic visit, Life threatening illness (immediate risk of death from the event). Treatment was Nebulization, Prednisone, Breo. Outcome of the event was Not recovered. Follow-up attempts are completed. No further information is expected.
1674967-1	Started not feeling good on day of injection. This continued until I was diagnosed w Acute myeloid leukemia on May 28th 2021

VAERS ID	Adverse Event Description
<u>1685724-1</u>	Blood Clot embolism in lung. Hospitalized for four days on oxygen Had to be on oxygen for 1.5 months after release from hospital
<u>1686432-1</u>	Within ~12 hours of receipt of 3rd dose of vaccine on 9/3/21, patient (who has advanced multiple sclerosis) was noted to be moaning in sleep. Throughout 9/4/21, she was lethargic, somnolent, unresponsive, not verbalizing. On 9/5/21, these symptoms persisting, she was noted to be encephalopathic and to have right hemiparesis and was taken to medical center where she was febrile, experiencing SVT and having electrical status epilepticus (per VEEG). A CT scan of the brain w/wo contrast did not reveal evidence of a CVA. Serum lactate=12. LP (? traumatic) was performed. Empiric broad-spectrum antibiotics (including acyclovir) initiated. Hospitalized in Medical Step-Down Unit. Developed not-specific sparse macular-papular rash on 9/6/21. Seizures treated with Keppra and resolved. Sensorium and right hemiparesis improved/improving; remains hospitalized as of date of this report (9/9/21). Awaiting MRI of the brain (to assess status of MS and acute encephalopathy).
<u>1689440-1</u>	Increase in heart rate, blood pressure, fluttering/butterflies in chest, over past 3 months. One instance BP shot up to 220/110 with accelerated heart rate. EKG, blood work, chest xray normal.
<u>1693844-1</u>	Elevated Heart rate, extremely high blood pressure. Hospital ER (Cardizem administered), two days in the telemetry unit. Now diagnosed with supraventricular tachycardia, scheduled for ablation Sept. 24, 2021.
<u>1694379-1</u>	After about two weeks of the second dose Covid-19 vaccine, I feel more and more difficult in breath when I was running or doing sport excises. My chest felt painful when doing the excises. I normally run in 5.8 miles/hour. In two weeks of fully vacationed, I can only run in 3.8 miles/hour.
<u>1703873-1</u>	I suffered an acute stroke after 2nd shot 3 days later
<u>1704165-1</u>	Immediately the next morning I awoke with a 102.7 fever, aches, chills and a sore arm that lasted for about 36 hours. HOWEVER.... it's what happened later on that is what concerns me. I was a very HEALTHY and physically active person up until the morning of 6/13/21, when I awoke at 4am to a sharp pain in my chest upon inhaling. I went to the urgent care clinic where the PA urged me to go to the hospital under strong suspicion of a blood clot. I went to hospital where they did blood work and my D-Dimer was through the roof, indeed indicating a pulmonary embolism- so they started me on Heparin. It turned out I had not one, but three pulmonary embolisms. I could've died. I spent 6 days in the hospital while they tried to get the right dosing of the blood thinners to get my pulmonary embolisms (PEs) under control. Finally, I was discharged. Three weeks later, on 7/9, I got my menstrual cycle, and due to the dosage of blood thinners I was on, I began to hemorrhage. I called my doctor who sent me back to the hospital. They could not control the bleeding, and I wound up needing a blood transfusion along with multiple iron infusions over the next 6 days in the hospital (again). They also needed to stop my blood thinners to control the blood loss. Due to the hemorrhaging, they determined I would need a hysterectomy, and they would need to keep me off blood thinners to perform the operation safely. I began throwing superficial blood clots all over. Any and every time they took a blood sample, or placed an IV, my vein would collapse and I'd get another blood clot. They rushed my surgery as soon as they could. I had my hysterectomy on 8/6/21. They started me on blood thinners that same day, a preventative dose, however it was not good enough. On 8/9/21, I spiked a fever and it turned out I had developed 3 Deep vein thrombosis in my legs (DVTs) despite the blood thinners. So, they upped my blood thinners to the highest possible dosage for my body. I then began to hemorrhage again and was re-admitted back into the hospital (again) for iron infusions and management of my blood thinners. I spent 10 days in the hospital between 8/6/21 and 8/19/21 trying to save my own life. During this time, the doctors and hospital have done ALL genetic marker testing for my condition and ALL have come back NEGATIVE. There is no reason for me to be throwing these blood clots continuously like this. According to my hematologist, the only 'new' factor in my life is the Covid vaccine, which I am now wary of the booster (which I am due for in November).
<u>1704497-1</u>	Blood clot causing a heart attack and stent.
<u>1711785-1</u>	abdomen pain; metrorrhagia; This is a spontaneous report from a contactable consumer (patient). This 34-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number EW0165, on 01May2021 at single dose in left arm (at the age of 34-year-old) for COVID-19 immunization. Medical history was none. The patient had no known allergies. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. Concomitant medication was none. 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. The patient previously received first dose of BNT162B2, Lot number EN6207, on 10Apr2021 11:00 in left arm for Covid-19 Immunization. After getting 2nd dose, the patient started to have metrorrhagia starting the 2 days after (03May2021). It lasted for 2 weeks. She never had a metrorrhagia in her entire life. She called hospital to report side effects, but they said she needed to see her doctor regarding this. She went to gynecology to see what's going on, and he said there wasn't any study regarding women's metrorrhagia side effect, but he had seen a lot of women suffering similar issue after getting vaccine, such as re-starting period after menopause. It's been almost 4 months since she got vaccinated, and she still had abdomen pain sometimes. Her biggest concern was that it would affect her body for not getting pregnant. They had been trying to get pregnant since 3 months and it's not happening. She was really worried. She was hearing similar side effects from a lot of people nowadays. No treatment was received. The outcome of the events was not resolved. The event metrorrhagia was serious with life-threatening.
<u>1716104-1</u>	Woke up with severe chest pains, pale, blue lips, nausea, clammy. Brought him to Medical Center emergency room. Bloodwork, chest xray and EKG done. Bloodwork showed high levels of troponin. Transported via ambulance to a Medical Center pediatric intensive care unit. During stay at hospital he had telemetry monitoring, ekg, and regular bloodwork to check troponin levels. Diagnosed with Myopericarditis
<u>1722442-1</u>	Exactly one month after second dose patient began experiencing heart palpitations. Patient went to ER and was diagnosed with atrial fibrillation. Patient is a healthy active male with no prior medical history.
<u>1734208-1</u>	made her arm sore; symptoms of covid -19/tested positive for covid-19; I believe the Pfizer vaccine got me and my 12 year old daughter sick.; This is a spontaneous report from a contactable consumer reported for herself and her daughter, this case is for herself. A 41-year-old non-pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 26Aug2021 14:30 (Batch/Lot number was not reported) as DOSE 1, SINGLE for covid-19 immunisation at age of 41 years old. Medical history was none. Concomitant medication included semaglutide (OZEMPIC) taken for an unspecified indication, start and stop date were not reported. The patient reported that that prior to her first covid Pfizer shot on 26Aug2021, she had a negative covid test. Prior to vaccination, the patient was not diagnosed with COVID-19. The shot made her arm sore on 06Sep2021 at 12: 00, and on 06Sep2021 she started to get symptoms of covid -19. She tested positive for covid-19 on 09Sep2021. She believed the Pfizer vaccine got her and her 12 years old daughter sick. The events were serious per life threatening and required physician office visit. No treatment received for the events. The patient underwent lab tests and procedures which included Covid 19 test (Nasal Swab): negative on 17Sep2021. The outcome of the events was resolving. The lot number for the vaccine, [BNT162B2], was not provided and will be requested during follow up.
<u>1736057-1</u>	Covid vaccine caused AFIB which caused blood clots to form and break off and cause 8 strokes ! Very scary event could have killed my father !
<u>1750312-1</u>	9/30/2021 during morning round resident received resting in bed comfortably. AM care provided. Around 8:20am nurse entered the room to administer morning medication and noticed resident was making a gurgling sound, short of breath and hyperventilated. The resident had a wet non productive cough, tachycardia and temperature of 100.0. Oxygen administered, PRN nebulizer given, 911 activated, MD notify and POA made aware. Resident was transported to local Hospital for further evaluation and treatment. The Resident was admitted.

VAERS ID	Adverse Event Description
<u>1753230-1</u>	I had a heart attack on June 3rd 2021. Not sure if it had to do with vaccination?
<u>1754750-1</u>	Appendicitis, ruptured aappendix resulting in hospitalization and appendectomy 9/6/21. Complications of internal bleeding which necessitated transfusion and a second surgery. JP drain. Contracted c diff and thrush due to antibiotics. Developed anemia due to hemoglobin loss. Had treatment for c diff. Still with JP drain as of 10/1/21. Taking iron to treat low hemoglobin.
<u>1756001-1</u>	Heart attack; Arthrosclerosis; COPD; Other terms on autopsy report caller does not understand after the second dose; Not feeling well after the second dose; This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (Heart attack), JOINT STIFFNESS (Arthrosclerosis), CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) and ADVERSE EVENT (Other terms on autopsy report caller does not understand after the second dose) in a 74-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 17-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 14-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 16-Apr-2021, the patient experienced MALAISE (Not feeling well after the second dose). On 20-Apr-2021, the patient experienced MYOCARDIAL INFARCTION (Heart attack) (seriousness criteria death, medically significant and life threatening), JOINT STIFFNESS (Arthrosclerosis) (seriousness criteria death, medically significant and life threatening), CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) (seriousness criteria death, medically significant and life threatening) and ADVERSE EVENT (Other terms on autopsy report caller does not understand after the second dose) (seriousness criteria death, medically significant and life threatening). The patient died on 20-Sep-2021. The reported cause of death was Heart attack, Arthrosclerosis and copd. An autopsy was performed, but no results were provided. At the time of death, MALAISE (Not feeling well after the second dose) outcome was unknown. No concomitant medical information were reported. No treatment information was reported. Company comment: This case concerns a 74-year-old, male patient with no relevant medical history, who experienced the unexpected events of Myocardial infarction, Arthrosclerosis, Chronic obstructive pulmonary disease, and other Adverse event (Nos). Patient initially experienced malaise (not feeling well) approximately 3 days after the second dose of mRNA-1273 (Moderna Covid-19 vaccine). The patient reportedly passed away approximately 7 days after the second dose of mRNA-1273 (Moderna Covid-19 vaccine); and autopsy revealed cause of death as Myocardial infarction, Arthrosclerosis, Chronic obstructive pulmonary disease, and Other unspecified terms on autopsy (Adverse event Nos). The rechallenge was not applicable as events occurred after second dose with fatal outcome. The benefit-risk relationship of mRNA-1273 (Moderna Covid-19 vaccine) is not affected by this report.; Sender's Comments: This case concerns a 74-year-old, male patient with no relevant medical history, who experienced the unexpected events of Myocardial infarction, Arthrosclerosis, Chronic obstructive pulmonary disease, and other Adverse event (Nos). Patient initially experienced malaise (not feeling well) approximately 3 days after the second dose of mRNA-1273 (Moderna Covid-19 vaccine). The patient reportedly passed away approximately 7 days after the second dose of mRNA-1273 (Moderna Covid-19 vaccine); and autopsy revealed cause of death as Myocardial infarction, Arthrosclerosis, Chronic obstructive pulmonary disease, and Other unspecified terms on autopsy (Adverse event Nos). The rechallenge was not applicable as events occurred after second dose with fatal outcome. The benefit-risk relationship of mRNA-1273 (Moderna Covid-19 vaccine) is not affected by this report.; Reported Cause(s) of Death: Heart attack; arthrosclerosis; COPD
<u>1759390-1</u>	Brain Metastasis. Lost ability to pick the right words. Surgery on 7/28/2021. Hospitalized for 1 week.
<u>1762882-1</u>	CHRONIC PALPITATIONS PRIOR TO CHEST PAIN/CARDIAC EVENT LEADING TO TAKOSUBO CARDIOMYPATHY DIAGNOSIS/ HOSPITALIZED FOR 4 DAYS/ CARDIAC CATHETERIZATION. MEDICATION AND FOLLOW UP SPECIALISTS APPOINTMENTS.

VAERS ID	Adverse Event Description
1765011-1	<p>"As per cardiologist's note on 10/3/21: ""Cardiology was asked to urgently evaluate this 38-year-old male not previously known to my service who was brought into the emergency room at hospital after presumed cardiac arrest. Patient's recent history is quite complex and much of this information was obtained after cardiology's initial evaluation of patient. In short patient had received a second Pfizer COVID-19 vaccination yesterday which was Saturday, October 2, 2021. Patient had not had any reaction to first vaccination dose. Patient also denies Covid 19 infection previous to vaccination. Patient at approximately 3 AM woke with chills and rigors which was concerning to his wife however patient reassured her that he was okay and that this was just simply reaction to the vaccination. At approximately 5 AM patient had extreme chills rigors and apparent loss of consciousness but regained consciousness after approximately 45 seconds to a minute. Patient was slow to respond initially however did not exhibit any evidence of a postictal state. Patient had no loss of bladder or bowel function, no tongue biting. And although only was confused for a few moments after the event. Patient also did not complain any shortness of breath or chest pain although he felt weak. Patient had another similar episode for which wife called EMS however patient responded and patient deferred transfer to emergency room. Patient was shortly thereafter found unresponsive by wife once again. Patient this time was having tonic-clonic activity with questionable urinary incontinence. Patient was intubated in the field and in route received 4 shocks from an AED device. There are no strips available at this time for perusal however that may be a moot point as later patient had witnessed ventricular tachycardia and fibrillation. Please see critical care consultation which accompanies this dictation. Cardiology evaluated patient shortly after presentation to the ER as a good Samaritan gesture as I was not formally involved with the case. At this time I did a courtesy bedside echocardiogram using the emergency room's basic Sonos equipment. Obviously the initial concern was possible myocarditis post mRNA vaccination. Echocardiogram at that time showed robust, normal left ventricular function with ejection fraction of proximally 60%. As the patient story was extremely suggestive of arrhythmic nature, not neurologic I suggested to the emergency room physician that amiodarone 150 mg bolus to be given as it had not been given in the field. Ultimately cardiology was asked to formally evaluate and continue to treat. Anecdotally patient's mother is known to our practice. Of note patient does have a past medical history of migraines, but is not on any medications . Patient has not to anyone's knowledge taken any possible offending agents which could precipitate ventricular tachycardia and or torsades . As per the family, the patient is active physically without history of tobacco EtOH or illicit drug use. Patient exercises quite regularly and leads what would be considered a very healthy lifestyle. His brother describes having a very violent reaction to the Covid 19 Johnson & Johnson vaccination however he attributed that to the fact that he had had Covid several months prior. Patient did have symptoms of what could be considered a generalized flulike illness beginning several days prior to presentation but was not was not characterized by the wife or family as a major illness of any sort Patient had 2 additional cardiac events which will be described in more detail in separate progress note, however in summary patient was witnessed to go into torsades and required defibrillation x2. Patient was rebolused with amiodarone and additional IV magnesium given. Patient proxy an hour later became fairly hypotensive and initially after discussion with cardiac electrophysiology it was initially felt that we would want to avoid pressors as they may precipitate further arrhythmias and plans were made for intra-aortic balloon pump to be placed. Patient's blood pressure dropped precipitously and small doses of Neo-Syneprine given by cardiology without any further ventricular arrhythmias. Patient did well on just very low-dose Neo-Syneprine was monitored by cardiology on transfer to ICU within the ICU. Decision to place intra-aortic balloon pump defer at this time after discussion with intensivist and cardiac electrophysiology. Of note when patient became hypotensive propofol was discontinued and during that time patient was seen to wake fully, before given IV Ativan"" On 10/4/21, the patient was discharged to Medical Center for more advanced cardiac care. On 10/4/21 (day of transfer), a consulting cardiologist documented the following: ASSESSMENT AND PLAN: Migraine headaches VT/VF arrest Syncope Seizure Acute hypoxic respiratory failure ? Severe Myocarditis s/p COVID vaccine ? Brugada Syndrome Hypotension Bradycardia CHF, acute systolic VT/VF storm in setting of ? severe myocarditis vs brugada syndrome with reduced EF EKG reviewed Initial Echo 10/3 EF 55, mild TR Repeat Echo 10/4 EF 20, global hypokinesis of LV LHC 10/4 showed normal coronaries IABP placed, 1:1; TVP settings: A-paced rate 70, output 0.8, sensing 3.0 On IV Amiodarone and Lidocaine drips Plan to transfer today for possible Impella placement. The history is also suggestive of Brugada VT storm as he came with a fever after vaccine. The baseline EKG has incomplete RBBB and episodes of spontaneous VF HE does have BBR VT, fascicular VT or CPVT on any of these episodes Likely diagnosis is either Brugada or severe myocarditis. Would recommend Isuprel along with PO quinidine which are not available at facility Possibly will also need ventricular biopsy to rule out myocarditis.""</p>
1771789-1	<p>The date reported is the 2nd dose. Patient started complaining of severe pain in the back of his neck a few days after the shot. We would treat it with heating pads, or advil. On 6/22 and 6/23/21 he suffered multiple strokes which then lead into a series of other events (eg craniectomy)</p>
1773645-1	<p>Developed appendicitis 14 days after first shot; This is a spontaneous report from a contactable consumer (patient). A 16-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration, administered in arm left on 31Mar2021 16:00 (Batch/Lot Number: ER8737) (at the age of 16 years old) as dose 1, single for COVID-19 immunisation. The patient was not pregnant at the time of vaccination. Facility type vaccine was reported as Pharmacy or Drug Store. There were no known allergies and no other medical history. There were no other vaccine in four weeks and no other medications in two weeks. No COVID-19 prior vaccination. On 14Apr2021 00:00 (12:00 AM), the patient developed appendicitis 14 days after first shot. Event resulted in emergency room/department or urgent care, it was life threatening illness (immediate risk of death from the event). Treatment included appendectomy. The patient received BNT162B2 in left arm on 21Apr2021 16:00 (Lot number: ER8736) at dose 2.COVID-19 test post vaccination was Nasal Swab (PCR) on 21Jul2021 with negative result. The outcome of the event was recovered on unknown date.</p>
1773653-1	<p>I got COVID 19 September 3,2021, 4 months after vaccinated it doesn't protect me at all.; I got COVID 19 September 3,2021, 4 months after vaccinated it doesn't protect me at all.; This is a spontaneous report from a contactable consumer (Patient). A 67-year-old non pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, solution for injection, Batch/Lot Number: EWO167 and expiration date was not reported), first dose via an unspecified route of administration, administered in left arm on 06May2021 at 15:00 (at the age of 67-year-old) as single for COVID-19 immunization. The patient had no medical history and no known allergies. The patient did not receive any other vaccine in four weeks. Patient had no Covid prior vaccination and patient was tested Covid post vaccination. The patient received herbal medications in two weeks. On 03Sep2021 at 19:30, the patient experienced COVID 19. The patient reported that, she got vaccinated on 06May2021 and got COVID 19 on 03Sep2021, 4 months (3 months 28 days) after vaccination and it doesn't protect at all. The patient had drug ineffectiveness. The patient underwent lab tests and procedures which included SARS-CoV-2 test (Nasal Swab) and the results were: positive on 03Sep2021 and negative on 15Sep2021. Adverse event resulted in doctor or other healthcare professional office/clinic visit and considered event as life threatening illness (immediate risk of death from the event). The patient did not receive ant treatment for events. On an unspecified date in 2021, the patient recovered with sequelae (Recovered with lasting effects).</p>
1775406-1	<p>Anaphylactic shock, was hospitalized for 6 days discharged home was out of work for one month at which time I developed hives one week after discharge, had issues with breathing , weakness and highly sensitive. Would have allergic type reactions to smells, would go into breathing issues with activity. To date, still have issues with the breathing aspect but have found out since that the residual effects include vocal cord dysfunction.</p>
1783151-1	<p>After receiving the vaccine, throughout the next week, I started experiencing headaches. I went to the pharmacy and checked my blood pressure. It was 210/110. I went straight to ER. While at the ER, they gave me amlodipine 5mg and it did not help any, but they sent me home. A day later, my BP was at 171/111. I went back to the ER and they performed an EKG, and drew blood. Those results came back normal. They told me to see my PCP. I couldn't get in to see him for over two weeks time. In between my appointment, I went to a different hospital, ER, and my BP spiked to 225/120 and then to 225/130. I was admitted to the hospital. I was admitted for two days to the hospital because of my high BP. I was given an IV that lowered my BP instantly. They wanted to put me into ICU, but I told them to just remove the IV. I am now taking 20 mg lisinopril and 10mg of Amlodipine. I still have spikes from time to time. I then took the second dose and it spiked again. I went back to Medical Center since they took great care of me. I also have a cardiologist that I see regularly.</p>

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<u>1783164-1</u>	Diabetes Type 1. Bed-wetting, dehydration, nose bleed, fatigue, unconscious state, excessive sleepiness, excessive urination, rapid weight loss from 250LBs to 165LBs (1 month prior to ER visit).
<u>1783177-1</u>	There were no indication or bumps prior to 06/06/2021. Then on 06/06/2021- I noticed a raised bump above my collar bone. I went to my PCP, he ordered an ultrasound. He said it was suspicious of lymphoma, I had a excisional biopsy at the site of the bump, they took out a whole lymph node and determined it was Hodgkin's Lymphoma. And a PET scan after that determined it was stage 2 unfavorable. It was unfavorable because the size of the mass was over 10 cm. I went to 3 different oncologist and got their opinion on what treatment I should take. I preceded with and started treatment on 07/17/2021, and I go every 2 weeks. Disability yes, risk to my heart and lungs from the aggressive chemo meds.
<u>1788176-1</u>	7 minutes after the vaccine was administered, the patient (my son) passed out (lost his consciousness). The pharmacist Dr. performed chest compression to bring him back to consciousness. It was successful, and by the time the Emergency team arrived, my son was already in a conscious state.
<u>1794011-1</u>	Increase heart rate during the night when at rest. Heart rate 136BPM-144BPM.
<u>1794346-1</u>	Blood clot in brain
<u>1795077-1</u>	I am a 63-year-old woman, who was in good health with no preexisting conditions. I took the first injection Moderna COVID19 vaccine shot on Friday, September 24, 2021 due to the mandate to keep my job as a substitute teacher. I started feeling bad and my breathing deteriorated each day to the point where I was out of breath. On Wednesday, September 29, 2021, I went to urgent care. After initial check-up, they called the ambulance and I was transported to the Emergency Room and immediately placed on high flow oxygen. One more day delay and I would have died due to lack of oxygen. At the hospital, on Thursday, September 30, 2021, the doctor removed ONE Liter (Quart) of fluid from my right lung, the next day the doctor removed ONE and ONE THIRD liters of fluid from my left lung. The fluid was a rusty reddish color. At the hospital, all kinds to tests were performed, heart test, cancer test, COVID19 test and bacterial tests, all results were negative. By Saturday, I was off oxygen and was released from the hospital on Monday, October 4, 2021. By the end of the week, I again started feeling out of breath. On Monday, October 11, the doctor ordered a chest X-ray. The x-ray was read on Tuesday morning. The Doctor immediately called me and told me to go to Emergency Room at Medical Center. On Wednesday, October 13, 2021, surgery was performed on me to install draining tubes from both of my lungs. More than a liter of fluid was removed from each of my lungs. Again, more tests were performed on me to find the root cause and none were found. On Friday, October 15, I was released from the hospital with tubes from my lungs. On Sunday, October 17, 2021, the visiting nurse came to my house and drained 25 ml from my right lung and 75 ml from my left lung. The nurse is scheduled to come three times a week to remove the fluid. I am currently suffering from swelling in my feet, myocarditis and pericarditis and unable to work in this condition, as a result of the Moderna vaccine.
<u>1797736-1</u>	Onset of Diabetes; Keto Acidosis;
<u>1798434-1</u>	Vaccine 9/29/21, no problems until 10/06/21 when what seemed to be a small cold starting with dry cough, clear runny nose, small amount of congestion, by 10/10/21 shortness of breathe started to do breathing treatments, same on 10/11/21 at approx 5:45pm I was completed winded and out of breathe and was taken to Medical Center in respiratory distress. I spend the next 3 days in ICU then transferred to medical floor for the next 5 days. I am home now on oxygen and recovering slowly. I was also on a Bipap machine and slowly weaned off of that.
<u>1800990-1</u>	Patient presented on 10/11/2021 with complaints of dyspnea x1 month. Patient is healthy with no significant underlying conditions. EKG at that time in my office was abnormal, patient sent to ER for evaluation and treatment. Found to have EF of 17%, acute systolic Heart failure with no CAD on cardiac cath. Patient discharged to home on 10/13/2021 with Life Vest and cardiac follow up.
<u>1818759-1</u>	DVT
<u>1819218-1</u>	shortness of breath, heart issues, severe headache, severe blood dots in leg and lungs
<u>1823653-1</u>	"lowoxygen; exhaustion; received a third dose; received a third dose; couldntot walk more than 10feet; difficulty to breath; This is a spontaneous report from a contactable consumer (the patient). An 87-year-old female patient received the third dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: FD8448) via an unspecified route of administration in left arm on 16Aug2021 at age of 87-year-old (age at vaccination) at single dose for COVID-19 immunisation. Medical history included ongoing COPD/emphysema from 2010. There were no concomitant medications. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot/batch number: EN6199) intramuscular in left arm on 06Mar2021 for COVID-19 immunization; second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot/batch number: EP7534) intramuscular in left arm on 27Mar2021 for COVID-19 immunization. It also reported the patient previously took FLU vaccine given the same day (the vaccination date was not specified), the patient have no information on it. The patient experienced exhaustion on 18Aug2021, the event was serious with seriousness criteria of persistent/significant disability, important medical event, treatment (additional predinasone) received for the event, the event required visit to-physician office. The patient experienced low oxygen on 25Aug2021, the event was serious with seriousness criteria of persistent/significant disability, life threatening, important medical event, treatment (additional predinasone ,3 weeks) received for the event, the event required visit to-physician office. The patient stated about 10 days after combined vaccination oxygen level fell into the 80's. Could not walk more than 10 feet out of breathe (Aug2021). It has been 7 week and still difficult to breathe at times. within 2 day exhausted no energy, then problems breathing them low oxygen, getting better slowly. The outcome of the event(s) ""received a third dose"" was unknown, of other events was recovering. Follow-up attempts are completed. No further information is expected."
<u>1829892-1</u>	Patient had initially filled out online questionnaire for Pfizer vaccine and made appointment for 10/30. Patient came in evening around 7pm 10/29 and asked if she could get vaccine tonight, and requested we change to Moderna. Changed to Moderna, as requested. Prepared IMZ, spoke to patient, who appeared very nervous when I called her over for shot. Patient mentioned that she has a pseudoseizure disorder and fibromyalgia. Patient requested her husband come into the IMZ booth with her to calm her, which he did. Went into IMZ booth to give patient her Moderna shot (dose #1). Administered dose 1 and patient immediately seemed to be out of it. Her eyes were glazed, and she started complaining her arm hurt tremendously. I told her she was okay, and I was going to be right back. Went to get patient water and a cold compress. Returned, pt took a sip of water, and started trembling. Patient appeared to have seizure, as eyes closed, unable to speak, and trembled. Patient's husband sat with patient while I called 911 (one tech on break, one tech helping someone on other end of pharmacy). I immediately called 911, who dispatched paramedics. Code white was called, and management responded. Shot was given approx 7:12pm, paramedics arrived approx 7:30pm. Paramedics delivered at least one (but I believe a second dose was also given) doses of Versed. Patient did not respond to Versed. Paramedics took her blood pressure, blood sugar, all stable. Patient did not stop trembling while paramedics were here. Paramedics loaded patient onto stretcher and took her to local hospital.
<u>1831884-1</u>	Ideopathic ImmunoThrombocytopenic Purpura (ITP) - Bloody Nose, Bleeding Gums, Bruising, Petechiae, Platelet Count of 2000. Given IV fluids, steroids through IV and orally. Continual bloodwork monitoring platelet count. Hospitalization for 5 days.
<u>1837453-1</u>	Stroke on 2/12/2021, death on 2/28/2021 Was in 3 hospitals:

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<u>1839199-1</u>	Ewing Sarcoma in 3 tumor surrounding right lung; fever; persistent cough; Pleural effusion; scoliosis; This is a spontaneous report from a contactable consumer (patient). This 14-year-old female patient received the second dose of BNT162B2 (lot number unknown) at left arm at single dose for COVID-19 immunisation on 17Jun2021 at 15:00. Relevant history included known allergies to Etoposide chemo medicine. Relevant concomitant drug was unknown. The patient previously received the first dose of BNT162B2 for COVID-19 immunisation on 27May2021 at 15:00 at left arm. The patient was not pregnant. The patient was diagnosed as scoliosis in Jul2021. On 16Aug2021, the patient experienced persistent cough and fever, then emergency visit to hospital for pleural effusion from lung cavity and diagnosis of Ewing Sarcoma in 3 tumor surrounding right lung. The events resulted in Emergency room/department or urgent care. The patient was hospitalized for 35 days. The events were considered as life-threatening. Treatment therapy included Chemotherapy. The outcome of event scoliosis was unknown. The outcome of other events was not resolved. Lab tests included Covid-19 RT-PCR test on 20Aug2021 with negative result (Nasal Swab), COVID-19 PCR COMBO on 10Sep2021 and on 27Oct2021, both with negative result (Nasal Swab), RAPID SARS-COV-2 on 13Oct2021 with negative result (Nasal Swab). The patient did not receive any other vaccines within 4 weeks prior to the COVID. The patient did not receive any other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. The lot number for the vaccine, [BNT162B2], was not provided and will be requested during follow up.
<u>1842227-1</u>	Booster; heart attack; This is a spontaneous report from a contactable consumer. An elderly female patient (not Pregnant at the time of vaccination) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 3 via an unspecified route of administration on Oct2021 (Batch/Lot number was not reported) as DOSE 3 (BOOSTER), SINGLE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. Historical vaccine included the patient received first dose of BNT162B2 on 06Jan2021 for Covid-19 Immunization; second dose of BNT162B2 on 26Jan2021 for Covid-19 Immunization. The patient had heart attack after receiving booster in Oct2021. There was no prior history of heart conditions. She was stable the next day, transferring back to long term care facility. The event resulted in hospitalization, life threatening illness (immediate risk of death from the event). The patient was hospitalized for heart attack from Oct2021 to an unknown date. Therapeutic measures were taken as a result of heart attack included Lasix to remove fluid from heart and nitro paste. The outcome of the events was resolving. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.
<u>1845410-1</u>	unprovoked blood clots; This is a spontaneous report from a contactable other HCP. A 73 year old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left at age of 72 years old on 04Feb2021 09:00 (Batch/Lot number was not reported) as DOSE 2, SINGLE for covid-19 immunisation. Pregnancy at time of Vaccination: No. Medical history included hypertension (HBP), sleep apnoea, osteoporosis. No covid prior vaccination. Concomitant medication(s) included calcium (CALCIUM) taken for an unspecified indication, start and stop date were not reported; colecalciferol (VITAMIN D) taken for an unspecified indication, start and stop date were not reported; hydrochlorothiazide, losartan potassium (LOSARTAN HCT) taken for an unspecified indication, start and stop date were not reported. The patient previously received first dose of bnt162b2 at age of 72 years old 14Jan2021 08:00 AM arm left for covid-19 immunisation, took dimerol and experienced drug allergy. The patient experienced unprovoked blood clots on 16Jun2021 02:30 AM for which patient was hospitalized for 3 days. Treatment included blood thinner. The patient underwent lab tests and procedures which included covid test type post vaccination=Blood test: negative on 16Jun2021. Outcome of event was recovered in 2021. Event was resulted in: [Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event)]. The lot number for the vaccine, [BNT162B2], was not provided and will be requested during follow up.; Sender's Comments: Considering the temporal association, a causal association between administration of bnt162b2 and the onset of unprovoked blood clots cannot be excluded. The history of hypertension may provide an explanation. 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.
<u>1867867-1</u>	Tinnitus - immediately after vaccine, no treatment, has improved minimally Purple Sparkles in vision - later in the evening on the same day of the vaccine, improved after 3 months but came back 2 months later as bad as initially Blind spot - In right eye. Occurred within a week of the vaccine, diagnosed as Neuroretinitis, fluid/swelling improved but blind spot is still present (more opaque) currently and imaging shows inflammatory cells are still present Flashes, floaters and halos around lights - in both eyes. Occurred within 2 weeks of the vaccine and got progressively worse. Retina images are normal, doctors believe its neurological Purple delayed afterimages - Began in September 2021, retina imaging is unremarkable so doctor's believe it is neurological Hypertension - Had pre hypertension in the past which was under control with 25mg Losartan (as needed), did not need to take medication majority of the time. Stage 2 resistant hypertension began within a week of the vaccine. I have taken 5 different medications (at high doses and in combinations) and still get high readings, spiking up to hypertension crisis (203/105) while on high doses of medication. Brain fog - Began immediately after the vaccine, no diagnosis or treatment Migraine - Debilitating migraine for 5 days beginning immediately after the vaccine. Excruciating pain and nausea and was unable to leave bed. No medication (Tylenol or Excedrin) worked went away after 5 days.
<u>1868421-1</u>	Developed Osteomyelitis in spine.
<u>1879620-1</u>	has had 3 subacute ischemic strokes with possible CNS vasculitis a very rare autoimmune disease; has had 3 subacute ischemic strokes with possible CNS vasculitis a very rare autoimmune disease; diagnosis of a brain blood clot; her mental status decline; This is a spontaneous report from a contactable Nurse (reported for his/her mother). A 61-year-old non-pregnant female patient received second dose of bnt162b2 (Solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date in May2021 at the age of 61 years old as single dose for covid-19 immunisation. Medical history included hypertension and shellfish allergy, both from an unknown date. The patient did not experienced Covid-19 prior to vaccination and the patient was not tested for Covid-19 post vaccination. There were no concomitant medications. The patient previously received first dose of bnt162b2 (Batch/Lot No: Unknown. Unable to locate or read the details) on an unspecified date in Apr2021 at the age of 61 years old for COVID-19 immunization. There were no other vaccines received in four weeks and there were no other medications received in two weeks. After the patient received the Pfizer vaccine bnt162b2, her mental status decline in Jul2021 and in Aug2021 the patient was brought to the Emergency room with diagnosis of a brain blood clot the patient has been treated with pradaxa for blood clot, although now in Nov2021 the patient has had 3 subacute ischemic strokes with possible CNS vasculitis a very rare autoimmune disease - possibly brought out by bnt162b2. The reported events resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event), Disability or permanent damage. The patient was hospitalized for 5 days. The patient underwent lab tests which included blood work, multiple CT scans, magnetic resonance imaging with unknown results on an unknown date in 2021. Therapeutic measures which included multiple CT scans, magnetic resonance imaging, spinal tap, blood work, and blood thinners were taken as a result of reported events. The outcome of the events was not recovered. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 vaccine can not be excluded for the reported events of Mental status changes, Thrombosis, Ischaemic stroke, Central nervous system vasculitis and Autoimmune disorder. 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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<u>1885878-1</u>	Developed a small blood clot in my right lung. Initial symptoms started on Mon. 6/7/21. Felt like indigestion. Started early afternoon. Did not take anything that day (may have had some tea). Next day slight increase in symptoms. Took acid-indigestion medicine early afternoon followed by muscle relaxant followed by one (1) Aleve Muscle and Back pain tablet (these were all taken hours apart). Note: I work from home; shift ends at 2am. Symptoms did not subside but increased by that evening. By end of shift, was experiencing intense pain in chest area that hurt whether sitting, standing, bending over, laying down or moving. Included shortness of breath. Tried to sleep and eventually got up around 7am on 6/9/21 and decided to go to nearest ER. Managed to get dressed and took Uber to ER. Was admitted to ER as soon as I arrived. Received ECG, blood pressure test, chest x-ray, covid test, chest MRI scan (w/ and w/o contrast), ultra sound of the legs, TTC w/ doppler and color, and various blood tests. The testing revealed the small blood clot in my right lung. Was admitted into the hospital and given Eliquis (oral, tablets) for that day and next and prescribed prescription for initially one month. I informed my cardiologist, my primary doctor and neurologist of what was happening. Was eventually given a prescription by primary doctor for three (3) month supply of Eliquis and referral to hematologist by attending physician at ER and cardiologist to find out if I was susceptible to blood clots as there is not a known history of this in my family. Returned to the ER two times afterwards (6/18 - not admitted and 6/23 - admitted) for additional pain and shortness of breath. Was given an ECG, blood tests, blood pressure test, chest x-rays for both. Was given a chest CAT scan on the 6/23 visit. It was discovered during this visit that the blood clot had dissolved. On 6/24, was given a stress test by my cardiologist (he is affiliated with this hospital). Passed. Saw Hematologist in 8/2021; returned for results on 9/13/21. No propensity was found for blood clots. Conclusion - clot resulted from vaccine. Informed that I could stop taking Eliquis at end of month. I did return to the ER just recently (11/10/21) due to the same/similar symptoms that I experienced back in June 2021 (heaviness in chest area). Similar test given (ECG, blood pressure, blood tests, chest x-ray, and chest MRI (w/ and w/o contrast). Also received pain meds and muscle relaxant (given before MRI in case this was muscle related). Results indicated no new blood clots, some small cysts in right lung.
<u>1888063-1</u>	Was fine then pain in groin ,cold white leg called ambulance had clot from groin to below knee. Heart ejection fraction 32%
<u>1889774-1</u>	Pericarditis
<u>1893326-1</u>	Booster; Congestive Heart Failure; Arrhythmia; Heart Attack; This is a spontaneous report from a contactable consumer. An elderly female patient received bnt162b2 (BNT162B2), dose 3 via an unspecified route of administration on 22Oct2021 (Batch/Lot number was not reported) as DOSE 3 (BOOSTER), SINGLE for covid-19 immunisation. Medical history included covid-19. Historical vaccine included bnt162b2 dose 1 on 06Jan2021 and dose 2 on 26Jan2021 both for COVID-19 immunization. The patient's concomitant medications were not reported. The patient experienced congestive heart failure (death, hospitalization, life threatening) on 26Oct2021, arrhythmia (death, hospitalization, life threatening) on 26Oct2021, heart attack (death, hospitalization, life threatening) on 26Oct2021. Therapeutic measures were taken Laxix, Nitro paste (nitroglycerin); Transferred back to Long-Term Care Facility. The patient died on 30Oct2021. Autopsy was not performed. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Reported Cause(s) of Death: Heart Attack; Arrhythmia; Congestive Heart Failure
<u>1896981-1</u>	Pt had several life threatening blood clots in his veins and arteries in his legs, and blood clots in his lungs.
<u>1914054-1</u>	On the evening of November 16th the patient began to show signs of total short term memory loss, confusion and hallucination. He was admitted to the hospital and was diagnosed with suffering a hemorrhagic stroke which subsequently caused swelling in the brain. He was immediately administered steroids and blood thinners. In three days the swelling diminished and he was released from the hospital on November 20th.
<u>1919248-1</u>	A 78-year-old male patient (my father) received two doses of mRNA-1273 (Moderna Covid-19 Vaccine) in April 2021. Medical history included ongoing (managed) hypertension. No acute health issues, no cardiac issues, no family history of cardiac issues, never had COVID-19. Patient does not smoke or drink and leads fairly active lifestyle. The patient awoke on Monday morning, November 29, 2021 with acute chest and stomach pain, nausea and bowel discomfort. He was rushed to the hospital and diagnosed with type A aortic dissection and emergency open heart surgery was performed to repair the dissection. Outcome: not recovered. Patient still in ICU. This Type A aortic dissection occurred seven months after vaccination.
<u>1919904-1</u>	Is chest pain, exhaustion, fluttering in the heart, Passed out Admitted to the hospital for 7 days, they found low ejection fraction with myocarditis.
<u>1920259-1</u>	Ventricular tachycardia started 9/6/2021 at 7 pm exactly 14 days after my J&J shot. I went to ER 9/7/2021 at 11 am. Zero issues prior to this shot. Healthy 53-year-old. No medicines. Due to damage in heart had to undergo epicardial ablation.
<u>1921138-1</u>	Patient developed a febrile illness accompanied by abdominal pain, rash, neck pain, headaches and conjunctivitis 5 days after vaccination. She was admitted to our hospital on 12/1 with hypotensive shock and is being treated with antibiotics and treatment for MIS-C given unclear picture of her clinical decompensation. At this time, all cultures including blood, urine, throat and sputum are negative. Imaging significant for mesenteric adenitis, cervical adenitis, and small b/l pleural effusions. Patient is currently intubated and on vasoactive support.
<u>1924554-1</u>	2 days after the second dose, felt pain in right leg during regular morning run. Patient continued in pain for a month, then went the the Emergency Room in Morristown Medical Center. During the ER visit, DRs saw DEEP VEIN THROMBOSIS , prescribed Xarelto 20MG & 15 MG (2x/day for the first 30 days) FOLLOW UP 9/7/2021 - HAD VASCULAR VENOUS DUPLEX LOWER BILATERAL - CHECK-UP
<u>1928038-1</u>	"Breathing problems- sent to hospital a few times; This is a spontaneous report received from a contactable reporter (Consumer). The reporter is the patient. A 57 year-old female patient (not pregnant) received bnt162b2 (BNT162B2), administered in arm right, administration date 15May2021 10:00 (Batch/Lot number: unknown) at the age of 57 years as dose 2, single for covid-19 immunisation. The patient's relevant medical history was not reported. No known allergies. No covid prior vaccination. No covid tested post vaccination. There were no concomitant medications (No other vaccine in four weeks, no other medications in two weeks). Vaccination history included: Bnt162b2 (Dose 1, in left arm), administration date and time: 24Apr2021 10:00 AM, when the patient was 54 years old, for Covid-19 immunization. The following information was reported: DYSPNOEA (hospitalization, life threatening) with onset 16May2021 12:00, outcome ""not recovered"", described as ""Breathing problems- sent to hospital a few times"". The patient was hospitalized for dyspnoea (hospitalization duration: 1 day(s)). The event ""breathing problems- sent to hospital a few times"" was evaluated at the physician office visit and emergency room visit. Therapeutic measures were not taken as a result of dyspnoea. The lot number for bnt162b2 was not provided and will be requested during follow up."
<u>1943401-1</u>	10 days later, I developed generalized uticaria-type rash. Painful, itching. I developed swelling to joints, and pain. I developed throat pain and Shortness of breath. My HR was fast, at 150. I had to be hospitalized and placed on IV Solumedrol and Benadryl for 4 days. I was then discharged on Oral Prednisone, Atarax, and Singulair.
<u>1947308-1</u>	Appendicitis
<u>1947946-1</u>	Upper body / chest / arm / shoulder / back pain. Diagnosis: Primary Sternal Osteomyelitis
<u>1948184-1</u>	Left lower quadrant abdominal pain. Diverticulitis of intestine with abscess and rupture treated with bowel rest and IV antibiotics, blood transfusion, 7 day hospital stay(12/6/21-12/12/21), and discharged home on antibiotics and follow-up care.
<u>1952445-1</u>	Three months after receiving the second dose of the vaccine, I was admitted into the ICU (September 7th, 2021) and treated for being in DKA. My blood sugar was +500, and A1C was 12.6 and estimated by doctors that my average blood sugar for the past 3 months was 300. My thyroid hormone levels also pointed to hypothyroidism. I was given 2 kinds of insulin and levothyroxine to take daily. Later, I was officially diagnosed with Type 1 Diabetes and Hashimotos disease.

VAERS ID	Adverse Event Description
<u>1955664-1</u>	Got the vaccine in April,. 2021. I don't have any underlying conditions at time of vaccine. On or around June 25 I experienced a very severe dizzy spell while driving the likes of which I have NEVER experienced. It managed to clear up with continual heavy breathing and just trying to get O2 in my body and specifically my head. Also experienced gradual shortness of breath just walking around which I thought was unusual on June 26-27. On the night of June 28th I experienced lower leg cramps in calf and foot area like I have never felt before. On the morning I woke up and couldn't breath properly. Off to hospital. Blood clots both lungs and left leg. Surprise.
<u>1962851-1</u>	"About 36 hours after my dose, or the 2nd night, I woke up at 6am with a racing heartbeat of 90-100 beats per minute. My normal sleeping heart rate is in the mid to high 40's, or low 50's. I had no idea why my heart was racing at 90-100 beats per minute but I quickly realized there was something wrong. Waiting at the hospital waiting room it was consistently around 83 bpm, very high from my normal resting heart rate of 53. I also had some vague chest tightness but only for a few moments, and a vague pain, again, only for a few moments. Mostly very rapid heart rate that lasted for HOURS. and a lot of shortness of breath. They did tests for some hours and could not find anything officially heart-wise and as I was laying there trying to relax my heart rate came down slightly, into the 70's and touching 69 I was lay still and as relaxed as I could, so they discharged me. Back in the car my bpm was back in the 80's as I was no longer laying down and while driving home back to 100ish, but I felt a bit better knowing I wasn't having a life threatening issue in the moment. I was fortunately able to sleep, making sure to keep my arm at my side in bed and not putting even 1 bit of pressure on my chest, and not sleeping on my side or my chest, as I slept on my side that night of the problem and that is when my heart started fluttering I believe. So if I lay in bed on my back and lay completley still, I have been able to sleep and not feel wierd chest feelings as I normally might. But the scariest part now is the extreme shortness of breath. The first day after (day 3 from shot - Thursday, shot was Monday at 4:30pm) I could barely go 5 steps without being completely winded. I could barely go up or down stairs, or do much of anything. Each day I get just slightly..better...as now on day 5 I can go up the stairs in only 1 minute...instead of 2. I still have to go step by step and it feels like I am climbing a mountain and then am very tired and must rest. I am hoping I continue to get better but I am very concerned if this will have any long term health effects for me, as that is the entire reason why I avoided covid to such a great degree, as I knew I had some kind of allergic asthmya like condition perhaps, but not officially asthmya (that I know of.) Presently now Sunday night day 6, my heart rate is often in the 70's although when sleeping and resting it does go down to mid 40's during sleep and 50s sometimes when still. but other times sitting still it can be 70's or 80's which is abnormal and my ox level often goes to down to 93, while I am sitting and doing no movement. It also often says 96 or 97, again while doing...nothing. and being still. While walking just a few steps it went down to 89 on the first or 2nd day. I have not exerted myself much as I cannot much, and out of fear of creating another problem, or something worse. I was givin no treatment and they told me I had ""stress"", which clearly I do not, I was as relaxed as possible which thankfully brought the bpm down to 69/70's range, but for me that is still much elevated and I knew something was not right, but I understood that they likely could not find anything and it was getting busier and they likely had to fill the beds with others. I am on day 6 and this feels like it could last likely weeks, or months, again, I have been given no medication and have no diagnosis and medical professionals and been of very little help, besides doing some tests and watching me during the intial heart rate issue. This issue must be studied much more to understand what is happening and it is unacceptable that not enough people know these risks."
<u>1967265-1</u>	After second COVID vaccination by Pfizer. Cardiac pain, NSTEMI caused by pericarditis.Required hospitalization and transfer to higher level hospital. Undergoing cardiac rehab presently. In shape hiker prior to vaccine .Able to hike at elevations over 12000 feet . Now am in cardiac rehab because I can't breathe due to pericarditis caused by this vaccine . My lifestyle has been ruined, thanks to Pfizer. It's been 6 months of tests and rehab and I'm still not able to even jog for 30 seconds.
<u>1975332-1</u>	Intense ?coffee grind vomit? 12 days no food/water Chest racing Feeling of hollowness in chest Zofran for a few crackers during two separate 15 days total hospitalization 6/7/15 hospital and 10/28-11/2 other hospital No fluid while hospitalized had iv and now I have no veins left from weeks with many iv
<u>1980906-1</u>	Pulmonary Embolism Symptoms: Shortness of breath when climbing stairs. Pulse Oxygen level 85% prompted visit to Emergency room. Symptoms thought to be COVID but tests during ER visit showed negative COVID result but Pulmonary Embolism in both lungs found.
<u>1981107-1</u>	Major hemorrhagic stroke
<u>1981702-1</u>	10/26/21 patient received 3rd dose (booster) of pfizer covid-19 vaccine. 11/10/21, patient presented to ED after syncopal event while eating, had been feeling unwell for a few days prior to admission. Upon arrival to ED, during PIV placement, patient vagal'ed and was in complete heart block, bradycardic, this degenerated into asystole and cardiac arrest. Concurrent with the arrest was loss of consciousness, posturing, upward gaze and deep erratic respirations, ROSC ensued. Post arrest ECG showed Sinus tachycardia with ST elevations, Troponin elevated to 108, patient brought emergently to cardiac cath lab. There she received PCI to LAD for 100% occlusion (drug eluting stent x 1), transvenous pacemaker placement for complete heart block, and had an intra-aortic balloon pump placed for acute heart failure EF 27%. She was hospitalized until 11/18/21, when she was discharged home on heart failure medications with presumed ischemic cardiomyopathy. Follow up outpatient ECHO on 12/22/21 showed worsening Ejection Fraction to 15% and a moderate to large pericardial effusion with tamponade physiology and she was re-admitted to the hospital. She was taken emergently to the OR for cardiac tamponade on 12/26/21 and remains admitted.
<u>1988824-1</u>	My blood pressure immediately spiked. My whole body felt tingly, warm and I felt light headed. The nurses kept me there and monitored me for almost an hour. I did not want to go to the hospital. The week after I kept calling my primary doctor saying I didn't feel well. Even though my Primary doctor originally told me not to get the vaccine, and I went against him and got it to make it easier to travel for me. I had the antibodies because my family and I had covid in the beginning on March 2020 very badly. My doctor kept disregarding my chest pains and left arm pains and numbing sensation. I ended up admitting myself to ER 3 weeks later. And I was instructed to follow up with a cardiologist.
<u>1999156-1</u>	On 11/21/2021, at 6 PM, I developed a rapid and irregular heartbeat of 120 (as per at home blood pressure machine). I went to the local Medical Center ER at 9 PM. An IV was started, I was placed on a heart monitor, a Lovenox injection was given, a chest X-ray and blood work was done. When my heart rate did not slow on its own, I was place on a Cardizem IV drip. I was admitted to the hospital at approx. 2 AM. I remained on the Cardizem drip until mid-morning, when it was determined that my heart rate had slowed. I was started on Eliquis 5 mg on Monday, 11/22/2021. I remained in the hospital until 6 PM on 11/23/21 when I was discharged. I am to remain on Eliquis for the foreseeable future.
<u>1999191-1</u>	Patient received Covid-19 Vaccine, mRNA, Bnt162b2, Lnp-S (Pfizer) on March 8, 2021 batch # EN6205 and second shot on March 29, 2021 Batch# ER8727. Admitted to Hospital, April 6, 2021- DIAGNOSIS double pneumonia, kidney failure, lung disease, heart failure. Sepsis. Discharged April 12, 2021. Cardio appointment April 14, 2021 - progress good. Admitted to ER April 16, 2021, Extreme hypoxemia (71), difficulty breathing. Intubated in ICU on April 17, 2021, given last rites. Needs higher quality of care. Airlifted to ICU April 20, 2021- June 4, 2021 DIAGNOSIS: ACUTE HYPOXEMIC RESPIRATORY FAILURE, PERSISTENT ATRIAL FIBRILLATION WITH RVR, ACUTE KIDNEY INJURY, HYPERNATREMIA, GRANULOMATOSIS WITH POLYANGITIS WITH MULTISYSTEM INVOLVEMENT, INTRA-ALVEOLAR HEMORRHAGE, VOLUME OVERLOAD, VANCOMYCIN-RESISTANT ENTEROCOCCI (VRE), INFECTION due to ESBL-producing Klebsiella pneumoniae, SEPSIS
<u>2014155-1</u>	2 strokes, irregular heartbeat, enlarged heart muscle, clotting
<u>2019850-1</u>	Difficulty breathing, white spots in throat, swollen lymph node, high 104 degree fevers that persisted for 9 days, was put on antibiotics without any relief.
<u>2024412-1</u>	Severe panic attack, Suicidal ideation

VAERS ID	Adverse Event Description
2028634-1	On 3/3/21 I received my second Moderna vaccine on 3/12/21 I felt severe chest and back pains on 3/14/21 intermittently which continued and became more severe. I was unable to lay down without experiencing excruciating pain on the right side of my chest. I was transported via ambulance to Hospital and admitted with a Pulmonary Embolism. I had no prior history of blood clots. It was determined that the cause of my blood clots may have been a reaction to the Covid vaccine. There is no other evidence from all follow up tests and doctor's visits to say otherwise.
2031518-1	Hospitalized for Pulmonary embolisms
2038292-1	Chest pain, heart pain, tachycardia
2043721-1	Acute myocarditis Assessment & Plan Status post recent Moderna vaccination x1 Developed symptoms shortly Status post cardiac cath with no intervention clean coronaries Troponins elevated will trend Consulting ID as well for their expert opinion NSTEMI (non-ST elevated myocardial infarction) Assessment & Plan Trend troponins Secondary to myocarditis status post recent vaccination Cardiology on consult. Status post cath with no intervention Will monitor, likely hydrate gently and await further recommendations Patient is a 18 y.o. male with no pmhx here w/ cp s/p receiving 1 dose of moderna recently. Pt had severe cp after vaccine along with feeling feverish, bodyaches. Says went to dentist the following day and pain radiated to jaw. Was sent in and had cardiac cath via groin with no intervention or findings; pt dx w/ acute myocarditis post covid vaccine.
2047690-1	Myocardial and pulmonary embolism
2047733-1	Pulmonary Embolism
2054190-1	Fever for a week up to 104 at one point, chills, body aches, pain on entire left side of body, lump and rash at the site of injection, loss of consciousness and seizure. Went to hospital and released same day. Continued with rest, Advil and Tylenol and was better a week later.
2064420-1	A few days after the 2nd shot, fatigue set in and continued getting worse as time went on. Finally went to my PCP and he ran tests and I was in kidney failure. This was June 3, 2021. Was on emergency dialysis within 12 hours. I had an AKI. I have never had any kidney issues ever in my life.
2075598-1	Patient developed MIS-C (fever, rash, abdominal pain, eye changes, extremity changes, myocarditis). Symptoms starting Jan 23, 2022. Had laparoscopic appendectomy 1/28/2022 then developed cardiogenic shock. Currently recovering after anti-inflammatory treatment.
2080060-1	Moderna COVID vaccine - 1 dose in March 2021 and 1 dose in April 2021. In June 2021, pt diagnosed w/ Epstein-Barr virus. Then starting 11/1/2022, pt developed transverse infectious myelitis, L4-L5 vertebrae. Hospitalized 3 times. numbness in muscles on most of body making him unable to walk without assistance or perform activities of daily living, fecal and urinary incontinence, high fevers, shivering, and UTI with pseudomonas aeruginosa, kidney stones, ureter stent (now removed), multiple IV courses including Zosyn (3 courses). Pt has had 2 ablations for Atrial Fibrillation since being vaccinated for COVID. Pt has home health care coming in for activities of daily living, physical therapy coming to home, psychology consult for depression coming up. Pt just got IV line PIC line put in for cefepime antibiotic infusion therapy to be given at home.
2088245-1	Takotsubo cardiomyopathy, heart failure, arrhythmia, sudden death
2091752-1	Heart Failure
2098491-1	Slurred speech, R sided paralysis: STROKE
2102749-1	heart inflammation, pericardial effusion, inflammation of the heart, fluid drained from heart. on January 7th, 2022. I am a healthy person, eat correctly, exercise, into fitness, in martial arts, i had a healthy heart, and no health problems at all. since the vaccines, i have been getting colds, and cough. off and on. i never had covid at all either. I had a procedure on January 7th 2022 where fluid collected around my heart and right lung. i went to see the blood doctor, a rheumatologist and a cardiologist, and my regular doctor, none of them can figure out why this happened to me.
2105918-1	Difficulty breathing caused by a myasthenia exacerbation (has never happened before after over 40 yrs of having myasthenia). Hospitalized after 2 weeks, when oral meds didn't work. Received IVIG treatment in the hospital x5 consecutive days. Received IVIG treatment at home every 2 weeks for 3 months. Out of work for 2 and 1/2 months, transitioned back to 1 day/ week x 1/2 month, then 2 days/ week x 1 month, then 3 days/ week x1 month, and just began 4 days/ week this month. Also experiencing ongoing fatigue.
2109045-1	"anaphylaxis; seizure; hives; Covid test date=19Jan2022, Covid test result=Positive; Covid test date=19Jan2022, Covid test result=Positive; This is a spontaneous report received from a contactable reporter (Other HCP). The reporter is the patient. A 37-year-old female patient (not pregnant) received bnt162b2 (BNT162B2), administered in arm right, administration date Jan2021 (Batch/Lot number: unknown) at the age of 37 years as dose 1, single for COVID-19 immunisation. Relevant medical history included: Polycystic ovarian syndrome ("PCOS") (unspecified if ongoing); Gastroesophageal reflux disease ("GERD") (unspecified if ongoing); "known allergies: shellfish" (unspecified if ongoing); "known allergies: nuts" (unspecified if ongoing); "known allergies: figs" (unspecified if ongoing); "known allergies: pollen" (unspecified if ongoing); "known allergies: eggs" (unspecified if ongoing), all notes: known allergies: shellfish, nuts, figs, pollen, eggs. Concomitant medications included: OMEPRAZOLE; METFORMIN. The following information was reported: ANAPHYLACTIC REACTION (hospitalization, medically significant, life threatening) with onset 20Jan2021, outcome "recovered with sequelae", described as "anaphylaxis"; SEIZURE (hospitalization, medically significant, life threatening) with onset 20Jan2021, outcome "recovered with sequelae", described as "seizure"; URTICARIA (hospitalization, life threatening) with onset 20Jan2021, outcome "recovered with sequelae", described as "hives"; DRUG INEFFECTIVE (medically significant), COVID-19 (medically significant) all with onset 19Jan2022, outcome "unknown" and all described as "Covid test date=19Jan2022, Covid test result=Positive". The events "anaphylaxis", "seizure" and "hives" were evaluated at the physician office visit and emergency room visit. The patient underwent the following laboratory tests and procedures: Nasal Swab: (19Jan2022) positive. Therapeutic measures were taken as a result of anaphylactic reaction, seizure, urticaria, which included epinephrine (EPIPEN). Clinical course: Facility type vaccine: Hospital. The patient did not receive any other vaccines within four weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. The lot number for 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 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."
2116088-1	Arterial Blood clots in both legs and descending aorta
2122793-1	Sick a few days later intense pain in stomach, after testing found a clot in deep vein, never had any clots.

VAERS ID	Adverse Event Description
<u>2131561-1</u>	11/3/21 booster vaccine received half dose: more severe headache lasting til stroke on Sunday, 11/07/2021; mild fever first day or two after booster, body aches at least Wednesday, 11/03/2021 to Saturday, 11/06/2021. Numbness and tingling in tip, lateral border and dorsal surface of tongue, maxillary and mandibular lips, hard palate, all on the left side beginning at 3:47PM, Sunday 11/07/2021. Numbness also in pads of fingers, left hand. Did have mild tingling in face on left, and post-auricular on left side as well. Taken by EMTs to Medical Center. Had CT, CTA, MRI BLOODWORK, EKG, ECHOCARDIOGRAM. Diagnosis: stroke, Treatment: PLAVIX (300 mg, THEN 75 MG DAILY), 21 DAY Adverse event Continued Crestor 30mg daily beginning 11/08/2021 also instructed by neurologist to take 81 mg aspirin in addition to the 2 other medications. Discharged Tuesday 11/9/2021 Cardiologist and neurologist in private practice. Followed up with specialist within days of event. CONTINUE TO HAVE NUMBNESS IN THE SAME LOCATIONS ON LEFT TIPS, TONGUE, HARD PALATE AND SEVERAL TIPS, DIFFERENT TYPE OF HEADACHES SINCE STROKE SINCE STROKE EXTREME FATIGUE. Records available from hospital.
<u>2139974-1</u>	multiple brain infarcts
<u>2148213-1</u>	My dad had COPD and that is the reason why he took the vaccine to protect his lungs. 4 months after taking 2 shot of this horrible vaccine he developed severe leg and joint pain in the right leg. he was unable to walk and breathe properly. On Jan 1, 2022 my dad was rushed to the hospital by ambulance because he could not breathe. Upon entering hospital I had to authorize my father to be intubated because he had gotten covid 19 or he would die. On Jan 5th he was taken off life support and was put on a covid floor for 3 weeks. They had discovered a blood clot in the right leg, lungs were continuously filling up with fluid and he could not get his breathing normalized. He then had to be intubated again on Jan 29th his birthday and started declining rapidly. On Feb 2nd my dad went into cardiac arrest and never had heart issues prior. He was still intubated and now his blood pressures, heart rate, breathing and organs started failing rapidly. He was then placed on Feb 7th on a CRRT machine for his kidneys and the on Feb 8th he passed away going into cardiac arrest again and having multi system organ failure, covid 19, and lungs not working anymore. Due to this my father had passed away at 1:37 pm on Feb 8th, 2022. He never had any issues like this before only after he took your horrible vaccine and your vaccine killed my father. He was otherwise healthy and only had COPD which was fully controlled by his pulmonologist. I want answers!!! Now to this day I have to live without my father because of this so called innoculation!!!! it was suppose to protect him and not have him hospitalized and intubated but it was proven not effective for him and probably for many others. Thank you for not taking care of the elderly people now I dont have my dad with us anymore and you dont realize what this has done to my family.
<u>2148245-1</u>	"Brain fog started around 1 week after vaccine, then continued with progressive worsening up through 3 weeks after. Patient was ""zoning out"", ""staring at walls"", struggling to concentrate, getting lost several times on routine drives, struggled to perform work duties and communicate, etc. Patient reported significant worsening of depression symptoms, whether direct or indirect (due to brain fog and not being ""in control"" of own mind): ""crying multiple times a day for weeks"" and increased suicidal ideation with plan."
<u>2148498-1</u>	Ruptured Cerebral Aneurysm Left Middle Cerebral Artery Circulation (02/25/2022) leading to death (02/27/2022)
<u>2150900-1</u>	2nd covid booster with moderna for first time, I am a diabetic type 2, Blood sugar levels have doubled since receiving the moderna vaccine and not responding to increased insulin.
<u>2152365-1</u>	HEART ATTACK 2 BLOCKAGES WITH BLOOD CLOT IN EACH, 1 STENT WAS PERFORMED, DOUBLE BYPASS SURGERY WAS NEEDED AND PERFORMED AT MEDICAL CENTER ON DECEMBER 6, 2021. NO HISTORY OF PRIOR HEART DISEASE.
<u>2163509-1</u>	SOB Bronchospasm
<u>2170684-1</u>	After taking the second Pfizer vaccine, I experienced drop foot on my left leg while walking. It's been around 9 months and still experiencing the same.
<u>2194332-1</u>	Within 24 hrs I started having weakness in my legs, that was wed. P.m., thurs., fri., sat., sun., had extreme weakness in legs and severe shortness of breath. Saw dr on that Mon., he did an EKG I was in total v-tack, he called for ambulance, taken to hospital. Released on wed nite, echo car diagram showed no heart problem, I have also had a heart mri which results were perfect. In other words this booster sent me to the hospital in a dire condition. I was put on heart meds to be taken till heart MRI which made my hair fall out in clumps
<u>2200826-1</u>	DKA. Headache, vomiting, abd pain, hyperglycemia, acidosis.
<u>2207361-1</u>	Myocarditis...heart inflammation...full cardiac arrest...brought back by CPR On ventilator for 6 days and ECMO...in hospital for 15 DAYS PERMANENT DEFIBRILLATOR INPLANT...ONLY GIVEN 1% CHANCE OF SURVIVAL. VISITING NURSE AND OCCUPATIONAL THERAPY AND JUST FINISHED CARDIAC REHAB 6 MONTHS...DESTROYED MY LIFE!!
<u>2213941-1</u>	Bilateral pulmonary emboli-hospitalized on January 21, 2022 X 2 days. Currently taking Eliquis 5mg BID Also has discolored circular large ring on arm at the injection site
<u>2216389-1</u>	left transverse and sigmoid sinus thrombosis
<u>2220532-1</u>	STROKE, CVA, blood clot in brain; carotid artery-- medication, blood thinners and rehab--left side weakness, neglect; left paralyzed on left side- leg and arm and hand L in-patient rehab for 5 weeks; hospitalized 2 weeks before that; consistent therapy to regain ability continues to date-- I have an ongoing bill at hospital that to date, is more than \$1000. I dont know how I'll ever pay that.
<u>2237887-1</u>	"Within 4 weeks developed a severe DVT in right leg and multiple pulmonary emboli bilaterally in both lungs; Within 4 weeks developed a severe DVT in right leg and multiple pulmonary emboli bilaterally in both lungs; This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP). The reporter is the patient. A 54-year-old male patient received BNT162b2 (BNT162B2), on 27Dec2021 as dose 3 (booster), single (Lot number: FG3527) at the age of 54 years for covid-19 immunisation. The patient's relevant medical history included: ""Sleep apnoea syndrome"" (unspecified if ongoing). The patient's concomitant medications were not reported. Vaccination history included: moderna (Prev dose product=COVID 19, Prev dose brand=Moderna, Prev dose brand unknown=False, Prev dose lot number=019821A, Prev dose lot unknown=False, Prev dose administration date=09Apr2021, Prev dose number=2), administration date: 09Apr2021, when the patient was 53-year-old, for COVID-19 Immunization; moderna (Prev dose product=COVID 19, Prev dose brand=Moderna, Prev dose brand unknown=False, Prev dose lot number=03021A, Prev dose lot unknown=False, Prev dose administration date=12Mar2021, Prev dose number=1), administration date: 12Mar2021, when the patient was 53-year-old, for Covid-19 immunization. The following information was reported: PULMONARY EMBOLISM (hospitalization, disability, medically significant, life threatening), DEEP VEIN THROMBOSIS (hospitalization, disability, medically significant, life threatening) all with onset 26Jan2022, outcome ""not recovered"" and all described as ""Within 4 weeks developed a severe DVT in right leg and multiple pulmonary emboli bilaterally in both lungs"". The patient was hospitalized for pulmonary embolism, deep vein thrombosis (hospitalization duration: 7 day(s)). The events ""within 4 weeks developed a severe dvt in right leg and multiple pulmonary emboli bilaterally in both lungs"" required physician office visit and emergency room visit. The patient underwent the following laboratory tests and procedures: SARS-CoV-2 test: (01Feb2022) Negative. Therapeutic measures were taken as a result of pulmonary embolism, deep vein thrombosis. Clinical course: Treated with Heparin by IV and Eliquest for up to 1 year. No covid prior vaccination. No known allergies. No follow-up attempts are needed. No further information is expected."
<u>2274609-1</u>	after getting vaccine in 10 days minor symptoms light eachy rednees after 15 days getting severe allergyic reaction whole body spot eachy readness when i each swelling whole body all body is severe eachy last time also happen same thing when i took second doose coming same allergyic reaction its stay 6 month i am taken everyday medicine hardly after 6 month gone

VAERS ID	Adverse Event Description
<u>2277559-1</u>	<p>"Adrenal crisis secondary to Covid-19 vaccination in patient with hypopituitarism; This is a literature report for the following literature source(s). A 74-year-old male patient received BNT162b2 (BNT162B2), in Mar2021 as dose 2, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history included: ""hypopituitarism"" (ongoing); ""significant for prolactinoma"" start date: 1980 (unspecified if ongoing); ""surgical resection"" start date: 1980 (unspecified if ongoing); ""hormone replacement therapy"" (unspecified if ongoing), notes: subsequent hypopituitarism; ""diabetes mellitus type 2"" (ongoing); ""essential hypertension"" (ongoing). The patient's concomitant medications were not reported. Past drug history included: Hydrocortisone for hypopituitarism, notes: 10 mg twice daily; Levothyroxine for hypopituitarism, notes: 150 mcg daily; Desmopressin for hypopituitarism, notes: 0.1 mg half of tablet twice daily; Testosterone gel for hypopituitarism; Glargine for diabetes mellitus, notes: 20 units at bedtime; Insulin for diabetes mellitus, notes: diabetes mellitus; Glipizide for diabetes mellitus, notes: 2.5 mg twice daily; Sitagliptin for diabetes mellitus, notes: 100 mg daily. Vaccination history included: BNT162b2 (1st dose), administration date: 09Mar2021, for Covid-19 vaccination. The following information was reported: ADRENOCORTICAL INSUFFICIENCY ACUTE (hospitalization, intervention required, medically significant, life threatening), outcome ""recovering"" described as ""Adrenal crisis secondary to Covid-19 vaccination in patient with hypopituitarism"". The event ""adrenal crisis secondary to covid-19 vaccination in patient with hypopituitarism"" required emergency room visit. The patient underwent the following laboratory tests and procedures: Angiogram: negative, notes: for any acute central 61 nervous system (CNS) pathology; Bacterial test: negative; Blood alcohol: undetectable; Blood cortisol: 1.91 ug/dL; Blood glucose: 20 mg/dl; 143 mg/dl, notes: Workup in the ED; Blood pressure measurement: 145/84 mmHg; 107/71 mmHg, notes: subsequently decreased; Blood thyroid stimulating hormone: 0.006, notes: UIU/ml; Body temperature: 103.5 Fahrenheit, notes: Fever; Computerised tomogram head: negative, notes: for any acute central nervous system (CNS) pathology; CSF test: within normal limits; Full blood count: normal; Heart rate: 105, notes: Units:beats/minute; Metabolic function test: normal; physical exam: The patient was stuporous, notes: responsive only to painful stimuli with no focal deficit; Thyroxine free: 1.90 ng/dL; Urine analysis: negative; Viral test: negative. Therapeutic measures were taken as a result of adrenocortical insufficiency acute. Clinical course included: Patient received his first dose of Covid-19 mRNA vaccine (BNT162b2) on 9Mar2021 and the second dose of the same vaccine 3 weeks after first dose at 1pm and within few hours experienced lethargy and confusion. Overnight patient developed fever which was treated with acetaminophen. The next day, patient was unable to converse, was more somnolent and sleeping for more than 24 hours. Patient did not have any recent sick contact, travel, change in medications or illicit drug use. During first day of hospital stay lumbar puncture was done and cerebrospinal fluid analysis was within normal limits with negative viral and bacterial cultures. Patient has been started on parenteral glucocorticoids and after 24h of intravenous hydrocortisone 50 mg every 6 hours patient had significant improvement in mental status, became more awake, oriented to himself, place and eventually time. Patient has been discharged on oral hydrocortisone with plan to taper the dose down to his maintenance dose. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: As there is limited information in the case provided, the causal association between the events Adrenal Crisis and the suspect drug cannot be excluded. The case will be reassessed once new information is available. ,Linked Report(s) : US-PFIZER INC-202200640343 Same article/ drug/event and different patient:"</p>
<u>2290013-1</u>	RARE PORTAL VEIN THROMBOSIS , EXTREM INFLAMMATION, DISCOVERED AFTER RARE AND NEVER EXPERIENCED GASTROINTESTINAL EVENT TOOK ME TO HOSPITAL ENTIRELY HEALTH 57 YEAR OLD WOMAN NO HISTORY OF ANY HEALTH ISSUES
<u>2316662-1</u>	Induced Acute interstitial lung disease Pulmonary Fibrosis
<u>2339447-1</u>	Failed echocardiogram, failed stress test, heart catheterization with 2 stents implanted.
<u>2371493-1</u>	<p>"Acute Lymphoblastic Leukemia; appetite reduced; This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP). A 5-year-old male patient received BNT162b2 (BNT162B2), on 10May2022 at 14:00 as dose 2, single (Lot number: FI8094) at the age of 5 years, in left arm for covid-19 immunisation. The patient had no relevant medical history. The patient's concomitant medications were not reported. Vaccination history included: BNT162b2 (DOSE 1, lot number FI8092, dose administration time 3:00 PM, vaccine location Left arm), administration date: 19Apr2022, when the patient was 5-year-old, for COVID-19 Immunization. No other vaccine in four weeks. No covid prior vaccination. No covid tested post vaccination. No Known allergies. The following information was reported: ACUTE LYMPHOCYTIC LEUKAEMIA (hospitalization, life threatening) with onset 12May2022, outcome ""unknown"" described as ""Acute Lymphoblastic Leukemia""; DECREASED APPETITE (hospitalization, life threatening) with onset 12May2022, outcome ""unknown"" described as ""appetite reduced"". The events ""acute lymphoblastic leukemia"" and ""appetite reduced"" required emergency room visit. The patient underwent the following laboratory tests and procedures: Blood test: (Oct2021) growth are all normal, notes: Child was 100% healthy and previous blood reports Oct2021. Therapeutic measures were taken as a result of acute lymphocytic leukaemia included Chemotherapy. After receiving COVID vaccine, kids appetite reduced and after a month kid diagnosed ""Acute Lymphoblastic Leukemia""."</p>
<u>2374739-1</u>	On July 3 2022 in the evening I started to feel sick. I woke up middle of the night I woke up dizzy and fainted. I did an at home COVID-19 on July 4 2022. From then I got sicker. I couldn't eat or drink with nausea. Then I thought I was getting better. I spoke with my doctor and they told me to go to the emergency room. I went to the emergency room on July 11 2022. I was hooked up with fluids. I have never been that sick. I had a CT of my face, chest x-ray, and EKG at the emergency room. I was given Zofran. I was sent back home from the emergency room the same day with Zofran. I still a cough and congestion today. The fatigue lasted about one week.
<u>2390957-1</u>	1st morning after shot I woke up on floor with lump on chin and urinated pants. Same the 2nd morning after vaccination except lump on forehead. 3rd morning after vaccine I became light headed dizzy, had to pull over to store parking lot. 3 state police arrived after I had seizure like episode inside the store. These events have never happened before in my life happened the first 3 mornings after my 1st and only dose. 3 less severe mild but similar incidents since.
<u>2403508-1</u>	I hate to be one of these people. But, I dont smoke, drink, do drugs and live a healthy active lifestyle. Cancer does not run in my family and I am not exposed to paint or chemicals. I was diagnosed with high grade t1 kidney and bladder cancer in July 2022. Symptoms started around May. Last June I did get a kidney stone which is rare for me as well. Again, not a crazy blame vaccine person but this seems very odd.

VAERS ID	Adverse Event Description
<u>2405461-1</u>	<p>"they had two patients that recieved the Diluted Maroon Pfizer Covid 19 Vaccine past the 12 hour window in the fridge after first puncture; they had two patients that recieved the Diluted Maroon Pfizer Covid 19 Vaccine past the 12 hour window in the fridge after first puncture; This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP) from medical information team. A 2-year-old female patient received BNT162b2 (BNT162B2), on 04Aug2022 as dose 1 (maroon cap), single (Lot number: FT9142, Expiration Date: 04Oct2022) at the age of 2 years intramuscular, in right deltoid for covid-19 immunisation. The patient had no relevant medical history. The patient's concomitant medications were not reported. The following information was reported: POOR QUALITY PRODUCT ADMINISTERED (life threatening), PRODUCT ADMINISTRATION ERROR (life threatening) all with onset 04Aug2022 and all described as ""they had two patients that recieved the Diluted Maroon Pfizer Covid 19 Vaccine past the 12 hour window in the fridge after first puncture"". Therapeutic measures were not taken as a result of poor quality product administered, product administration error. Clinical course: It was reported as Per caller they had two patients that received the Diluted Maroon Pfizer Covid 19 Vaccine past the 12 hour window in the fridge after first puncture. The caller reports it was probably another 9 hours. Per caller the fridge was at 38.8F. Received the vaccine after 12 hours of puncture in the refrigerator and it was probably another 9 hours after those 12 hours when they were left in the refrigerator. Maroon cap Pfizer Covid vaccine for ages 6 months to 4 years old a Pfizer product. One patient was a female age 2 years old and the other was a male patient age 3 years old so he wanted to report this. Agent provided the caller with the off label information for the additional 12 hours for a total of 24 hours if they choose to use that and the refrigerator temperature was 38.8 degrees Fahrenheit. 59267007801 was NDC number of maroon cap Pfizer Covid vaccine for ages 6 months to 4 years old. No follow-up attempts are possible. No further information is expected."</p>
<u>2405468-1</u>	<p>"they had two patients that recieved the Diluted Maroon Pfizer Covid 19 Vaccine past the 12 hour window in the fridge after first puncture; they had two patients that recieved the Diluted Maroon Pfizer Covid 19 Vaccine past the 12 hour window in the fridge after first puncture; This is a spontaneous report received from contactable reporter(s) (Other HCP) from medical information team. A 3-year-old male patient received BNT162b2 (BNT162B2), on 04Aug2022 as dose 1 (maroon cap), single (Lot number: FT9142, Expiration Date: 04Oct2022) at the age of 3 years intramuscular, in left deltoid for covid-19 immunisation. The patient had no relevant medical history. There were no concomitant medications. The following information was reported: POOR QUALITY PRODUCT ADMINISTERED (life threatening), PRODUCT ADMINISTRATION ERROR (life threatening) all with onset 04Aug2022 and all described as ""they had two patients that recieved the Diluted Maroon Pfizer Covid 19 Vaccine past the 12 hour window in the fridge after first puncture"". Clinical course: Per caller they had two patients that received the Diluted Maroon Pfizer Covid19 Vaccine past the 12 hour window in the fridge after first puncture. The caller reports it was probably another 9 hours. Per caller the fridge was at 38.8F. Caller asking for stability guidance. No other Conditions, Investigations and other products. NDC number of maroon cap Pfizer Covid vaccine for ages 6 months to 4 years old: 59267007801. A medical assistant on the line calling about the maroon cap Pfizer Covid vaccine for ages 6 months to 4 years old and had two patients that received the vaccine after 12 hours of puncture in the refrigerator and it was probably another 9 hours after those 12 hours when they were left in the refrigerator and one patient was a female age 02-year-old and the other was a male patient age 03-year-old so he wanted to report this; agent provided the caller with the off label information for the additional 12 hours for a total of 24 hours if they choose to use that and the refrigerator temperature was 38.8 degrees Fahrenheit. Patient did not require treatment for the reported event. Last height and weight from Dec2021 and he was 35 inches in height and 27 pounds."</p>
<u>2405506-1</u>	<p>"diagnosed with myasthenia gravis/trouble with her vision; This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP). The reporter is the patient. A 59-year-old female patient (not pregnant) received BNT162b2 (BNT162B2), on 30Apr2021 at 01:15 as dose 2, single (Lot number: EP6955) at the age of 59 years, in left arm for covid-19 immunisation. The patient had no relevant medical history. Concomitant medication(s) included: PREVACID. Vaccination history included: BNT162b2 (DOSE 1, lot number EP7533, at 09Apr2021 12:00 PM, vaccine location Left arm), administration date: 09Apr2021, when the patient was 59-year-old, for COVID-19 immunization. The following information was reported: MYASTHENIA GRAVIS (caused and prolonged hospitalization, disability, life threatening) with onset 07May2021 at 13:15, outcome ""recovering"", described as ""diagnosed with myasthenia gravis/trouble with her vision"". The patient was hospitalized and prolonged hospitalization for myasthenia gravis (hospitalization duration: 25 day(s)). The event ""diagnosed with myasthenia gravis/trouble with her vision"" required physician office visit and emergency room visit. The patient underwent the following laboratory tests and procedures: Blood test: (2021) myasthenia gravis; Lab tests: (2021) Nothing wrong. Therapeutic measures were taken as a result of myasthenia gravis. Clinical course: No other vaccine in four weeks. No covid tested prior and post vaccination. No Known allergies. Within a week of receiving the second dose, patient had trouble with her vision. She saw her eye doctor, nothing wrong, she saw her general practitioner, bunch of test, nothing wrong, saw a neurologist many many tests including a blood test where she was diagnosed with myasthenia gravis. AE treatment included Thyectomy, 17 plasmapheresis treatments."</p>

VAERS ID	Adverse Event Description
2416660-1	<p>RECURRENT SEVERE THROMBOCYTOPENIA; This spontaneous report received from a physician concerned a 75 year old male of unspecified race and ethnicity. The patient's weight was 148 kilograms, and height was 179 centimeters. The patient's concurrent conditions included: crohn's disease, non smoker, alcohol user (moderate), high blood pressure, indigestion, nausea, and sleep, and other pre-existing medical conditions included: Patient had no allergies and no history of drug abuse. The patient received combination product ustekinumab (solution for injection in pre-filled syringe, subcutaneous, batch number: KE5071OH expiry: 20-APR-2023, batch number: 21AO12MB expiry: 28-FEB-2024, batch number: LO57KMA expiry: 03-JAN-2024, and batch number: 21A142MC expiry: 04-JAN-2024) 90 mg, 1 time every 2 months, from 02-JUN-2021, 90 mg, 1 time every 2 months, from 07-OCT-2021, 90 mg, 1 time every 2 months, from 19-OCT-2021, and 90 mg, 1 time every 2 months, from 21-JUN-2022 for crohn's disease. Product constituent parts included ultrasafe passive (route of admin, lot, serial number, model number, UDI number, and expiration were not reported); and ultrasafe passive accessory (route of admin, lot, serial number, model number, UDI number, and expiration were not reported). All required follow-up attempts have been made. The Batch number for ustekinumab has not been provided. No concomitant medications were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin and batch number were not reported, expiry: unknown) dose, start therapy date were not reported, 1 total, administered for covid-19 prophylaxis. The batch number was not reported and has been requested. Concomitant medications included losartan for blood pressure, omeprazole for indigestion, ondansetron for nausea, and trazodone for sleep. Physician stated that 10 to 14 days after his patient takes his STELARA 90 mg injection, his platelet levels go down. The physician stated that the patient platelet levels were 125,000 prior to receiving ustekinumab. On 21-APR-2022, 10 days after receiving ustekinumab injection, patient's levels were at 28,000. On 25-APR-2022, patient's levels were at 34,000. On 20-MAY-2022, Laboratory data included: Platelet count 103. Physician stated that patient has shown signs of severe thrombocytopenia with platelet counts of 8000 and 10,000 (coded as recurrent severe thrombocytopenia). This has happened three times after three doses of ustekinumab. Patient had severe thrombocytopenia after the third maintenance dose of Stelara with platelet count dropping to 25000. It was initially attributed to covid vaccination and it returned to normal 120000 but after the fourth maintenance dose his platelet count dropped to 14. Patient developed thrombocytopenia after each of 3 subcutaneous injections of stelara 8 weeks apart. Stelara was discontinued and platelet count improved up to 103 on 20-MAY-2022. The action taken with covid-19 vaccine ad26.cov2.s was not applicable and treatment with ustekinumab was withdrawn. The patient had not recovered from recurrent severe thrombocytopenia. This report was serious (Life Threatening). This case, from the same reporter is linked to 20120512531, 20111202680 and 20040600797. Additional information received from nurse on 09-AUG-2022. The following information was updated and incorporated into the case narrative: All required follow-up attempts have been made. The Batch number for ustekinumab has not been provided, reporter (nurse as contact) added, Patient demographics (height weight) added, Lab data added, suspect product (Janssen covid-19 vaccine) added, product Stelara information (therapy dates, expiry dates, batch number for 4 doses added), concomitant drugs added, narrative updated.; Sender's Comments: V3: This follow up version updates- All required follow-up attempts have been made. The Batch number for ustekinumab has not been provided, reporter (nurse as contact) added, Patient demographics (height weight) added, Lab data added, suspect product (Janssen covid-19 vaccine) added, product Stelara information (therapy dates, expiry dates, batch number for 4 doses added), concomitant drugs added, narrative updated. MAC updated. 20220457359-covid-19 vaccine ad26.cov2.s-Recurrent severe thrombocytopenia. Follow-up received regarding Clinical Details. 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). Therefore, this event(s) is considered unassessable. 20220457359-Stelara-Recurrent severe thrombocytopenia. Follow-up received regarding Clinical Details. 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). Therefore, this event(s) is considered unassessable.</p>
2419503-1	<p>Left vertebral artery dissection diagnosed two weeks after vaccination. Initial symptoms: Eyes rolling and loss of vision followed by dizziness and weakness.</p>

VAERS ID	Adverse Event Description
2420177-1	<p>Excruciating lower back pain, unable to move or walk, pressure in my head Rushed to hospital via ambulance MRI done in ER; admitted to hospital MRI showed an epidural abscess L2-L5 Emergency surgery performed on Monday, April 26, 2021 - removal of epidural abscess and laminectomies L3 & L4 Sepsis with Methicillin Susceptible Staphylococcus Aureus (MSSA) in my bloodstream Multiple dots in upper extremities Discharged home with PIC line for 6-8 weeks of IV antibiotics. On April 20, 2021, I received my first Pfizer Covid-19 vaccine, at a local pharmacy. Two days later on Thursday April 22, 2021 I began to have pain in my lower back around 11:30 pm. I had traveled on Thursday morning for a celebration. I awoke at 4:00 am on Friday April 23, 2021, with not being able to walk without extreme pain in my lower back. I finally made it to the toilet and after releasing my bladder, I couldn't stand, felt nauseated and as if I were going to pass out. I lowered myself off the toilet onto the bathroom floor of the hotel and laid there in excruciating pain. I tried taking Motrin and putting ice on my lower back with no relief, finally I told my sister to call 911 that I needed to get to a hospital. EMS arrived shortly thereafter and I was taken to the hospital. There I was treated with an IV and pain medications. My daughter, a Physician Assistant, came to see me in the ER and spoke with the doctors; she was concerned that I may have cauda equina, (Cauda equina syndrome occurs when the nerve roots in the lumbar spine are compressed, cutting off sensation and movement. Nerve roots that control the function of the bladder and bowel are especially vulnerable to damage.) The doctors at the hospital said oh no worries she doesn't have it. The doctors offered to do an MRI or I could wait and do the diagnostic testing once I got home and follow up with a doctor in my home town. The doctors were treating me for sciatica. I was discharged from the hospital on Friday, April 23, 2021 in the afternoon, with muscle relaxants and anti-inflammatories. Sunday April 25th, 2021 I flew home not feeling well at all..I could hardly walk when all of sudden out of nowhere a young girl with a wheelchair comes up behind me and asks me if I needed assistance in the wheelchair, there was an angel watching down over me who sent this young lady to my rescue. She proceeded to push me in the wheelchair to my gate. The flight home is a blur as I was feeling so horrible. That evening around 11:00 pm I went up to bed to try and sleep but couldn't, I laid there in agony for about 2 hours; feeling as if my head were going to burst. I finally said to my husband, I need to go to the ER. He tried to help me out of bed and every time I tried to move I would scream in excruciating pain. After some time, I finally said once again, to call 911 so I can be brought to the hospital. EMS arrived shortly after the call, and the EMS put me into a chair to bring me down the stairsàànot without me having the excruciating pain; from the chair I was transferred on to the stretcher again in agony and screaming because of the pain. The ambulance took me to another hospital. There in the ER I was tested for Covid-19 and was negative. IV was started and pain medication was given, blood drawn, etc. Dr. said that I would be admitted since the pain was so excruciating that it wasn't going to be managed on an outpatient basisà..he said I am going to send you for an MRI to rule out an epidural abscess, I don't think you have it but I need to rule it out. Monday, April 26th 5:00 am went for an MRI and then was admitted to my room on the floor. Not long after I was in my room, a spinal surgeon came and informed me that I had an epidural abscess and needed emergency surgery today. The abscess was from lumbar 2 through lumbar 5 and it needed to be removed as soon as possible. He would not be the surgeon doing the surgery but a doctor from his group would be. I went into surgery around 5:30 pm that evening. The surgery was removal of the abscess and laminectomies of L3 & 4. As though this was not enough to handle, but I was also informed that I was septic and blood cultures were drawn multiple days in a row to try to figure out the microorganism that was traveling around in my blood. After many days of a fever and on antibiotics, I was found to have Methicillin Susceptible Staphylococcus Aureus (MSSA) in my blood and was started on an appropriate antibiotic. At this point I also went for diagnostic testing, CT Scans, Ultrasounds etc ù It was found that I had multiple dots in both upper extremities. I continued to be in the hospital for another week or soà. On Thursday, May 6, 2021 in the morning I had been coughing for the last few days, the doctors were talking about discharging me on Friday, May 7, 2021 so the doctor ordered me a chest x ray to rule out Covid-19, after I came back from the chest x ray, the discharge planning nurse came in and said since you may be discharged home we have to do a covid-19 test on you before discharge. The Covid-19 test was done around mid-morningàà early afternoon my doctor comes in and says that my chest x ray looks like I might have Covid-19 that I will need a test. I informed the doctor that a Covid-19 was just completed a couple hours ago for my discharge. It was around 4:00 pm that the doctor and nurses all came in and told me I was positive for Covid and I had to be rushed up to the Covid Floor, this was Thursday May 6, 2021 4:00 pm. I was supposed to be going for a PIC Line procedure Friday in the am to be discharged Friday afternoon. Well once I was found to be positive for Covid, the PIC line procedure was changed to Friday at the end of the day. I laid on the Covid unit for 24 hoursà.On Friday May 7, 2021 I went down to the OR for a PIC line insertion in my left upper arm to be able to go home on IV antibiotics for the next 6-8 weeks. I was discharged home on Saturday May 8, 2021 in the am, with a PIC line in left upper arm, walker, on IV antibiotics q 8 hours, Eliquis (blood thinner for clots), pain meds, etc ., , homecare, PT and following up with infectious disease doctor, spinal surgeon and the vascular doctor. When the Covid vaccine was given to me on Tuesday, April 20, 2021 it was given to me by a Pharmacist at a local pharmacy. A multi dose vial was being use, and I did not see him clean off the top of the vial with alcohol, when the injection was performed he cleaned my upper arm off in one area and gave the injection to me in a totally different area of my arm that was not cleaned properly with alcohol. The injection was not performed properly and therefore a bacterium was introduced into my blood stream via the injection. As a result of receiving my first dose of Covid immunization, I had an epidural abscess, back surgery, and sepsis which I nearly died from.</p>
2421576-1	Extensive Meningitis Sepsis Infected CSF Please contact Hospital for completely information
2462228-1	Blood Clots in lung and leg
2473550-1	<p>As soon as I received the Pfizer booster I was immediately sick. I was suffering severe headaches, dizziness etc. I followed up 5 days later with my ENT and expressed what I was feeling. He assured me that it had nothing to do with my sinuses, etc. The headaches did not go away and 7 weeks later I suffered a hemorrhagic stroke. On February 27, 2022 my left side went completely numb and I was rushed to the hospital and put into a CT scan where I heard the techs talking about my serious bleed. That was the last thing I remember until mid April. I was sedated and in an induced coma. A bolt was placed in my head and then a drain to try to relieve the pressure. I have been in extensive rehabilitation since April 1, 2022 but I have not regained any function of my left side and I am in a wheelchair. My wife and children take care of me on a daily basis. I have had several CT scans and MRI's as well as having been seen by many Neurologists and Neuosurgeons looking for answers. Before Feb 27, I was in great shape. I exercised, ate right and never once ever had High BP until the day I was given the Pfizer booster injection.</p>
2479614-1	High fever over 103 admitted to hospital on Sept. 12, 2002.
2480365-1	<p>Before COVID vaccine I had no health condition, all vitals were never showed anything abnormal, APE done on June-2021 was fully good but post vaccine in July-2021 every thing changed below are the details: Had covid: Tested positive for COVID on 15-April-2021 and recovered fully in 2 weeks with negative COVID test report. Blood work done on 3rd-June and July-23rd were completely fine but somewhere around 2-3 week of Aug, I intermittently started feeling shortness of breath, fatigue, stomach ache, was continuously consulting PCP but no medicine any other advise provided. In 3rd week of Oct-2021 patient had-Shortness of breath, change in urine color to pink, abdominal pain, and feeling tired all time and went to see PCP again. There was a blood work done 1st week on NOV-2021 which had following major issues- Low Hemoglobin 8.0 High Protein leak in urine Blood in urine no advise from PCP other than OTC iron supplement and repeat blood work after 6-8 weeks. Repeat blood work done in Jan-2022 had many severely bad reading with creatinine level above 9, which pushed me to ER and blood work done in ER had creatinine > 10 . This whole this caused major injury to kidneys, several blood work, procedures were performed including plasmapheresis 3 Chemo infusions.</p>
2482176-1	<p>7/22/22 urgent urination and incontinence began 7/25/22 headache 7/26/22 headache, slow speech, slow movement 7/27/22 headache, vomited 7/28/22 fell onto back, tired, very weak, mental confusion 7/29/22 too weak to climb stairs, mental confusion; transported and admitted to local hospital with fever of 103, ferritin 75,000, low white blood cells, low platelets. 7/30/22 Diagnosed with hemophagocytic lymphohistiocytosis , treated with 16 mg dexamethasone daily. received platelets, cryoprecipitate. Hospitalized through 8/10/22. Rehab facility through 8/17/22</p>

VAERS ID	Adverse Event Description
2497482-1	Covid bivalent administered to my 90 year old mother on 10/13/2022 in healthcare setting and by 10/16/2022 she was vomiting and became unresponsive. IV started for hydration. Placed on hospice 10/19/2022. She is awake but continues to be declining since the COVID bivalent. She had been eating and drinking without difficulty prior but now barely drinking and not able to eat except for few bites of pureed food. She had received all prior boosters without incident. Since she is now on hospice, we have not gotten any blood work or additional testing. She turned 91. I would not recommend this bivalent to anyone with any underlying conditions. At 91, she was in good condition but had progressing renal failure and memory loss. The renal failure due to no intake has to be much worse. No meds able to be swallowed at this point so BP elevated.
2504540-1	symptoms- severe stomach pain for several days, fever emergency room visit - appendicitis, emergency surgery performed to remove appendix (there was a hole in appendix) appendix removal
2517361-1	I was 24 weeks pregnant when I had my baby boy .he was born 1lb and 6 oz . He was born August 1 2022 and my due date was November 20 2022
2519657-1	"New Onset Anti-GBM Glomerulonephritis on a Background of IgA Nephropathy Post-SARS-CoV-2 Vaccination; New Onset Anti-GBM Glomerulonephritis on a Background of IgA Nephropathy Post-SARS-CoV-2 Vaccination; This is a literature report for the following literature source: A 41-year-old female patient received BNT162b2 (BNT162B2), in Jun2021 as dose 1, single (Batch/Lot number: unknown) and in Jul2021 as dose 2, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history included: ""hypothyroidism"" (unspecified if ongoing); ""COVID-19"" , start date: Apr2021 (unspecified if ongoing), notes: was tested positive for Covid-19 in April 2021. The patient's concomitant medications were not reported. The following information was reported: ANTI-GLOMERULAR BASEMENT MEMBRANE DISEASE (hospitalization, medically significant, life threatening), IGA NEPHROPATHY (hospitalization, medically significant, life threatening), outcome ""recovering"" and all described as ""New Onset Anti-GBM Glomerulonephritis on a Background of IgA Nephropathy Post-SARS-CoV-2 Vaccination"". The patient underwent the following laboratory tests and procedures: Anti-glomerular basement membrane antibody (normal high range <1): (2021) 4.6, notes: elevated; Biopsy kidney: (2021) performed to confirm the diagnosis, which showed, notes: acute anti-GBM nephritis - crescentic glomerulonephritis with 2-3+ linear IgG staining with incidental mesangial IgA deposits; Blood bicarbonate: (2021) 16 mmol/L, notes: metabolic acidosis; Blood creatinine: (2021) 9.8 mg/dl; Blood immunoglobulin A: (2021) elevated; Blood immunoglobulin G: (2021) elevated; Blood potassium: (2021) 5.4; Blood test: (Apr2021) Anaemia; Blood urea: (2021) 70 mg/dl; Blood urea nitrogen/creatinine ratio: (2021) 81/10.13 mg/dl; Chest scan: (2021) negative; Haemoglobin: (2021) 6.8 g/dl; Immunology test: (2021) negative; Complete review of systems: (2021) unremarkable, notes: with no signs of extrarenal manifestations; Protein urine: (2021) 5.7 g/dl; Protein urine: (2021) 300 mg/dl; Red blood cells urine: (2021) greater than 50 per high power field (HPF); Renal function test: (2021) gradually improved, notes: on treatment regimen; SARS-CoV-2 antibody test: (Apr2021) Positive; Urine analysis: (2021) revealed significant microscopic hematuria and, notes: proteinuria. Therapeutic measures were taken as a result of anti-glomerular basement membrane disease, iga nephropathy. Additional information: Introduction: Anti-glomerular basement membrane (anti-GBM) nephritis is a rare, but potentially fatal pathology that occurs due to development of IgG autoantibodies against an autoantigen expressed in the basement membrane of kidneys. The authors present a case of anti-GBM nephritis as an uncommon immune-mediated adverse effect post mRNA Covid-19 vaccination. Case Description: This is a 41-year-old female with a history of hypothyroidism, who was tested positive for Covid-19 in April 2021. Post-covid, she received the Pfizer-SARS-CoV vaccine in June and July 2021. Few weeks later, she presented with anemia to her primary care physician, and a couple of months after, a urinalysis revealed significant microscopic hematuria and proteinuria. Further workup revealed a blood urea nitrogen (BUN) of 70 mg/dL and serum creatinine of 9.8 mg/dL which subsequently led to hospitalization for workup of acute kidney injury. Her labs were significant for hemoglobin 6.8 g/dL, BUN/Creatinine 81/10.13 mg/dL, potassium of 5.4, metabolic acidosis (HCO3 16mmol/L), and a urinalysis showing >50 red blood cells (RBCs) per high power field (HPF) with a protein of 300 mg/dL and 24-hour protein excretion of 5.7 g/dL. Complete review of systems was unremarkable with no signs of extrarenal manifestations and negative chest imaging. Immunological workup was negative except for elevated anti-GBM titer at 4.6 (normal <1) and elevated IgG and IgA serum proteins. A renal biopsy was performed to confirm the diagnosis, which showed acute anti-GBM nephritis - crescentic glomerulonephritis with 2-3+ linear IgG staining with incidental mesangial IgA deposits. She was initiated on IV pulse steroids, plasma exchange therapy, and IV Cyclophosphamide. Renal function gradually improved on this treatment regimen. Discussion: The occurrence of anti-GBM nephritis with concomitant IgA nephropathy post-SARS-CoV-2 mRNA vaccination has been rarely reported in literature. The etiology remains speculative; however, these cases highlight the need to exercise vigilance in patients presenting with symptoms or lab findings suggesting acute kidney injury with a preceding history of recent vaccination. Early identification and intervention may prevent progression of disease.; Sender's Comments: Based on the current available limited information in the case provided, the causal association between the events Anti-glomerular basement membrane disease, IgA nephropathy and the use of suspect product BNT162b2 cannot be fully excluded. The case will be reassessed once further 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."
2524830-1	Received booster on Sat and on Sunday felt funny, slightly sob. Thought I was getting an infection, drove to my daughter's house. Had to wear oxygen while driven because of increase sob. My daughter took me to urgent care to get antibiotics and steroids. They sent me to the hospital. They did bld work , cat scan, ekg, and was diagnosed with a bad clot and admitted to hosp. Started on heparin and switched to eliquise
2536891-1	It started with that Saturday when I was at the gym and had shortness of breath. I went to the doctor and they thought it was a virus. By Tuesday, I could not breathe. We called 911 and I went to the hospital. They did a CAT scan and noted I had 20+ blood clots, but two of them were large and pushing on my heart causing heart failure. I was transferred to another hospital and when I was stable enough they did a thrombectomy. A week later I was discharged and I was better, but not 100%. I was put on blood thinner and will be on them for lifetime.
2537278-1	No event description for this event.

VAERS ID	Adverse Event Description
<u>2537283-1</u>	"Ischemic Stroke; This is a literature report for the following literature source(s): ""Stroke in Patient With Controlled Preexisting Hypercoagulability After COVID- 19 Vaccine Booster: A 55-year-old female patient received BNT162b2 (BNT162B2), as dose 3 (booster), single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history included: ""factor V Leiden"" (unspecified if ongoing); ""protein C deficiency"" (unspecified if ongoing). Concomitant medication(s) included: ENOXAPARIN taken for anticoagulant therapy. Vaccination history included: Covid-19 vaccine (DOSE 1, SINGLE (Unknown Manufacturer)), for COVID-19 immunization; Covid-19 vaccine (DOSE 2, SINGLE (Unknown Manufacturer)), for COVID-19 immunization. The following information was reported: ISCHAEMIC STROKE (hospitalization, medically significant, life threatening), outcome ""recovering"", described as ""Ischemic Stroke"". The patient underwent the following laboratory tests and procedures: Magnetic resonance imaging: revealed an acute left thalamic, left posterior, notes: internal capsule, and bilateral middle cerebellar infarcts. Therapeutic measures were taken as a result of ischaemic stroke. Clinical course: On admission, she presented with acute-onset right-sided weakness and numbness. She received the BNT162b2 vaccine booster dose 27 days prior to admission. Prior to this incident, she was successfully maintained on the same dose of enoxaparin for 19 years without clotting event along with recent outpatient hematology monitoring. After medical stabilization, she was admitted to the acute inpatient rehabilitation facility where she regained full motor strength and gait, although numbness persisted. Following consultation with her outpatient hematologist, she was discharged at an independent level with unchanged enoxaparin dosing.; Sender's Comments: Based on known drug safety profile, there is reasonable possibility of causal association between the ""Ischemic Stroke"" and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE). The same was blamed as a possible trigger by the reporter, and it can possibly be explained by the mechanism as stated in the full article. 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."
<u>2560184-1</u>	STROKE
<u>2560289-1</u>	Left 2 sided stoke
<u>2560772-1</u>	FELT IRREGULAR HEART BEAT, CALLED CARDIOLOGIST APPT MADE, FOUND TO HAVE NEW ONSET ATRIAL FIBRILLATION, HAD TO FOLLOW UP WITH ELECTROPHYSIOLOGIST MD, MEDICATIONS WERE CHANGED, STILL HAVE ATRIAL FIBRILLATION WVEN WITH NEW MEDICATIONS, PREVIOUS ATACAND AND BISOPROLOL DISCONTINUED, NOW ON DILTIAZEM, EDARBI AND ELIQUIS,,,
<u>2561114-1</u>	"Seizure; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP). The reporter is the patient. A 48-year-old male patient received BNT162b2, BNT162b2 omi ba.4-5 (BNT162B2, BNT162B2 OMI BA.4-5), on 09Dec2022 at 16:30 as dose 4 (booster), single (Lot number: G33274) at the age of 48 years, in left arm for covid-19 immunisation. The patient had no relevant medical history. The patient has no known allergies. The patient did not receive any other vaccines within 4 weeks prior vaccination and had not been diagnosed with COVID-19 prior vaccination. There were no concomitant medications. Vaccination history included: Covid-19 vaccine (DOSE 1; MANUFACTURER UNKNOWN), for Covid-19 immunization; Covid-19 vaccine (DOSE 2; MANUFACTURER UNKNOWN), for Covid-19 immunization; Covid-19 vaccine (DOSE 3 (BOOSTER); MANUFACTURER UNKNOWN), for Covid-19 immunization. The following information was reported: SEIZURE (hospitalization, medically significant, life threatening) with onset 02Jan2023, outcome ""unknown"". The patient was hospitalized for seizure (hospitalization duration: 2 day(s)). The event ""seizure"" required emergency room visit. The patient underwent the following laboratory tests and procedures: SARS-CoV-2 test: (02Jan2023) Negative, notes: Covid test post vaccination: Nasal Swab. Therapeutic measures were taken as a result of seizure."
<u>2563383-1</u>	Shortly after receiving the vaccine I started to experience shortness of breath. The condition worsened over the next few months until I was admitted to the hospital in June of 2022. I was advised to immediately go to an emergency room by Doctor office after the discovery of dual pulmonary embolisms from a previous scan.

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

Caveats: VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine.

Key considerations and limitations of VAERS data:

- Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS, whether or not they believe the vaccine was the cause.
- Reports may include incomplete, inaccurate, coincidental and unverified information.
- The number of reports alone cannot be interpreted or used to reach conclusions about the existence, severity, frequency, or rates of problems associated with vaccines.
- VAERS data are limited to vaccine adverse event reports received between 1990 and the most recent date for which data are available.
- VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information.

Some items may have more than 1 occurrence in any single event report, such as Symptoms, Vaccine Products, Manufacturers, and Event Categories. If data are grouped by any of these items, then the number in the Events Reported column may exceed the total number of unique events. If percentages are shown, then the associated percentage of total unique event reports will exceed 100% in such cases. For example, the number of Symptoms mentioned is likely to exceed the number of events reported, because many reports include more than 1 Symptom. When more than 1 Symptom occurs in a single report, then the percentage of Symptoms to unique events is more than 100%. More information. ([/wonder/help/vaers.html#Suppress](#))

Data contains VAERS reports processed as of 01/27/2023. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information. ([/wonder/help/vaers.html#Reporting](#))

Values of Event Category field vary in their availability over time due to changes in the reporting form. The "Emergency Room/Office Visit" value was available only for events reported using the VAERS-1 form, active 07/01/1990 to 06/29/2017. The "Congenital Anomaly/Birth Defect", "Emergency Room", and "Office Visit" values are available only for events reported using the VAERS 2.0 form, active 06/30/2017 to present. These changes must be considered when evaluating count of events for these categories.

About COVID19 vaccines:

- For more information on how many persons have been vaccinated in the US for COVID19 to date, see <https://covid.cdc.gov/covid-data-tracker/#vaccinations/> (<https://covid.cdc.gov/covid-data-tracker/#vaccinations/>).
- One report may state that the patient received more than one brand of COVID-19 vaccine on the same visit. This is a reporting error, but explains why the total number of reports may not equal the total number of COVID-19 vaccine doses.

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation ([/wonder/help/vaers.html](#)) for more information.

Query Date: Feb 6, 2023 2:54:31 AM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 01/27/2023, CDC WONDER On-line Database. Accessed at <http://wonder.cdc.gov/vaers.html> on Feb 6, 2023 2:54:31 AM

Query Criteria:

Title: NJ Covid Life Threatening Report
Event Category: Life Threatening
State / Territory: New Jersey
Vaccine Products: COVID19 VACCINE (COVID19)
VAERS ID: All
Group By: VAERS ID
Show Totals: False
Show Zero Values: False