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<?xml version="1.0" encoding="UTF-8" ?>
- <MCCI_IN200100UV01 ITSVersion="XML_1.0" xsi:schemaLocation="urn:hl7-org:v3
../4_ICH_ICSR_Schema_Files/multicacheschemas/MCCI_IN200100UV01.xsd" xmlns="urn:hl7-org:v3"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  <id extension="1230ABC700" root="2.16.840.1.113883.3.989.2.1.3.22" />
  <!-- Batch Number -->
  <creationTime value="20101214151617" />
  <!-- Date of Batch Transmission -->
  <responseModeCode code="D" />
  <interactionId extension="MCCI_IN200100UV01" root="2.16.840.1.113883.1.6" />
  <name code="ichicsr" codeSystem="2.16.840.1.113883.3.989.2.1.1.1" />
  <!-- Us this string for all ICSR batches -->
  <!-- Message #1 -->
- <PORR_IN049016UV>
  <id extension="2345660-ARCH-2345" root="2.16.840.1.113883.3.989.2.1.3.1" />
  <!-- Message Identifier -->
  <creationTime value="20101214151617" />
  <!-- Date of Message Creation -->
  <interactionId extension="PORR_IN049016UV" root="2.16.840.1.113883.1.6" />
  <processingCode code="P" />
  <processingModeCode code="T" />
  <acceptAckCode code="AL" />
- <receiver typeCode="RCV">
  - <device classCode="DEV" determinerCode="INSTANCE">
    <id extension="ZZFDA" root="2.16.840.1.113883.3.989.2.1.3.12" />
    <!-- Message Receiver Identifier -->
  </device>
</receiver>
- <sender typeCode="SND">
  - <device classCode="DEV" determinerCode="INSTANCE">
    <id extension="456789012" root="2.16.840.1.113883.3.989.2.1.3.11" />
    <!-- Message Sender Identifier -->
  </device>
</sender>
- <controlActProcess classCode="CACT" moodCode="EVN">
  <code code="PORR_TE049016UV" codeSystem="2.16.840.1.113883.1.18" />
  <!-- HL7 Trigger Event ID -->
  <effectiveTime value="20101214151617" />
  <!-- Date of Creation -->
- <subject typeCode="SUBJ">
  - <investigationEvent classCode="INVSTG" moodCode="EVN">
    <id extension="US-APHARMA-8744554B" root="2.16.840.1.113883.3.989.2.1.3.1" />
    <!-- Sender's (case) Safety Report Unique Identifier -->
    <id extension="US-APHARMA-8744554B" root="2.16.840.1.113883.3.989.2.1.3.2" />
    <!-- Worldwide Unique Case Identification Number -->
    <code code="PAT_ADV_EVNT" codeSystem="2.16.840.1.113883.5.4" />
    <text mediaType="text/plain">Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and
Additional Relevant Information Consumer report from the www.abbott.com of bad side effects coincident with
ADALIMUMAB (HUMIRA PRE-FILLED SYRINGE) therapy. On an unknown date, the patient started HUMIRA PRE-
FILLED SYRINGE therapy for an unknown indication. On an unknown date, the patient experienced bad side
effects. Initial information was received from the mother of a 20 month old female child. The parent states she
thinks the child may have accidentally ingested one or some amount of Zantac tablets of an unspecified dosage,
on an unspecified date. The lot number, expiration date, or treatment for the event was not reported.
Concomitant medications and medical history were not reported. It was not reported if Zantac was discontinued
or if the patient has recovered Note, this text pastes together info from two separate reports.</text>
<!-- Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant
Information -->
    <statusCode code="active" />
  - <effectiveTime>
    <low value="20090101" />
    <!-- Date Report Was First Received from Source -->
  </effectiveTime>
    <availabilityTime value="20090101" />
    <!-- Date of Most Recent Information for This Report -->
  - <reference typeCode="REFR">
    - <document classCode="DOC" moodCode="EVN">
      <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" displayName="documentsHeldBySender"
/>
      <title>Sample Autopsy Report</title>
      <!-- Documents Held by Sender (repeat as necessary) #1 -->
      <text mediaType="pdf" compression="DF" representation="B64">SUMMARY OF CLINICAL HISTORY: The
patient was a 35 year old African American male with no significant past medical history who called EMS
with shortness of breath and chest pain. Upon EMS arrival, patient was tachypneic at 40 breaths per
minute with oxygen saturation of 90%. At the scene, EMS administered breathing treatments and

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checked lung sounds that did not reveal any evidence of fluid in the lung fields. EMS also reports patient was agitated upon their arrival at his residence. Two minutes after arrival at UTMB at 1500, the patient became unresponsive, apneic, and had oxygen saturations from 80-90%. The patient's heart rate decreased to asystole, was intubated with good breath sounds and air movement. Patient then had wide complex bradycardia and ACLS protocol for pulseless electrical activity was followed for 45 minutes. The patient was administered TPA with no improvement. Bedside echocardiogram showed no pericardial effusion. The patient was administered D5W, Narcan, and multiple rounds of epinephrine and atropine, calcium chloride, and sodium bicarbonate. The patient had three episodes of ventricular tachycardia/fibrillation with cardioversion/defibrillation resulting in asystole. The patient was pronounced dead at 1605 with fixed, dilated pupils, no heart sounds, no pulse and no spontaneous respirations. DESCRIPTION OF GROSS LESIONS: EXTERNAL EXAMINATION: The body is that of a 35 year old well developed, well nourished male. There is no peripheral edema of the extremities. There is an area of congestion/erythema on the upper chest and anterior neck. There are multiple small areas of hemorrhage bilaterally in the conjunctiva. A nasogastric tube and endotracheal tube are in place. There is an intravenous line in the right hand and left femoral region. The patient has multiple lead pads on the thorax. The patient has no other major surgical scars. INTERNAL EXAMINATION (BODY CAVITIES): The right and left pleural cavity contains 10 ml of clear fluid with no adhesions. The pericardial sac is yellow, glistening without adhesions or fibrosis and contains 30 ml of a straw colored fluid. There is minimal fluid in the peritoneal cavity. HEART: The heart is large with a normal shape and a weight of 400 grams. The pericardium is intact. The epicardial fat is diffusely firm. As patient was greater than 48 hours post mortem, no TTC staining was utilized. Upon opening the heart was grossly normal without evidence of infarction. There were slightly raised white plaques in the left ventricle wall lining. The left ventricle measures 2.2 cm, the right ventricle measures 0.2 cm, the tricuspid ring measures 11 cm, the pulmonic right measures 8 cm, the mitral ring measures 10.2 cm, and the aortic ring measures 7 cm. The foramen ovale is closed. The circulation is left dominant. Examination of the great vessels of the heart reveals minimal atherosclerosis with the area of greatest stenosis (20% stenosis) at the bifurcation of the LAD. AORTA: There is minimal atherosclerosis with no measurable plaques along the full length of the ascending and descending aorta. LUNGS: The right lung weighed 630 grams, the left weighed 710 grams. The lung parenchyma is pink without evidence of congestion or hemorrhage. The bronchi are grossly normal. In the right lung, there are two large organizing thrombo-emboli. The first is located at the first branch of the pulmonary artery with an older, organizing area adherent to the vessel wall measuring 1.0 x 1.0 x 2.5 cm. Surrounding this organizing area is a newer area of apparent thrombosis completely occluding the bifurcation. The other large organizing, adherent embolus is located further in out in the vasculature measuring approximately 1.0 x 1.0 x 1.5 cm. There are multiple other emboli located in smaller pulmonary vessels that show evidence of distending the vessels they are located inside. GASTROINTESTINAL SYSTEM: The esophagus and stomach are normal in appearance without evidence of ulcers or varices. The stomach contains approximately 800 ml, without evidence of any pills or other non food stuff material. The pancreas shows a normal lobular cut surface with evidence of autolysis. The duodenum, ileum, jejunum and colon are all grossly normal without evidence of abnormal vasculature or diverticuli. An appendix is present and is unremarkable. The liver weighs 2850 grams and the cut surface reveals a normal liver with no fibrosis present grossly. The gallbladder is in place with a probe patent bile duct through to the ampulla of Vater. RETICULOENDOTHELIAL SYSTEM: The spleen is large weighing 340 grams, the cut surface reveals a normal appearing white and red pulp. No abnormally large lymph nodes were noted. GENITOURINARY SYSTEM: The right kidney weighs 200 grams, the left weighs 210 grams. The left kidney contains a 1.0 x 1.0 x 1.0 simple cyst containing a clear fluid. The cut surface reveals a normal appearing cortex and medulla with intact calyces. The prostate and seminal vessels were cut revealing normal appearing prostate and seminal vesicle tissue without evidence of inflammation or embolus. ENDOCRINE SYSTEM: The adrenal glands are in the normal position and weigh 8.0 grams on the right and 11.6 grams on the left. The cut surface of the adrenal glands reveals a normal appearing cortex and medulla. The thyroid gland weighs 12.4 grams and is grossly normal. EXTREMITIES: Both legs and calves were measured and found to be very similar in circumference. Both legs were also milked and produced no clots in the venous system. CLINICOPATHOLOGIC CORRELATION This patient died shortly after a previous pulmonary embolus completely occluded the right pulmonary artery vasculature. The most significant finding on autopsy was the presence of multiple old and new thromboemboli in the pulmonary vasculature of the right lung. The autopsy revealed evidence of multiple emboli in the right lung that were at least a few days old because the emboli that were organizing were adherent to the vessel wall. In order to be adherent to the vessel wall, the emboli must be in place long enough to evoke a fibroblast response, which takes at least a few days. The fatal event was not the old emboli in the right lung, but rather the thrombosis on top of the large saddle thrombus residing in the pulmonary artery. This created a high pressure situation that the right ventricle could not handle resulting in cardiac dysfunction and ultimately the patient's demise. Although this case is fairly straight forward in terms of what caused the terminal event, perhaps the more interesting question is why a relatively healthy 35 year old man would develop a fatal pulmonary embolism. Virchow's triad suggests we should investigate endothelial injury, stasis and a hypercoagulable state as possible etiologies. The age of the patient probably precludes venous stasis as the sole reason for the embolus although it could have certainly contributed. The autopsy revealed no evidence of endothelial damage in the pulmonary vasculature that would have caused the occlusion. The next logical reason would be a hypercoagulable state. Some possibilities include obesity, trauma, surgery, cancer, Factor V Leiden deficiency (as well as other inherited disorders-prothrombin gene mutation, deficiencies in protein C, protein S, or antithrombin III, and disorders of plasminogen), and Lupus anticoagulant. Of these risks factors, obesity was the only risk factor the patient was known to have. The patient had no evidence of trauma, surgery, cancer or the stigmata of SLE, therefore these are unlikely. Perhaps the most fruitful search would be an examination of the genetic possibilities for a hypercoagulable state (Factor V Leiden being the most common). In summary, this patient died of a pulmonary embolism, the underlying cause of which is currently

undetermined. A definitive diagnosis may be ascertained with either genetic or other laboratory tests and a more detailed history. SUMMARY AND REFLECTION: What I learned from this autopsy: I learned that although a cause of death may sometimes be obvious, the underlying mechanism for the death may still be elusive. This patient was an otherwise completely healthy 35 year old man with one known risk factor for a hypercoaguable state. Remaining unanswered questions: Basically the cause of the hypercoaguable state is undetermined. Once that question is answered I believe this autopsy will have done a great service for the patient's family.</text>

<!-- : Included Documents #1 -->

</document>

</reference>

- <reference typeCode="REFR">

- <document classCode="DOC" moodCode="EVN">

<code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" displayName="documentsHeldBySender" />

<title>Medication Information</title>

<text mediaType="image/jpeg" representation="B64" compression="DF">Why is this medication prescribed? .

Erythromycin is an antibiotic used to treat certain infections caused by bacteria, such as bronchitis; diphtheria; Legionnaires' disease; pertussis (whooping cough); pneumonia; rheumatic fever; venereal disease (VD); and ear, intestine, lung, urinary tract, and skin infections. It is also used before some surgery or dental work to prevent infection. Antibiotics will not work for colds, flu, or other viral infections. This medication is sometimes prescribed for other uses; ask your doctor or pharmacist for more information. How should this medicine be used? . Erythromycin comes as a capsule, tablet, long-acting capsule, long-acting tablet, chewable tablet, liquid, and pediatric drops to take by mouth. It usually is taken every 6 hours (four times a day) or every 8 hours (three times a day) for 7 to 21 days. Some infections may require a longer time. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take erythromycin exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor. Shake the liquid and pediatric drops well before each use to mix the medication evenly. Use the bottle dropper to measure the dose of pediatric drops. The chewable tablets should be crushed or chewed thoroughly before they are swallowed. The other capsules and tablets should be swallowed whole and taken with a full glass of water. Continue to take erythromycin even if you feel well. Do not stop taking erythromycin without talking to your doctor. What special precautions should I follow? Return to top . Before taking erythromycin, •tell your doctor and pharmacist if you are allergic to erythromycin, azithromycin (Zithromax), clarithromycin (Biaxin), dirithromycin (Dynabac), or any other drugs. •tell your doctor and pharmacist what prescription and nonprescription medications you are taking, especially other antibiotics, anticoagulants ('blood thinners'), astemizole (Hismanal), carbamazepine (Tegretol), cisapride (Propulsid), clozapine (clozaril), cyclosporine (Neoral, Sandimmune), digoxin (Lanoxin), disopyramide (Norpace), ergotamine, felodipine (Plendil), lovastatin (Mevacor), phenytoin (Dilantin), pimozide (Orap), terfenadine (Seldane), theophylline (Theo-Dur), triazolam (Halcion), and vitamins. •tell your doctor if you have or have ever had liver disease, yellowing of the skin or eyes, colitis, or stomach problems. •tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking erythromycin, call your doctor. •if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking erythromycin. What special dietary instructions should I follow? Return to top . Take erythromycin at least 1 hour before or 2 hours after meals. Do not take this medication with, or just after, fruit juices or carbonated drinks. Certain brands of erythromycin may be taken with meals; check with your doctor or pharmacist. What should I do if I forget a dose? Return to top . Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one. </text>

</document>

</reference>

- <reference typeCode="REFR">

- <document classCode="DOC" moodCode="EVN">

<code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" displayName="literatureReference" />

<text mediaType="application/pdf" representation="B64">The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS is a post-marketing safety surveillance program, collecting information about adverse events (possible side effects) that occur after the administration of vaccines licensed for use in the United States. VAERS provides a nationwide mechanism by which adverse events following immunization may be reported, analyzed, and made available to the public. VAERS also provides a vehicle for disseminating vaccine safety-related information to parents and guardians, health care providers, vaccine manufacturers, state vaccine programs, and other constituencies.</text>

<bibliographicDesignationText> Author (last name first), "Article Title." Name of newspaper, city, state of publication. (date): edition if available, section, page number(s).</bibliographicDesignationText >

</document>

</reference>

- <component typeCode="COMP">

- <adverseEventAssessment classCode="INVSTG" moodCode="EVN">

- <subject1 typeCode="SBJ">

- <primaryRole classCode="INVSBJ">

- <player1 classCode="PSN" determinerCode="INSTANCE">

- <name>

<prefix>Mr.</prefix>

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    <given>John</given>
    <given>James</given>
    <family>Doe</family>
  </name>
  <!-- Patient (name or initials) -->
  <telecom value="tel:6667771234" />
  <telecom value="mailto:emailaddress@home.com" />
  <administrativeGenderCode code="1" codeSystem="1.0.5218" />
  <!-- Sex -->
  <birthTime value="19990101" />
  <!-- Date of Birth -->
  <deceasedTime value="20090101" />
  <!-- Date of Death -->
- <addr>
  <streetAddressLine>124 Any Street</streetAddressLine>
  <streetAddressLine>Apt. 4</streetAddressLine>
  <city>Center City</city>
  <state>AL</state>
  <postalCode>12345</postalCode>
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  <id extension="83444908" root="2.16.840.1.113883.3.989.2.1.3.7" />
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  Record Number) -->
  <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" displayName="GP" />
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- <asIdentifiedEntity classCode="IDENT">
  <id extension="8999-B" root="2.16.840.1.113883.3.989.2.1.3.8" />
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  Record Number) -->
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  <id extension="3333444A32" root="2.16.840.1.113883.3.989.2.1.3.9" />
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  Record Number) -->
  <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" displayName="Hospital
  Record" />
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- <asIdentifiedEntity classCode="IDENT">
  <id extension="09233347580934" root="2.16.840.1.113883.3.989.2.1.3.10" />
  <!-- Patient Medical Record Number(s) and Source(s) of the Record Number
  (Investigation Number) -->
  <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" displayName="Investigation"
  />
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- <role classCode="PRS">
  <!-- Parent information - used when a substance administration by the parent triggers
  a reaction in a child. -->
  <code code="PRN" codeSystem="2.16.840.1.113883.5.111" />
- <associatedPerson classCode="PSN" determinerCode="INSTANCE">
  - <name>
    <prefix>Ms.</prefix>
    <given>Jane</given>
    <given>S</given>
    <family>Doe</family>
  </name>
  <!-- Parent (name or initials) -->
  <administrativeGenderCode code="2" codeSystem="1.0.5218" />
  <!-- parent sex -->
  <birthTime value="10940621" />
  <!-- Date of Birth -->
</associatedPerson>
- <subjectOf2 typeCode="SBJ">
  - <observation classCode="OBS" moodCode="EVN">
    <code code="C17049" displayName="Race" codeSystem="2.16.840.1.113883.3.26.1.1"
    />
    <value xsi:type="CE" code="C41260" displayName="Asian"
    codeSystem="2.16.840.1.113883.3.26.1.1" />
  </observation>
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- <subjectOf2 typeCode="SBJ">
  - <observation classCode="OBS" moodCode="EVN">
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        codeSystem="2.16.840.1.113883.3.26.1.1" />
        <value xsi:type="CE" code="C174595" displayName="Hispanic or Latino"
        codeSystem="2.16.840.1.113883.3.26.1.1" />
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- <observation classCode="OBS" moodCode="EVN">
    <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="age at
    onset of reaction" />
    <value xsi:type="PQ" value="10" unit="a_g" />
    <!-- Age at Time of Onset of Reaction / Event (number) -->
    <!-- Age at Time of Onset of Reaction / Event (unit) -->
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
    <code code="C25150" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="age"
    />
    <value xsi:type="PQ" value="10" unit="a_g" />
    <!-- VAERS Parent Age -->
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
    <code code="C103173" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="age
    at time of vaccination" />
    <value xsi:type="PQ" value="10" unit="a_g" />
    <!-- Age at Time of vaccination -->
</observation>
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- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
    <code code="22" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="lastMenstrualPeriodDate" />
    <value xsi:type="TS" value="20090101" />
    <!-- Last Menstrual Period Date of Parent -->
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
    <code code="7" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="bodyWeight" />
    <value xsi:type="PQ" value="50" unit="kg" />
    <!-- Body Weight (kg) of Parent -->
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
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    displayName="height" />
    <value xsi:type="PQ" value="160" unit="cm" />
    <!-- Height (cm) of Parent -->
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <organizer classCode="CATEGORY" moodCode="EVN">
    <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.20"
    displayName="relevantMedicalHistoryAndConcurrentConditions" />
    - <component typeCode="COMP">
        - <observation classCode="OBS" moodCode="EVN">
            <code code="10000621" displayName="Actinomycotic abdominal infection"
            codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="12.0" />
            <!-- MedDRA Version for Medical History #1 -->
            <!-- Medical History (disease / surgical procedure/ etc.) (MedDRA code)
            #1 -->
            - <effectiveTime xsi:type="IVL_TS">
                <low value="20010926" />
                <!-- Start Date -->
                <high value="20011031" />
                <!-- End Date -->
            </effectiveTime>
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        displayName="comment" />
        <value xsi:type="ED">This is what we thought</value>
        <!-- Comments -->
    </observation>
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- <outboundRelationship2 typeCode="COMP">
- <observation classCode="OBS" moodCode="EVN">
    <code code="38" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
        displayName="family history" />
    <value xsi:type="BL" value="false" />
    <!-- Family History -->
</observation>
</outboundRelationship2>
- <inboundRelationship typeCode="REFR">
- <observation classCode="OBS" moodCode="EVN">
    <code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
        displayName="continuing" />
    <value xsi:type="BL" value="false" />
    <!-- Continuing #1 -->
</observation>
</inboundRelationship>
</observation>
</component>
- <component typeCode="COMP">
- <observation classCode="OBS" moodCode="EVN">
    <code code="10010538" codeSystem="2.16.840.1.113883.6.163"
        codeSystemVersion="12.0" />
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    <!-- Medical History (disease / surgical procedure/ etc.) (MedDRA code)
        -->
- <effectiveTime xsi:type="IVL_TS">
    <low value="20090101" />
    <!-- Start Date -->
    <high value="20090101" />
    <!-- End Date -->
</effectiveTime>
- <outboundRelationship2 typeCode="COMP">
- <observation classCode="OBS" moodCode="EVN">
    <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
        displayName="comment" />
    <value xsi:type="ED">Further relevant comments</value>
    <!-- Comments -->
</observation>
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- <outboundRelationship2 typeCode="COMP">
- <observation classCode="OBS" moodCode="EVN">
    <code code="38" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
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    <!-- Family History -->
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- <inboundRelationship typeCode="REFR">
- <observation classCode="OBS" moodCode="EVN">
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- <observation classCode="OBS" moodCode="EVN">
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        codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="12.0" />
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    <!-- Medical History (disease / surgical procedure/ etc.) (MedDRA code)
        -->
</observation>
</component>
- <component typeCode="COMP">
- <observation classCode="OBS" moodCode="EVN">
    <code code="10023637" displayName="Lacrimal sac cellulitis"

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        codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="12.0" />
<!-- MedDRA Version for Medical History -->
<!-- Medical History (disease / surgical procedure/ etc.) (MedDRA code)
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- <component typeCode="COMP">
- <observation classCode="OBS" moodCode="EVN">
  <code code="18" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
  displayName="historyAndConcurrentConditionText" />
  <value xsi:type="ED">Systems Review 1.Constitutional: energy level generally
  good, weight is stable at 160 lbs, height 5'8" 2.HEENT: No headaches Eyes:
  wears reading glasses but thinks vision getting is worse, no diplopia or eye
  pain Ears: hearing loss for many years, wears hearing aid now Nose: no
  epistaxis or obstruction No history of tonsillitis or tonsillectomy Wears full
  set of dentures for more than 20 years, works well. 3.Respiratory: No
  history of pleurisy, cough, wheezing, asthma, hemoptysis, pulmonary
  emboli, pneumonia, TB or TB exposure 4.Cardiac: See HPI 5.Vascular: No
  history of claudication, gangrene, deep vein thrombosis, aneurysm. Has
  chronic venous stasis skin changes for many years 6.G.I.: Admitted to CPMC
  in 1980 after two days of melena and hematemesis. Upper G.I. series was
  negative but endoscopy showed evidence of gastritis, presumed to be
  caused by ibuprofen intake. Her hematocrit was 24% on admission and she
  received four units of packed cells. Colonoscopy revealed multiple diverticuli.
  Since then her stool has been brown and consistently hematest negative
  when checked in clinic. Several months after this admission she was noted
  to be mildly jaundiced and had elevated liver enzymes, at this time it was
  realized that she contracted hepatitis B from the transfusions. Since then
  she has not had any evidence of chronic hepatitis.</value>
  <!-- Text for Relevant Medical History and Concurrent Conditions of
  Parent -->
</observation>
</component>
- <component typeCode="COMP">
- <observation classCode="OBS" moodCode="EVN">
  <code code="11" displayName="presence of concomitant therapies"
  codeSystem="2.16.840.1.113883.3.989.2.1.1.19" />
  <value xsi:type="BL" value="true" />
</observation>
</component>
</organizer>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <organizer classCode="CATEGORY" moodCode="EVN">
  <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.20"
  displayName="drugHistory" />
- <component typeCode="COMP">
- <substanceAdministration classCode="SBADM" moodCode="EVN">
  - <effectiveTime xsi:type="IVL_TS">
    <low value="20090101" />
    <!-- Start Date #1 -->
    <high value="20090101" />
    <!-- End Date #1 -->
  </effectiveTime>
- <consumable typeCode="CSM">
- <instanceOfKind classCode="INST">
  - <kindOfProduct classCode="MMAT" determinerCode="KIND">
    <code code="65044-5208" codeSystem="2.16.840.1.113883.6.69" />
    <!-- MPID Version Date / Number -->
    <!-- Medicinal Product Identifier (MPID) -->
    <name>Molds, Rusts and Smuts, Penicillium notatum</name>
    <!-- Name of Drug as Reported -->
  - <asEntityWithGeneric classCode="GRIC">
    - <genericMedicine classCode="MMAT" determinerCode="KIND">
      <name>Penicillium notatum</name>
      <!-- Generic name is provided for vaccines when the
      name supplied is a non-US name. -->
    </genericMedicine>
    </asEntityWithGeneric>
  </kindOfProduct>
</instanceOfKind>
</consumable>
- <outboundRelationship2 typeCode="RSON">
- <observation classCode="OBS" moodCode="EVN">

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    <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
      displayName="indication" />
    <value xsi:type="CE" code="10054929"
      codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="12.0" />
    <!-- MedDRA Version for Indication -->
    <!-- Indication (MedDRA code) -->
  </observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="CAUS">
- <observation classCode="OBS" moodCode="EVN">
  <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="reaction" />
  <value xsi:type="CE" code="10060051"
    codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="12.0" />
  <!-- MedDRA Version for Reaction -->
  <!-- Reactions (MedDRA code) -->
</observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="FLFS">
  <sequenceNumber value="3" />
  <substanceAdministration moodCode="INT" classCode="SBADM" />
</outboundRelationship2>
</substanceAdministration>
</component>
- <component typeCode="COMP">
- <substanceAdministration classCode="SBADM" moodCode="EVN">
- <effectiveTime xsi:type="IVL_TS">
  <low value="20090101" />
  <!-- Start Date -->
  <high value="20090101" />
  <!-- End Date -->
</effectiveTime>
- <consumable typeCode="CSM">
- <instanceOfKind classCode="INST">
- <kindOfProduct classCode="MMAT" determinerCode="KIND">
  <code code="14505-488" codeSystem="2.16.840.1.113883.6.69" />
  <!-- PhPID Version Date / Number -->
  <!-- Pharmaceutical Product Identifier (PhPID) -->
  <name>Guaifenesin, Dextromethorphan</name>
  <!-- Name of Drug as Reported -->
- <asEntityWithGeneric classCode="GRIC">
- <genericMedicine classCode="MMAT" determinerCode="KIND">
  <name>Generic name</name>
  <!-- Generic name is provided for vaccines when the
    name supplied is a non-US name. -->
  </genericMedicine>
</asEntityWithGeneric>
</kindOfProduct>
</instanceOfKind>
</consumable>
- <outboundRelationship2 typeCode="RSON">
- <observation classCode="OBS" moodCode="EVN">
  <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="indication" />
  <value xsi:type="CE" code="10061372" displayName="Streptococcal
    infection" codeSystem="2.16.840.1.113883.6.163"
    codeSystemVersion="12.0" />
  <!-- MedDRA Version for Indication -->
  <!-- Indication (MedDRA code) -->
</observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="CAUS">
- <observation classCode="OBS" moodCode="EVN">
  <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="reaction" />
  <value xsi:type="CE" code="10036960" displayName="bleeding"
    codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="12.0" />
  <!-- MedDRA Version for Reaction -->
  <!-- Reactions (MedDRA code) -->
</observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="FLFS">
  <sequenceNumber value="3" />
  <substanceAdministration moodCode="INT" classCode="SBADM" />

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        </outboundRelationship2>
        </substanceAdministration>
    </component>
</organizer>
</subjectOf2>
</role>
- <role classCode="PRS">
    <!-- Sibling information VAERS only -->
    <code code="SIB" codeSystem="2.16.840.1.113883.5.111" />
    <associatedPerson classCode="PSN" determinerCode="INSTANCE" />
- <subjectOf2 typeCode="SBJ">
    - <observation classCode="OBS" moodCode="EVN">
        <code code="C88065" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="onset
        age" />
        <value xsi:type="PQ" value="10" unit="a_g" />
        <!-- Age at Time of Onset of Reaction / Event (number) -->
        <!-- Age at Time of Onset of Reaction / Event (unit) -->
    </observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
    - <organizer classCode="CATEGORY" moodCode="EVN">
        <code code="C102470" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="adverse event following prior vaccination" />
    - <component typeCode="COMP">
        - <substanceAdministration classCode="SBADM" moodCode="EVN">
            - <consumable typeCode="CSM">
                - <instanceOfKind classCode="INST">
                    - <kindOfProduct classCode="MMAT" determinerCode="KIND">
                        <code code="765444" codeSystem="2.16.840.1.113883.6.69" />
                        <!-- MPID Version Date / Number -->
                        <!-- Medicinal Product Identifier (MPID) -->
                        <name>Acme Improve</name>
                        <!-- Name of Drug as Reported -->
                    - <asEntityWithGeneric classCode="GRIC">
                        - <genericMedicine classCode="MMAT" determinerCode="KIND">
                            <name>Generic name</name>
                            <!-- Generic name is provided for vaccines when the
                            "Name of Drug as Reported" supplied is a non-US name.
                            -->
                        </genericMedicine>
                    </asEntityWithGeneric>
                </kindOfProduct>
            </instanceOfKind>
        </consumable>
    - <outboundRelationship2 typeCode="CAUS">
        - <observation classCode="OBS" moodCode="EVN">
            <code code="C41331" codeSystem="2.16.840.1.113883.3.26.1.1"
            displayName="Adverse Event" />
            <value xsi:type="CE" code="12345678"
            codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="12.0" />
            <!-- MedDRA Version for Reaction -->
            <!-- Reactions (MedDRA code) -->
        </observation>
    </outboundRelationship2>
    - <outboundRelationship2 typeCode="FLFS">
        <sequenceNumber value="3" />
        <!-- VAERS Sibling dose in series -->
        <substanceAdministration moodCode="INT" classCode="SBADM" />
    </outboundRelationship2>
    </substanceAdministration>
</component>
</organizer>
</subjectOf2>
</role>
</player1>
- <subjectOf1 typeCode="SBJ">
    - <researchStudy classCode="CLNTRL" moodCode="EVN">
        <id extension="4555-3" root="2.16.840.1.113883.3.989.2.1.3.5" />
        <!-- C Sponsor Study Number -->
        <code code="2" displayName="Individual patient use"
        codeSystem="2.16.840.1.113883.3.989.2.1.1.8" />
        <!-- Study Type Where Reaction(s) / Event(s) Were Observed -->
        <title>Profound Study</title>
        <!-- Study Name -->
    - <authorization typeCode="AUTH">

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- <studyRegistration classCode="ACT" moodCode="EVN">
  <id extension="23489-34" root="2.16.840.1.113883.3.989.2.1.3.6" />
  <!-- Study Registration Number -->
- <author typeCode="AUT">
  - <territorialAuthority classCode="TERR">
    - <governingPlace classCode="COUNTRY" determinerCode="INSTANCE">
      <code code="US" codeSystem="1.0.3166.1.2.2" />
      <!-- Study Registration Country -->
    </governingPlace>
  </territorialAuthority>
  </author>
</studyRegistration>
</authorization>
- <authorization typeCode="AUTH">
- <studyRegistration classCode="ACT" moodCode="EVN">
  <id extension="876444" root="2.16.840.1.113883.3.989.2.1.3.6" />
  <!-- Study Registration Number -->
- <author typeCode="AUT">
  - <territorialAuthority classCode="TERR">
    - <governingPlace classCode="COUNTRY" determinerCode="INSTANCE">
      <code code="FR" codeSystem="1.0.3166.1.2.2" />
      <!-- C Study Registration Country -->
    </governingPlace>
  </territorialAuthority>
  </author>
</studyRegistration>
</authorization>
</researchStudy>
</subjectOf1>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
  <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="age at onset
of reaction" />
  <value xsi:type="PQ" value="10" unit="a_g" />
  <!-- Age at Time of Onset of Reaction / Event (number) -->
  <!-- Age at Time of Onset of Reaction / Event (unit) -->
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
  <code code="C25150" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="age" />
  <value xsi:type="PQ" value="10" unit="a_g" />
  <!-- VAERS Patient Age -->
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
  <code code="C103173" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="age at time
of vaccination" />
  <value xsi:type="PQ" value="10" unit="a_g" />
  <!-- Age at Time of vaccination -->
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
  <code code="16" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
displayName="gestationPeriod" />
  <value xsi:type="PQ" value="10" unit="wk" />
  <!-- Gestation Period When Reaction / Event Was Observed in the Foetus (number) -->
  <!-- Gestation Period When Reaction / Event Was Observed in the Foetus (unit) -->
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
  <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="ageGroup" />
  <value xsi:type="CE" code="4" displayName="adolescent"
codeSystem="2.16.840.1.113883.3.989.2.1.1.9" />
  <!-- Patient Age Group (as per reporter) -->
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
  <code code="7" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="bodyWeight"
/>

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        <value xsi:type="PQ" value="48.2" unit="kg" />
        <!-- Body Weight (kg) -->
    </observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
    <code code="C76325" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="birthWeight" />
    <value xsi:type="PQ" value="3" unit="kg" />
    <!-- Birth Weight (kg) -->
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
    <code code="17" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="height" />
    <value xsi:type="PQ" value="152" unit="cm" />
    <!-- Height (cm) -->
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
    <code code="22" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
        displayName="lastMenstrualPeriodDate" />
    <value xsi:type="TS" value="20090101" />
    <!-- Last Menstrual Period Date -->
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
    <code code="C76325" displayName="birthWeight" codeSystem="2.16.840.1.113883.3.26.1.1" />
    <value xsi:type="PQ" value="400" unit="gm" />
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
    <code code="C102469" displayName="numberOfSiblings"
        codeSystem="2.16.840.1.113883.3.26.1.1" />
    <value xsi:type="INT" value="2" />
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
    <code code="C17049" displayName="Race" codeSystem="2.16.840.1.113883.3.26.1.1" />
    <value xsi:type="CE" code="C41260" displayName="Asian"
        codeSystem="2.16.840.1.113883.3.26.1.1" />
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
    <code code="C16564" displayName="ethnicGroup" codeSystem="2.16.840.1.113883.3.26.1.1" />
    <value xsi:type="CE" code="C174595" displayName="Hispanic or Latino"
        codeSystem="2.16.840.1.113883.3.26.1.1" />
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
    <code code="C102468" displayName="illnessAtTimeOfVaccination"
        codeSystem="2.16.840.1.113883.3.26.1.1" />
    <value xsi:type="CE" code="87442323" codeSystem="2.16.840.1.113883.6.163"
        codeSystemVersion="12.0" />
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <organizer classCode="CATEGORY" moodCode="EVN">
    <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.20"
        displayName="relevantMedicalHistoryAndConcurrentConditions" />
- <component typeCode="COMP">
- <observation classCode="OBS" moodCode="EVN">
    <code code="10061122" codeSystem="2.16.840.1.113883.6.163"
        codeSystemVersion="12.0" />
    <!-- MedDRA Version for Medical History #1 -->
    <!-- Medical History (disease / surgical procedure / etc.) (MedDRA code) #1

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-->
- < effectiveTime xsi:type="IVL_TS">
  < low value="20090101" />
  <!-- : Start Date #1 -->
  < high value="20090101" />
  <!-- End Date #1 -->
</effectiveTime>
- < outboundRelationship2 typeCode="COMP">
  - < observation classCode="OBS" moodCode="EVN">
    < code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
      displayName="comment" />
    < value xsi:type="ED"> Comment </value>
    <!-- Comments #1 -->
  </observation>
</outboundRelationship2>
- < outboundRelationship2 typeCode="EXPL">
  - < observation classCode="OBS" moodCode="EVN">
    < code code="38" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
      displayName="familyHistory" />
    < value xsi:type="BL" value="true" />
    <!-- Family History #1 -->
  </observation>
</outboundRelationship2>
- < inboundRelationship typeCode="REFR">
  - < observation classCode="OBS" moodCode="EVN">
    < code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
      displayName="continuing" />
    < value xsi:type="BL" value="true" />
    <!-- Continuing #1 -->
  </observation>
</inboundRelationship>
</observation>
</component>
- < component typeCode="COMP">
  - < observation classCode="OBS" moodCode="EVN">
    < code code="10012431" codeSystem="2.16.840.1.113883.6.163"
      codeSystemVersion="12.0" />
    <!-- MedDRA Version for Medical History -->
    <!-- Medical history (disease / surgical procedure / etc.) (MedDRA code) -->
  </observation>
  - < effectiveTime xsi:type="IVL_TS">
    < low value="20020101" />
    <!-- Start Date -->
    < high value="20060101" />
    <!-- End Date -->
  </effectiveTime>
  - < outboundRelationship2 typeCode="COMP">
    - < observation classCode="OBS" moodCode="EVN">
      < code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
        displayName="comment" />
      < value xsi:type="ED"> The condition was accentuated by poor diet. </value>
      <!-- Comments -->
    </observation>
  </outboundRelationship2>
  - < outboundRelationship2 typeCode="EXPL">
    - < observation classCode="OBS" moodCode="EVN">
      < code code="38" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
        displayName="familyHistory" />
      < value xsi:type="BL" value="true" />
      <!-- Family History -->
    </observation>
  </outboundRelationship2>
  - < inboundRelationship typeCode="REFR">
    - < observation classCode="OBS" moodCode="EVN">
      < code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
        displayName="continuing" />
      < value xsi:type="BL" value="true" />
      <!-- Continuing -->
    </observation>
  </inboundRelationship>
</observation>
</component>
- < component typeCode="COMP">
  - < observation classCode="OBS" moodCode="EVN">
    < code code="18" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"

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        displayName="historyAndConcurrentConditionText" />
<value xsi:type="ED">The patient's medical history does not show anything very out
of the ordinary.</value>
<!-- Text for Relevant Medical History and Concurrent Conditions (not
including reaction / event) -->
</observation>
</component>
- <component typeCode="COMP">
- <observation classCode="OBS" moodCode="EVN">
  <code code="11" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
  displayName="concomitantTherapy" />
  <value xsi:type="BL" value="true" />
  <!-- Concomitant Therapies -->
</observation>
</component>
</organizer>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <organizer classCode="CATEGORY" moodCode="EVN">
  <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" displayName="drugHistory"
  />
- <component typeCode="COMP">
- <substanceAdministration classCode="SBADM" moodCode="EVN">
  - <effectiveTime xsi:type="IVL_TS">
    <low value="20090101" />
    <!-- Start Date #1 -->
    <high value="20090101" />
    <!-- End Date #1 -->
  </effectiveTime>
  - <consumable typeCode="CSM">
  - <instanceOfKind classCode="INST">
    - <kindOfProduct classCode="MMAT" determinerCode="KIND">
      <code code="0071-0220" codeSystem="2.16.840.1.113883.6.69" />
      <!-- MPID Version Date / Number #1 -->
      <!-- Medicinal Product Identifier (NDC) -->
      <name>ACCURETIC</name>
      <!-- Name of Drug as Reported #1 -->
    </kindOfProduct>
  </instanceOfKind>
  </consumable>
  - <outboundRelationship2 typeCode="RSON">
  - <observation classCode="OBS" moodCode="EVN">
    <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="indication" />
    <value xsi:type="CE" code="10028094" displayName="Mucopolysaccharidosis
    IH" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="12.0" />
    <!-- MedDRA Version for Indication #1 -->
    <!-- Indication (MedDRA code) #1 -->
  </observation>
  </outboundRelationship2>
  - <outboundRelationship2 typeCode="CAUS">
  - <observation classCode="OBS" moodCode="EVN">
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="reaction" />
    <value xsi:type="CE" code="10067994" codeSystem="2.16.840.1.113883.6.163"
    codeSystemVersion="12.0" />
    <!-- MedDRA Version for Reaction #1 -->
    <!-- Reaction (MedDRA code) #1 -->
  </observation>
  </outboundRelationship2>
  - <outboundRelationship2 typeCode="FLFS">
    <sequenceNumber value="3" />
    <substanceAdministration moodCode="INT" classCode="SBADM" />
  </outboundRelationship2>
  </substanceAdministration>
</component>
- <component typeCode="COMP">
- <substanceAdministration classCode="SBADM" moodCode="EVN">
  - <effectiveTime xsi:type="IVL_TS">
    <low value="20090101" />
    <!-- Start Date -->
    <high value="20090101" />
    <!-- End Date -->
  </effectiveTime>

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- < consumable typeCode="CSM">
- < instanceOfKind classCode="INST">
- < kindOfProduct classCode="MMAT" determinerCode="KIND">
  < code code="43742-0053" codeSystem="2.16.840.1.113883.6.69" />
  <!-- PhPID Version Date / Number -->
  <!-- Pharmaceutical Product Identifier (PhPID) -->
  < name >Spine and Nerve Balance Core Formula</name>
  <!-- Name of Drug as Reported -->
- < asEntityWithGeneric classCode="GRIC">
- < genericMedicine classCode="MMAT" determinerCode="KIND">
  < name >Deseret Homeopaths</name>
  <!-- Generic name is provided for vaccines when the name
  supplied is a non-US name. -->
  </genericMedicine>
</asEntityWithGeneric>
</kindOfProduct>
</instanceOfKind>
</consumable>
- < outboundRelationship2 typeCode="RSON">
- < observation classCode="OBS" moodCode="EVN">
  < code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
  displayName="indication" />
  < value xsi:type="CE" code="8345900" codeSystem="2.16.840.1.113883.6.163"
  codeSystemVersion="12.0" />
  <!-- MedDRA Version for Indication -->
  <!-- Indication (MedDRA code) -->
</observation>
</outboundRelationship2>
- < outboundRelationship2 typeCode="CAUS">
- < observation classCode="OBS" moodCode="EVN">
  < code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
  displayName="reaction" />
  < value xsi:type="CE" code="10050987" codeSystem="2.16.840.1.113883.6.163"
  codeSystemVersion="12.0" />
  <!-- MedDRA Version for Reaction -->
  <!-- Reaction (MedDRA code) -->
</observation>
</outboundRelationship2>
- < outboundRelationship2 typeCode="FLFS">
  < sequenceNumber value="3" />
  < substanceAdministration moodCode="INT" classCode="SBADM" />
</outboundRelationship2>
</substanceAdministration>
</component>
</organizer>
</subjectOf2>
- < subjectOf2 typeCode="SBJ">
- < organizer classCode="CATEGORY" moodCode="EVN">
  < code code="C102467" displayName="Other Vaccinations Given within Four Weeks"
  codeSystem="2.16.840.1.113883.3.26.1.1" />
- < component typeCode="COMP">
- < substanceAdministration classCode="SBADM" moodCode="EVN">
  < effectiveTime value="20090101" />
  < approachSiteCode code="C12421" codeSystem="2.16.840.1.113883.3.26.1.1" />
  < routeCode code="C38288" codeSystem="2.16.840.1.113883.3.26.1.1"
  displayName="ORAL" />
- < consumable typeCode="CSM">
- < instanceOfKind classCode="INST">
- < productInstance classCode="MMAT" determinerCode="INSTANCE">
  < lotNumberText >123444-AB</lotNumberText>
</productInstance>
- < kindOfProduct classCode="MMAT" determinerCode="KIND">
  < code code="49281-650" codeSystem="2.16.840.1.113883.12.549"
  codeSystemVersion="07-Oct-2013" />
  < name >INFLUENZA A VIRUS A/CALIFORNIA/7/2009(H1N1)-LIKE
  ANTIGEN (FORMALDEHYDE INACTIVATED)</name>
- < asManufacturedProduct classCode="MANU">
  < id root="1.3.6.1.4.1.519.1" extension="7891811" />
  - < manufacturerOrganization classCode="ORG"
  determinerCode="INSTANCE">
    < name >ACME Production Corp.</name>
  </manufacturerOrganization>
</asManufacturedProduct>
</kindOfProduct>

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    </instanceOfKind >
  </consumable >
  - < outboundRelationship2 typeCode="COMP" >
    - < observation classCode="OBS" moodCode="EVN" >
      < code code="C88065" displayName="ageAtTimeOfVaccination"
        codeSystem="2.16.840.1.113883.3.26.1.1" />
      < value xsi:type="PQ" value="3" unit="a_g" />
    </observation >
  </outboundRelationship2 >
  - < outboundRelationship2 typeCode="FLFS" >
    < sequenceNumber value="2" />
    < substanceAdministration classCode="SBADM" moodCode="INT" />
  </outboundRelationship2 >
  </substanceAdministration >
</component >
</organizer >
</subjectOf2 >
- < subjectOf2 typeCode="SBJ" >
  - < observation classCode="OBS" moodCode="EVN" >
    < code code="32" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
      displayName="reportedCauseOfDeath" />
    - < value xsi:type="CE" code="10036807" codeSystem="2.16.840.1.113883.6.163"
      codeSystemVersion="12.0" >
      <!-- MedDRA Version for Reported Cause(s) of Death #1 -->
      <!-- Reported Cause(s) of Death (MedDRA code) #1 -->
      <originalText>Progressive multifocal leukoencephalopathy</originalText >
      <!-- : Reported Cause(s) of Death (free text) #1 -->
    </value >
  </observation >
</subjectOf2 >
- < subjectOf2 typeCode="SBJ" >
  - < observation classCode="OBS" moodCode="EVN" >
    < code code="32" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
      displayName="reportedCauseOfDeath" />
    - < value xsi:type="CE" code="10036805" codeSystem="2.16.840.1.113883.6.163"
      codeSystemVersion="12.0" >
      <!-- : MedDRA Version for Reported Cause(s) of Death -->
      <!-- Reported Cause(s) of Death (MedDRA code) -->
      <originalText>Excessive Fibrosis</originalText >
      <!-- Reported Cause(s) of Death (free text) -->
    </value >
  </observation >
</subjectOf2 >
- < subjectOf2 typeCode="SBJ" >
  - < observation classCode="OBS" moodCode="EVN" >
    < code code="5" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="autopsy" />
    < value xsi:type="BL" value="true" />
    <!-- Was Autopsy Done? -->
    - < outboundRelationship2 typeCode="DRIV" >
      - < observation classCode="OBS" moodCode="EVN" >
        < code code="8" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
          displayName="causeOfDeath" />
        - < value xsi:type="CE" code="10067063" codeSystem="2.16.840.1.113883.6.163"
          codeSystemVersion="12.0" >
          <!-- MedDRA Version for Autopsy-determined Cause(s) of Death #1 -->
          <!-- Autopsy-determined Cause(s) of Death (MedDRA code) #1 -->
          <originalText>What we learned during the autopsy</originalText >
          <!-- Autopsy-determined Cause(s) of Death (free text) #1 -->
        </value >
      </observation >
    </outboundRelationship2 >
    - < outboundRelationship2 typeCode="DRIV" >
      - < observation classCode="OBS" moodCode="EVN" >
        < code code="8" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
          displayName="causeOfDeath" />
        - < value xsi:type="CE" code="10061227" codeSystem="2.16.840.1.113883.6.163"
          codeSystemVersion="12.0" >
          <!-- MedDRA Version for Autopsy-determined Cause(s) of Death -->
          <!-- Autopsy-determined Cause(s) of Death (MedDRA code) -->
          <originalText>Metabolic Abnormality</originalText >
          <!-- Autopsy-determined Cause(s) of Death (free text) -->
        </value >
      </observation >
    </outboundRelationship2 >

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    </observation>
  </subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
  <id root="154eb889-958b-45f2-a02f-42d4d6f4657f" />
  <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="reaction" />
- <effectiveTime xsi:type="IVL_TS">
  <low value="20090101" />
  <!-- Date of Start of Reaction / Event -->
  <high value="20090102" />
  <!-- Date of End of Reaction / Event -->
</effectiveTime>
<!-- It is also possible for the reaction to show a start date/time and a duration.
-->
- <value xsi:type="CE" code="10027940" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="12.0">
  <!-- MedDRA Version for Reaction / Event -->
  <!-- Reaction / Event (MedDRA code) -->
  <originalText language="Port">consciência alterada</originalText>
  <!-- Reaction / Event as Reported by the Primary Source in Native Language -->
  <!-- Reaction / Event as Reported by the Primary Source Language -->
</value>
- <location typeCode="LOC">
- <locatedEntity classCode="LOCE">
  - <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
    <code code="US" codeSystem="1.0.3166.1.2.2" />
    <!-- Identification of the Country Where the Reaction / Event Occurred -->
  </locatedPlace>
</locatedEntity>
</location>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
  <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
  displayName="reactionForTranslation" />
  <value xsi:type="ED">Altered Consciousness</value>
  <!-- Reaction / Event as Reported by the Primary Source for Translation -->
</observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
  <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
  displayName="termHighlightedByReporter" />
  <value xsi:type="CE" code="2" displayName="No, not highlighted by the reporter, NOT
  serious" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" />
  <!-- Term Highlighted by the Reporter -->
</observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
  <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
  displayName="resultsInDeath" />
  <value xsi:type="BL" value="true" />
  <!-- Results in Death -->
</observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
  <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
  displayName="isLifeThreatening" />
  <value xsi:type="BL" nullFlavor="NI" />
  <!-- Life Threatening -->
</observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
  <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
  displayName="requiresInpatientHospitalization" />
  <value xsi:type="BL" value="true" />
  <!-- Caused / Prolonged Hospitalisation -->
</observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
  <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"

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        displayName="resultsInPersistentOrSignificantDisability" />
        <value xsi:type="BL" nullFlavor="NI" />
        <!-- Disabling / Incapacitating -->
    </observation>
</outboundRelationship2 >
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
    <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
        displayName="congenitalAnomalyBirthDefect" />
    <value xsi:type="BL" nullFlavor="NI" />
    <!-- Congenital Anomaly / Birth Defect -->
</observation>
</outboundRelationship2 >
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
    <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
        displayName="otherMedicallyImportantCondition" />
    <value xsi:type="BL" value="true" />
    <!-- Other Medically Important Condition -->
</observation>
</outboundRelationship2 >
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
    <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
        displayName="medicalConfirmationByHealthProfessional" />
    <value xsi:type="BL" value="true" />
    <!-- Medical Confirmation by Healthcare Professional -->
</observation>
</outboundRelationship2 >
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
    <code code="C53513" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="Emergency Room" />
    <value xsi:type="BL" value="true" />
    <!-- Required visit to the emergency room -->
</observation>
</outboundRelationship2 >
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
    <code code="C16988" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="Physician Office" />
    <value xsi:type="BL" value="true" />
    <!-- Required visit to the Physician Office -->
</observation>
</outboundRelationship2 >
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
    <code code="C50414" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="Hospitalization required" />
    <value xsi:type="BL" value="true" />
    <!-- Required visit to the hospital -->
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
    <code code="C102443" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="number of hospitalization days" />
    <value xsi:type="INT" value="5" />
    <!-- number of hospitalization days -->
- <performer typeCode="PRF">
- <assignedEntity classCode="ASSIGNED">
    - <representedOrganization classCode="ORG" determinerCode="INSTANCE">
        <name>Memorial Hospital</name>
        - <addr>
            <city>Metropolis</city>
            <state>Pennsylvania</state>
        </addr>
    </representedOrganization>
    </assignedEntity>
    </performer>
</observation>
</outboundRelationship2 >
</outboundRelationship2 >
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">

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      <code code="C10450" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="Resulted in prolongation of hospitalization" />
      <value xsi:type="BL" value="false" />
      <!-- Resulted in prolongation of hospitalization -->
    </observation>
  </outboundRelationship2>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
  <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="outcome of reaction/event" />
  <value xsi:type="CE" code="3" displayName="not recovered/not resolved/ongoing"
    codeSystem="2.16.840.1.113883.3.989.2.1.1.10" />
  <!-- outcome -->
</observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
  <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="medical confirmation by healthcare professional" />
  <value xsi:type="BL" value="true" />
  <!-- medical confirmation -->
</observation>
</outboundRelationship2>
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <observation classCode="OBS" moodCode="EVN">
  <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220" />
  <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="reaction" />
- <effectiveTime xsi:type="IVL_TS">
  <low value="20090101" />
  <!-- Date of Start of Reaction / Event -->
  <width value="24" unit="min" />
  <!-- Duration of Reaction / Event (number) -->
  <!-- Duration of Reaction / Event (unit) -->
</effectiveTime>
- <value xsi:type="CE" code="10023508" codeSystem="2.16.840.1.113883.6.163"
  codeSystemVersion="12.0">
  <!-- MedDRA Version for Reaction / Event -->
  <!-- Reaction / Event (MedDRA code) -->
  <originalText language="EN">Heart disease</originalText>
  <!-- Reaction / Event as Reported by the Primary Source in Native Language -->
  <!-- Reaction / Event as Reported by the Primary Source Language -->
</value>
- <location typeCode="LOC">
- <locatedEntity classCode="LOCE">
  - <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
    <code code="US" codeSystem="1.0.3166.1.2.2" />
    <!-- Identification of the Country Where the Reaction / Event Occurred -->
  </locatedPlace>
</locatedEntity>
</location>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
  <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="resultsInDeath" />
  <value xsi:type="BL" value="true" />
  <!-- Results in Death -->
</observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
  <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="isLifeThreatening" />
  <value xsi:type="BL" nullFlavor="NI" />
  <!-- Life Threatening -->
</observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
  <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="requiresInpatientHospitalization" />
  <value xsi:type="BL" value="true" />

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    <!-- Caused / Prolonged Hospitalisation -->
  </observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
  <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="resultsInPersistentOrSignificantDisability" />
  <value xsi:type="BL" nullFlavor="NI" />
  <!-- Disabling / Incapacitating -->
</observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
  <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="congenitalAnomalyBirthDefect" />
  <value xsi:type="BL" nullFlavor="NI" />
  <!-- Congenital Anomaly / Birth Defect -->
</observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
  <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="otherMedicallyImportantCondition" />
  <value xsi:type="BL" value="true" />
  <!-- Other Medically Important Condition -->
</observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
  <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="medicalConfirmationByHealthProfessional" />
  <value xsi:type="BL" value="true" />
  <!-- Medical Confirmation by Healthcare Professional -->
</observation>
</outboundRelationship2>
</observation>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <organizer classCode="CATEGORY" moodCode="EVN">
  <code code="C102467" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="other
    vaccinations given within four weeks" />
- <component typeCode="COMP">
- <substanceAdministration moodCode="EVN" classCode="SBADM">
  <effectiveTime value="20090101" />
  <approachSiteCode code="C105633" displayName="Left Arm"
    codeSystem="2.16.840.1.113883.3.26.1.1" />
  <routeCode code="C28161" codeSystem="2.16.840.1.113883.3.26.1.1"
    displayName="Intramuscular route of administration" />
- <consumable typeCode="CSM">
- <instanceOfKind classCode="INST">
- <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
  <lotNumberText>123444-AB</lotNumberText>
</productInstanceInstance>
- <kindOfProduct classCode="MMAT" determinerCode="KIND">
  <code code="0052-0603" codeSystem="2.16.840.1.113883.12.549"
    codeSystemVersion="07-Oct-2013" />
  <name>BCG vaccine</name>
- <asManufacturedProduct classCode="MANU">
- <manufacturerOrganization classCode="ORG"
  determinerCode="INSTANCE">
  <name>ACME Production Corp.</name>
</manufacturerOrganization>
</asManufacturedProduct>
</kindOfProduct>
</instanceOfKind>
</consumable>
- <outboundRelationship2 typeCode="COMP">
- <observation classCode="OBS" moodCode="EVN">
  <code code="C88065" displayName="ageAtTimeOfVaccination"
    codeSystem="2.16.840.1.113883.3.26.1.1" />
  <value xsi:type="PQ" value="3" unit="a_g" />
</observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="FLFS">

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        <sequenceNumber value="2" />
        <substanceAdministration classCode="SBADM" moodCode="INT" />
    </outboundRelationship2>
</substanceAdministration>
</component>
</organizer>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <organizer classCode="CATEGORY" moodCode="EVN">
    <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.20"
        displayName="testsAndProceduresRelevantToTheInvestigation" />
- <component typeCode="COMP">
- <observation classCode="OBS" moodCode="EVN">
- <code code="10050520" codeSystem="2.16.840.1.113883.6.163"
    codeSystemVersion="12.0">
    <!-- MedDRA Version for Test Name #1 -->
    <!-- Test Name (MedDRA code) #1 -->
    <originalText>Calcium Level</originalText>
    <!-- Test Name (free text) #1 -->
    </code>
    <effectiveTime value="20090101" />
    <!-- : Test Date -->
- <value xsi:type="IVL_PQ">
    <center value="10" unit="mg/dl" />
    <!-- Test Result (value / qualifier) #1 -->
    <!-- Test Result (unit) #1 -->
    </value>
    <interpretationCode code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.12" />
    <!-- Test Result (code) #1 -->
- <referenceRange typeCode="REFV">
- <observationRange classCode="OBS" moodCode="EVN.CRT">
    <value xsi:type="PQ" value="40" unit="mg/dl" />
    <!-- Normal Low Value #1 -->
    <interpretationCode code="L" codeSystem="2.16.840.1.113883.5.83" />
    </observationRange>
    </referenceRange>
- <referenceRange typeCode="REFV">
- <observationRange classCode="OBS" moodCode="EVN.CRT">
    <value xsi:type="PQ" value="110" unit="mg/dl" />
    <!-- Normal High Value #1 -->
    <interpretationCode code="H" codeSystem="2.16.840.1.113883.5.83" />
    </observationRange>
    </referenceRange>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
    <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
        displayName="comment" />
    <value xsi:type="ED">These results may be skewed</value>
    <!-- Comments (free text) #1 -->
    </observation>
    </outboundRelationship2>
- <outboundRelationship2 typeCode="REFR">
- <observation classCode="OBS" moodCode="EVN">
    <code code="25" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
        displayName="moreInformationAvailable" />
    <value xsi:type="BL" value="true" />
    <!-- More Information Available #1 -->
    </observation>
    </outboundRelationship2>
</observation>
</component>
- <component typeCode="COMP">
- <observation classCode="OBS" moodCode="EVN">
- <code code="10059578" codeSystem="2.16.840.1.113883.6.163"
    codeSystemVersion="12.0">
    <!-- MedDRA Version for Test Name -->
    <!-- Test Name (MedDRA code) -->
    </code>
    <effectiveTime value="2009" />
    <!-- Test Date -->
- <value xsi:type="IVL_PQ">
    <low nullFlavor="NINF" />
    <high value="10" unit="mg/dl" inclusive="false" />
    </value>

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      <!-- Test Result (value / qualifier) -->
      <!-- Test Result (unit) -->
      <!-- LT 10 mg/dl -->
    </observation>
  </component>
- <component typeCode="COMP">
- <observation classCode="OBS" moodCode="EVN">
  - <code code="10059478" codeSystem="2.16.840.1.113883.6.163"
    codeSystemVersion="12.0">
    <originalText>Blood work</originalText>
    <!-- Test Name (free text) #3 -->
    </code>
    <effectiveTime value="20090101" />
    <!-- Test Date #3 -->
  - <value xsi:type="IVL_PQ">
    <low nullFlavor="NINF" />
    <high value="10" unit="mg/dl" inclusive="true" />
  </value>
  <!-- Test Result (value / qualifier) #3 -->
  <!-- Test Result (unit) #3 -->
  <!-- LE 10 mg/dl #3 -->
</observation>
</component>
- <component typeCode="COMP">
- <observation classCode="OBS" moodCode="EVN">
  - <code>
    <originalText>A special test</originalText>
  </code>
  <effectiveTime value="20090101" />
  <!-- Test Date #4 -->
  - <value xsi:type="IVL_PQ">
    <low value="10" unit="mg/dl" inclusive="false" />
    <high nullFlavor="PINF" />
  </value>
  <!-- Test Result (value / qualifier) #4 -->
  <!-- Test Result (unit) #4 -->
  <!-- GT 10 mg/dl #4 -->
</observation>
</component>
- <component typeCode="COMP">
- <observation classCode="OBS" moodCode="EVN">
  <code code="10005362" codeSystem="2.16.840.1.113883.6.163"
  codeSystemVersion="12.0" />
  <effectiveTime value="20090101" />
  <!-- Test Date #5 -->
  - <value xsi:type="IVL_PQ">
    <low value="10" unit="mg/dl" inclusive="true" />
    <high nullFlavor="PINF" />
  </value>
  <!-- : Test Result (value / qualifier) #5 -->
  <!-- Test Result (unit) #5 -->
  <!-- GE 10 mg/dl #5 -->
</observation>
</component>
- <component typeCode="COMP">
- <observation classCode="OBS" moodCode="EVN">
  <code code="10062994" codeSystem="2.16.840.1.113883.6.163"
  codeSystemVersion="12.0" />
  <effectiveTime value="20090101" />
  <value xsi:type="ED">The over all outcome was quite spectacular.</value>
  <!-- Result Unstructured Data (free text) #6 -->
</observation>
</component>
</organizer>
</subjectOf2>
- <subjectOf2 typeCode="SBJ">
- <organizer classCode="CATEGORY" moodCode="EVN">
  <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.20"
  displayName="drugInformation" />
  <!-- Drug(s) Information (repeat as necessary) #1 -->
  - <component typeCode="COMP">
  - <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4" />
    - <consumable typeCode="CSM">

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- <instanceOfKind classCode="INST">
- <kindOfProduct classCode="MMAT" determinerCode="KIND">
  <code code="0009-7663" codeSystem="2.16.840.1.113883.6.69" />
  <!-- Medicinal Product Identifier (MPID) -->
  <name>exemestane</name>
  <!-- Medicinal Product Name as Reported by the Primary Source -->
- <asManufacturedProduct classCode="MANU">
- <manufacturerOrganization classCode="ORG"
  determinerCode="INSTANCE">
  <name>Pharmacia and Upjohn Company</name>
  </manufacturerOrganization>
- <subjectOf typeCode="SBJ">
- <approval classCode="CNTRCT" moodCode="EVN">
  <id extension="ANDA012345"
  root="2.16.840.1.113883.3.989.2.1.3.4" />
  <!-- Authorisation / Application Number -->
- <holder typeCode="HLD">
- <role classCode="HLD">
  - <playingOrganization classCode="ORG"
  determinerCode="INSTANCE">
  <name>Pharmacia and Upjohn Company</name>
  <!-- Name of Holder / Applicant -->
  </playingOrganization>
  </role>
</holder>
- <author typeCode="AUT">
- <territorialAuthority classCode="TERR">
  - <territory classCode="NAT" determinerCode="INSTANCE">
  <code code="US" codeSystem="1.0.3166.1.2.2" />
  <!-- of Authorisation / Application -->
  </territory>
  </territorialAuthority>
</author>
</approval>
</subjectOf>
- <subjectOf typeCode="SBJ">
- <characteristic classCode="OBS" moodCode="EVN">
  <code code="C5469" displayName="combination product"
  codeSystem="2.16.840.1.113883.3.26.1.1" />
  <value xsi:type="CV" code="C73626" displayName="Bulk
  ingredient" codeSystem="2.16.840.1.113883.3.26.1.1" />
  </characteristic>
</subjectOf>
</asManufacturedProduct>
- <asEntityWithGeneric classCode="GRIC">
- <genericMedicine classCode="MMAT" determinerCode="KIND">
  <name>Generic name</name>
  <!-- Generic name is provided for vaccines when the name
  supplied is a non-US name. -->
  </genericMedicine>
</asEntityWithGeneric>
- <ingredient classCode="ACTI">
- <quantity>
  <numerator value="10" unit="mg" />
  <!-- Strength (number) #1-1 -->
  <!-- : Strength (unit) #1-1 -->
  <denominator value="1" />
</quantity>
- <ingredientSubstance classCode="MMAT" determinerCode="KIND">
  <code code="012C11ZU6G" codeSystem="2.16.840.1.113883.4.9" />
  <!-- : Substance / Specified Substance TermID Version Date /
  Number #1-1 -->
  <!-- : Substance / Specified Substance TermID #1-1 -->
  <name>Notabenzazine Hydrochloride</name>
  <!-- Substance / Specified Substance Name #1-1 -->
  </ingredientSubstance>
</ingredient>
</kindOfProduct>
- <subjectOf typeCode="SBJ">
- <productEvent classCode="ACT" moodCode="EVN">
  <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.18"
  displayName="retailSupply" />
  - <performer typeCode="PRF">
  - <assignedEntity classCode="ASSIGNED">

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- <representedOrganization classCode="ORG"
  determinerCode="INSTANCE">
- <addr>
  <country>US</country>
  <!-- Identification of the Country Where the Drug
    Was Obtained #1 -->
  </addr>
  </representedOrganization>
  </assignedEntity>
  </performer>
  </productEvent>
  </subjectOf>
  </instanceOfKind>
</consumable>
- <outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="d" />
  <!-- Time Interval between Beginning of Drug Administration and Start of
    Reaction / Event (number) Drug #1, Reaction #1 -->
  <!-- : Time Interval between Beginning of Drug Administration and Start of
    Reaction / Event (unit) Drug #1, Reaction #1 -->
- <actReference classCode="OBS" moodCode="EVN">
  <id root="154eb889-958b-45f2-a02f-42d4d6f4657f" />
</actReference>
</outboundRelationship1>
- <outboundRelationship1 typeCode="SAE">
  <pauseQuantity value="10" unit="min" />
  <!-- Time Interval between Last Dose of Drug and Start of Reaction /
    Event (number) Drug #1, Reaction #1 -->
  <!-- Time Interval between Last Dose of Drug and Start of Reaction /
    Event (unit) Drug #1, Reaction #1 -->
- <actReference classCode="OBS" moodCode="EVN">
  <id root="154eb889-958b-45f2-a02f-42d4d6f4657f" />
</actReference>
</outboundRelationship1>
- <outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="d" />
  <!-- Time Interval between Beginning of Drug Administration and Start of
    Reaction / Event (number) Drug #1, Reaction #2 -->
  <!-- Time Interval between Beginning of Drug Administration and Start of
    Reaction / Event (unit) Drug #1, Reaction #2 -->
- <actReference classCode="OBS" moodCode="EVN">
  <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220" />
</actReference>
</outboundRelationship1>
- <outboundRelationship1 typeCode="SAE">
  <pauseQuantity value="10" unit="d" />
  <!-- Time Interval between Last Dose of Drug and Start of Reaction /
    Event (number) Drug #1, Reaction #2 -->
  <!-- : Time Interval between Last Dose of Drug and Start of Reaction /
    Event (unit) Drug #1, Reaction #2 -->
- <actReference classCode="OBS" moodCode="EVN">
  <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220" />
</actReference>
</outboundRelationship1>
- <outboundRelationship2 typeCode="COMP">
  <!-- Dosage and Relevant Information (repeat as necessary) -->
- <substanceAdministration classCode="SBADM" moodCode="EVN">
  <text>unstructured dosing information, e.g. take by mouth 2 times a day with
    food</text>
  <!-- Dosage Text #1-1 -->
- <effectiveTime xsi:type="SXPR_TS">
  - <comp xsi:type="PIVL_TS">
    <period value="10" unit="d" />
    <!-- Number of Units in the Interval -->
    <!-- Definition of the Time Interval Unit -->
  </comp>
  - <comp xsi:type="IVL_TS" operator="A">
    <low value="20090101" />
    <!-- Date and Time of Start of Drug -->
    <high value="20090101" />
    <!-- Date and Time of Last Administration -->
  </comp>
  - <comp xsi:type="IVL_TS" operator="A">
    <width value="4" unit="wk" />

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        <!-- Duration of Drug Administration (number) -->
        <!-- Duration of Drug Administration (unit) -->
    </comp>
</effectiveTime>
<approachSiteCode code="C12421" codeSystem="2.16.840.1.113883.3.26.1.1"
/>
- <routeCode code="C38288" codeSystem="2.16.840.1.113883.3.26.1.1">
    <!-- Route of Administration TermID Version Date / Number -->
    <!-- Route of Administration TermID -->
    <originalText>Free text route content</originalText>
    <!-- Route of Administration (free text) -->
</routeCode>
<doseQuantity value="10" unit="mg" />
<!-- Dose (number) -->
<!-- Dose (unit) -->
- <consumable typeCode="CSM">
- <instanceOfKind classCode="INST">
    - <productInstanceInstance classCode="MMAT"
        determinerCode="INSTANCE">
        <lotNumberText>4577BN2</lotNumberText>
        <!-- Batch / Lot Number -->
    </productInstanceInstance>
    - <kindOfProduct classCode="MMAT" determinerCode="KIND">
        - <formCode code="C42998" displayName="tablet"
            codeSystem="2.16.840.1.113883.3.26.1.1">
            <!-- Pharmaceutical Dose Form TermID Version Date / Number
                -->
            <!-- Pharmaceutical Dose Form TermID -->
            <originalText>Big, round and colored white</originalText>
            <!-- Pharmaceutical Dose Form (free text) -->
        </formCode>
    </kindOfProduct>
</instanceOfKind>
</consumable>
- <performer typeCode="PRF">
- <assignedEntity classCode="ASSIGNED">
    <code code="C102430" displayName="vaccine administrator"
        codeSystem="2.16.840.1.113883.3.989.2.1.1.21" />
    - <assignedPerson classCode="PSN" determinerCode="INSTANCE">
        - <name>
            <prefix>Dr.</prefix>
            <given>Ralph</given>
            <given>Alexander</given>
            <family>Smith</family>
        </name>
        <telecom value="tel:6667778888" />
        <telecom value="fax:9991112222" />
        <telecom value="mailto:email@address.com" />
    - <addr>
        <streetAddressLine>24 Main St.</streetAddressLine>
        <streetAddressLine>Suite 2304</streetAddressLine>
        <city>Metropolis</city>
        <county>ND012</county>
        <state>ND</state>
        <postalCode>123245</postalCode>
        <country>USA</country>
    </addr>
</assignedPerson>
</assignedEntity>
</performer>
- <author typeCode="AUT">
- <assignedEntity classCode="ASSIGNED">
    - <assignedPerson classCode="PSN" determinerCode="INSTANCE">
        - <name>
            <prefix nullFlavor="NI" />
            <given>Joseph</given>
            <given nullFlavor="NI" />
            <family>Rabinowitz</family>
        </name>
        <telecom value="tel:9874562222" />
        <telecom value="mailto:email@address.com" />
    - <addr>
        <streetAddressLine>24 Main St.</streetAddressLine>
        <streetAddressLine>Suite 2304</streetAddressLine>

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        <city>Metropolis</city>
        <state>ND</state>
        <postalCode>123245</postalCode>
        <country>USA</country>
    </addr>
</assignedPerson>
</assignedEntity>
</author>
- <location typeCode="LOC">
- <locatedEntity classCode="LOCE">
    <code code="C16988" displayName="Physician office"
        codeSystem="2.16.840.1.114222.4.11.10562" />
    <!-- vaccination facility type code -->
- <locatedPlace classCode="PLC" determinerCode="INSTANCE">
- <addr>
    <!-- In the address postal code is used instead of country -->
    <streetAddressLine>33 Main St.</streetAddressLine>
    <city>Pleasantville</city>
    <county>CA3435</county>
    <state>CALifornia</state>
    <postalCode>99999</postalCode>
    </addr>
    </locatedPlace>
</locatedEntity>
</location>
- <inboundRelationship typeCode="REFR">
- <observation classCode="OBS" moodCode="EVN">
    <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
        displayName="parentRouteOfAdministration" />
- <value xsi:type="CE" code="C12421"
        codeSystem="2.16.840.1.113883.3.26.1.1">
    <!-- Parent Route of Administration TermID Version Date /
        Number #1-1 -->
    <!-- Parent Route of Administration TermID #1-1 -->
    <originalText>Text to describe the route if needed</originalText>
    <!-- : Parent Route of Administration (free text) #1-1 -->
    </value>
</observation>
</inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
- <outboundRelationship2 typeCode="COMP">
    <!-- Dosage and Relevant Information (repeat as necessary) -->
- <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>more information on the next course</text>
- <effectiveTime xsi:type="SXPR_TS">
- <comp xsi:type="PIVL_TS">
    <period value="10" unit="d" />
    <!-- Number of Units in the Interval #1-2 -->
    <!-- Definition of the Time Interval Unit #1-2 -->
</comp>
- <comp xsi:type="IVL_TS" operator="A">
    <low value="20090101" />
    <!-- Date and Time of Start of Drug #1-2 -->
    <high value="20090101" />
    <!-- Date and Time of Last Administration #1-2 -->
</comp>
</effectiveTime>
</substanceAdministration>
</outboundRelationship2>
- <outboundRelationship2 typeCode="PERT">
- <observation classCode="OBS" moodCode="EVN">
    <code code="6" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
        displayName="blinded" />
    <value xsi:type="BL" value="false" />
    <!-- Investigational Product Blinded #1 -->
</observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="SUMM">
- <observation classCode="OBS" moodCode="EVN">
    <code code="14" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
        displayName="cumulativeDoseToReaction" />
    <value xsi:type="PQ" value="150" unit="mg" />

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    <!-- Cumulative Dose to First Reaction (number) #1 -->
    <!-- Cumulative Dose to First Reaction (unit) #1 -->
  </observation>
</outboundRelationship2>
- < outboundRelationship2 typeCode="PERT">
- < observation classCode="OBS" moodCode="EVN">
  < code code="16" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="gestationPeriod" />
  < value xsi:type="PQ" value="10" unit="wk" />
  <!-- Gestation Period at Time of Exposure (number) #1 -->
  <!-- Gestation Period at Time of Exposure (unit) #1 -->
</observation>
</outboundRelationship2>
- < outboundRelationship2 typeCode="PERT">
- < observation classCode="OBS" moodCode="EVN">
  < code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="recurrenceOfReaction" />
  < value xsi:type="CE" code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
    />
  <!-- Did Reaction Recur on Re-administration? Drug #1, Reaction #1 --
  >
- < outboundRelationship1 typeCode="REFR">
- < actReference classCode="OBS" moodCode="EVN">
  < id root="154eb889-958b-45f2-a02f-42d4d6f4657f" />
</actReference>
</outboundRelationship1>
</observation>
</outboundRelationship2>
- < outboundRelationship2 typeCode="PERT">
- < observation classCode="OBS" moodCode="EVN">
  < code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="recurrenceOfReaction" />
  < value xsi:type="CE" code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
    />
  <!-- Did Reaction Recur on Re-administration? Drug #1, Reaction --
  >
- < outboundRelationship1 typeCode="REFR">
- < actReference classCode="OBS" moodCode="EVN">
  < id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220" />
</actReference>
</outboundRelationship1>
</observation>
</outboundRelationship2>
- < outboundRelationship2 typeCode="REFR">
- < observation classCode="OBS" moodCode="EVN">
  < code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="codedDrugInformation" />
  < value xsi:type="CE" code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"
    />
  <!-- Additional Information on Drug (coded)(repeat as necessary) #1-1
  -->
</observation>
</outboundRelationship2>
- < outboundRelationship2 typeCode="REFR">
- < observation classCode="OBS" moodCode="EVN">
  < code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="codedDrugInformation" />
  < value xsi:type="CE" code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"
    />
  <!-- Additional Information on Drug (coded)(repeat as necessary) #1-2
  -->
</observation>
</outboundRelationship2>
- < outboundRelationship2 typeCode="REFR">
- < observation classCode="OBS" moodCode="EVN">
  < code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="codedDrugInformation" />
  < value xsi:type="CE" code="10"
    codeSystem="2.16.840.1.113883.3.989.2.1.1.17" />
  <!-- Additional Information on Drug (coded)(repeat as necessary) #1-2
  -->
</observation>
</outboundRelationship2>
- < outboundRelationship2 typeCode="REFR">
- < observation classCode="OBS" moodCode="EVN">

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    <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
      displayName="additional information" />
    <value xsi:type="ST">Something seemed strange about the way it went
      down.</value>
    <!-- Additional Information on Drug (free text) #1 -->
  </observation>
</outboundRelationship2>
- <outboundRelationship2 typeCode="FLFS">
  <sequenceNumber value="3" />
  <substanceAdministration moodCode="INT" classCode="SBADM" />
</outboundRelationship2>
- <inboundRelationship typeCode="RSON">
  - <observation classCode="OBS" moodCode="EVN">
    <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
      displayName="indication" />
    - <value xsi:type="CE" code="10028813" codeSystem="2.16.840.1.113883.6.163"
      codeSystemVersion="12.0">
      <!-- MedDRA Version for Indication #1-1 -->
      <!-- Indication (MedDRA code) #1-1 -->
      <originalText>Medication was prescribed to address sickness to the
        stomach.</originalText>
      <!-- ndication as Reported by the Primary Source #1 -->
    </value>
    - <performer typeCode="PRF">
      - <assignedEntity classCode="ASSIGNED">
        <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21"
          displayName="sourceReporter" />
        </assignedEntity>
      </performer>
    </observation>
  </inboundRelationship>
- <inboundRelationship typeCode="RSON">
  - <observation classCode="OBS" moodCode="EVN">
    <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
      displayName="indication" />
    - <value xsi:type="CE" code="10047340" codeSystem="2.16.840.1.113883.6.163"
      codeSystemVersion="12.0">
      <!-- MedDRA Version for Indication #1-2 -->
      <!-- Indication (MedDRA code) #1-2 -->
      <originalText />
      <!-- Indication as Reported by the Primary Source #1-2 -->
    </value>
    - <performer typeCode="PRF">
      - <assignedEntity classCode="ASSIGNED">
        <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21"
          displayName="sourceReporter" />
        </assignedEntity>
      </performer>
    </observation>
  </inboundRelationship>
- <inboundRelationship typeCode="REFR">
  - <observation classCode="OBS" moodCode="EVN">
    <code code="C114865" displayName="vaccinationAtMilitarySite"
      codeSystem="2.16.840.1.113883.3.26.1.1" />
    <value xsi:type="BL" value="true" />
  </observation>
</inboundRelationship>
- <inboundRelationship typeCode="REFR">
  - <observation classCode="OBS" moodCode="EVN">
    <code code="C71740" displayName="Participation Status"
      codeSystem="2.16.840.1.113883.3.26.1.1" />
    <value xsi:type="CE" code="C114859" displayName="TRICARE beneficiary"
      codeSystem="2.16.840.1.113883.3.26.1.1" />
  </observation>
</inboundRelationship>
- <inboundRelationship typeCode="REFR">
  - <observation classCode="OBS" moodCode="EVN">
    <code code="C102431" displayName="fundingSourceForProduct"
      codeSystem="2.16.840.1.113883.3.26.1.1" />
    <value xsi:type="CE" code="C102433" displayName="Military funding"
      codeSystem="2.16.840.1.113883.3.26.1.1" />
  </observation>
</inboundRelationship>
- <inboundRelationship typeCode="CAUS">

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- < act classCode="ACT" moodCode="EVN">
  < code code="2" displayName="Dose reduced"
    codeSystem="2.16.840.1.113883.3.989.2.1.1.15" />
  <!-- Action(s) Taken with Drug #1 -->
</act>
</inboundRelationship>
</substanceAdministration>
</component>
<!-- Drug(s) Information (repeat as necessary) -->
- < component typeCode="COMP">
- < substanceAdministration classCode="SBADM" moodCode="EVN">
  < id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9" />
  - < consumable typeCode="CSM">
  - < instanceOfKind classCode="INST">
    - < kindOfProduct classCode="MMAT" determinerCode="KIND">
      < name >Aspirin</name>
      <!-- Substance administration and product details have been removed
        from the second iteration of the substance administration. -->
      </kindOfProduct>
    </instanceOfKind>
  </consumable>
</substanceAdministration>
</component>
</organizer>
</subjectOf2>
</primaryRole>
</subject1>
- < component typeCode="COMP">
- < causalityAssessment classCode="OBS" moodCode="EVN">
  < code code="20" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="interventionCharacterization" />
  < value xsi:type="CE" code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.13" />
  <!-- Characterisation of Drug Role Drug #1 -->
  - < subject2 typeCode="SUBJ">
    - < productUseReference classCode="SBADM" moodCode="EVN">
      < id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4" />
    </productUseReference>
  </subject2>
</causalityAssessment>
</component>
- < component typeCode="COMP">
- < causalityAssessment classCode="OBS" moodCode="EVN">
  < code code="20" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
    displayName="interventionCharacterization" />
  < value xsi:type="CE" code="1" displayName="suspect"
    codeSystem="2.16.840.1.113883.3.989.2.1.1.13" />
  <!-- Characterisation of Drug Role Drug -->
  - < subject2 typeCode="SUBJ">
    - < productUseReference classCode="SBADM" moodCode="EVN">
      < id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9" />
    </productUseReference>
  </subject2>
</causalityAssessment>
</component>
- < component typeCode="COMP">
- < causalityAssessment classCode="OBS" moodCode="EVN">
  < code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="causality" />
  < value xsi:type="ST">Highly related</value>
  <!-- : Result of Assessment Drug #1, Reaction #1, Assessment #1 -->
  - < methodCode>
    < originalText >Introspectioin</originalText>
    <!-- Method of Assessment Drug #1, Reaction #1, Assessment #1 -->
  </methodCode>
  - < author typeCode="AUT">
    - < assignedEntity classCode="ASSIGNED">
      - < code>
        < originalText >Reporter</originalText>
        <!-- Source of Assessment Drug #1, Reaction #1, Assessment #1 -->
      </code>
    </assignedEntity>
  </author>
  - < subject1 typeCode="SUBJ">
    - < adverseEffectReference classCode="OBS" moodCode="EVN">
      < id root="154eb889-958b-45f2-a02f-42d4d6f4657f" />

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        </adverseEffectReference >
    </subject1 >
    - < subject2 typeCode="SUBJ" >
        - < productUseReference classCode="SBADM" moodCode="EVN" >
            < id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4" />
        </productUseReference >
    </subject2 >
    </causalityAssessment >
</component >
- < component typeCode="COMP" >
    - < causalityAssessment classCode="OBS" moodCode="EVN" >
        < code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="causality" />
        < value xsi:type="ST" > 80% </value >
        <!-- Result of Assessment Drug #1, Reaction #2, Assessment #1 -->
    - < methodCode >
        < originalText > algorithm </originalText >
        <!-- : Method of Assessment Drug #1, Reaction #2, Assessment #1 -->
    </methodCode >
    - < author typeCode="AUT" >
        - < assignedEntity classCode="ASSIGNED" >
            - < code >
                < originalText > Company </originalText >
                <!-- Source of Assessment Drug #1, Reaction #2, Assessment #1 -->
            </code >
        </assignedEntity >
    </author >
    - < subject1 typeCode="SUBJ" >
        - < adverseEffectReference classCode="OBS" moodCode="EVN" >
            < id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220" />
        </adverseEffectReference >
    </subject1 >
    - < subject2 typeCode="SUBJ" >
        - < productUseReference classCode="SBADM" moodCode="EVN" >
            < id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4" />
        </productUseReference >
    </subject2 >
    </causalityAssessment >
</component >
- < component typeCode="COMP" >
    - < causalityAssessment classCode="OBS" moodCode="EVN" >
        < code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="causality" />
        < value xsi:type="ST" > Likely </value >
        <!-- Result of Assessment Drug #2, Reaction #2, Assessment #1 -->
    - < methodCode >
        < originalText > Bayesean </originalText >
        <!-- Method of Assessment Drug #2, Reaction #2, Assessment #1 -->
    </methodCode >
    - < author typeCode="AUT" >
        - < assignedEntity classCode="ASSIGNED" >
            - < code >
                < originalText > Company </originalText >
                <!-- Source of Assessment Drug #2, Reaction #2, Assessment #1 -->
            </code >
        </assignedEntity >
    </author >
    - < subject1 typeCode="SUBJ" >
        - < adverseEffectReference classCode="OBS" moodCode="EVN" >
            < id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220" />
        </adverseEffectReference >
    </subject1 >
    - < subject2 typeCode="SUBJ" >
        - < productUseReference classCode="SBADM" moodCode="EVN" >
            < id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9" />
        </productUseReference >
    </subject2 >
    </causalityAssessment >
</component >
- < component typeCode="COMP" >
    - < causalityAssessment classCode="OBS" moodCode="EVN" >
        < code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="causality" />
        < value xsi:type="ST" > The reason </value >
        <!-- Result of Assessment Drug #2, Reaction #2, Assessment -->
    - < methodCode >
        < originalText > Introspection </originalText >

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    <!-- Method of Assessment Drug #2, Reaction #2, Assessment -->
  </methodCode>
- < author typeCode="AUT">
- < assignedEntity classCode="ASSIGNED">
- < code>
  < originalText>Reporter</originalText>
  <!-- Source of Assessment Drug #2, Reaction #2, Assessment -->
  </code>
</assignedEntity>
</author>
- < subject1 typeCode="SUBJ">
- < adverseEffectReference classCode="OBS" moodCode="EVN">
  < id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220" />
</adverseEffectReference>
</subject1>
- < subject2 typeCode="SUBJ">
- < productUseReference classCode="SBADM" moodCode="EVN">
  < id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9" />
</productUseReference>
</subject2>
</causalityAssessment>
</component>
- < component1 typeCode="COMP">
- < observationEvent classCode="OBS" moodCode="EVN">
  < code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="comment" />
  < value xsi:type="ED">It appears very likely that the primary drug is responsible for all the
  reactions.</value>
  <!-- Reporter's Comments -->
- < author typeCode="AUT">
- < assignedEntity classCode="ASSIGNED">
  < code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21"
  displayName="sourceReporter" />
  </assignedEntity>
</author>
</observationEvent>
</component1>
- < component1 typeCode="COMP">
- < observationEvent classCode="OBS" moodCode="EVN">
  < code code="15" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="diagnosis" />
  < value xsi:type="CE" code="10047319" codeSystem="2.16.840.1.113883.6.163"
  codeSystemVersion="12.0" />
  <!-- MedDRA Version for Sender's Diagnosis / Syndrome and / or Reclassification of Reaction
  / Event #1 -->
  <!-- Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event (MedDRA
  code) #1 -->
- < author typeCode="AUT">
- < assignedEntity classCode="ASSIGNED">
  < code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" displayName="sender" />
  </assignedEntity>
</author>
</observationEvent>
</component1>
- < component1 typeCode="COMP">
- < observationEvent classCode="OBS" moodCode="EVN">
  < code code="15" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="diagnosis" />
  < value xsi:type="CE" code="10047334" codeSystem="2.16.840.1.113883.6.163"
  codeSystemVersion="12.0" />
  <!-- MedDRA Version for Sender's Diagnosis / Syndrome and / or Reclassification of Reaction
  / Event -->
  <!-- Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event (MedDRA
  code) -->
- < author typeCode="AUT">
- < assignedEntity classCode="ASSIGNED">
  < code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" displayName="sender" />
  </assignedEntity>
</author>
</observationEvent>
</component1>
- < component1 typeCode="COMP">
- < observationEvent classCode="OBS" moodCode="EVN">
  < code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="comment" />
  < value xsi:type="ED">The condition came on suddenly, and was a complete surprise to the
  responsible clinicians.</value>
  <!-- Sender's Comments -->

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- < author typeCode="AUT">
  - < assignedEntity classCode="ASSIGNED">
    < code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" displayName="sender" />
  </assignedEntity>
</author>
</observationEvent>
</component1>
</adverseEventAssessment>
</component>
- < component typeCode="COMP">
  - < observationEvent classCode="OBS" moodCode="EVN">
    < code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
      displayName="additionalDocumentsAvailable" />
    < value xsi:type="BL" value="true" />
    <!-- Are Additional Documents Available? -->
  </observationEvent>
</component>
- < component typeCode="COMP">
  - < observationEvent classCode="OBS" moodCode="EVN">
    < code code="23" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="localCriteriaForExpedited"
      />
    < value xsi:type="BL" value="true" />
    <!-- Does This Case Fulfil the Local Criteria for an Expedited Report? -->
  </observationEvent>
</component>
- < component typeCode="COMP">
  - < observationEvent classCode="OBS" moodCode="EVN">
    < code code="36" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="summaryAndComment" />
    < value xsi:type="ED" language="Port">Estudo de caso Incluindo Curso Clínico, medidas terapêuticas,
      Resultado e informações adicionais relevantes Relatório do Consumidor do www.abbott.com de efeitos
      colaterais ruins coincidente com Adalimumabe (Humira SERINGA PRÉ-CHEIA) terapia. Em data
      desconhecida, o paciente começou HUMIRA terapia seringa pré-cheia para uma indicação desconhecida.
      Em um desconhecido data, a paciente apresentou efeitos colaterais ruins. A informação inicial foi
      recebida da mãe de uma criança do sexo feminino 20 meses de idade. Os estados de pais ela pensa a
      criança pode ter ingerido acidentalmente um ou uma certa quantidade de comprimidos Zantac de uma
      dose não especificada, em um data não especificada. O número de lote, data de validade, ou tratamento
      para o evento não foi relatado. concomitante medicamentos e história médica não foram relatados. Não
      foi referido que Zantac foi interrompido ou se o paciente recuperou Note-se, neste texto cola juntos
      informações de dois relatórios separados.</value>
    <!-- Case Summary and Reporter's Comments Text #1 -->
    <!-- Case Summary and Reporter's Comments Language #1 -->
  </observationEvent>
  - < author typeCode="AUT">
    - < assignedEntity classCode="ASSIGNED">
      < code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" displayName="reporter" />
    </assignedEntity>
  </author>
</observationEvent>
</component>
- < outboundRelationship typeCode="SPRT">
  - < relatedInvestigation classCode="INVSTG" moodCode="EVN">
    < code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" displayName="initialReport" />
  - < subjectOf2 typeCode="SUBJ">
    - < controlActEvent classCode="CACT" moodCode="EVN">
      - < author typeCode="AUT">
        - < assignedEntity classCode="ASSIGNED">
          < code code="1" displayName="regulator" codeSystem="2.16.840.1.113883.3.989.2.1.1.3" />
          <!-- First Sender of This Case -->
        </assignedEntity>
      </author>
    </controlActEvent>
  </subjectOf2>
</relatedInvestigation>
</outboundRelationship>
- < outboundRelationship typeCode="SPRT">
  - < relatedInvestigation classCode="INVSTG" moodCode="EVN">
    < code nullFlavor="NA" />
  - < subjectOf2 typeCode="SUBJ">
    - < controlActEvent classCode="CACT" moodCode="EVN">
      < id extension="23345-PHARMA-344" root="2.16.840.1.113883.3.989.2.1.3.2" />
      <!-- Identification Number of the Report Which Is Linked to This Report (repeat as
        necessary) #1 -->
    </controlActEvent>
  </subjectOf2>
</relatedInvestigation>

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</outboundRelationship>
- < outboundRelationship typeCode="SPRT">
- < relatedInvestigation classCode="INVSTG" moodCode="EVN">
  < code nullFlavor="NA" />
- < subjectOf2 typeCode="SUBJ">
  - < controlActEvent classCode="CACT" moodCode="EVN">
    < id extension="FR-QPHARMA-12345678" root="2.16.840.1.113883.3.989.2.1.3.2" />
    <!-- Identification Number of the Report Which Is Linked to this Report (repeat as
    necessary) -->
  </controlActEvent>
</subjectOf2>
</relatedInvestigation>
</outboundRelationship>
- < outboundRelationship typeCode="SPRT">
  < priorityNumber value="1" />
  <!-- Primary Source for Regulatory Purposes #1 -->
- < relatedInvestigation classCode="INVSTG" moodCode="EVN">
  < code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" displayName="sourceReport" />
- < subjectOf2 typeCode="SUBJ">
  - < controlActEvent classCode="CACT" moodCode="EVN">
    - < author typeCode="AUT">
      - < assignedEntity classCode="ASSIGNED">
        - < addr>
          < streetAddressLine> 123 Main St.</streetAddressLine>
          <!-- Reporter's Street #1 -->
          < city> Anytown</city>
          <!-- Reporter's City #1 -->
          < state> State of Residence</state>
          <!-- Reporter's State or Province #1 -->
          < postalCode> 87654</postalCode>
          <!-- Reporter's Postcode #1 -->
        </addr>
        < telecom value="tel:3334445555" />
        <!-- Reporter's Telephone #1 -->
      - < assignedPerson classCode="PSN" determinerCode="INSTANCE">
        - < name>
          < prefix> Dr.</prefix>
          <!-- Reporter's Title #1 -->
          < given> Jerome</given>
          <!-- Reporter's Given Name #1 -->
          < given> James</given>
          <!-- Reporter's Middle Name #1 -->
          < family> Jacobs</family>
          <!-- Reporter's Family Name #1 -->
        </name>
        - < asQualifiedEntity classCode="QUAL">
          < code code="CC16960" codeSystem="2.16.840.1.113883.3.26.1.1" />
          <!-- Qualification #1 -->
        </asQualifiedEntity>
        - < asLocatedEntity classCode="LOCE">
          - < location classCode="COUNTRY" determinerCode="INSTANCE">
            < code code="US" codeSystem="1.0.3166.1.2.2" />
            <!-- Reporter's Country Code #1 -->
          </location>
        </asLocatedEntity>
      </assignedPerson>
    - < representedOrganization classCode="ORG" determinerCode="INSTANCE">
      < name> Reporting</name>
      <!-- Reporter's Department #1 -->
    - < assignedEntity classCode="ASSIGNED">
      - < representedOrganization classCode="ORG" determinerCode="INSTANCE">
        < name> Pharma Company</name>
        <!-- Reporter's Organisation #1 -->
      </representedOrganization>
    </assignedEntity>
  </author>
</controlActEvent>
</subjectOf2>
</relatedInvestigation>
</outboundRelationship>
- < outboundRelationship typeCode="SPRT">
  - < relatedInvestigation classCode="INVSTG" moodCode="EVN">

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<code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" displayName="sourceReport" />
- <subjectOf2 typeCode="SUBJ">
- <controlActEvent classCode="CACT" moodCode="EVN">
  - <author typeCode="AUT">
    - <assignedEntity classCode="ASSIGNED">
      - <addr>
        <streetAddressLine>89 Central Ave</streetAddressLine>
        <!-- Reporter's Street -->
        <city>Anytown</city>
        <!-- Reporter's City -->
        <state>Idaho</state>
        <!-- Reporter's State or Province -->
        <postalCode>01340</postalCode>
        <!-- Reporter's Postcode -->
      </addr>
      <telecom value="tel:8884562344" />
      <!-- : Reporter's Telephone -->
    - <assignedPerson classCode="PSN" determinerCode="INSTANCE">
      - <name>
        <prefix>Professor</prefix>
        <!-- Reporter's Title -->
        <given>Ronald</given>
        <!-- : Reporter's Given Name -->
        <given>Robert</given>
        <!-- Reporter's Middle Name -->
        <family>Rhodes</family>
        <!-- Reporter's Family Name -->
      </name>
      - <asQualifiedEntity classCode="QUAL">
        <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.6" />
        <!-- Qualification -->
      </asQualifiedEntity>
      - <asLocatedEntity classCode="LOCE">
        - <location classCode="COUNTRY" determinerCode="INSTANCE">
          <code code="US" codeSystem="1.0.3166.1.2.2" />
          <!-- Reporter's Country Code -->
        </location>
      </asLocatedEntity>
    </assignedPerson>
  - <representedOrganization classCode="ORG" determinerCode="INSTANCE">
    <name>Reporting</name>
    <!-- Reporter's Department -->
  - <assignedEntity classCode="ASSIGNED">
    - <representedOrganization classCode="ORG" determinerCode="INSTANCE">
      <name>Medium Size Pharma</name>
      <!-- Reporter's Organisation -->
    </representedOrganization>
  </assignedEntity>
</author>
</controlActEvent>
</subjectOf2>
</relatedInvestigation>
</outboundRelationship>
- <subjectOf1 typeCode="SUBJ">
- <controlActEvent classCode="CACT" moodCode="EVN">
  - <author typeCode="AUT">
    - <assignedEntity classCode="ASSIGNED">
      <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.7" />
      <!-- Sender Type -->
      - <addr>
        <streetAddressLine>49 Main St.</streetAddressLine>
        <!-- Sender's Street Address -->
        <city>Anytown</city>
        <!-- Sender's City -->
        <state>CT</state>
        <!-- Sender's State or Province -->
        <postalCode>23456</postalCode>
        <!-- Sender's Postcode -->
      </addr>
      <telecom value="tel:6108887766" />
      <!-- Sender's Telephone -->
      <telecom value="fax:6109991122" />
    </assignedEntity>
  </author>
</controlActEvent>
</subjectOf1>

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<!-- Sender's Fax -->
< telecom value="mailto:emailAddress@company.com" />
<!-- Sender's E-mail Address -->
- < assignedPerson classCode="PSN" determinerCode="INSTANCE" >
- < name >
  < prefix>Mr</prefix>
  <!-- Sender's Title -->
  < given>Charles</given>
  <!-- Sender's Given Name -->
  < given>Castile</given>
  <!-- Sender's Middle Name -->
  < family>Conner</family>
  <!-- : Sender's Family Name -->
</name >
- < asLocatedEntity classCode="LOCE" >
- < location classCode="COUNTRY" determinerCode="INSTANCE" >
  < code code="US" codeSystem="1.0.3166.1.2.2" />
  <!-- Sender's Country Code -->
</location >
</asLocatedEntity >
</assignedPerson >
- < representedOrganization classCode="ORG" determinerCode="INSTANCE" >
  < name>Management</name >
  <!-- Sender's Department -->
- < assignedEntity classCode="ASSIGNED" >
- < representedOrganization classCode="ORG" determinerCode="INSTANCE" >
  < name>Big Pharma</name >
  <!-- Sender's Organisation -->
</representedOrganization >
</assignedEntity >
</representedOrganization >
</assignedEntity >
</author >
</controlActEvent >
</subjectOf1 >
- < subjectOf1 typeCode="SUBJ" >
- < controlActEvent classCode="CACT" moodCode="EVN" >
  < id assigningAuthorityName="Reporting Ltd Corporation" extension="FR-RPTLTD-15998"
  root="2.16.840.1.113883.3.989.2.1.3.3" />
  <!-- Source(s) of the Case Identifier (repeat as necessary) #1 -->
  <!-- Case Identifier(s) #1 -->
</controlActEvent >
</subjectOf1 >
- < subjectOf1 typeCode="SUBJ" >
- < controlActEvent classCode="CACT" moodCode="EVN" >
  < id assigningAuthorityName="European Medicines Agency" extension="EU-EMA-999999"
  root="2.16.840.1.113883.3.989.2.1.3.3" />
  <!-- Source(s) of the Case Identifier (repeat as necessary) -->
  <!-- Case Identifier(s) -->
</controlActEvent >
</subjectOf1 >
- < subjectOf2 typeCode="SUBJ" >
- < investigationCharacteristic classCode="OBS" moodCode="EVN" >
  < code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" displayName="ichReportType" />
  < value xsi:type="CE" code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.2" />
  <!-- Type of Report -->
</investigationCharacteristic >
</subjectOf2 >
- < subjectOf2 typeCode="SUBJ" >
- < investigationCharacteristic classCode="OBS" moodCode="EVN" >
  < code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" displayName="otherCaseIds" />
  < value xsi:type="BL" value="true" />
  <!-- Other Case Identifiers in Previous Transmissions -->
</investigationCharacteristic >
</subjectOf2 >
- < subjectOf2 typeCode="SUBJ" >
- < investigationCharacteristic classCode="OBS" moodCode="EVN" >
  < code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.23"
  displayName="nullificationAmendmentCode" />
  < value xsi:type="CE" code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.5" />
  <!-- Report Nullification / Amendment -->
</investigationCharacteristic >
</subjectOf2 >
- < subjectOf2 typeCode="SUBJ" >

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- < investigationCharacteristic classCode="OBS" moodCode="EVN">
  < code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.23"
    displayName="nullificationAmendmentReason" />
- < value xsi:type="CE">
  < originalText>A text reason for amending the document</originalText>
  <!-- Reason for Nullification / Amendment -->
  </value>
</investigationCharacteristic>
</subjectOf2>
- < subjectOf2 typeCode="SUBJ">
- < investigationCharacteristic classCode="OBS" moodCode="EVN">
  < code code="C53576" displayName="Fifteen-Day Report" codeSystem="2.16.840.1.113883.3.26.1.1" />
  < value xsi:type="BL" value="true" />
</investigationCharacteristic>
</subjectOf2>
</investigationEvent>
</subject>
</controlActProcess>
</PORR_IN049016UV>
<!-- Message #1 -->
<!-- Message -->
- <!--
  PORR_IN049016UV
    Only a stub is provided for the second message.
  /PORR_IN049016UV
-->
<!-- Message -->
- < receiver typeCode="RCV">
- < device classCode="DEV" determinerCode="INSTANCE">
  < id extension="ZZFDA" root="2.16.840.1.113883.3.989.2.1.3.14" />
  <!-- Batch Receiver Identifier -->
</device>
</receiver>
- < sender typeCode="SND">
- < device classCode="DEV" determinerCode="INSTANCE">
  < id extension="123456789" root="1.3.6.1.4.1.519.1" />
  <!-- Batch Sender Identifier -->
</device>
</sender>
</MCCI_IN200100UV01>

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