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<?xml version="1.0" encoding="UTF-8"?>
<MCCI_IN200100UV01 ITSVersion="XML_1.0" xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd" xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  <id extension="N.1.2" root="2.16.840.1.113883.3.989.2.1.3.22"/>
  <!-- N.1.2: Batch Number -->
  <creationTime value="20101214151617"/>
  <!-- N.1.5: Date of Batch Transmission -->
  <responseModeCode code="D"/>
  <interactionId extension="MCCI_IN200100UV01" root="2.16.840.1.113883.1.6"/>
  <name code="N.1.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.1" codeSystemVersion="2.0"/>
  <!-- N.1.1: Type of Messages in Batch -->
  <!-- Message #1 -->
  <PORR_IN049016UV>
    <id extension="N.2.r.1" root="2.16.840.1.113883.3.989.2.1.3.1"/>
    <!-- N.2.r.1: Message Identifier -->
    <creationTime value="20101214151617"/>
    <!-- N.2.r.4: Date of Message Creation -->
    <interactionId extension="PORR_IN049016UV" root="2.16.840.1.113883.1.6"/>
    <processingCode code="P"/>
    <processingModeCode code="T"/>
    <acceptAckCode code="AL"/>
    <receiver typeCode="RCV">
      <device classCode="DEV" determinerCode="INSTANCE">
        <id extension="N.2.r.3" root="2.16.840.1.113883.3.989.2.1.3.12"/>
        <!-- N.2.r.3: Message Receiver Identifier -->
      </device>
    </receiver>
    <sender typeCode="SND">
      <device classCode="DEV" determinerCode="INSTANCE">
        <id extension="N.2.r.2" root="2.16.840.1.113883.3.989.2.1.3.11"/>
        <!-- N.2.r.2: Message Sender Identifier -->
      </device>
    </sender>
    <controlActProcess classCode="CACT" moodCode="EVN">
      <code code="PORR_TE049016UV" codeSystem="2.16.840.1.113883.1.18"/>
      <!-- HL7 Trigger Event ID -->
      <effectiveTime value="20101214151617"/>
      <!-- C.1.2: Date of Creation -->
      <subject typeCode="SUBJ">
        <investigationEvent classCode="INVSTG" moodCode="EVN">
          <id extension="C.1.1" root="2.16.840.1.113883.3.989.2.1.3.1"/>
          <!-- C.1.1: Sender's (case) Safety Report Unique Identifier -->
          <id extension="C.1.8.1" root="2.16.840.1.113883.3.989.2.1.3.2"/>
          <!-- C.1.8.1: Worldwide Unique Case Identification Number -->
          <id extension="J2.1b" root="2.16.840.1.113883.3.989.5.1.3.2.3.1"/>
          <!-- @@J2.1b: 識別番号 (番号) -->
          <code code="PAT_ADV_EVNT" codeSystem="2.16.840.1.113883.5.4"/>
          <text>H.1</text>
          <!-- H.1: Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant Information -->
          <statusCode code="active"/>
          <!-- @@J2.7.1 完了、未完了区分 -->
          <effectiveTime>
            <low value="20090101"/>
            <!-- C.1.4: Date Report Was First Received from Source -->
          </effectiveTime>
          <availabilityTime value="20090101"/>
          <!-- C.1.5: Date of Most Recent Information for This Report -->
          <reference typeCode="REFR">
            <document classCode="DOC" moodCode="EVN">
              <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" codeSystemVersion="1.0" displayName="documentsHeldBySender"/>
              <title>C.1.6.1.r.1</title>
              <!-- C.1.6.1.r.1: Documents Held by Sender (repeat as necessary) #1 -->
              <text mediaType="application/pdf" representation="B64">C.1.6.1.r.2</text>
              <!-- C.1.6.1.r.2: Included Documents #1 -->
            </document>
          </reference>
          <reference typeCode="REFR">
            <document classCode="DOC" moodCode="EVN">
              <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" codeSystemVersion="1.0" displayName="documentsHeldBySender"/>
              <title>C.1.6.1.r.1</title>
              <!-- C.1.6.1.r.1: Documents Held by Sender (repeat as necessary) #2 -->
              <text mediaType="image/jpeg" representation="B64" compression="DF">C.1.6.1.r.2</text>
              <!-- C.1.6.1.r.2: Included Documents #2 -->
            </document>
          </reference>
          <reference typeCode="REFR">
            <document classCode="DOC" moodCode="EVN">
              <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" codeSystemVersion="1.0" displayName="literatureReference"/>
              <title>J2.17.r</title>
              <!-- @@J2.17.r 試験/研究の分類 #1 -->
              <text mediaType="application/pdf" representation="B64">C.4.r.2</text>
              <!-- C.4.r.2: Included Documents #1 -->
              <bibliographicDesignationText>C.4.r.1</bibliographicDesignationText>
              <!-- C.4.r.1: Literature Reference(s) #1 -->
            </document>
          </reference>
        </investigationEvent>
      </subject>
    </controlActProcess>
  </PORR_IN049016UV>
</MCCI_IN200100UV01>

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    <participation typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <representedOrganization classCode="ORG" determinerCode="INSTANCE">
          <asLocatedEntity classCode="LOCE">
            <location classCode="COUNTRY" determinerCode="INSTANCE">
              <code code="J2.15.r" codeSystem="1.0.3166.1.2.2"/>
              <!-- @@@J2.15.r 公表国 #1 -->
            </location>
          </asLocatedEntity>
        </representedOrganization>
      </assignedEntity>
    </participation>
  </document>
</reference>
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  <document classCode="DOC" moodCode="EVN">
    <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" codeSystemVersion="1.0" displayName="literatureReference"/>
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    <!-- C.4.r.2: Included Documents #2 -->
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    <!-- C.4.r.1: Literature Reference(s) #2 -->
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          <asLocatedEntity classCode="LOCE">
            <location classCode="COUNTRY" determinerCode="INSTANCE">
              <code code="J2.15.r" codeSystem="1.0.3166.1.2.2"/>
              <!-- @@@J2.15.r 公表国 #2 -->
            </location>
          </asLocatedEntity>
        </representedOrganization>
      </assignedEntity>
    </participation>
  </document>
</reference>
<component typeCode="COMP">
  <adverseEventAssessment classCode="INVSTG" moodCode="EVN">
    <subject1 typeCode="SBJ">
      <primaryRole classCode="INVSBJ">
        <player1 classCode="PSN" determinerCode="INSTANCE">
          <name>D.1</name>
          <!-- D.1: Patient (name or initials) -->
          <administrativeGenderCode code="D.5" codeSystem="1.0.5218"/>
          <!-- D.5 Sex -->
          <birthTime value="20090101"/>
          <!-- D.2.1: Date of Birth -->
          <deceasedTime value="20090101"/>
          <!-- D.9.1: Date of Death -->
          <asIdentifiedEntity classCode="IDENT">
            <id extension="D.1.1.1" root="2.16.840.1.113883.3.989.2.1.3.7"/>
            <!-- D.1.1.1: Patient Medical Record Number(s) and Source(s) of the Record Number (GP Medical Record Number) -->
            <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" codeSystemVersion="1.0" displayName="GP"/>
          </asIdentifiedEntity>
          <asIdentifiedEntity classCode="IDENT">
            <id extension="D.1.1.2" root="2.16.840.1.113883.3.989.2.1.3.8"/>
            <!-- D.1.1.2: Patient Medical Record Number(s) and Source(s) of the Record Number (Specialist Record Number) -->
            <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" codeSystemVersion="1.0" displayName="Specialist"/>
          </asIdentifiedEntity>
          <asIdentifiedEntity classCode="IDENT">
            <id extension="D.1.1.3" root="2.16.840.1.113883.3.989.2.1.3.9"/>
            <!-- D.1.1.3: Patient Medical Record Number(s) and Source(s) of the Record Number (Hospital Record Number) -->
            <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" codeSystemVersion="1.0" displayName="Hospital
Record"/>
          </asIdentifiedEntity>
          <asIdentifiedEntity classCode="IDENT">
            <id extension="D.1.1.4" root="2.16.840.1.113883.3.989.2.1.3.10"/>
            <!-- D.1.1.4: Patient Medical Record Number(s) and Source(s) of the Record Number (Investigation Number) -->
            <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" codeSystemVersion="1.0" displayName="
Investigation"/>
          </asIdentifiedEntity>
          <role classCode="PRS">
            <code code="PRN" codeSystem="2.16.840.1.113883.5.111"/>
            <associatedPerson classCode="PSN" determinerCode="INSTANCE">
              <name>D.10.1</name>
              <!-- D.10.1: Parent Identification -->
              <administrativeGenderCode code="D.10.6" codeSystem="1.0.5218"/>
              <!-- D.10.6: Sex of Parent -->
              <birthTime value="20090101"/>
            </associatedPerson>
          </role>
        </player1>
      </primaryRole>
    </subject1>
  </adverseEventAssessment>
</component>

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        <!-- D.10.2.1: Date of Birth of Parent -->
    </associatedPerson>
    <subjectOf2 typeCode="SBJ">
        <observation classCode="OBS" moodCode="EVN">
            <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="age"
/>
            <value xsi:type="PQ" value="10" unit="D.10.2.2b"/>
            <!-- D.10.2.2a: Age of Parent (number) -->
            <!-- D.10.2.2b: Age of Parent (unit) -->
        </observation>
    </subjectOf2>
    <subjectOf2 typeCode="SBJ">
        <observation classCode="OBS" moodCode="EVN">
            <code code="22" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
lastMenstrualPeriodDate"/>
            <value xsi:type="TS" value="20090101"/>
            <!-- D.10.3: Last Menstrual Period Date of Parent -->
        </observation>
    </subjectOf2>
    <subjectOf2 typeCode="SBJ">
        <observation classCode="OBS" moodCode="EVN">
            <code code="7" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
bodyWeight"/>
            <value xsi:type="PQ" value="50" unit="kg"/>
            <!-- D.10.4: Body Weight (kg) of Parent -->
        </observation>
    </subjectOf2>
    <subjectOf2 typeCode="SBJ">
        <observation classCode="OBS" moodCode="EVN">
            <code code="17" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
height"/>
            <value xsi:type="PQ" value="160" unit="cm"/>
            <!-- D.10.5: Height (cm) of Parent -->
        </observation>
    </subjectOf2>
    <subjectOf2 typeCode="SBJ">
        <organizer classCode="CATEGORY" moodCode="EVN">
            <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" codeSystemVersion="1.0" displayName="
relevantMedicalHistoryAndConcurrentConditions"/>
            <component typeCode="COMP">
                <observation classCode="OBS" moodCode="EVN">
                    <code code="D.10.7.1.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.10.7.1.r.
1a"/>
                    <!-- D.10.7.1.r.1a: MedDRA Version for Medical History #1 -->
                    <!-- D.10.7.1.r.1b: Medical History (disease / surgical procedure/ etc.) (MedDRA code) #1 -->
                    <effectiveTime xsi:type="IVL_TS">
                        <low value="20090101"/>
                        <!-- D.10.7.1.r.2: Start Date #1 -->
                        <high value="20090101"/>
                        <!-- D.10.7.1.r.4: End Date #1 -->
                    </effectiveTime>
                    <outboundRelationship2 typeCode="COMP">
                        <observation classCode="OBS" moodCode="EVN">
                            <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="comment"/>
                            <value xsi:type="ED">D.10.7.1.r.5</value>
                            <!-- D.10.7.1.r.5: Comments #1 -->
                        </observation>
                    </outboundRelationship2>
                    <inboundRelationship typeCode="REFR">
                        <observation classCode="OBS" moodCode="EVN">
                            <code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="continuing"/>
                            <value xsi:type="BL" value="true"/>
                            <!-- D.10.7.1.r.3: Continuing #1 -->
                        </observation>
                    </inboundRelationship>
                </observation>
            </component>
            <component typeCode="COMP">
                <observation classCode="OBS" moodCode="EVN">
                    <code code="D.10.7.1.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.10.7.1.r.
1a"/>
                    <!-- D.10.7.1.r.1a: MedDRA Version for Medical History #2 -->
                    <!-- D.10.7.1.r.1b: Medical History (disease / surgical procedure/ etc.) (MedDRA code) #2 -->
                    <effectiveTime xsi:type="IVL_TS">
                        <low value="20090101"/>
                        <!-- D.10.7.1.r.2: Start Date #2 -->
                        <high value="20090101"/>
                        <!-- D.10.7.1.r.4: End Date #2 -->
                    </effectiveTime>
                    <outboundRelationship2 typeCode="COMP">
                        <observation classCode="OBS" moodCode="EVN">
                            <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"

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displayName="comment"/>
        <value xsi:type="ED">D.10.7.1.r.5</value>
        <!-- D.10.7.1.r.5: Comments #2 -->
    </observation>
</outboundRelationship2>
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        <code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="continuing"/>
        <value xsi:type="BL" value="true"/>
        <!-- D.10.7.1.r.3: Continuing #2 -->
    </observation>
</inboundRelationship>
</observation>
</component>
<component typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
        <code code="18" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="historyAndConcurrentConditionText"/>
        <value xsi:type="ED">D.10.7.2</value>
        <!-- D.10.7.2: Text for Relevant Medical History and Concurrent Conditions of Parent -->
    </observation>
</component>
</organizer>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <organizer classCode="CATEGORY" moodCode="EVN">
        <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" codeSystemVersion="1.0" displayName="
drugHistory"/>
        <component typeCode="COMP">
            <substanceAdministration classCode="SBADM" moodCode="EVN">
                <effectiveTime xsi:type="IVL_TS">
                    <low value="20090101"/>
                    <!-- D.10.8.r.4: Start Date #1 -->
                    <high value="20090101"/>
                    <!-- D.10.8.r.5: End Date #1 -->
                </effectiveTime>
                <consumable typeCode="CSM">
                    <instanceOfKind classCode="INST">
                        <kindOfProduct classCode="MMAT" determinerCode="KIND">
                            <code code="D.10.8.r.2b" codeSystem="TBD-MPID" codeSystemVersion="D.10.8.r.2a"/>
                            <!-- D.10.8.r.2a: MPID Version Date / Number #1 -->
                            <!-- D.10.8.r.2b: Medicinal Product Identifier (MPID) #1 -->
                            <name>D.10.8.r.1</name>
                            <!-- D.10.8.r.1: Name of Drug as Reported #1 -->
                        </kindOfProduct>
                    </instanceOfKind>
                </consumable>
                <outboundRelationship2 typeCode="RSON">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="indication"/>
                        <value xsi:type="CE" code="D.10.8.r.6b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.8.r.6a"/>
                        <!-- D.10.8.r.6a: MedDRA Version for Indication #1 -->
                        <!-- D.10.8.r.6b: Indication (MedDRA code) #1 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="CAUS">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
                        <value xsi:type="CE" code="D.10.8.r.7b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.8.r.7a"/>
                        <!-- D.10.8.r.7a: MedDRA Version for Reaction #1 -->
                        <!-- D.10.8.r.7b: Reactions (MedDRA code) #1 -->
                    </observation>
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            </substanceAdministration>
        </component>
</component typeCode="COMP">
    <substanceAdministration classCode="SBADM" moodCode="EVN">
        <effectiveTime xsi:type="IVL_TS">
            <low value="20090101"/>
            <!-- D.10.8.r.4: Start Date #2 -->
            <high value="20090101"/>
            <!-- D.10.8.r.5: End Date #2 -->
        </effectiveTime>
        <consumable typeCode="CSM">
            <instanceOfKind classCode="INST">
                <kindOfProduct classCode="MMAT" determinerCode="KIND">
                    <code code="D.10.8.r.3b" codeSystem="TBD-PhPID" codeSystemVersion="D.10.8.r.3a"/>
                    <!-- D.10.8.r.3a: PhPID Version Date / Number #2 -->
                    <!-- D.10.8.r.3b: Pharmaceutical Product Identifier (PhPID) #2 -->
                </kindOfProduct>
            </instanceOfKind>
        </consumable>
    </substanceAdministration>
</component typeCode="COMP">

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        <name>D. 10. 8. r. 1</name>
        <!-- D. 10. 8. r. 1: Name of Drug as Reported #2 -->
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    </instanceOfKind>
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    <outboundRelationship2 typeCode="RSON">
        <observation classCode="OBS" moodCode="EVN">
            <code code="19" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 19" codeSystemVersion="1. 1"
                displayName="indication"/>
            <value xsi:type="CE" code="D. 10. 8. r. 6b" codeSystem="2. 16. 840. 1. 113883. 6. 163"
                codeSystemVersion="D. 10. 8. r. 6a"/>
            <!-- D. 10. 8. r. 6a: MedDRA Version for Indication #2 -->
            <!-- D. 10. 8. r. 6b: Indication (MedDRA code) #2 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="CAUS">
        <observation classCode="OBS" moodCode="EVN">
            <code code="29" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 19" codeSystemVersion="1. 1"
                displayName="reaction"/>
            <value xsi:type="CE" code="D. 10. 8. r. 7b" codeSystem="2. 16. 840. 1. 113883. 6. 163"
                codeSystemVersion="D. 10. 8. r. 7a"/>
            <!-- D. 10. 8. r. 7a: MedDRA Version for Reaction #2 -->
            <!-- D. 10. 8. r. 7b: Reactions (MedDRA code) #2 -->
        </observation>
    </outboundRelationship2>
    </substanceAdministration>
    </component>
    </organizer>
    </subjectOf2>
    </role>
    </player1>
    <subjectOf1 typeCode="SBJ">
        <researchStudy classCode="CLNTRL" moodCode="EVN">
            <id extension="C. 5. 3" root="2. 16. 840. 1. 113883. 3. 989. 2. 1. 3. 5"/>
            <!-- C. 5. 3: Sponsor Study Number -->
            <code code="C. 5. 4" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 8" codeSystemVersion="2. 0"/>
            <!-- C. 5. 4: Study Type Where Reaction(s) / Event(s) Were Observed -->
            <title>C. 5. 2</title>
            <!-- C. 5. 2: Study Name -->
            <authorization typeCode="AUTH">
                <studyRegistration classCode="ACT" moodCode="EVN">
                    <id extension="C. 5. 1. r. 1" root="2. 16. 840. 1. 113883. 3. 989. 2. 1. 3. 6"/>
                    <!-- C. 5. 1. r. 1: Study Registration Number #1 -->
                    <author typeCode="AUT">
                        <territorialAuthority classCode="TERR">
                            <governingPlace classCode="COUNTRY" determinerCode="INSTANCE">
                                <code code="C. 5. 1. r. 2" codeSystem="1. 0. 3166. 1. 2. 2"/>
                                <!-- C. 5. 1. r. 2: Study Registration Country #1 -->
                            </governingPlace>
                        </territorialAuthority>
                    </author>
                </studyRegistration>
            </authorization>
            <authorization typeCode="AUTH">
                <studyRegistration classCode="ACT" moodCode="EVN">
                    <id extension="C. 5. 1. r. 1" root="2. 16. 840. 1. 113883. 3. 989. 2. 1. 3. 6"/>
                    <!-- C. 5. 1. r. 1 Study Registration Number #2 -->
                    <author typeCode="AUT">
                        <territorialAuthority classCode="TERR">
                            <governingPlace classCode="COUNTRY" determinerCode="INSTANCE">
                                <code code="C. 5. 1. r. 2" codeSystem="1. 0. 3166. 1. 2. 2"/>
                                <!-- C. 5. 1. r. 2: Study Registration Country #2 -->
                            </governingPlace>
                        </territorialAuthority>
                    </author>
                </studyRegistration>
            </authorization>
        </researchStudy>
    </subjectOf1>
    <subjectOf2 typeCode="SBJ">
        <observation classCode="OBS" moodCode="EVN">
            <code code="3" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 19" codeSystemVersion="1. 1" displayName="age"/>
            <value xsi:type="PQ" value="10" unit="D. 2. 2b"/>
            <!-- D. 2. 2a: Age at Time of Onset of Reaction / Event (number) -->
            <!-- D. 2. 2b: Age at Time of Onset of Reaction / Event (unit) -->
        </observation>
    </subjectOf2>
    <subjectOf2 typeCode="SBJ">
        <observation classCode="OBS" moodCode="EVN">
            <code code="16" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 19" codeSystemVersion="1. 1" displayName="
                gestationPeriod"/>
            <value xsi:type="PQ" value="10" unit="D. 2. 2. 1b"/>
            <!-- D. 2. 2. 1a: Gestation Period When Reaction / Event Was Observed in the Foetus (number) -->
            <!-- D. 2. 2. 1b: Gestation Period When Reaction / Event Was Observed in the Foetus (unit) -->
        </observation>
    </subjectOf2>

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    </observation>
  </subjectOf2>
  <subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
      <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="ageGroup"/>
      <value xsi:type="CE" code="D.2.3" codeSystem="2.16.840.1.113883.3.989.2.1.1.9" codeSystemVersion="2.0"/>
      <!-- D.2.3: Patient Age Group (as per reporter) -->
    </observation>
  </subjectOf2>
  <subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
      <code code="7" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="bodyWeight"/>
      <value xsi:type="PQ" value="48.2" unit="kg"/>
      <!-- D.3: Body Weight (kg) -->
    </observation>
  </subjectOf2>
  <subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
      <code code="17" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="height"/>
      <value xsi:type="PQ" value="152" unit="cm"/>
      <!-- D.4: Height (cm) -->
    </observation>
  </subjectOf2>
  <subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
      <code code="22" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
LastMenstrualPeriodDate"/>
      <value xsi:type="TS" value="20090101"/>
      <!-- D.6: Last Menstrual Period Date -->
    </observation>
  </subjectOf2>
  <subjectOf2 typeCode="SBJ">
    <organizer classCode="CATEGORY" moodCode="EVN">
      <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" codeSystemVersion="1.0" displayName="
relevantMedicalHistoryAndConcurrentConditions"/>
      <component typeCode="COMP">
        <observation classCode="OBS" moodCode="EVN">
          <code code="D.7.1.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.7.1.r.1a"/>
          <!-- D.7.1.r.1a: MedDRA Version for Medical History #1 -->
          <!-- D.7.1.r.1b: Medical History (disease / surgical procedure / etc.) (MedDRA code) #1 -->
          <effectiveTime xsi:type="IVL_TS">
            <low value="20090101"/>
            <!-- D.7.1.r.2: Start Date #1 -->
            <high value="20090101"/>
            <!-- D.7.1.r.4: End Date #1 -->
          </effectiveTime>
          <outboundRelationship2 typeCode="COMP">
            <observation classCode="OBS" moodCode="EVN">
              <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="comment"/>
              <value xsi:type="ED">D.7.1.r.5</value>
              <!-- D.7.1.r.5: Comments #1 -->
            </observation>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="EXPL">
            <observation classCode="OBS" moodCode="EVN">
              <code code="38" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="familyHistory"/>
              <value xsi:type="BL" value="true"/>
              <!-- D.7.1.r.6: Family History #1 -->
            </observation>
          </outboundRelationship2>
          <inboundRelationship typeCode="REFR">
            <observation classCode="OBS" moodCode="EVN">
              <code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="continuing"/>
              <value xsi:type="BL" value="true"/>
              <!-- D.7.1.r.3: Continuing #1 -->
            </observation>
          </inboundRelationship>
        </observation>
      </component>
    </organizer>
  </subjectOf2>
  <component typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
      <code code="D.7.1.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.7.1.r.1a"/>
      <!-- D.7.1.r.1a: MedDRA Version for Medical History #2 -->
      <!-- D.7.1.r.1b: Medical history (disease / surgical procedure / etc.) (MedDRA code) #2 -->
      <effectiveTime xsi:type="IVL_TS">
        <low value="20090101"/>
        <!-- D.7.1.r.2: Start Date #2 -->
        <high value="20090101"/>
        <!-- D.7.1.r.4: End Date #2 -->
      </effectiveTime>
    </observation>
  </component>

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        <outboundRelationship2 typeCode="COMP">
          <observation classCode="OBS" moodCode="EVN">
            <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
              <value xsi:type="ED">D.7.1.r.5</value>
              <!-- D.7.1.r.5: Comments #2 -->
            </observation>
          </outboundRelationship2>
        <outboundRelationship2 typeCode="EXPL">
          <observation classCode="OBS" moodCode="EVN">
            <code code="38" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
              <value xsi:type="BL" value="true"/>
              <!-- D.7.1.r.6: Family History #2 -->
            </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" codeSystemVersion="1.1"
              <value xsi:type="BL" value="true"/>
              <!-- D.7.1.r.3: Continuing #2 -->
            </observation>
          </inboundRelationship>
        </observation>
      </component>
    <component typeCode="COMP">
      <observation classCode="OBS" moodCode="EVN">
        <code code="18" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
          <value xsi:type="ED">D.7.2</value>
          <!-- D.7.2: Text for Relevant Medical History and Concurrent Conditions (not including reaction /
            event) -->
        </observation>
      </component>
    <component typeCode="COMP">
      <observation classCode="OBS" moodCode="EVN">
        <code code="11" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
          <value xsi:type="BL" value="true"/>
          <!-- D.7.3: Concomitant Therapies -->
        </observation>
      </component>
    </organizer>
  </subjectOf2>
  <subjectOf2 typeCode="SBJ">
    <organizer classCode="CATEGORY" moodCode="EVN">
      <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" codeSystemVersion="1.0" displayName="drugHistory"
    </organizer>
  </subjectOf2>
</component typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <effectiveTime xsi:type="IVL_TS">
      <low value="20090101"/>
      <!-- D.8.r.4: Start Date #1 -->
      <high value="20090101"/>
      <!-- D.8.r.5: End Date #1 -->
    </effectiveTime>
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          <code code="D.8.r.2b" codeSystem="TBD-MPID" codeSystemVersion="D.8.r.2a"/>
          <!-- D.8.r.2a: MPID Version Date / Number #1 -->
          <!-- D.8.r.2b: Medicinal Product Identifier (MPID) #1 -->
          <name>D.8.r.1</name>
          <!-- D.8.r.1: Name of Drug as Reported #1 -->
        </kindOfProduct>
      </instanceOfKind>
    </consumable>
    <outboundRelationship2 typeCode="RSON">
      <observation classCode="OBS" moodCode="EVN">
        <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
          <value xsi:type="CE" code="D.8.r.6b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="
            D.8.r.6a"/>
          <!-- D.8.r.6a: MedDRA Version for Indication #1 -->
          <!-- D.8.r.6b: Indication (MedDRA code) #1 -->
        </observation>
      </outboundRelationship2>
    <outboundRelationship2 typeCode="CAUS">
      <observation classCode="OBS" moodCode="EVN">
        <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
          <value xsi:type="CE" code="D.8.r.7b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="
            D.8.r.7a"/>
        </observation>
      </outboundRelationship2>
    </substanceAdministration>
  </component typeCode="COMP">

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        <!-- D.8.r.7a: MedDRA Version for Reaction #1 -->
        <!-- D.8.r.7b: Reaction (MedDRA code) #1 -->
    </observation>
</outboundRelationship2>
</substanceAdministration>
</component>
<component typeCode="COMP">
    <substanceAdministration classCode="SBADM" moodCode="EVN">
        <effectiveTime xsi:type="IVL_TS">
            <low value="20090101"/>
            <!-- D.8.r.4: Start Date #2 -->
            <high value="20090101"/>
            <!-- D.8.r.5: End Date #2 -->
        </effectiveTime>
        <consumable typeCode="CSM">
            <instanceOfKind classCode="INST">
                <kindOfProduct classCode="MMAT" determinerCode="KIND">
                    <code code="D.8.r.3b" codeSystem="TBD-PhPID" codeSystemVersion="D.8.r.3a"/>
                    <!-- D.8.r.3a: PhPID Version Date / Number -->
                    <!-- D.8.r.3b: Pharmaceutical Product Identifier (PhPID) #2 -->
                    <name>D.8.r.1</name>
                    <!-- D.8.r.1: Name of Drug as Reported #2 -->
                </kindOfProduct>
            </instanceOfKind>
        </consumable>
        <outboundRelationship2 typeCode="RSON">
            <observation classCode="OBS" moodCode="EVN">
                <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
                    displayName="indication"/>
                <value xsi:type="CE" code="D.8.r.6b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="
                    D.8.r.6a"/>
                <!-- D.8.r.6a: MedDRA Version for Indication #2 -->
                <!-- D.8.r.6b: Indication (MedDRA code) #2 -->
            </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="CAUS">
            <observation classCode="OBS" moodCode="EVN">
                <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
                    displayName="reaction"/>
                <value xsi:type="CE" code="D.8.r.7b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="
                    D.8.r.7a"/>
                <!-- D.8.r.7a: MedDRA Version for Reaction #2 -->
                <!-- D.8.r.7b: Reaction (MedDRA code) #2 -->
            </observation>
        </outboundRelationship2>
    </substanceAdministration>
</component>
</organizer>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <code code="32" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
            reportedCauseOfDeath"/>
        <value xsi:type="CE" code="D.9.2.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.9.2.r.1a">
            <!-- D.9.2.r.1a: MedDRA Version for Reported Cause(s) of Death #1 -->
            <!-- D.9.2.r.1b: Reported Cause(s) of Death (MedDRA code) #1 -->
            <originalText>D.9.2.r.2</originalText>
            <!-- D.9.2.r.2: Reported Cause(s) of Death (free text) #1 -->
        </value>
    </observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <code code="32" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
            reportedCauseOfDeath"/>
        <value xsi:type="CE" code="D.9.2.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.9.2.r.1a">
            <!-- D.9.2.r.1a: MedDRA Version for Reported Cause(s) of Death #2 -->
            <!-- D.9.2.r.1b: Reported Cause(s) of Death (MedDRA code) #2 -->
            <originalText>D.9.2.r.2</originalText>
            <!-- D.9.2.r.2: Reported Cause(s) of Death (free text) #2 -->
        </value>
    </observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <code code="5" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="autopsy"/>
        <value xsi:type="BL" value="true"/>
        <!-- D.9.3 Was Autopsy Done? -->
        <outboundRelationship2 typeCode="DRIV">
            <observation classCode="OBS" moodCode="EVN">
                <code code="8" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
                    causeOfDeath"/>
                <value xsi:type="CE" code="D.9.4.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.9.4.
                    r.1a"/>
            </observation>
        </outboundRelationship2>
    </observation>
</subjectOf2>

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        <!-- D.9.4.r.1a: MedDRA Version for Autopsy-determined Cause(s) of Death #1 -->
        <!-- D.9.4.r.1b Autopsy-determined Cause(s) of Death (MedDRA code) #1 -->
        <originalText>D.9.4.r.2</originalText>
        <!-- D.9.4.r.2: Autopsy-determined Cause(s) of Death (free text) #1 -->
    </value>
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="DRIV">
  <observation classCode="OBS" moodCode="EVN">
    <code code="8" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
causeOfDeath"/>
    <value xsi:type="CE" code="D.9.4.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.9.4.
r.1a">
      <!-- D.9.4.r.1a: MedDRA Version for Autopsy-determined Cause(s) of Death #2 -->
      <!-- D.9.4.r.1b Autopsy-determined Cause(s) of Death (MedDRA code) #2 -->
      <originalText>D.9.4.r.2</originalText>
      <!-- D.9.4.r.2: Autopsy-determined Cause(s) of Death (free text) #2 -->
    </value>
  </observation>
</outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reaction"/>
    <effectiveTime xsi:type="IVL_TS">
      <low value="20090101"/>
      <!-- E.i.4: Date of Start of Reaction / Event #1 -->
      <high value="20090102"/>
      <!-- E.i.5: Date of End of Reaction / Event #1 -->
    </effectiveTime>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
      <!-- E.i.2.1a: MedDRA Version for Reaction / Event #1 -->
      <!-- E.i.2.1b: Reaction / Event (MedDRA code) #1 -->
      <originalText language="E.i.1.1b">E.i.1.1a</originalText>
      <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #1 -->
      <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #1 -->
    </value>
    <location typeCode="LOC">
      <locatedEntity classCode="LOCE">
        <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
          <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
          <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #1 -->
        </locatedPlace>
      </locatedEntity>
    </location>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
reactionForTranslation"/>
        <value xsi:type="ED">E.i.1.2</value>
        <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #1 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
termHighlightedByReporter"/>
        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="
2.0"/>
        <!-- E.i.3.1: Term Highlighted by the Reporter #1 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInDeath"/>
        <value xsi:type="BL" value="true"/>
        <!-- E.i.3.2a: Results in Death #1 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
isLifeThreatening"/>
        <value xsi:type="BL" nullFlavor="NI"/>
        <!-- E.i.3.2b: Life Threatening #1 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="

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requiresInpatientHospitalization"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #1 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
    <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInPersistentOrSignificantDisability"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2d: Disabling / Incapacitating #1-->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
    <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
congenitalAnomalyBirthDefect"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #1 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
    <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
otherMedicallyImportantCondition"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2f: Other Medically Important Condition #1 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
    <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
outcome"/>
    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="2.
0"/>
    <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #1 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
    <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
medicalConfirmationByHealthProfessional"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.8: Medical Confirmation by Healthcare Professional #1 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
    <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
"未知・既知"/>
    <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.1"/>
    <!-- @J2.14.i 未知・既知 #1 -->
    </observation>
</outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
    <id root="2baa28d6-c9e8-4e6a-93e9-5b860b314220"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reaction"/>
    <effectiveTime xsi:type="IVL_TS">
    <low value="20090101"/>
    <!-- E.i.4: Date of Start of Reaction / Event #2 -->
    <width value="24" unit="E.i.6b"/>
    <!-- E.i.6a: Duration of Reaction / Event (number) #2 -->
    <!-- E.i.6b: Duration of Reaction / Event (unit) #2 -->
    </effectiveTime>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
    <!-- E.i.2.1a: MedDRA Version for Reaction / Event #2 -->
    <!-- E.i.2.1b: Reaction / Event (MedDRA code) #2 -->
    <originalText language="E.i.1.1b">E.i.1.1a</originalText>
    <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #2 -->
    <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #2 -->
    </value>
    <location typeCode="LOC">
    <locatedEntity classCode="LOCE">
    <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
    <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
    <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #2 -->
    </locatedPlace>
    </locatedEntity>
    </location>
</location>

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<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
reactionForTranslation"/>
    <value xsi:type="ED">E.i.1.2</value>
    <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #2 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
termHighlightedByReporter"/>
    <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="
2.0"/>
    <!-- E.i.3.1: Term Highlighted by the Reporter #2 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInDeath"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2a: Results in Death #2 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
isLifeThreatening"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2b: Life Threatening #2 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
requiresInpatientHospitalization"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #2 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInPersistentOrSignificantDisability"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2d: Disabling / Incapacitating #2 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
congenitalAnomalyBirthDefect"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #2 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
otherMedicallyImportantCondition"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2f: Other Medically Important Condition #2 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
outcome"/>
    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="2.
0"/>
    <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #2 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
medicalConfirmationByHealthProfessional"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.8: Medical Confirmation by Healthcare Professional #2 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">

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        <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName=
"未知·既知"/>
        <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.1"/>
        <!-- @@@J2.14.i 未知·既知 #2 -->
    </observation>
</outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430adf"/>
        <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reaction"/>

        <effectiveTime xsi:type="IVL_TS">
            <width value="24" unit="E.i.6b"/>
            <!-- E.i.6a: Duration of Reaction / Event (number) #3 -->
            <!-- E.i.6b: Duration of Reaction / Event (unit) #3 -->
            <high value="20101201"/>
            <!-- E.i.5: Date of End of Reaction / Event #3 -->
        </effectiveTime>
        <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
            <!-- E.i.2.1a: MedDRA Version for Reaction / Event #3 -->
            <!-- E.i.2.1b: Reaction / Event (MedDRA code) #3 -->
            <originalText language="E.i.1.1b">E.i.1.1a</originalText>
            <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #3 -->
            <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #3 -->
        </value>
        <location typeCode="LOC">
            <locatedEntity classCode="LOCE">
                <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
                    <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
                    <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #3 -->
                </locatedPlace>
            </locatedEntity>
        </location>
        <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
                <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
reactionForTranslation"/>
                <value xsi:type="ED">E.i.1.2</value>
                <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #3 -->
            </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
                <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
termHighlightedByReporter"/>
                <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="
2.0"/>
                <!-- E.i.3.1:Term Highlighted by the Reporter #3 -->
            </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
                <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInDeath"/>
                <value xsi:type="BL" value="true"/>
                <!-- E.i.3.2a: Results in Death #3 -->
            </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
                <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
isLifeThreatening"/>
                <value xsi:type="BL" nullFlavor="NI"/>
                <!-- E.i.3.2b: Life Threatening #3 -->
            </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
                <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
requiresInpatientHospitalization"/>
                <value xsi:type="BL" value="true"/>
                <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #3 -->
            </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
                <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInPersistentOrSignificantDisability"/>
                <value xsi:type="BL" nullFlavor="NI"/>
                <!-- E.i.3.2d: Disabling / Incapacitating #3 -->
            </observation>
    </subjectOf2>

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</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
congenitalAnomalyBirthDefect"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #3 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
otherMedicallyImportantCondition"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2f: Other Medically Important Condition #3 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
outcome"/>
    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="2.
0"/>
    <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #3 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
medicalConfirmationByHealthProfessional"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.8: Medical Confirmation by Healthcare Professional #3 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
未知·既知"/>
    <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.1"/>
    <!-- @J2.14.i 未知·既知 #3 -->
  </observation>
</outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reaction"/>
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="IVL_TS">
        <low value="20090101"/>
        <!-- E.i.4: Date of Start of Reaction / Event #4 -->
        <high value="20101201"/>
        <!-- E.i.5: Date of End of Reaction / Event #4 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <width value="24" unit="E.i.6b"/>
        <!-- E.i.6a: Duration of Reaction / Event (number) #4 -->
        <!-- E.i.6b: Duration of Reaction / Event (unit) #4 -->
      </comp>
    </effectiveTime>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
      <!-- E.i.2.1a: MedDRA Version for Reaction / Event #4 -->
      <!-- E.i.2.1b: Reaction / Event (MedDRA code) #4 -->
      <originalText language="E.i.1.1b">E.i.1.1a</originalText>
      <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #4 -->
      <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #4 -->
    </value>
    <location typeCode="LOC">
      <locatedEntity classCode="LOCE">
        <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
          <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
          <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #4 -->
        </locatedPlace>
      </locatedEntity>
    </location>
  </subjectOf2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
reactionForTranslation"/>
    <value xsi:type="ED">E.i.1.2</value>
    <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #4 -->
  </observation>
</outboundRelationship2>

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        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
termHighlightedByReporter"/>
            <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="
2.0"/>
            <!-- E.i.3.1:Term Highlighted by the Reporter #4 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInDeath"/>
            <value xsi:type="BL" value="true"/>
            <!-- E.i.3.2a: Results in Death #4 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
isLifeThreatening"/>
            <value xsi:type="BL" nullFlavor="NI"/>
            <!-- E.i.3.2b: Life Threatening #4 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
requiresInpatientHospitalization"/>
            <value xsi:type="BL" value="true"/>
            <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #4 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInPersistentOrSignificantDisability"/>
            <value xsi:type="BL" nullFlavor="NI"/>
            <!-- E.i.3.2d: Disabling / Incapacitating #4 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
congenitalAnomalyBirthDefect"/>
            <value xsi:type="BL" nullFlavor="NI"/>
            <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #4 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
otherMedicallyImportantCondition"/>
            <value xsi:type="BL" value="true"/>
            <!-- E.i.3.2f: Other Medically Important Condition #4 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
outcome"/>
            <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="2.
0"/>
            <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #4 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
medicalConfirmationByHealthProfessional"/>
            <value xsi:type="BL" value="true"/>
            <!-- E.i.8: Medical Confirmation by Healthcare Professional #4 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
"未知·既知"/>
            <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.1"/>
            <!-- @J2.14.i 未知·既知 #4 -->
        </observation>

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        </outboundRelationship2>
      </observation>
    </subjectOf2>
  </subjectOf2 typeCode="SBJ"/>
  <observation classCode="OBS" moodCode="EVN">
    <id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reaction"/>

    <effectiveTime xsi:type="IVL_TS">
      <low value="20090101"/>
      <!-- E.i.4: Date of Start of Reaction / Event #5 -->
    </effectiveTime>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
      <!-- E.i.2.1a: MedDRA Version for Reaction / Event #5 -->
      <!-- E.i.2.1b: Reaction / Event (MedDRA code) #5 -->
      <originalText language="E.i.1.1b">E.i.1.1a</originalText>
      <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #5 -->
      <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #5 -->
    </value>
    <location typeCode="LOC">
      <locatedEntity classCode="LOCE">
        <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
          <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
          <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #5 -->
        </locatedPlace>
      </locatedEntity>
    </location>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
reactionForTranslation"/>

        <value xsi:type="ED">E.i.1.2</value>
        <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #5 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
termHighlightedByReporter"/>

        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="
2.0"/>

        <!-- E.i.3.1:Term Highlighted by the Reporter #5 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInDeath"/>

        <value xsi:type="BL" value="true"/>
        <!-- E.i.3.2a: Results in Death #5 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
isLifeThreatening"/>

        <value xsi:type="BL" nullFlavor="NI"/>
        <!-- E.i.3.2b: Life Threatening #5 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
requiresInpatientHospitalization"/>

        <value xsi:type="BL" value="true"/>
        <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #5 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInPersistentOrSignificantDisability"/>

        <value xsi:type="BL" nullFlavor="NI"/>
        <!-- E.i.3.2d: Disabling / Incapacitating #5 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
congenitalAnomalyBirthDefect"/>

        <value xsi:type="BL" nullFlavor="NI"/>
        <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #5 -->
      </observation>
    </outboundRelationship2>
  </observation>

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<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
otherMedicallyImportantCondition"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2f: Other Medically Important Condition #5 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
outcome"/>
    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="2.
0"/>
    <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #5 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
medicalConfirmationByHealthProfessional"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.8: Medical Confirmation by Healthcare Professional #5 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
"未知・既知"/>
    <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.1"/>
    <!-- @J2.14.i 未知・既知 #5 -->
  </observation>
</outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="1f927283-10b6-4334-9d43-e925640fb18f"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reaction"/>
    <effectiveTime xsi:type="IVL_TS">
      <high value="20090101"/>
      <!-- E.i.4: Date of Start of Reaction / Event #6 -->
    </effectiveTime>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
      <!-- E.i.2.1a: MedDRA Version for Reaction / Event #6 -->
      <!-- E.i.2.1b: Reaction / Event (MedDRA code) #6 -->
      <originalText language="E.i.1.lb">E.i.1.la</originalText>
      <!-- E.i.1.la: Reaction / Event as Reported by the Primary Source in Native Language #6 -->
      <!-- E.i.1.lb: Reaction / Event as Reported by the Primary Source Language #6 -->
    </value>
    <location typeCode="LOC">
      <locatedEntity classCode="LOCE">
        <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
          <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
          <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #6 -->
        </locatedPlace>
      </locatedEntity>
    </location>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
reactionForTranslation"/>
        <value xsi:type="ED">E.i.1.2</value>
        <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #6 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
termHighlightedByReporter"/>
        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="
2.0"/>
        <!-- E.i.3.1: Term Highlighted by the Reporter #6 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInDeath"/>
        <value xsi:type="BL" value="true"/>
        <!-- E.i.3.2a: Results in Death #6 -->
      </observation>
    </outboundRelationship2>
  </subjectOf2>
</subjectOf2>

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</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
isLifeThreatening"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2b: Life Threatening #6 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
requiresInpatientHospitalization"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #6 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInPersistentOrSignificantDisability"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2d: Disabling / Incapacitating #6 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
congenitalAnomalyBirthDefect"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #6 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
otherMedicallyImportantCondition"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2f: Other Medically Important Condition #6 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
outcome"/>
    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="2.
0"/>
    <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #6 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
medicalConfirmationByHealthProfessional"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.8: Medical Confirmation by Healthcare Professional #6 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
"未知·既知"/>
    <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.1"/>
    <!-- @@@J2.14.i 未知·既知 #6 -->
  </observation>
</outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reaction"/>
    <effectiveTime xsi:type="IVL_TS">
      <width value="24" unit="E.i.6b"/>
      <!-- E.i.6a: Duration of Reaction / Event (number) #7 -->
      <!-- E.i.6b: Duration of Reaction / Event (unit) #7 -->
    </effectiveTime>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
      <!-- E.i.2.1a: MedDRA Version for Reaction / Event #7 -->
      <!-- E.i.2.1b: Reaction / Event (MedDRA code) #7 -->
      <originalText language="E.i.1.1b">E.i.1.1a</originalText>
      <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #7 -->
    </value>
  </observation>
</subjectOf2>

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        <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #7 -->
    </value>
    <location typeCode="LOC">
        <locatedEntity classCode="LOCE">
            <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
                <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
                <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #7 -->
            </locatedPlace>
        </locatedEntity>
    </location>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
reactionForTranslation"/>
            <value xsi:type="ED">E.i.1.2</value>
            <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #7 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
termHighlightedByReporter"/>
            <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="
2.0"/>
            <!-- E.i.3.1: Term Highlighted by the Reporter #7 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInDeath"/>
            <value xsi:type="BL" value="true"/>
            <!-- E.i.3.2a: Results in Death #7 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
isLifeThreatening"/>
            <value xsi:type="BL" nullFlavor="NI"/>
            <!-- E.i.3.2b: Life Threatening #7 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
requiresInpatientHospitalization"/>
            <value xsi:type="BL" value="true"/>
            <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #7 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInPersistentOrSignificantDisability"/>
            <value xsi:type="BL" nullFlavor="NI"/>
            <!-- E.i.3.2d: Disabling / Incapacitating #7 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
congenitalAnomalyBirthDefect"/>
            <value xsi:type="BL" nullFlavor="NI"/>
            <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #7 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
otherMedicallyImportantCondition"/>
            <value xsi:type="BL" value="true"/>
            <!-- E.i.3.2f: Other Medically Important Condition #7 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
outcome"/>
            <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="2.
0"/>
            <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #7 -->
        </observation>
    </outboundRelationship2>

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<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
medicalConfirmationByHealthProfessional"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.8: Medical Confirmation by Healthcare Professional #7 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
"未知・既知"/>
    <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.1"/>
    <!-- @@@J2.14.i 未知・既知 #7 -->
  </observation>
</outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="a15be092-8070-426d-af04-6863263443e0"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reaction"/>
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="IVL_TS">
        <low value="20090101"/>
        <!-- E.i.4: Date of Start of Reaction / Event #8 -->
        <width value="24" unit="E.i.6b"/>
        <!-- E.i.6a: Duration of Reaction / Event (number) #8 -->
        <!-- E.i.6b: Duration of Reaction / Event (unit) #8 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <high value="20101201"/>
        <!-- E.i.5: Date of End of Reaction / Event #8 -->
      </comp>
    </effectiveTime>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
      <!-- E.i.2.1a: MedDRA Version for Reaction / Event #8 -->
      <!-- E.i.2.1b: Reaction / Event (MedDRA code) #8 -->
      <originalText language="E.i.1.1b">E.i.1.1a</originalText>
      <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #8 -->
      <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #8 -->
    </value>
    <location typeCode="LOC">
      <locatedEntity classCode="LOCE">
        <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
          <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
          <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #8 -->
        </locatedPlace>
      </locatedEntity>
    </location>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
reactionForTranslation"/>
        <value xsi:type="ED">E.i.1.2</value>
        <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #8 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
termHighlightedByReporter"/>
        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="
2.0"/>
        <!-- E.i.3.1: Term Highlighted by the Reporter #8 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInDeath"/>
        <value xsi:type="BL" value="true"/>
        <!-- E.i.3.2a: Results in Death #8 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
isLifeThreatening"/>
        <value xsi:type="BL" nullFlavor="NI"/>
        <!-- E.i.3.2b: Life Threatening #8 -->
      </observation>
    </outboundRelationship2>
  </subjectOf2>
</subjectOf2>

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</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
requiresInpatientHospitalization"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #8 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInPersistentOrSignificantDisability"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2d: Disabling / Incapacitating #8 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
congenitalAnomalyBirthDefect"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #8 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
otherMedicallyImportantCondition"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2f: Other Medically Important Condition #8 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
outcome"/>
    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="2.
0"/>
    <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #8 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
medicalConfirmationByHealthProfessional"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.8: Medical Confirmation by Healthcare Professional #8 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
"未知・既知"/>
    <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.1"/>
    <!-- @@J2.14.i 未知・既知 #8 -->
  </observation>
</outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <organizer classCode="CATEGORY" moodCode="EVN">
    <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" codeSystemVersion="1.0" displayName="
testsAndProceduresRelevantToTheInvestigation"/>
    <component typeCode="COMP">
      <observation classCode="OBS" moodCode="EVN">
        <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
          <!-- F.r.2.2a: MedDRA Version for Test Name #1 -->
          <!-- F.r.2.2b: Test Name (MedDRA code) #1 -->
          <originalText>F.r.2.1</originalText>
          <!-- F.r.2.1: Test Name (free text) #1 -->
        </code>
        <effectiveTime value="20090101"/>
        <!-- F.r.1: Test Date #1 -->
        <value xsi:type="IVL_PQ">
          <center value="10" unit="mg/dl"/>
          <!-- F.r.3.2: Test Result (value / qualifier) #1 -->
          <!-- F.r.3.3: Test Result (unit) #1 -->
        </value>
        <interpretationCode code="F.r.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.12" codeSystemVersion="2.
0"/>
        <!-- F.r.3.1: Test Result (code) #1 -->
        <referenceRange typeCode="REFV">

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        <observationRange classCode="OBS" moodCode="EVN.CRT">
            <value xsi:type="PQ" value="40" unit="mg/dl"/>
            <!-- F.r. 4: Normal Low Value #1 -->
            <interpretationCode code="L" codeSystem="2.16.840.1.113883.5.83"/>
        </observationRange>
    </referenceRange>
    <referenceRange typeCode="REFV">
        <observationRange classCode="OBS" moodCode="EVN.CRT">
            <value xsi:type="PQ" value="110" unit="mg/dl"/>
            <!-- F.r. 5: Normal High Value #1-->
            <interpretationCode code="H" codeSystem="2.16.840.1.113883.5.83"/>
        </observationRange>
    </referenceRange>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
                displayName="comment"/>
            <value xsi:type="ED">F.r. 6</value>
            <!-- F.r. 6: Comments (free text) #1 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="REFR">
        <observation classCode="OBS" moodCode="EVN">
            <code code="25" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
                displayName="moreInformationAvailable"/>
            <value xsi:type="BL" value="true"/>
            <!--F.r. 7: More Information Available #1 -->
        </observation>
    </outboundRelationship2>
</observation>
</component>
<component typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
        <code code="F.r. 2. 2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r. 2. 2a">
            <!-- F.r. 2. 2a: MedDRA Version for Test Name #2 -->
            <!-- F.r. 2. 2b: Test Name (MedDRA code) #2 -->
            <originalText>F.r. 2. 1</originalText>
            <!-- F.r. 2. 1: Test Name (free text) #2 -->
        </code>
        <effectiveTime value="20090101"/>
        <!-- F.r. 1: Test Date #2 -->
        <value xsi:type="IVL_PQ">
            <low nullFlavor="NINF"/>
            <high value="10" unit="mg/dl" inclusive="false"/>
        </value>
        <!-- F.r. 3. 2: Test Result (value / qualifier) #2 -->
        <!-- F.r. 3. 3: Test Result (unit) #2 -->
        <!-- LT 10 mg/dl #2 -->
    </observation>
</component>
<component typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
        <code code="F.r. 2. 2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r. 2. 2a">
            <!-- F.r. 2. 2a: MedDRA Version for Test Name #3 -->
            <!-- F.r. 2. 2b: Test Name (MedDRA code) #3 -->
            <originalText>F.r. 2. 1</originalText>
            <!-- F.r. 2. 1: Test Name (free text) #3 -->
        </code>
        <effectiveTime value="20090101"/>
        <!-- F.r. 1: Test Date #3 -->
        <value xsi:type="IVL_PQ">
            <low nullFlavor="NINF"/>
            <high value="10" unit="mg/dl" inclusive="true"/>
        </value>
        <!-- F.r. 3. 2: Test Result (value / qualifier) #3 -->
        <!-- F.r. 3. 3: Test Result (unit) #3 -->
        <!-- LE 10 mg/dl #3-->
    </observation>
</component>
<component typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
        <code code="F.r. 2. 2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r. 2. 2a">
            <!-- F.r. 2. 2a: MedDRA Version for Test Name #4 -->
            <!-- F.r. 2. 2b: Test Name (MedDRA code) #4 -->
            <originalText>F.r. 2. 1</originalText>
            <!-- F.r. 2. 1: Test Name (free text) #4 -->
        </code>
        <effectiveTime value="20090101"/>
        <!-- F.r. 1: Test Date #4 -->
        <value xsi:type="IVL_PQ">
            <low value="10" unit="mg/dl" inclusive="false"/>
            <high nullFlavor="PINF"/>
        </value>
        <!-- F.r. 3. 2: Test Result (value / qualifier) #4 -->
    </observation>
</component>

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        <!-- F.r.3.3: Test Result (unit) #4 -->
        <!-- GT 10 mg/dl #4 -->
    </observation>
</component>
<component typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
        <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
            <!-- F.r.2.2a: MedDRA Version for Test Name #5 -->
            <!-- F.r.2.2b: Test Name (MedDRA code) #5 -->
            <originalText>F.r.2.1</originalText>
            <!-- F.r.2.1: Test Name (free text) #5 -->
        </code>
        <effectiveTime value="20090101"/>
        <!-- F.r.1: Test Date #5 -->
        <value xsi:type="IVL_PQ">
            <low value="10" unit="mg/dl" inclusive="true"/>
            <high nullFlavor="PINF"/>
        </value>
        <!-- F.r.3.2: Test Result (value / qualifier) #5 -->
        <!-- F.r.3.3: Test Result (unit) #5 -->
        <!-- GE 10 mg/dl #5 -->
    </observation>
</component>
<component typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
        <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
            <!-- F.r.2.2a: MedDRA Version for Test Name #6 -->
            <!-- F.r.2.2b: Test Name (MedDRA code) #6 -->
            <originalText>F.r.2.1</originalText>
            <!-- F.r.2.1: Test Name (free text) #6 -->
        </code>
        <effectiveTime value="20090101"/>
        <!-- F.r.1: Test Date #6 -->
        <value xsi:type="ED">F.r.3.4</value>
        <!-- F.r.3.4: Result Unstructured Data (free text) #6 -->
    </observation>
</component>
</organizer>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <organizer classCode="CATEGORY" moodCode="EVN">
        <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" codeSystemVersion="1.0" displayName="
drugInformation"/>
        <!-- G.k Drug(s) Information (repeat as necessary) #1 -->
    </organizer>
    <component typeCode="COMP">
        <substanceAdministration classCode="SBADM" moodCode="EVN">
            <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
            <consumable typeCode="CSM">
                <instanceOfKind classCode="INST">
                    <kindOfProduct classCode="MMAT" determinerCode="KIND">
                        <code code="G.k.2.1.1b" codeSystem="TBD-MPID" codeSystemVersion="G.k.2.1.1a"/>
                        <!-- G.k.2.1.1a: MPID Version Date / Number #1 -->
                        <!-- G.k.2.1.1b: Medicinal Product Identifier (MPID) #1 -->
                        <name>G.k.2.2</name>
                        <!-- G.k.2.2: Medicinal Product Name as Reported by the Primary Source #1 -->
                        <asManufacturedProduct classCode="MANU">
                            <subjectOf typeCode="SBJ">
                                <approval classCode="CNTRCT" moodCode="EVN">
                                    <id extension="G.k.3.1" root="2.16.840.1.113883.3.989.2.1.3.4"/>
                                    <!-- G.k.3.1: Authorisation / Application Number #1 -->
                                    <holder typeCode="HLD">
                                        <role classCode="HLD">
                                            <playingOrganization classCode="ORG" determinerCode="INSTANCE">
                                                <name>G.k.3.3</name>
                                                <!-- G.k.3.3: Name of Holder / Applicant #1 -->
                                            </playingOrganization>
                                        </role>
                                    </holder>
                                    <author typeCode="AUT">
                                        <territorialAuthority classCode="TERR">
                                            <territory classCode="NAT" determinerCode="INSTANCE">
                                                <code code="G.k.3.2" codeSystem="1.0.3166.1.2.2"/>
                                                <!-- G.k.3.2: Country of Authorisation / Application #1 -->
                                            </territory>
                                        </territorialAuthority>
                                    </author>
                                    <pertinentInformation typeCode="PERT">
                                        <policy classCode="POLICY" moodCode="EVN">
                                            <code code="J2.5.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.4"
codeSystemVersion="1.1"/>
                                            <!-- @@@J2.5.k: 一般用医薬品等のリスク区分等 #1 -->
                                        </policy>
                                    </pertinentInformation>
                                </approval>
                            </subjectOf>
                        </asManufacturedProduct>
                    </kindOfProduct>
                </instanceOfKind>
            </consumable>
        </substanceAdministration>
    </component>

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</subjectOf>
<subjectOf typeCode="SBJ">
  <characteristic classCode="OBS" moodCode="EVN">
    <code code="1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10"
codeSystemVersion="1.0" displayName="新医薬品等の状況区分"/>
    <value xsi:type="CE" code="J2.4.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.
2.1.3" codeSystemVersion="1.1"/>
    <!-- @@J2.4.k: 新医薬品等の状況区分 #1 -->
  </characteristic>
</subjectOf>
</asManufacturedProduct>
<asSpecializedKind classCode="GEN">
  <generalizedMaterialKind classCode="MAT" determinerCode="KIND">
    <code>
      <originalText>J2.12</originalText>
      <!-- @@J2.12: 治験成分記号 -->
    </code>
  </generalizedMaterialKind>
</asSpecializedKind>
<ingredient classCode="ACTI">
  <quantity>
    <numerator value="10" unit="G.k.2.3.r.3b"/>
    <!-- G.k.2.3.r.3a: Strength (number) #1-1 -->
    <!-- G.k.2.3.r.3b: Strength (unit) #1-1 -->
    <denominator value="1"/>
  </quantity>
  <ingredientSubstance classCode="MMAT" determinerCode="KIND">
    <code code="G.k.2.3.r.2b" codeSystem="TBD-Substance" codeSystemVersion="G.k.2.3.r.
2a"/>
    <!-- G.k.2.3.r.2a: Substance / Specified Substance TermID Version Date / Number
#1-1 -->
    <!-- G.k.2.3.r.2b: Substance / Specified Substance TermID #1-1 -->
    <name>G.k.2.3.r.1</name>
    <!-- G.k.2.3.r.1: Substance / Specified Substance Name #1-1 -->
  </ingredientSubstance>
</ingredient>
<ingredient classCode="ACTI">
  <quantity>
    <numerator value="10" unit="G.k.2.3.r.3b"/>
    <!-- G.k.2.3.r.3a: Strength (number) #1-2 -->
    <!-- G.k.2.3.r.3b: Strength (unit) #1-2 -->
    <denominator value="1"/>
  </quantity>
  <ingredientSubstance classCode="MMAT" determinerCode="KIND">
    <code code="G.k.2.3.r.2b" codeSystem="TBD-Substance" codeSystemVersion="G.k.2.3.r.
2a"/>
    <!-- G.k.2.3.r.2a: Substance / Specified Substance TermID Version Date / Number
#1-2 -->
    <!-- G.k.2.3.r.2b: Substance / Specified Substance TermID #1-2 -->
    <name>G.k.2.3.r.1</name>
    <!-- G.k.2.3.r.1: Substance / Specified Substance Name #1-2 -->
  </ingredientSubstance>
</ingredient>
</kindOfProduct>
<subjectOf typeCode="SBJ">
  <productEvent classCode="ACT" moodCode="EVN">
    <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.18" codeSystemVersion="1.0"
displayName="retailSupply"/>
    <performer typeCode="PRF">
      <assignedEntity classCode="ASSIGNED">
        <representedOrganization classCode="ORG" determinerCode="INSTANCE">
          <addr>
            <country>G.k.2.4</country>
            <!-- G.k.2.4: Identification of the Country Where the Drug Was
Obtained #1 -->
          </addr>
        </representedOrganization>
      </assignedEntity>
    </performer>
  </productEvent>
</subjectOf>
<subjectOf typeCode="SBJ">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="2" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.
0" displayName="一般用医薬品の入手経路"/>
    <value xsi:type="CE" code="J2.6.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.5"
codeSystemVersion="1.1"/>
    <!-- @@J2.6.k: 一般用医薬品の入手経路 #1 -->
  </observationEvent>
</subjectOf>
</instanceOfKind>
</consumable>
<outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>

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Event (number) Drug #1, Reaction #1 -->      <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (unit) Drug #1, Reaction #1 -->      <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /
                                             <actReference classCode="OBS" moodCode="EVN">
                                             <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
                                             </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAE">
  <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
  <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number)
Drug #1, Reaction #1 -->                    <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)
Drug #1, Reaction #1 -->                    <actReference classCode="OBS" moodCode="EVN">
                                             <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
                                             </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
  <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (number) Drug #1, Reaction #2 -->      <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (unit) Drug #1, Reaction #2 -->      <actReference classCode="OBS" moodCode="EVN">
                                             <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
                                             </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAE">
  <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
  <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number)
Drug #1, Reaction #2 -->                    <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)
Drug #1, Reaction #2 -->                    <actReference classCode="OBS" moodCode="EVN">
                                             <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
                                             </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
  <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (number) Drug #1, Reaction #3 -->      <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (unit) Drug #1, Reaction #3 -->      <actReference classCode="OBS" moodCode="EVN">
                                             <id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430adf"/>
                                             </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAE">
  <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
  <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number)
Drug #1, Reaction #3 -->                    <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)
Drug #1, Reaction #3 -->                    <actReference classCode="OBS" moodCode="EVN">
                                             <id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430adf"/>
                                             </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
  <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (number) Drug #1, Reaction #4 -->      <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (unit) Drug #1, Reaction #4 -->      <actReference classCode="OBS" moodCode="EVN">
                                             <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
                                             </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAE">
  <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
  <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number)
Drug #1, Reaction #4 -->                    <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)
Drug #1, Reaction #4 -->                    <actReference classCode="OBS" moodCode="EVN">
                                             <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
                                             </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
  <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (number) Drug #1, Reaction #5 -->      <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (unit) Drug #1, Reaction #5 -->

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        <actReference classCode="OBS" moodCode="EVN">
          <id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
        </actReference>
      </outboundRelationship1>
      <outboundRelationship1 typeCode="SAE">
        <pauseQuantity value="10" unit="G. k. 9. i. 3. 2b"/>
        <!-- G. k. 9. i. 3. 2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number)
Drug #1, Reaction #5 -->
        <!-- G. k. 9. i. 3. 2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)
Drug #1, Reaction #5 -->
        <actReference classCode="OBS" moodCode="EVN">
          <id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
        </actReference>
      </outboundRelationship1>
      <outboundRelationship1 typeCode="SAS">
        <pauseQuantity value="10" unit="G. k. 9. i. 3. 1b"/>
        <!-- G. k. 9. i. 3. 1a: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (number) Drug #1, Reaction #6 -->
        <!-- G. k. 9. i. 3. 1b: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (unit) Drug #1, Reaction #6 -->
        <actReference classCode="OBS" moodCode="EVN">
          <id root="1f927283-10b6-4334-9d43-e925640fb18f"/>
        </actReference>
      </outboundRelationship1>
      <outboundRelationship1 typeCode="SAE">
        <pauseQuantity value="10" unit="G. k. 9. i. 3. 2b"/>
        <!-- G. k. 9. i. 3. 2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number)
Drug #1, Reaction #6 -->
        <!-- G. k. 9. i. 3. 2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)
Drug #1, Reaction #6 -->
        <actReference classCode="OBS" moodCode="EVN">
          <id root="1f927283-10b6-4334-9d43-e925640fb18f"/>
        </actReference>
      </outboundRelationship1>
      <outboundRelationship1 typeCode="SAS">
        <pauseQuantity value="10" unit="G. k. 9. i. 3. 1b"/>
        <!-- G. k. 9. i. 3. 1a: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (number) Drug #1, Reaction #7 -->
        <!-- G. k. 9. i. 3. 1b: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (unit) Drug #1, Reaction #7 -->
        <actReference classCode="OBS" moodCode="EVN">
          <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
        </actReference>
      </outboundRelationship1>
      <outboundRelationship1 typeCode="SAE">
        <pauseQuantity value="10" unit="G. k. 9. i. 3. 2b"/>
        <!-- G. k. 9. i. 3. 2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number)
Drug #1, Reaction #7 -->
        <!-- G. k. 9. i. 3. 2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)
Drug #1, Reaction #7 -->
        <actReference classCode="OBS" moodCode="EVN">
          <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
        </actReference>
      </outboundRelationship1>
      <outboundRelationship1 typeCode="SAS">
        <pauseQuantity value="10" unit="G. k. 9. i. 3. 1b"/>
        <!-- G. k. 9. i. 3. 1a: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (number) Drug #1, Reaction #8 -->
        <!-- G. k. 9. i. 3. 1b: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (unit) Drug #1, Reaction #8 -->
        <actReference classCode="OBS" moodCode="EVN">
          <id root="a15be092-8070-426d-af04-6863263443e0"/>
        </actReference>
      </outboundRelationship1>
      <outboundRelationship1 typeCode="SAE">
        <pauseQuantity value="10" unit="G. k. 9. i. 3. 2b"/>
        <!-- G. k. 9. i. 3. 2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number)
Drug #1, Reaction #8 -->
        <!-- G. k. 9. i. 3. 2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)
Drug #1, Reaction #8 -->
        <actReference classCode="OBS" moodCode="EVN">
          <id root="a15be092-8070-426d-af04-6863263443e0"/>
        </actReference>
      </outboundRelationship1>
      <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
          <code code="6" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 19" codeSystemVersion="1. 1"
displayName="blinded"/>
          <value xsi:type="BL" value="true"/>
          <!-- G. k. 2. 5: Investigational Product Blinded #1 -->
        </observation>
      </outboundRelationship2>
      <outboundRelationship2 typeCode="COMP">
        <!-- G. k. 4. r: Dosage and Relevant Information (repeat as necessary) #1-1 -->

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<substanceAdministration classCode="SBADM" moodCode="EVN">
  <text>G.k.4.r.8</text>
  <!-- G.k.4.r.8: Dosage Text #1-1 -->
  <effectiveTime xsi:type="SXPR_TS">
    <comp xsi:type="PIVL_TS">
      <period value="10" unit="G.k.4.r.3"/>
      <!-- G.k.4.r.2: Number of Units in the Interval #1-1 -->
      <!-- G.k.4.r.3: Definition of the Time Interval Unit #1-1 -->
    </comp>
    <comp xsi:type="IVL_TS" operator="A">
      <low value="20090101"/>
      <!-- G.k.4.r.4: Date and Time of Start of Drug #1-1 -->
      <high value="20090101"/>
      <!-- G.k.4.r.5: Date and Time of Last Administration #1-1 -->
    </comp>
    <comp xsi:type="IVL_TS" operator="A">
      <width value="4" unit="G.k.4.r.6b"/>
      <!-- G.k.4.r.6a: Duration of Drug Administration (number) #1-1 -->
      <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #1-1 -->
    </comp>
  </effectiveTime>
  <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
    <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #1-1 -->
    <!-- G.k.4.r.10.2b: Route of Administration TermID #1-1 -->
    <originalText>G.k.4.r.10.1</originalText>
    <!-- G.k.4.r.10.1: Route of Administration (free text) #1-1 -->
  </routeCode>
  <doseQuantity value="10" unit="G.k.4.r.1b"/>
  <!-- G.k.4.r.1a Dose (number) #1-1 -->
  <!-- G.k.4.r.1b: Dose (unit) #1-1 -->
  <consumable typeCode="CSM">
    <instanceOfKind classCode="INST">
      <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
        <lotNumberText>G.k.4.r.7</lotNumberText>
        <!-- G.k.4.r.7: Batch / Lot Number #1-1 -->
      </productInstanceInstance>
      <kindOfProduct classCode="MMAT" determinerCode="KIND">
        <formCode code="G.k.4.r.9.2b" codeSystem="TBD=DoseForm" codeSystemVersion="G.k.4.
r.9.2a">
          <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-1 -->
          <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #1-1 -->
          <originalText>G.k.4.r.9.1</originalText>
          <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #1-1 -->
        </formCode>
      </kindOfProduct>
    </instanceOfKind>
  </consumable>
  <inboundRelationship typeCode="REFR">
    <observation classCode="OBS" moodCode="EVN">
      <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
      <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.
14" codeSystemVersion="G.k.4.r.11.2a">
        <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number
#1-1 -->
        <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-1 -->
        <originalText>G.k.4.r.11.1</originalText>
        <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-1 -->
      </value>
    </observation>
  </inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #1-2 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #1-2 -->
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <period value="10" unit="G.k.4.r.3"/>
        <!-- G.k.4.r.2: Number of Units in the Interval #1-2 -->
        <!-- G.k.4.r.3: Definition of the Time Interval Unit #1-2 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <low value="20090101"/>
        <!-- G.k.4.r.4: Date and Time of Start of Drug #1-2 -->
        <high value="20090101"/>
        <!-- G.k.4.r.5: Date and Time of Last Administration #1-2 -->
      </comp>
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14">

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