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H:\Wo1 <?xml version="1.0" encoding="UTF-8"?>
2 <MCCI_IN200100UV01 ITSVersion="XML_1.0" xmlns="urn:hl7-org:v3" xmlns:xsi="
http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3
file:///H:/WorkFile1/Review%20Management/Projects%20and%20Status%20Report/CBER%20Data%20Standards%20Board/ISO
%20Standards/ISO%20ICSR/ICSR%20PART%202/output/processable/multicacheschemas/MCCI_IN200100UV01.xsd">
3 <id extension="1230ABC700" root="2.16.840.1.113883.3.989.2.1.3.22"/>
4 <!-- Batch Number -->
5 <creationTime value="20101214151617"/>
6 <!-- Date of Batch Transmission -->
7 <responseModeCode code="D"/>
8 <interactionId extension="MCCI_IN200100UV01" root="2.16.840.1.113883.1.6"/>
9 <name code="ichicsr" codeSystem="2.16.840.1.113883.3.989.2.1.1.1"/>
10 <!-- Use this string for all ICSR batches -->
11 <!-- Message #1 -->
12 <PORR_IN049016UV>
13 <id extension="XXXXXXX" root="2.16.840.1.113883.3.989.2.1.3.1"/>
14 <!-- Message Identifier -->
15 <creationTime value="20101214151617"/>
16 <!-- Date of Message Creation -->
17 <interactionId extension="PORR_IN049016UV" root="2.16.840.1.113883.1.6"/>
18 <processingCode code="P"/>
19 <processingModeCode code="T"/>
20 <acceptAckCode code="AL"/>
21 <receiver typeCode="RCV">
22 <device classCode="DEV" determinerCode="INSTANCE">
23 <id extension="ZZFDA" root="2.16.840.1.113883.3.989.2.1.3.12"/>
24 <!-- Message Receiver Identifier -->
25 </device>
26 </receiver>
27 <sender typeCode="SND">
28 <device classCode="DEV" determinerCode="INSTANCE">
29 <id extension="456789012" root="2.16.840.1.113883.3.989.2.1.3.11"/>
30 <!-- Message Sender Identifier -->
31 </device>
32 </sender>
33 <controlActProcess classCode="CACT" moodCode="EVN">
34 <code code="PORR_TE049016UV" codeSystem="2.16.840.1.113883.1.18"/>
35 <!-- HL7 Trigger Event ID -->
36 <effectiveTime value="20101214151617"/>
37 <!-- Date of Creation -->
38 <subject typeCode="SUBJ">
39 <investigationEvent classCode="INVSTG" moodCode="EVN">
40 <id extension="US-APHARMA-8744554B" root="2.16.840.1.113883.3.989.2.1.3.1"/>
41 <!-- Sender's (case) Safety Report Unique Identifier -->
42 <id extension="US-APHARMA-8744554B" root="2.16.840.1.113883.3.989.2.1.3.2"/>
43 <!-- Worldwide Unique Case Identification Number -->
44 <code code="PAT_ADV_EVNT" codeSystem="2.16.840.1.113883.5.4"/>
45 <text mediaType="text/plain">H.1</text>
46 <!-- Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant Information
-->
47 <statusCode code="active"/>
48 <effectiveTime>
49 <low value="20090101"/>
50 <!-- Date Report Was First Received from Source -->
51 </effectiveTime>
52 <availabilityTime value="20090101"/>
53 <!-- Date of Most Recent Information for This Report -->
54 <reference typeCode="REFR">
55 <document classCode="DOC" moodCode="EVN">
56 <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" displayName="documentsHeldBySender"/>
57 <title>Important report</title>
58 <!-- Documents Held by Sender (repeat as necessary) #1 -->
59 <text mediaType="pdf" compression="DF" representation="B64">Document Text goes here</text>
60 <!-- : Included Documents #1 -->
61 </document>
62 </reference>
63 <reference typeCode="REFR">
64 <document classCode="DOC" moodCode="EVN">
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65 <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" displayName="documentsHeldBySender"/>
66 <title>Document Name</title>
67 <text mediaType="image/jpeg" representation="B64" compression="DF">Text or other content as defined.</
text>
68 </document>
69 </reference>
70 <reference typeCode="REFR">
71 <document classCode="DOC" moodCode="EVN">
72 <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" displayName="literatureReference"/>
73 <text mediaType="application/pdf" representation="B64">Document Content</text>
74 <bibliographicDesignationText>Include Bibliographic Description here</bibliographicDesignationText>
75 </document>
76 </reference>
77 <component typeCode="COMP">
78 <adverseEventAssessment classCode="INVSTG" moodCode="EVN">
79 <subject1 typeCode="SBJ">
80 <primaryRole classCode="INVSBJ">
81 <player1 classCode="PSN" determinerCode="INSTANCE">
82 <name>
83 <prefix>Mr.</prefix>
84 <given>John</given>
85 <given>James</given>
86 <family>Doe</family>
87 </name>
88 <!-- Patient (name or initials) -->
89 <telecom value="tel:6667771234"/>
90 <telecom value="mailto:emailaddress@home.com"/>
91 <administrativeGenderCode code="M" codeSystem="1.0.5218"/>
92 <!-- Sex -->
93 <birthTime value="20090101"/>
94 <!-- Date of Birth -->
95 <deceasedTime value="20090101"/>
96 <!-- Date of Death -->
97 <addr>
98 <streetAddressLine>124 Any Street</streetAddressLine>
99 <streetAddressLine>Apt. 4</streetAddressLine>
100 <city>Center City</city>
101 <state>AL</state>
102 <postalCode>12345</postalCode>
103 </addr>
104 <asIdentifiedEntity classCode="IDENT">
105 <id extension="83444908" root="2.16.840.1.113883.3.989.2.1.3.7"/>
106 <!-- Patient Medical Record Number(s) and Source(s) of the Record Number (GP Medical Record
Number) -->
107 <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" displayName="GP"/>
108 </asIdentifiedEntity>
109 <asIdentifiedEntity classCode="IDENT">
110 <id extension="8999-B" root="2.16.840.1.113883.3.989.2.1.3.8"/>
111 <!-- Patient Medical Record Number(s) and Source(s) of the Record Number (Specialist Record
Number) -->
112 <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" displayName="Specialist"/>
113 </asIdentifiedEntity>
114 <asIdentifiedEntity classCode="IDENT">
115 <id extension="3333444A32" root="2.16.840.1.113883.3.989.2.1.3.9"/>
116 <!-- Patient Medical Record Number(s) and Source(s) of the Record Number (Hospital Record
Number) -->
117 <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" displayName="Hospital Record"/>
118 </asIdentifiedEntity>
119 <asIdentifiedEntity classCode="IDENT">
120 <id extension="09233347580934" root="2.16.840.1.113883.3.989.2.1.3.10"/>
121 <!-- Patient Medical Record Number(s) and Source(s) of the Record Number (Investigation Number)
-->
122 <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" displayName="Investigation"/>
123 </asIdentifiedEntity>
124 <role classCode="PRS">
125 <!-- Parent information - used when a substance administration by the parent triggers a reaction in a
child. -->
126 <code code="PRN" codeSystem="2.16.840.1.113883.5.111"/>

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H:\127 <associatedPerson classCode="PSN" determinerCode="INSTANCE">
128   <name>
129     <prefix>Ms.</prefix>
130     <given>Jane</given>
131     <given>S</given>
132     <family>Doe</family>
133   </name>
134   <!-- Parent (name or initials) -->
135   <administrativeGenderCode code="F" codeSystem="1.0.5218"/>
136   <!-- parent sex -->
137   <birthTime value="10940621"/>
138   <!-- Date of Birth -->
139 </associatedPerson>
140 <subjectOf2 typeCode="SBJ">
141   <observation classCode="OBS" moodCode="EVN">
142     <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="age"/>
143     <value xsi:type="PQ" value="10" unit="a_g"/>
144     <!-- Age at Time of Onset of Reaction / Event (number) -->
145     <!-- Age at Time of Onset of Reaction / Event (unit) -->
146   </observation>
147 </subjectOf2>
148 <subjectOf2 typeCode="SBJ">
149   <observation classCode="OBS" moodCode="EVN">
150     <code code="C25159" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="age"/>
151     <value xsi:type="PQ" value="10" unit="a_g"/>
152     <!-- VAERS Parent Age -->
153   </observation>
154 </subjectOf2>
155 <subjectOf2 typeCode="SBJ">
156   <observation classCode="OBS" moodCode="EVN">
157     <code code="C103173" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="age"/>
158     <value xsi:type="PQ" value="10" unit="a_g"/>
159     <!-- Age at Time of vaccination -->
160   </observation>
161 </subjectOf2>
162 <subjectOf2 typeCode="SBJ">
163   <observation classCode="OBS" moodCode="EVN">
164     <code code="22" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
lastMenstrualPeriodDate"/>
165     <value xsi:type="TS" value="20090101"/>
166     <!--Last Menstrual Period Date of Parent -->
167   </observation>
168 </subjectOf2>
169 <subjectOf2 typeCode="SBJ">
170   <observation classCode="OBS" moodCode="EVN">
171     <code code="7" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="bodyWeight"/>
172     <value xsi:type="PQ" value="50" unit="kg"/>
173     <!-- Body Weight (kg) of Parent -->
174   </observation>
175 </subjectOf2>
176 <subjectOf2 typeCode="SBJ">
177   <observation classCode="OBS" moodCode="EVN">
178     <code code="17" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="height"/>
179     <value xsi:type="PQ" value="160" unit="cm"/>
180     <!-- Height (cm) of Parent -->
181   </observation>
182 </subjectOf2>
183 <subjectOf2 typeCode="SBJ">
184   <organizer classCode="CATEGORY" moodCode="EVN">
185     <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" displayName="
relevantMedicalHistoryAndConcurrentConditions"/>
186     <component typeCode="COMP">
187       <observation classCode="OBS" moodCode="EVN">
188         <code code="xxy3-55" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="3.2"/>
189         <!-- MedDRA Version for Medical History #1 -->
190         <!-- Medical History (disease / surgical procedure/ etc.) (MedDRA code) #1 -->
191         <effectiveTime xsi:type="IVL_TS">
192           <low value="20090101"/>
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comment"/>
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family history"/>
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continuing"/>
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comment"/>
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family history"/>
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continuing"/>
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<!-- 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">This is what we thought</value>
    <!-- Comments -->
  </observation>
</outboundRelationship2>
<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="true"/>
    <!-- Continuing #1 -->
  </observation>
</inboundRelationship>
</observation>
</component>
<component typeCode="COMP">
  <observation classCode="OBS" moodCode="EVN">
    <code code="56444" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="12.0"/>
    <!-- MedDRA Version for Medical History -->
    <!-- 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>
    </outboundRelationship2>
    <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="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">
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255         <observation classCode="OBS" moodCode="EVN">
256             <code code="18" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
historyAndConcurrentConditionText"/>
257             <value xsi:type="ED">Text for Relevant Medical History and Concurrent Conditions (not
including reaction / event</value>
258             <!-- Text for Relevant Medical History and Concurrent Conditions of Parent -->
259             </observation>
260             </component>
261             <component typeCode="COMP">
262                 <observation classCode="OBS" moodCode="EVN">
263                     <code code="11" displayName="presence of concomitant therapies" codeSystem="
2.16.840.1.113883.3.989.2.1.1.19"/>
264                     <value xsi:type="BL" value="true"/>
265                     </observation>
266                     </component>
267                     </organizer>
268                 </subjectOf2>
269                 <subjectOf2 typeCode="SBJ">
270                     <organizer classCode="CATEGORY" moodCode="EVN">
271                         <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" displayName="drugHistory"/>
272                         <component typeCode="COMP">
273                             <substanceAdministration classCode="SBADM" moodCode="EVN">
274                                 <effectiveTime xsi:type="IVL_TS">
275                                     <low value="20090101"/>
276                                     <!-- Start Date #1 -->
277                                     <high value="20090101"/>
278                                     <!-- End Date #1 -->
279                                 </effectiveTime>
280                                 <consumable typeCode="CSM">
281                                     <instanceOfKind classCode="INST">
282                                         <kindOfProduct classCode="MMAT" determinerCode="KIND">
283                                             <code code="765444" codeSystem="2.16.840.1.113883.6.69"/>
284                                             <!-- MPID Version Date / Number -->
285                                             <!-- Medicinal Product Identifier (MPID) -->
286                                             <name>Product Name</name>
287                                             <!-- Name of Drug as Reported -->
288                                             <asEntityWithGeneric classCode="GRIC">
289                                                 <genericMedicine classCode="MMAT" determinerCode="KIND">
290                                                     <name>Generic name</name>
291                                                     <!-- Generic name is provided for vaccines when the name supplied is a
non-US name. -->
292                                                 </genericMedicine>
293                                             </asEntityWithGeneric>
294                                         </kindOfProduct>
295                                     </instanceOfKind>
296                                 </consumable>
297                             <outboundRelationship2 typeCode="RSON">
298                                 <observation classCode="OBS" moodCode="EVN">
299                                     <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
indication"/>
300                                     <value xsi:type="CE" code="34567855" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="12.1"/>
301                                     <!-- MedDRA Version for Indication -->
302                                     <!-- Indication (MedDRA code) -->
303                                 </observation>
304                             </outboundRelationship2>
305                             <outboundRelationship2 typeCode="CAUS">
306                                 <observation classCode="OBS" moodCode="EVN">
307                                     <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
reaction"/>
308                                     <value xsi:type="CE" code="12345678" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="12.1"/>
309                                     <!-- MedDRA Version for Reaction -->
310                                     <!-- Reactions (MedDRA code) -->
311                                 </observation>
312                             </outboundRelationship2>
313                             <outboundRelationship2 typeCode="GOAL">
314                                 <sequenceNumber value="3"/>

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315         <substanceAdministration moodCode="INT" classCode="SBADM"/>
316     </outboundRelationship2>
317 </substanceAdministration>
318 </component>
319 <component typeCode="COMP">
320     <substanceAdministration classCode="SBADM" moodCode="EVN">
321         <effectiveTime xsi:type="IVL_TS">
322             <low value="20090101"/>
323             <!-- Start Date -->
324             <high value="20090101"/>
325             <!-- End Date -->
326         </effectiveTime>
327         <consumable typeCode="CSM">
328             <instanceOfKind classCode="INST">
329                 <kindOfProduct classCode="MMAT" determinerCode="KIND">
330                     <code code="347766" codeSystem="2.16.840.1.113883.6.69"/>
331                     <!-- PhPID Version Date / Number -->
332                     <!-- Pharmaceutical Product Identifier (PhPID) -->
333                     <name>Drug Name</name>
334                     <!-- Name of Drug as Reported -->
335                     <asEntityWithGeneric classCode="GRIC">
336                         <genericMedicine classCode="MMAT" determinerCode="KIND">
337                             <name>Generic name</name>
338                             <!-- Generic name is provided for vaccines when the name supplied is a
non-US name. -->
339                         </genericMedicine>
340                     </asEntityWithGeneric>
341                 </kindOfProduct>
342             </instanceOfKind>
343         </consumable>
344         <outboundRelationship2 typeCode="RSON">
345             <observation classCode="OBS" moodCode="EVN">
346                 <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
indication"/>
347                 <value xsi:type="CE" code="D.10.8.r.6b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.8.r.6a"/>
348                 <!-- D.10.8.r.6a: MedDRA Version for Indication -->
349                 <!-- D.10.8.r.6b: Indication (MedDRA code) -->
350             </observation>
351         </outboundRelationship2>
352         <outboundRelationship2 typeCode="CAUS">
353             <observation classCode="OBS" moodCode="EVN">
354                 <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
reaction"/>
355                 <value xsi:type="CE" code="D.10.8.r.7b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.8.r.7a"/>
356                 <!-- D.10.8.r.7a: MedDRA Version for Reaction -->
357                 <!-- D.10.8.r.7b: Reactions (MedDRA code) -->
358             </observation>
359         </outboundRelationship2>
360     </substanceAdministration>
361 </component>
362 </organizer>
363 </subjectOf2>
364 </role>
365 <role classCode="PRS">
366     <!-- Sibling information VAERS only -->
367     <code code="SIB" codeSystem="2.16.840.1.113883.5.111"/>
368     <associatedPerson classCode="PSN" determinerCode="INSTANCE">
369
370 </associatedPerson>
371 <subjectOf2 typeCode="SBJ">
372     <observation classCode="OBS" moodCode="EVN">
373         <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="age"/>
374         <value xsi:type="PQ" value="10" unit="a_g"/>
375         <!-- Age at Time of Onset of Reaction / Event (number) -->
376         <!-- Age at Time of Onset of Reaction / Event (unit) -->
377     </observation>

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378 </subjectOf2>
379 <subjectOf2 typeCode="SBJ">
380   <organizer classCode="CATEGORY" moodCode="EVN">
381     <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" displayName="drugHistory"/>
382     <component typeCode="COMP">
383       <substanceAdministration classCode="SBADM" moodCode="EVN">
384         <consumable typeCode="CSM">
385           <instanceOfKind classCode="INST">
386             <kindOfProduct classCode="MMAT" determinerCode="KIND">
387               <code code="765444" codeSystem="2.16.840.1.113883.6.69"/>
388               <!-- MPID Version Date / Number #1 -->
389               <!-- Medicinal Product Identifier (MPID) #1 -->
390               <name>Acme Improve</name>
391               <!-- Name of Drug as Reported #1 -->
392               <asEntityWithGeneric classCode="GRIC">
393                 <genericMedicine classCode="MMAT" determinerCode="KIND">
394                   <name>Generic name</name>
395                   <!-- Generic name is provided for vaccines when the name supplied is a
non-US name. -->
396                 </genericMedicine>
397               </asEntityWithGeneric>
398             </kindOfProduct>
399           </instanceOfKind>
400         </consumable>
401       <outboundRelationship2 typeCode="CAUS">
402         <observation classCode="OBS" moodCode="EVN">
403           <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
reaction"/>
404           <value xsi:type="CE" code="12345678" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="12.1"/>
405           <!-- MedDRA Version for Reaction #1 -->
406           <!-- Reactions (MedDRA code) #1 -->
407         </observation>
408       </outboundRelationship2>
409     <outboundRelationship2 typeCode="GOAL">
410       <sequenceNumber value="3"/>
411       <substanceAdministration moodCode="INT" classCode="SBADM"/>
412     </outboundRelationship2>
413   </substanceAdministration>
414 </component>
415 </organizer>
416 </subjectOf2>
417 </role>
418 </player1>
419 <subjectOf1 typeCode="SBJ">
420   <researchStudy classCode="CLNTRL" moodCode="EVN">
421     <id extension="4555-3" root="2.16.840.1.113883.3.989.2.1.3.5"/>
422     <!-- C Sponsor Study Number -->
423     <code code="2" displayName="Individual patient use" codeSystem="2.16.840.1.113883.3.989.2.1.1.8
"/>
424     <!-- Study Type Where Reaction(s) / Event(s) Were Observed -->
425     <title>Profound Study</title>
426     <!-- Study Name -->
427     <authorization typeCode="AUTH">
428       <studyRegistration classCode="ACT" moodCode="EVN">
429         <id extension="23489-34" root="2.16.840.1.113883.3.989.2.1.3.6"/>
430         <!-- Study Registration Number #1 -->
431         <author typeCode="AUT">
432           <territorialAuthority classCode="TERR">
433             <governingPlace classCode="COUNTRY" determinerCode="INSTANCE">
434               <code code="US" codeSystem="1.0.3166.1.2.2"/>
435               <!-- Study Registration Country #1 -->
436             </governingPlace>
437           </territorialAuthority>
438         </author>
439       </studyRegistration>
440     </authorization>
441     <authorization typeCode="AUTH">

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H:\442 <studyRegistration classCode="ACT" moodCode="EVN">
443 <id extension="876444" root="2.16.840.1.113883.3.989.2.1.3.6"/>
444 <!-- Study Registration Number -->
445 <author typeCode="AUT">
446 <territorialAuthority classCode="TERR">
447 <governingPlace classCode="COUNTRY" determinerCode="INSTANCE">
448 <code code="FR" codeSystem="1.0.3166.1.2.2"/>
449 <!-- C Study Registration Country -->
450 </governingPlace>
451 </territorialAuthority>
452 </author>
453 </studyRegistration>
454 </authorization>
455 </researchStudy>
456 </subjectOf1>
457 <subjectOf2 typeCode="SBJ">
458 <observation classCode="OBS" moodCode="EVN">
459 <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="age"/>
460 <value xsi:type="PQ" value="10" unit="a_g"/>
461 <!-- Age at Time of Onset of Reaction / Event (number) -->
462 <!-- Age at Time of Onset of Reaction / Event (unit) -->
463 </observation>
464 </subjectOf2>
465 <subjectOf2 typeCode="SBJ">
466 <observation classCode="OBS" moodCode="EVN">
467 <code code="C25159" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="age"/>
468 <value xsi:type="PQ" value="10" unit="a_g"/>
469 <!-- VAERS Patient Age -->
470 </observation>
471 </subjectOf2>
472 <subjectOf2 typeCode="SBJ">
473 <observation classCode="OBS" moodCode="EVN">
474 <code code="C103173" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="age"/>
475 <value xsi:type="PQ" value="10" unit="a_g"/>
476 <!-- Age at Time of vaccination -->
477 </observation>
478 </subjectOf2>
479 <subjectOf2 typeCode="SBJ">
480 <observation classCode="OBS" moodCode="EVN">
481 <code code="16" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="gestationPeriod"/>
482 <value xsi:type="PQ" value="10" unit="D.2.2.1b"/>
483 <!-- Gestation Period When Reaction / Event Was Observed in the Foetus (number) -->
484 <!-- Gestation Period When Reaction / Event Was Observed in the Foetus (unit) -->
485 </observation>
486 </subjectOf2>
487 <subjectOf2 typeCode="SBJ">
488 <observation classCode="OBS" moodCode="EVN">
489 <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="ageGroup"/>
490 <value xsi:type="CE" code="D.2.3" codeSystem="2.16.840.1.113883.3.989.2.1.1.9"/>
491 <!-- Patient Age Group (as per reporter) -->
492 </observation>
493 </subjectOf2>
494 <subjectOf2 typeCode="SBJ">
495 <observation classCode="OBS" moodCode="EVN">
496 <code code="7" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="bodyWeight"/>
497 <value xsi:type="PQ" value="48.2" unit="kg"/>
498 <!-- Body Weight (kg) -->
499 </observation>
500 </subjectOf2>
501 <subjectOf2 typeCode="SBJ">
502 <observation classCode="OBS" moodCode="EVN">
503 <code code="C76325" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="birthWeight"/>
504 <value xsi:type="PQ" value="3" unit="kg"/>
505 <!-- Birth Weight (kg) -->
506 </observation>
507 </subjectOf2>
508 <subjectOf2 typeCode="SBJ">
509 <observation classCode="OBS" moodCode="EVN">
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510         <code code="17" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="height"/>
511         <value xsi:type="PQ" value="152" unit="cm"/>
512         <!-- Height (cm) -->
513     </observation>
514 </subjectOf2>
515 <subjectOf2 typeCode="SBJ">
516     <observation classCode="OBS" moodCode="EVN">
517         <code code="22" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
lastMenstrualPeriodDate"/>
518         <value xsi:type="TS" value="20090101"/>
519         <!-- Last Menstrual Period Date -->
520     </observation>
521 </subjectOf2>
522 <subjectOf2 typeCode="SBJ">
523     <observation classCode="OBS" moodCode="EVN">
524         <code code="C76325" displayName="birthWeight" codeSystem="2.16.840.1.113883.3.26.1.1"/>
525         <value xsi:type="PQ" value="400" unit="gm"/>
526     </observation>
527 </subjectOf2>
528 <subjectOf2 typeCode="SBJ">
529     <observation classCode="OBS" moodCode="EVN">
530         <code code="C102469" displayName="numberOfSiblings" codeSystem="2.16.840.1.113883.3.26.1.1
"/>
531         <value xsi:type="INT" value="2"/>
532     </observation>
533 </subjectOf2>
534 <subjectOf2 typeCode="SBJ">
535     <observation classCode="OBS" moodCode="EVN">
536         <code code="C17049" displayName="Race" codeSystem="2.16.840.1.113883.3.26.1.1"/>
537         <value xsi:type="CE" code="C41260" displayName="Asian" codeSystem="
2.16.840.1.113883.3.26.1.1"/>
538     </observation>
539 </subjectOf2>
540 <subjectOf2 typeCode="SBJ">
541     <observation classCode="OBS" moodCode="EVN">
542         <code code="C16564" displayName="ethnicGroup" codeSystem="2.16.840.1.113883.3.26.1.1"/>
543         <value xsi:type="CE" code="C174595" displayName="Hispanic or Latino" codeSystem="
2.16.840.1.113883.3.26.1.1"/>
544     </observation>
545 </subjectOf2>
546 <subjectOf2 typeCode="SBJ">
547     <observation classCode="OBS" moodCode="EVN">
548         <code code="C102468" displayName="illnessAtTimeOfVaccination" codeSystem="
2.16.840.1.113883.3.26.1.1"/>
549         <value xsi:type="CE" code="87442323" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="12.0"/>
550     </observation>
551 </subjectOf2>
552 <subjectOf2 typeCode="SBJ">
553     <organizer classCode="CATEGORY" moodCode="EVN">
554         <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" displayName="
relevantMedicalHistoryAndConcurrentConditions"/>
555         <component typeCode="COMP">
556             <observation classCode="OBS" moodCode="EVN">
557                 <code code="844555" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="12.0"/>
558                 <!-- MedDRA Version for Medical History #1 -->
559                 <!-- Medical History (disease / surgical procedure / etc.) (MedDRA code) #1 -->
560                 <effectiveTime xsi:type="IVL_TS">
561                     <low value="20090101"/>
562                     <!-- : Start Date #1 -->
563                     <high value="20090101"/>
564                     <!-- End Date #1 -->
565                 </effectiveTime>
566                 <outboundRelationship2 typeCode="COMP">
567                     <observation classCode="OBS" moodCode="EVN">
568                         <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
comment"/>
569                         <value xsi:type="ED">Comment</value>

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570         <!-- Comments #1 -->
571     </observation>
572 </outboundRelationship2>
573 <outboundRelationship2 typeCode="EXPL">
574     <observation classCode="OBS" moodCode="EVN">
575         <code code="38" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
familyHistory"/>
576         <value xsi:type="BL" value="true"/>
577         <!-- Family History #1 -->
578     </observation>
579 </outboundRelationship2>
580 <inboundRelationship typeCode="REFR">
581     <observation classCode="OBS" moodCode="EVN">
582         <code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
continuing"/>
583         <value xsi:type="BL" value="true"/>
584         <!-- Continuing #1 -->
585     </observation>
586 </inboundRelationship>
587 </observation>
588 </component>
589 <component typeCode="COMP">
590     <observation classCode="OBS" moodCode="EVN">
591         <code code="833456" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="12.0"/>
592         <!-- MedDRA Version for Medical History -->
593         <!-- Medical history (disease / surgical procedure / etc.) (MedDRA code) -->
594         <effectiveTime xsi:type="IVL_TS">
595             <low value="20090101"/>
596             <!-- Start Date -->
597             <high value="20090101"/>
598             <!-- End Date -->
599         </effectiveTime>
600         <outboundRelationship2 typeCode="COMP">
601             <observation classCode="OBS" moodCode="EVN">
602                 <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
comment"/>
603                 <value xsi:type="ED">D.7.1.r.5</value>
604                 <!-- Comments -->
605             </observation>
606         </outboundRelationship2>
607         <outboundRelationship2 typeCode="EXPL">
608             <observation classCode="OBS" moodCode="EVN">
609                 <code code="38" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
familyHistory"/>
610                 <value xsi:type="BL" value="true"/>
611                 <!-- Family History -->
612             </observation>
613         </outboundRelationship2>
614         <inboundRelationship typeCode="REFR">
615             <observation classCode="OBS" moodCode="EVN">
616                 <code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
continuing"/>
617                 <value xsi:type="BL" value="true"/>
618                 <!-- Continuing -->
619             </observation>
620         </inboundRelationship>
621     </observation>
622 </component>
623 <component typeCode="COMP">
624     <observation classCode="OBS" moodCode="EVN">
625         <code code="18" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
historyAndConcurrentConditionText"/>
626         <value xsi:type="ED">D.7.2</value>
627         <!-- Text for Relevant Medical History and Concurrent Conditions (not including reaction / event)
-->
628     </observation>
629 </component>
630 </component typeCode="COMP">

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632 <observation classCode="OBS" moodCode="EVN">
633 <code code="11" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
concomitantTherapy"/>
634 <value xsi:type="BL" value="true"/>
635 <!-- Concomitant Therapies -->
636 </observation>
637 </component>
638 </organizer>
639 </subjectOf2>
640 <subjectOf2 typeCode="SBJ">
641 <organizer classCode="CATEGORY" moodCode="EVN">
642 <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" displayName="drugHistory"/>
643 <component typeCode="COMP">
644 <substanceAdministration classCode="SBADM" moodCode="EVN">
645 <effectiveTime xsi:type="IVL_TS">
646 <low value="20090101"/>
647 <!-- Start Date #1 -->
648 <high value="20090101"/>
649 <!-- End Date #1 -->
650 </effectiveTime>
651 <consumable typeCode="CSM">
652 <instanceOfKind classCode="INST">
653 <kindOfProduct classCode="MMAT" determinerCode="KIND">
654 <code code="456666" codeSystem="2.16.840.1.113883.6.69"/>
655 <!-- MPID Version Date / Number #1 -->
656 <!-- Medicinal Product Identifier (NDC) -->
657 <name>Best Treatment</name>
658 <!-- Name of Drug as Reported #1 -->
659 <asEntityWithGeneric classCode="GRIC">
660 <genericMedicine classCode="MMAT" determinerCode="KIND">
661 <name>Generic name</name>
662 <!-- Generic name is provided for vaccines when the name supplied is a non-US
name. -->
663 </genericMedicine>
664 </asEntityWithGeneric>
665 </kindOfProduct>
666 </instanceOfKind>
667 </consumable>
668 <outboundRelationship2 typeCode="RSON">
669 <observation classCode="OBS" moodCode="EVN">
670 <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
indication"/>
671 <value xsi:type="CE" code="D.8.r.6b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.8.r.6a"/>
672 <!-- D.8.r.6a: MedDRA Version for Indication #1 -->
673 <!-- D.8.r.6b: Indication (MedDRA code) #1 -->
674 </observation>
675 </outboundRelationship2>
676 <outboundRelationship2 typeCode="CAUS">
677 <observation classCode="OBS" moodCode="EVN">
678 <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="reaction"
/>
679 <value xsi:type="CE" code="D.8.r.7b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.8.r.7a"/>
680 <!-- D.8.r.7a: MedDRA Version for Reaction #1 -->
681 <!-- D.8.r.7b: Reaction (MedDRA code) #1 -->
682 </observation>
683 </outboundRelationship2>
684 </substanceAdministration>
685 </component>
686 <component typeCode="COMP">
687 <substanceAdministration classCode="SBADM" moodCode="EVN">
688 <effectiveTime xsi:type="IVL_TS">
689 <low value="20090101"/>
690 <!-- D.8.r.4: Start Date -->
691 <high value="20090101"/>
692 <!-- D.8.r.5: End Date -->
693 </effectiveTime>
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name. -->
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indication"/>
713
codeSystemVersion="12.1"/>
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720
/>
721
codeSystemVersion="12.1"/>
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732
2.16.840.1.113883.3.26.1.1"/>
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07-Oct-2013"/>
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754 H:\work\... name. --> <!-- Generic name is provided for vaccines when the name supplied is a non-US
755 </genericMedicine>
756 </asEntityWithGeneric>
757 </kindOfProduct>
758 </instanceOfKind>
759 </consumable>
760 <outboundRelationship2 typeCode="COMP">
761 <observation classCode="OBS" moodCode="EVN">
762 <code code="C88065" displayName="ageAtTimeOfVaccination" codeSystem="
2.16.840.1.113883.3.26.1.1"/>
763 <value xsi:type="PQ" value="3" unit="a_g"/>
764 </observation>
765 </outboundRelationship2>
766 <outboundRelationship2 typeCode="REFR">
767 <sequenceNumber value="2"/>
768 <substanceAdministration classCode="SBADM" moodCode="INT"/>
769 </outboundRelationship2>
770 </substanceAdministration>
771 </component>
772 </organizer>
773 </subjectOf2>
774 <subjectOf2 typeCode="SBJ">
775 <observation classCode="OBS" moodCode="EVN">
776 <code code="32" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
reportedCauseOfDeath"/>
777 <value xsi:type="CE" code="D.9.2.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.9.2.r.1a">
778 <!-- D.9.2.r.1a: MedDRA Version for Reported Cause(s) of Death #1 -->
779 <!-- D.9.2.r.1b: Reported Cause(s) of Death (MedDRA code) #1 -->
780 <originalText>D.9.2.r.2</originalText>
781 <!-- D.9.2.r.2: Reported Cause(s) of Death (free text) #1 -->
782 </value>
783 </observation>
784 </subjectOf2>
785 <subjectOf2 typeCode="SBJ">
786 <observation classCode="OBS" moodCode="EVN">
787 <code code="32" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
reportedCauseOfDeath"/>
788 <value xsi:type="CE" code="D.9.2.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.9.2.r.1a">
789 <!-- D.9.2.r.1a: MedDRA Version for Reported Cause(s) of Death -->
790 <!-- D.9.2.r.1b: Reported Cause(s) of Death (MedDRA code) -->
791 <originalText>D.9.2.r.2</originalText>
792 <!-- D.9.2.r.2: Reported Cause(s) of Death (free text) -->
793 </value>
794 </observation>
795 </subjectOf2>
796 <subjectOf2 typeCode="SBJ">
797 <observation classCode="OBS" moodCode="EVN">
798 <code code="5" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="autopsy"/>
799 <value xsi:type="BL" value="true"/>
800 <!-- D.9.3 Was Autopsy Done? -->
801 <outboundRelationship2 typeCode="DRIV">
802 <observation classCode="OBS" moodCode="EVN">
803 <code code="8" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="causeOfDeath
"/>
804 <value xsi:type="CE" code="D.9.4.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.9.4.r.1a">
805 <!-- D.9.4.r.1a: MedDRA Version for Autopsy-determined Cause(s) of Death #1 -->
806 <!-- D.9.4.r.1b Autopsy-determined Cause(s) of Death (MedDRA code) #1 -->
807 <originalText>D.9.4.r.2</originalText>
808 <!-- D.9.4.r.2: Autopsy-determined Cause(s) of Death (free text) #1 -->
809 </value>
810 </observation>
811 </outboundRelationship2>
812 <outboundRelationship2 typeCode="DRIV">
813 <observation classCode="OBS" moodCode="EVN">
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814      <code code="8" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="causeOfDeath
"/>
815      <value xsi:type="CE" code="D.9.4.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.9.4.r.1a">
816          <!-- D.9.4.r.1a: MedDRA Version for Autopsy-determined Cause(s) of Death -->
817          <!-- D.9.4.r.1b Autopsy-determined Cause(s) of Death (MedDRA code) -->
818          <originalText>D.9.4.r.2</originalText>
819          <!-- D.9.4.r.2: Autopsy-determined Cause(s) of Death (free text) -->
820          </value>
821          </observation>
822          </outboundRelationship2>
823          </observation>
824      </subjectOf2>
825      <subjectOf2 typeCode="SBJ">
826          <observation classCode="OBS" moodCode="EVN">
827              <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
828              <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="reaction"/>
829              <effectiveTime xsi:type="IVL_TS">
830                  <low value="20090101"/>
831                  <!-- Date of Start of Reaction / Event -->
832                  <high value="20090102"/>
833                  <!-- Date of End of Reaction / Event -->
834              </effectiveTime>
835              <!-- It is also possible for the reaction to show a start date/time and a duration. -->
836              <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="
12.0">
837                  <!-- MedDRA Version for Reaction / Event -->
838                  <!-- Reaction / Event (MedDRA code) -->
839                  <originalText language="E.i.1.1b">E.i.1.1a</originalText>
840                  <!-- Reaction / Event as Reported by the Primary Source in Native Language -->
841                  <!-- Reaction / Event as Reported by the Primary Source Language -->
842                  </value>
843                  <location typeCode="LOC">
844                      <locatedEntity classCode="LOCE">
845                          <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
846                              <code code="US" codeSystem="1.0.3166.1.2.2"/>
847                              <!-- identification of the Country Where the Reaction / Event Occurred -->
848                          </locatedPlace>
849                      </locatedEntity>
850                  </location>
851                  <outboundRelationship2 typeCode="PERT">
852                      <observation classCode="OBS" moodCode="EVN">
853                          <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
reactionForTranslation"/>
854                          <value xsi:type="ED">E.i.1.2</value>
855                          <!-- Reaction / Event as Reported by the Primary Source for Translation-->
856                      </observation>
857                  </outboundRelationship2>
858                  <outboundRelationship2 typeCode="PERT">
859                      <observation classCode="OBS" moodCode="EVN">
860                          <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
termHighlightedByReporter"/>
861                          <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"/>
862                          <!-- Term Highlighted by the Reporter -->
863                      </observation>
864                  </outboundRelationship2>
865                  <outboundRelationship2 typeCode="PERT">
866                      <observation classCode="OBS" moodCode="EVN">
867                          <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
resultsInDeath"/>
868                          <value xsi:type="BL" value="true"/>
869                          <!-- Results in Death-->
870                      </observation>
871                  </outboundRelationship2>
872                  <outboundRelationship2 typeCode="PERT">
873                      <observation classCode="OBS" moodCode="EVN">
874                          <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="

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875         <value xsi:type="BL" nullFlavor="NI"/>
876         <!-- Life Threatening -->
877     </observation>
878 </outboundRelationship2>
879 <outboundRelationship2 typeCode="PERT">
880     <observation classCode="OBS" moodCode="EVN">
881         <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
requiresInpatientHospitalization"/>
882         <value xsi:type="BL" value="true"/>
883         <!-- Caused / Prolonged Hospitalisation -->
884     </observation>
885 </outboundRelationship2>
886 <outboundRelationship2 typeCode="PERT">
887     <observation classCode="OBS" moodCode="EVN">
888         <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
resultsInPersistentOrSignificantDisability"/>
889         <value xsi:type="BL" nullFlavor="NI"/>
890         <!-- Disabling / Incapacitating-->
891     </observation>
892 </outboundRelationship2>
893 <outboundRelationship2 typeCode="PERT">
894     <observation classCode="OBS" moodCode="EVN">
895         <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
congenitalAnomalyBirthDefect"/>
896         <value xsi:type="BL" nullFlavor="NI"/>
897         <!-- Congenital Anomaly / Birth Defect -->
898     </observation>
899 </outboundRelationship2>
900 <outboundRelationship2 typeCode="PERT">
901     <observation classCode="OBS" moodCode="EVN">
902         <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
otherMedicallyImportantCondition"/>
903         <value xsi:type="BL" value="true"/>
904         <!-- Other Medically Important Condition -->
905     </observation>
906 </outboundRelationship2>
907 <outboundRelationship2 typeCode="PERT">
908     <observation classCode="OBS" moodCode="EVN">
909         <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
medicalConfirmationByHealthProfessional"/>
910         <value xsi:type="BL" value="true"/>
911         <!-- Medical Confirmation by Healthcare Professional -->
912     </observation>
913 </outboundRelationship2>
914 <outboundRelationship2 typeCode="PERT">
915     <observation classCode="OBS" moodCode="EVN">
916         <code code="C53513" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="Emergency
Room"/>
917         <value xsi:type="BL" value="true"/>
918         <!-- Required visit to the emergency room -->
919     </observation>
920 </outboundRelationship2>
921 <outboundRelationship2 typeCode="PERT">
922     <observation classCode="OBS" moodCode="EVN">
923         <code code="C16988" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="Physician
Office"/>
924         <value xsi:type="BL" value="true"/>
925         <!-- Required visit to the Physician Office -->
926     </observation>
927 </outboundRelationship2>
928 <outboundRelationship2 typeCode="PERT">
929     <observation classCode="OBS" moodCode="EVN">
930         <code code="C50414" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="
Hospitalization required"/>
931         <value xsi:type="BL" value="true"/>
932         <!-- Required visit to the hospital -->
933     </observation>
934 </outboundRelationship2 typeCode="PERT">
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934         <observation classCode="OBS" moodCode="EVN">
935             <code code="C102443" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="
number of hospitalization days"/>
936             <value xsi:type="INT" value="5"/>
937             <!-- number of hospitalization days -->
938             <performer typeCode="PRF">
939                 <assignedEntity classCode="ASSIGNED">
940                     <representedOrganization classCode="ORG" determinerCode="INSTANCE">
941                         <name>Memorial Hospital</name>
942                         <addr>
943                             <city>Metropolis</city>
944                             <state>Pennsylvania</state>
945                         </addr>
946                     </representedOrganization>
947                 </assignedEntity>
948             </performer>
949         </observation>
950     </outboundRelationship2>
951 </observation>
952 </outboundRelationship2>
953 <outboundRelationship2 typeCode="PERT">
954     <observation classCode="OBS" moodCode="EVN">
955         <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="outcome of
reaction/event"/>
956         <value xsi:type="CE" code="3" displayName="not recovered/not resolved/ongoing" codeSystem
="2.16.840.1.113883.3.989.2.1.1.10"/>
957         <!-- outcome -->
958     </observation>
959 </outboundRelationship2>
960 <outboundRelationship2 typeCode="PERT">
961     <observation classCode="OBS" moodCode="EVN">
962         <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="medical
confirmation by healthcare professional"/>
963         <value xsi:type="BL" value="true"/>
964         <!-- medical confirmation -->
965     </observation>
966 </outboundRelationship2>
967 </observation>
968 </subjectOf2>
969 <subjectOf2 typeCode="SBJ">
970     <observation classCode="OBS" moodCode="EVN">
971         <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
972         <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="reaction"/>
973         <effectiveTime xsi:type="IVL_TS">
974             <low value="20090101"/>
975             <!-- Date of Start of Reaction / Event -->
976             <width value="24" unit="min"/>
977             <!-- Duration of Reaction / Event (number) -->
978             <!-- Duration of Reaction / Event (unit) -->
979         </effectiveTime>
980         <value xsi:type="CE" code="455563" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="
12.0">
981             <!-- MedDRA Version for Reaction / Event-->
982             <!-- Reaction / Event (MedDRA code) -->
983             <originalText language="EN">the problem appears to be serious</originalText>
984             <!-- Reaction / Event as Reported by the Primary Source in Native Language -->
985             <!-- Reaction / Event as Reported by the Primary Source Language -->
986         </value>
987         <location typeCode="LOC">
988             <locatedEntity classCode="LOCE">
989                 <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
990                     <code code="US" codeSystem="1.0.3166.1.2.2"/>
991                     <!-- Identification of the Country Where the Reaction / Event Occurred -->
992                 </locatedPlace>
993             </locatedEntity>
994         </location>
995         <!-- Reaction associated observations have been omitted for the second reaction. -->
996     </observation>

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997       </subjectOf2>
998       <subjectOf2 typeCode="SBJ">
999         <organizer classCode="CATEGORY" moodCode="EVN">
1000           <code code="C102467" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="other
vaccinations given within four weeks"/>
1001           <component typeCode="COMP">
1002             <substanceAdministration moodCode="EVN" classCode="SBADM">
1003               <effectiveTime value="20090101"/>
1004               <approachSiteCode code="C105633" displayName="Left Arm" codeSystem="
2.16.840.1.113883.3.26.1.1"/>
1005               <routeCode code="C28161" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="
Intramuscular route of administration"/>
1006               <consumable typeCode="CSM">
1007                 <instanceOfKind classCode="INST">
1008                   <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
1009                     <lotNumberText>123444-AB</lotNumberText>
1010                   </productInstanceInstance>
1011                   <kindOfProduct classCode="MMAT" determinerCode="KIND">
1012                     <code code="6669" codeSystem="2.16.840.1.113883.12.549" codeSystemVersion="
07-Oct-2013"/>
1013                     <name>Measles vaccine</name>
1014                     <asManufacturedProduct classCode="MANU">
1015                       <manufacturerOrganization classCode="ORG" determinerCode="INSTANCE">
1016                         <name>ACME Production Corp.</name>
1017                       </manufacturerOrganization>
1018                     </asManufacturedProduct>
1019                   </kindOfProduct>
1020                 </instanceOfKind>
1021               </consumable>
1022             <outboundRelationship2 typeCode="COMP">
1023               <observation classCode="OBS" moodCode="EVN">
1024                 <code code="C88065" displayName="ageAtTimeOfVaccination" codeSystem="
2.16.840.1.113883.3.26.1.1"/>
1025                 <value xsi:type="PQ" value="3" unit="a_g"/>
1026               </observation>
1027             </outboundRelationship2>
1028           <outboundRelationship2 typeCode="REFR">
1029             <sequenceNumber value="2"/>
1030             <substanceAdministration classCode="SBADM" moodCode="INT">
1031               <text mediaType="text/plain">Series</text>
1032             </substanceAdministration>
1033           </outboundRelationship2>
1034         </substanceAdministration>
1035       </component>
1036     </organizer>
1037   </subjectOf2>
1038   <subjectOf2 typeCode="SBJ">
1039     <organizer classCode="CATEGORY" moodCode="EVN">
1040       <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" displayName="
testsAndProceduresRelevantToTheInvestigation"/>
1041       <component typeCode="COMP">
1042         <observation classCode="OBS" moodCode="EVN">
1043           <code code="458832" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="12.0">
1044             <!-- MedDRA Version for Test Name #1 -->
1045             <!-- Test Name (MedDRA code) #1 -->
1046             <originalText>A name for the test</originalText>
1047             <!-- Test Name (free text) #1 -->
1048           </code>
1049           <effectiveTime value="20090101"/>
1050           <!-- : Test Date -->
1051           <value xsi:type="IVL_PQ">
1052             <center value="10" unit="mg/dl"/>
1053             <!-- Test Result (value / qualifier) #1 -->
1054             <!-- Test Result (unit) #1 -->
1055           </value>
1056           <interpretationCode code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.12"/>
1057           <!-- F.r.3.1: Test Result (code) #1 -->
1058         </referenceRange typeCode="REFV">

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1059         <observationRange classCode="OBS" moodCode="EVN.CRT">
1060             <value xsi:type="PQ" value="40" unit="mg/dl"/>
1061             <!-- F.r.4: Normal Low Value #1 -->
1062             <interpretationCode code="L" codeSystem="2.16.840.1.113883.5.83"/>
1063         </observationRange>
1064     </referenceRange>
1065     <referenceRange typeCode="REFV">
1066         <observationRange classCode="OBS" moodCode="EVN.CRT">
1067             <value xsi:type="PQ" value="110" unit="mg/dl"/>
1068             <!-- F.r.5: Normal High Value #1-->
1069             <interpretationCode code="H" codeSystem="2.16.840.1.113883.5.83"/>
1070         </observationRange>
1071     </referenceRange>
1072     <outboundRelationship2 typeCode="PERT">
1073         <observation classCode="OBS" moodCode="EVN">
1074             <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
comment"/>
1075             <value xsi:type="ED">F.r.6</value>
1076             <!-- F.r.6: Comments (free text) #1 -->
1077         </observation>
1078     </outboundRelationship2>
1079     <outboundRelationship2 typeCode="REFR">
1080         <observation classCode="OBS" moodCode="EVN">
1081             <code code="25" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
moreInformationAvailable"/>
1082             <value xsi:type="BL" value="true"/>
1083             <!--F.r.7: More Information Available #1 -->
1084         </observation>
1085     </outboundRelationship2>
1086 </observation>
1087 </component>
1088 <component typeCode="COMP">
1089     <observation classCode="OBS" moodCode="EVN">
1090         <code code="87655" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="12.0">
1091             <!-- MedDRA Version for Test Name -->
1092             <!-- Test Name (MedDRA code) -->
1093         </code>
1094         <effectiveTime value="2009"/>
1095         <!-- Test Date -->
1096         <value xsi:type="IVL_PQ">
1097             <low nullFlavor="NINF"/>
1098             <high value="10" unit="mg/dl" inclusive="false"/>
1099         </value>
1100         <!-- Test Result (value / qualifier) -->
1101         <!-- Test Result (unit) -->
1102         <!-- LT 10 mg/dl -->
1103     </observation>
1104 </component>
1105 <component typeCode="COMP">
1106     <observation classCode="OBS" moodCode="EVN">
1107         <code code="1834" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="12/0">
1108             <originalText>F.r.2.1</originalText>
1109             <!-- F.r.2.1: Test Name (free text) #3 -->
1110         </code>
1111         <effectiveTime value="20090101"/>
1112         <!-- F.r.1: Test Date #3 -->
1113         <value xsi:type="IVL_PQ">
1114             <low nullFlavor="NINF"/>
1115             <high value="10" unit="mg/dl" inclusive="true"/>
1116         </value>
1117         <!-- Test Result (value / qualifier) #3 -->
1118         <!-- Test Result (unit) #3 -->
1119         <!-- LE 10 mg/dl #3-->
1120     </observation>
1121 </component>
1122 <component typeCode="COMP">
1123     <observation classCode="OBS" moodCode="EVN">
1124         <code>

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1125         <originalText>A special test</originalText>
1126     </code>
1127     <effectiveTime value="20090101"/>
1128     <!-- Test Date #4 -->
1129     <value xsi:type="IVL_PQ">
1130         <low value="10" unit="mg/dl" inclusive="false"/>
1131         <high nullFlavor="PINF"/>
1132     </value>
1133     <!-- Test Result (value / qualifier) #4 -->
1134     <!-- Test Result (unit) #4 -->
1135     <!-- GT 10 mg/dl #4 -->
1136 </observation>
1137 </component>
1138 <component typeCode="COMP">
1139     <observation classCode="OBS" moodCode="EVN">
1140         <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
1141
1142         </code>
1143         <effectiveTime value="20090101"/>
1144         <!-- Test Date #5 -->
1145         <value xsi:type="IVL_PQ">
1146             <low value="10" unit="mg/dl" inclusive="true"/>
1147             <high nullFlavor="PINF"/>
1148         </value>
1149         <!-- : Test Result (value / qualifier) #5 -->
1150         <!-- Test Result (unit) #5 -->
1151         <!-- GE 10 mg/dl #5 -->
1152     </observation>
1153 </component>
1154 <component typeCode="COMP">
1155     <observation classCode="OBS" moodCode="EVN">
1156         <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
1157         </code>
1158         <effectiveTime value="20090101"/>
1159         <value xsi:type="ED">The over all outcome was quite spectacular.</value>
1160         <!-- Result Unstructured Data (free text) #6 -->
1161     </observation>
1162 </component>
1163 </organizer>
1164 </subjectOf2>
1165 <subjectOf2 typeCode="SBJ">
1166     <organizer classCode="CATEGORY" moodCode="EVN">
1167         <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" displayName="drugInformation"/>
1168         <!-- Drug(s) Information (repeat as necessary) #1 -->
1169         <component typeCode="COMP">
1170             <substanceAdministration classCode="SBADM" moodCode="EVN">
1171                 <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
1172                 <consumable typeCode="CSM">
1173                     <instanceOfKind classCode="INST">
1174                         <kindOfProduct classCode="MMAT" determinerCode="KIND">
1175                             <code code="3455896744" codeSystem="2.16.840.1.113883.6.69"/>
1176                             <!-- Medicinal Product Identifier (MPID) -->
1177                             <name>CureAll</name>
1178                             <!-- Medicinal Product Name as Reported by the Primary Source -->
1179                             <asManufacturedProduct classCode="MANU">
1180                                 <manufacturerOrganization classCode="ORG" determinerCode="INSTANCE">
1181                                     <name>Acme Pharma Manufacturer</name>
1182                                 </manufacturerOrganization>
1183                                 <subjectOf typeCode="SBJ">
1184                                     <approval classCode="CNTRCT" moodCode="EVN">
1185                                         <id extension="ANDA012345" root="2.16.840.1.113883.3.989.2.1.3.4"/>
1186                                         <!-- Authorisation / Application Number -->
1187                                         <holder typeCode="HLD">
1188                                             <role classCode="HLD">
1189                                                 <playingOrganization classCode="ORG" determinerCode="INSTANCE">
1190                                                     <name>Big Pharma</name>
1191                                                     <!-- Name of Holder / Applicant -->
1192                                                 </playingOrganization>

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1193         </role>
1194     </holder>
1195     <author typeCode="AUT">
1196         <territorialAuthority classCode="TERR">
1197             <territory classCode="NAT" determinerCode="INSTANCE">
1198                 <code code="US" codeSystem="1.0.3166.1.2.2"/>
1199                 <!-- of Authorisation / Application-->
1200             </territory>
1201         </territorialAuthority>
1202     </author>
1203 </approval>
1204 </subjectOf>
1205 <subjectOf typeCode="SBJ">
1206     <characteristic classCode="OBS" moodCode="EVN">
1207         <code code="C5469" displayName="combination product" codeSystem="
2.16.840.1.113883.3.26.1.1"/>
1208         <value xsi:type="CV" code="C73626" displayName="Bulk ingredient"
codeSystem="2.16.840.1.113883.3.26.1.1"/>
1209     </characteristic>
1210 </subjectOf>
1211 </asManufacturedProduct>
1212 <ingredient classCode="ACTI">
1213     <quantity>
1214         <numerator value="10" unit="G.k.2.3.r.3b"/>
1215         <!-- Strength (number) #1-1 -->
1216         <!-- : Strength (unit) #1-1 -->
1217         <denominator value="1"/>
1218     </quantity>
1219     <ingredientSubstance classCode="MMAT" determinerCode="KIND">
1220         <code code="012C11ZU6G" codeSystem="2.16.840.1.113883.4.9"/>
1221         <!-- : Substance / Specified Substance TermID Version Date / Number #1-1 -->
1222         <!-- : Substance / Specified Substance TermID #1-1 -->
1223         <name>Notabenazine Hydrochloride</name>
1224         <!-- Substance / Specified Substance Name #1-1 -->
1225     </ingredientSubstance>
1226 </ingredient>
1227 </kindOfProduct>
1228 <subjectOf typeCode="SBJ">
1229     <productEvent classCode="ACT" moodCode="EVN">
1230         <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.18" displayName="
retailSupply"/>
1231     <performer typeCode="PRF">
1232         <assignedEntity classCode="ASSIGNED">
1233             <representedOrganization classCode="ORG" determinerCode="INSTANCE">
1234                 <addr>
1235                     <country>US</country>
1236                     <!-- Identification of the Country Where the Drug Was Obtained #1 -->
1237                 </addr>
1238             </representedOrganization>
1239         </assignedEntity>
1240     </performer>
1241 </productEvent>
1242 </subjectOf>
1243 </instanceOfKind>
1244 </consumable>
1245 <outboundRelationship1 typeCode="SAS">
1246     <pauseQuantity value="10" unit="d"/>
1247     <!-- Time Interval between Beginning of Drug Administration and Start of Reaction / Event
(number) Drug #1, Reaction #1 -->
1248     <!-- : Time Interval between Beginning of Drug Administration and Start of Reaction / Event
(unit) Drug #1, Reaction #1 -->
1249 </actReference classCode="OBS" moodCode="EVN">
1250     <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
1251 </actReference>
1252 </outboundRelationship1>
1253 <outboundRelationship1 typeCode="SAE">
1254     <pauseQuantity value="10" unit="min"/>
1255     <!-- Time Interval between Last Dose of Drug and Start of Reaction / Event (number) Drug
Registered to Lisa Stevens (Food and Drug Administration)

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1256 <!-- Time Interval between Last Dose of Drug and Start of Reaction / Event (unit) Drug #1,
Reaction #1 -->
1257 <actReference classCode="OBS" moodCode="EVN">
1258 <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
1259 </actReference>
1260 </outboundRelationship1>
1261 <outboundRelationship1 typeCode="SAS">
1262 <pauseQuantity value="10" unit="d"/>
1263 <!-- Time Interval between Beginning of Drug Administration and Start of Reaction / Event
(number) Drug #1, Reaction #2 -->
1264 <!-- Time Interval between Beginning of Drug Administration and Start of Reaction / Event
(unit) Drug #1, Reaction #2 -->
1265 <actReference classCode="OBS" moodCode="EVN">
1266 <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
1267 </actReference>
1268 </outboundRelationship1>
1269 <outboundRelationship1 typeCode="SAE">
1270 <pauseQuantity value="10" unit="d"/>
1271 <!-- Time Interval between Last Dose of Drug and Start of Reaction / Event (number) Drug
#1, Reaction #2 -->
1272 <!-- : Time Interval between Last Dose of Drug and Start of Reaction / Event (unit) Drug #1,
Reaction #2 -->
1273 <actReference classCode="OBS" moodCode="EVN">
1274 <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
1275 </actReference>
1276 </outboundRelationship1>
1277 <outboundRelationship2 typeCode="COMP">
1278 <!-- Dosage and Relevant Information (repeat as necessary) #1-1 -->
1279 <substanceAdministration classCode="SBADM" moodCode="EVN">
1280 <text>unstructured dosing information, e.g. take by mouth 2 times a day with food </text>
1281 <!-- Dosage Text #1-1 -->
1282 <effectiveTime xsi:type="SXPR_TS">
1283 <comp xsi:type="PIVL_TS">
1284 <period value="10" unit="G.k.4.r.3"/>
1285 <!-- Number of Units in the Interval #1-1 -->
1286 <!-- Definition of the Time Interval Unit #1-1 -->
1287 </comp>
1288 <comp xsi:type="IVL_TS" operator="A">
1289 <low value="20090101"/>
1290 <!-- Date and Time of Start of Drug -->
1291 <high value="20090101"/>
1292 <!-- Date and Time of Last Administration #1-1 -->
1293 </comp>
1294 <comp xsi:type="IVL_TS" operator="A">
1295 <width value="4" unit="G.k.4.r.6b"/>
1296 <!-- Duration of Drug Administration (number) #1-1 -->
1297 <!-- Duration of Drug Administration (unit) #1-1 -->
1298 </comp>
1299 </effectiveTime>
1300 <approachSiteCode code="C12421" codeSystem="2.16.840.1.113883.3.26.1.1"/>
1301 <routeCode code="C38288" codeSystem="2.16.840.1.113883.3.26.1.1">
1302 <!-- Route of Administration TermID Version Date / Number #1-1 -->
1303 <!-- Route of Administration TermID #1-1 -->
1304 <originalText>Free text route content</originalText>
1305 <!-- Route of Administration (free text) -->
1306 </routeCode>
1307 <doseQuantity value="10" unit="mg"/>
1308 <!-- Dose (number) -->
1309 <!-- Dose (unit) -->
1310 <consumable typeCode="CSM">
1311 <instanceOfKind classCode="INST">
1312 <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
1313 <lotNumberText>G.k.4.r.7</lotNumberText>
1314 <!-- Batch / Lot Number -->
1315 </productInstanceInstance>
1316 <kindOfProduct classCode="MMAT" determinerCode="KIND">
1317 <formCode code="C42998" displayName="tablet" codeSystem="

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1318 <!-- Pharmaceutical Dose Form TermID Version Date / Number #1-1 -->
1319 <!-- Pharmaceutical Dose Form TermID #1-1 -->
1320 <originalText>Big, round and colored white</originalText>
1321 <!-- Pharmaceutical Dose Form (free text) #1-1 -->
1322 </formCode>
1323 </kindOfProduct>
1324 </instanceOfKind>
1325 </consumable>
1326 <performer typeCode="PRF">
1327 <assignedEntity classCode="ASSIGNED">
1328 <code code="C102430" codeSystem="2.16.840.1.113883.3.989.2.1.1.21"/>
1329 <assignedPerson classCode="PSN" determinerCode="INSTANCE">
1330 <name>
1331 <prefix>Dr.</prefix>
1332 <given>Ralph</given>
1333 <given>Alexander</given>
1334 <family>Smith</family>
1335 </name>
1336 <telecom value="tel:6667778888"/>
1337 <telecom value="fax:9991112222"/>
1338 <telecom value="mailto:email@address.com"/>
1339 </assignedPerson>
1340 </assignedEntity>
1341 </performer>
1342 <author typeCode="AUT">
1343 <assignedEntity classCode="ASSIGNED">
1344 <assignedPerson classCode="PSN" determinerCode="INSTANCE">
1345 <name>
1346 <prefix nullFlavor="NI"/>
1347 <given>Joseph</given>
1348 <given nullFlavor="NI"/>
1349 <family>Rabinowitz</family>
1350 </name>
1351 <telecom value="tel:9874562222"/>
1352 <telecom value="mailto:email@address.com"/>
1353 <addr>
1354 <streetAddressLine>24 Main St.</streetAddressLine>
1355 <streetAddressLine>Suite 2304</streetAddressLine>
1356 <city>Metropolis</city>
1357 <state>Northside</state>
1358 <postalCode>123245</postalCode>
1359 <county>USA</county>
1360 </addr>
1361 </assignedPerson>
1362 </assignedEntity>
1363 </author>
1364 <location typeCode="LOC">
1365 <locatedEntity classCode="LOCE">
1366 <code code="C16988" displayName="Physician office" codeSystem="
2.16.840.1.114222.4.11.10562"/>
<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>Calveras</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">

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1383         <!-- Parent Route of Administration TermID Version Date / Number #1-1 -->
1384         <!-- Parent Route of Administration TermID #1-1 -->
1385         <originalText>Text to describe the route if needed</originalText>
1386         <!-- : Parent Route of Administration (free text) #1-1 -->
1387     </value>
1388 </observation>
1389 </inboundRelationship>
1390 </substanceAdministration>
1391 </outboundRelationship2>
1392 <outboundRelationship2 typeCode="COMP">
1393     <!-- Dosage and Relevant Information (repeat as necessary) -->
1394     <substanceAdministration classCode="SBADM" moodCode="EVN">
1395         <text>more information on the next course</text>
1396         <effectiveTime xsi:type="SXPRTS">
1397             <comp xsi:type="PIVLTST">
1398                 <period value="10" unit="G.k.4.r.3"/>
1399                 <!-- Number of Units in the Interval #1-2 -->
1400                 <!-- Definition of the Time Interval Unit #1-2 -->
1401             </comp>
1402             <comp xsi:type="IVLTST" operator="A">
1403                 <low value="20090101"/>
1404                 <!-- Date and Time of Start of Drug #1-2 -->
1405                 <high value="20090101"/>
1406                 <!-- Date and Time of Last Administration #1-2 -->
1407             </comp>
1408         </effectiveTime>
1409     </substanceAdministration>
1410 </outboundRelationship2>
1411 <outboundRelationship2 typeCode="PERT">
1412     <observation classCode="OBS" moodCode="EVN">
1413         <code code="6" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="blinded"/>
1414         <value xsi:type="BL" value="true"/>
1415         <!-- G.k.2.5: Investigational Product Blinded #1 -->
1416     </observation>
1417 </outboundRelationship2>
1418 <outboundRelationship2 typeCode="SUMM">
1419     <observation classCode="OBS" moodCode="EVN">
1420         <code code="14" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
cumulativeDoseToReaction"/>
1421         <value xsi:type="PQ" value="10" unit="G.k.5b"/>
1422         <!-- Cumulative Dose to First Reaction (number) #1 -->
1423         <!-- Cumulative Dose to First Reaction (unit) #1 -->
1424     </observation>
1425 </outboundRelationship2>
1426 <outboundRelationship2 typeCode="PERT">
1427     <observation classCode="OBS" moodCode="EVN">
1428         <code code="16" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
gestationPeriod"/>
1429         <value xsi:type="PQ" value="10" unit="G.k.6b"/>
1430         <!-- Gestation Period at Time of Exposure (number) #1 -->
1431         <!-- Gestation Period at Time of Exposure (unit) #1 -->
1432     </observation>
1433 </outboundRelationship2>
1434 <outboundRelationship2 typeCode="PERT">
1435     <observation classCode="OBS" moodCode="EVN">
1436         <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
recurrenceOfReaction"/>
1437         <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"/>
1438         <!-- Did Reaction Recur on Re-administration? Drug #1, Reaction #1 -->
1439         <outboundRelationship1 typeCode="REFR">
1440             <actReference classCode="OBS" moodCode="EVN">
1441                 <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
1442             </actReference>
1443         </outboundRelationship1>
1444     </observation>
1445 </outboundRelationship2>
1446 <outboundRelationship2 typeCode="PERT">
1447     <observation classCode="OBS" moodCode="EVN">

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1448 recurrenceOfReaction"/>
1449
1450 <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
1451
1452 <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"/>
1453 <!-- Did Reaction Recur on Re-administration? Drug #1, Reaction -->
1454 <outboundRelationship1 typeCode="REFR">
1455 <actReference classCode="OBS" moodCode="EVN">
1456 <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
1457 </actReference>
1458 </outboundRelationship1>
1459 </observation>
1460 </outboundRelationship2>
1461 <outboundRelationship2 typeCode="REFR">
1462 <observation classCode="OBS" moodCode="EVN">
1463 <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
1464 codedDrugInformation"/>
1465
1466 <value xsi:type="CE" code="G.k.10.r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"/>
1467 <!-- Additional Information on Drug (coded)(repeat as necessary) #1-1 -->
1468 </observation>
1469 </outboundRelationship2>
1470 <outboundRelationship2 typeCode="REFR">
1471 <observation classCode="OBS" moodCode="EVN">
1472 <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
1473 codedDrugInformation"/>
1474
1475 <value xsi:type="CE" code="G.k.10.r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"/>
1476 <!-- Additional Information on Drug (coded)(repeat as necessary) #1-2 -->
1477 </observation>
1478 </outboundRelationship2>
1479 <outboundRelationship2 typeCode="REFR">
1480 <observation classCode="OBS" moodCode="EVN">
1481 <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
1482 additionalInformation"/>
1483
1484 <value xsi:type="ST">Something seemed strange about the way it went down.</value>
1485 <!-- Additional Information on Drug (free text) #1 -->
1486 </observation>
1487 </outboundRelationship2>
1488 <outboundRelationship2 typeCode="REFR">
1489 <sequenceNumber value="3"/>
1490 <substanceAdministration moodCode="INT" classCode="SBADM"/>
1491 </outboundRelationship2>
1492 <inboundRelationship typeCode="RSON">
1493 <observation classCode="OBS" moodCode="EVN">
1494 <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
1495 indication"/>
1496
1497 <value xsi:type="CE" code="98744-3" codeSystem="2.16.840.1.113883.6.163"
1498 codeSystemVersion="12.0">
1499
1500 <!-- MedDRA Version for Indication #1-1 -->
1501 <!-- Indication (MedDRA code) #1-1 -->
1502 <originalText>The actual words used by the primary source</originalText>
1503 <!-- Indication as Reported by the Primary Source #1 -->
1504 </value>
1505 <performer typeCode="PRF">
1506 <assignedEntity classCode="ASSIGNED">
1507 <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" displayName="
1508 sourceReporter"/>
1509
1510 </assignedEntity>
1511 </performer>
1512 </observation>
1513 </inboundRelationship>
1514 <inboundRelationship typeCode="RSON">
1515 <observation classCode="OBS" moodCode="EVN">
1516 <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
1517 indication"/>
1518
1519 <value xsi:type="CE" code="G.k.7.r.2b" codeSystem="2.16.840.1.113883.6.163"
1520 codeSystemVersion="G.k.7.r.2a">
1521
1522 <!-- G.k.7.r.2a: MedDRA Version for Indication #1-2 -->
1523 <!-- G.k.7.r.2b: Indication (MedDRA code) #1-2 -->
1524 <originalText>G.k.7.r.1</originalText>
1525 <!-- G.k.7.r.1: Indication as Reported by the Primary Source #1-2 -->

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1507         </value>
1508     <performer typeCode="PRF">
1509         <assignedEntity classCode="ASSIGNED">
1510             <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" displayName="
sourceReporter"/>
1511         </assignedEntity>
1512     </performer>
1513 </observation>
1514 </inboundRelationship>
1515 <inboundRelationship typeCode="REFR">
1516     <observation classCode="OBS" moodCode="EVN">
1517         <code code="Cxxxx" displayName="vaccinationAtMilitarySite" codeSystem="
2.16.840.1.113883.3.26.1.1"/>
1518         <value xsi:type="BL" value="true"/>
1519     </observation>
1520 </inboundRelationship>
1521 <inboundRelationship typeCode="REFR">
1522     <observation classCode="OBS" moodCode="EVN">
1523         <code code="Cxxxxx" displayName="patientMilitaryStatus" codeSystem="
2.16.840.1.113883.3.26.1.1"/>
1524         <value xsi:type="CE" code="Cxxxx" displayName="TRICARE beneficiary" codeSystem="
2.16.840.1.113883.3.26.1.1"/>
1525     </observation>
1526 </inboundRelationship>
1527 <inboundRelationship typeCode="REFR">
1528     <observation classCode="OBS" moodCode="EVN">
1529         <code code="C102431" displayName="fundingSourceForProduct" codeSystem="
2.16.840.1.113883.3.26.1.1"/>
1530         <value xsi:type="CE" code="C102433" displayName="Military funding" codeSystem="
2.16.840.1.113883.3.26.1.1"/>
1531     </observation>
1532 </inboundRelationship>
1533 <inboundRelationship typeCode="CAUS">
1534     <act classCode="ACT" moodCode="EVN">
1535         <code code="2" displayName="Dose reduced" codeSystem="
2.16.840.1.113883.3.989.2.1.1.15"/>
1536         <!-- Action(s) Taken with Drug #1 -->
1537     </act>
1538 </inboundRelationship>
1539 <inboundRelationship typeCode="REFR">
1540     <substanceAdministration classCode="SBADM" moodCode="EVN">
1541         <repeatNumber>
1542             <low value="2"/>
1543             <high value="2"/>
1544         </repeatNumber>
1545     </substanceAdministration>
1546 </inboundRelationship>
1547 </substanceAdministration>
1548 </component>
1549 <!-- Drug(s) Information (repeat as necessary) -->
1550 <component typeCode="COMP">
1551     <substanceAdministration classCode="SBADM" moodCode="EVN">
1552         <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
1553         <consumable typeCode="CSM">
1554             <instanceOfKind classCode="INST">
1555                 <kindOfProduct classCode="MMAT" determinerCode="KIND">
1556                     <name>Aspirin</name>
1557                     <!-- Substance administration and product details have been removed from the second
iteration of the substance administration. -->
1558                 </kindOfProduct>
1559             </instanceOfKind>
1560         </consumable>
1561     </substanceAdministration>
1562 </component>
1563 </organizer>
1564 </subjectOf2>
1565 </primaryRole>
1566 </subject1>

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1567 <component typeCode="COMP">
1568 <causalityAssessment classCode="OBS" moodCode="EVN">
1569 <code code="20" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
interventionCharacterization"/>
1570 <value xsi:type="CE" code="G.k.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.13"/>
1571 <!-- G.k.1: Characterisation of Drug Role Drug #1 -->
1572 <subject2 typeCode="SUBJ">
1573 <productUseReference classCode="SBADM" moodCode="EVN">
1574 <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
1575 </productUseReference>
1576 </subject2>
1577 </causalityAssessment>
1578 </component>
1579 <component typeCode="COMP">
1580 <causalityAssessment classCode="OBS" moodCode="EVN">
1581 <code code="20" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="
interventionCharacterization"/>
1582 <value xsi:type="CE" code="1" displayName="suspect" codeSystem="2.16.840.1.113883.3.989.2.1.1.13"/>
1583 <!-- Characterisation of Drug Role Drug -->
1584 <subject2 typeCode="SUBJ">
1585 <productUseReference classCode="SBADM" moodCode="EVN">
1586 <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
1587 </productUseReference>
1588 </subject2>
1589 </causalityAssessment>
1590 </component>
1591 <component typeCode="COMP">
1592 <causalityAssessment classCode="OBS" moodCode="EVN">
1593 <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="causality"/>
1594 <value xsi:type="ST">Highly related</value>
1595 <!-- : Result of Assessment Drug #1, Reaction #1, Assessment #1 -->
1596 <methodCode>
1597 <originalText>Introspectioin</originalText>
1598 <!-- Method of Assessment Drug #1, Reaction #1, Assessment #1 -->
1599 </methodCode>
1600 <author typeCode="AUT">
1601 <assignedEntity classCode="ASSIGNED">
1602 <code>
1603 <originalText>Reporter</originalText>
1604 <!-- Source of Assessment Drug #1, Reaction #1, Assessment #1 -->
1605 </code>
1606 </assignedEntity>
1607 </author>
1608 <subject1 typeCode="SUBJ">
1609 <adverseEffectReference classCode="OBS" moodCode="EVN">
1610 <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
1611 </adverseEffectReference>
1612 </subject1>
1613 <subject2 typeCode="SUBJ">
1614 <productUseReference classCode="SBADM" moodCode="EVN">
1615 <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
1616 </productUseReference>
1617 </subject2>
1618 </causalityAssessment>
1619 </component>
1620 <component typeCode="COMP">
1621 <causalityAssessment classCode="OBS" moodCode="EVN">
1622 <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="causality"/>
1623 <value xsi:type="ST">G.k.9.i.2.r.3</value>
1624 <!--G.k.9.i.2.r.3: Result of Assessment Drug #1, Reaction #2, Assessment #1 -->
1625 <methodCode>
1626 <originalText>G.k.9.i.2.r.2</originalText>
1627 <!--G.k.9.i.2.r.2: Method of Assessment Drug #1, Reaction #2, Assessment #1 -->
1628 </methodCode>
1629 <author typeCode="AUT">
1630 <assignedEntity classCode="ASSIGNED">
1631 <code>
1632 <originalText>G.k.9.i.2.r.1</originalText>

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1633         <!-- G.k.9.i.2.r.1: Source of Assessment Drug #1, Reaction #2, Assessment #1 -->
1634     </code>
1635     </assignedEntity>
1636 </author>
1637 <subject1 typeCode="SUBJ">
1638     <adverseEffectReference classCode="OBS" moodCode="EVN">
1639         <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
1640     </adverseEffectReference>
1641 </subject1>
1642 <subject2 typeCode="SUBJ">
1643     <productUseReference classCode="SBADM" moodCode="EVN">
1644         <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
1645     </productUseReference>
1646 </subject2>
1647 </causalityAssessment>
1648 </component>
1649 <component typeCode="COMP">
1650     <causalityAssessment classCode="OBS" moodCode="EVN">
1651         <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="causality"/>
1652         <value xsi:type="ST">G.k.9.i.2.r.3</value>
1653         <!--G.k.9.i.2.r.3: Result of Assessment Drug #2, Reaction #2, Assessment #1 -->
1654         <methodCode>
1655             <originalText>G.k.9.i.2.r.2</originalText>
1656             <!--G.k.9.i.2.r.2: Method of Assessment Drug #2, Reaction #2, Assessment #1 -->
1657         </methodCode>
1658         <author typeCode="AUT">
1659             <assignedEntity classCode="ASSIGNED">
1660                 <code>
1661                     <originalText>G.k.9.i.2.r.1</originalText>
1662                     <!-- G.k.9.i.2.r.1: Source of Assessment Drug #2, Reaction #2, Assessment #1 -->
1663                 </code>
1664             </assignedEntity>
1665         </author>
1666         <subject1 typeCode="SUBJ">
1667             <adverseEffectReference classCode="OBS" moodCode="EVN">
1668                 <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
1669             </adverseEffectReference>
1670         </subject1>
1671         <subject2 typeCode="SUBJ">
1672             <productUseReference classCode="SBADM" moodCode="EVN">
1673                 <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
1674             </productUseReference>
1675         </subject2>
1676     </causalityAssessment>
1677 </component>
1678 <component typeCode="COMP">
1679     <causalityAssessment classCode="OBS" moodCode="EVN">
1680         <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="causality"/>
1681         <value xsi:type="ST">G.k.9.i.2.r.3</value>
1682         <!--G.k.9.i.2.r.3: Result of Assessment Drug #2, Reaction #2, Assessment -->
1683         <methodCode>
1684             <originalText>G.k.9.i.2.r.2</originalText>
1685             <!--G.k.9.i.2.r.2: Method of Assessment Drug #2, Reaction #2, Assessment -->
1686         </methodCode>
1687         <author typeCode="AUT">
1688             <assignedEntity classCode="ASSIGNED">
1689                 <code>
1690                     <originalText>G.k.9.i.2.r.1</originalText>
1691                     <!-- G.k.9.i.2.r.1: Source of Assessment Drug #2, Reaction #2, Assessment -->
1692                 </code>
1693             </assignedEntity>
1694         </author>
1695         <subject1 typeCode="SUBJ">
1696             <adverseEffectReference classCode="OBS" moodCode="EVN">
1697                 <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
1698             </adverseEffectReference>
1699         </subject1>
1700         <subject2 typeCode="SUBJ">

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1701         <productUseReference classCode="SBADM" moodCode="EVN">
1702             <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
1703         </productUseReference>
1704     </subject2>
1705 </causalityAssessment>
1706 </component>
1707 <component1 typeCode="COMP">
1708     <observationEvent classCode="OBS" moodCode="EVN">
1709         <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="comment"/>
1710         <value xsi:type="ED">H.2</value>
1711         <!-- H.2: Reporter's Comments -->
1712         <author typeCode="AUT">
1713             <assignedEntity classCode="ASSIGNED">
1714                 <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" displayName="sourceReporter"/>
1715             </assignedEntity>
1716         </author>
1717     </observationEvent>
1718 </component1>
1719 <component1 typeCode="COMP">
1720     <observationEvent classCode="OBS" moodCode="EVN">
1721         <code code="15" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="diagnosis"/>
1722         <value xsi:type="CE" code="H.3.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="
H.3.r.1a"/>
1723         <!-- H.3.r.1a: MedDRA Version for Sender's Diagnosis / Syndrome and / or Reclassification of Reaction /
Event #1 -->
1724         <!-- H.3.r.1b: Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event (MedDRA
code) #1 -->
1725         <author typeCode="AUT">
1726             <assignedEntity classCode="ASSIGNED">
1727                 <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" displayName="sender"/>
1728             </assignedEntity>
1729         </author>
1730     </observationEvent>
1731 </component1>
1732 <component1 typeCode="COMP">
1733     <observationEvent classCode="OBS" moodCode="EVN">
1734         <code code="15" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="diagnosis"/>
1735         <value xsi:type="CE" code="H.3.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="
H.3.r.1a"/>
1736         <!-- H.3.r.1a: MedDRA Version for Sender's Diagnosis / Syndrome and / or Reclassification of Reaction /
Event -->
1737         <!-- H.3.r.1b: Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event (MedDRA
code) -->
1738         <author typeCode="AUT">
1739             <assignedEntity classCode="ASSIGNED">
1740                 <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" displayName="sender"/>
1741             </assignedEntity>
1742         </author>
1743     </observationEvent>
1744 </component1>
1745 <component1 typeCode="COMP">
1746     <observationEvent classCode="OBS" moodCode="EVN">
1747         <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="comment"/>
1748         <value xsi:type="ED">H.4</value>
1749         <!-- H.4: Sender's Comments -->
1750         <author typeCode="AUT">
1751             <assignedEntity classCode="ASSIGNED">
1752                 <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" displayName="sender"/>
1753             </assignedEntity>
1754         </author>
1755     </observationEvent>
1756 </component1>
1757 </adverseEventAssessment>
1758 </component>
1759 <component typeCode="COMP">
1760     <observationEvent classCode="OBS" moodCode="EVN">
1761         <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="

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1762         <value xsi:type="BL" value="true"/>
1763         <!-- Are Additional Documents Available? -->
1764     </observationEvent>
1765 </component>
1766 <component typeCode="COMP">
1767     <observationEvent classCode="OBS" moodCode="EVN">
1768         <code code="23" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="localCriteriaForExpedited"/>
1769         <value xsi:type="BL" value="true"/>
1770         <!-- Does This Case Fulfil the Local Criteria for an Expedited Report? -->
1771     </observationEvent>
1772 </component>
1773 <component typeCode="COMP">
1774     <observationEvent classCode="OBS" moodCode="EVN">
1775         <code code="36" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="summaryAndComment"/>
1776         <value xsi:type="ED" language="H.5.r.1b">H.5.r.1a</value>
1777         <!-- H.5.r.1a: Case Summary and Reporter's Comments Text #1 -->
1778         <!-- H.5.r.1b: Case Summary and Reporter's Comments Language #1 -->
1779         <author typeCode="AUT">
1780             <assignedEntity classCode="ASSIGNED">
1781                 <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" displayName="reporter"/>
1782             </assignedEntity>
1783         </author>
1784     </observationEvent>
1785 </component>
1786 <component typeCode="COMP">
1787     <observationEvent classCode="OBS" moodCode="EVN">
1788         <code code="36" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="summaryAndComment"/>
1789         <value xsi:type="ED" language="H.5.r.1b">H.5.r.1a</value>
1790         <!-- H.5.r.1a: Case Summary and Reporter's Comments Text -->
1791         <!-- H.5.r.1b: Case Summary and Reporter's Comments Language -->
1792         <author typeCode="AUT">
1793             <assignedEntity classCode="ASSIGNED">
1794                 <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" displayName="reporter"/>
1795             </assignedEntity>
1796         </author>
1797     </observationEvent>
1798 </component>
1799 <outboundRelationship typeCode="SPRT">
1800     <relatedInvestigation classCode="INVSTG" moodCode="EVN">
1801         <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" displayName="initialReport"/>
1802         <subjectOf2 typeCode="SUBJ">
1803             <controlActEvent classCode="CACT" moodCode="EVN">
1804                 <author typeCode="AUT">
1805                     <assignedEntity classCode="ASSIGNED">
1806                         <code code="1" displayName="regulator" codeSystem="2.16.840.1.113883.3.989.2.1.1.3"/>
1807                         <!-- First Sender of This Case -->
1808                     </assignedEntity>
1809                 </author>
1810             </controlActEvent>
1811         </subjectOf2>
1812     </relatedInvestigation>
1813 </outboundRelationship>
1814 <outboundRelationship typeCode="SPRT">
1815     <relatedInvestigation classCode="INVSTG" moodCode="EVN">
1816         <code nullFlavor="NA"/>
1817         <subjectOf2 typeCode="SUBJ">
1818             <controlActEvent classCode="CACT" moodCode="EVN">
1819                 <id extension="23345-PHARMA-344" root="2.16.840.1.113883.3.989.2.1.3.2"/>
1820                 <!-- Identification Number of the Report Which Is Linked to This Report (repeat as necessary) #1 -->
1821             </controlActEvent>
1822         </subjectOf2>
1823     </relatedInvestigation>
1824 </outboundRelationship>
1825 <outboundRelationship typeCode="SPRT">
1826     <relatedInvestigation classCode="INVSTG" moodCode="EVN">
1827         <code nullFlavor="NA"/>
1828         <subjectOf2 typeCode="SUBJ">
1829             <controlActEvent classCode="CACT" moodCode="EVN">

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1830     <id extension="FR-QPHARMA-12345678" root="2.16.840.1.113883.3.989.2.1.3.2"/>
1831     <!-- Identification Number of the Report Which Is Linked to this Report (repeat as necessary) -->
1832     </controlActEvent>
1833     </subjectOf2>
1834     </relatedInvestigation>
1835     </outboundRelationship>
1836     <outboundRelationship typeCode="SPRT">
1837         <priorityNumber value="1"/>
1838         <!-- Primary Source for Regulatory Purposes #1 -->
1839         <relatedInvestigation classCode="INVSTG" moodCode="EVN">
1840             <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" displayName="sourceReport"/>
1841             <subjectOf2 typeCode="SUBJ">
1842                 <controlActEvent classCode="CACT" moodCode="EVN">
1843                     <author typeCode="AUT">
1844                         <assignedEntity classCode="ASSIGNED">
1845                             <addr>
1846                                 <streetAddressLine>123 Main St.</streetAddressLine>
1847                                 <!-- Reporter's Street #1 -->
1848                                 <city>Anytown</city>
1849                                 <!-- Reporter's City #1 -->
1850                                 <state>State of Residence</state>
1851                                 <!-- Reporter's State or Province #1 -->
1852                                 <postalCode>87654</postalCode>
1853                                 <!-- Reporter's Postcode #1 -->
1854                             </addr>
1855                             <telecom value="tel:3334445555"/>
1856                             <!-- Reporter's Telephone #1 -->
1857                             <assignedPerson classCode="PSN" determinerCode="INSTANCE">
1858                                 <name>
1859                                     <prefix>Dr.</prefix>
1860                                     <!-- Reporter's Title #1 -->
1861                                     <given>Jerome</given>
1862                                     <!-- Reporter's Given Name #1 -->
1863                                     <given>James</given>
1864                                     <!-- Reporter's Middle Name #1 -->
1865                                     <family>Jacobs</family>
1866                                     <!-- Reporter's Family Name #1 -->
1867                                 </name>
1868                                 <asQualifiedEntity classCode="QUAL">
1869                                     <code code="CC16960" codeSystem="2.16.840.1.113883.3.26.1.1"/>
1870                                     <!-- Qualification #1 -->
1871                                 </asQualifiedEntity>
1872                                 <asLocatedEntity classCode="LOCE">
1873                                     <location classCode="COUNTRY" determinerCode="INSTANCE">
1874                                         <code code="US" codeSystem="1.0.3166.1.2.2"/>
1875                                         <!-- Reporter's Country Code #1 -->
1876                                     </location>
1877                                 </asLocatedEntity>
1878                             </assignedPerson>
1879                             <representedOrganization classCode="ORG" determinerCode="INSTANCE">
1880                                 <name>Reporting</name>
1881                                 <!-- Reporter's Department #1 -->
1882                                 <assignedEntity classCode="ASSIGNED">
1883                                     <representedOrganization classCode="ORG" determinerCode="INSTANCE">
1884                                         <name>Pharma Company</name>
1885                                         <!-- Reporter's Organisation #1 -->
1886                                     </representedOrganization>
1887                                 </assignedEntity>
1888                             </representedOrganization>
1889                         </assignedEntity>
1890                     </author>
1891                 </controlActEvent>
1892             </subjectOf2>
1893         </relatedInvestigation>
1894     </outboundRelationship>
1895     <outboundRelationship typeCode="SPRT">
1896         <relatedInvestigation classCode="INVSTG" moodCode="EVN">
1897             <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" displayName="sourceReport"/>

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1898 <subjectOf2 typeCode="SUBJ">
1899 <controlActEvent classCode="CACT" moodCode="EVN">
1900 <author typeCode="AUT">
1901 <assignedEntity classCode="ASSIGNED">
1902 <addr>
1903 <streetAddressLine>89 Central Ave</streetAddressLine>
1904 <!-- Reporter's Street -->
1905 <city>Anytown</city>
1906 <!-- Reporter's City -->
1907 <state>Idaho</state>
1908 <!-- Reporter's State or Province -->
1909 <postalCode> 01340</postalCode>
1910 <!--Reporter's Postcode -->
1911 </addr>
1912 <telecom value="tel:8884562344"/>
1913 <!-- : Reporter's Telephone -->
1914 <assignedPerson classCode="PSN" determinerCode="INSTANCE">
1915 <name>
1916 <prefix>Professor</prefix>
1917 <!-- Reporter's Title -->
1918 <given>Ronald</given>
1919 <!-- : Reporter's Given Name -->
1920 <given>Robert</given>
1921 <!-- Reporter's Middle Name -->
1922 <family>Rhodes</family>
1923 <!-- Reporter's Family Name -->
1924 </name>
1925 <asQualifiedEntity classCode="QUAL">
1926 <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.6"/>
1927 <!-- Qualification -->
1928 </asQualifiedEntity>
1929 <asLocatedEntity classCode="LOCE">
1930 <location classCode="COUNTRY" determinerCode="INSTANCE">
1931 <code code="US" codeSystem="1.0.3166.1.2.2"/>
1932 <!-- Reporter's Country Code -->
1933 </location>
1934 </asLocatedEntity>
1935 </assignedPerson>
1936 <representedOrganization classCode="ORG" determinerCode="INSTANCE">
1937 <name>C.2.r.2.2</name>
1938 <!-- C.2.r.2.2: Reporter's Department -->
1939 <assignedEntity classCode="ASSIGNED">
1940 <representedOrganization classCode="ORG" determinerCode="INSTANCE">
1941 <name>C.2.r.2.1</name>
1942 <!-- C.2.r.2.1: Reporter's Organisation -->
1943 </representedOrganization>
1944 </assignedEntity>
1945 </representedOrganization>
1946 </assignedEntity>
1947 </author>
1948 </controlActEvent>
1949 </subjectOf2>
1950 </relatedInvestigation>
1951 </outboundRelationship>
1952 <subjectOf1 typeCode="SUBJ">
1953 <controlActEvent classCode="CACT" moodCode="EVN">
1954 <author typeCode="AUT">
1955 <assignedEntity classCode="ASSIGNED">
1956 <code code="C.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.7"/>
1957 <!-- C.3.1: Sender Type -->
1958 <addr>
1959 <streetAddressLine>C.3.4.1</streetAddressLine>
1960 <!-- C.3.4.1: Sender's Street Address -->
1961 <city>C.3.4.2</city>
1962 <!-- C.3.4.2: Sender's City -->
1963 <state>C.3.4.3</state>
1964 <!-- C.3.4.3: Sender's State or Province -->
1965 <postalCode>C.3.4.4</postalCode>

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1966         <!-- C.3.4.4: Sender's Postcode -->
1967     </addr>
1968     <telecom value="tel:C.3.4.6"/>
1969     <!-- C.3.4.6: Sender's Telephone -->
1970     <telecom value="fax:C.3.4.7"/>
1971     <!-- C.3.4.7: Sender's Fax -->
1972     <telecom value="mailto:C.3.4.8"/>
1973     <!-- C.3.4.8: Sender's E-mail Address -->
1974     <assignedPerson classCode="PSN" determinerCode="INSTANCE">
1975         <name>
1976             <prefix>C.3.3.2</prefix>
1977             <!-- C.3.3.2: Sender's Title -->
1978             <given>C.3.3.3</given>
1979             <!-- C.3.3.3: Sender's Given Name -->
1980             <given>C.3.3.4</given>
1981             <!-- C.3.3.4: Sender's Middle Name -->
1982             <family>C.3.3.5</family>
1983             <!-- C.3.3.5: Sender's Family Name -->
1984         </name>
1985         <asLocatedEntity classCode="LOCE">
1986             <location classCode="COUNTRY" determinerCode="INSTANCE">
1987                 <code code="C.3.4.5" codeSystem="1.0.3166.1.2.2"/>
1988                 <!-- C.3.4.5: Sender's Country Code -->
1989             </location>
1990         </asLocatedEntity>
1991     </assignedPerson>
1992     <representedOrganization classCode="ORG" determinerCode="INSTANCE">
1993         <name>C.3.3.1</name>
1994         <!-- C.3.3.1: Sender's Department -->
1995         <assignedEntity classCode="ASSIGNED">
1996             <representedOrganization classCode="ORG" determinerCode="INSTANCE">
1997                 <name>C.3.2</name>
1998                 <!-- C.3.2: Sender's Organisation -->
1999             </representedOrganization>
2000         </assignedEntity>
2001     </representedOrganization>
2002 </assignedEntity>
2003 </author>
2004 </controlActEvent>
2005 </subjectOf1>
2006 <subjectOf1 typeCode="SUBJ">
2007     <controlActEvent classCode="CACT" moodCode="EVN">
2008         <id assigningAuthorityName="C.1.9.1.r.1" extension="C.1.9.1.r.2" root="2.16.840.1.113883.3.989.2.1.3.3"/>
2009         <!-- C.1.9.1.r.1: Source(s) of the Case Identifier (repeat as necessary) #1 -->
2010         <!-- C.1.9.1.r.2 Case Identifier(s) #1 -->
2011     </controlActEvent>
2012 </subjectOf1>
2013 <subjectOf1 typeCode="SUBJ">
2014     <controlActEvent classCode="CACT" moodCode="EVN">
2015         <id assigningAuthorityName="C.1.9.1.r.1" extension="C.1.9.1.r.2" root="2.16.840.1.113883.3.989.2.1.3.3"/>
2016         <!-- C.1.9.1.r.1: Source(s) of the Case Identifier (repeat as necessary) -->
2017         <!-- C.1.9.1.r.2 Case Identifier(s) -->
2018     </controlActEvent>
2019 </subjectOf1>
2020 <subjectOf2 typeCode="SUBJ">
2021     <investigationCharacteristic classCode="OBS" moodCode="EVN">
2022         <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" displayName="ichReportType"/>
2023         <value xsi:type="CE" code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.2"/>
2024         <!-- Type of Report -->
2025     </investigationCharacteristic>
2026 </subjectOf2>
2027 <subjectOf2 typeCode="SUBJ">
2028     <investigationCharacteristic classCode="OBS" moodCode="EVN">
2029         <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" displayName="otherCaselds"/>
2030         <value xsi:type="BL" value="true"/>
2031         <!-- Other Case Identifiers in Previous Transmissions -->
2032     </investigationCharacteristic>
2033 </subjectOf2>

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2034     <subjectOf2 typeCode="SUBJ">
2035         <investigationCharacteristic classCode="OBS" moodCode="EVN">
2036             <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" displayName="nullificationAmendmentCode"
/>
2037         <value xsi:type="CE" code="C.1.11.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.5"/>
2038         <!-- Report Nullification / Amendment -->
2039     </investigationCharacteristic>
2040 </subjectOf2>
2041 <subjectOf2 typeCode="SUBJ">
2042     <investigationCharacteristic classCode="OBS" moodCode="EVN">
2043         <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" displayName="
nullificationAmendmentReason"/>
2044         <value xsi:type="CE">
2045             <originalText>A text reason for ammding the document</originalText>
2046             <!-- Reason for Nullification / Amendment -->
2047         </value>
2048     </investigationCharacteristic>
2049 </subjectOf2>
2050 <subjectOf2 typeCode="SUBJ">
2051     <investigationCharacteristic classCode="OBS" moodCode="EVN">
2052         <code code="C53576" displayName="Fifteen-Day Report" codeSystem="2.16.840.1.113883.3.26.1.1"/>
2053         <value xsi:type="BL" value="true"/>
2054     </investigationCharacteristic>
2055 </subjectOf2>
2056 </investigationEvent>
2057 </subject>
2058 </controlActProcess>
2059 </PORR_IN049016UV>
2060 <!-- Message #1 -->
2061 <!-- Message -->
2062 <!-- PORR_IN049016UV
2063 Only a stub is provided for the second message.
2064 /PORR_IN049016UV -->
2065 <!-- Message -->
2066 <receiver typeCode="RCV">
2067     <device classCode="DEV" determinerCode="INSTANCE">
2068         <id extension="ZZFDA" root="2.16.840.1.113883.3.989.2.1.3.14"/>
2069         <!-- Batch Receiver Identifier -->
2070     </device>
2071 </receiver>
2072 <sender typeCode="SND">
2073     <device classCode="DEV" determinerCode="INSTANCE">
2074         <id extension="123456789" root="1.3.6.1.4.1.519.1"/>
2075         <!-- Batch Sender Identifier -->
2076     </device>
2077 </sender>
2078 </MCCI_IN200100UV01>
2079

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