The Vaccine Adverse Event Reporting System (VAERS) Results

NJ Covid VAERS Death Report

Data current as of 01/27/2023

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VAERS ID	Adverse Event Description
0921175-1	Resident received Covid Vaccine, noted after 30 mins with labored breathing BP 161/77, HR 116, R 38, T 101.4,
0943397-1	On day due for 2nd dose, Patient was found unresponsive at work in the hospital. Patient pupils were fixed and dilated. Full ACLS was initiated for 55 minutes with multiple rounds of bicarb, calcium chloride, magnesium, and epinephrine. Patient was intubated. Patient continued into V. Fib arrest and was shocked multiple times.
0953754-1	patient suddenly developed pneumonia 7 days after vaccination and died the evening of developing pneumonia
0955532-1	COVID 19 Vaccination administered by pharmacy staff. No adverse effect at the present time. Staff will continue to observe adverse reaction. Will continue to monitor. Patient at start of shift awake in the bed. Pt at 3am was on the commode leaned to the side. Patient body still warm to touch no pulse. Called for assistance Asap. Cpr started promptly. Cpr given patient on floor 911 arrived at the scene at 3:10am Cpr rotated Between Nursing and EMT on Scene. Cpr was given to patient for over 45 minutes. Patient was pronounced at the scene at 3:50am. Call placed to Pt family by supervisor on shift. MD to be notified. AT 3:00am, I was notified by the nurse that resident is unresponsive. Upon entering room, resident was sitting on the commode unresponsive with absent respiration and pulse. Resident lowered down on the floor with 4 person assist. CPR initiated, AED pads placed on chest with no shock indicated. 911 called and EMT and paramedics arrived around 3:10am. ACLS performed until code stopped and pronounced death at 3:48am. I called and notified family member of his demise and awaiting for family to call us back for funeral arrangements.
0956761-1	Family was told that Patient expired in his sleep during the early morning hours of 1/15. I spoke with him the evening before (on 1/14), which was a day after he had received the Covid vaccine. He was not having any symptoms of allergy or reaction then. He did say that he felt tired, but he often complained of feeling tired over time.
0956811-1	Resident was noted unresponsive, no respiration, no blood pressure, no pulse, code blue called according to facility protocol, resident is full code, CPR started, 911 called, arrived and took over from staff. Resident was pronounced dead at 1:16pm 1/18/21
0957163-1	Resident received 1st on 1/11/21 at 12:10am (1/12/21) resident was found unresponsive. Code Blue, 911 called at 12:11am. FD and EMS arrived, resident pronounced at 12:51am.
0982472-1	Worsening respiratory failure 1/20/2021 death 1/27/2021
1037124-1	Patient was at a gym watching his daughter. He slumped over unconscious. EMS was called. He was found to be in fine ventricular fibrillation and resuscitation efforts failed. He was brought to Hospital ED where he was pronounced dead. He had underlying cardiac disease but his family requested I report this event as possibly related to the recent COVID vaccination.
1046347-1	When family members came to receive the second dose of their COVID vaccine, they informed us that the above patient had passed away.
1052070-1	2/22/2021 10:09 pm resident reported 1 episode of being nauseous and having dry heaves, no temperature, MD notified and nurse was told to continue to monitor, no new orders, daughter made aware. Vital signs being done every 4 hours. 2/23/2021 3:04am resident complains of nausea, scant BM amount x 2, MD notified and no new orders, continue to monitor and encourage fluids, vital signs continue every 4 hours.
1056518-1	The coroner said it was some type of heart attack; A spontaneous Report Received from a Health care professional concerning a 84 year old male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and who experienced a heart attack / myocardial infarction. The patient's had undergone triple bypass surgery years ago. Concomitant medications were vitamins. On 18-Jan-2021 prior to onset of events the patient received his first of first two planned doses of (mRNA-1273) COVID-19 vaccine of unknown batch no, unknown route and unknown site of administration for prophylaxis of COVID-19 infection. On 13-Feb-2021 the patient experienced death 27 days after the first dose of the vaccine. The coroner said it was some type of heart attack and think he expired sometime Saturday 13-Feb-2021. On 16-Feb-2021 the patient was supposed to have his second dose of (mRNA-1273) COVID-19 vaccine. The event, heart attack, was fatal.; Reporter's Comments: This is a case of death to heart attack in a 84-year-old female subject with a hx of triple bypass surgery, who died 27 days after receiving first dose of vaccine. Very limited information has been provided at this time. No death certificate provided. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of Death
1056659-1	heart issue; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient passed away after taking the vaccine. He was healthy but developed heart issue after taking vaccine. The patient died on an unspecified date. It was not reported if an autopsy was performed.; Reported Cause(s) of Death: heart issue
1062961-1	Called patient to refill medication and spoke with daughter. She stated that her father had passed away last week.
1066617-1	"Patient reported on 2/24/2021 to have expired on an unknown date during the interim between first dose and scheduled 2nd dose. On 2/24/2021, the person reporting death stated that patient died ""last week."" Patient is not known to us for primary care and vaccine was administered during a vaccine event at senior public housing. We have no further medical details about the cause of death or if it is vaccine related."
1073682-1	pulmonary edema; Low heart rate; chest pain; This is a spontaneous report from a contactable pharmacist. An 80-years-old male patient received his second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in left arm on 28Jan2021 at single dose for COVID-19 Immunisation. Medical history included dementia, high blood pressure, COVID prior vaccination. He had no known allergies. Concomitant medication included diltiazem hydrochloride (CARDIZEM), anastrozole (ARIMIDEX), simvastatin and lorazepam. Historical Vaccine included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 07Jan2021 (at the age of 80-years-old) at single dose for COVID-19 Immunization. There was no other vaccine received in four weeks. The patient experienced pulmonary edema, low heart rate and chest pain on 26Feb2021. The events resulted in hospitalization and patient died. The patient was hospitalized from 26Feb2021 for 1 day. Treatment received for the events included Epinephrine, morphine, nitroglycerine. The patient underwent lab tests and procedures which included Covid test Nasal Swab post vaccination on 26Feb2021 indicated Negative. The patient died on 26Feb2021. An autopsy was not performed. information on the lot/batch number has been requested.; Sender's Comments: Pulmonary edema, low heart rate, and chest pain, all reported as fatal, are deemed unrelated to BNT162B2 vaccine, being rather accidental occurrences, likely favored by the patient's age and by the mentioned high blood pressure, known risk factor for cardiovascular diseases. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Low heart rate; pulmonary edema; chest pain

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VAERS ID	Adverse Event Description
1075608-1	Patient waited 15 mins after covid vaccination on Wednesday 3/3, cleared by EMT to leave. I was notified by nurse at the senior building where patient resides that she had expired Thursday evening at home. Paramedics were called. No other additional information.
1081132-1	Severe thrombocytopenia approx. 10 days after vaccine administration.
1085254-1	Severe abdominal pain unable to eat or sleep for 36 hours. He went by ambulance to the Hospital emergency room. They tried to pump his stomach but he aspirated and and went into cardiac arrest. He was revived but never regained consciousness. (The ICU Dr said that he had blood clots in his abdomen from a recent stroke. We were unaware of him having a stroke other than in 2026. The same Dr. said that he had necrosis in his lungs from aspirating. The necrosis was from his bowel dying) He was put on a ventilator and given drugs to increase his heart rate. On 3-5-21 the heart drugs were reduced and he died. I was with him when he recieved the vaccination and he was healthy, just old. I think that the shot killed him.
1085375-1	Patient presented to medical center emergency room on 02/21/2020 at 19:00, patient complained of shortness of breath and feeling fullness of her throat. Patient stated that she had Motrin 800 mg TID and Flexeril PRN due to her back pain. Patient also stated that she ate a banana after she took her medications. Her systolic blood pressure was 50, and her HR was 109, patient also stated that she had her 2 shots of Moderna Vaccine, her first shot was on 01/06 and her second shot was on 02/02. Patient was treated with: 1 Duoneb, 0.3 ML IM of epinephrine, Solumedrol 125 mg, Benadryl IV 50 mg, Normal Saline infusion IV 1000 ml/hr, and Pepcid IV 20 mg. Patient lactic acid was 10.6, WBC 24.2 and Temp 97 F, patient was diagnosed as sepsis shock and patient received: Piperacillin-tazobactam 3.375 g in D5W 50 ml IVPB (3.375 g once) Vancomycin 1 g in D5W 200 ml IVPB (1 g once). Patient pH was < 6.780 and PCO2 was 55 and bicarbonate level was 5.0, patient received Sodium bicarbonate IV 50 mEq once. Patient was not stable as her BP and HR were fluctuating patient received DilTlazem IV 2.5 mg for 2 doses. Patient received Levophed 16 mg /NS 250 ml IV. At 23:13 patient was intubated, patient received a local anesthesia through a central line of lidocaine 2% without epinephrine, and patient was transferred to the ICU to be monitored. At 00:33 CODE BLUE was called and patient became unresponsive and lost pulse while patient was brought to ICU. Patient was coded twice before ROSC, during intubation patient patient noted to have coffee-ground drainage.
1099326-1	A few days after vaccination patient had an unusual dry cough/ and then a pain in his chest, He called our Doctor she said call your cardiologist now, patient called Dr and told him he wanted to go to his office, explained the pain he was experiencing - the doctor told him said he couldn't see him wanted to do a telemed exam. and proceeded to tell patient to see an gastro entomologist, take Tums, no tomatoes, no coffee and a few other foods and that patient was suffering from Acid Reflux and to call him back net week.
1112370-1	The patient got the Moderna vaccine on 3/2/2021. On 3/3/2021 he suffered a dissection of the ascending thoracic aorta and died.
1112579-1	Pulmonary embolism resulting in sudden death
1124671-1	3 days after vaccination, person was somewhat disoriented. 4th day after vaccination, patient fell, hit head and developed subdural hematoma from which he subsequently died.
1135292-1	Stroke shortly after the first dose; A spontaneous report was received from a consumer concerning an 81 year old, male patient who experienced stroke shortly after the first dose (cerebrovascular accident). The patient's medical history was not provided. No relevant concomitant medications were reported. On 11 FEB 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 for prophylaxis of COVID-19 infection. It was reported that the patient experienced stroke shortly after the first dose. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the event of stroke shortly after the first dose (cerebrovascular accident) was considered unknown.; Reporter's Comments: This is a case of sudden death in a 93-year-old female subject with no medical hx reported who suffered a stroke (unspecified days) after receiving first dose of vaccine. Very limited information has been provided at this time. Further information will be pursued..
1140864-1	My mom received her second covid shot at 10:05 AM on 3/26 and experienced no adverse symptoms. At around 6 am the following day, on the morning of 3/27 she was found on the floor, and presumably suffered from a heart attack. After devastation to our family, we called her physician and he himself was also surprised. Although she is a type 2 diabetic with high blood pressure she has maintained great health and kept her conditions under control with her medications. This, unfortunately, seems too coincidental to not have been in some way or completely caused by the second dose of the shot.
1141641-1	Received first Pfizer Covid19 vaccine on 2/28/21. Developed fever 102.8, chills, SOB on 3/2/21 and was transported by EMS to ER and admitted. He was tested 3 times for COVID 19 and found to be negative. CT scan was concerning for viral pneumonia and suspected COVID. He was treated and released to home on 3/4/21. Followed by pulmonologist. Received second Pfizer COVID19 vaccine on 3/21/21. On 3/23/21 developed fatigue, weakness, shakiness, nausea and vomiting. had significant decline over the week. Has acute event on 3/27/21 and was pronounced dead at home.
1149905-1	Died; A spontaneous report was received from a Consumer concerning a patient where age and gender unspecified who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced event Death. The patient's medical history was not provided. No relevant concomitant medications were reported. On unknown date, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) in the Anatomical location unspecified for prophylaxis of COVID-19 infection. On unknown date, The patient experienced the event Death. Laboratory details were not provided. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the event was Fatal. The reporter assessed the event Death related to the study drug was unknown.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death
1156579-1	Per Hospital medical records patient was admitted to hospital 3/14/2021 at 1021. Notes from 3/14/21 indicate patient presented with 1 week of nonproductive cough. Received chemotherapy 4 days ago. 3 days ago developed fever, chills, dyspnea, anorexia.

VAERS ID	Adverse Event Description
1168970-1	ATRIAL FIBRILLATION; INABILITY TO SWALLOW; BLOOD CLOT IN RIGHT ARM; LOW BLOOD PRESSURE; DEATH 4 DAYS AFTER RECEIVING VACCINE; This spontaneous report received from a vaccine facility via a company representative concerned a 95-year-old female. The patient's height, and weight were not reported. The patient's concurrent conditions included atrial fibrillation. The patient received COVID-19 VACCINE AD26.COV2.S (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 2021 for prophylactic vaccination. No concomitant medications were reported. The batch number was not reported and has been requested. It was reported that on an unspecified date in 2021 the patient received Janssen Covid-19 Vaccine and within 6hrs she had a major atrial fibrillation episode, then several the following day. The next day, she lost her ability to swallow. Two days later she was on oxygen. Three days later she developed a blood clot in her right arm, was still on oxygen and blood pressure was falling. On an unspecified date, the patient died 4 days after receiving vaccine. The action taken with COVID-19 VACCINE AD26.COV2.S was not applicable. The patient died 4 days after receiving vaccine on an unspecified date, and the outcome of atrial fibrillation, inability to swallow, blood clot in right arm and low blood pressure was not reported. This report was serious (Death, Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: 20210400509: This spontaneous report received from a vaccine facility via a company representative involved a 95-year-old female with the past medical history remarkable for atrial fibrillation who received the Janssen COVID-19 Vaccine for prevention of COVID-19 infection and within 6hrs had a major atrial fibrillation episode. No concomitant medications were reported. The next day, she lost her ability to swallow. Two days later she was on oxygen. Three days later she developed a blood clot in her right arm, was still on oxygen and blood pressure was falling. On an unspecified date, the patient died 4 days after receiving vaccine. No information was provided regarding the cause of death. Considering the patient's past medical history of atrial fibrillation, the causality for the event of atrial fibrillation, as well the consequent events is assessed not related to the Janssen COVID-19 Vaccine.; Reported Cause(s) of Death: DEATH 4 DAYS AFTER RECEIVING VACCINE
1187758-1	PATIENT WAS GIVEN JANSSEN COVID 19 VACCINE AT AROUND 12PM WHEN PATIENT WAS ACCOMPANIED BY HIS SON. HE WAS OBSERVED FOR 15 MINUTES AFTER THE VACCINATION AND LEFT PHARMACY WITHOUT ANY PROBLEM. PATIENT'S DAUGHTER CALLED AROUND 6PM AND REPORTED HER FATHER JUST DIED. SHE REPORTED HER FATHER ALL OF SUDDEN WAS SHAKING AND DIED RIGHT AFTER.
1204680-1	Suddent Death approximately 75 hours after second dose of Moderna Vaccine
1205121-1	twelve hours after getting the shot my wife woke up with an upset stomach; her blood sugar was also slightly elevated; within ~the next two hours she became disoriented and confused; I called 911 and within a couple of minutes of the first 911 call she stopped breathing and could not be revived.
1205518-1	Resident was inoculated on 04/09. According to family members, he began to feel unwell that evening, cold sweats, high fever, dehydration. According to family members, he refused to get medical attention. After not hearing from him for a few days, family members called for a wellfare check on 04/12 at which time he was found deceased.
1209903-1	I DON'T KNOW THE EXACT EVENTS FOR THE CASE, BUT WAS ASKED TO FILL IN THE INFORMATION THE BEST I COULD WITH THE INFORMATION I HAD ON HAND. THIS YOUNG LADY, RECEIVED A COVID-19 VACCINE ON 3/6/2021 AND EXPIRED ON MARCH 13, 2021. THIS IS MOST OF THE INFORMATION THAT I HAVE. YOU WOULD NEED TO CONTACT THE MEDICAL EXAMINER'S OFFICE, THAT WILL BE ABEL TO PROVIDE YOU WITH MOST DETAIL FOR THIS CASE.
1209906-1	On March 4 patient experienced vomiting. Early morning March 5 he fell and landed on his hip after being disoriented and experienced aches, weakness, and nausea without vomiting throughout the day. On March 6 he experienced excruciating pain in his left hip and went to the local emergency room following guidance from his primary care physician. He was diagnosed with fluid near his hip joint at the hospital and was discharged the same day. The next day, March 7 he was still in pain but able to walk with assistance. On March 8 he got an x-ray from an orthopedic physician and severe arthritis was found. March 10 the severe pain persisted, but he was able to walk with a walker. On March 12 he received a cortisone shot and required emergency medical assistance to get into a personal vehicle with a family member who drove to the appointment. The next few days, the pain persisted, became worse, and spread throughout his body. On March 16 he was transported by emergency medical services to the local emergency room for treatment and was diagnosed with sepsis and pneumonia. On March 18 he was still being treated when he experienced cardiac arrest while being intubated. He was resuscitated and was on a ventilator being treated for a few more days but ultimately succumbed to sepsis on March 30.
1211145-1	Deceased unexpectedly. From day of second dose 3/18/21, patient reported feeling tired (no fever, no shortness of breath) but was able to walk 3 flights of stairs on 4/11/21 and felt slightly better. Went to church that Sunday 4/11. Was not seen after that, then found deceased at home 4/14/21 with blood in mouth, no other signs such as lacerations or incontinence or other vomitus.
1216264-1	Patient admitted 3/28/2021 with severe COVID 19 pneumonia. She progressed to acute respiratory failure and was intubated. During her hospitalization she was diagnosed with acute myeloblastic leukemia. Her family withdrew care and she died on 4/7/2021
1217480-1	DEATH; This spontaneous report received from a consumer concerned a 60 year old African American, Not Hispanic or Latino male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose was not reported, 1 total administered as approximately on 26-Mar-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 01-APR-2021, the patient died from unknown cause of death. It was reported that, the patient death occurred about 6-7 days after receiving the vaccine. It was unknown, if an autopsy was performed. The patient death occurred about 6-7 days after receiving the vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: 20210416142-covid-19 vaccine ad26.cov2.s -Death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH
1218288-1	4/14/2021 at ~8am, Patient was out of bed and in his wheelchair and consumed 100% of his breakfast. During lunch time, he only consumed 25% of his meal. At ~2pm, patient was noted to be unresponsive. Oxygen saturation was 88% and B/P was low and oxygen was administered and Oxygen Saturation increased to 92%. The patient was placed in bed and Dr and the family were notified. The resident was continuously monitored by the Hospice nurse, who happened to be on-site and the primary nurse. At ~6:30pm it was noted that patient was having labored breathing so 0.25 ml of Morphine Sulfate Solution 20mg/ml was administered with releif. At 8:30pm, patient expired.
1226364-1	Patient developed unspecified pneumonia which led to extremely high troponin levels. Patient died due to cardio pulmonary disease due to complications from COVID vaccine.

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1227279-1	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
1227926-1	BLOOD CLOT; This spontaneous report received from a consumer via a company representative and concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, a week or so after the Covid-19 vaccination the patient passed away in his sleep. The patient had no underlying condition. An autopsy was performed on an unspecified date and the patient was found to have blood clot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0: A male patient of unspecified age passed away in his sleep an unspecified time after receiving the Janssen COVID-19 vaccine for prevention of COVID-19 infection. It stated that the patient had no underlying condition. A blood clot was found by autopsy; no further details are provided. There is insufficient information to make a meaningful medical assessment. Additional information is being sought.; Reported Cause(s) of Death: BLOOD CLOT; Autopsy-determined Cause(s) of Death: BLOOD CLOT
1228372-1	Patient's wife called in mid March 2021 letting us know that the patient, needed to re-schedule his 2nd dose of Moderna Covid-19 vaccine - he had missed his scheduled 2nd dose date due to being hospitalized - doctors had thought he might need a defibrillator but then discharged him without one. Patient's wife called back on 4/16 to let us know that he passed away on 4/14.
1229152-1	101.5 fever Friday night, followed by a seizure at 3am. She was found unresponsive late Saturday afternoon, and was pronounced dead at the hospital. Sudden cardiac arrest.
1230246-1	My husband developed severe COVID symptoms, despite testing negative for COVID via pcr tests on Sunday 3/21 /21 and Tuesday 3/23. He was hospitalized on 3/28 due to low blood oxygen levels. Was diagnosed with COVID and pneumonia. Treated with remdesivir and a steroid, then monoclonal antibodies. Despite making progress to the extent doctors were cautiously optimistic on 4/9/21 he would be discharged on 4/16/21, he instead was transferred to ICU on 4/10/21, placed on a ventilator on 4/11/21 and died on 4/15/21.
1232541-1	Patient found unresponsive at approximately 12:00 am 10/11. EMS called and patient was pronounced dead at scene.
1232707-1	Patient died at home per medical examiner, suspected cardiovascular event
1236916-1	On 4/16 at around 10:24AM, patient presented to emergency department via EMS status post a witnessed cardiac arrest. After the witnessed cardiac arrest, EMS was called and reported that the patient was unresponsive. Per EMS, patient was immediately intubated and chest compressions started. EMS reports an initial cardiac rhythm of VFib and shocked patient once. Patient was given 3 epinephrine and brought into the ED. After prolonged CPR and resuscitation for more than hour and a half, the patient was made DNR/DNI and was pronounced dead at 11:45AM.
1238440-1	Patient presented to ED on 3/15/2021 with fatigue, subjective fevers, dry cough, and diarrhea found to have COVID pneumonia. CT PE negative at that time. Hospitalization complicated by RUE superficial cephalic vein thrombus, epistaxis, GIB, gluteal abscess, and AKI. Patient made DNR. Suspected cause of death: ventricular tachycardia secondary to renal failure and metabolic abnormalities in the setting of COVID ARDS.
1242118-1	Patient presented after being found down next to toilet found to have COVID-pneumonia and sepsis needing intubation for ARDS and CRRT for hyperkalemia and oliguria. Hospitalization complicated by GIB s/p rectal artery embolization by IR and GNR bacteremia requiring cefepime. Due to worsening hypoxia and shock, patient was made comfort care/hospice by family and passed away on 4/9.
1242660-1	Patient has a long standing chronic history of CHF which he was recently hospitalized for, returning from an overnight stay at the hospital as a DNR/DNH/DNI.
1249559-1	respiratory distress; cardiac arrest; pulmonary emboliasm; This spontaneous case was reported by a consumer and describes the occurrence of RESPIRATORY DISTRESS (respiratory distress), CARDIAC ARREST (cardiac arrest) and PULMONARY EMBOLISM (pulmonary emboliasm) in a 76-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Lipid metabolism disorder NOS. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Apr-2021, the patient experienced RESPIRATORY DISTRESS (respiratory distress) (seriousness criterion death), CARDIAC ARREST (cardiac arrest) (seriousness criterion death) and PULMONARY EMBOLISM (pulmonary emboliasm) (seriousness criterion death). The patient died on 11-Apr-2021. It is unknown if an autopsy was performed. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. NO treatment or Concomitant medication were provided. Company Comment This is a case of sudden death in a 76-year-old female patient with a history of Lipid metabolism disorder, who died (date unknown) of respiratory distress, cardiac arrest and PULMONARY EMBOLISM after receiving first dose of vaccine. Very limited information has been provided at this time.
1255748-1	Patient tested positive for Covid; Patient tested positive for Covid; The patient died; This is a spontaneous report from a contactable consumer. An 86-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in right arm on Feb2021 (Batch/Lot Number: En6303) as single dose, and dose 2 via an unspecified route of administration on 16Mar2021 (Batch/Lot Number: Ep7534) as single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient tested positive for COVID on 08Apr2021 which resulted in Emergency room/department or urgent care, and hospitalization for 3 days. Treatment included high flow oxygen, doxycycline, inhalers, and Rocephin. The patient underwent lab tests and procedures which included Nasal Swab: positive on 08Apr2021. The patient died on an unspecified date. It was not reported if an autopsy was performed.; Reported Cause(s) of Death: The patient died
1258524-1	Patient passed away in between dose 1 and 2. Cause unknown.

VAERS ID	Adverse Event Description
1262174-1	DEATH; FROTHING AT MOUTH; COVID-19; This spontaneous report received from a consumer concerned a 63 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included obese and diabetes. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date in Mar-2021, (7-10 days after vaccination), the patient developed COVID 19. The patient self quarantined for 14 days. On 14-APR-2021, the patient went to emergency room with the complaint of shortness of breath. Her D-Dimer was very elevated, but had a ventilation/perfusion scan (VQ) scan which came back negative. They treated her with heparin. On 15-APR-2021, early morning at 06:00, the patient coded (cardiopulmonary arrest) and frothing at the mouth. The team gave her epinephrine, but did not get a return to circulation. It did not revive her. The patient coded for 30-40 minutes. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of death on an unspecified date, and the outcome of covid-19 and frothing at mouth was not reported. This report was serious (Death, and Other Medically Important Condition).; Sender's Comments: V0-covid-19 vaccine ad26.cov2.s-Death and Covid 19. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: PATIENT CODED
1266405-1	Patient received J&J COVID vaccine on 4/10/2021. She underwent elective R total knee arthroplasty on 4/20/2021. On 4/21, patient developed chest pain and was found to have a STEMI (large embolus in the posterolateral branch of the right coronary artery). She underwent thrombectomy and angioplasty on 4/21 with no evidence of CAD elsewhere. She developed hypoxic respiratory failure evening of 4/21 and was found to have bilateral pulmonary embolus with saddle type emboli and distal emboli throughout both lungs. She underwent IR guided thrombectomy on4/22 and had a cardiac arrest intra-operatively. Given timing of onset and recent J&J COVID vaccination, the patient was treated with IVIG, steroids, and placed argatroban. She continued to have multiorgan failure requiring mechanical ventilation and hemodialysis. On 4/26, CT head was positive for small area of subarachnoid hemorrhage. Patient was transitioned to comfort care measures and palliatively extubated on 4/26.
1267350-1	Shortness of Breath Fever Body Pains - Shoulder, Hand pain
1269804-1	nose bleeds, black and blue marks weeks later,
1270605-1	His brother reporting that he got the vaccine, the following day he was coughing. The coughing caused him not to be able to sleep and was weak due to that. He could feel his throat closing and he was having a hard time breathing and he called his brother who told him to call 9-1-1. He was taken to Medical Center 4/17/2021, diagnosed with possibly COVID. He was admitted to the COVID ward and he died on 4/26/2021. The doctor that pronounced him was . Cause of death diagnosis. Hypoxic respiratory arrest, COVID 19
1272393-1	Her conditions (leg swelling, coughing) get deteriorated after the vaccination. She was found pericardial effusions and plural effusions 2 weeks after the second dose. She stayed in ICU for 6 weeks and passed away.
1276582-1	DEATH; This spontaneous report received from a consumer concerned a patient of unspecified age and sex. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included unknown cause of death. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for 1 total administered for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient received the Janssen COVID-19 vaccine and then died 15 days later. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death). .; Sender's Comments: V0-20210456256- COVID-19 VACCINE AD26.COV2.S.adverse effect . This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH
1282523-1	Pt received first COVID Pfizer vaccine on 3/2/21 and second vaccine dose of Pfizer on 3/23/21 and tested positive for COVID 3/24/21 was admitted through the ED on 3/24/21 with decreased oxygen levels (50%) and SOB. Admitted to the floor on 3/25/21, Patient was never intubated but was put on continuous BiPap. Patient treated with acetaminophine, albuterol, solumedrol, and remdesivir. Patient expired on 4/15/21. Cause of death was secondary COVID pneumonia and acute respiratory failure.
1283733-1	on April 2nd patient woke up at around 4:30 am and complained of pain in his back. I rubbed his back and he wondered if it was just something he ate. He then tried to calm down and got back into bed . He was holding my hand when suddenly his hand felt cold. I turned on the light to find his eyes rolled back and he was gasping his last breath . This was about 5:20 AM . Patient was a healthy active man.
1286114-1	At 11:30am on April 6th my dad had a type A Aortic Dissection. He was rushed in an ambulence to Hospital. 4 hours later, they evaluated him and sent him by medivac to Hospital for emergency open heart surgery. Dr. performed the surgery which my dad survived. He continued to have additional complications in the ICU including a right brain stroke which may have happened during surgery. While in the ICU, he contracted pneumonia and his lungs and kidneys began declining. 20 days after the aortic dissection he died in the hospital.
1286275-1	Death due to a Subarachnoid hemorrhage
1292046-1	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
1295164-1	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.
1314603-1	Illness set in either the day of the vaccination being administered or the day after, according to phone records. Signs include: nausea/vomiting, back aches, fever, chills, passing out, lack of appetite, extreme fatigue and low energy, bitter taste in the mouth and water tasting bitter.
1323593-1	Family reported patient passed away in the evening.
1337058-1	The patient had Covid 19 from approximately January 28, 2021 through early February 2021. He received the first dose of the Pfizer Vaccine on March 26, 2021. On March 27, 2021 at approximately 7:30 PM, the patient suddenly became unable to speak clearly and walk normally. The ambulance was called at approximately 7:45 PM. The patient was evaluated and placed in the ambulance by approximately 8:15 PM. He stopped breathing in the ambulance. He was resuscitated and placed on a ventilator at some point. After evaluation at the hospital, it was found that he had suffered a pontine hemorrhage. He was kept alive until his heart stopped on March 29, 2021.

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1343001-1	Went to er on March 3rd around 2am with discoloration on body with confusion and pain. Was told possible ttp. Condition quickly declined and was transferred to hospital main campus around 12pm. Condition continued to rapidly decline and passed away on March 4th at 11am. There is much more to tell about this. To much to write down. I have called several times no one has called me back.
1347547-1	The injury that led to the death occurred within 1 day of the decedent receiving the vaccine
1351581-1	Complaint of cramping in legs on April 26. 2021. Resolved for a short period of time. Earlier in May 2021 Complaint of Left Flank pain with Radiating pain to Left Thigh. Appointment with Orthopod cancelled due to inability to drive with pain. On May 15, 2021 complaint of continued Left Flank Pain Radiating to to Left thigh with burning and discoloration. Unresponsive on May 16, 2021. Pronounced Dead at 1:52pm by County Coroner. Cause of death noted as CV. Nature of death :Natural This is being reported in case another patient complains of these same symptoms. There may or may not be a Correlation with this Death and The Jassen Covid-19 Vaccine
1359313-1	My husband had a stroke on 01/25/2021, with one large blood clot and many small blood clots. He was put on a ventilator until 02/06/2021 when I asked to have it removed. I died within 5 minutes after it being removed.
1361723-1	Weaknesses. Dizziness. Headaches. Blurry vision both eyes. Sleepiness. Strokes. Hospitalization. Death
1362539-1	Pt presented to the hospital with abdominal pain and shortness of breath May 28, 2021 Noted to be thrombocytopenic - had normal platelet 20 days prior Had bruising, melena
1369968-1	Fatigue on 6/2/21 followed by cardiac arrest & death
1374104-1	Died 2/26/2021
1374169-1	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.
1381212-1	Hypoxic respiratory failure; pneumonia; Stomach cramps; Could not breathe well; She had back problems; COVID-19; COVID-19; This is a spontaneous report from a contactable consumer (patient's husband). A 65-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 07Mar2021 (Lot Number: EN6206) at the age of 65 years, as single dose for covid-19 immunisation. Medical history included back disorder from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. Previously the patient received the first dose of bnt162b2 on 14Feb2021 at the age of 65 years, lot number: ENG201, injection in arm, possibly in left arm: patient had no problems with the first shot. The patient experienced covid-19 (death, medically significant) on 07Mar2021, hypoxic respiratory failure (death, hospitalization) on 08Mar2021, pneumonia (death, hospitalization) on 08Mar2021, stomach cramps (non-serious) on an unspecified date with outcome of unknown, could not breathe well (non-serious) on an unspecified date with outcome of unknown, she had back problems (non-serious) on an unspecified date with outcome of unknown. Patient went to Emergency Room (ER) 8 hours later administration of the second dose and on 08Mar2021 was admitted to hospital. Patient was in hospital from 08Mar2021 till she died. Patient was positive for covid 19 on unknown date. She was diagnosed with covid when she went to ER. Patient was on a ventilator. The patient underwent lab tests and procedures which included endoscopy: gerd or abdomen problem on unspecified date, COVID test: positive on unknown date. Therapeutic measures were taken as a result of hypoxic respiratory failure and pneumonia (on ventilator). The patient died on 16Apr2021. An autopsy was not performed. It was stated that cause of death on death certificate listed as Covid 19, pneumonia, hypoxic respiratory failure. Follow attempts are needed. Further information is expected; Reported Cause(s) of Death: COVID-19; Drug ineffective; pneumonia; Respiratory failure
1395843-1	Dad woke up on January 29, 2021 with severe stomach pains and vomiting. He was very uncomfortable and ended up going back to bed. He was miserable all day. I called his physician and we decided to keep him comfortable at home and give him the BRAT diet which seemed to be helping with the pain and vomiting. Dad never got out of bed again. On February 4th, Dad was placed on Hospice and died on February 7, 2021.
1413571-1	Stroke on the 23rd, hospilized for 10 days. Second stroke on the 12th. Died on the 18th.
1414035-1	2 months after last dose, a routine bloodwork revealed high kidney numbers. Voice became hoarse and difficulty in swallowing ease was noted. Repeat blood work confirmed kidney numbers still high after hydration, IV fluids given at home. Fatigue increased and I took my mother to the ER. She was admitted and she spent 3 weeks in the hospital, 1 week in ICU. She was eventually diagnosed with the autoimmune disease ANCA Vasculitis. Biopsy confirmed. No previous kidney disease or abnormal blood work. She was treated with high dose steroids and chemotherapy. There was no positive response to treatment. Condition worsened and she was moved to Hospice care. My mother died on 05/16/2021
1417182-1	I am the epidemiologist reporting on behalf of patient who tested positive for COVID-19 via PCR on 5/15/21 after the completion of a full Pfizer vaccine series (Dose 1 on 2/8 and Dose 2 on 3/1). The patient later died on 5/28/21. Cause of Death is listed as ?Acute hypoxemic respiratory failure Pneumonia COVID-19?. Pre-existing conditions listed as: CARDIOVASCULAR DISEASE, DIABETES MELLITUS, CHRONIC LUNG DISEASE (ASTHMA/EMPHYSEMA/COPD)
1417204-1	I am the epidemiologist reporting on behalf of patient who tested positive for COVID-19 via PCR on 5/30/21 after the completion of a full Janssen vaccine series (Dose 1 on 5/5/21). The patient later died on 6/03/21. Cause of Death is listed as ?Upper gastrointestinal hemorrhage?. Comments:==========nnJune 01, 2021 at 3:07 PM by HD nn6/1 3:06 Supervisor Review completed by HD): ICP needednPT resides at ..nPT admitted to hospital- as asymptomatic. No dates were provided. shows specimen collected via hospital on 5/30 and no notes regarding admittance.nClosed as medical barriers.nnn==========nnJune 01, 2021 at 2:34 PM by CNA, case is hospitalized since 5/30. Head of Nursing sent her to hospital for vomiting and is not currently in the ICU or being treated for any respiratory issues related to COVID,
1417223-1	I am the epidemiologist reporting on behalf of patient who tested positive for COVID-19 via PCR on 5/14/21 after the completion of a full Moderna vaccine series (Dose 1 on 4/1 and Dose 2 on 4/29). The patient later died on 6/5/21 . Cause of Death is listed as cardiac arrest; hypoxic RF; Extensive PAD and ischemic leg/foot ulcers s/p bypass surgery. Pre-existing conditions listed as: OTHER CHRONIC DISEASES, CARDIOVASCULAR DISEASE, DIABETES MELLITUS, CHRONIC LUNG DISEASE (ASTHMA/EMPHYSEMA/COPD)
1417263-1	I am the epidemiologist reporting on behalf of patient who tested positive for COVID-19 via PCR on 4/29/21 after the completion of a full Pfizer vaccine series (Dose 1 on 1/24 and Dose 2 on 2/14). The patient later died on 5/04/21. Pre-existing conditions listed as: OTHER CHRONIC DISEASES, IMMUNOCOMPROMISED CONDITION. Comments:05/04/21:Patient was admitted to the hospital on 4/28/2021 for COVID-19 infection, pneumonia, and acute on chronic renal failure. He was transferred to the ICU on 4/29/2021 due to acute hypoxic respiratory failure requiring intubation. Despite maximum therapies, the patient's respiratory status did not improve. He remained mechanically ventilated from 4/29 through 5/4. On 5/4, the patient became hypotensive and bradycardic. The patient died at 10:45.
1417278-1	I am the epidemiologist reporting on behalf of patient who tested positive for COVID-19 via PCR on 4/22/21 after the completion of a full Moderna vaccine series (Dose 1 on 2/11 and Dose 2 on 3/11). The patient later died on 5/13/21 . Cause of Death is listed as ?Intestinal Obstruction?.

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1417294-1	I am the epidemiologist for reporting on behalf of patient who tested positive for COVID-19 via PCR on 4/14/21 after the completion of a full Pfizer vaccine series (Dose 1 on 2/28 and Dose 2 on 3/21). The patient later died on 5/08/21. Cause of Death is listed as ?cardiopulmonary arrest; Anoxic encephalopathy; V. Fib cardiac arrest; Myocardial infaction?. Pre-existing conditions listed as: OTHER CHRONIC DISEASES, CARDIOVASCULAR DISEASE, IMMUNOCOMPROMISED CONDITION Case went to Hospital ER on 4/14 after experiencing chest pains for 2-3 days. Rapid COVID test on 4/14 was negative & PCR test on 4/14 was positive. Case remained in ER for retesting on 4/15 (PCR - negative) so she could be admitted to hospital for cardiac catheterization. Case reports having a mild fever at hospital on evening of 4/15 & morning of 4/16. Hospital Internist DX was mild case of COVID with elevated enzymes that indicated a cardiac event. Case is fully vaccinated (1st dose of Pfizer 2/28 & 2nd dose of Pfizer 3/21). Case has history of lupus & rheumatoid arthritis (immuno-suppressed). She receives PT 2-3x/week & biologic treatment (last infusion of Orencia was 4/13). Advised case to follow-up with her PCP & cardiac specialist. Case agreed to isolation guidelines. Case lives alone but has 2 adult sons who live nearby that will provide food drop-offs at door. Emailing vaccination breakthrough info to Epidemiologist & supervisors.nnn==========nnApril 15, 2021 at 3:28 PM ET Left SMS/VM.
1417329-1	I am the epidemiologist reporting on behalf of patient who tested positive for COVID-19 via PCR on 4/5/21 after the completion of a full Pfizer vaccine series (Dose 1 on 12/28/20 and Dose 2 on 1/18/21). The patient later died on 4/9/21. Cause of Death is listed as ?Metastatic Rectal cancer?. Pre-existing conditions listed as: OTHER CHRONIC DISEASES, CARDIOVASCULAR DISEASE, IMMUNOCOMPROMISED CONDITION, DIABETES MELLITUS Comments: Spoke to the case adult daughter. She informed that the case resides at a rehabilitation center. The case's daughter stated that her mother is not having any symptoms and was fully vaccinated. The daughter did not have all the information on dates of vaccine. called center spoke to the administrator who provided the information. The case was at the hospital from 3/27-4/1. Rehab requires a (-) test result to return and a (-) test four days after returning. The case test (+) on her 4th day 4/5.nnn
1430661-1	Fatigue, chills, fever, exhaustion. The following Sunday, 9 days after his second dose he went to bed and never woke up.
1432196-1	The day she received the second dose she started with flu like symptoms. She also had tingling hands and feet her condition did not get better and was rushed to the ER. She was there for 4 days and sent to a long term facility where her condition worsen. She started having breathing issues went back to the ER with chronic breathing complications. At the hospital she had low oxygen level, lung complications, kidney failure and went into cardiac arrest. She was resuscitate and put on a ventilator for 3 days. She started breathing on her own and was taken off the machines. She was sent home a few days later and nine days later went into cardiac arrest again and this time did not make it.
1432736-1	Death; Cardiac arrest; Fatigue; This case was received on 15-Jun-2021 and was forwarded to Moderna on 15-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death), CARDIAC ARREST (Cardiac arrest) and FATIGUE (Fatigue) in a 73-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Hemodialysis. Concurrent medical conditions included Chronic kidney disease (On HD). On 01-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 02-Jun-2021, the patient experienced DEATH (Death) (seriousness criteria death and medically significant), CARDIAC ARREST (Cardiac arrest) (seriousness criteria death and medically significant) and FATIGUE (Fatigue) (seriousness criterion death). The patient died on 02-Jun-2021. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No treatment/concomitant medications were reported. Very limited information regarding these events has been provided at this time. No further follow-up information is expected.; Sender's Comments: Very limited information regarding these events has been provided at this time. No further follow-up information is expected.; Reported Cause(s) of Death: Unknown cause of death
1437490-1	Patient was feeling in good health prior to receipt of vaccination- Patient reported not feeling well right after receiving the dose; fainted the following day- sought medical care that same day- no issues detected; patient continued to say he did not feel like something was right. Patient died on June 4, 2021- brain bleed - transferred to different hospital-intraparenchymal bleed ---please note- there are NO LOT NUMBERS WRITTEN ON PT VACCINE RECORD!
1445735-1	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

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1445766-1	she died from a blood clot that ran into her heart; felt very very tired; nauseas for the first couple of days; nauseas for the first couple of daysdidn't eat well for the first couple of days; This spontaneous case was reported by a consumer and describes the occurrence of INTRACARDIAC THROMBUS (she died from a blood clot that ran into her heart), FATIGUE (felt very very tired), NAUSEA (nauseas for the first couple of days) and DECREASED APPETITE (nauseas for the first couple of daysdidn't eat well for the first couple of days) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. In March 2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. In April 2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. In March 2021, the patient experienced NAUSEA (nauseas for the first couple of days) (seriousness criterion death) and DECREASED APPETITE (nauseas for the first couple of daysdidn't eat well for the first couple of days) (seriousness criterion death). On 04-Apr-2021, the patient experienced FATIGUE (felt very very tired) (seriousness criterion death). On 08-Apr-2021, the patient experienced INTRACARDIAC THROMBUS (she died from a blood clot that ran into her heart) (seriousness criteria death and medically significant). The patient died on 08-Apr-2021. The reported cause of death was she died from a blood clot that ran into her heart. It is unknown if an autopsy was performed. As per source document the patient received the 2nd dose on 4 or 5 April 2021 and she died from a blood clot that ran into her heart on 8Apr2021. Treatment medication was not reported. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Relevant concomitant medications were not provided by the reporter.; 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.; Reported Cause(s) of Death: she died from a blood clot that ran into her heart
1450281-1	Daughter stated that patient got very weak about a week after the 2nd dose of pfizer vaccine. Daughter also stated that patient was taken to ER bc she was unresponsive and her blood pressure was dropping, patient passed at ER on 05/19/2021
1454063-1	I am the epidemiologist reporting on behalf of patient. Patient received two doses of Pfizer on 01/09/21 and 02/02/21. Case was admitted to hospital on 6/26 due to slurred speech, low heartrate, and low oxygen (75%) and tested positive for COVID-19 via a PCR test. The patient passed away on 07/01/21. Cause of death is listed as sepsis. Death cert # 20210042573.
1454169-1	Death
1456619-1	DEATH; COMPUTERISED TOMOGRAM HEAD ABNORMAL; MULTIPLE ORGAN DYSFUNCTION SYNDROME; HYPOXIA; HYPOTENSION; CONTINUOUS HAEMODIAFILTRATION; ENDOTRACHEAL INTUBATION; DEEP VEIN THROMBOSIS; ULTRASOUND DOPPLER ABNORMAL; LUNG ASSIST DEVICE THERAPY; DYSPNOEA; PAIN IN EXTREMITY; PERIPHERAL SWELLING; HYPOXIC-ISCHAEMIC ENCEPHALOPATHY; BRAIN INJURY; BRAIN OEDEMA; ACUTE KIDNEY INJURY; MENTAL IMPAIRMENT; HEPATIC STEATOSIS; THROMBECTOMY; PULMONARY EMBOLISM; PULMONARY INFARCTION; RIGHT VENTRICULAR DYSFUNCTION; ANGIOGRAM PULMONARY ABNORMAL; WITHDRAWAL OF LIFE SUPPORT; This spontaneous report received from a health care professional via a Regulatory Authority, VAERS (Vaccine Adverse Event Reporting System), concerned a 55 year old female. The patient's height, and weight were not reported. The patient's past medical history included ethyl alcohol abuse, and concurrent conditions included hypertension. The patient had no known drug allergies. The patient had no known other illness at the time of vaccination. The patient was not pregnant at the time of vaccination. The patient had not taken any prescriptions, over the counter medications, dietary supplements or herbal remedies at the time of vaccination. The patient had no adverse event following any previous vaccine. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, and batch number: 206A21A expiry: UNKNOWN) dose was not reported, 1 total administered on 21-APR-2021 on left arm for prophylactic vaccination. No concomitant medications were reported. On 08-MAY-2021, the patient's laboratory data included CT (computed tomography) angiography of chest showed severe burden of acute pulmonary embolism (PE) with severe right heart strain, small early infarct posteromedial left lower lobe (LLL), hepatic steatosis and interventional radiology (IR) thrombectomy procedure showed large bilateral pulmonary emboli. On 09-MAY-2021 (approximately 3 weeks after vaccination), the patient was presented to the emergency room due to progressively worsening shortness of breath. The patient also had pain and swelling in the left calf and leg. On the same day, the patient experienced brain injury, brain oedema, acute kidney injury, hypoxic-ischaemic encephalopathy, mental impairment, pain in extremity, peripheral swelling and had lung assist device therapy. The patient was hospitalized on an unspecified date. On 10-MAY-2021, the patient's ultrasound venous Doppler showed complete thrombosis left femoral, popliteal, posterior tibial, peroneal and anterior tibial veins, partial thrombosis of left common femoral vein. The patient underwent urgent thrombectomy, however, on 11-MAY-2021 (the next morning), she became more hypoxic and hypotensive and was intubated and was urgently placed on extracorporeal membrane oxygenation (ECMO). The patient developed multi-organ failure and was started on continuous veno-venous hemofiltration (CVVH) for oliguric renal failure. On 13-MAY-2021, CT computerised tomogram (CT) scan of the patient's head showed diffuse cerebral edema, which was most likely a result of hypoxic encephalopathy. With no improvement in her mental status over the course of the next few days, the patient was taken off life support and died on 15-MAY-2021 due to unknown cause. The patient was in hospital for 7 days. It was unknown if autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of death, multiple organ dysfunction syndrome, hypoxic-ischaemic encephalopathy, brain injury, brain oedema, acute kidney injury, mental impairment, deep vein thrombosis, pulmonary embolism, pulmonary infarction, hypoxia, dyspnoea, pain in extremity, peripheral swelling, hepatic steatosis, hypotension, right ventricular dysfunction, continuous haemodiafiltration, endotracheal intubation, thrombectomy, lung assist device therapy, withdrawal of life support, angiogram pulmonary abnormal, computerised tomogram head abnormal and ultrasound doppler abnormal on 15-MAY-2021. This report was serious (Death, and Hospitalization Caused / Prolonged). This case, involving the same patient is linked to 20210542597. Additional information was received from patient on 01-JUN-2021. The following information was updated and incorporated in to the case narrative: Patient demographics (race, ethnic origin), added patient history, added ethyl alcohol abuse in disease tab, added batch number, added facility type and other identification numbers updated.; Sender's Comments: V1: This spontaneous report received from a health care professional via Regulatory Authority VAERS (Vaccine Adverse Event Reporting System), concerns a 55 year old female patient, who was noted to experience acute pulmonary embolism (PE), with severe right heart strain, 18 days after receiving the Janssen Covid-19 vaccine. The patient sought consult at the emergency room due to worsening of the shortness of breath. The patient also had pain and swelling in the left calf and leg. Computed Tomography Angiography (CTA) of chest showed acute pulmonary embolism (PE) with severe right heart strain, small early infarct posteromedial left lower lobe (LLL), hepatic steatosis. Venous doppler showed complete thrombosis left femoral, popliteal, posterior tibial, peroneal and anterior tibial veins, partial thrombosis of left common femoral vein. The patient underwent urgent thrombectomy. However, she became more hypoxic and hypotensive, was intubated and was urgently placed on extracorporeal membrane oxygenation (ECMO). Later, she developed multi-organ failure and was started on continuous veno-venous hemofiltration (CVVH) for renal failure. Nineteen (19) days after receiving the vaccine, Computerised tomogram (CT) scan of the patient's head showed diffuse cerebral edema, which was most likely a result of hypoxic encephalopathy. With no improvement in her mental status, life support was said to be taken off which resulted to death. It was unknown if autopsy was performed. Patient's height and weight were not reported. The patient's past medical history included ethyl alcohol abuse and concurrent conditions included hypertension. The patient had no known drug allergies. The patient was not pregnant at the time of vaccination. Information is limited in this case. However, a relationship with Janssen Covid-19 vaccine cannot be ruled out and the relationship is considered indeterminate. Additional information has been requested.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID	Adverse Event Description
1464403-1	As per patients family, approx 2 days after receiving Moderna Dose #2 Immunization(was received 5/13/21) patient developed soreness of Rt Arm, body ache, shortness of breath. Was sleeping upright in wheelchair.in order to breath easier. Family stated due to pt having polio as a child, he was fearful of hospitals and refused to have family call 911 These symptoms continued until 6/1/2021 when pt was found dead in wheelchair.by family.
1481780-1	lungs filled up with fluids; terrible pain in his back; couldn't lay had to sleep sat down; swelling of his ankles; swelling of his hands; shortness of breath; chills; died; This spontaneous case was reported by a patient family member or friend and describes the occurrence of DEATH (died) and PULMONARY OEDEMA (lungs filled up with fluids) in a 72-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. unknown) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Blood pressure and Diabetes. In May 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 PULMONARY OEDEMA (lungs filled up with fluids) (seriousness criterion medically significant), BACK PAIN (terrible pain in his back), MOBILITY DECREASED (couldn't lay had to sleep sat down), JOINT SWELLING (swelling of his ankles), PERIPHERAL SWELLING (swelling of his hands), DYSPNOEA (shortness of breath) and CHILLS (chills). The patient died on 01-Jun-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, PULMONARY OEDEMA (lungs filled up with fluids), BACK PAIN (terrible pain in his back), MOBILITY DECREASED (couldn't lay had to sleep sat down), JOINT SWELLING (swelling of his ankles), PERIPHERAL SWELLING (swelling of his hands), DYSPNOEA (shortness of breath) and CHILLS (chills) outcome was unknown. No treatment medication was provided. Patient took concomitant medication for Blood pressure and Diabetes.; Sender's Comments: This is case of death in a 72-year-old male patient with medical history of blood pressure and diabetes who died more than a month after receiving the mRNA-1273 vaccine. Cause of death was not reported. Very limited information regarding the event has been provided at this time. Further information has been requested. Based on the current available information and temporal association between the use of the product and the start date of the remaining events, a causal relationship cannot be excluded.; Reported Cause(s) of Death: unknown cause of death
1484736-1	Pt.'s mother states that after receiving the 2nd dose of Phizer vaccine the Pt. collapsed 05/26/2021 and passed away. Currently waiting for Autopsy results.
1498879-1	Bilateral retinal branch vein occlusions 1 month after. Died 5/7/21
1501182-1	Suicide
1507866-1	Aortic Dissection hemostatic shock; Anaphylactic shock; Paralyze in the lower half of her body; Clotting; Excessive bleeding; Burning sensation going down to her spine; Difficulty breathing; This spontaneous case was reported by a patient family member or friend and describes the occurrence of ANAPHYLACTIC SHOCK (Anaphylactic shock), PARALYSIS (Paralyze in the lower half of her body), THROMBOSIS (Clotting), HAEMORRHAGE (Excessive bleeding), BURNING SENSATION (Burning sensation going down to her spine), DYSPNOEA (Difficulty breathing) and AORTIC DISSECTION (Aortic Dissection hemostatic shock) in a 75-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 054c21a and 009c21a) for COVID-19 vaccination. The patient's past medical history included Open heart surgery on 18-May-2021. On 22-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Jun-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 22-Jun-2021, the patient experienced ANAPHYLACTIC SHOCK (Anaphylactic shock) (seriousness criteria death, hospitalization and medically significant), PARALYSIS (Paralyze in the lower half of her body) (seriousness criteria death, hospitalization and medically significant), THROMBOSIS (Clotting) (seriousness criteria death, hospitalization and medically significant), HAEMORRHAGE (Excessive bleeding) (seriousness criteria death, hospitalization and medically significant), BURNING SENSATION (Burning sensation going down to her spine) (seriousness criteria death and hospitalization) and DYSPNOEA (Difficulty breathing) (seriousness criteria death and hospitalization). On an unknown date, the patient experienced AORTIC DISSECTION (Aortic Dissection hemostatic shock) (seriousness criteria death, hospitalization and medically significant). The patient was hospitalized from 22-Jun-2021 to 04-Jul-2021 due to ANAPHYLACTIC SHOCK, BURNING SENSATION, DYSPNOEA, HAEMORRHAGE, PARALYSIS and THROMBOSIS. The patient died on 04-Jul-2021. The reported cause of death was aortic dissection hemostatic shock. An autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Jun-2021, Blood pressure measurement: decreased (abnormal) Systolic blood pressure <90 mmHg. On 22-Jun-2021, Heart rate: increased (abnormal) Heart rate >100 beats per min. No relevant concomitant medications were reported. Oxygen was given as treatment. She had the second dose on 22JUN2021. 5 hours after the vaccine, she had a burning sensation going down to her spine. Then she was paralyzed in the lower half of her body. She was rush to the local hospital. She was medevac to another hospital. She had clotting and excessive bleeding. She was in the hospital for 13 days. She passed on 04JUL2021 Company comment: This is a case of sudden death in a 75-year-old male subject with hx of open heart surgery, who died 12 days after receiving second dose of vaccine. Very limited information has been provided at this time. However, recent open heart surgery might have at least partially contributed to the events occurrence. Most recent FOLLOW-UP information incorporated above includes: On 26-Jul-2021: Follow-up received- Patient demographics, cause of death, lab data, causality and vaccination details updated.; Sender's Comments: This is a case of sudden death in a 75-year-old male subject with hx of open heart surgery, who died 12 days after receiving second dose of vaccine. Very limited information has been provided at this time. However, recent open heart surgery might have at least partially contributed to the events occurrence.; Reported Cause(s) of Death: Aortic Dissection hemostatic shock
1522680-1	I am the epidemiologist reporting on behalf of patient. The patient is fully vaccinated and the second dose of Pfizer. Date of second vaccine was listed as 05/08. Case began new medication, began vommiting 6/25. Got tested for COVID-19, tested +,. The patient was is in end stage liver disease awaiting a transplant and was tested as part of routine testing for weekly paracentesis. The patient's wife reports that he began three new medications on 6/24 and began vomiting that evening. Patient was admitted after testing positive because the test caused him to miss his paracentesis procedure and has no other symptoms. Patient is listed as having died from COVID-19, end stage liver failure, and liver cirrhosis.
1540347-1	I am the epidemiologist reporting on behalf of patient. Case was admitted after daughter found Dad on the floor was previously being treated for a UTI -- Transported to the ED as he had Difficulty breathing -- during hospital start was treated for COVID Pneumonia -- was treatment at hospital and discharged 8/6 -- 8/7 Returned to ED w/Acute Respiratory Distress -- Daughter was by bedside declined Mechanical Inc -- pt. expired 3 hrs later. Patient was fully vaccinated with Pfizer on 2/17 and 3/10.
1550084-1	DEATH; BLOOD CLOTS; This spontaneous report received from a consumer via social media concerned multiple patients (6 or 7) with unspecified race and ethnicity. The patient's weight, height, and medical history were not reported. The patients received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) 1 total dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patients experienced blood clots and died from unknown cause of death. It was unspecified if was an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clots was not reported. This report was serious (Death, and Other Medically Important Condition). This case, from the same reporter is linked to 20210818227, 20210818107, 20210817805 and 20210818021.; Sender's Comments: V0: 20210818401 -covid-19 vaccine ad26.cov2.s- death, Blood clots. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH
1578274-1	Patient expired 4/10/2021 as reported by husband

VAERS ID	Adverse Event Description
1586540-1	I am the epidemiologist reporting on behalf of patient. The patient received two doses of the Pfizer vaccine on 2/17 and 3/10. On 8/10/21, the patient tested positive via a PCR test for COVID-19 (vaccine breakthrough). The patient died on 8/10 and the cause of death is listed as ?Respiratory Arrest.? I do not have any further detail regarding pre-existing conditions or provider information.
1586554-1	I am the epidemiologist reporting on behalf of patient. The patient received two doses of the Pfizer vaccine on 03/09 and 03/30. The patient was initially hospitalized on 07/19 with an initial diagnosis of pneumonia. The patient tested COVID + on 07/20 and again on 07/28 via a PCR test (vaccination breakthrough). The patient was reported as having died on 08/15. Cause of death is listed as acute, hypoxic, respiratory failure; pneumonia/ARDS; COVID 19; Acute on Chronic Renal Failure. Underlying health conditions include chronic lung disease (asthma/emphysema/copd), chronic renal disease.
1592078-1	HX: Prior to event pt reported weakness for 5 days post vaccine. On 06/17 c/o chest pain throughout the day. Pt experienced syncopal episode on EMS arrival at home. Afib- Asystole- Cardiac Arrest. Shocked and cowated, transport - ed. Tarry black stool on arrival to ED. Cardiac arrest in ED, CPR initiated- ACLS algorithm followed. Lab h/h 2.8/10.4, APTT 5635, PT 17.5, INR 1.4, BNP POCT 308, LACTIC ACID 20.00 /Patient died at 8:00 pm 06/21/21. ME accepted the case.
1602687-1	Increasingly weak after receiving vaccine. Tremors started 5 days after vaccine
1608978-1	Leukemia/Ldiagnosed Leukemia; Covid-19 Symptoms; Cramps; Diarrhea; Mouth sores,canker sore-like on the roof of her mouth and on backside of the gum behind her back tooth; Pain on right side of her head and feels like a chronic headache; Dry eye; Tinnitus was louder than normal; Vertigo; Light headed; Nauseas/ She still felt queasy; Stiffness in her neck, going up back of her head; Joint pain as an increase in the arthritis pain; This spontaneous case was reported by a patient and describes the occurrence of LEUKAEMIA (Leukemia/Ldiagnosed Leukemia) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 018B21A and 012A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Venous ulcer NOS. Concurrent medical conditions included Arthritis and Tinnitus. On 27-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 27-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 29-Mar-2021, the patient experienced ARTHRITIS (Joint pain as an increase in the arthritis pain). On 09-Apr-2021, the patient experienced MUSCULOSKELETAL STIFFNESS (Stiffness in her neck, going up back of her head). On 10-Apr-2021, the patient experienced VERTIGO (Vertigo), DIZZINESS (Light headed) and NAUSEA (Nauseas/ She still felt queasy). On 11-Apr-2021, the patient experienced TINNITUS (Tinnitus was louder than normal) and DRY EYE (Dry eye). On 17-Apr-2021, the patient experienced STOMATITIS (Mouth sores,canker sore-like on the roof of her mouth and on backside of the gum behind her back tooth) and HEADACHE (Pain on right side of her head and feels like a chronic headache). On 19-Apr-2021, the patient experienced DIARRHOEA (Diarrhea) and MUSCLE SPASMS (Cramps). On an unknown date, the patient experienced LEUKAEMIA (Leukemia/Ldiagnosed Leukemia) (seriousness criteria death and medically significant) and SUSPECTED COVID-19 (Covid-19 Symptoms). The patient was treated with PARACETAMOL (TYLENOL) at an unspecified dose and frequency. On 11-Apr-2021, VERTIGO (Vertigo), DIZZINESS (Light headed) and NAUSEA (Nauseas/ She still felt queasy) had resolved. The patient died on an unknown date. It is unknown if an autopsy was performed. At the time of death, MUSCULOSKELETAL STIFFNESS (Stiffness in her neck, going up back of her head), DIARRHOEA (Diarrhea), SUSPECTED COVID-19 (Covid-19 Symptoms), TINNITUS (Tinnitus was louder than normal), MUSCLE SPASMS (Cramps), DRY EYE (Dry eye), STOMATITIS (Mouth sores,canker sore-like on the roof of her mouth and on backside of the gum behind her back tooth), ARTHRITIS (Joint pain as an increase in the arthritis pain) and HEADACHE (Pain on right side of her head and feels like a chronic headache) outcome was unknown. Concomitant medications were not provided. Additional treatment information also included the use of unspecified eye drops. Patient was on chemotherapy for 4 weeks. Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded except for the event of Leukemia which the Company believes is unlikely related due to the natural course of the disease. This case was linked to US-MODERNATX, INC.-MOD-2021-080458 (E2B Linked Report). Most recent FOLLOW-UP information incorporated above includes: On 03-Aug-2021: Significant followup contains new event Leukamia with outcome fatal. On 03-Aug-2021: Follow up received included no new significant information. On 03-Aug-2021: Non Significant follow up appended included no new significant information (AE contact info updated); Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded except for the event of Leukemia which the Company believes is unlikely related due to the natural course of the disease. US-MODERNATX, INC.-MOD-2021-080458:Husband case
1624591-1	Mom started with pain in her left ankle less than 24 hours after receiving the vaccine. The pain made its way up her leg and after 3 phone calls to 911over the course of 6 days she finally agreed to go to the hospital. These severe leg spasms would last for 3 hours and she had them about 4 times a day. She would state her pain level was a 20. She was admitted to the hospital and the Drs said due to the severe pain her BP was highly elevated and she was in congestive heart failure. She spent 2 weeks in the hospital. Went into A-fib. The spasms stopped exactly 2 weeks after they started but at that point she was so weak from being in bed that they wanted to discharge her to a rehab facility but she would have needed her second vaccine and it wasnt time yet(plus she refused because all her issues seemed to stem from the first vaccine). Or she would have to be in complete quarantine for 14 days and she was hard od hearing and that would not have been good either. So we brought her home for myseld and my sister to care for her. She was independent before this vaccine and needed complete care when she got home. She was home for 6 days and progressivly got worse each day and we had to put her on hospice on the 6 day and she passed that night.
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.
1645093-1	People have died from the Moderna vaccine; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of DEATH (People have died from the Moderna vaccine) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event (no medical history per source document). On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant products were reported. No treatment information provided. Company comment: This is a case of sudden death in a patient with unknown age and gender and with unknown past medical history who died in unknown days after receiving a dose of the vaccine. Very limited information has been provided at this time.; Sender's Comments: This is a case of sudden death in a patient with unknown age and gender and with unknown past medical history who died in unknown days after receiving a dose of the vaccine. Very limited information has been provided at this time.; Reported Cause(s) of Death: People have died from the Moderna vaccine

VAERS ID	Adverse Event Description
1646411-1	he passed away within 48 hours; This is a spontaneous report from a contactable consumer. A 64-year-old male patient received bnt162b2 (Pfizer-Biontech Covid-19 vaccine), dose 1 via an unspecified route of administration, administered in Arm Right on 09Feb2021 15:30 (Batch/Lot Number: em9809) as dose 1, single for covid-19 immunisation. The patient has no medical history. Concomitant medication included atorvastatin calcium (LIPITOR) taken for an unspecified indication, start and stop date were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 11Feb2021, 12:00, the patient passed away within 48 hours. The patient received defibrillation as treatment for the event. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The patient died on 11Feb2021 due to cardiac disorder. An autopsy was not performed.; Reported Cause(s) of Death: Cardiac
1646975-1	passed away; heart problem; This is a spontaneous report from a contactable consumer. A 73-year-old male patient (reporter's father) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as dose 1, single for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient passed away from taking Covid vaccine. He never had a heart problem until he took the first Covid vaccine shot. The outcome of event heart problem was unknown. The patient died on an unspecified date. It was not reported if an autopsy was performed. The lot number for the vaccine, bnt162b2, was not provided and will be requested during follow up.; Reported Cause(s) of Death: passed away
1658487-1	I am the epidemiologist reporting on behalf of 60 year old male patient. The patient received two doses of the Moderna vaccine on 5/17 and 6/14. On 8/9/21, the patient tested positive via a PCR test for COVID-19 (vaccine breakthrough). The patient died on 8/26 and the cause of death is listed as ?Cardiac arrest, myocardial infarction, gangrene LLE, Covid pneumonia.? Pre-existing conditions are listed as DIABETES MELLITUS, CARDIOVASCULAR DISEASE.
1658499-1	I am the epidemiologist reporting on behalf of 79-year-old female patient. The patient received two doses of the Pfizer vaccine on 3/04 and 3/25. On 8/12/21 and again on 8/13/21, the patient tested positive via a PCR test for COVID-19 (vaccine breakthrough). The patient died on 8/25 and the cause of death is listed as ?Pneumonia; COVID 19.? Pre-existing conditions are unknown.
1658515-1	I am the epidemiologist reporting on behalf of 88-year-old male patient. The patient received two doses of the Moderna vaccine on 3/21 and 4/18. The patient later took three antigen tests. The first two were on 8/16 (one was negative and one was positive) and the third was on 8/17 (positive). The patient died on 8/27 and the cause of death is not listed although it is considered a probable COVID-19 death according to state guidance. Pre-existing conditions are listed as ?CHRONIC LUNG DISEASE (ASTHMA/EMPHYSEMA/COPD), CARDIOVASCULAR DISEASE, CHRONIC RENAL DISEASE.?
1662149-1	I am the epidemiologist reporting on behalf of 89-year-old female patient. The patient received two doses of the Pfizer vaccine on 1/20/21 and 2/10/21. The patient tested COVID + via rapid antigen test on 7/24/21 and again on 8/27/21 via both PCR and antigen test (vaccination breakthrough). The patient was reported as having died on 8/30/21. Cause of death is listed as acute hypoxic respiratory failure; COVID 19 pneumonia. Underlying health conditions are not provided in system.
1666166-1	DEATH
1666949-1	Within hours was short of breath climbing stairs he climbed daily and it never happened before. Doctor diagnosed that his heart was out of rhythm at next appointment. He was treated with a few different drugs but it couldn't be controlled and he never felt well again. On 4/19/21 he was transported to Hospital by ambulance with AFib. The next morning he was found unresponsive and moved to ICU. His oxygen level was low and carbon dioxide level was high. For 2 weeks he suffered greatly. Doctors tried to balance his high heart rate with his low blood pressure. He was intubated twice. He died on May 2, 2021. His cause of death was acute respiratory failure with hypercapnia and hypoxemia. He had never had heart or lung problems before that.
1675107-1	He died , found dead after 24 hours, Closed casket, no foul play. I am unable to get an autopsy.
1682490-1	I am the epidemiologist reporting on behalf of 61-year-old female patient. The patient received two doses of the Pfizer vaccine on 1/29/21 and 2/19/21. The patient tested positive for COVID-19 on 8/10/21 via PCR. The patient died 9/1/21 and the cause of death is listed as ?ARDS Covid-19?. I do not have further information regarding immunodeficiency status or underlying health conditions.
1682500-1	I am the epidemiologist reporting on behalf of 84-year-old female patient. The patient received two doses of the Moderna vaccine on 3/11/21 and 4/8/21. The patient tested positive for COVID-19 on 8/23/21 via PCR. On 8/26/21, nurse at facility where patient resided reported the patient?s only symptom as ?a bit of weakness.? The patient died 8/30/21 and the cause of death is listed as ?Acute Respiratory Failure; Pneumonia; Covid-19?. I do not have further information regarding immunodeficiency status or underlying health conditions.
1711885-1	died after getting one dose of the pfizer covid 19-vaccine; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age (reported as 57) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as dose 1 , single for COVID-19 immunisation. Medical history included overweight and diabetes, from an unknown date. The patient's concomitant medications were not reported. On an unspecified date, the patient died after getting one dose of the Pfizer COVID 19-vaccine, was not specific if it was due to the vaccine. The patient died on an unspecified date. Outcome of the event was fatal. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: died after getting one dose of the pfizer covid 19-vaccine
1718935-1	91 year old lady with hx dementia, HTN, HLP, PAFib, was brought INTO the hospital for worsening mental status, fatigue and body aches. In the ED she was found to be in atrial fibrillation RVR rate 120s, . She is afebrile but was hypoxic on room air 88%. Patient tested positive for covid. CTA positive for bilateral infiltrates r>L with bilat effusions and noted to have a small non occlusive embolus of subsegmental branch of right lower lobe with no right heart strain, and ascending aortic dilatation, no dissection, and CT head shows remote lacunar infarcts and age related small vessel changes. .
1734644-1	Vaccine Breakthrough Case - led to hospitalization and death Vaccinated Moderna: 2/12/2021 & 3/12/2021 The individual tested positive for COVID-19 on several respiratory tests beginning on 9/10/21. Her symptoms began on 9/8/21, and she was admitted to the hospital on 9/10. She was found to have double pneumonia. The patient also had acute respiratory distress syndrome. The patient unfortunately passed away on 9/24/21. The case has a positive test from 6/18/21, because she was supposed to go in for a procedure, but was asymptomatic at the time and tested negative on 6/23/21.
1745752-1	fever and weakness day after vaccine with increasing weakness at home /admitted to hospital 4 days later with weakness /progressive decline with weakness and paralysis of left arm / stroke suspected but could not be confirmed on 2 magnetic resonance scans /inability to speak and then swallow / treated for possible aspiration pneumonia /progressed to being obtunded and respiratory distress / died 9/25/21

VAERS ID	Adverse Event Description
1749557-1	Arrival to ED: 9/23/21 @ 1:45pm Patient arrived to ED via EMS with chief complaint of altered mental status and emesis. His nephew was at his side. Patient's nephew and EMS stated patient received COVID-19 vaccine the day before and became progressively more weak and lethargic. Patient's baseline is AA0x4 and he takes care of himself. Pt is non verbal and vomited x1 prior to arrival. Upon presentation in the ED, the patient was obtunded and unresponsive. Patient was seen immediately on arrival. The patient's history was provided by the EMS personnel and a relative (nephew). Medical staff were unable to obtain history from patient due to his condition. Physical Exam findings: Constitutional: Obtunded Eyes: Pinpoint pupils bilaterally, minimally reactive Neck: JVD Pulmonary: Breath sounds with rhonchi present bilaterally (R>L); spontaneous respirations Musculoskeletal: Edema to Right Lower Leg and Left Lower Leg; bilateral edema pitting to mid tibia Neurological: Unresponsive to painful stimuli; No posturing noted Vitals on presentation to ED: BP 145/86; HR 88; Resp 21; SpO2 83% Patient seen by critical are provider at 2:15pm Patient placed on nonrebreather oxygen mask with improvement to oxygen saturation (to low 90s). Discussed plan of care with nephew (living will states patient wanted to be DNR/DNI) Stat Imaging ordered and results interpreted Infectious workup initiated & IV antibiotics ordered Discussed case with inpatient admitted MD ED diagnosis: Pneumonia of both lungs due to infectious organism Medication Administration Zosyn 4.5gram IV @ 3:05pm Vancomycin 1,000 mg IV @ 3:05pm Patient expired while in the ED. Time of death, 7:13pm.
1756001-1	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
1779892-1	DEATH
1779903-1	Coughing then turned to pneumonia
1782792-1	I am the epidemiologist reporting on behalf of 75-year-old male patient. The patient received two doses of the Moderna vaccine on 3/19/21 and 4/16/21. The patient tested positive for COVID-19 on 4/23/21 (5 days post second dose) via PCR. The patient died 5/1/21 (15 days post second dose) and the cause of death is listed as ?Pneumonia secondary to COVID 19?. Other significant conditions contributing to death but not resulting in underlying cause are listed as ?gastrointestinal hemorrhage, acute cholecystitis, and congestive heart failure.?
1782965-1	I am the epidemiologist reporting on behalf of 77-year-old female patient. According to records, patient was a 77 y/o woman with a hx of hypertension, hyperlipidemia, hx of tachycardia-induced cardiomyopathy (with normalization of LV function), chronic atrial fibrillation complicated by embolic renal infarction (on rivaroxaban), hx of rectal cancer, sacral decubitus ulcer, resident who had been positive for COVID19 since about a month prior to admission who presented to ED on 1/26 with substernal chest pain, where she was found to be in atrial fibrillation with bradycardia and to have an inferior STEMI. A transvenous pacer was emergently placed in the emergency room and patient was intubated because of hypoxia and unresponsiveness. Of note, COVID19 PCR was still positive. Emergent cardiac catheterization was done, which demonstrated a totally occluded RCA. PCI was performed and three drug eluting stents were placed in the RCA. The transvenous pacer was repositioned under fluoroscopic guidance. Vasopressor support was started in the cath lab. Upon ICU arrival, patient had rapidly escalating vasopressor requirements and persistent bradycardia, but the pacer was no longer capturing (despite maximal output). Echocardiography demonstrated severe systolic dysfunction. Mrs. Wightman had three consecutive cardiac arrests. TIMELINE: The patient tested positive for COVID-19 on 11/24/20 and 12/08/21 via PCR. The patient then received two doses of the Pfizer vaccine on 12/30/20 and 1/20/21. The patient tested positive for COVID-19 again on 1/26. The patient died on 1/27/21, one week after their second dose of Pfizer vaccine and one day after testing positive for COVID-19. The suspected cause of death is listed as ?cardiac arrest secondary to STEMI, cardiogenic shock?. I am reporting this case now because vaccination status was not considered to be a factor in cardiac arrest at the time this report was initially made.
1783015-1	I am the epidemiologist reporting on behalf of 71-year-old male patient. The patient received two doses of the Pfizer vaccine on 3/3/21 and 3/25/21. The patient initially tested positive for COVID via a PCR test on 3/27/21 (two days after second dose) and again on 4/21/21. Patient was in ICU, on a Vent 4/2/21 until 4/25/21; Covid pneumonia, hypoxia, completed Remdesivir, patient had an arterial thrombosis LLE required a thrombectomy and fasciotomy on 4/4/21. Patient expired on 4/25/21 (one month after receiving second dose of Pfizer vaccine). Cause of death is listed as multiorgan failure secondary to COVID-19, ventilator dependent respiratory failure and ARDS. Other significant conditions contributing to death but not resulting in underlying cause are thrombocytopenia, anemia, right MCA infarct-subacute. I am reporting this to VAERS now because vaccination status was not considered at the time of the report.
1786208-1	Patient died suddenly. Because there was no foul play, an autopsy was not done. ER doc guessed massive heart attack. Patient's cardiologist does not believe it was a heart attack because his labs were fine in July. His blood pressure was controlled.
1795506-1	10/16 patient falls from sob and low 02 level. Patient sent to ER and passed away 10/17/21.
1795563-1	vomiting

VAERS ID	Adverse Event Description
1821139-1	COVID-19 Vaccine Breakthrough Case: Hospitalization & Death The case tested positive for COVID and went to the emergency room and was admitted on 10/9/21. The case unfortunately passed away on 10/20/21. The individual received a monoclonal antibody infusion on 10/9/21. As part of his COVID-19 symptoms, the individual had difficulty breathing, loss of smell/taste, and a fever. The case also developed pneumonia and acute respiratory distress syndrome (ARDS).
1825328-1	"I am the epidemiologist reporting on behalf of 92-year-old male patient. The patient received two doses of the Pfizer vaccine on 02/09/21 and 03/02/21. The patient received their third dose of the Pfizer vaccine on 10/01/21. On 10/10/21 (10 days post dose 3), the patient took a PCR test and a rapid test and was positive on both. According to contact tracing team who spoke with daughter of case, case was asymptomatic with the 3rd dose of the Pfizer vaccine. On 10/12, the case was moved to Hospice care as they are not treating the case for COVID, however, as they speaker mentioned a ""heart attack."" The patient died on 10/15/21 (15 days post 3rd dose). The cause of death is listed as ?Acute respiratory failure; Pneumonia due to Covid ;Covid? on the death certificate. Other significant conditions contributing to death but not resulting in underlying causes are listed as ?adult failure to thrive syndrome.? Known pre-existing conditions include cardiovascular disease."
1837453-1	Stroke on 2/12/2021, death on 2/28/2021 Was in 3 hospitals:
1845414-1	died as a result of the Pfizer BioNTech Covid-19 vaccine; This is a spontaneous report from a contactable consumer received from a Pfizer sponsored program. A 39-year-old male patient (consumer neighbor's son) received BNT162B2 (COMIRNATY, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date (at an unspecified age) as dose number unknown, single for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient died as a result of the Pfizer BioNTech Covid-19 vaccine on an unspecified date. It was not reported if an autopsy was performed. The lot number for BNT162B2, was not provided and will be requested during follow up.; Reported Cause(s) of Death: died as a result of the Pfizer BioNTech Covid-19 vaccine
1864369-1	Pulmonary embolism; Cerebral small vessel ischaemic disease; Atrial fibrillation; Hypoxia; Lacunar infarction; Aortic dilatation; COVID-19; Condition aggravated; Fatigue; Lung infiltration; Mental status changes; Pain; Pleural effusion; Computerised tomogram head abnormal; Myocardial strain imaging; Angiogram pulmonary abnormal; SARS-CoV-2 antibody test positive; SARS-CoV-2 test positive; SUSPECTED CLINICAL VACCINATION FAILURE; This spontaneous report received from a health care professional via a Regulatory Authority Vaccine Adverse Event Reporting System (VAERS) (VAER reference number 1718935) concerned a 91 year old female of unknown race and ethnicity. Initial information received on 01-OCT-2021 was processed with additional information received on 06-OCT-2021. The patient's height, and weight were not reported. The patient's height, and weight were not reported. The patient's past medical history included: hyperkeratosis lenticularis perstans (HLP), paroxysmal atrial fibrillation, colon cancer remotely post RT and chemotherapy, and colon resection, and concurrent conditions included: hypertension (HTN), Chronic obstructive pulmonary disease (COPD), dementia, and arteriosclerotic heart disease (ASHD), and former smoker, and other pre-existing medical conditions included: The patient had no known drug allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 042A21A expiry: unknown) dose was not reported, 1 total, administered on 08-APR-2021 for an unspecified indication. Concomitant medications included amlodipine 10 mg tablet, one tablet oral daily, metoprolol tartrate 25 mg tablet, one tablet oral every twelve hours, and simvastatin 20 mg tablet, 1 tablet oral daily at bedtime. On 20-SEP-2021, patient was brought into the hospital for worsening mental status fatigue and body aches in the emergency department patient was found to be in atrial fibrillation, rapid ventricular rate (RVR) was 120s. She was afebrile but was hypoxic on room air (Oxygen saturation) 88 percent. Patient tested positive for covid. Computed tomography angiography (CTA) positive for bilateral infiltrates r greater than L with bilateral effusions and noted to have a small non occlusive embolus of subsegmental branch of right lower lobe with no right heart strain and ascending aortic dilatation no dissection and computed tomography (CT) head shows remote lacunar infarcts and age related small vessel changes. the patient experienced cerebral small vessel ischaemic disease, lung infiltration, pleural effusion, pulmonary embolism, condition aggravated and suspected clinical vaccination failure. It was unspecified if an autopsy was performed. Laboratory data on the same day included: Angiogram pulmonary (NR: not provided) abnormal, Computerised tomogram head (NR: not provided) abnormal, Myocardial strain (NR: not provided) not reported, and SARS-CoV-2 antibody test (NR: not provided) IgM 0 07 and IgG 0 03. Laboratory data (dates unspecified) included: SARS-CoV-2 test (NR: not provided) Positive. On 20-SEP-2021, the patient died from pulmonary embolism, cerebral small vessel ischaemic disease, atrial fibrillation, hypoxia, lacunar infarction, aortic dilatation, covid-19, condition aggravated, fatigue, lung infiltration, mental status changes, pain, pleural effusion, computerised tomogram head abnormal, myocardial strain imaging, sars-cov-2 antibody test positive, angiogram pulmonary abnormal, and sars-cov-2 test positive. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the suspected clinical vaccination failure was not reported. This report was serious (Death, and Other Medically Important Condition). This report was associated with product quality complaint: 90000196325. The suspected product quality complaint has been confirmed to be the reported allegation could not be confirmed. A manufacturing related root cause could not be identified based on the PQC evaluation/investigation performed. Additional information received from Central Complaint Vigilance department on 09-NOV-2021. The following information was updated and incorporated into the case narrative: Product quality complaint investigation result.; Sender's Comments: V2: Additional information in this version updates: Product quality complaint investigation result. This updated information does not alter the causality of previously reported events. 20211009613-COVID-19 VACCINE AD26.COV2.S-pulmonary embolism, cerebral small vessel ischaemic disease, atrial fibrillation, hypoxia, lacunar infarction, aortic dilatation, covid-19, condition aggravated, fatigue, lung infiltration, mental status changes, pain, pleural effusion, computerised tomogram head abnormal, myocardial strain imaging, sars-cov-2 antibody test positive, angiogram pulmonary abnormal, and sars-cov-2 test positive. These events are considered unassessable. The events have a compatible/suggestive temporal relationship, are unlabeled, and have unknown scientific plausibility. There is no information on any other factors potentially associated with the events. V0 20211009613-COVID-19 VACCINE AD26.COV2.S-Suspected clinical vaccination failure. This event is considered not related. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event than the drug. Specifically: SPECIAL SITUATIONS.; Reported Cause(s) of Death: CEREBRAL SMALL VESSEL ISCHAEMIC DISEASE; ATRIAL FIBRILLATION; HYPOXIA; PULMONARY EMBOLISM; LACUNAR INFARCTION; AORTIC DILATATION; COVID-19; CONDITION AGGRAVATED; FATIGUE; LUNG INFILTRATION; MENTAL STATUS CHANGES; PAIN; PLEURAL EFFUSION; COMPUTERISED
1865333-1	I am the epidemiologist reporting on behalf of 42 year-old male patient. Patient received three doses of the Pfizer vaccine, according to immunization records. The first dose was on 02/13/21, the second on 03/06/21, and the third was on 10/16/2021. According to death certificate, patient was found dead on 10/31/21 at home (15 days post dose 3). Immediate cause of death listed is ?complications of pericarditis.? Interval between onset and death is listed as ?unknown.? I do not have any further details on underlying health conditions that may have contributed to this fatality.
1865373-1	I am the epidemiologist reporting on behalf of 59 year-old female patient. Patient received two doses of the Pfizer vaccine, according to immunization records. The first dose was on 03/31/21 and the second was on 04/21/2021. The patient died 4/30/21 (nine days post dose 2) in hospital emergency room (outpatient). The death certificate lists ?cardiovascular collapse? as the immediate cause of death. Interval between onset and death is listed as ?5 minutes.? Known underlying health conditions include (but are not limited to) diabetes.
1865402-1	I am the epidemiologist reporting on behalf of 69 year-old male patient. Patient received two doses of the Pfizer vaccine, according to immunization records. The first dose was on 1/11/21 and the second was on 02/01/2021. The patient died on 02/02/21 (one day post dose 2) in nursing home. The death certificate lists ?acute myocardial infarction? as the immediate cause of death secondary to ?hypertensive heart disease? (unknown onset). Other significant conditions contributing to death but not resulting in underlying cause include Parkinson?s disease, hypothyroidism, and hyperlipidemia.

VAERS ID	Adverse Event Description
1865504-1	I am the epidemiologist reporting on behalf of 75 year-old female patient. Patient received two doses of the Moderna vaccine, according to immunization records. The first dose was on 4/23/21 and the second was on 5/17/2021. The patient was found dead at home on 5/19/2021 (2 days post second dose). The death certificate lists ?cardiopulmonary arrest? as the immediate cause of death secondary to ?CHF, Interstitial Lung Disease, OSA, AFIB (FEW weeks) and RHEUMATOID ARTHRITIS, HTN, DIABETES (MANY years).? No additional information is available.
1865612-1	I am the epidemiologist reporting on behalf of 57 year-old male patient. Patient received one dose of the Pfizer vaccine on 04/06/2021, according to immunization records. The patient passed away on 4/09/2021 (3 days post first dose, hospital emergency room). The death certificate lists ?cardiac arrest? as the immediate cause of death. No additional information regarding underlying conditions that may have contributed to this death is available.
1872949-1	I am the epidemiologist reporting on behalf of 59 year-old male patient. Patient received one dose of the Pfizer vaccine on 4/06/2021, according to immunization records. The patient passed away on 4/08/2021 (2 days post first dose, hospital inpatient). The death certificate lists ?ST Elevation, Myocardial Infarction? as the immediate cause of death due to or as a consequence of acute cholecystitis and diabetic ketoacidosis. No additional information regarding underlying conditions that may have contributed to this death is available.
1872966-1	I am the epidemiologist reporting on behalf of 62 year-old male patient. Patient received one dose of the Pfizer vaccine on 3/15/2021, according to immunization records. The patient passed away on 3/17/2021 (2 days post first dose, hospital inpatient). The death certificate lists ?Cardiac Arrest? as the immediate cause of death due to or as a consequence of esophageal cancer, possible bowel ischemia and colon cancer. No additional information regarding underlying conditions that may have contributed to this death is available.
1872995-1	I am the epidemiologist reporting on behalf of 81 year-old male patient. Patient received one dose of the Pfizer vaccine on 3/25/2021, according to immunization records. The patient was found deceased at home on 3/28/2021 (3 days post first dose). The death certificate lists ?Cardiopulmonary failure? as the immediate cause of death. No additional information regarding underlying conditions that may have contributed to this death is available.
1873014-1	I am the epidemiologist reporting on behalf of 83 year-old male patient. Patient received one dose of the Pfizer vaccine on 3/19/2021, according to immunization records. The patient passed away at home on 3/21/2021 (2 days post first dose). The death certificate lists ?Sudden Cardiac Death? as the immediate cause of death secondary to non-ischemic cardiomyopathy (18 months). No additional information regarding underlying conditions that may have contributed to this death is available.
1873163-1	I am the epidemiologist reporting on behalf of 80 year-old male patient. Patient received one dose of the Pfizer vaccine on 2/04/2021, according to immunization records. The patient passed away on 2/11/2021 (7 days post first dose, hospital inpatient). The death certificate lists ?Acute Hypoxic Respiratory Failure (3 Days)? as the immediate cause of death secondary to acute heart failure (few days). Other significant conditions contributing to death but not resulting in underlying cause include acute kidney injury requiring hemodialysis, staph bacteremia, chronic systolic heart failure. No additional information regarding underlying conditions that may have contributed to this death is available.
1873627-1	I am the epidemiologist reporting on behalf of 73 year-old female patient. The patient received two doses of the Pfizer Vaccine: First: 2/27/2021 Second: 03/20/2021 The patient was found dead at home on 3/27/2021 (7 days post second dose). The immediate cause of death listed on the death certificate is ?cardiopulmonary arrest? (few minutes) secondary to ?arrhythmia? (few minutes) and ?hypertensive heart disease? (few years). I do not have any additional information about other underlying conditions that may have contributed to this person?s death.
1873689-1	I am the epidemiologist reporting on behalf of 65 year-old male patient. The patient received two doses of the Pfizer Vaccine: First: 3/17/2021 Second: 4/07/2021 The patient was found dead at home on 4/19/2021 (12 days post second dose). The immediate cause of death listed on the death certificate is ?coronary artery disease.? Other significant conditions contributing to death but not resulting in underlying cause are listed as ?hypertension COPD?. I do not have any additional information about other underlying conditions that may have contributed to this person?s death.
1885533-1	I am the epidemiologist reporting on behalf of 77 year-old female patient. Patient was a resident of a facility for approximately two years prior to death. Patient received three doses of the Pfizer vaccine. The first was on 1/03/2021, the second was on 1/24/21 and the third was on 9/30/2021, according to immunization records. The patient passed away on 9/30/2021 (the same day the third dose was received) in nursing facility. The death certificate lists ?Cerebral Arteriosclerosis (1 year)? as the immediate cause of death. Prior medical information (obtained from facility) includes: 2019-Time of Death: Hypertension, Wernicke?s encephalopathy 2020- Time of Death: Liver cirrhosis, history of TIAs, unspecified chronic kidney disease (stage 3), 2021- Time of Death: Hyperlipidemia The patient was prescribed amlodipine (heart medicine) and Lipitor.
1890222-1	Death
1893326-1	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 inlcuded 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 Lavix, 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
1893818-1	Received the Booster shot 12pm on 11/5/2021, had chest pain at 9pm 11/5/2021. Was hospitalized at 10pm on 11/5/2021. Heart stopped on 11/10/2021 was revived and placed on a ventilator. Heart stopped again on 11/11/2021 at around 7pm was again revived. Died on 11/13/2021

VAERS ID	Adverse Event Description
1901073-1	CONFIRMED COVID19 INFECTION; DEATH; CONFIRMED CLINICAL VACCINATION FAILURE; This spontaneous report received from a consumer concerned a 76 year old male. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 206A21A, expiry: unknown) dose was not reported, 1 total was administered to right arm on 09-AUG-2021 for prophylactic vaccination. No concomitant medications were reported. About the first week of OCT-2021, the patient felt ill and went to an urgent care, performed rapid test result came negative, two days later he went to the ears, nose, throat (ENT) with worsening symptoms, and had another rapid test still negative. On 15-OCT-2021, the patient went to the hospital and was feeling severely ill, he was critical in the hospital and did polymerase chain reaction (PCR) test and tested positive (confirmed clinical vaccination failure, confirmed covid19 infection (acute hypoxia)), by then he was advanced and had significant lung damage. The number of hospitalized day was unspecified. On 03-NOV-2021, the patient died from unknown cause of death. An autopsy was not performed. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The outcome of event death was fatal and outcome of confirmed clinical vaccination failure and confirmed covid19 infection was not reported. This report was serious (Death, Hospitalization Caused / Prolonged, and Other Medically Important Condition). This case, from the same reporter is linked to 20211152663. This report was associated with product quality complaint.; Sender's Comments: V0: 20211151782-Covid-19 vaccine ad26.cov2.s-Confirmed clinical vaccination failure . This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: SPECIAL SITUATIONS 20211151782-Covid-19 vaccine ad26.cov2.s-Death, Confirmed covid19 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).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH
1909307-1	I am the epidemiologist reporting on behalf of 73-year-old male LTCF patient. The patient received their first dose of the Pfizer vaccine on 1/06/21. The patient tested positive for COVID-19 on 1/26/21 via PCR (20 days post dose 1). The patient received their second dose of the Pfizer vaccine on 5/26/21 and their third dose of the Pfizer vaccine on 10/27/21. The patient tested positive for COVID-19 a second time via PCR on 11/16/21. On 11/27/21 (one-month post dose-3 and 11 days post positive test) the patient expired (listed as COVID-19 death). The cause of death listed on the death certificate is atherosclerosis (3 years). Known patient history includes cardiovascular disease. This is the first instance I have observed within my home county of a person with a repeat infection, fully vaccinated + boosted, passing away with COVID.
1909575-1	This is a 61-year-old female with history of chronic back pain, hypertension, GERD who was recently discharged after being admitted to hospital for acute kidney injury, monomorphic V-tach, paroxysmal atrial fibrillation, hematuria and pancytopenia with UTI. She was at the subacute rehabilitation center Bartley. She was doing okay until last few days when she started having some diarrhea, and urinary frequency, urine analysis and cultures were sent and she was started empirically on ciprofloxacin. Yesterday in the morning patient became acutely short of breath and had severe sore throat with acute hypoxia down to 70s and hypotension with systolic blood pressure in 70s as well hence she was referred to the ER. Her covid test came out positive. In the ER patient was started on empiric antibiotics as per sepsis protocol after cultures were sent, she did not respond to fluid resuscitation hence she was started on Levophed and admitted to ICU.
1912752-1	I am the epidemiologist reporting on behalf of 68 year-old female patient. Patient received their first and second doses of the Moderna vaccine on 4/21/21 and 5/18/21 respectively, according to immunization records. Patient received their third dose of the Moderna Vaccine on 11/22/21. The patient was found deceased at home on 11/23/2021 (1 day after third dose). The death certificate lists ?hypertension (5 years)? as the immediate cause of death. Other significant conditions contributing to the death but not resulting in underlying cause include hyperlipidemia. I have no further information regarding the patient?s medical history.
1942804-1	Patients girlfriend is claiming that patient passed away in his sleep 3 days after getting the vaccine. Reported chills and tiredness. No other information was given
1963262-1	"12/10/2021 patient received 3rd dose of moderna vaccine (0.25 mL). 12/11/2021 patient experienced chest wall ache (center of chest). Area was sore to touch and was relieved by repositioning. She reported she had similar symptoms with 2nd Moderna dose. pain as a ""4"" in severity (on a 1-to-10 scale), dull, and aching., nausea and headache 12/15/2021 patient was found expired at home"
1997533-1	1. 1st Moderna Injection on 2/26/21 (Lot 013A21A) 2. 3/17/21 - Unknown Bleeding around the left eye causing dark bruise 3. 2nd Moderna Injection on 3/26/21 (Lot 008B21A) 4. 5/18/21 - collapsed 5. week of 6/7/21 - legs felt weak, 6/12/21 - arms felt weak - went to emergency room 6. 6/12/21 - admitted to hospital mild heart attack 7. 6/12/21 - the night admitted to hospital - stroke 8. 7/11/21 - died
2001867-1	Pt.'s Daughter states that after receiving the 2nd dose of Moderna 03/27/2021, started experiencing symptoms 2hrs of Appendicitis with GI bleed. Hospitalized at Hospital (ICU 3 weeks) discharged to Rehabilitation. Suffered a Ischemic Stroke during being Hospitalized. Pt. suffered another Massive Stroke 05/13/2021 during Hospitalization due to Stroke D.O.D 05/15/2021.
2014296-1	Covid #1 given on 2/15/2021, #2 on 3/15/2021 and boosted on 10/31/2021. Boosted was with 0.25 mL and not 0.5, which would have been more appropriate for an immunocompromised patient. Booster dose given at Pharmacy. Patient admitted to hospital on 12/30/2021 and expired on 1/6/2022 Tested positive for Covid-19 on admission
2048171-1	On the evening of the booster vaccination (approx 8-9 hours post vaccination), the patient developed fever and chills that progressed over the next 24 hours. On the morning of 1/19/22, the patient's family member discovered the patient had passed away during the overnite
2065541-1	My mom got her booster on 12/20 and she later on notified a family friend for Benedryl since she did not feel well and tried to sleep it off but later died in her sleep.
2072050-1	Patient received his Moderna Vaccines on 1/15/21, 2/12/21, and 11/2/21. He was admitted to medical facility for Rehab-on 1/19/22. He tested positive for COVID-19 on 1/20/22. He was asymptomatic. On 1/24/22, patient was found unresponsive in his room. CPR and ACLS was performed but patient could not be resuscitated.
2074928-1	Hx of metastatic rectal cancer, on chemo. Admitted wit cough, dyspnea, found with COVID 19
2148213-1	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 jan5th 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 continusouly 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 pulmonlogist. 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 hosptialzied 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.

VAERS ID	Adverse Event Description
2148498-1	Ruptured Cerebral Aneurysm Left Middle Cerebral Artery Circulation (02/25/2022) leading to death (02/27/2022)
2155186-1	Four days after vaccine booster started having serious pain in right ankle, leg and back. Went to Emergency Room at a local Hospital on 11-25-2021 (Thanksgiving Day) with severe leg/ back pain. Numerous tests were done in hospital and nothing was found. Sent home on the 29th and health declined rapidly. Started having extreme leg/ back pain. Started having severe memory issues and also started hallucinating. Legs became very weak and he couldn?t stand on his own. Became very weak. Took him for an MRI on 01/05/2022 and it was negative: no stroke, mass effect or bleed. Lost all control of legs and memory declined severely and frequent hallucinations. Died on 01-22-2922.
2165466-1	Resident passed away 5 days after getting the booster dose. Received Primary Moderna vaccine on 8/20/2021 and 9/17/2021. Booster dose on 3/2/2022. Resident died on 3/7/2022.
2184246-1	Death
2204058-1	Patient reported to her Dermatologist that two weeks following her Covid vaccine (Pfizer) in 3/2021 she developed she had a significant eruption of tense blisters heavily effecting her BL lower extremities.
2216685-1	May 2021, my husband complained of memory issues and stated it got worse after getting the vaccine. On June 1, 2021, he completed suicide by hanging. In a note he left he stated that ?something in my brain went wrong.? That it was his ? failure to function at work and trying to remember things that did this to me.?
2261803-1	Reported dark colored emesis x2 episodes Tachycardia Tachypnea, SPO2 <89% on room air- Started on Oxygen Recently was being treated for constipation with episodes of emesis prior to vaccination
2261830-1	Change in status- lethergy Tachypnea in respiratory distress
2263442-1	Shortness of breath, respiratory distress
2277758-1	Started Guanfacine 1 mg twice daily and Prozac 10 mg every other day on Monday, April 11, 2022. Saturday April 16, 2022 began having dull ache in back and left arm, discontinued Guanfacine. Thursday, April 21, 2022, collapsed and was unable to be resusitated. Pronounced dead.

VAERS ID	Adverse Event Description
2284498-1	Two heart attacks/Leg stents failed after hearth attacks; Cardiogenic shock; Acute renal failure; ischemic cardiomyopathy; Phlegm/Cough; Lack of drug effect; tested positive for Covid 19; This spontaneous case was reported by a consumer and describes the occurrence of CARDIOGENIC SHOCK (Cardiogenic shock), ACUTE KIDNEY INJURY (Acute renal failure), ISCHAEMIC CARDIOMYOPATHY (ischemic cardiomyopathy), MYOCARDIAL INFARCTION (Two heart attacks/Leg stents failed after hearth attacks) and COVID-19 (tested positive for Covid 19) in a 69-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 052C21A and 050C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Stent placement (stent put in her leg) on 16-Jun-2021, Stent placement (she also had stents put in her legs and because suffered the 2 heart attacks) in July 2021, Bypass surgery (leg bypass surgery) in September 2021 and Amputation above knee on 24-Dec-2021. Concurrent medical conditions included Penicillin allergy, Allergy to antibiotic (Amoxicillin), Allergy (Aspirin) and Diabetes. Concomitant products included INSULIN for Diabetes. On 16-Jun-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 14-Jul-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 18-Jul-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced MYOCARDIAL INFARCTION (Two heart attacks/Leg stents failed after hearth attacks) (seriousness criteria hospitalization and medically significant). On 31-Dec-2021, the patient experienced COVID-19 (tested positive for Covid 19) (seriousness criterion medically significant). On an unknown date, the patient experienced CARDIOGENIC SHOCK (Cardiogenic shock) (seriousness criteria death and medically significant), ACUTE KIDNEY INJURY (Acute renal failure) (seriousness criteria death and medically significant), ISCHAEMIC CARDIOMYOPATHY (ischemic cardiomyopathy) (seriousness criteria death and medically significant), PRODUCTIVE COUGH (Phlegm/Cough) and DRUG INEFFECTIVE (Lack of drug effect). The patient was treated with SACUBITRIL, VALSARTAN (ENTRESTO) at an unspecified dose and frequency; RANOLAZINE at an unspecified dose and frequency; METOPROLOL at an unspecified dose and frequency; CLOPIDOGREL at an unspecified dose and frequency and ATORVASTATIN at an unspecified dose and frequency. The patient died on 23-Feb-2022. The reported cause of death was Ischemic cardiomyopathy, Cardiogenic shock and Acute renal failure. An autopsy was not performed. At the time of death, MYOCARDIAL INFARCTION (Two heart attacks/Leg stents failed after hearth attacks), COVID-19 (tested positive for Covid 19), PRODUCTIVE COUGH (Phlegm/Cough) and DRUG INEFFECTIVE (Lack of drug effect) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 31-Dec-2021, SARS-CoV-2 test: positive (Positive) positive. This case was linked to MOD-2022-566930 (Patient Link). Company Comment: This spontaneous case concerns a 69-year-old old female patient with relevant concurrent condition of diabetes mellitus and medical history of stent placement for unspecified peripheral condition who experienced the fatal, unexpected, serious (medically significant) adverse events of special interest of Cardiogenic shock, Ischaemic cardiomyopathy and Acute kidney injury and twice reported unexpected, serious (hospitalization, medically significant) adverse event of special interest of Myocardial infarction and unexpected, serious (medically significant) adverse event of special interest of COVID-19 which occurred after receiving the second dose of mRNA-1273 vaccine. Patient developed chest pain a day after the second dose of vaccination. She was admitted in a hospital and diagnosed to have two episodes of Myocardial infarction. She was discharged and prescribed with Entresto, Ranolazine, Metoprolol, Clopidogrel and Atorvastatin. Her leg stents failed on the same month of vaccination thus she underwent peripheral vascular bypass surgery two months after. Approximately 5 months after vaccination, she underwent above the knee leg amputation for unknown indication. She was started on physical rehabilitation since then. Patient developed COVID-19 (with a positive SARS-CoV-2 test) approximately five months after the second dose of mRNA-1273 vaccine. Drug ineffective was also considered (COVID-19 occurred approximately five months post-completion of primary vaccination of mRNA-1273 and within the recommended dosing interval). It was mentioned that COVID-19 is contributory to the patient demise however the clinical presentation, diagnostic evaluation and treatment details was not reported in this case. Death occurred approximately seven months after second dose of mRNA-1273 vaccine. The cause of death was reported as Cardiogenic shock, Ischemic cardiomyopathy, and Acute renal failure. It is unknown if an autopsy was performed. Patient¦s advanced age and concurrent condition remain as confounders for the events Myocardial infarction, Cardiogenic shock, Ischaemic cardiomyopathy and Acute kidney injury and the fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.; Sender's Comments: This spontaneous case concerns a 69-year-old old female patient with relevant concurrent condition of diabetes mellitus and medical history of stent placement for unspecified peripheral condition who experienced the fatal, unexpected, serious (medically significant) adverse events of special interest of Cardiogenic shock, Ischaemic cardiomyopathy and Acute kidney injury and twice reported unexpected, serious (hospitalization, medically significant) adverse event of special interest of Myocardial infarction and unexpected, serious (medically significant) adverse event of special interest of COVID-19 which occurred after receiving the second dose of mRNA-1273 vaccine. Patient developed chest pain a day after the second dose of vaccination. She was admitted in a hospital and diagnosed to have two episodes of Myocardial infarction. She was discharged and prescribed with Entresto, Ranolazine, Metoprolol, Clopidogrel and Atorvastatin. Her leg stents failed on the same month of vaccination thus she underwent peripheral vascular bypass surgery two months after. Approximately 5 months after vaccination, she underwent above the knee leg amputation for unknown indication. She was started on physical rehabilitation since then. Patient developed COVID-19 (with a positive SARS-CoV-2 test) approximately five months after the second dose of mRNA-1273 vaccine. Drug ineffective was also considered (COVID-19 occurred approximately five months post-completion of primary vaccination of mRNA-1273 and within the recommended dosing interval). It was mentioned that COVID-19 is contributory to the patient demise however the clinical presentation, diagnostic evaluation and treatment details was not reported in this case. Death occurred approximately seven months after second dose of mRNA-1273 vaccine. The cause of death was reported as Cardiogenic shock, Ischemic cardiomyopathy, and Acute renal failure. It is unknown if an autopsy was performed. Patient¦s advanced age and concurrent condition remain as confounders for the events Myocardial infarction, Cardiogenic shock, Ischaemic cardiomyopathy and Acute kidney injury and the fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.; Reported Cause(s) of Death: ischemic cardiomyopathy; cardiogenic shock; acute renal failure
2323904-1	"died of a heart attack; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP). A male patient received BNT162b2 (BNT162B2), on 06Apr2021 as dose 1, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history included: ""COVID 19"", start date: 02Dec2020 (unspecified if ongoing), notes: He had been previously diagnosed with COVID 19 on or about 02Dec2020. The patient's concomitant medications were not reported. The following information was reported: MYOCARDIAL INFARCTION (death, medically significant) with onset 09Apr2021, outcome ""fatal"", described as ""died of a heart attack"". The patient date of death was 09Apr2021. Reported cause of death: ""died of a heart attack"". Clinical course: The patient received his first COVID 19 vaccine on 06Apr021. He died of a heart attack on 09Apr2021. He had been previously diagnosed with COVID 19 on or about 02Dec2020. He had no symptoms of indicating a heart issue prior to his heart attack. It has been thought by the reporter that it was important to report, in regards to efficacy and side effects of the vaccine. The information on the batch/lot number for BNT162b2 has been requested and will be submitted if and when received.; Reported Cause(s) of Death: died of a heart attack"

VAERS ID	Adverse Event Description
2324175-1	I am the epidemiologist reporting on behalf of 61 year-old male patient. This patient experienced a fatal heart attack the same day as receiving the fourth dose of a Pfizer vaccine on 4/22/22, according to state immunization records. He previously received the first dose of the Pfizer vaccine on 4/23/2021, the second dose of the Pfizer vaccine on 5/14/2021, and the third dose of the Pfizer vaccine on 12/3/2021. The patient has previously tested positive for COVID-19 on 1/9/22 and 1/10/22 via PCR. He subsequently had two negative PCR tests on 3/4/2022, 3/29/22 and 4/21/22, according to records. There is no previous infection history documented prior to 2022. According to provider notes, The patient was found down unresponsive and pulseless. On EMS arrival, ACLS was begun and he was found to be in pulseless electrical activity (PEA). He received 40 minutes of advanced cardiovascular life support (ACLS) with 5 rounds of epi, achieved return of spontaneous circulation (ROSC) twice, and was intubated for airway protection, but he lost pulses again prior to arrival. On arrival, CPR in progress with Lucas device, rhythm PEA. Calcium and epi were given. After 2 rounds of CPR ROSC was achieved. Levophed was started as he was hypotensive. Propofol and fentanyl initiated. Femoral central line and left radial arterial line were placed. Patient was last seen eating dinner at 7 PM by facility staff and was noted to be more tired than usual. The HPI, ROS, past medical history, social history and family history documentation element(s) were limited due to the patient being unconscious. Etiology of cardiac arrest is unclear at this time, consider pulmonary embolism (PE) given his malignancy although he was not hypoxic on resuscitation will consider hypoxic in the setting of large pleural effusion and malignant. Patient has a past medical history of Anemia, Cerebral amyloid angiopathy (CODE), CKD (chronic kidney disease), Diabetes mellitus, Diabetes type 2, controlled, Esophageal reflux, History of peptic ulcer disease, Hyperlipidemia, Hypertension, and Metastatic breast cancer (03/07/2019). The cause of death is listed as ?multiorgan failure as a consequence of acute myocardial infarction and metastatic breast cancer? on the death certificate. This patient is also currently being enumerated as a COVID-19 related fatality, based on previous infection history.
2335253-1	"He died on the 11May; I would say may be a week or two later his dementia got a lot worse; Acute renal failure; He started developing twitches, big twitches; He started acting strange; This is a spontaneous report received from a contactable reporter(s) (Physician). A 62-year-old male patient received BNT162b2 (BNT162B2), as dose 4 (booster), single (Lot number: FJ6369), in arm for covid-19 immunisation. The patient's relevant medical history included: ""He had an underlying neurologic disease that's called Cadasil"" (unspecified if ongoing), notes: he had an underlying neurologic disease that's called Cadasil. The patient took concomitant medications. Vaccination history included: Bnt162b2 (Dose 1, single), for COVID-19 Immunization; Bnt162b2 (Dose 2, single), for COVID-19 Immunization; Bnt162b2 (Dose 3 (Booster), single), for COVID-19 Immunization. The following information was reported: ACUTE KIDNEY INJURY (medically significant) with onset 05Feb2021, outcome ""unknown"", described as ""Acute renal failure""; ABNORMAL BEHAVIOUR (non-serious) with onset 05Feb2021, outcome ""unknown"", described as ""He started acting strange""; MUSCLE TWITCHING (non-serious) with onset 05Feb2021, outcome ""unknown"", described as ""He started developing twitches, big twitches""; DEMENTIA (medically significant) with onset 05Feb2021, outcome ""unknown"", described as ""I would say may be a week or two later his dementia got a lot worse""; DEATH (death) with onset 11May2022, outcome ""fatal"", described as ""He died on the 11May"". The events ""i would say may be a week or two later his dementia got a lot worse"", ""acute renal failure"", ""he started developing twitches, big twitches"" and ""he started acting strange"" required emergency room visit. The patient underwent the following laboratory tests and procedures: Lab Work: Unknown results, notes: Doctor stated, He had a lot of it at the hospital. Therapeutic measures were not taken as a result of dementia, acute kidney injury, muscle twitching, abnormal behaviour. The patient date of death was 11May2022. The reported cause of death was unknown. No autopsy was performed. No follow-up attempts are needed. No further information is expected.; Sender's Comments: Based on the current available limited information in the case provided, the causal association between the events death, dementia, acute kidney injury and the use of suspect product BNT162B2 cannot be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: He died on the 11May"

VAERS ID	Adverse Event Description
2355837-1	COVID-19 PNEUMONIA; ACUTE RESPIRATORY FAILURE; ACUTE MYELOID LEUKEMIA (AML); SCLERODERMA; SJOGREN'S SYNDROME; SUSPECTED CLINICAL VACCINATION FAILURE; CHRONIC MYELOMONOCYTIC LEUKEMIA (CMML); This spontaneous report was received from company representative via social media (traditional media report) and from other health professional via literature: This report concerned a 74 year old female of unspecified race and ethnicity. The objective of this study was to present a rare case of CMML (chronic myelomonocytic leukemia) after receiving the J and J COVID-19 vaccines, in association with limited scleroderma. The patient's height, and weight were not reported. The patient's concurrent conditions included: asthma, hypertension, dyslipidemia. On an unspecified date in OCT-2020, Laboratory data included: Absolute neutrophil count (NR: 1.7 - 7) 3.7 10x3/uL, Eosinophils (NR: 0 - 0.5) 0.2 10x3/uL, Hematocrit (NR: 34.9 - 44.5) 35.8 percent, Hemoglobin (NR: 12 - 15.5) 11.8 g/dL, Lymphocytes (NR: 0.9 - 2.9) 1.8 10x3/uL, Monocytes (NR: 0.3 - 0.9) 0.6 10x3/uL, Platelet count (NR: 150 - 450) 199 v10x3/uL, Red blood cell count (NR: 3.9 - 5.03) 3.77 10x6/uL, Reticulocyte count (NR: 0.5 - 1.5) not reported, and White blood cells (NR: 4.4 - 11) 6.3 103x/uL. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported, expiry: unknown) dose was not reported, 1 total, administered on 08-MAY-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient presented to the emergency department with complaints of shortness of breath and generalized weakness for two days. The patient reported that symptoms began after receiving the first dose of the Johnson and Johnson vaccine for COVID-19. Patient was hemodynamically stable with a heart rate of 94, a respiratory rate of 21, and a saturation rate of 99 percent on room air. Physical examination was widely unremarkable except for decreased air entry with mild diffuse wheezes bilaterally on lung auscultation. No cyanosis or edema of the extremities. On 12-MAY-2021, Laboratory data included: Absolute neutrophil count 3.9 10x3/uL, Eosinophils 0.1 10x3/uL, Hematocrit 29.5 percent, Hemoglobin 9.9 g/dL, Lymphocytes 3.8 10x3/uL, Monocytes 11.5 10x3/uL, Platelet count 37 10x3/uL, Red blood cell count 3.01 10x6/uL, Reticulocyte count not reported, and White blood cells 19.4 10x3/uL. On 18-JUN-2021, Laboratory data included: Absolute neutrophil count 9.6 10x3/uL, Eosinophils 0.0 10x3/uL, Hematocrit 20 percent, Hemoglobin 6.8 g/dL, Lymphocytes 5.5 10x3/uL, Monocytes 19.1 10x3/uL, Platelet count 10 10x3/uL, Red blood cell count 1.99 10x6/uL, Reticulocyte count 1.9 percent, and White blood cells 34.5 10x3/uL. On 12-MAY-2021, patient presented with anemia, thrombocytopenia, and leukocytosis after the COVID-19 vaccine. The hepatitis panel and human immunodeficiency virus were negative. The thrombocytopenia was concerning for vaccine-related immune thrombocytopenic purpura (ITP). The patient received a tapering dose of steroids and two doses of intravenous immunoglobulin (1 g/kg) as a treatment for ITP, with only a transient rise in platelets. On further follow-up, platelets continued to trend down, even refractory to steroids. Eventually, the patient developed transfusion-dependent thrombocytopenia. Patient also started complaining of dry mouth, difficulty swallowing, and new-onset episodes of whitish discoloration of the fingers in cold temperatures. Patient had concomitant CMML and scleroderma, which were unmasked after the patient received the COVID-19 vaccine and patient had scleroderma with elevated centromere 2b antibodies and the symptoms of difficulty swallowing and Raynaud's phenomenon. On an unspecified date, the patient had Sjogren's syndrome with elevated anti-SSA and dryness of the mouth. Rheumatologic workup was positive for anti-centromere antibodies and Sojgren's anti-SSA (anti Sjogren's-syndrome-related antigen A autoantibodies). C-ANCA, P-ANCA (Antineutrophil Cytoplasmic Antibodies), RF (Rheumatoid factor), anti-SSB, and anti-scleroderma 70 were negative. Cryoglobulin, cold agglutinin, and direct coombs were also negative. On follow-up, it was observed that the patient was progressing to severe anemia and leukocytosis with persistently high and up-trending monocytes. Flow cytometry on peripheral blood and bone marrow biopsies was done to rule out leukemia. Bone marrow biopsy results were significant for chronic myelomonocytic leukemia stage 0 (CMML 0) in a hypercellular marrow. The blasts and promonocytes were not increased; in the setting of severe anemia and thrombocytopenia with monocytosis (AMC 12.6 K/¦L - 53.8 percent of total leucocytes) was consistent with CMML 0. Next-generation sequencing detected KRAS (Kirsten rat sarcoma viral oncogene homolog), NPM1 (nucleophosmin gene), and TET2 (Tet methylcytosine dioxygenase 2) gene variations, and karyotyping showed 46, XX female karyotypes. Flow cytometry showed monocytosis (60 percent) and dysgranulopoiesis with no increased blasts or lymphoproliferative disorder. There is no increase in CD34-positive myeloblasts, and they comprise 0.4 percent of the total cells. The monocytes (60 percent) are increased with decreased CD13 and CD14 and increased HLA-DR (Human leukocyte antigen), suggesting left-shifted maturation. The granulocytes (19 percent) show decreased side scatter, suggesting hypogranularity with left-shifted CD13/CD16 maturation pattern and aberrant CD56 coexpression, suggesting dysgranulopoiesis. The B-cells (1.7 percent) are polytypic and the T-cells (8.2 percent) show a normal CD4:CD8 ratio with no pan T-cell antigen deletion. Viability is 91.13 percent. The AML panel in the cytogenetics FISH (fluorescence in situ hybridization) study was negative for RUNX1T1/RUNX1 (ETO/AML1), KMT2A (MLL), PML/RARA, CBFB rearrangement, negative for monosomy 5, and deletion of CSF1R/RPS14 on the long arm of chromosome 5 at q33, negative for monosomy 7, and deletion of MDFIC on the long arm of chromosome 7 at q31. The MPN/CML (Chronic myeloid leukemia) panel was also negative for BCR/ABL1 rearrangement, trisomy 8, 9, and deletion of DLEU1, DLEU2 on the long arm of chromosome 13 at q14, and deletion of PTPRT on the long arm of chromosome 20 at q12. Risk stratification based on the Molecular Model classified her as high risk with a score of 3 points and intermediate-risk. Based on the functional status and physical fitness, the patient was deemed to be an intermediate risk but infusion dependent as patient has received multiple platelets and pRBC (Packed red blood cells) transfusions. As a result, the patient was started on Azacitidine therapy, which significantly improved her cell count after two cycles. However, on further follow-up, it was found that patient had progressed to AML (acute myeloid leukemia) and died due to acute respiratory failure secondary to COVID-19 pneumonia. Thus, patient had suspected clinical vaccination failure. It was unknown whether autopsy was performed or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the acute myeloid leukemia (aml), scleroderma, chronic myelomonocytic leukemia (cmml), suspected clinical vaccination failure and sjogren's syndrome was not reported. The authors emphasized the fact that, based on the previous studies reported, the association of scleroderma with CMML is very rare. Also they suspect that the COVID-19 vaccine has triggered and unmasked both the CMML and the associated scleroderma in patient, considering the acute onset and absence of other known triggering factors. The importance of the COVID-19 vaccine is undeniable during this time. This case suggested the possibility of developing CMML associated with limited scleroderma after receiving the J and J COVID vaccine. However, further research needs to be done to confirm the hypothesis and to know the pathogenesis behind the association. This report was serious (Death, and Other Medically Important Condition). This report was associated with product quality complaint: 90000236774.; Sender's Comments: V0:20220645431- covid-19 vaccine ad26.cov2.s-acute respiratory failure,COVID-19 pneumonia, scleroderma, sjogren's syndrome - 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. 20220645431-covid-19 vaccine ad26.cov2.s-chronic myelomonocytic leukemia, acute myeloid leukemia - The event(s) shows an incompatible temporal relationship. Therefore, this event(s) is considered not related.(Temporality considered as not suggestive as patient started experiencing events within 4 days; diagnosed as chronic myelomonocytic leukemia which progressed to acute myeloid leukemia) 20220645431-COVID-19 VACCINE Ad26.COV2.S--suspected clinical vaccination failure . The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: SPECIAL SITUATIONS. Therefore, this event(s) is considered not related.; Reported Cause(s) of Death: COVID-19 PNEUMONIA; ACUTE RESPIRATORY FAILURE
2357930-1	Within 1 hour of injection began to have flu like symptoms. Symptoms persisted over several weeks time. Was tested for flu and covid multiple times with negative results. Flu like symptoms persist and worsen. Begins to have shortness of breath and loss of apatite. January 30th began having bouts of vomiting. Unable to go to work on January 31. Feb 6 visit Urgent Care again test negative for Flu and Covid. Was prescribed Pantoprazole SOD DR 40 mg and Ondansetron HCL 4 mg for nausea and vomiting. February 7 had difficulty breathing-taken to Emergency Room at Medical Center. Tested negative for covid. Had internal bleeding and bleeding into lungs. Ventilated and admitted to ICU from February 7- February 11.
2359835-1	Jaw pain Not hungry Sudden death

VAERS ID	Adverse Event Description
2359853-1	THIS FORM IS SUBMITTED AS PER FAMILY REQUEST: DO not have the details of the vaccine Patient presented with abdominal pain 1 day after receiving her 2nd booster dose admitted for acute pancreatitis with necrosis with respiratory failure and renal failure
2426622-1	"Mother reports he got his vaccine, he reported that he didn't do that good. He complained of tiredness. He just didn't feel right, and that something wasn't right with him. He felt like his stamina was down, he was very athletic and felt that he was not doing his normal routine. He went to work as usual, that morning he told his mother that ""they want to kill us all"". He went to work, thought that he was going to be OK. He came home for lunch, he ate lunch and went to work and then he came back within 5 minutes and said that he did not feel good. He collapsed on the floor and she called 9-1-1, they resuscitated him and taken to the hospital and he died. He did not have any history of heart disease prior to the vaccine. He had routine blood work and had no issues other than some high blood pressure. In January of 2021 he did have COVID which did not require hospitalization and recovered at home without any issues. They had cough, exhaustion and fatigue. He recovered fully and was back to his baseline and back to work without any problems prior to the vaccine. He saw the doctor for his COVID who told him he was OK to go back to work. He was a very active, athletic and ran in all the marathons and eat healthy foods."
2455611-1	patient died 48 hours later with Moderna; This spontaneous case was reported by an other health care professional and describes the occurrence of DEATH (patient died 48 hours later with Moderna) in a female patient of an unknown age who received mRNA-1273 (Spikevax) for COVID-19 prophylaxis. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not reported. No treatment information was provided by the reporter. Company comment: This spontaneous case concerns a female patient of unknown age with no reported medical history, who experienced unexpected death, which occurred at an unknown time with regards to vaccination with mRNA-1273. It was reported that the patient died 48 hours after vaccination. No further information was provided. The cause of death is unknown, and it was not disclosed if an autopsy was done. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.; Sender's Comments: This spontaneous case concerns a female patient of unknown age with no reported medical history, who experienced unexpected death, which occurred at an unknown time with regards to vaccination with mRNA-1273. It was reported that the patient died 48 hours after vaccination. No further information was provided. The cause of death is unknown, and it was not disclosed if an autopsy was done. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.; Reported Cause(s) of Death: Unknown cause of death

VAERS ID	Adverse Event Description
2466459-1	infections & fever from a bed sore; Hemorrhage stroke; Heart attack; only 25% of his heart is working; bed sore/pressure sore injury/Infection/Infected/pressure ulcer infected; Death; Sore at the injection site; Tired; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Death), HAEMORRHAGIC STROKE (Hemorrhage stroke), MYOCARDIAL INFARCTION (Heart attack), CARDIAC DYSFUNCTION (only 25% of his heart is working) and INFECTION (infections & fever from a bed sore) in a 79-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 022C21A and 039B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included WARFARIN, ATORVASTATIN CALCIUM, DILTIAZEM, LOSARTAN and TAMSULOSIN for an unknown indication. On 14-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 12-May-2021 at 11:00 AM, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 12-May-2021, the patient experienced VACCINATION SITE PAIN (Sore at the injection site) and FATIGUE (Tired). On 13-May-2021, the patient experienced HAEMORRHAGIC STROKE (Hemorrhage stroke) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced MYOCARDIAL INFARCTION (Heart attack) (seriousness criterion medically significant), CARDIAC DYSFUNCTION (only 25% of his heart is working) (seriousness criterion medically significant), INFECTION (infections & fever from a bed sore) (seriousness criterion hospitalization) and DECUBITUS ULCER (bed sore/pressure sore injury/Infection/Infected/pressure ulcer infected). The patient died on 30-Sep-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, HAEMORRHAGIC STROKE (Hemorrhage stroke), MYOCARDIAL INFARCTION (Heart attack), CARDIAC DYSFUNCTION (only 25% of his heart is working), INFECTION (infections & fever from a bed sore), DECUBITUS ULCER (bed sore/pressure sore injury/Infection/Infected/pressure ulcer infected), VACCINATION SITE PAIN (Sore at the injection site) and FATIGUE (Tired) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered INFECTION (infections & fever from a bed sore) and DECUBITUS ULCER (bed sore/pressure sore injury/Infection/Infected/pressure ulcer infected) to be related. No further causality assessments were provided for DEATH (Death), HAEMORRHAGIC STROKE (Hemorrhage stroke), MYOCARDIAL INFARCTION (Heart attack), CARDIAC DYSFUNCTION (only 25% of his heart is working), VACCINATION SITE PAIN (Sore at the injection site) and FATIGUE (Tired). Company comment: This is a fatal spontaneous case concerning a 79 year-old, male patient with no reported medical history and concomitant use of warfarin and atorvastatin, who experienced the serious unexpected, events of Haemorrhagic stroke (AESI), Myocardial infarction (AESI), Cardiac dysfunction, after the second dose of mRNA-1273 vaccine. One day after vaccination, the patient experienced headache, weakness in legs and profuse vomiting. The patient was transferred to a hospital with diagnosis of haemorrhagic stroke and subsequent left side hemiplegia. The patient developed infected decubital ulcer, myocardial infarction that was not initially noted, as well as cardiac dysfunction with just 25% of his heart working during hospitalization. The patient died approximately 4 months after the events onset and vaccine administration. Cause of death was not reported and it was not reported whether an autopsy was performed. The mentioned concomitant medication remains a confounder for the event Haemorrhagic stroke. No further information was available for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Patient reported that on 12-May-2021, he experienced headache, was sore at the injection site, & was tired. On 13-May-2021 he had headache, weakness in his legs & almost fell, profuse vomiting, & throwing up in his mouth because he was sitting up and could not move. The ER Dr said he had a hemorrhage stroke. He was paralyzed on his left side. He was at that hospital for only a few hrs.On 13-May-2021 - 04-Jun-2021, he was transferred to another hospital, because the Neurologist he needed was not available at that hospital. Patient reported that on 04-Jun-2021 - 24-Jun-2021, he was transferred to a rehab facility. They didn't take good care of him. while he was there, he developed a bad bed sore. He also had a heart attack while there but nobody knew. Only 25% of his heart was working. 04-Jun-2021 - 24-Jun-2021, admitted to a rehab facility. 21-Jun-2021 - 26-Jun-2021, he was admitted to the hospital. 26-Jun-2011, he was discharged back to the rehab facility. 06-Jul-2021 - 20-Jul-2021, he was admitted to the hospital. 20-Jul-2021, he was discharged to a different rehab facility. He was also on a feeding tube. Treatment information was not provided. Prior to passing patient was in the ICU again and returned to the nursing home and died 3 days later. Upon on internal review on 28-SEP-2022, it was identified that, for the case MOD-2021-301245, one of the report (FDA) was erroneously nullified instead of submitting a follow up report. Since only one report cannot be nullified, the entire case has to be nullified and a new case MOD-2021-653702 has been created. All the information from the case MOD-2021-301245 has been incorporated into the case MOD-2021-653702 which will be retained. The newly created case MOD-2021-653702 should be added as a part of open QI as it was identified in the reconciliation. Hence, the case MOD-2021-301245 will be nullified and deleted from safety database. This case was linked to MOD-2021-302089 (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 30-Aug-2021: Updated patient initial On 30-Aug-2021: Follow Up received on 30 Aug 2021 contains added Events On 18-Oct-2021: Follow-up document contains significant information (Patient death). On 28-Sep-2022: Upon on internal review on 28-SEP-2022, it was identified that, for the case MOD-2021-301245, one of the report (FDA) was erroneously nullified instead of submitting a follow up report. Since only one report cannot be nullified, the entire case has to be nullified and a new case MOD-2021-653702 has been created. All the information from the case MOD-2021-301245 has been incorporated into the case MOD-2021-653702 which will be retained. The newly created case MOD-2021-653702 should be added as a part of open QI as it was identified in the reconciliation. Hence, the case MOD-2021-301245 will be nullified and deleted from safety database. Events hemiplegia, muscular weakness, vomiting, headache, Dysgraphia and Mobility decreased were deleted as these are symptoms of the event Haemorrhagic stroke; Sender's Comments: This is a fatal spontaneous case concerning a 79 year-old, male patient with no reported medical history and concomitant use of warfarin and atorvastatin, who experienced the serious unexpected, events of Haemorrhagic stroke (AESI), Myocardial infarction (AESI), Cardiac dysfunction, after the second dose of mRNA-1273 vaccine. One day after vaccination, the patient experienced headache, weakness in legs and profuse vomiting. The patient was transferred to a hospital with diagnosis of haemorrhagic stroke and subsequent left side hemiplegia. The patient developed infected decubital ulcer, myocardial infarction that was not initially noted, as well as cardiac dysfunction with just 25% of his heart working during hospitalization. The patient died approximately 4 months after the events onset and vaccine administration. Cause of death was not reported and it was not reported whether an autopsy was performed. The mentioned concomitant medication remains a confounder for the event Haemorrhagic stroke. No further information was available for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.; Reported Cause(s) of Death: Unknown cause of death
2477168-1	1 week post vaccine person was restless overnight and went into cardiac arrest.
2477176-1	expired on 5/16/2021

VAERS ID	Adverse Event Description
2486502-1	The day after he received the booster shot, (Fri, 4/8/22) my husband complained of a bad headache and he sounded awful. I saw my husband on Sat (4/9/22) afternoon, two days after the vaccination and he was unsteady on his feet and he seemed out of it/not himself -- I?m not sure he even muttered a word. That afternoon he went to the infirmary and he told me they gave him a Tylenol and sent him back to his bunk. The following morning, Sunday (4/10/22), they found him on the floor of the shower room and sent him to the hospital. The hospital staff thought he?d had a stroke and did a CT scan but there were no signs of a stroke. They did note that his platelets were extremely low at 9,000. I found out on Monday (4/11/22) around noon that my husband was sent to the hospital, and by that time my husband was already in a coma and on a ventilator. They showed me the scans where he?d suffered a massive brain hemorrhage and said there was nothing that they could do. I?d told the Dr that my husband had just received the booster on Thurs but he said they never gave him that information. I?d asked the Dr. to please run a test for Vaccine-Induced Thrombotic Thrombocytopenia (VITT) to see if my husband?s extremely low platelet count was related to the booster, but he did not/would not run the test. They did run additional tests to confirm he was brain dead and we took him off the ventilator on Thurs (4/14/22). My husband was sent for an autopsy where they determined his cause of death: Hypertensive Intracerebral Hemorrhage. I?d also asked the Medical Examiner?s Office (ME) to test for VITT and was told it was outside what they were able to test for, but that they stored specimen for a year in case I wanted an outside lab to do the VITT test. Unfortunately, the ME office requires a court order to release the specimen which I imagine is costly. If that is something that you are able to do, please let me know and I?d be more than happy to work with you so my family and I have some resolution.

VAERS ID	Adverse Event Description
2533662-1	Ventricular fibrillation; Cardiac arrest; Acquired thrombotic thrombocytopenic purpura; Respiratory failure; Acute kidney injury; altered mental status; Patient was administered second dose of moderna vaccine 3 weeks after first dose; This literature-non-study case was reported in a literature article and describes the occurrence of VENTRICULAR FIBRILLATION (Ventricular fibrillation), CARDIAC ARREST (Cardiac arrest), THROMBOTIC THROMBOCYTOPENIC PURPURA (Acquired thrombotic thrombocytopenic purpura), RESPIRATORY FAILURE (Respiratory failure), ACUTE KIDNEY INJURY (Acute kidney injury) and ALTERED STATE OF CONSCIOUSNESS (altered mental status) in a 58-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 prophylaxis. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Antiretroviral therapy (to treat Human immunodeficiency virus (HIV) infection) since an unknown date. Concurrent medical conditions included Hypertension, Morbid obesity and HIV infection. Concomitant products included DOLUTEGRAVIR, LOPINAVIR and RITONAVIR for HIV infection. On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced VENTRICULAR FIBRILLATION (Ventricular fibrillation) (seriousness criteria death, hospitalization and medically significant), CARDIAC ARREST (Cardiac arrest) (seriousness criteria death, hospitalization and medically significant), THROMBOTIC THROMBOCYTOPENIC PURPURA (Acquired thrombotic thrombocytopenic purpura) (seriousness criteria hospitalization and medically significant), RESPIRATORY FAILURE (Respiratory failure) (seriousness criteria hospitalization and medically significant), ACUTE KIDNEY INJURY (Acute kidney injury) (seriousness criteria hospitalization and medically significant), ALTERED STATE OF CONSCIOUSNESS (altered mental status) (seriousness criteria hospitalization and medically significant) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Patient was administered second dose of moderna vaccine 3 weeks after first dose). The patient was treated with DEXAMETHASONE (intravenous) at a dose of 10 milligram twice a day. The patient died on an unknown date. The reported cause of death was Ventricular fibrillation and Cardiac arrest. An autopsy was not performed. At the time of death, THROMBOTIC THROMBOCYTOPENIC PURPURA (Acquired thrombotic thrombocytopenic purpura), RESPIRATORY FAILURE (Respiratory failure), ACUTE KIDNEY INJURY (Acute kidney injury), ALTERED STATE OF CONSCIOUSNESS (altered mental status) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Patient was administered second dose of moderna vaccine 3 weeks after first dose) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, ADAMTS13 activity assay (66.8-Unknown): less than 2.8% and (Positive) 48 unit/ml, elevated ADAMTS13 antibodies confirmed diagnosis of thrombotic thrombocytopenic purpura. On an unknown date, Activated partial thromboplastin time (21.3-35.1): 27.4 Second. On an unknown date, Alanine aminotransferase (0-44): 21 U/L. On an unknown date, Anti-cyclic citrullinated peptide antibody: Negative. On an unknown date, Antibody test: Negative. On an unknown date, Antinuclear antibody: Negative, Negative, Negative, Negative and Negative. On an unknown date, Antiribosomal P antibody: Negative. On an unknown date, Aspartate aminotransferase (0-44): 38 U/L. On an unknown date, Bacterial test: (Negative) rare. On an unknown date, Blood HIV RNA (Unknown-20): Less than 20. On an unknown date, Blood bilirubin (0.3-1.1): 4.7 g/dL. On an unknown date, Blood creatine phosphokinase (30-223): 110 U/L. On an unknown date, Blood creatinine (0.74-1.35): 1.62 mg/dl. On an unknown date, Blood culture: Negative. On an unknown date, Blood fibrinogen (183-510): 512 mg/dl. On an unknown date, Blood lactate dehydrogenase (140-271): 936 U/L. On an unknown date, Blood urea (6-24): 28 mg/dl. On an unknown date, Blood urine present: large. On an unknown date, CD4 lymphocytes (359-1519): 500 per microlitre on time of presentation and 506 per microlitre four months prior to presentation. On an unknown date, CD8 lymphocytes (109-897): 340 per microlitre. On an unknown date, Cold agglutinins: Negative. On an unknown date, Coombs direct test: Negative. On an unknown date, Cryptococcus test: Negative. On an unknown date, Culture urine: Negative. On an unknown date, Cytomegalovirus test: Negative. On an unknown date, Double stranded DNA antibody: Negative. On an unknown date, Drug screen: Negative. On an unknown date, Epstein-Barr virus antibody: Negative. On an unknown date, Fibrin D dimer (Unknown-0.5): 1.56 microgram per millilitre. On an unknown date, Haemoglobin (13.5-17.5): 13.4 g/dL. On an unknown date, Haptoglobin (30-200): Less than 10 mg/dl. On an unknown date, Hepatitis A antibody: Negative. On an unknown date, Hepatitis B antibody: Negative. On an unknown date, Hepatitis C antibody: Negative. On an unknown date, Influenza virus test: Negative and (Negative) Parainfluenza was negative. On an unknown date, International normalised ratio: 1.0. Normal reference- Critical greater than 4.0. On an unknown date, Legionella test: Negative. On an unknown date, Mean cell volume (80.0-100.0): 93 fL. On an unknown date, Mycoplasma test: (Negative) Mycoplasma Pneumoniae was negative. On an unknown date, Nitrite urine: Negative. On an unknown date, Parvovirus B19 test: Negative. On an unknown date, Physical examination: was unremarkable except for non-painful ecchymosis in the antecubital fossa of his right arm. On an unknown date, Platelet count (140-440): 5 thousand per cubic millimetre on presentation, 170 thousand per cubic millimetre 3 month before presentation and 12 thousand per cubic millimetre. On an unknown date, Prothrombin time (12.2-14.9): 13.2 Second. On an unknown date, Red blood cell count (4.33-5.83): 4.26 thousand per cubic millimetre. On an unknown date, Red blood cells urine (0-3): Greater than 100 cells per cubic millimetre. On an unknown date, Red cell distribution width (11.5-16.5): 13.2 %. On an unknown date, Respiratory syncytial virus test: Negative. On an unknown date, Reticulocyte count (0.5-2.0): 2.61 %. On an unknown date, SARS-CoV-2 test: Negative. On an unknown date, Smear test: on initial presentation peripheral smear is revealing thrombocytopenia, decreased lymphocytes, few schistocytes, target cells, few reticulocytes and Peripheral smear within hours later from presentation revealing markedly abnormal cells including thrombocytopenia, lymphopenia, target cells, and abundant schistocytes. On an unknown date, Staphylococcus test: Negative. On an unknown date, Troponin (3-23): 209 pg/ml and 7229 pg/ml. On an unknown date, Troponin I: Increased. On an unknown date, Urine analysis: Color/appearance: Amber/ cloudy. Normal reference- Clear yellow. On an unknown date, Urine leukocyte esterase: Negative. On an unknown date, White blood cell count (4.5-11): 5.2 thousand per cubic millimetre. On an unknown date, White blood cells urine (0-3): 6-10 cells/mm3. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. The patient was sent to the emergency room by his primary care physician. The patient complained of significant fatigue, non-traumatic bruises on his right arm, and persistent dark colored urine. Patient denied any other active muco-cutaneous bleeding or lesions, headache, confusion, dizziness, recent nausea, vomiting, diarrhea, upper or lower respiratory symptoms, or neurological deficits. He denied any recent changes in medications, recent antibiotic, or herbal supplements use. Patient received the 1st dose of the Moderna vaccine 6 weeks prior to presentation, followed by the 2nd dose of the same vaccine 3 weeks later without any complications. Precise platelet count when he received the 1st and 2nd doses of the vaccine is unknown. In the ER, patient was afebrile, and hemodynamically stable. Patient also had acute kidney injury and hematuria. Patient had a high PLASMIC score of 6, thrombotic thrombocytopenic purpura (TTP) was considered the working diagnosis. Laboratory results were suggestive for microangiopathic hemolyticanemia (MAHA). The patient was started on temporary resuscitation measures while preparing for therapeutic plasma exchange (TPE). He received two units of plasma (approximately 10 to 15 mL/kg), in addition to Dexamethasone, and planned to transition to methylprednisolone 80 mg IV q8h in the following day. He was also initiated on mechanical venous thromboembolism prophylaxis given his severe thrombocytopenia and the active bleeding. CT scans of the head, chest, abdomen and pelvis were done to rule out any possibility of active internal bleeding and/or any source of infection. Unfortunately, within the subsequent 12 hours before initiating TPE, the patient quickly decompensated with rapidly rising troponin-I, and developed altered mental status, and respiratory failure. Eventually, patient went into ventricular fibrillation and cardiac arrest. Full resuscitative measures were implemented with no return of spontaneous circulation. Company Comment This literature non-study case concerns a 58 year-old, male patient with history of hypertension, morbid obesity, and human immunodeficiency virus (HIV) infection on HAART (highly active antiretroviral therapy), complaint with his medication and with stable CD4 count(506) reported, who experienced the serious (fatal/medically significant/hospitalization) unexpected events of Ventricular fibrillation(AESI) and Cardiac arrest, serious (medically significant/hospitalization) unexpected events of Thrombotic thrombocytopenic purpura(AESI), Acute kidney injury(AESI), Respiratory failure , Altered state of consciousness about 3 weeks after the second dose of mRNA-1273 vaccination. Patient was referred by his primary care physician for platelet count of 12+10^3/mm3, with complaints of significant fatigue, non-traumatic bruises on his right arm, and persistent dark colored urine. He denied any other active muco-cutaneous bleeding or lesions, headache, confusion, dizziness, recent nausea, vomiting, diarrhea, upper or lower respiratory symptoms, or neurological deficits, no prior history of TTP, no past covid-19 infection, no recent changes with medications. Patient had received first dose of

VAERS ID	Adverse Event Description
	mRNA-1273 vaccine 6 weeks prior to presentation, followed by the second dose of the same vaccine 3 weeks later, so Inappropriate schedule of product administration was noted. Patient's average platelet count (PLT) was stable three months before presentation. In the ER, he was afebrile with stable hemodynamics, unremarkable physical examination except for non-painful ecchymosis in the antecubital fossa of his right arm. Admission labs were significant for normocytic anemia with marked thrombocytopenia 5 (x10^3/mm3) and elevated absolute reticulocyte count 2.61% indicating adequate bone marrow response. He also had acute kidney injury 1.62 mg/dL and hematuria. His peripheral smear demonstrated schistocytes (>2-3/HPF). Further laboratory results were suggestive for microangiopathic hemolytic anemia (MAHA) with negative direct Coombs test and disseminated intravascular coagulopathy (DIC). No evidence of acute infection (including opportunistic infections in HIV) was noted clinically or on laboratory testing. Viral/bacterial studies were negative. He had undetectable HIV viral load with stable, high CD4 to CD8 ratio. Given his high PLASMC score of 6, thrombotic thrombocytopenic purpura (TTP) was considered the working diagnosis. Patient was started on temporary resuscitation measures while preparing for therapeutic plasma exchange (TPE). He received two units of plasma (approximately 10 to 15 mL/kg), in addition to Dexamethasone 10 mg intravenously twice daily, and planned to transition to methylprednisolone 80 mg IV q8h in the following day. He was also initiated on mechanical venous thromboembolism prophylaxis given his severe thrombocytopenia and the active bleeding. Further laboratories had definitely ruled out an active source of infection, underlying Systemic auto-immune diseases (SAID). Computed tomography scans of the head, chest, abdomen and pelvis were done to rule out any possibility of active internal bleeding or any source of infection. Finally, ADAMTS13 activity was reported to be low less than 2.8%, with positive elevated ADAMTS13 antibodies 48 unit/mL which confirmed the diagnosis. Unfortunately, within the subsequent 12 hours before initiating TPE, patient quickly decompensated with rapidly rising troponin-I, and developed altered mental status, and respiratory failure. Eventually, he went into ventricular fibrillation and cardiac arrest. Full resuscitative measures were implemented with no return of spontaneous circulation. Cause of death was considered as ventricular fibrillation and cardiac arrest. Date of death was not available. No autopsy was performed on the patient. Author concludes that given the high mortality rates of TTP with delayed adequate treatment, the criteria for presumptive diagnosis only rely on thrombocytopenia with active hemolysis, in the absence of an obvious alternative cause, as in this case. Although the exact pathophysiology is still in question, one theory suggests it`s secondary to immune complex mediated or direct cytokine mediated endothelial injury. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 08-Dec-2022: Live follow up received by safety on 09-Dec-2022 has Email with full text article received contains significant information: Reporter information, literature information, patient details, medical history, laboratory tests, product details, concomitant, treatment medications, event, seriousness and narrative were updated.; Sender's Comments: This literature non-study case concerns a 58 year-old, male patient with history of hypertension, morbid obesity, and human immunodeficiency virus (HIV) infection on HAART (highly active antiretroviral therapy), complaint with his medication and with stable CD4 count(506) reported, who experienced the serious (fatal/medically significant/hospitalization) unexpected events of Ventricular fibrillation(AESI) and Cardiac arrest, serious (medically significant/hospitalization) unexpected events of Thrombotic thrombocytopenic purpura(AESI), Acute kidney injury(AESI), Respiratory failure , Altered state of consciousness about 3 weeks after the second dose of mRNA-1273 vaccination. Patient was referred by his primary care physician for platelet count of 12+10^3/mm3, with complaints of significant fatigue, non-traumatic bruises on his right arm, and persistent dark colored urine. He denied any other active muco-cutaneous bleeding or lesions, headache, confusion, dizziness, recent nausea, vomiting, diarrhea, upper or lower respiratory symptoms, or neurological deficits, no prior history of TTP, no past covid-19 infection, no recent changes with medications. Patient had received first dose of mRNA-1273 vaccine 6 weeks prior to presentation, followed by the second dose of the same vaccine 3 weeks later, so Inappropriate schedule of product administration was noted. Patient's average platelet count (PLT) was stable three months before presentation. In the ER, he was afebrile with stable hemodynamics, unremarkable physical examination except for non-painful ecchymosis in the antecubital fossa of his right arm. Admission labs were significant for normocytic anemia with marked thrombocytopenia 5 (x10^3/mm3) and elevated absolute reticulocyte count 2.61% indicating adequate bone marrow response. He also had acute kidney injury 1.62 mg/dL and hematuria. His peripheral smear demonstrated schistocytes (>2-3/HPF). Further laboratory results were suggestive for microangiopathic hemolytic anemia (MAHA) with negative direct Coombs test and disseminated intravascular coagulopathy (DIC). No evidence of acute infection (including opportunistic infections in HIV) was noted clinically or on laboratory testing. Viral/bacterial studies were negative. He had undetectable HIV viral load with stable, high CD4 to CD8 ratio. Given his high PLASMC score of 6, thrombotic thrombocytopenic purpura (TTP) was considered the working diagnosis. Patient was started on temporary resuscitation measures while preparing for therapeutic plasma exchange (TPE). He received two units of plasma (approximately 10 to 15 mL/kg), in addition to Dexamethasone 10 mg intravenously twice daily, and planned to transition to methylprednisolone 80 mg IV q8h in the following day. He was also initiated on mechanical venous thromboembolism prophylaxis given his severe thrombocytopenia and the active bleeding. Further laboratories had definitely ruled out an active source of infection, underlying Systemic auto-immune diseases (SAID). Computed tomography scans of the head, chest, abdomen and pelvis were done to rule out any possibility of active internal bleeding or any source of infection. Finally, ADAMTS13 activity was reported to be low less than 2.8%, with positive elevated ADAMTS13 antibodies 48 unit/mL which confirmed the diagnosis. Unfortunately, within the subsequent 12 hours before initiating TPE, patient quickly decompensated with rapidly rising troponin-I, and developed altered mental status, and respiratory failure. Eventually, he went into ventricular fibrillation and cardiac arrest. Full resuscitative measures were implemented with no return of spontaneous circulation. Cause of death was considered as ventricular fibrillation and cardiac arrest. Date of death was not available. No autopsy was performed on the patient. Author concludes that given the high mortality rates of TTP with delayed adequate treatment, the criteria for presumptive diagnosis only rely on thrombocytopenia with active hemolysis, in the absence of an obvious alternative cause, as in this case. Although the exact pathophysiology is still in question, one theory suggests it`s secondary to immune complex mediated or direct cytokine mediated endothelial injury. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.; Reported Cause(s) of Death: Ventricular fibrillation; Cardiac arrest
2559695-1	He got sick on 07/13/2021 finally ended up going to the hospital 07/16/2021 for body aches headache & weakness they sent him home and said it was a allergic reaction no bloodwork they prescribed him Zoltan oft 4 mg oral tablet

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 avaliable 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 2:31:55 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 2:31:55 AM

Query Criteria:

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