The Vaccine Adverse Event Reporting System (VAERS) Results

Vaccine Type	VAERS ID	Adverse Event Description
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE (DTAP)	**0806371-1**	4 hours after my daughter got her shots her fever wouldn't go down. At 11pm that night she begain to have complex febrial seizures. She had 3 that night. After coming home she wasn't the same. One of her eyes didn't open as much as it should have and she was slower. Almost a month later she died in her sleep because of another febrial seizure.
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE (DTAP)	**0851409-1**	Dear Officer, My five months old son passed away on 10-28-2019 after vaccination done on 10-23-2019. Here is the sequences of incidents: Wednesday 10-23-2019 : We went to Clinic for vaccinations and regular check-ups. Dr. is primary pediatrician for my son. After the checkup, she told us that baby is good in growth. Vaccination done on 10-23-2019 at 11.30 AM EST. Attached vaccination card in this email. Please check. On the same day around 3 pm, kid was sleeping and suddenly we heard some grunting sounds. We checked baby and observed that baby eyes were rolling and unconscious and unable to breathe. We tried to wake him up but he didn't wake up. Immediately, we understand the seriousness and called 911. Ambulance came in less than five minutes and they pump the air for breathing problem and they took the baby to hospital. They helped him breathing, given IV fluids, removed urine using catheter, and some first-aid process. Also taken chest x-ray and CT SCAN. They said that X-ray and CT-scan were good. Baby opened eyes, crying a lot and my wife feed him (breast feeding). On the same day around 7 PM, Pediatrician sent the baby to hospital for observation. Baby reached Hospital around 8 PM. Sr.physician Told me that it may be Hypoxia/seizures due to low level Oxygen in blood and baby is in life & death situation. At this time, the baby is almost normal, opening eyes and recognizing us and crying for pain (May be pain in hand - intravenous drip) They Started Brain ECG and started giving treatment for seizures. Baby was not sleeping and crying the complete night. (They started giving medicine for stopping seizures, antibiotics, sodium carbonate, liquids and IV fluids.) Thursday 10-24-2019: My son was crying throughout night. He got a fever 102c and in mid night around 2.30 AM and 5.30 AM, he just moved his legs, hands, and head. Doctors said that this may be seizures as they are rhythmic movement. They took him to MRI scan and spinal tap(extract liquid from spinal) test. They said that MRI and spinal tap test looks good. Evening, Baby got the flu and fever went up to 104. Baby eyes were swollen and can't open. Baby was crying through out night. They continue the seizure medicines and also given Tamiflu, tylenol, antibiotics etc. Friday 10-25-2019: They said the baby had a series of seizures on Thursday night and not stopping. They are using Keppra along with some other medicine for seizures. Also Tamiflu, antibiotics, sodium bicarbonate , and tylenol gave him. He went to deep sleep due to high Seizures medicine dose. Doctors put the baby on ventilator. Also, inserted pipe to stomach through the nose for feeding. No movement.. no crying... Saturday 10-26-2019: Doctors told us that seizures controlled a little bit but the brain is generating abnormal waves. Now they reduced seizures dose. But again seizures come back. Continued same medicine till evening. Doctors told us that baby is in very critical condition. Sunday 10-27-2019: They did MRI again and say that brain damaged and can't irreversible. Now, they have given (pentabola- something, not sure), to put him on comma and trying to save my baby. Doctors stitched(for intravenous drip) on his groin and wrist. They used catheter to remove urine from bladder. And now they say it's a five percent chance of living and if he lives, he will have different health issues in the future. At 9.30 Pm, nurses and doctors treating my son continuously till 12.30 AM (Monday) Monday 10-28-2019: 12.30 AM :Doctor told us that brain dead and kidneys also failed, heart also will stop in a couple of hours. They stopped treatment. We were in deep sad and crying. Baby's heart beat is reducing slowly. Around 11.40 AM, heart beating also stopped. My son had very painful, dreadful, unbearable treatment but he is not alive. We are crying from the incident (10-23-2019). we had very terrible days and sleepless crying nights. Before Incident: Baby was born. He was a full term 40-week baby and no health issues. First Vaccination on 07-05-2019. (Baby cried a lot about 20 to 30 mints. After that, the baby was normal. We thought that the baby was crying due to pain in thighs. No fever, no other issues.) Baby was in this country till 07-11-2019. Baby went to parents home country with parents on 07-11-2019 and returned this country on 10-20-2019. When baby was in parents home country, no health issues except 1. mild fever - fever about 100c (on 09-10-2019) - gave Tylenol for 2 times in a day and the baby was fine. 2. Constipation problem for 3 days (on 09-22-2019) - Consulted Pediatrician and baby was fine the next day. I have requested medical reports and waiting for them from hospital. Once, I recieved them, I will submit.
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE (DTAPIPV)	**0798255-1**	Patient found unresponsive at home. Brought to the emergency room by EMS. Found to be in asystole, cyanotic and GCS = 3. Cardiopulmonary resuscitation initiated and central line placed, but patient remained unresponsive. Patent was pronounced dead at 02:41.
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + HEPATITIS B + INACTIVATED POLIOVIRUS VACCINE (DTAPHEPBIP)	**0801369-1**	Child was in office on February 12th for his four month well visit where he received four vaccines, PEDIARIX, PREVNAR, Hib and Rotavirus. While in office he was alert and happy, smiling, and active. Per mother he was also alert and happy at home until he was put down for tummy time by the father around 5pm. Previously child was fed by dad and layed down on his stomach on the parent's bed for tummy time, per dad. Father stepped out of the room to the living room and fell asleep. Next time child was checked on was once mom got home from work at 10:30pm and mom noticed he was blue but still breathing. Mother called 911 and once paramedics arrived he seemed to be having a seizure and was given medication. Child was rushed to hospital where he was put in NICU, and doctors stated there was nothing else that could be done. Child was disconnected the morning of Feb. 13th, 2019.
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + HEPATITIS B + INACTIVATED POLIOVIRUS VACCINE (DTAPHEPBIP)	**0804153-1**	Patient seen for routine well child exam 2-27-2019 with no abnormal findings. Vaccines given and no adverse reactions noted at time of injection.

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DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + HEPATITIS B + INACTIVATED POLIOVIRUS VACCINE (DTAPHEPBIP)	**0806809-1**	She began spitting up more than normal and would not eat like she normally would. She ran no fever though. On the 10th of January she stopped breathing in her sleep. I am not sure that the vaccines were the cause of her death.
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + HEPATITIS B + INACTIVATED POLIOVIRUS VACCINE (DTAPHEPBIP)	**0807785-1**	My son was sick when he got his vaccines. He was only 2 months old. He had a fever when they gave it to him, they were only going to do one and somehow she thought it be a good idea to do three more. This was at his two month old well check up, but I was also bringing him there because he had a horrible cough and was sick. So after the vaccines he just got sicker and sicker throwing up fever Sunday 03/17/2019 I ended up at Hospital Emergency Room and they did nothing for him. They kept us there for 5 hrs and gave him ZOFRAN and another shot an antibiotic shot for Sepsis. They ran blood work, it wasn't the flu. They did an X-ray it wasn't pneumonia. The Dr ordered an IV but since the hospital didn't have small enough needles didn't do anything for him; didn't send us to somewhere to treat my baby. He was dry heaving choking on his foam and saliva, it was awful my baby died the next morning when I got up they told me he would be fine this is so wrong.
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + HEPATITIS B + INACTIVATED POLIOVIRUS VACCINE (DTAPHEPBIP)	**0815652-1**	Child tolerated administration of vaccines well. Child left office with family after appointment. Our office was notified the following day (5/22/2019) that child died overnight. She was found unresponsive. She was taken to an Emergency Department. Resuscitation was attempted.
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + HEPATITIS B + INACTIVATED POLIOVIRUS VACCINE (DTAPHEPBIP)	**0818256-1**	death
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + HEPATITIS B + INACTIVATED POLIOVIRUS VACCINE (DTAPHEPBIP)	**0818703-1**	Unknown-Received a call that patient died 6/12/2019 @ Hospital
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + HEPATITIS B + INACTIVATED POLIOVIRUS VACCINE (DTAPHEPBIP)	**0836425-1**	Anaphylactoid reaction based on postmortem tryptase level of 87.1 ng/ml. This postmortem level is elevated.
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + HEPATITIS B + INACTIVATED POLIOVIRUS VACCINE (DTAPHEPBIP)	**0850821-1**	INFANT DIED PROBABLY NOT RELATED TO IMMUNIZATION
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE + HAEMOPHILUS B CONJUGATE VACCINE (DTAPIPVHIB)	**0800352-1**	"Over the next 4 days, showed a lack of smiling/laughing/playing, markedly increased sleep, began making bubbles. Slightly improving on 5th to 6th day, but still longer sleep patterns. On day 6, made ""cooing"" noise while being burped, then became unresponsive. Transported to the hospital and brain death pronounced the next day. Cause of death unknown."
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE + HAEMOPHILUS B CONJUGATE VACCINE (DTAPIPVHIB)	**0818499-1**	Patient quit breathing at home on 06/08/19. Parents started CPR and called 911. Patient taken to hospital, arrived in asystole. Unable to be revived. Underlying medical conditions as noted above. *Note - RotaTeq vaccine given via G-Tube*

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DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE + HAEMOPHILUS B CONJUGATE VACCINE (DTAPIPVHIB)	**0829148-1**	Baby was found unresponsive in swing and pronounced dead on 8/10/19
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE + HAEMOPHILUS B CONJUGATE VACCINE (DTAPIPVHIB)	**0833913-1**	Child died.
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE + HAEMOPHILUS B CONJUGATE VACCINE (DTAPIPVHIB)	**0845673-1**	He got air bubbles on the brain ... he had a high fever slept all day long minus 3 hours a day
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE + HAEMOPHILUS B CONJUGATE VACCINE (DTAPIPVHIB)	**0849007-1**	Seizure; Information was received from an investigator concerning a 6-month-old male subject enrolled in a study. The subject's concurrent conditions and concomitant therapies were not reported. The subject's medical history included shoulder dystocia. ^^The subject had family history of seizures (2 maternal cousins had seizures when they were toddlers). the infant was born at 38 4/7 weeks gestational age, length 52 cm, weight 3470 grams, head circumference 35 cm. No neonatal problems except shoulder dystocia^^ On 11-JUL-2019, the subject was randomized into the study protocol. On that date, at 15:06, the subject was vaccinated with the first dose of Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ) (dose: 2 mL) orally (PO), and on the same day, at 15:07, he was vaccinated with the first dose of V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) 0.5 mL intramuscularly (IM), 4 doses in visits 1, 2, 3 and 5. He as was also vaccinated at 15:08, with the first dose of diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine, inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL) vaccine (dose: 0.5 mL) IM, and at 15:09, with Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB) (dose: 0.5 mL) IM. On an unspecified date, the subject was also vaccinated with Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) (HIBERIX) (dose details not reported). V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) was administered as prophylaxis for pneumococcal disease; while, all other vaccines were administered as prophylaxis (unspecified). On 10-SEP-2019 at 10:31, 10:32 and 10:33, the subject received second doses of Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ) and the second dose of V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) (doses and route of administration as previously described) and diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine, inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL). On 12-NOV-2019 at 14:42, 14:44, 14:45 and 14:46, the subject received third doses of Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ) and the second dose of V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) (doses and route of administration as previously described), diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine, inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL) and Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB). Since an unspecified date (reported since the subject was 4-month-old), the subject's mother reported that he had episodes of seizures that lasted several seconds; ^^the child did not present with seizures prior to randomization at 2 months age. There were no similar events experienced after the administration of the first and second doses of study vaccines, and there were no signs and/or symptoms prior to the administration of the third dose of study vaccines. No evidence of failure to thrive^^. On 12-NOV-2019, the subject was seen for his 6-month well child check. ^^During the clinic visit, his mother reported that a few weeks ago, the child started having episodes where he would be crying and then he would tighten his arms and his legs. This would only last for a few seconds and then he was fine. She reported that last week, the maternal grandmother noted that he did this, and eyes rolled to the back of his head and he seemed like he was not breathing. She blew in his face and then he started crying again. He was immediately fine after this and not lethargic or drowsy. At the WCC, the child was assessed as 6-month-old male with normal growth and development. The episodes of tightening his arms and legs were considered to be more like temper tantrums but it was discussed with the parent that if that was seizure, he would be needed to be evaluated further.^^ Moreover, the physician asked the mother to record a video of the seizures and they would be referred to a specialist for workup and possible treatment. On 13-NOV-2019 at 13:15, the subject was in the grandmother's arms when he started crying and screaming for several seconds, his eyes rolled back, and he became limp and stopped breathing. The subject experienced seizure (severe)

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		back, and he became limp and stopped breathing. The subject experienced seizure (severe). ^^There were no relevant signs / symptoms, apart from crying already noted, prior or concurrent to previous episodes of possible seizures^^. His grandmother took him to freestanding emergency room (ER) (outside the site facility). At the outside facility, the subject was found to be in asystole and apneic; became bradycardic down to 50's then coded. ^^On that day, his glucose was 246 mg/dl.^^ Cardio pulmonary resurrection (CPR) started with return of spontaneous circulation. He was transferred by ambulance to the site ER but lost the pulse again in route; 6 doses of epinephrine were administered prior to arrival. During transfer pulse less electrical activity noted and asystole on emergency medical services (EMS) monitors, CPR was performed while bagged, EMS attempted to intubate without success in route. An oral airway was placed and bilateral intraosseous lines in lower extremities. They arrived at the site ER with the subject in cardiac arrest and apneic. On arrival to the site, the subject was intubated, epinephrine, atropine, bicarbonate and naloxone (NARCAN) were administered ^^for cardiac arrest^^. An ultrasound for pulse check showed no cardiac activity. ^^It was reported that the subject was hospitalized^^. Core temperature was 94.6 Fahrenheit rectally, CRP continued with no success an at 14:19 (after 1 hour) the subject died due to ^^seizure^^ as per hospital records. ^^An autopsy was performed. No imaging testing to evaluate the seizures was carried out; no medications were given for previous episodes of possible seizures. The subject died in the ER before he could be admitted to the hospital; therefore, admission date, discharge date and discharge diagnosis were not applicable. There was no confirmed diagnosis of seizures prior to the day of death and no further information available regarding onset dates of 'episodes' reported by the mother^^. The action taken with the study therapies was reported as ^^dose not changed^^. The investigator considered the seizure (severe) to be related to V114 or pneumococcal 13valent conjugate vaccine (CRM197) (PREVNAR 13), Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ), Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB), to diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL) vaccine and Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) (HIBERIX), but not related to the study procedure. ^^The investigator assessed the event related to administration of all vaccines due to temporal relationship and no other definitive cause of death^^. The investigator considered the seizure (severe) to be a life-threatening event. Updated information received on 15-NOV-2019 from the investigator has been captured in between double caret (^^). The record for this subject was unblinded on 18-NOV-2019. Company Causality Assessment: Although there is a family history of seizures and co-suspect use RECOMBIVAX HB (known to be associated with non-fatal seizure), based on the clinically relevant information currently available for this individual case, there is a possibility that the reported serious adverse event of Seizure with a fatal outcome is related to the use of the investigational vaccines (blinded investigational vaccine [V114 or PREVNAR 13] and open-label study vaccine [PENTACEL and HIBERIX). The plausible temporal relationship, the known safety profiles of the blinded comparator (known to be associated with non-fatal seizure and apnea) and open label study vaccines (PENTACEL [known to be associated with non-fatal apnea] and HIBERIX [known to be associated with non-fatal convulsions]) support the possible relationship. Additional information regarding laboratory data due to increased glucose prior to CPR, autopsy report and the history of shoulder dystocia with unknown complications are needed for further assessment. Important missing information includes any record of fever accompanying the event. Febrile seizures have previously been reported in children who have received pneumococcal conjugate vaccines (PREVNAR 13). An Analysis of Similar Events regarding this follow up report of the adverse reaction of Seizure with the serious criteria of hospitalization, life threatening and death was performed. This case refers to a 6-month-old male subject who experienced Seizure after the third dose of the investigational vaccines (blinded investigational vaccine [V114 or pneumococcal 13 valent conjugate vaccine (CRM197) PREVNAR 13] and open label study vaccines [PENTACEL and HIBERIX]). This is the first reported case of Seizure in association with the investigational vaccines (blinded investigational vaccine [V114 or pneumococcal 13 valent conjugate vaccine (CRM197) PREVNAR 13] and open label study vaccines [PENTACEL and HIBERIX]) submitted to the FDA. The Suspected Adverse Reactions of Seizure does not alter the existing benefit-risk profile of the product. Merck and Co., Inc., known as MSD outside of certain countries, will continue to monitor this event and other serious adverse events reported in association with V-114 and will communicate any relevant changes to the protocol, Investigator's Brochure and/or Core Safety Information.; Reported Cause(s) of Death: Seizure
HAEMOPHILUS B CONJUGATE VACCINE (HIBV)	0801369-1	Child was in office on February 12th for his four month well visit where he received four vaccines, PEDIARIX, PREVNAR, Hib and Rotavirus. While in office he was alert and happy, smiling, and active. Per mother he was also alert and happy at home until he was put down for tummy time by the father around 5pm. Previously child was fed by dad and layed down on his stomach on the parent's bed for tummy time, per dad. Father stepped out of the room to the living room and fell asleep. Next time child was checked on was once mom got home from work at 10:30pm and mom noticed he was blue but still breathing. Mother called 911 and once paramedics arrived he seemed to be having a seizure and was given medication. Child was rushed to hospital where he was put in NICU, and doctors stated there was nothing else that could be done. Child was disconnected the morning of Feb. 13th, 2019.
HAEMOPHILUS B CONJUGATE VACCINE (HIBV)	0806371-1	4 hours after my daughter got her shots her fever wouldn't go down. At 11pm that night she begain to have complex febrial seizures. She had 3 that night. After coming home she wasn't the same. One of her eyes didn't open as much as it should have and she was slower. Almost a month later she died in her sleep because of another febrial seizure.
HAEMOPHILUS B CONJUGATE VACCINE (HIBV)	0806809-1	She began spitting up more than normal and would not eat like she normally would. She ran no fever though. On the 10th of January she stopped breathing in her sleep. I am not sure that the vaccines were the cause of her death.
HAEMOPHILUS B CONJUGATE VACCINE (HIBV)	0807785-1	My son was sick when he got his vaccines. He was only 2 months old. He had a fever when they gave it to him, they were only going to do one and somehow she thought it be a good idea to do three more. This was at his two month old well check up, but I was also bringing him there because he had a horrible cough and was sick. So after the vaccines he just got sicker and sicker throwing up fever Sunday 03/17/2019 I ended up at Hospital Emergency Room and they did nothing for him. They kept us there for 5 hrs and gave him ZOFRAN and another shot an antibiotic shot for Sepsis. They ran blood work, it wasn't the flu. They did an X-ray it wasn't pneumonia. The Dr ordered an IV but since the hospital didn't have small enough needles didn't do anything for him; didn't send us to somewhere to treat my baby. He was dry heaving choking on his foam and saliva, it was awful my baby died the next morning when I got up they told me he would be fine this is so wrong.

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HAEMOPHILUS B CONJUGATE VACCINE (HIBV)	**0810943-1**	The child had seen his pediatric provider 2 days prior to presentation to emergency department and had immunizations. The day prior to presentation, the child was seen for loose stools. He was described as nontoxic in appearance and feeding okay with normal urinary output. Presented to the emergency department via ambulance with CPR in progress after suffering an in-home arrest. Resuscitation was terminated after patient's arrival and patient was pronounced as deceased.
HAEMOPHILUS B CONJUGATE VACCINE (HIBV)	**0815652-1**	Child tolerated administration of vaccines well. Child left office with family after appointment. Our office was notified the following day (5/22/2019) that child died overnight. She was found unresponsive. She was taken to an Emergency Department. Resuscitation was attempted.
HAEMOPHILUS B CONJUGATE VACCINE (HIBV)	**0818703-1**	Unknown-Received a call that patient died 6/12/2019 @ Hospital
HAEMOPHILUS B CONJUGATE VACCINE (HIBV)	**0836425-1**	Anaphylactoid reaction based on postmortem tryptase level of 87.1 ng/ml. This postmortem level is elevated.
HAEMOPHILUS B CONJUGATE VACCINE (HIBV)	**0849007-1**	Seizure; Information was received from an investigator concerning a 6-month-old male subject enrolled in a study. The subject's concurrent conditions and concomitant therapies were not reported. The subject's medical history included shoulder dystocia. ^^The subject had family history of seizures (2 maternal cousins had seizures when they were toddlers). the infant was born at 38 4/7 weeks gestational age, length 52 cm, weight 3470 grams, head circumference 35 cm. No neonatal problems except shoulder dystocia^^ On 11-JUL-2019, the subject was randomized into the study protocol. On that date, at 15:06, the subject was vaccinated with the first dose of Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ) (dose: 2 mL) orally (PO), and on the same day, at 15:07, he was vaccinated with the first dose of V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) 0.5 mL intramuscularly (IM), 4 doses in visits 1, 2, 3 and 5. He as was also vaccinated at 15:08, with the first dose of diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine, inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL) vaccine (dose: 0.5 mL) IM, and at 15:09, with Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB) (dose: 0.5 mL) IM. On an unspecified date, the subject was also vaccinated with Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) (HIBERIX) (dose details not reported). V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) was administered as prophylaxis for pneumococcal disease; while, all other vaccines were administered as prophylaxis (unspecified). On 10-SEP-2019 at 10:31, 10:32 and 10:33, the subject received second doses of Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ) and the second dose of V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) (doses and route of administration as previously described) and diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine, inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL). On 12-NOV-2019 at 14:42, 14:44, 14:45 and 14:46, the subject received third doses of Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ) and the second dose of V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) (doses and route of administration as previously described), diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine, inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL) and Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB). Since an unspecified date (reported since the subject was 4-month-old), the subject's mother reported that he had episodes of seizures that lasted several seconds; ^^the child did not present with seizures prior to randomization at 2 months age. There were no similar events experienced after the administration of the first and second doses of study vaccines, and there were no signs and/or symptoms prior to the administration of the third dose of study vaccines. No evidence of failure to thrive^^. On 12-NOV-2019, the subject was seen for his 6-month well child check. ^^During the clinic visit, his mother reported that a few weeks ago, the child started having episodes where he would be crying and then he would tighten his arms and his legs. This would only last for a few seconds and then he was fine. She reported that last week, the maternal grandmother noted that he did this, and eyes rolled to the back of his head and he seemed like he was not breathing. She blew in his face and then he started crying again. He was immediately fine after this and not lethargic or drowsy. At the WCC, the child was assessed as 6-month-old male with normal growth and development. The episodes of tightening his arms and legs were considered to be more like temper tantrums but it was discussed with the parent that if that was seizure, he would be needed to be evaluated further.^^ Moreover, the physician asked the mother to record a video of the seizures and they would be referred to a specialist for workup and possible treatment. On 13-NOV-2019 at 13:15, the subject was in the grandmother's arms when he started crying and screaming for several seconds, his eyes rolled back, and he became limp and stopped breathing. The subject experienced seizure (severe). ^^There were no relevant signs / symptoms, apart from crying already noted, prior or concurrent to previous episodes of possible seizures^^. His grandmother took him to freestanding emergency room (ER) (outside the site facility). At the outside facility, the subject was found to be in asystole and apneic; became bradycardic down to 50's then coded. ^^On that day, his glucose was 246 mg/dl.^^ Cardio pulmonary resurrection (CPR) started with return of spontaneous circulation. He was transferred by ambulance to the site ER but lost the pulse again in route; 6 doses of epinephrine were administered prior to arrival. During transfer pulse less electrical activity noted and asystole on emergency medical services (EMS) monitors, CPR was performed while bagged, EMS attempted to intubate without success in route. An oral airway was placed and bilateral intraosseous lines in lower extremities. They arrived at the site ER with the subject in cardiac arrest and apneic. On arrival to the site, the subject was intubated, epinephrine, atropine, bicarbonate and naloxone (NARCAN) were administered ^^for cardiac arrest^^. An ultrasound for pulse check showed no cardiac activity. ^^It was reported that the subject was hospitalized^^. Core temperature was 94.6 Fahrenheit rectally, CRP continued with no success an at 14:19 (after 1 hour) the subject died due to ^^seizure^^ as per hospital records. ^^An autopsy was performed. No imaging testing to evaluate the seizures was carried out; no medications were given for previous episodes of possible seizures. The subject died in the ER before he could be admitted to the hospital; therefore, admission date, discharge date and discharge diagnosis were not applicable. There was no confirmed diagnosis of seizures prior to the day of death and no further information available regarding onset dates of 'episodes' reported by the mother^^. The action taken with the study therapies was reported as ^^dose not changed^^. The investigator considered the seizure (severe) to be related to V114 or pneumococcal 13valent conjugate vaccine (CRM197) (PREVNAR 13), Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ), Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB), to diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB)

Vaccine Type	VAERS ID	Adverse Event Description
		(unspecified) (+) poliovirus vaccine inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL) vaccine and Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) (HIBERIX), but not related to the study procedure. ^^The investigator assessed the event related to administration of all vaccines due to temporal relationship and no other definitive cause of death^^. The investigator considered the seizure (severe) to be a life-threatening event. Updated information received on 15-NOV-2019 from the investigator has been captured in between double caret (^^). The record for this subject was unblinded on 18-NOV-2019. Company Causality Assessment: Although there is a family history of seizures and co-suspect use RECOMBIVAX HB (known to be associated with non-fatal seizure), based on the clinically relevant information currently available for this individual case, there is a possibility that the reported serious adverse event of Seizure with a fatal outcome is related to the use of the investigational vaccines (blinded investigational vaccine [V114 or PREVNAR 13] and open-label study vaccine [PENTACEL and HIBERIX). The plausible temporal relationship, the known safety profiles of the blinded comparator (known to be associated with non-fatal seizure and apnea) and open label study vaccines (PENTACEL [known to be associated with non-fatal apnea] and HIBERIX [known to be associated with non-fatal convulsions]) support the possible relationship. Additional information regarding laboratory data due to increased glucose prior to CPR, autopsy report and the history of shoulder dystocia with unknown complications are needed for further assessment. Important missing information includes any record of fever accompanying the event. Febrile seizures have previously been reported in children who have received pneumococcal conjugate vaccines (PREVNAR 13). An Analysis of Similar Events regarding this follow up report of the adverse reaction of Seizure with the serious criteria of hospitalization, life threatening and death was performed. This case refers to a 6-month-old male subject who experienced Seizure after the third dose of the investigational vaccines (blinded investigational vaccine [V114 or pneumococcal 13 valent conjugate vaccine (CRM197) PREVNAR 13] and open label study vaccines [PENTACEL and HIBERIX]). This is the first reported case of Seizure in association with the investigational vaccines (blinded investigational vaccine [V114 or pneumococcal 13 valent conjugate vaccine (CRM197) PREVNAR 13] and open label study vaccines [PENTACEL and HIBERIX]) submitted to the FDA. The Suspected Adverse Reactions of Seizure does not alter the existing benefit-risk profile of the product. Merck and Co., Inc., known as MSD outside of certain countries, will continue to monitor this event and other serious adverse events reported in association with V-114 and will communicate any relevant changes to the protocol, Investigator's Brochure and/or Core Safety Information.; Reported Cause(s) of Death: Seizure
HEPATITIS A (HEPA)	**0798970-1**	Vaccines provided on 01/24/2019 due to contact of acute hepatitis A. Patient died on 01/27/2019.
HEPATITIS A (HEPA)	**0823475-1**	Patient died 7/11/2019
HEPATITIS B VACCINE (HEP)	**0806371-1**	4 hours after my daughter got her shots her fever wouldn't go down. At 11pm that night she begain to have complex febrial seizures. She had 3 that night. After coming home she wasn't the same. One of her eyes didn't open as much as it should have and she was slower. Almost a month later she died in her sleep because of another febrial seizure.
HEPATITIS B VACCINE (HEP)	**0806809-1**	She began spitting up more than normal and would not eat like she normally would. She ran no fever though. On the 10th of January she stopped breathing in her sleep. I am not sure that the vaccines were the cause of her death.
HEPATITIS B VACCINE (HEP)	**0813998-1**	Patient was very congested, her body was very hot and she stopped breathing in her sleep.
HEPATITIS B VACCINE (HEP)	**0818499-1**	Patient quit breathing at home on 06/08/19. Parents started CPR and called 911. Patient taken to hospital, arrived in asystole. Unable to be revived. Underlying medical conditions as noted above. *Note - RotaTeq vaccine given via G-Tube*
HEPATITIS B VACCINE (HEP)	**0819943-1**	I don?t know what hep b they gave him just that it was the hep b shot. His records are closed right now. He died exactly a week later on the 31st of May. We had some people say to report his death to you just in case. He didn?t have any other symptoms so I have no idea if it?s related. As of now we are being told it was sids.
HEPATITIS B VACCINE (HEP)	**0823271-1**	Death / Death NOS; Had not eaten; This case was reported by a physician via call center representative and described the occurrence of unknown cause of death in a 6-week-old female patient who received HBV (Engerix B) (batch number 4RB3J, expiry date unknown) for prophylaxis. On 1st July 2019, the patient received Engerix B. On 2nd July 2019, 1 days after receiving Engerix B, the patient experienced unknown cause of death (serious criteria death and GSK medically significant) and appetite absent. On 2nd July 2019, the outcome of the unknown cause of death was fatal and the outcome of the appetite absent was recovered/resolved. The patient died on 2nd July 2019. The reported cause of death was unknown cause of death. The reporter considered the unknown cause of death to be related to Engerix B. It was unknown if the reporter considered the appetite absent to be related to Engerix B. Additional details were provided as follows: The patient was not known to have any pre-existing health conditions. The patient had not eaten since the morning of 2nd July 2019 (for 12 hours) and died on the way to the hospital. The patient's parents believed that, the patient's death was due to the vaccine. But the physician stated that, the patient could had passed away due to other reasons, of which she did not provide. The reporter also stated that, two other patients received vaccines of the same lot and nothing had been reported. The physician would like to be followed up with as soon as possible so she would know what the next steps would be for investigation. No other details were provided.; Reported Cause(s) of Death: Unknown cause of death
HEPATITIS B VACCINE (HEP)	**0823475-1**	Patient died 7/11/2019
HEPATITIS B VACCINE (HEP)	**0849007-1**	Seizure; Information was received from an investigator concerning a 6-month-old male subject enrolled in a study. The subject's concurrent conditions and concomitant therapies were not reported. The subject's medical history included shoulder dystocia. ^^The subject had family history of seizures (2 maternal cousins had seizures when they were toddlers). the infant was born at 38 4/7 weeks gestational age, length 52 cm, weight 3470 grams, head circumference 35 cm. No neonatal problems except shoulder dystocia^^ On 11-JUL-2019, the subject was randomized into the study protocol. On that date, at 15:06, the subject was vaccinated with the first dose of Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ) (dose: 2 mL) orally (PO), and on the same day, at 15:07, he was vaccinated with the first dose of V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) 0.5 mL intramuscularly (IM), 4 doses in visits 1, 2, 3 and 5. He as was also vaccinated at 15:08, with the first dose of diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine, inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL) vaccine (dose: 0.5 mL) IM, and at 15:09, with Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB) (dose: 0.5 mL) IM. On an unspecified date, the subject was also vaccinated with Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) (HIBERIX) (dose details not

Vaccine Type	VAERS ID	Adverse Event Description
		reported). V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) was administered as prophylaxis for pneumococcal disease; while, all other vaccines were administered as prophylaxis (unspecified). On 10-SEP-2019 at 10:31, 10:32 and 10:33, the subject received second doses of Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ) and the second dose of V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) (doses and route of administration as previously described) and diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine, inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL). On 12-NOV-2019 at 14:42, 14:44, 14:45 and 14:46, the subject received third doses of Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ) and the second dose of V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) (doses and route of administration as previously described), diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine, inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL) and Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB). Since an unspecified date (reported since the subject was 4-month-old), the subject's mother reported that he had episodes of seizures that lasted several seconds; ^^the child did not present with seizures prior to randomization at 2 months age. There were no similar events experienced after the administration of the first and second doses of study vaccines, and there were no signs and/or symptoms prior to the administration of the third dose of study vaccines. No evidence of failure to thrive^^. On 12-NOV-2019, the subject was seen for his 6-month well child check. ^^During the clinic visit, his mother reported that a few weeks ago, the child started having episodes where he would be crying and then he would tighten his arms and his legs. This would only last for a few seconds and then he was fine. She reported that last week, the maternal grandmother noted that he did this, and eyes rolled to the back of his head and he seemed like he was not breathing. She blew in his face and then he started crying again. He was immediately fine after this and not lethargic or drowsy. At the WCC, the child was assessed as 6-month-old male with normal growth and development. The episodes of tightening his arms and legs were considered to be more like temper tantrums but it was discussed with the parent that if that was seizure, he would be needed to be evaluated further.^^ Moreover, the physician asked the mother to record a video of the seizures and they would be referred to a specialist for workup and possible treatment. On 13-NOV-2019 at 13:15, the subject was in the grandmother's arms when he started crying and screaming for several seconds, his eyes rolled back, and he became limp and stopped breathing. The subject experienced seizure (severe). ^^There were no relevant signs / symptoms, apart from crying already noted, prior or concurrent to previous episodes of possible seizures^^. His grandmother took him to freestanding emergency room (ER) (outside the site facility). At the outside facility, the subject was found to be in asystole and apneic; became bradycardic down to 50's then coded. ^^On that day, his glucose was 246 mg/dl.^^ Cardio pulmonary resurrection (CPR) started with return of spontaneous circulation. He was transferred by ambulance to the site ER but lost the pulse again in route; 6 doses of epinephrine were administered prior to arrival. During transfer pulse less electrical activity noted and asystole on emergency medical services (EMS) monitors, CPR was performed while bagged, EMS attempted to intubate without success in route. An oral airway was placed and bilateral intraosseous lines in lower extremities. They arrived at the site ER with the subject in cardiac arrest and apneic. On arrival to the site, the subject was intubated, epinephrine, atropine, bicarbonate and naloxone (NARCAN) were administered ^^for cardiac arrest^^. An ultrasound for pulse check showed no cardiac activity. ^^It was reported that the subject was hospitalized^^. Core temperature was 94.6 Fahrenheit rectally, CRP continued with no success an at 14:19 (after 1 hour) the subject died due to ^^seizure^^ as per hospital records. ^^An autopsy was performed. No imaging testing to evaluate the seizures was carried out; no medications were given for previous episodes of possible seizures. The subject died in the ER before he could be admitted to the hospital; therefore, admission date, discharge date and discharge diagnosis were not applicable. There was no confirmed diagnosis of seizures prior to the day of death and no further information available regarding onset dates of 'episodes' reported by the mother^^. The action taken with the study therapies was reported as ^^dose not changed^^. The investigator considered the seizure (severe) to be related to V114 or pneumococcal 13valent conjugate vaccine (CRM197) (PREVNAR 13), Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ), Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB), to diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL) vaccine and Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) (HIBERIX), but not related to the study procedure. ^^The investigator assessed the event related to administration of all vaccines due to temporal relationship and no other definitive cause of death^^. The investigator considered the seizure (severe) to be a life-threatening event. Updated information received on 15-NOV-2019 from the investigator has been captured in between double caret (^^). The record for this subject was unblinded on 18-NOV-2019. Company Causality Assessment: Although there is a family history of seizures and co-suspect use RECOMBIVAX HB (known to be associated with non-fatal seizure), based on the clinically relevant information currently available for this individual case, there is a possibility that the reported serious adverse event of Seizure with a fatal outcome is related to the use of the investigational vaccines (blinded investigational vaccine [V114 or PREVNAR 13] and open-label study vaccine [PENTACEL and HIBERIX). The plausible temporal relationship, the known safety profiles of the blinded comparator (known to be associated with non-fatal seizure and apnea) and open label study vaccines (PENTACEL [known to be associated with non-fatal apnea] and HIBERIX [known to be associated with non-fatal convulsions]) support the possible relationship. Additional information regarding laboratory data due to increased glucose prior to CPR, autopsy report and the history of shoulder dystocia with unknown complications are needed for further assessment. Important missing information includes any record of fever accompanying the event. Febrile seizures have previously been reported in children who have received pneumococcal conjugate vaccines (PREVNAR 13). An Analysis of Similar Events regarding this follow up report of the adverse reaction of Seizure with the serious criteria of hospitalization, life threatening and death was performed. This case refers to a 6-month-old male subject who experienced Seizure after the third dose of the investigational vaccines (blinded investigational vaccine [V114 or pneumococcal 13 valent conjugate vaccine (CRM197) PREVNAR 13] and open label study vaccines [PENTACEL and HIBERIX]). This is the first reported case of Seizure in association with the investigational vaccines (blinded investigational vaccine [V114 or pneumococcal 13 valent conjugate vaccine (CRM197) PREVNAR 13] and open label study vaccines [PENTACEL and HIBERIX]) submitted to the FDA. The Suspected Adverse Reactions of Seizure does not alter the existing benefit-risk profile of the product. Merck and Co., Inc., known as MSD outside of certain countries, will continue to monitor this event and other serious adverse events reported in association with V-114 and will communicate any relevant changes to the protocol, Investigator's Brochure and/or Core Safety Information.; Reported Cause(s) of Death: Seizure

Vaccine Type	VAERS ID	Adverse Event Description
INFLUENZA VIRUS VACCINE, QUADRIVALENT (INJECTED) (FLU4(SEASONAL))	**0795791-1**	Per ER report, patient received his Flu vaccine at his 9 month well check. Parents took him home. He fed and then went down for a nap. One to two hours later mother reports finding the child cyanotic and unresponsive. EMS called and found him in asystole. EMS attempted resuscitation en route to ER by placing IO and attempted intubation. He was given epinephrine x 2. CPR continued in the ED. Warmed to 35.4, intubated with 3.5 cuffed ET and received multiple rounds of epinephrine. Chest compressions were recorded for 18 minutes. Time of death was called at 1814.
INFLUENZA VIRUS VACCINE, QUADRIVALENT (INJECTED) (FLU4(SEASONAL))	**0806371-1**	4 hours after my daughter got her shots her fever wouldn't go down. At 11pm that night she begain to have complex febrial seizures. She had 3 that night. After coming home she wasn't the same. One of her eyes didn't open as much as it should have and she was slower. Almost a month later she died in her sleep because of another febrial seizure.
INFLUENZA VIRUS VACCINE, QUADRIVALENT (INJECTED) (FLU4(SEASONAL))	**0811881-1**	This is a spontaneous case, initially received from other health professional on 07-Mar-2019, concerning a 59-year-old, adult male patient. The patient's current conditions included hypertension, coronary heart disease, chronic obstructive pulmonary disease (COPD) and biventricular congestive heart failure (reported as medical history). The patient's concomitant medications included Albuterol, INCRUSE ELLIPTA, carvedilol, atorvastatin, furosemide, SPIRIVA, lisinopril, clopidogrel and ipratropium bromide. It was reported that on 11-Feb-2019, vaccines reached lowest temperature of 32.4 F (first excursion) and it was out of range for 1 hour. On 02-Mar-2019, temperature of the vaccines again reached 26.2 for 1 1/2 hours. On 05-Mar-2019, the patient was administered AFLURIA QUADRIVALENT [dose: 0.5 ml, route of administration: intramuscular, anatomical location: right deltoid, batch number: YF44209 and expiry date: 30-Jun-2019] which underwent temperature excursion for active immunization against influenza. On the same day, the patient was also administered with non-company suspect vaccine PNEUMOVAX [anatomical location: left deltoid, dose, route of administration, batch number and expiry date: not reported] for immunization against pneumococcal disease. It was reported that, on an unspecified date, the patient passed away due to cardiac complications of pre-existing medical conditions. The reporter assessed the case as non-serious. Case re-opened for completion of full data entry: 07-Mar-2019. Follow up received from other health professional on 17-Apr-2019: It was reported that they had no information on the patient, until they were recently informed that the patient passed away due to cardiac complications of pre-existing medical conditions. Hence, the event 'cardiac disorder' with fatal outcome was added in the event tab. Hence, the classification 'special case with no AE' was deleted in general tab. The case was upgraded from non-serious to serious. The case outcome was changed from unknown to fatal. The narrative and case comment were amended accordingly. Reporter's Comments: A 59-year-old male patient with concurrent conditions hypertension, coronary heart disease, chronic obstructive pulmonary disease (COPD) and biventricular congestive heart failure was administered AFLURIA QUADRIVALENT vaccine which underwent temperature excursion. The patient died due to cardiac complications, unspecified period post vaccination. Despite the lack of onset latency, the company assessed the causality of the event cardiac disorder as not related, considering the pre-existing heart conditions as the alternative aetiology. The event incorrect product storage assessed as not related to suspect vaccine, considering the incidental nature of the event and the event drug administration error assessed as not related to suspect vaccine, considering the accidental nature of the event. The company assessed the event 'cardiac disorder' as serious (medically significant). Reported Cause(s) of Death: Due to cardiac complications of pre-existing medical condition.
INFLUENZA VIRUS VACCINE, QUADRIVALENT (INJECTED) (FLU4(SEASONAL))	**0839106-1**	Pt. presented to clinic (Urgent Care) with mom on 10/1/19 at approx. 1945. He was lathargic, responsive to sternal rub, nonverbal and incoherent. 911 was called, pt. was taken by ambulance to the ED. Pt passed away on the evening of 10/1/19.
INFLUENZA VIRUS VACCINE, QUADRIVALENT (INJECTED) (FLU4(SEASONAL))	**0848765-1**	Pt was reported to be found dead the morning after vaccination. There is no clear association between vaccination and death, considering patient age and comorbidities. Medical examiner office informed clinic the next day
INFLUENZA VIRUS VACCINE, QUADRIVALENT (INJECTED) (FLU4(SEASONAL))	**0851942-1**	10/09/2019-Patient presented to PCPs office with chief complaint of watery eyes, runny nose, cough, and SOB. Generalized weakness worsening and appetite continues to decline. Memory continues to decline, Itching in hands. Spontaneous bruising. Treatment-Add Megace for appetite, Hold Coumadin and recheck Friday, Increase Ensure to 3 times daily as tolerated, Eat greens today
INFLUENZA VIRUS VACCINE, QUADRIVALENT, RECOMBINANT (INJECTED) (FLUR4(SEASONAL))	**0846472-1**	Family reported death from unknown cause. Coroners report did not identify cause of death. Patient died driving on the way to work 8 hours after receiving vaccination.
INFLUENZA VIRUS VACCINE, TRIVALENT (INJECTED) (FLU3(SEASONAL))	**0844189-1**	Patient Fainted when he got to his cart. Pharmacist rushed to his side. He was already blue, and pharmacist could not feel a pulse. Patient was moved quickly to start CPR. CPR was started and patient was aspirating. Mouth and nose were cleared out. CPR was continued. Patient was aspirating and breaths could not me administered. CPR was continued until EMT arrived. EMT continued CPR. Patient was not responsive. EMT called time of death.
INFLUENZA VIRUS VACCINE, TRIVALENT (INJECTED) (FLU3(SEASONAL))	**0852688-1**	Patient has Autism. Shortly after shot he began acting different & this was noticed by school, family & friends. Almost a month afterwards, despite seeming much happier & outgoing, he committed suicide.
INFLUENZA VIRUS VACCINE, TRIVALENT (INJECTED) (FLU3(SEASONAL))	**0853847-1**	Patient died within hours of receiving fluzone hd.
INFLUENZA VIRUS VACCINE, TRIVALENT, ADJUVANT (INJECTED) (FLUA3(SEASONAL))	**0844360-1**	Patient experienced neck pain and diarrhea which then progressed to weakness. On 10/16/19 daughter drove to hospital. Patient was transferred to Medical Center. Patient with weakness starting in lower extremities, then upper extremities, areflexic bilateral upper and lower. Dx w/Guillain-Barre Sysndrome. Patient on ventilator support and receiving immunoglobulin

Vaccine Type	VAERS ID	Adverse Event Description
MENINGOCOCCAL B VACCINE (MENB)	**0823758-1**	The patient was visiting, where she received the Men B vaccine about 2 weeks before presenting to our hospital gravely ill. Within days of receiving the vaccine she developed malaise. A few days before presenting to our hospital she developed subjective fevers and worsening malaise. On the day of presentation she had persistent vomiting, then had a seizure (no history of seizures) that was treated with anti-epileptics at an outside hospital. She was transferred to our institution and, en route, developed agonal breathing and abnormal posturing, with uncal herniation found on head CT soon after arrival. She received ceftriaxone and acyclovir and underwent external ventricular drain placement, but was declared brain dead <24 hours after arrival at our hospital. Autopsy is underway, but no causative agent has been identified yet. - Note: As the MenB vaccine was given somewhere else, we do not know the exact date / details of the vaccine (date listed in this form is estimated, as the family stated it was given 2 weeks before she presented to our hospital on 7/4/19)
PNEUMOCOCCAL VACCINE, POLYVALENT (PPV)	**0795514-1**	"On Monday 1/7 my mother had her yearly physical and reported everything was fine and she was in good health. This was confirmed by the physician's assistant. My mother reported getting the PNEUMOVAX 23 vaccine at pharmacy around 12:30 p.m. on 1/9/2019. That evening at 6:25 she sent a text message saying ""my right arm is achy from my pneumonia shot and I'm getting chills. I'll go home and take Tylenol."" Then at 7:11 p.m. she reported ""I am lying down at home."" This was her last communication. The next morning she was found dead. THIS MUST BE INVESTIGATED IMMEDIATELY IN CASE THERE IS A BROADER ISSUE WITH THIS VACCINE LOT."
PNEUMOCOCCAL VACCINE, POLYVALENT (PPV)	**0806371-1**	4 hours after my daughter got her shots her fever wouldn't go down. At 11pm that night she began to have complex febrial seizures. She had 3 that night. After coming home she wasn't the same. One of her eyes didn't open as much as it should have and she was slower. Almost a month later she died in her sleep because of another febrial seizure.
PNEUMOCOCCAL VACCINE, POLYVALENT (PPV)	**0811881-1**	This is a spontaneous case, initially received from other health professional on 07-Mar-2019, concerning a 59-year-old, adult male patient. The patient's current conditions included hypertension, coronary heart disease, chronic obstructive pulmonary disease (COPD) and biventricular congestive heart failure (reported as medical history). The patient's concomitant medications included Albuterol, INCRUSE ELLIPTA, carvedilol, atorvastatin, furosemide, SPIRIVA, lisinopril, clopidogrel and ipratropium bromide. It was reported that on 11-Feb-2019, vaccines reached lowest temperature of 32.4 F (first excursion) and it was out of range for 1 hour. On 02-Mar-2019, temperature of the vaccines again reached 26.2 for 1 1/2 hours. On 05-Mar-2019, the patient was administered AFLURIA QUADRIVALENT [dose: 0.5 ml, route of administration: intramuscular, anatomical location: right deltoid, batch number: YF44209 and expiry date: 30-Jun-2019] which underwent temperature excursion for active immunization against influenza. On the same day, the patient was also administered with non-company suspect vaccine PNEUMOVAX [anatomical location: left deltoid, dose, route of administration, batch number and expiry date: not reported] for immunization against pneumococcal disease. It was reported that, on an unspecified date, the patient passed away due to cardiac complications of pre-existing medical conditions. The reporter assessed the case as non-serious. Case re-opened for completion of full data entry: 07-Mar-2019. Follow up received from other health professional on 17-Apr-2019: It was reported that they had no information on the patient, until they were recently informed that the patient passed away due to cardiac complications of pre-existing medical conditions. Hence, the event 'cardiac disorder' with fatal outcome was added in the event tab. Hence, the classification 'special case with no AE' was deleted in general tab. The case was upgraded from non-serious to serious. The case outcome was changed from unknown to fatal. The narrative and case comment were amended accordingly. Reporter's Comments: A 59-year-old male patient with concurrent conditions hypertension, coronary heart disease, chronic obstructive pulmonary disease (COPD) and biventricular congestive heart failure was administered AFLURIA QUADRIVALENT vaccine which underwent temperature excursion. The patient died due to cardiac complications, unspecified period post vaccination. Despite the lack of onset latency, the company assessed the causality of the event cardiac disorder as not related, considering the pre-existing heart conditions as the alternative aetiology. The event incorrect product storage assessed as not related to suspect vaccine, considering the incidental nature of the event and the event drug administration error assessed as not related to suspect vaccine, considering the accidental nature of the event. The company assessed the event 'cardiac disorder' as serious (medically significant). Reported Cause(s) of Death: Due to cardiac complications of pre-existing medical condition.
PNEUMOCOCCAL VACCINE, POLYVALENT (PPV)	**0814543-1**	This spontaneous report as received from a physician via a company representative refers to a 3-year-old male patient with Wiedemann-Steiner syndrome (captured as short stature, developmental delay, muscle hypotonia, facial dysmorphism and hairy elbow syndrome). No other information regarding his pertinent medical history, drug reactions or allergies and concomitant medications was reported. On 12-MAR-2019, the patient was vaccinated with a dose of PNEUMOVAX 23 injection (lot # R025297 has been verified to be a valid lot number, expiration date 08-JUN-2020) (exact dose, route of administration and injection site were not provided) as immunization for the prevention of pneumococcal disease. On 13-MAR-2019, he began to experience coughing and sneezing. The patient did not seek medical treatment for the events. On 14-MAR-2019, the patient died. The cause of death was unknown. It was unknown what medical intervention was sought or performed on 14-MAR-2019 or if an autopsy was performed. The outcome of the coughing and sneezing was unknown. The relatedness between the events and the suspect vaccine was not provided.
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	**0798255-1**	Patient found unresponsive at home. Brought to the emergency room by EMS. Found to be in asystole, cyanotic and GCS = 3. Cardiopulmonary resuscitation initiated and central line placed, but patient remained unresponsive. Patent was pronounced dead at 02:41.
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	**0798970-1**	Vaccines provided on 01/24/2019 due to contact of acute hepatitis A. Patient died on 01/27/2019.
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	**0800352-1**	"Over the next 4 days, showed a lack of smiling/laughing/playing, markedly increased sleep, began making bubbles. Slightly improving on 5th to 6th day, but still longer sleep patterns. On day 6, made ""cooing"" noise while being burped, then became unresponsive. Transported to the hospital and brain death pronounced the next day. Cause of death unknown."

Vaccine Type	VAERS ID	Adverse Event Description
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	**0801369-1**	Child was in office on February 12th for his four month well visit where he received four vaccines, PEDIARIX, PREVNAR, Hib and Rotavirus. While in office he was alert and happy, smiling, and active. Per mother he was also alert and happy at home until he was put down for tummy time by the father around 5pm. Previously child was fed by dad and layed down on his stomach on the parent's bed for tummy time, per dad. Father stepped out of the room to the living room and fell asleep. Next time child was checked on was once mom got home from work at 10:30pm and mom noticed he was blue but still breathing. Mother called 911 and once paramedics arrived he seemed to be having a seizure and was given medication. Child was rushed to hospital where he was put in NICU, and doctors stated there was nothing else that could be done. Child was disconnected the morning of Feb. 13th, 2019.
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	**0804153-1**	Patient seen for routine well child exam 2-27-2019 with no abnormal findings. Vaccines given and no adverse reactions noted at time of injection.
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	**0806809-1**	She began spitting up more than normal and would not eat like she normally would. She ran no fever though. On the 10th of January she stopped breathing in her sleep. I am not sure that the vaccines were the cause of her death.
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	**0807785-1**	My son was sick when he got his vaccines. He was only 2 months old. He had a fever when they gave it to him, they were only going to do one and somehow she thought it be a good idea to do three more. This was at his two month old well check up, but I was also bringing him there because he had a horrible cough and was sick. So after the vaccines he just got sicker and sicker throwing up fever Sunday 03/17/2019 I ended up at Hospital Emergency Room and they did nothing for him. They kept us there for 5 hrs and gave him ZOFRAN and another shot an antibiotic shot for Sepsis. They ran blood work, it wasn't the flu. They did an X-ray it wasn't pneumonia. The Dr ordered an IV but since the hospital didn't have small enough needles didn't do anything for him; didn't send us to somewhere to treat my baby. He was dry heaving choking on his foam and saliva, it was awful my baby died the next morning when I got up they told me he would be fine this is so wrong.
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	**0810943-1**	The child had seen his pediatric provider 2 days prior to presentation to emergency department and had immunizations. The day prior to presentation, the child was seen for loose stools. He was described as nontoxic in appearance and feeding okay with normal urinary output. Presented to the emergency department via ambulance with CPR in progress after suffering an in-home arrest. Resuscitation was terminated after patient's arrival and patient was pronounced as deceased.
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	**0815652-1**	Child tolerated administration of vaccines well. Child left office with family after appointment. Our office was notified the following day (5/22/2019) that child died overnight. She was found unresponsive. She was taken to an Emergency Department. Resuscitation was attempted.
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	**0817340-1**	"Total immobility, terribly weak, bladder not working within days, eventual urinary tract infection w. use of catheter. Home w cath., in a few days, another U.R.I infection. My husband was given a pneumonia shot 1/15/19 after a routine Dr's. visit, within weeks he had full blown pneumonia. He was totally immobile. He said, ""get an ambulance"". In Emer. room a great number of tests. Dr. looked in the room and said, ""we don't know what it is!"" Days later, after admission to hospital we were told it was pneumonia. In days, his bladder quit and he was sporting a catheter. In days we were in a nursing home. He received some therapy, after 30 days they said he no longer needed ""nursing"" care, we came home and in three days he had a UTI. Back to the hospital, wearing diapers, weak, etc. 5 days in hosp. to another nursing home. Same nursing home where our 37 yr. old grandson is a patient. After ? days, another UTI antibiotics. Not much progress. Within days, comatose, eight days in that state. Dead late in day on May 11, with hospice in attendance. What an ordeal. All this after the pneumonia shot. Every day prior to these events, he was walking on the track and the ""x"" (a mile!). I can provide witnesses to verify this information!"
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	**0818499-1**	Patient quit breathing at home on 06/08/19. Parents started CPR and called 911. Patient taken to hospital, arrived in asystole. Unable to be revived. Underlying medical conditions as noted above. *Note - RotaTeq vaccine given via G-Tube*
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	**0818703-1**	Unknown-Received a call that patient died 6/12/2019 @ Hospital
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	**0823707-1**	Pt's mother states that pt had fever for 24hrs, stopped breathing and was rushed to Hospital, but was deceased on arrival. Coroner contacted mother and informed her that pt appeared to have had meningitis (H. Flu), but death listed as non-conclusive.
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	**0833913-1**	Child died.
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	**0836425-1**	Anaphylactoid reaction based on postmortem tryptase level of 87.1 ng/ml. This postmortem level is elevated.
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	**0853488-1**	PATIENT HAS PASSED AWAY
POLIOVIRUS VACCINE INACTIVATED (IPV)	**0806371-1**	4 hours after my daughter got her shots her fever wouldn't go down. At 11pm that night she begain to have complex febrial seizures. She had 3 that night. After coming home she wasn't the same. One of her eyes didn't open as much as it should have and she was slower. Almost a month later she died in her sleep because of another febrial seizure.
ROTAVIRUS VACCINE, LIVE, ORAL (RV1)	**0807785-1**	My son was sick when he got his vaccines. He was only 2 months old. He had a fever when they gave it to him, they were only going to do one and somehow she thought it be a good idea to do three more. This was at his two month old well check up, but I was also bringing him there because he had a horrible cough and was sick. So after the vaccines he just got sicker and sicker throwing up fever Sunday 03/17/2019 I ended up at Hospital Emergency Room and they did nothing for him. They kept us there for 5 hrs and gave him ZOFRAN and another shot an antibiotic shot for Sepsis. They ran blood work, it wasn't the flu. They did an X-ray it wasn't pneumonia. The Dr ordered an IV but since the hospital didn't have small enough needles didn't do anything for him; didn't send us to somewhere to treat my baby. He was dry heaving choking on his foam and saliva, it was awful my baby died the next morning when I got up they told me he would be fine this is so wrong.

Vaccine Type	VAERS ID	Adverse Event Description
ROTAVIRUS VACCINE, LIVE, ORAL (RV1)	**0845673-1**	He got air bubbles on the brain ... he had a high fever slept all day long minus 3 hours a day
ROTAVIRUS VACCINE, LIVE, ORAL (RV1)	**0851409-1**	Dear Officer, My five months old son passed away on 10-28-2019 after vaccination done on 10-23-2019. Here is the sequences of incidents: Wednesday 10-23-2019 : We went to Clinic for vaccinations and regular check-ups. Dr. is primary pediatrician for my son. After the checkup, she told us that baby is good in growth. Vaccination done on 10-23-2019 at 11.30 AM EST. Attached vaccination card in this email. Please check. On the same day around 3 pm, kid was sleeping and suddenly we heard some grunting sounds. We checked baby and observed that baby eyes were rolling and unconscious and unable to breathe. We tried to wake him up but he didn't wake up. Immediately, we understand the seriousness and called 911. Ambulance came in less than five minutes and they pump the air for breathing problem and they took the baby to hospital. They helped him breathing, given IV fluids, removed urine using catheter, and some first-aid process. Also taken chest x-ray and CT SCAN. They said that X-ray and CT-scan were good. Baby opened eyes, crying a lot and my wife feed him (breast feeding). On the same day around 7 PM, Pediatrician sent the baby to hospital for observation. Baby reached Hospital around 8 PM. Sr.physician Told me that it may be Hypoxia/seizures due to low level Oxygen in blood and baby is in life & death situation. At this time, the baby is almost normal, opening eyes and recognizing us and crying for pain (May be pain in hand - intravenous drip) They Started Brain ECG and started giving treatment for seizures. Baby was not sleeping and crying the complete night. (They started giving medicine for stopping seizures, antibiotics, sodium carbonate, liquids and IV fluids.) Thursday 10-24-2019: My son was crying throughout night. He got a fever 102c and in mid night around 2.30 AM and 5.30 AM, he just moved his legs, hands, and head. Doctors said that this may be seizures as they are rhythmic movement. They took him to MRI scan and spinal tap(extract liquid from spinal) test. They said that MRI and spinal tap test looks good. Evening, Baby got the flu and fever went up to 104. Baby eyes were swollen and can't open. Baby was crying through out night. They continue the seizure medicines and also given Tamiflu, tylenol, antibiotics etc. Friday 10-25-2019: They said the baby had a series of seizures on Thursday night and not stopping. They are using Keppra along with some other medicine for seizures. Also Tamiflu, antibiotics, sodium bicarbonate , and tylenol gave him. He went to deep sleep due to high Seizures medicine dose. Doctors put the baby on ventilator. Also, inserted pipe to stomach through the nose for feeding. No movement.. no crying... Saturday 10-26-2019: Doctors told us that seizures controlled a little bit but the brain is generating abnormal waves. Now they reduced seizures dose. But again seizures come back. Continued same medicine till evening. Doctors told us that baby is in very critical condition. Sunday 10-27-2019: They did MRI again and say that brain damaged and can't irreversible. Now, they have given (pentabola- something, not sure), to put him on comma and trying to save my baby. Doctors stitched(for intravenous drip) on his groin and wrist. They used catheter to remove urine from bladder. And now they say it's a five percent chance of living and if he lives, he will have different health issues in the future. At 9.30 Pm, nurses and doctors treating my son continuously till 12.30 AM (Monday) Monday 10-28-2019: 12.30 AM :Doctor told us that brain dead and kidneys also failed, heart also will stop in a couple of hours. They stopped treatment. We were in deep sad and crying. Baby's heart beat is reducing slowly. Around 11.40 AM, heart beating also stopped. My son had very painful, dreadful, unbearable treatment but he is not alive. We are crying from the incident (10-23-2019). we had very terrible days and sleepless crying nights. Before Incident: Baby was born. He was a full term 40-week baby and no health issues. First Vaccination on 07-05-2019. (Baby cried a lot about 20 to 30 mints. After that, the baby was normal. We thought that the baby was crying due to pain in thighs. No fever, no other issues.) Baby was in this country till 07-11-2019. Baby went to parents home country with parents on 07-11-2019 and returned this country on 10-20-2019. When baby was in parents home country, no health issues except 1. mild fever - fever about 100c (on 09-10-2019) - gave Tylenol for 2 times in a day and the baby was fine. 2. Constipation problem for 3 days (on 09-22-2019) - Consulted Pediatrician and baby was fine the next day. I have requested medical reports and waiting for them from hospital. Once, I recieved them, I will submit.
ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT (RV5)	**0800352-1**	"Over the next 4 days, showed a lack of smiling/laughing/playing, markedly increased sleep, began making bubbles. Slightly improving on 5th to 6th day, but still longer sleep patterns. On day 6, made ""cooing"" noise while being burped, then became unresponsive. Transported to the hospital and brain death pronounced the next day. Cause of death unknown."
ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT (RV5)	**0801369-1**	Child was in office on February 12th for his four month well visit where he received four vaccines, PEDIARIX, PREVNAR, Hib and Rotavirus. While in office he was alert and happy, smiling, and active. Per mother he was also alert and happy at home until he was put down for tummy time by the father around 5pm. Previously child was fed by dad and layed down on his stomach on the parent's bed for tummy time, per dad. Father stepped out of the room to the living room and fell asleep. Next time child was checked on was once mom got home from work at 10:30pm and mom noticed he was blue but still breathing. Mother called 911 and once paramedics arrived he seemed to be having a seizure and was given medication. Child was rushed to hospital where he was put in NICU, and doctors stated there was nothing else that could be done. Child was disconnected the morning of Feb. 13th, 2019.
ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT (RV5)	**0806809-1**	She began spitting up more than normal and would not eat like she normally would. She ran no fever though. On the 10th of January she stopped breathing in her sleep. I am not sure that the vaccines were the cause of her death.
ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT (RV5)	**0810943-1**	The child had seen his pediatric provider 2 days prior to presentation to emergency department and had immunizations. The day prior to presentation, the child was seen for loose stools. He was described as nontoxic in appearance and feeding okay with normal urinary output. Presented to the emergency department via ambulance with CPR in progress after suffering an in-home arrest. Resuscitation was terminated after patient's arrival and patient was pronounced as deceased.
ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT (RV5)	**0815652-1**	Child tolerated administration of vaccines well. Child left office with family after appointment. Our office was notified the following day (5/22/2019) that child died overnight. She was found unresponsive. She was taken to an Emergency Department. Resuscitation was attempted.
ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT (RV5)	**0818499-1**	Patient quit breathing at home on 06/08/19. Parents started CPR and called 911. Patient taken to hospital, arrived in asystole. Unable to be revived. Underlying medical conditions as noted above. *Note - RotaTeq vaccine given via G-Tube*

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ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT (RV5)	**0818703-1**	Unknown-Received a call that patient died 6/12/2019 @ Hospital
ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT (RV5)	**0823707-1**	Pt's mother states that pt had fever for 24hrs, stopped breathing and was rushed to Hospital, but was deceased on arrival. Coroner contacted mother and informed her that pt appeared to have had meningitis (H. Flu), but death listed as non-conclusive.
ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT (RV5)	**0833913-1**	Child died.
ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT (RV5)	**0836425-1**	Anaphylactoid reaction based on postmortem tryptase level of 87.1 ng/ml. This postmortem level is elevated.
ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT (RV5)	**0849007-1**	Seizure; Information was received from an investigator concerning a 6-month-old male subject enrolled in a study. The subject's concurrent conditions and concomitant therapies were not reported. The subject's medical history included shoulder dystocia. ^^The subject had family history of seizures (2 maternal cousins had seizures when they were toddlers). the infant was born at 38 4/7 weeks gestational age, length 52 cm, weight 3470 grams, head circumference 35 cm. No neonatal problems except shoulder dystocia^^ On 11-JUL-2019, the subject was randomized into the study protocol. On that date, at 15:06, the subject was vaccinated with the first dose of Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ) (dose: 2 mL) orally (PO), and on the same day, at 15:07, he was vaccinated with the first dose of V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) 0.5 mL intramuscularly (IM), 4 doses in visits 1, 2, 3 and 5. He as was also vaccinated at 15:08, with the first dose of diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine, inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL) vaccine (dose: 0.5 mL) IM, and at 15:09, with Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB) (dose: 0.5 mL) IM. On an unspecified date, the subject was also vaccinated with Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) (HIBERIX) (dose details not reported). V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) was administered as prophylaxis for pneumococcal disease; while, all other vaccines were administered as prophylaxis (unspecified). On 10-SEP-2019 at 10:31, 10:32 and 10:33, the subject received second doses of Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ) and the second dose of V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) (doses and route of administration as previously described) and diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine, inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL). On 12-NOV-2019 at 14:42, 14:44, 14:45 and 14:46, the subject received third doses of Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ) and the second dose of V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) (doses and route of administration as previously described), diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine, inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL) and Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB). Since an unspecified date (reported since the subject was 4-month-old), the subject's mother reported that he had episodes of seizures that lasted several seconds; ^^the child did not present with seizures prior to randomization at 2 months age. There were no similar events experienced after the administration of the first and second doses of study vaccines, and there were no signs and/or symptoms prior to the administration of the third dose of study vaccines. No evidence of failure to thrive^^. On 12-NOV-2019, the subject was seen for his 6-month well child check. ^^During the clinic visit, his mother reported that a few weeks ago, the child started having episodes where he would be crying and then he would tighten his arms and his legs. This would only last for a few seconds and then he was fine. She reported that last week, the maternal grandmother noted that he did this, and eyes rolled to the back of his head and he seemed like he was not breathing. She blew in his face and then he started crying again. He was immediately fine after this and not lethargic or drowsy. At the WCC, the child was assessed as 6-month-old male with normal growth and development. The episodes of tightening his arms and legs were considered to be more like temper tantrums but it was discussed with the parent that if that was seizure, he would be needed to be evaluated further.^^ Moreover, the physician asked the mother to record a video of the seizures and they would be referred to a specialist for workup and possible treatment. On 13-NOV-2019 at 13:15, the subject was in the grandmother's arms when he started crying and screaming for several seconds, his eyes rolled back, and he became limp and stopped breathing. The subject experienced seizure (severe). ^^There were no relevant signs / symptoms, apart from crying already noted, prior or concurrent to previous episodes of possible seizures^^. His grandmother took him to freestanding emergency room (ER) (outside the site facility). At the outside facility, the subject was found to be in asystole and apneic; became bradycardic down to 50's then coded. ^^On that day, his glucose was 246 mg/dl.^^ Cardio pulmonary resurrection (CPR) started with return of spontaneous circulation. He was transferred by ambulance to the site ER but lost the pulse again in route; 6 doses of epinephrine were administered prior to arrival. During transfer pulse less electrical activity noted and asystole on emergency medical services (EMS) monitors, CPR was performed while bagged, EMS attempted to intubate without success in route. An oral airway was placed and bilateral intraosseous lines in lower extremities. They arrived at the site ER with the subject in cardiac arrest and apneic. On arrival to the site, the subject was intubated, epinephrine, atropine, bicarbonate and naloxone (NARCAN) were administered ^^for cardiac arrest^^. An ultrasound for pulse check showed no cardiac activity. ^^It was reported that the subject was hospitalized^^. Core temperature was 94.6 Fahrenheit rectally, CRP continued with no success an at 14:19 (after 1 hour) the subject died due to ^^seizure^^ as per hospital records. ^^An autopsy was performed. No imaging testing to evaluate the seizures was carried out; no medications were given for previous episodes of possible seizures. The subject died in the ER before he could be admitted to the hospital; therefore, admission date, discharge date and discharge diagnosis were not applicable. There was no confirmed diagnosis of seizures prior to the day of death and no further information available regarding onset dates of 'episodes' reported by the mother^^. The action taken with the study therapies was reported as ^^dose not changed^^. The investigator considered the seizure (severe) to be related to V114 or pneumococcal 13valent conjugate vaccine (CRM197) (PREVNAR 13), Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ), Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB), to diphtheria

Vaccine Type	VAERS ID	Adverse Event Description
		Pentavalent (ROTATEQ)) Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB)) to diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL) vaccine and Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) (HIBERIX), but not related to the study procedure. ^^The investigator assessed the event related to administration of all vaccines due to temporal relationship and no other definitive cause of death^^. The investigator considered the seizure (severe) to be a life-threatening event. Updated information received on 15-NOV-2019 from the investigator has been captured in between double caret (^^). The record for this subject was unblinded on 18-NOV-2019. Company Causality Assessment: Although there is a family history of seizures and co-suspect use RECOMBIVAX HB (known to be associated with non-fatal seizure), based on the clinically relevant information currently available for this individual case, there is a possibility that the reported serious adverse event of Seizure with a fatal outcome is related to the use of the investigational vaccines (blinded investigational vaccine [V114 or PREVNAR 13] and open-label study vaccine [PENTACEL and HIBERIX). The plausible temporal relationship, the known safety profiles of the blinded comparator (known to be associated with non-fatal seizure and apnea) and open label study vaccines (PENTACEL [known to be associated with non-fatal apnea] and HIBERIX [known to be associated with non-fatal convulsions]) support the possible relationship. Additional information regarding laboratory data due to increased glucose prior to CPR, autopsy report and the history of shoulder dystocia with unknown complications are needed for further assessment. Important missing information includes any record of fever accompanying the event. Febrile seizures have previously been reported in children who have received pneumococcal conjugate vaccines (PREVNAR 13). An Analysis of Similar Events regarding this follow up report of the adverse reaction of Seizure with the serious criteria of hospitalization, life threatening and death was performed. This case refers to a 6-month-old male subject who experienced Seizure after the third dose of the investigational vaccines (blinded investigational vaccine [V114 or pneumococcal 13 valent conjugate vaccine (CRM197) PREVNAR 13] and open label study vaccines [PENTACEL and HIBERIX]). This is the first reported case of Seizure in association with the investigational vaccines (blinded investigational vaccine [V114 or pneumococcal 13 valent conjugate vaccine (CRM197) PREVNAR 13] and open label study vaccines [PENTACEL and HIBERIX]) submitted to the FDA. The Suspected Adverse Reactions of Seizure does not alter the existing benefit-risk profile of the product. Merck and Co., Inc., known as MSD outside of certain countries, will continue to monitor this event and other serious adverse events reported in association with V-114 and will communicate any relevant changes to the protocol, Investigator's Brochure and/or Core Safety Information.; Reported Cause(s) of Death: Seizure
TETANUS AND DIPHTHERIA TOXOIDS AND ACELLULAR PERTUSSIS VACCINE (BOOSTRIX/ADACEL) (TDAP)	0840255-1	Death within 4 months of receiving the booster TDAP. My sister passed away this past Sat, Oct 5th. She was a healthy, happy 56-year-old women. Her death makes no sense and we have not been provided with any answers from medical professionals. In a nutshell, my sister started having minor pain in her head (ear area) in early June 2019, exactly two weeks after receiving the TDAP booster shot. The nerve pain that she had been experiencing had progressed to an unbearable state within a few short months. Before all this happened, she was a healthy, active woman. She was never officially diagnosed with an illness/disease because her neurologist was not able to find an underlying cause after subjecting her to every logical test available. She was prescribed with pain medication, but the pain became too intense for her to bear. The doctor suggested that she might be suffering with Small Fiber Neuropathy (SFN) condition, but it was just a suggestion. In just a few short months the symptoms progressed to the point where she felt burning pain throughout her entire body. The pain was transient and intense. She was desperate for relief and answers. Approximately four weeks before her death her symptoms progressed to affect her autoimmune system and she began to have trouble swallowing, producing tears, breathing, heart palpitations, and digestive issues. She believed that she would not survive this pain and accompanying symptoms (she feared the autoimmune symptoms). After her own online research and was convinced that all these symptoms were as a result of a reaction, she had from the TDAP booster. Everything she believed that was going to happen to her, did. I wonder if she was also right about the TDAP booster shot being the catalyst for her ultimate death. Her body is with the coroner now and we are awaiting the autopsy report to understand the cause of death but I am wondering if there are any tests that can be performed that could determine if the TDAP played any role in the symptoms she was experiencing as described above and her ultimate, untimely, early death. Please call me so I can provide additional information. She visited the neurologist only twice and was told that her blood tests were perfect...all of the blood tests that were given to her came out clean. Yet, she passed away within four months of receiving the TDAP booster.
ZOSTER VACCINE (VARZOS)	0799571-1	Patient had migratory pains the night after the vaccination. He died within 24 hours of unknown cause, unknown if related to vaccine.
ZOSTER VACCINE (VARZOS)	0803655-1	The patient (my wife) died on Jan 25, 2019.
ZOSTER VACCINE (VARZOS)	0813993-1	This case was reported by a pharmacist via call center representative and described the occurrence of death nos in a 61-year-old male patient who received SHINGRIX (batch number 23JK5, expiry date 13th April 2020) for prophylaxis. On 4th May 2019, the patient received the 1st dose of SHINGRIX (intramuscular). On 4th May 2019, 4 hrs after receiving SHINGRIX, the patient experienced death nos (serious criteria death and GSK medically significant). On an unknown date, the outcome of the death nos was fatal. The reported cause of death was unknown cause of death. It was unknown if the reporter considered the death nos to be related to SHINGRIX. Additional details were provided as follows: The patient tolerated the SHINGRIX dose at the pharmacy with no noted issues. The reporter had no specific details on cause of death. Follow up information received on 9th May 2019: Following a review of the inventory status for batch number 23JK5 the entire batch has been distributed as of on 12th April 2019. With regards to the complaint history for this batch number to date there were two complaints neither of which were related to the nature of the reported adverse event. There was no product quality issue noted by the pharmacist upon vaccination and the cause of death for the patient was currently unknown. The pharmacist did not have reason to believe that the vaccine was compromised, but she would like further guidance to be certain. Reported Cause(s) of Death: Death NOS.
ZOSTER VACCINE (VARZOS)	0818175-1	Patient's daughter called the clinic to inform the staff that the patient passed away. She reports that a couple of weeks after getting the vaccine, the patient began experiencing weakness in his knees, slurring of his words and developed hallucinations. Patient was ultimately admitted to ER and passed away 10 days later.

Vaccine Type	VAERS ID	Adverse Event Description
ZOSTER VACCINE (VARZOS)	**0831053-1**	Patient presented to the emergency department with tongue and throat swelling. According to hospital visit note, approximately 15 minutes prior to arrival, pt had an unknown exposure and began developing swelling in his throat and tongue. He felt that it began affecting his breathing, and he immediately came into the Emergency Department. He was not having any rash, abdominal pain, vomiting, diarrhea, chest pain or palpitations, but was having some difficulty breathing. He received epinephrine, Benadryl, Pepcid and steroids, and after a few minutes, he was felt to require intubation. Anesthesia was called for an airway alert. Attempts at oral intubation had failed and anesthesia then proceeded with fiberoptic nasotracheal intubation. Once the airway was secured, he was admitted to the Intensive Care Unit on a propofol drip for sedation and placed in restraints. Patient expired 07/19/19.
ZOSTER VACCINE (VARZOS)	**0832488-1**	Daughter came in on 9/7/19 to report that her mother passed away. She reported that patient was complaining to friends 8/15/19 thursday night of soreness due shingrix. on the same day 08/15/19 at about 9:20pm her grand daughter was texting her but is she is not making sense anymore. She was found deceased on 8/18/19 , decomposed and autopsy report's caused of death is Coronary Artery Disease. She was cremated on 8/20/19 Tuesday
ZOSTER VACCINE (VARZOS)	**0837231-1**	STEMI (likely unrelated), complex treatment course, died 9/7/19
ZOSTER VACCINE (VARZOS)	**0851436-1**	The day after receiving the vaccine he complained of chills and fatigue that lasted 2 days and local site injection redness pain and swelling. The third day he felt better, but the evening of the 15th he complained of left hand tingling and collapsed in a vfib arrest.
UNKNOWN VACCINES (UNK)	**0818256-1**	death
UNKNOWN VACCINES (UNK)	**0829166-1**	Unexplained sudden death
UNKNOWN VACCINES (UNK)	**0845122-1**	Im not sure what all my new born son received as his records are being held from me
UNKNOWN VACCINES (UNK)	**0849007-1**	Seizure; Information was received from an investigator concerning a 6-month-old male subject enrolled in a study. The subject's concurrent conditions and concomitant therapies were not reported. The subject's medical history included shoulder dystocia. ^^The subject had family history of seizures (2 maternal cousins had seizures when they were toddlers). the infant was born at 38 4/7 weeks gestational age, length 52 cm, weight 3470 grams, head circumference 35 cm. No neonatal problems except shoulder dystocia^^ On 11-JUL-2019, the subject was randomized into the study protocol. On that date, at 15:06, the subject was vaccinated with the first dose of Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ) (dose: 2 mL) orally (PO), and on the same day, at 15:07, he was vaccinated with the first dose of V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) 0.5 mL intramuscularly (IM), 4 doses in visits 1, 2, 3 and 5. He as was also vaccinated at 15:08, with the first dose of diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine, inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL) vaccine (dose: 0.5 mL) IM, and at 15:09, with Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB) (dose: 0.5 mL) IM. On an unspecified date, the subject was also vaccinated with Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) (HIBERIX) (dose details not reported). V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) was administered as prophylaxis for pneumococcal disease; while, all other vaccines were administered as prophylaxis (unspecified). On 10-SEP-2019 at 10:31, 10:32 and 10:33, the subject received second doses of Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ) and the second dose of V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) (doses and route of administration as previously described) and diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine, inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL). On 12-NOV-2019 at 14:42, 14:44, 14:45 and 14:46, the subject received third doses of Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ) and the second dose of V114 or pneumococcal 13 valent conjugate vaccine (CRM197) (PREVNAR 13) (doses and route of administration as previously described), diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine, inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL) and Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB). Since an unspecified date (reported since the subject was 4-month-old), the subject's mother reported that he had episodes of seizures that lasted several seconds; ^^the child did not present with seizures prior to randomization at 2 months age. There were no similar events experienced after the administration of the first and second doses of study vaccines, and there were no signs and/or symptoms prior to the administration of the third dose of study vaccines. No evidence of failure to thrive^^. On 12-NOV-2019, the subject was seen for his 6-month well child check. ^^During the clinic visit, his mother reported that a few weeks ago, the child started having episodes where he would be crying and then he would tighten his arms and his legs. This would only last for a few seconds and then he was fine. She reported that last week, the maternal grandmother noted that he did this, and eyes rolled to the back of his head and he seemed like he was not breathing. She blew in his face and then he started crying again. He was immediately fine after this and not lethargic or drowsy. At the WCC, the child was assessed as 6-month-old male with normal growth and development. The episodes of tightening his arms and legs were considered to be more like temper tantrums but it was discussed with the parent that if that was seizure, he would be needed to be evaluated further.^^ Moreover, the physician asked the mother to record a video of the seizures and they would be referred to a specialist for workup and possible treatment. On 13-NOV-2019 at 13:15, the subject was in the grandmother's arms when he started crying and screaming for several seconds, his eyes rolled back, and he became limp and stopped breathing. The subject experienced seizure (severe). ^^There were no relevant signs / symptoms, apart from crying already noted, prior or concurrent to previous episodes of possible seizures^^. His grandmother took him to freestanding emergency room (ER) (outside the site facility). At the outside facility, the subject was found to be in asystole and apneic; became bradycardic down to 50's then coded. ^^On that day, his glucose was 246 mg/dl.^^ Cardio pulmonary resurrection (CPR) started with return of spontaneous circulation. He was transferred by ambulance to the site ER but lost the pulse again in route; 6 doses of epinephrine were administered prior to arrival. During transfer pulse less electrical activity noted and asystole on emergency medical services (EMS) monitors, CPR was performed while bagged, EMS attempted to intubate without success in route. An oral airway was placed and bilateral intraosseous lines in lower extremities. They arrived at the site ER with the subject in cardiac arrest and apneic. On arrival to the site, the subject was intubated, epinephrine, atropine, bicarbonate and naloxone (NARCAN) were administered ^^for cardiac arrest^^. An

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		ultrasound for pulse check showed no cardiac activity. ^^It was reported that the subject was hospitalized^^. Core temperature was 94.6 Fahrenheit rectally, CRP continued with no success an at 14:19 (after 1 hour) the subject died due to ^^seizure^^ as per hospital records. ^^An autopsy was performed. No imaging testing to evaluate the seizures was carried out; no medications were given for previous episodes of possible seizures. The subject died in the ER before he could be admitted to the hospital; therefore, admission date, discharge date and discharge diagnosis were not applicable. There was no confirmed diagnosis of seizures prior to the day of death and no further information available regarding onset dates of 'episodes' reported by the mother^^. The action taken with the study therapies was reported as ^^dose not changed^^. The investigator considered the seizure (severe) to be related to V114 or pneumococcal 13valent conjugate vaccine (CRM197) (PREVNAR 13), Rotavirus Vaccine, Live, Oral, Pentavalent (ROTATEQ), Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB), to diphtheria toxoid (+) Haemophilus b conjugate vaccine (unspecified carrier) (+) pertussis acellular vaccine (unspecified) (+) poliovirus vaccine inactivated (unspecified) (+) tetanus toxoid (DTAP-IPV HIB) (PENTACEL) vaccine and Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) (HIBERIX), but not related to the study procedure. ^^The investigator assessed the event related to administration of all vaccines due to temporal relationship and no other definitive cause of death^^. The investigator considered the seizure (severe) to be a life-threatening event. Updated information received on 15-NOV-2019 from the investigator has been captured in between double caret (^^). The record for this subject was unblinded on 18-NOV-2019. Company Causality Assessment: Although there is a family history of seizures and co-suspect use RECOMBIVAX HB (known to be associated with non-fatal seizure), based on the clinically relevant information currently available for this individual case, there is a possibility that the reported serious adverse event of Seizure with a fatal outcome is related to the use of the investigational vaccines (blinded investigational vaccine [V114 or PREVNAR 13] and open-label study vaccine [PENTACEL and HIBERIX). The plausible temporal relationship, the known safety profiles of the blinded comparator (known to be associated with non-fatal seizure and apnea) and open label study vaccines (PENTACEL [known to be associated with non-fatal apnea] and HIBERIX [known to be associated with non-fatal convulsions]) support the possible relationship. Additional information regarding laboratory data due to increased glucose prior to CPR, autopsy report and the history of shoulder dystocia with unknown complications are needed for further assessment. Important missing information includes any record of fever accompanying the event. Febrile seizures have previously been reported in children who have received pneumococcal conjugate vaccines (PREVNAR 13). An Analysis of Similar Events regarding this follow up report of the adverse reaction of Seizure with the serious criteria of hospitalization, life threatening and death was performed. This case refers to a 6-month-old male subject who experienced Seizure after the third dose of the investigational vaccines (blinded investigational vaccine [V114 or pneumococcal 13 valent conjugate vaccine (CRM197) PREVNAR 13] and open label study vaccines [PENTACEL and HIBERIX]). This is the first reported case of Seizure in association with the investigational vaccines (blinded investigational vaccine [V114 or pneumococcal 13 valent conjugate vaccine (CRM197) PREVNAR 13] and open label study vaccines [PENTACEL and HIBERIX]) submitted to the FDA. The Suspected Adverse Reactions of Seizure does not alter the existing benefit-risk profile of the product. Merck and Co., Inc., known as MSD outside of certain countries, will continue to monitor this event and other serious adverse events reported in association with V-114 and will communicate any relevant changes to the protocol, Investigator's Brochure and/or Core Safety Information.; Reported Cause(s) of Death: Seizure
UNKNOWN VACCINES (UNK)	**0850272-1**	Pneumonia / Died this past week because his body couldn't fight it off; Lungs were congested; Couldn't breathe; This case was reported by a consumer via interactive digital media and described the occurrence of pneumonia in a male patient who received Flu Seasonal QIV Dresden (Influenza vaccine Quadrivalent 2019-2020 season) for prophylaxis. Concurrent medical conditions included hospitalization (hospital this past month) and sedation (was in a sedative state). In October 2019, the patient received Influenza vaccine Quadrivalent 2019-2020 season. In October 2019, 1 day after receiving Influenza vaccine Quadrivalent 2019-2020 season, the patient experienced pneumonia (serious criteria death, hospitalization and GSK medically significant), lung congestion (serious criteria hospitalization and GSK medically significant) and difficulty breathing (serious criteria hospitalization). The patient was treated with oxygen. In November 2019, the outcome of the pneumonia was fatal. On an unknown date, the outcome of the lung congestion and difficulty breathing were unknown. The patient died in November 2019. The reported cause of death was pneumonia. It was unknown if the reporter considered the pneumonia, lung congestion and difficulty breathing to be related to Influenza vaccine Quadrivalent 2019-2020 season. Additional details were provided as follows: The age at vaccination was not reported. The patient was in the hospital, and while he was in a sedative state, the patient was vaccinated with a flu shot without his permission, and never even told his wife and kids. The day after vaccination, the patient couldn't breathe, and his lungs were congested. The patient was put on oxygen, because he got pneumonia. The patient died because his body couldn't fight it off.; Reported Cause(s) of Death: Pneumonia
UNKNOWN VACCINES (UNK)	**0850861-1**	Liver failure. Septic. Legs Swollen, couldn't walk. Was given Shingles and possibly flu vaccine.
UNKNOWN VACCINES (UNK)	**0853341-1**	Patient had rash begin the same day which led to larger rash that was not treated. Patient was seen at Medical Center more than once and then was transferred for higher level of care due to skin condition from Medical Center.

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UNKNOWN VACCINES (UNK)	**0854032-1**	Foetal exposure during pregnancy; Stillbirth; Low birth weight; Premature birth; This is an observational study case, initially received from other health professional on 16-Dec-2019 with an additional information received on 18-Dec-2019 (being processed together), concerning a male, neonatal subject. The subject's mother was 33-year-old pregnant female of body weight: 246 Ibs, height: 67 in and body mass index (BMI) 38.5 enrolled in a prospective observational safety study. The subject's mother current medical condition included history of venous thromboembolism, gestational hypertension (GHTN), anxiety, nausea, vomiting, history of deep vein thrombosis (DVT) and obesity. The subject's mother concomitant medication included Prenatal vitamins (unspecified vitamins and minerals) for pregnancy, Lexapro (escitalopram oxalate) for anxiety, promethazine for nausea and vomiting and Lovenox (enoxaparin sodium) for history of venous thromboembolism. The subject's mother had no previous pregnancies. The subject's mother had no maternal or paternal history with major congenital malformations (MCMs). The subject's mother had no history of offspring with MCM. The subject's mother did not use tobacco, alcohol or illicit drugs during pregnancy. The subject's mother last menstrual period (LMP) date was 24-Jun-2019. Estimated delivery date (EDD) was reported as 30-Mar-2020 and corrected estimated delivery date (CEDD) was not reported. The type of pregnancy was singleton. On 18-Sep-2019, the subject's mother underwent first sequential and nuchal translucency. No MCMs were noted. On 16-Oct-2019, at approximately 16 weeks of gestation, the subject's mother was administered Afluria QIV [influenza vaccine, subunit influenza virus vaccine polyvalent, cell cultured derived, batch number: P100112488, dose, route of administration, anatomical location and expiration date: not reported] (explicitly coded as æFoetal exposure during pregnancy') for an influenza immunisation. On the same day, the subject's mother underwent second sequential and no MCMs were noted. On 30-Oct-2019, the subject's mother underwent early glucose tolerance test and per reporter, it failed. On 04-Nov-2019, the subject's mother underwent three-hour glucose tolerance test and no MCMs were noted. At approximately 22 weeks of gestation, mother vaginally delivered a stillbirth male neonate, (explicitly coded as 'Premature birth'). The pregnancy outcome was stillbirth. The characteristics of the neonate included weight: 417 grams, head circumference and length were not reported. Appearance, pulse, grimace, activity, and respiration (APGAR) scores were not reported. No MCMs were identified at the time of birth. On the same day, the subject's mother was diagnosed with HELLP syndrome (characterised with hemolysis, elevated liver enzymes, and a low platelet count). It was reported that the factors that may had impact on fetal loss included mother's HELLP syndrome and history of DVT. It was unknown whether the autopsy was performed. The event of stillbirth is considered as serious due to fatal outcome, while the events of low birth weight baby and premature birth are considered as serious due to criterion of medical significance. The reporter did not provide causality assessment to Afluria QIV. This case is linked to case 201907406 (corresponding mother case). Company comment: The patient experienced preterm birth and low birth weight, one months and 14 days after maternal receipt of Afluria QIV. The pregnancy outcome was stillbirth. The subject's mother was administered vaccine at approximately 16 weeks of gestation. Chronology is plausible. Mother's medical history of venous thromboembolism, gestational hypertension and concomitant drugs used during pregnancy may have contributed to development of the events. However, causal role of the suspect vaccine cannot be totally excluded and is assessed as related. The event foetal exposure during pregnancy is assessed as not related to the suspect vaccine.; Sender's Comments: The patient experienced preterm birth and low birth weight, one months and 14 days after maternal receipt of Afluria QIV. The pregnancy outcome was stillbirth. The subject's mother was administered vaccine at approximately 16 weeks of gestation. Chronology is plausible. Mother's medical history of venous thromboembolism, gestational hypertension and concomitant drugs used during pregnancy may have contributed to development of the events. However, causal role of the suspect vaccine cannot be totally excluded and is assessed as related. The event foetal exposure during pregnancy is assessed as not related to the suspect vaccine.; Reported Cause(s) of Death: Unknown cause of death

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 then 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 07/16/2021. 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)

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

Query Date: Jul 26, 2021 9:29:09 PM

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 - 07/16/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Jul 26, 2021 9:29:09 PM

Query Criteria:

Date Died:	2019
Date of Onset:	2019
Date Report Completed:	2019
Date Report Received:	2019
Date Vaccinated:	2019
State / Territory:	The United States/Territories/Unknown
VAERS ID:	All
Group By:	Vaccine Type; VAERS ID
Show Totals:	False
Show Zero Values:	False