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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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            <location classCode="COUNTRY" determinerCode="INSTANCE">
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              <!-- @J2.15.r 公表国 #2 -->
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          </asLocatedEntity>
        </representedOrganization>
      </assignedEntity>
    </participation>
  </document>
</reference>
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  <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>
<inboundRelationship typeCode="REFR">
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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>
                </outboundRelationship2>
            </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>
    </organizer>
</subjectOf2>

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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>
</consumable>
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    <observation classCode="OBS" moodCode="EVN">
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            <value xsi:type="CE" code="D.10.8.r.6b" codeSystem="2.16.840.1.113883.6.163"
                <!-- 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"
                <value xsi:type="CE" code="D.10.8.r.7b" codeSystem="2.16.840.1.113883.6.163"
                    <!-- 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>

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</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
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    <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>
      </outboundRelationship>
    </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"

displayName="comment"/>

    <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"

displayName="familyHistory"/>

    <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"

displayName="continuing"/>

    <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="

historyAndConcurrentConditionText"/>

    <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="

concomitantTherapy"/>

    <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"

/>

    <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"

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 #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"

displayName="reaction"/>

            <value xsi:type="CE" code="D.8.r.7b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="

D.8.r.7a"/>

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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: 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: 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">

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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>
    </subjectOf2>

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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-c9e8-4e6c-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>

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reactionForTranslation"/>
    <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="
                <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="
                <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="
                <!-- 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="
                <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="
                <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="
                <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="
                <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="
                <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="
                <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="
                <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="2.
                <!-- 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="
                <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">
            <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="

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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"/>
        <!-- 000J2.14.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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congenitalAnomalyBirthDefect"/>
</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="
    <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"/>
    <!-- 000J2.14.i 未知・既知 #3 -->
  </observation>
</outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="2a99840f-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>
    <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 -->

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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"/>
          <!-- 000J2.14.i 未知·既知 #4 -->
        </observation>

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        </outboundRelationship2>
      </observation>
    </subjectOf2>
    <subjectOf2 typeCode="SRJ">
      <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>

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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.1.1b">E.i.1.1a</originalText>
      <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #6 -->
      <!-- E.i.1.1b: 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>

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isLifeThreatening"/>
</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="
    <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="
    <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="
    <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="
    <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="
    <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="
    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="2.
    <!-- 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="
    <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="
    <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
    <!-- 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>

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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="LOC">
        <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>

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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"
            <value xsi:type="ED">F.r. 6</value>
            <!-- F.r. 6: Comments (free text) #1 -->
          </code>
        </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"
            <value xsi:type="BL" value="true"/>
            <!-- F.r. 7: More Information Available #1 -->
          </code>
        </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 -->

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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="SEADM" 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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codeSystemVersion="1.0" displayName="新医薬品等の状況区分"/>
2.1.3" codeSystemVersion="1.1"/>

</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">
      <value xsi:type="CE" code="J2.4.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10">
        <!-- @J2.4.k: 新医薬品等の状況区分 #1 -->
      </value>
    </code>
  </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 -->
    <!-- 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 -->
    <!-- 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" />
    <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 -->
          </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" />
    <value xsi:type="CE" code="J2.6.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.5">
      <!-- @J2.6.k: 一般用医薬品の入手経路 #1 -->
    </value>
  </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"/>
Drug #1, Reaction #1 →	<!-- 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)
	<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"/>
Event (number) Drug #1, Reaction #2 →	<!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (unit) Drug #1, Reaction #2 →	<!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /
	<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"/>
Drug #1, Reaction #2 →	<!-- 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)
	<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"/>
Event (number) Drug #1, Reaction #3 →	<!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (unit) Drug #1, Reaction #3 →	<!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /
	<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"/>
Drug #1, Reaction #3 →	<!-- 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)
	<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"/>
Event (number) Drug #1, Reaction #4 →	<!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (unit) Drug #1, Reaction #4 →	<!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /
	<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"/>
Drug #1, Reaction #4 →	<!-- 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)
	<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"/>
Event (number) Drug #1, Reaction #5 →	<!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (unit) Drug #1, Reaction #5 →	<!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /

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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-cel4bc279d8e"/>
    </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-cel4bc279d8e"/>
    </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">
      <productInstance classCode="MMAT" determinerCode="INSTANCE">
        <lotNumberText>G.k.4.r.7</lotNumberText>
        <!-- G.k.4.r.7: Batch / Lot Number #1-1 -->
      </productInstance>
      <kindOfProduct classCode="MMAT" determinerCode="KIND">
        <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm" codeSystemVersion="G.k.4.
          <!-- 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"
        <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.
          <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number
            <!-- 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 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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codeSystemVersion="G.k.4.r.10.2a">

r.9.2a">

—>

displayName="parentRouteOfAdministration"/>

14" codeSystemVersion="G.k.4.r.11.2a">

#1-2 —>

codeSystemVersion="G.k.4.r.10.2a">

r.9.2a">

—>

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

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

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    </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 #1-6 -->
    <!-- G.k.4.r.10.2b: Route of Administration TermID #1-6 -->
    <originalText>G.k.4.r.10.1</originalText>
    <!-- G.k.4.r.10.1: Route of Administration (free text) #1-6 -->
  </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">
      <productInstance classCode="MMAT" determinerCode="INSTANCE">
        <lotNumberText>G.k.4.r.7</lotNumberText>
        <!-- G.k.4.r.7: Batch / Lot Number #1-1 -->
      </productInstance>
      <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 #1-6
-->
        <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #1-6 -->
        <originalText>G.k.4.r.9.1</originalText>
        <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #1-6 -->
      </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"
    <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.
    <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number
    <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-6 -->
    <originalText>G.k.4.r.11.1</originalText>
    <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-6 -->
  </value>
</observation>
</inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #1-7 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #1-7 -->
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="IVL_TS">
        <low value="20090101"/>
        <!-- G.k.4.r.4: Date and Time of Start of Drug #1-7 -->
        <width value="4" unit="G.k.4.r.6b"/>
        <!-- G.k.4.r.6a: Duration of Drug Administration (number) #1-7 -->
        <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #1-7 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <high value="20090101"/>
        <!-- G.k.4.r.5: Date and Time of Last Administration #1-7 -->
      </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 #1-7 -->
      <!-- G.k.4.r.10.2b: Route of Administration TermID #1-7 -->
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #1-7 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #1-7 -->
    <!-- G.k.4.r.1b: Dose (unit) #1-7 -->
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        <productInstance classCode="MMAT" determinerCode="INSTANCE">
          <lotNumberText>G.k.4.r.7</lotNumberText>
          <!-- G.k.4.r.7: Batch / Lot Number #1-7 -->
        </productInstance>
        <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 #1-7
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    <!-- G.k. 4. r. 9. 2b: Pharmaceutical Dose Form TermID #1-7 -->
    <originalText>G.k. 4. r. 9. 1</originalText>
    <!-- G.k. 4. r. 9. 1: Pharmaceutical Dose Form (free text) #1-7 -->
    </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"
          <value xsi:type="CE" code="G.k. 4. r. 11. 2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.
            <!-- G.k. 4. r. 11. 2a: Parent Route of Administration TermID Version Date / Number
              <!-- G.k. 4. r. 11. 2b: Parent Route of Administration TermID #1-7 -->
              <originalText>G.k. 4. r. 11. 1</originalText>
              <!-- G.k. 4. r. 11. 1: Parent Route of Administration (free text) #1-7 -->
            </value>
          </observation>
        </inboundRelationship>
      </substanceAdministration>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="SUMM">
      <observation classCode="OBS" moodCode="EVN">
        <code code="14" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
          <value xsi:type="PQ" value="10" unit="G.k. 5b"/>
          <!-- G.k. 5a: Cumulative Dose to First Reaction (number) #1 -->
          <!-- G.k. 5b: Cumulative Dose to First Reaction (unit) #1 -->
        </observation>
      </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="16" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
          <value xsi:type="PQ" value="10" unit="G.k. 6b"/>
          <!-- G.k. 6a: Gestation Period at Time of Exposure (number) #1 -->
          <!-- G.k. 6b: Gestation Period at Time of Exposure (unit) #1 -->
        </observation>
      </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
          <value xsi:type="CE" code="G.k. 9. i. 4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
            <!-- G.k. 9. i. 4: Did Reaction Recur on Re-administration? Drug #1, Reaction #1 -->
            <outboundRelationship1 typeCode="REFR">
              <actReference classCode="OBS" moodCode="EVN">
                <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
              </actReference>
            </outboundRelationship1>
          </observation>
        </outboundRelationship2>
      <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
          <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
            <value xsi:type="CE" code="G.k. 9. i. 4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
              <!-- G.k. 9. i. 4: Did Reaction Recur on Re-administration? Drug #1, Reaction #2 -->
              <outboundRelationship1 typeCode="REFR">
                <actReference classCode="OBS" moodCode="EVN">
                  <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
                </actReference>
              </outboundRelationship1>
            </observation>
          </outboundRelationship2>
        <outboundRelationship2 typeCode="REFR">
          <observation classCode="OBS" moodCode="EVN">
            <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
              <value xsi:type="CE" code="G.k. 10. r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"
                <!-- G.k. 10. r: Additional Information on Drug (coded) (repeat as necessary) #1-1 -->
              </value>
            </observation>
          </outboundRelationship2>
        <outboundRelationship2 typeCode="REFR">
          <observation classCode="OBS" moodCode="EVN">
            <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
              <value xsi:type="CE" code="G.k. 10. r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"

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codeSystemVersion="2.0"/>
    <!-- G.k.10.r: Additional Information on Drug (coded) (repeat as necessary) #1-2 -->
    </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="REFR">
        <observation classCode="OBS" moodCode="EVN">
            <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"

displayName="additionalInformation"/>

            <value xsi:type="ST">G.k.11</value>
            <!-- G.k.11: Additional Information on Drug (free text) #1 -->
            </observation>
            </outboundRelationship2>
            <inboundRelationship 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="G.k.7.r.2a" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion=

"G.k.7.r.2a">

                        <!-- G.k.7.r.2a: MedDRA Version for Indication #1-1 -->
                        <!-- G.k.7.r.2b: Indication (MedDRA code) #1-1 -->
                        <originalText>G.k.7.r.1</originalText>
                        <!-- G.k.7.r.1: Indication as Reported by the Primary Source #1-1 -->
                        </value>
                        <performer typeCode="PRF">
                            <assignedEntity classCode="ASSIGNED">
                                <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"

displayName="sourceReporter"/>

                                </assignedEntity>
                            </performer>
                        </observation>
                        </inboundRelationship>
                        <inboundRelationship typeCode="RSON">
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"

displayName="indication"/>

                                <value xsi:type="CE" code="G.k.7.r.2a" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion=

"G.k.7.r.2a">

                                    <!-- G.k.7.r.2a: MedDRA Version for Indication #1-2 -->
                                    <!-- G.k.7.r.2b: Indication (MedDRA code) #1-2 -->
                                    <originalText>G.k.7.r.1</originalText>
                                    <!-- G.k.7.r.1: Indication as Reported by the Primary Source #1-2 -->
                                    </value>
                                    <performer typeCode="PRF">
                                        <assignedEntity classCode="ASSIGNED">
                                            <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"

displayName="sourceReporter"/>

                                            </assignedEntity>
                                        </performer>
                                    </observation>
                                    </inboundRelationship>
                                    <inboundRelationship typeCode="CAUS">
                                        <act classCode="ACT" moodCode="EVN">
                                            <code code="G.k.8" codeSystem="2.16.840.1.113883.3.989.2.1.1.15" codeSystemVersion="2.0"/>
                                            <!-- G.k.8: Action(s) Taken with Drug #1 -->
                                            </act>
                                        </inboundRelationship>
                                    </substanceAdministration>
                                </component>
                                <!-- G.k Drug(s) Information (repeat as necessary) #2 -->
                                <component typeCode="COMP">
                                    <substanceAdministration classCode="SEADM" moodCode="EVN">
                                        <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
                                        <consumable typeCode="CSM">
                                            <instanceOfKind classCode="INST">
                                                <kindOfProduct classCode="MMAT" determinerCode="KIND">
                                                    <code code="G.k.2.1.2b" codeSystem="TBD-PhPID" codeSystemVersion="G.k.2.1.2a"/>
                                                    <!-- G.k.2.1.2a: PhPID Version Date / Number #2 -->
                                                    <!-- G.k.2.1.2b: Pharmaceutical Product Identifier (PhPID) #2 -->
                                                    <name>G.k.2.2</name>
                                                    <!-- G.k.2.2: Medicinal Product Name as Reported by the Primary Source #2 -->
                                                    <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 #2 -->
                                                                <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 #2 -->
                                                                        </playingOrganization>
                                                                    </role>
                                                                </holder>
                                                            <author typeCode="AUT">

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codeSystemVersion="1.1"/>
codeSystemVersion="1.0" displayName="新医薬品等の状況区分"/>
2.1.3" codeSystemVersion="1.1"/>
2a"/>
#2-1 -->
2a"/>
2 -->
displayName="retailSupply"/>
Obtained #2 -->
0" displayName="一般用医薬品の入手経路"/>
codeSystemVersion="1.1"/>
<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 #2 -->
  </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">
      <!-- @J2.5.k: 一般用医薬品等のリスク区分等 #2 -->
    </code>
  </policy>
</pertinentInformation>
</approval>
</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">
      <value xsi:type="CE" code="J2.4.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10">
        <!-- @J2.4.k: 新医薬品等の状況区分 #2 -->
      </value>
    </code>
  </characteristic>
</subjectOf>
</asManufacturedProduct>
<ingredient classCode="ACTI">
  <quantity>
    <numerator value="10" unit="G.k.2.3.r.3b"/>
    <!-- G.k.2.3.r.3a: Strength (number) #2-1 -->
    <!-- G.k.2.3.r.3b: Strength (unit) #2-1 -->
    <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.2b">
      <!-- G.k.2.3.r.2a: Substance / Specified Substance TermID Version Date / Number #2-1 -->
    </code>
  </ingredientSubstance>
  <name>G.k.2.3.r.1</name>
  <!-- G.k.2.3.r.1: Substance / Specified Substance Name #2-1 -->
</ingredient>
<ingredient classCode="ACTI">
  <quantity>
    <numerator value="10" unit="G.k.2.3.r.3b"/>
    <!-- G.k.2.3.r.3a: Strength (number) #2-2 -->
    <!-- G.k.2.3.r.3b: Strength (unit) #2-2 -->
    <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.2b">
      <!-- G.k.2.3.r.2a: Substance / Specified Substance TermID Version Date/Number #2-2 -->
    </code>
  </ingredientSubstance>
  <name>G.k.2.3.r.1</name>
  <!-- G.k.2.3.r.1: Substance / Specified Substance Name #2-2 -->
</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">
      <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 #2 -->
            </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">
      <value xsi:type="CE" code="J2.6.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.5">

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<!-- 000J2.6.k: 一般用医薬品の入手経路 #2 -->
</observationEvent>
</subjectOf>
</instanceOfKind>
</consumable>
<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 /
  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /

Event (number) Drug #2, Reaction #1 -->
Event (unit) Drug #2, Reaction #1 -->

  <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)
  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)

Drug #2, Reaction #1 -->
Drug #2, 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 /
  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /

Event (number) Drug #2, Reaction #2 -->
Event (unit) Drug #2, 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)
  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)

Drug #2, Reaction #2 -->
Drug #2, 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 /
  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /

Event (number) Drug #2, Reaction #3 -->
Event (unit) Drug #2, 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)
  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)

Drug #2, Reaction #3 -->
Drug #2, 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 /
  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /

Event (number) Drug #2, Reaction #4 -->
Event (unit) Drug #2, 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)
  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)

Drug #2, Reaction #4 -->
Drug #2, Reaction #4 -->

  <actReference classCode="OBS" moodCode="EVN">
    <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
  </actReference>

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</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 #2, Reaction #5 -->

  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /

Event (unit) Drug #2, Reaction #5 -->

  <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 #2, Reaction #5 -->

  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)

Drug #2, 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 #2, Reaction #6 -->

  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /

Event (unit) Drug #2, 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 #2, Reaction #6 -->

  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)

Drug #2, 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 #2, Reaction #7 -->

  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /

Event (unit) Drug #2, Reaction #7 -->

  <actReference classCode="OBS" moodCode="EVN">
    <id root="e0342969-38be-423f-b6bb-cel4bc279d8e"/>
  </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 #2, Reaction #7 -->

  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)

Drug #2, Reaction #7 -->

  <actReference classCode="OBS" moodCode="EVN">
    <id root="e0342969-38be-423f-b6bb-cel4bc279d8e"/>
  </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 #2, Reaction #8 -->

  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /

Event (unit) Drug #2, 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 #2, Reaction #8 -->

  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)

Drug #2, 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"

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displayName="blinded"/>
<value xsi:type="BL" value="true"/>
<!-- G.k.2.5: Investigational Product Blinded #2 -->
</observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
<!-- G.k.4.r : Dosage and Relevant Information (repeat as necessary) #2-1 -->
<substanceAdministration classCode="SBADM" moodCode="EVN">
<text>G.k.4.r.8</text>
<!-- G.k.4.r.8: Dosage Text #2-1 -->
<effectiveTime xsi:type="IVL_TS">
<low value="20090101"/>
<!-- G.k.4.r.4: Date and Time of Start of Drug #2-1 -->
<high value="20090101"/>
<!-- G.k.4.r.5: Date and Time of Last Administration #2-1 -->
</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 #2-1 -->
<!-- G.k.4.r.10.2b: Route of Administration TermID #2-1 -->
<originalText>G.k.4.r.10.1</originalText>
<!-- G.k.4.r.10.1: Route of Administration (free text) #2-1 -->
</routeCode>
<doseQuantity value="10" unit="G.k.4.r.1b"/>
<!-- G.k.4.r.1a Dose (number) #2-1 -->
<!-- G.k.4.r.1b: Dose (unit) #2-1 -->
<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 #2-1 -->
</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 #2-1 -->
<!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-1 -->
<originalText>G.k.4.r.9.1</originalText>
<!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-1 -->
</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"
14" codeSystemVersion="G.k.4.r.11.2a">
<value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.
#2-1 -->
<!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number
#2-1 -->
<!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-1 -->
<originalText>G.k.4.r.11.1</originalText>
<!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-1 -->
</value>
</observation>
</inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
<!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-2 -->
<substanceAdministration classCode="SBADM" moodCode="EVN">
<text>G.k.4.r.8</text>
<!-- G.k.4.r.8: Dosage Text #2-2 -->
<effectiveTime xsi:type="IVL_TS">
<low value="20090101"/>
<!-- G.k.4.r.4: Date and Time of Start of Drug #2-2 -->
<width value="4" unit="G.k.4.r.6b"/>
<!-- G.k.4.r.6a: Duration of Drug Administration (number) #2-2 -->
<!-- G.k.4.r.6b: Duration of Drug Administration (unit) #2-2 -->
</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 #2-2 -->
<!-- G.k.4.r.10.2b: Route of Administration TermID #2-2 -->
<originalText>G.k.4.r.10.1</originalText>
<!-- G.k.4.r.10.1: Route of Administration (free text) #2-2 -->
</routeCode>
<doseQuantity value="10" unit="G.k.4.r.1b"/>
<!-- G.k.4.r.1a Dose (number) #2-2 -->
<!-- G.k.4.r.1b: Dose (unit) #2-2 -->
<consumable typeCode="CSM">
<instanceOfKind classCode="INST">

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<productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
  <lotNumberText>G.k.4.r.7</lotNumberText>
  <!-- G.k.4.r.7: Batch / Lot Number #2-2 -->
</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 #2-2 -->
    <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-2 -->
    <originalText>G.k.4.r.9.1</originalText>
    <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-2 -->
  </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
#2-2 -->
      <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-2 -->
      <originalText>G.k.4.r.11.1</originalText>
      <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-2 -->
    </value>
  </observation>
</inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-3 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-3 -->
    <effectiveTime xsi:type="IVL_TS">
      <width value="4" unit="G.k.4.r.6b"/>
      <!-- G.k.4.r.6a: Duration of Drug Administration (number) #2-3 -->
      <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #2-3 -->
      <high value="20090101"/>
      <!-- G.k.4.r.5: Date and Time of Last Administration #2-3 -->
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
      <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-3 -->
      <!-- G.k.4.r.10.2b: Route of Administration TermID #2-3 -->
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-3 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-3 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-3 -->
    <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 #2-3 -->
        </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 #2-3 -->
            <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-3 -->
            <originalText>G.k.4.r.9.1</originalText>
            <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-3 -->
          </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
#2-3 -->
              <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-3 -->
              <originalText>G.k.4.r.11.1</originalText>
              <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-3 -->
            </value>
          </observation>
        </inboundRelationship>
      </instanceOfKind>
    </consumable>
  </substanceAdministration>
</outboundRelationship2>

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<originalText>G.k.4.r.10.1</originalText>
<!-- G.k.4.r.10.1: Route of Administration (free text) #2-5 -->
</routeCode>
<doseQuantity value="10" unit="G.k.4.r.1b"/>
<!-- G.k.4.r.1a Dose (number) #2-5 -->
<!-- G.k.4.r.1b: Dose (unit) #2-5 -->
<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 #2-5 -->
    </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 #2-5
-->
        <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-5 -->
        <originalText>G.k.4.r.9.1</originalText>
        <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-5 -->
      </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
#2-5 -->
      <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-5 -->
      <originalText>G.k.4.r.11.1</originalText>
      <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-5 -->
    </value>
  </observation>
</inboundRelationship>
</substanceAdministration>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #2-6 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-6 -->
    <effectiveTime xsi:type="SXP_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 #2-6 -->
        <!-- G.k.4.r.3: Definition of the Time Interval Unit #2-6 -->
      </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) #2-6 -->
        <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #2-6 -->
      </comp>
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
      <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-6 -->
      <!-- G.k.4.r.10.2b: Route of Administration TermID #2-6 -->
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-6 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-6 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-6 -->
    <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 #2-6 -->
        </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 #2-6
-->
            <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-6 -->
            <originalText>G.k.4.r.9.1</originalText>
            <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-6 -->
          </formCode>
        </kindOfProduct>
      </instanceOfKind>

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    </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"
          <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.
            <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number
              <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-6 -->
              <originalText>G.k.4.r.11.1</originalText>
              <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-6 -->
            </value>
          </observation>
        </inboundRelationship>
      </substanceAdministration>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="COMP">
      <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-7 -->
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <text>G.k.4.r.8</text>
        <!-- G.k.4.r.8: Dosage Text #2-7 -->
        <effectiveTime xsi:type="PIVL_TS">
          <period value="10" unit="G.k.4.r.3"/>
          <!-- G.k.4.r.2: Number of Units in the Interval #2-7 -->
          <!-- G.k.4.r.3: Definition of the Time Interval Unit #2-7 -->
        </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 #2-7 -->
          <!-- G.k.4.r.10.2b: Route of Administration TermID #2-7 -->
          <originalText>G.k.4.r.10.1</originalText>
          <!-- G.k.4.r.10.1: Route of Administration (free text) #2-7 -->
        </routeCode>
        <doseQuantity value="10" unit="G.k.4.r.1b"/>
        <!-- G.k.4.r.1a Dose (number) #2-7 -->
        <!-- G.k.4.r.1b: Dose (unit) #2-7 -->
        <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 #2-7 -->
            </productInstanceInstance>
            <kindOfProduct classCode="MMAT" determinerCode="KIND">
              <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm" codeSystemVersion="G.k.4.
                <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-7
                  <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-7 -->
                  <originalText>G.k.4.r.9.1</originalText>
                  <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-7 -->
                </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"
              <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.
                <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number
                  <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-7 -->
                  <originalText>G.k.4.r.11.1</originalText>
                  <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-7 -->
                </value>
              </observation>
            </inboundRelationship>
          </substanceAdministration>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="COMP">
          <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-8 -->
          <substanceAdministration classCode="SBADM" moodCode="EVN">
            <text>G.k.4.r.8</text>
            <!-- G.k.4.r.8: Dosage Text #2-8 -->
            <effectiveTime xsi:type="IVL_TS">
              <low value="20090101"/>
              <!-- G.k.4.r.4: Date and Time of Start of Drug #2-8 -->
            </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 #2-8 -->
              <!-- G.k.4.r.10.2b: Route of Administration TermID #2-8 -->
            </routeCode>

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        <originalText>G.k.4.r.10.1</originalText>
        <!-- G.k.4.r.10.1: Route of Administration (free text) #2-8 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-8 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-8 -->
    <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 #2-8 -->
            </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 #2-8
-->
                <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-8 -->
                <originalText>G.k.4.r.9.1</originalText>
                <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-8 -->
            </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">
            #2-8 -->
            <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number
-->
            <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-8 -->
            <originalText>G.k.4.r.11.1</originalText>
            <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-8 -->
        </value>
    </observation>
    </inboundRelationship>
    </substanceAdministration>
    <outboundRelationship2>
    <outboundRelationship2 typeCode="COMP">
        <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #2-9 -->
        <substanceAdministration classCode="SBADM" moodCode="EVN">
            <text>G.k.4.r.8</text>
            <!-- G.k.4.r.8: Dosage Text #2-9 -->
            <effectiveTime xsi:type="IVL_TS">
                <high value="20090101"/>
                <!-- G.k.4.r.5: Date and Time of Last Administration #2-9 -->
            </effectiveTime>
            <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
            <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-9 -->
            <!-- G.k.4.r.10.2b: Route of Administration TermID #2-9 -->
            <originalText>G.k.4.r.10.1</originalText>
            <!-- G.k.4.r.10.1: Route of Administration (free text) #2-9 -->
        </routeCode>
        <doseQuantity value="10" unit="G.k.4.r.1b"/>
        <!-- G.k.4.r.1a Dose (number) #2-9 -->
        <!-- G.k.4.r.1b: Dose (unit) #2-9 -->
        <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 #2-9 -->
                </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 #2-9
-->
                    <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-9 -->
                    <originalText>G.k.4.r.9.1</originalText>
                    <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-9 -->
                </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
-->

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#2-9 -->

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<!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-9 -->
<originalText>G.k.4.r.11.1</originalText>
<!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-9 -->
</value>
</observation>
</inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-10 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-10 -->
    <effectiveTime xsi:type="IVL_TS">
      <width value="4" unit="G.k.4.r.6b"/>
      <!-- G.k.4.r.6a: Duration of Drug Administration (number) #2-10 -->
      <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #2-10 -->
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
      <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-10 -->
      <!-- G.k.4.r.10.2b: Route of Administration TermID #2-10 -->
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-10 -->
      </routeCode>
      <doseQuantity value="10" unit="G.k.4.r.1b"/>
      <!-- G.k.4.r.1a Dose (number) #2-10 -->
      <!-- G.k.4.r.1b: Dose (unit) #2-10 -->
      <consumable typeCode="CSM">
        <instanceOfKind classCode="INST">
          <productInstance classCode="MMAT" determinerCode="INSTANCE">
            <lotNumberText>G.k.4.r.7</lotNumberText>
            <!-- G.k.4.r.7: Batch / Lot Number #2-10 -->
          </productInstance>
          <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 #2-
10 -->
              <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-10 -->
              <originalText>G.k.4.r.9.1</originalText>
              <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-10 -->
            </formCode>
          </kindOfProduct>
        </instanceOfKind>
      </consumable>
    </substanceAdministration 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
#2-10 -->
          <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-10 -->
          <originalText>G.k.4.r.11.1</originalText>
          <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-10 -->
        </value>
      </observation>
    </inboundRelationship>
  </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="SUMM">
  <observation classCode="OBS" moodCode="EVN">
    <code code="14" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="cumulativeDoseToReaction"/>
    <value xsi:type="PQ" value="10" unit="G.k.5b"/>
    <!-- G.k.5a: Cumulative Dose to First Reaction (number) #2 -->
    <!-- G.k.5b: Cumulative Dose to First Reaction (unit) #2 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="16" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="gestationPeriod"/>
    <value xsi:type="PQ" value="10" unit="G.k.6b"/>
    <!-- G.k.6a: Gestation Period at Time of Exposure (number) #2 -->
    <!-- G.k.6b: Gestation Period at Time of Exposure (unit) #2 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
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displayName="recurrenceOfReaction"/>
codeSystemVersion="2.0"/>
<value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
<!-- G.k.9.i.4: Did Reaction Recur on Re-administration? Drug #2, Reaction #1 -->
<outboundRelationship1 typeCode="REFR">
  <actReference classCode="OBS" moodCode="EVN">
    <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
  </actReference>
</outboundRelationship1>
</observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
<value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
<!-- G.k.9.i.4: Did Reaction Recur on Re-administration? Drug #2, Reaction #2 -->
<outboundRelationship1 typeCode="REFR">
  <actReference classCode="OBS" moodCode="EVN">
    <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
  </actReference>
</outboundRelationship1>
</observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
<value xsi:type="CE" code="G.k.10.r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"
<!-- G.k.10.r: Additional Information on Drug (coded) (repeat as necessary) #2-1 -->
</observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
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<value xsi:type="CE" code="G.k.10.r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"
<!-- G.k.10.r: Additional Information on Drug (coded) (repeat as necessary) #2-2 -->
</observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
<value xsi:type="ST">G.k.11</value>
<!-- G.k.11: Additional Information on Drug (free text) #2 -->
</observation>
</outboundRelationship2>
<inboundRelationship 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="G.k.7.r.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion=
  <!-- G.k.7.r.2a: MedDRA Version for Indication #2-1 -->
  <!-- G.k.7.r.2b: Indication (MedDRA code) #2-1 -->
  <originalText>G.k.7.r.1</originalText>
  <!-- G.k.7.r.1: Indication as Reported by the Primary Source #2-1 -->
</value>
<performer typeCode="PRF">
  <assignedEntity classCode="ASSIGNED">
    <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="sourceReporter"/>
  </assignedEntity>
</performer>
</observation>
</inboundRelationship>
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  <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="G.k.7.r.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion=
  <!-- G.k.7.r.2a: MedDRA Version for Indication #2-2 -->
  <!-- G.k.7.r.2b: Indication (MedDRA code) #2-2 -->
  <originalText>G.k.7.r.1</originalText>
  <!-- G.k.7.r.1: Indication as Reported by the Primary Source #2-2 -->
</value>
<performer typeCode="PRF">
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displayName="sourceReporter"/>
        </assignedEntity>
        </performer>
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    </inboundRelationship>
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      <act classCode="ACT" moodCode="EVN">
        <code code="G.k.8" codeSystem="2.16.840.1.113883.3.989.2.1.1.15" codeSystemVersion="2.0"/>
        <!-- G.k.8: Action(s) Taken with Drug #2 -->
      </act>
    </inboundRelationship>
  </substanceAdministration>
</component>
</organizer>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <organizer classCode="CATEGORY" moodCode="EVN">
    <code code="1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.11" codeSystemVersion="1.0" displayName="治験の概
要"/>
    <component typeCode="COMP">
      <observation classCode="OBS" moodCode="EVN">
        <code code="7" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
届出回数"/>
        <value xsi:type="INT" value="1"/>
        <!-- @@@J2.13.r.1: 届出回数 #1 -->
      </observation>
    </component>
    <component typeCode="COMP">
      <observation classCode="OBS" moodCode="EVN">
        <code code="8" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
対象疾患"/>
        <value xsi:type="ED">J2.13.r.2</value>
        <!-- @@@J2.13.r.2: 対象疾患 #1 -->
      </observation>
    </component>
    <component typeCode="COMP">
      <observation classCode="OBS" moodCode="EVN">
        <code code="9" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
開発相"/>
        <value xsi:type="CE" code="J2.13.r.3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.7"
codeSystemVersion="1.1"/>
        <!-- @@@J2.13.r.3: 開発相 #1 -->
      </observation>
    </component>
    <component typeCode="COMP">
      <observation classCode="OBS" moodCode="EVN">
        <code code="10" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
投薬中の症例の有無"/>
        <value xsi:type="BL" value="true"/>
        <!-- @@@J2.13.r.4: 投薬中の症例の有無 #1 -->
      </observation>
    </component>
  </organizer>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <organizer classCode="CATEGORY" moodCode="EVN">
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要"/>
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届出回数"/>
        <value xsi:type="INT" value="1"/>
        <!-- @@@J2.13.r.1: 届出回数 #2 -->
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      <observation classCode="OBS" moodCode="EVN">
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対象疾患"/>
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        <!-- @@@J2.13.r.2: 対象疾患 #2 -->
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    </component>
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開発相"/>
        <value xsi:type="CE" code="J2.13.r.3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.7"
codeSystemVersion="1.1"/>
        <!-- @@@J2.13.r.3: 開発相 #2 -->
      </observation>
    </component>
    <component typeCode="COMP">

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        <observation classCode="OBS" moodCode="EVN">
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"投薬中の症例の有無"/>
          <value xsi:type="BL" value="false"/>
          <!-- @@@J2.13.r.4: 投薬中の症例の有無 #2 -->
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    </organizer>
  </subjectOf2>
</primaryRole>
</subject1>
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  <causalityAssessment classCode="OBS" moodCode="EVN">
    <code code="20" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
interventionCharacterization"/>
    <value xsi:type="CE" code="G.k.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.13" codeSystemVersion="2.0"/>
    <!-- G.k.1: Characterisation of Drug Role Drug #1 -->
    <subject2 typeCode="SUBJ">
      <productUseReference classCode="SBADM" moodCode="EVN">
        <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
      </productUseReference>
    </subject2>
  </causalityAssessment>
</component>
<component typeCode="COMP">
  <causalityAssessment classCode="OBS" moodCode="EVN">
    <code code="20" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
interventionCharacterization"/>
    <value xsi:type="CE" code="G.k.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.13" codeSystemVersion="2.0"/>
    <!-- G.k.1: Characterisation of Drug Role Drug #2 -->
    <subject2 typeCode="SUBJ">
      <productUseReference classCode="SBADM" moodCode="EVN">
        <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
      </productUseReference>
    </subject2>
  </causalityAssessment>
</component>
<component typeCode="COMP">
  <causalityAssessment classCode="OBS" moodCode="EVN">
    <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="causality"/>
    <value xsi:type="ST">G.k.9.i.2.r.3</value>
    <!-- G.k.9.i.2.r.3: Result of Assessment Drug #1, Reaction #1, Assessment #1 -->
    <methodCode>
      <originalText>G.k.9.i.2.r.2</originalText>
      <!-- G.k.9.i.2.r.2: Method of Assessment Drug #1, Reaction #1, Assessment #1 -->
    </methodCode>
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code>
          <originalText>G.k.9.i.2.r.1</originalText>
          <!-- G.k.9.i.2.r.1: Source of Assessment Drug #1, Reaction #1, Assessment #1 -->
        </code>
      </assignedEntity>
    </author>
    <subject1 typeCode="SUBJ">
      <adverseEffectReference classCode="OBS" moodCode="EVN">
        <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
      </adverseEffectReference>
    </subject1>
    <subject2 typeCode="SUBJ">
      <productUseReference classCode="SBADM" moodCode="EVN">
        <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
      </productUseReference>
    </subject2>
  </causalityAssessment>
</component>
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  <causalityAssessment classCode="OBS" moodCode="EVN">
    <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="causality"/>
    <value xsi:type="ST">G.k.9.i.2.r.3</value>
    <!-- G.k.9.i.2.r.3: Result of Assessment Drug #1, Reaction #2, Assessment #1 -->
    <methodCode>
      <originalText>G.k.9.i.2.r.2</originalText>
      <!-- G.k.9.i.2.r.2: Method of Assessment Drug #1, Reaction #2, Assessment #1 -->
    </methodCode>
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code>
          <originalText>G.k.9.i.2.r.1</originalText>
          <!-- G.k.9.i.2.r.1: Source of Assessment Drug #1, Reaction #2, Assessment #1 -->
        </code>
      </assignedEntity>
    </author>
    <subject1 typeCode="SUBJ">

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        <adverseEffectReference classCode="OBS" moodCode="EVN">
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        </adverseEffectReference>
      </subject1>
      <subject2 typeCode="SUBJ">
        <productUseReference classCode="SBADM" moodCode="EVN">
          <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
        </productUseReference>
      </subject2>
    </causalityAssessment>
  </component>
  <component typeCode="COMP">
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      <!-- G.k.9.i.2.r.3: Result of Assessment Drug #2, Reaction #2, Assessment #1 -->
      <methodCode>
        <originalText>G.k.9.i.2.r.2</originalText>
        <!-- G.k.9.i.2.r.2: Method of Assessment Drug #2, Reaction #2, Assessment #1 -->
      </methodCode>
      <author typeCode="AUT">
        <assignedEntity classCode="ASSIGNED">
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            <!-- G.k.9.i.2.r.1: Source of Assessment Drug #2, Reaction #2, Assessment #1 -->
          </code>
        </assignedEntity>
      </author>
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        <adverseEffectReference classCode="OBS" moodCode="EVN">
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        </adverseEffectReference>
      </subject1>
      <subject2 typeCode="SUBJ">
        <productUseReference classCode="SBADM" moodCode="EVN">
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        </productUseReference>
      </subject2>
    </causalityAssessment>
  </component>
  <component typeCode="COMP">
    <causalityAssessment classCode="OBS" moodCode="EVN">
      <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="causality"/>
      <value xsi:type="ST">G.k.9.i.2.r.3</value>
      <!-- G.k.9.i.2.r.3: Result of Assessment Drug #2, Reaction #2, Assessment #2 -->
      <methodCode>
        <originalText>G.k.9.i.2.r.2</originalText>
        <!-- G.k.9.i.2.r.2: Method of Assessment Drug #2, Reaction #2, Assessment #2 -->
      </methodCode>
      <author typeCode="AUT">
        <assignedEntity classCode="ASSIGNED">
          <code>
            <originalText>G.k.9.i.2.r.1</originalText>
            <!-- G.k.9.i.2.r.1: Source of Assessment Drug #2, Reaction #2, Assessment #2 -->
          </code>
        </assignedEntity>
      </author>
      <subject1 typeCode="SUBJ">
        <adverseEffectReference classCode="OBS" moodCode="EVN">
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        </adverseEffectReference>
      </subject1>
      <subject2 typeCode="SUBJ">
        <productUseReference classCode="SBADM" moodCode="EVN">
          <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
        </productUseReference>
      </subject2>
    </causalityAssessment>
  </component>
  <component1 typeCode="COMP">
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      <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="comment"/>
      <value xsi:type="ED">H.2</value>
      <!-- H.2: Reporter's Comments -->
      <author typeCode="AUT">
        <assignedEntity classCode="ASSIGNED">
          <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0" displayName="
sourceReporter"/>
        </assignedEntity>
      </author>
    </observationEvent>
  </component1>
  <component1 typeCode="COMP">
    <observationEvent classCode="OBS" moodCode="EVN">

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<code code="15" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="diagnosis"/>
<value xsi:type="CE" code="H.3.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="H.3.r.1a"/>
<!-- H.3.r.1a: MedDRA Version for Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event #1 -->
<!-- H.3.r.1b: Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event (MedDRA code) #1 -->
<author typeCode="AUT">
  <assignedEntity classCode="ASSIGNED">
    <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0" displayName="sender"/>
  </assignedEntity>
</author>
</observationEvent>
</component1>
<component1 typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="15" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="diagnosis"/>
    <value xsi:type="CE" code="H.3.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="H.3.r.1a"/>
    <!-- H.3.r.1a: MedDRA Version for Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event #2 -->
    <!-- H.3.r.1b: Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event (MedDRA code) #2 -->
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0" displayName="sender"/>
      </assignedEntity>
    </author>
  </observationEvent>
</component1>
<component1 typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
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    <value xsi:type="ED">H.4</value>
    <!-- H.4: Sender's Comments -->
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0" displayName="sender"/>
      </assignedEntity>
    </author>
  </observationEvent>
</component1>
<component1 typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="未完了に対するコ
    <value xsi:type="ED">J2.7.2</value>
    <!-- @J2.7.2: 未完了に対するコメント -->
  </observationEvent>
</component1>
<component1 typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="4" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="感染症の遡及調査
    <value xsi:type="ED">J2.9</value>
    <!-- @J2.9: 感染症の遡及調査 -->
  </observationEvent>
</component1>
<component1 typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="5" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="今後の対応"/>
    <value xsi:type="ED">J2.10</value>
    <!-- @J2.10: 今後の対応 -->
  </observationEvent>
</component1>
<component1 typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="6" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="その他参考事項等
    <value xsi:type="ED">J2.11</value>
    <!-- @J2.11: その他参考事項等 -->
  </observationEvent>
</component1>
<component1 typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="12" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="報告内容の要点
    <value xsi:type="ED">J2.16</value>
    <!-- @J2.16: 報告内容の要点 -->
  </observationEvent>
</component1>
<component1 typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="13" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="備考1"/>
    <value xsi:type="ED">J2.19</value>
    <!-- @J2.19: 備考1 -->
  </observationEvent>
</component1>
<component1 typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">

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        <code code="14" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="備考2"/>
        <value xsi:type="ED">J2.20</value>
        <!-- @J2.20: 備考2 -->
      </observationEvent>
    </component1>
    <component1 typeCode="COMP">
      <observationEvent classCode="OBS" moodCode="EVN">
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        <value xsi:type="ED">J2.21</value>
        <!-- @J2.21: 備考3 -->
      </observationEvent>
    </component1>
    <component1 typeCode="COMP">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code code="16" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="備考4"/>
        <value xsi:type="ED">J2.22</value>
        <!-- @J2.22: 備考4 -->
      </observationEvent>
    </component1>
  </adverseEventAssessment>
</component>
<component typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="additionalDocumentsAvailable"/>
    <value xsi:type="BL" value="true"/>
    <!-- C.1.6.1: Are Additional Documents Available? -->
  </observationEvent>
</component>
<component typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="23" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="localCriteriaForExpedited"/>
    <value xsi:type="BL" value="true"/>
    <!-- C.1.7: Does This Case Fulfil the Local Criteria for an Expedited Report? -->
  </observationEvent>
</component>
<component typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="36" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="summaryAndComment"/>
    <value xsi:type="ED" language="H.5.r.1b">H.5.r.1a</value>
    <!-- H.5.r.1a: Case Summary and Reporter's Comments Text #1 -->
    <!-- H.5.r.1b: Case Summary and Reporter's Comments Language #1 -->
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0" displayName="reporter"/>
      </assignedEntity>
    </author>
  </observationEvent>
</component>
<component typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="36" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="summaryAndComment"/>
    <value xsi:type="ED" language="H.5.r.1b">H.5.r.1a</value>
    <!-- H.5.r.1a: Case Summary and Reporter's Comments Text #2 -->
    <!-- H.5.r.1b: Case Summary and Reporter's Comments Language #2 -->
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0" displayName="reporter"/>
      </assignedEntity>
    </author>
  </observationEvent>
</component>
<outboundRelationship typeCode="SPRT">
  <relatedInvestigation classCode="INVSTG" moodCode="EVN">
    <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" codeSystemVersion="1.0" displayName="initialReport"/>
    <subjectOf2 typeCode="SUBJ">
      <controlActEvent classCode="CACT" moodCode="EVN">
        <author typeCode="AUT">
          <assignedEntity classCode="ASSIGNED">
            <code code="C.1.8.2" codeSystem="2.16.840.1.113883.3.989.2.1.1.3" codeSystemVersion="2.0"/>
            <!-- C.1.8.2: First Sender of This Case -->
          </assignedEntity>
        </author>
      </controlActEvent>
    </subjectOf2>
  </relatedInvestigation>
</outboundRelationship>
<outboundRelationship typeCode="SPRT">
  <relatedInvestigation classCode="INVSTG" moodCode="EVN">
    <code nullFlavor="NA"/>
    <subjectOf2 typeCode="SUBJ">
      <controlActEvent classCode="CACT" moodCode="EVN">
        <id extension="C.1.10.1" root="2.16.840.1.113883.3.989.2.1.3.2"/>
      </controlActEvent>
    </subjectOf2>
  </relatedInvestigation>
</outboundRelationship>

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        <!-- C.1.10.r: Identification Number of the Report Which Is Linked to This Report (repeat as necessary) #1 -->
      </controlActEvent>
    </subjectOf2>
  </relatedInvestigation>
</outboundRelationship>
<outboundRelationship typeCode="SPRT">
  <relatedInvestigation classCode="INVSTG" moodCode="EVN">
    <code nullFlavor="NA"/>
    <subjectOf2 typeCode="SUBJ">
      <controlActEvent classCode="CACT" moodCode="EVN">
        <id extension="C.1.10.r" root="2.16.840.1.113883.3.989.2.1.3.2"/>
        <!-- C.1.10.r: Identification Number of the Report Which Is Linked to this Report (repeat as necessary) #2 -->
      </controlActEvent>
    </subjectOf2>
  </relatedInvestigation>
</outboundRelationship>
<outboundRelationship typeCode="SPRT">
  <priorityNumber value="1"/>
  <!-- C.2.r.5: Primary Source for Regulatory Purposes #1 -->
  <relatedInvestigation classCode="INVSTG" moodCode="EVN">
    <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" codeSystemVersion="1.0" displayName="sourceReport"/>
    <subjectOf2 typeCode="SUBJ">
      <controlActEvent classCode="CACT" moodCode="EVN">
        <author typeCode="AUT">
          <assignedEntity classCode="ASSIGNED">
            <addr>
              <streetAddressLine>C.2.r.2.3</streetAddressLine>
              <!-- C.2.r.2.3: Reporter's Street #1 -->
              <city>C.2.r.2.4</city>
              <!-- C.2.r.2.4: Reporter's City #1 -->
              <state>C.2.r.2.5</state>
              <!-- C.2.r.2.5: Reporter's State or Province #1 -->
              <postalCode>C.2.r.2.6</postalCode>
              <!-- C.2.r.2.6: Reporter's Postcode #1 -->
            </addr>
            <telecom value="tel:C.2.r.2.7"/>
            <!-- C.2.r.2.7: Reporter's Telephone #1 -->
            <assignedPerson classCode="PSN" determinerCode="INSTANCE">
              <name>
                <prefix>C.2.r.1.1</prefix>
                <!-- C.2.r.1.1: Reporter's Title #1 -->
                <given>C.2.r.1.2</given>
                <!-- C.2.r.1.2: Reporter's Given Name #1 -->
                <given>C.2.r.1.3</given>
                <!-- C.2.r.1.3: Reporter's Middle Name #1 -->
                <family>C.2.r.1.4</family>
                <!-- C.2.r.1.4: Reporter's Family Name #1 -->
              </name>
              <asQualifiedEntity classCode="QUAL">
                <code code="C.2.r.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.6" codeSystemVersion="2.0"/>
                <!-- C.2.r.4: Qualification #1 -->
              </asQualifiedEntity>
              <asLocatedEntity classCode="LOCE">
                <location classCode="COUNTRY" determinerCode="INSTANCE">
                  <code code="C.2.r.3" codeSystem="1.0.3166.1.2.2"/>
                  <!-- C.2.r.3: Reporter's Country Code #1 -->
                </location>
              </asLocatedEntity>
            </assignedPerson>
            <representedOrganization classCode="ORG" determinerCode="INSTANCE">
              <name>C.2.r.2.2</name>
              <!-- C.2.r.2.2: Reporter's Department #1 -->
              <assignedEntity classCode="ASSIGNED">
                <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                  <name>C.2.r.2.1</name>
                  <!-- C.2.r.2.1: Reporter's Organisation #1 -->
                </representedOrganization>
              </assignedEntity>
            </representedOrganization>
          </assignedEntity>
        </author>
      </controlActEvent>
    </subjectOf2>
  </relatedInvestigation>
</outboundRelationship>
<outboundRelationship typeCode="SPRT">
  <relatedInvestigation classCode="INVSTG" moodCode="EVN">
    <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" codeSystemVersion="1.0" displayName="sourceReport"/>
    <subjectOf2 typeCode="SUBJ">
      <controlActEvent classCode="CACT" moodCode="EVN">
        <author typeCode="AUT">
          <assignedEntity classCode="ASSIGNED">
            <addr>
              <streetAddressLine>C.2.r.2.3</streetAddressLine>

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<!-- C.2.r.2.3: Reporter's Street #2 -->
<city>C.2.r.2.4</city>
<!-- C.2.r.2.4: Reporter's City #2 -->
<state>C.2.r.2.5</state>
<!-- C.2.r.2.5: Reporter's State or Province #2 -->
<postalCode>C.2.r.2.6</postalCode>
<!-- C.2.r.2.6: Reporter's Postcode #2 -->
</addr>
<telecom value="tel:C.2.r.2.7"/>
<!-- C.2.r.2.7: Reporter's Telephone #2 -->
<assignedPerson classCode="PSN" determinerCode="INSTANCE">
  <name>
    <prefix>C.2.r.1.1</prefix>
    <!-- C.2.r.1.1: Reporter's Title #2 -->
    <given>C.2.r.1.2</given>
    <!-- C.2.r.1.2: Reporter's Given Name #2 -->
    <given>C.2.r.1.3</given>
    <!-- C.2.r.1.3: Reporter's Middle Name #2 -->
    <family>C.2.r.1.4</family>
    <!-- C.2.r.1.4: Reporter's Family Name #2 -->
  </name>
  <asQualifiedEntity classCode="QUAL">
    <code code="C.2.r.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.6" codeSystemVersion="2.0"/>
    <!-- C.2.r.4: Qualification #2 -->
  </asQualifiedEntity>
  <asLocatedEntity classCode="LOCE">
    <location classCode="COUNTRY" determinerCode="INSTANCE">
      <code code="C.2.r.3" codeSystem="1.0.3166.1.2.2"/>
      <!-- C.2.r.3: Reporter's Country Code #2 -->
    </location>
  </asLocatedEntity>
</assignedPerson>
<representedOrganization classCode="ORG" determinerCode="INSTANCE">
  <name>C.2.r.2.2</name>
  <!-- C.2.r.2.2: Reporter's Department #2 -->
  <assignedEntity classCode="ASSIGNED">
    <representedOrganization classCode="ORG" determinerCode="INSTANCE">
      <name>C.2.r.2.1</name>
      <!-- C.2.r.2.1: Reporter's Organisation #2 -->
    </representedOrganization>
  </assignedEntity>
</representedOrganization>
</assignedEntity>
</author>
</controlActEvent>
</subjectOf2>
</relatedInvestigation>
</outboundRelationship>
<subjectOf1 typeCode="SUBJ">
  <controlActEvent classCode="CACT" moodCode="EVN">
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code code="C.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.7" codeSystemVersion="2.0"/>
        <!-- C.3.1: Sender Type -->
        <addr>
          <streetAddressLine>C.3.4.1</streetAddressLine>
          <!-- C.3.4.1: Sender's Street Address -->
          <city>C.3.4.2</city>
          <!-- C.3.4.2: Sender's City -->
          <state>C.3.4.3</state>
          <!-- C.3.4.3: Sender's State or Province -->
          <postalCode>C.3.4.4</postalCode>
          <!-- C.3.4.4: Sender's Postcode -->
        </addr>
        <telecom value="tel:C.3.4.6"/>
        <!-- C.3.4.6: Sender's Telephone -->
        <telecom value="fax:C.3.4.7"/>
        <!-- C.3.4.7: Sender's Fax -->
        <telecom value="mailto:C.3.4.8"/>
        <!-- C.3.4.8: Sender's E-mail Address -->
        <assignedPerson classCode="PSN" determinerCode="INSTANCE">
          <name>
            <prefix>C.3.3.2</prefix>
            <!-- C.3.3.2: Sender's Title -->
            <given>C.3.3.3</given>
            <!-- C.3.3.3: Sender's Given Name -->
            <given>C.3.3.4</given>
            <!-- C.3.3.4: Sender's Middle Name -->
            <family>C.3.3.5</family>
            <!-- C.3.3.5: Sender's Family Name -->
          </name>
          <asLocatedEntity classCode="LOCE">
            <location classCode="COUNTRY" determinerCode="INSTANCE">
              <code code="C.3.4.5" codeSystem="1.0.3166.1.2.2"/>

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        <!-- C.3.4.5: Sender's Country Code -->
        </location>
    </asLocatedEntity>
</assignedPerson>
    <representedOrganization classCode="ORG" determinerCode="INSTANCE">
        <name>C.3.3.1</name>
        <!-- C.3.3.1: Sender's Department -->
        <assignedEntity classCode="ASSIGNED">
            <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                <name>C.3.2</name>
                <!-- C.3.2: Sender's Organisation -->
            </representedOrganization>
        </assignedEntity>
    </representedOrganization>
</author>
    <primaryInformationRecipient typeCode="PRCP">
        <assignedEntity classCode="ASSIGNED">
            <assignedPerson classCode="PSN" determinerCode="INSTANCE">
                <name>
                    <prefix>J2.18.2</prefix>
                    <!-- @J2.18.2: 受信者 肩書き -->
                    <family>J2.18.3</family>
                    <!-- @J2.18.3: 受信者 姓 -->
                    <given>J2.18.4</given>
                    <!-- @J2.18.4: 受信者 名 -->
                </name>
            </assignedPerson>
            <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                <name>J2.18.1</name>
                <!-- @J2.18.1: 受信者 組織名 -->
            </representedOrganization>
        </assignedEntity>
    </primaryInformationRecipient>
</controlActEvent>
</subjectOf1>
<subjectOf1 typeCode="SUBJ">
    <controlActEvent classCode="CACT" moodCode="EVN">
        <id assigningAuthorityName="C.1.9.1.r.1" extension="C.1.9.1.r.2" root="2.16.840.1.113883.3.989.2.1.3.3"/>
        <!-- C.1.9.1.r.1: Source(s) of the Case Identifier (repeat as necessary) #1 -->
        <!-- C.1.9.1.r.2 Case Identifier(s) #1 -->
    </controlActEvent>
</subjectOf1>
<subjectOf1 typeCode="SUBJ">
    <controlActEvent classCode="CACT" moodCode="EVN">
        <id assigningAuthorityName="C.1.9.1.r.1" extension="C.1.9.1.r.2" root="2.16.840.1.113883.3.989.2.1.3.3"/>
        <!-- C.1.9.1.r.1: Source(s) of the Case Identifier (repeat as necessary) #2 -->
        <!-- C.1.9.1.r.2 Case Identifier(s) #2 -->
    </controlActEvent>
</subjectOf1>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" codeSystemVersion="1.0" displayName="ichReportType"/>
        <value xsi:type="CE" code="C.1.3" codeSystem="2.16.840.1.113883.3.989.2.1.1.2" codeSystemVersion="2.0"/>
        <!-- C.1.3 Type of Report -->
    </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" codeSystemVersion="1.0" displayName="otherCaseIds"/>
        <value xsi:type="BL" value="true"/>
        <!-- C.1.9.1 Other Case Identifiers in Previous Transmissions -->
    </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" codeSystemVersion="1.0" displayName="nullificationAmendmentCode"/>
        <value xsi:type="CE" code="C.1.11.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.5" codeSystemVersion="2.0"/>
        <!-- C.1.11.1: Report Nullification / Amendment -->
    </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" codeSystemVersion="1.0" displayName="nullificationAmendmentReason"/>
        <value xsi:type="CE">
            <originalText>C.1.11.2</originalText>
            <!-- C.1.11.2: Reason for Nullification / Amendment -->
        </value>
    </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">

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        <code code="1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="識別番号 (報告分類)" />
        <value xsi:type="CE" code="J2.1a" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.1" codeSystemVersion="1.1" />
        <!-- @J2.1a: 識別番号 (報告分類) -->
    </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="2" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="報告起算日" />
        <value xsi:type="TS" value="20130107" />
        <!-- @J2.2.1: 報告起算日 -->
    </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="報告起算日に関するコメン
ト"/>
        <value xsi:type="ED">J2.2.2</value>
        <!-- @J2.2.2: 報告起算日に関するコメント -->
    </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="4" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="即時報告フラグ" />
        <value xsi:type="CE" code="J2.3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.2" codeSystemVersion="1.1" />
        <!-- @J2.3: 即時報告フラグ -->
    </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="5" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="報告対象外フラグ" />
        <value xsi:type="CE" code="J2.8.1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.6" codeSystemVersion="1.1" />
        <!-- @J2.8.1: 報告対象外フラグ -->
    </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="6" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="報告対象外の理由" />
        <value xsi:type="ED">J2.8.2</value>
        <!-- @J2.8.2: 報告対象外の理由 -->
    </investigationCharacteristic>
</subjectOf2>
</investigationEvent>
</subject>
</controlActProcess>
</PORR_IN049016UV>
<!-- Message #1 -->
<!-- Message #2 -->
<!-- PORR_IN049016UV -->
<!-- /PORR_IN049016UV -->
<!-- Message #2 -->
<receiver typeCode="RCV">
    <device classCode="DEV" determinerCode="INSTANCE">
        <id extension="N.1.4" root="2.16.840.1.113883.3.989.2.1.3.14" />
        <!-- N.1.4: Batch Receiver Identifier -->
    </device>
</receiver>
<sender typeCode="SND">
    <device classCode="DEV" determinerCode="INSTANCE">
        <id extension="N.1.3" root="2.16.840.1.113883.3.989.2.1.3.13" />
        <!-- N.1.3: Batch Sender Identifier -->
    </device>
</sender>
</MCCI_IN200100UV01>

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XML参照インスタンス（医薬部外品・化粧品用）

```

<?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="INVTG" 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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        <representedOrganization classCode="ORG" determinerCode="INSTANCE">
          <asLocatedEntity classCode="LOCE">
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              <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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    <title>J2.17.r</title>
    <!-- @J2.17.r 試験/研究の分類 #2 -->
    <text mediaType="application/pdf" representation="B64">C.4.r.2</text>
    <!-- C.4.r.2: Included Documents #2 -->
    <bibliographicDesignationText>C.4.r.1</bibliographicDesignationText>
    <!-- C.4.r.1: Literature Reference(s) #2 -->
    <participation typeCode="AUT">
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        <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 #2 -->
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          </asLocatedEntity>
        </representedOrganization>
      </assignedEntity>
    </participation>
  </document>
</reference>
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    <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 -->
          <role classCode="PRS">
            <code code="PRN" codeSystem="2.16.840.1.113883.5.111"/>
            <associatedPerson classCode="PSN" determinerCode="INSTANCE">
              </associatedPerson>
            <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>
          </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>
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            <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 -->
            </studyRegistration>
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        </researchStudy>
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    </subject1>
  </adverseEventAssessment>
</component>

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      <author typeCode="AUT">
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            <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>
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  <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>
<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="17" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" displayName="lastMenstrualPeriodDate" />
    <value xsi:type="CE" code="J2.28" codeSystemVersion="1.0" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.16" />
    <!-- J2.28: 妊娠の有無 -->
  </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 -->
      </observation>
      <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>
    </component>
    <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 -->
      </observation>
    </component>
  </organizer>
</subjectOf2>

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        <inboundRelationship typeCode="REFR">
            <observation classCode="OBS" moodCode="EVN">
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displayName="continuing"/>

                <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="

historyAndConcurrentConditionText"/>

        <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>
</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"

/>

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                <consumable typeCode="CSM">
                    <instanceOfKind classCode="INST">
                        <kindOfProduct classCode="MMAT" determinerCode="KIND">
                            <name>D.8.r.1</name>
                            <!-- D.8.r.1: Name of Drug as Reported #1 -->
                        </kindOfProduct>
                    </instanceOfKind>
                </consumable>
                <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 #1 -->
                        <!-- D.8.r.7b: Reaction (MedDRA code) #1 -->
                    </observation>
                </outboundRelationship2>
            </substanceAdministration>
        </component>
        <component typeCode="COMP">
            <substanceAdministration classCode="SBADM" moodCode="EVN">
                <consumable typeCode="CSM">
                    <instanceOfKind classCode="INST">
                        <kindOfProduct classCode="MMAT" determinerCode="KIND">
                            <name>D.8.r.1</name>
                            <!-- D.8.r.1: Name of Drug as Reported #2 -->
                        </kindOfProduct>
                    </instanceOfKind>
                </consumable>
                <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">
        <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 -->

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    <!-- E.i.2.1b: Reaction / Event (MedDRA code) #1 -->
    <originalText>E.i.1.1a</originalText>
    <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #1 -->
  </value>
  <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="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="J2.26.i" codeSystemVersion="1.0" codeSystem="2.16.840.1.113883.3.989.5.1.3.
2.1.14" />

      <!-- @J2.26.i 重篤性等 #1 -->
    </observation>
  </outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
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    <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 -->

    </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>E.i.1.1a</originalText>
      <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #2 -->
    </value>
    <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="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="J2.26.i" codeSystemVersion="1.0" codeSystem="2.16.840.1.113883.3.989.5.1.3.
2.1.14" />

        <!-- @J2.26.i 重篤性等 #2 -->
      </observation>
    </outboundRelationship2>
  </subjectOf2>
</subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
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    <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="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>E.i.1.1a</originalText>
      <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #3 -->
    </value>
    <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>

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    </observation>
  </subjectOf2>
  <subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
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      <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">
          </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>E.i.1.1a</originalText>
          <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #4 -->
        </value>
        <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>
      </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>E.i.1.1a</originalText>
          <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #5 -->
        </value>
        <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>
      </subjectOf2>
    </subjectOf2 typeCode="SBJ">
      <observation classCode="OBS" moodCode="EVN">
        <id root="1f927283-10b6-4334-9d43-a925640fb18f"/>
        <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>E.i.1.1a</originalText>
          <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #6 -->
        </value>
        <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>

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    </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"/>

      <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>E.i.1.1a</originalText>
        <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #7 -->
      </value>
      <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>
    </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 -->
        </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>E.i.1.1a</originalText>
        <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #8 -->
      </value>
      <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>
    </observation>
  </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 -->
      <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">
                <name>G.k.2.2</name>
                <!-- G.k.2.2: Medicinal Product Name as Reported by the Primary Source #1 -->
                <formCode code="J2.24.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.13"
codeSystemVersion="1.0" />
                <!-- 000J2.24.k 製品種別 #1 -->
              </kindOfProduct>
              <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>
                    </approval>
                  </subjectOf>
                </asManufacturedProduct>
              </instanceOfKind>
            </consumable>
          </substanceAdministration>
        </component>
      </organizer>
    </subjectOf2>
  </subjectOf2>

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        </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>
    </approval>
</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">
            <value xsi:type="CE" code="J2.4.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.3" />
            <!-- 000J2.4.k: 新医薬品等の状況区分 #1 -->
        </characteristic>
    </subjectOf>
</asManufacturedProduct>
<asNamedEntity>
    <name xml:lang="ja">J2.23.k</name>
    <!-- 000J2.23.k 愛称 #1 -->
    <assigningTerritory>
        <code code="JP" codeSystem="1.0.3166.1.2.2" />
    </assigningTerritory>
</asNamedEntity>
<ingredient classCode="ACTI">
    <quantity>
        <numerator/>
        <denominator value="1"/>
    </quantity>
    <ingredientSubstance classCode="MMAT" determinerCode="KIND">
        <name>G.k.2.3.r.1</name>
        <!-- G.k.2.3.r.1: Substance / Specified Substance Name #1-1 -->
        <asSpecializedKind classCode="GEN">
            <generalizedMaterialKind classCode="MAT" determinerCode="KIND">
                <code code="J2.25.k.r" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.17">
                    <!-- 000J2.25.k.r 成分の区分 #1-1 -->
                </generalizedMaterialKind>
            </asSpecializedKind>
        </ingredientSubstance>
    </ingredient>
    <ingredient classCode="ACTI">
        <quantity>
            <numerator/>
            <denominator value="1"/>
        </quantity>
        <ingredientSubstance classCode="MMAT" determinerCode="KIND">
            <name>G.k.2.3.r.1</name>
            <!-- G.k.2.3.r.1: Substance / Specified Substance Name #1-2 -->
            <asSpecializedKind classCode="GEN">
                <generalizedMaterialKind classCode="MAT" determinerCode="KIND">
                    <code code="J2.25.k.r" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.17">
                        <!-- 000J2.25.k.r 成分の区分 #1-2 -->
                    </generalizedMaterialKind>
                </asSpecializedKind>
            </ingredientSubstance>
        </ingredient>
    </kindOfProduct>
</instanceOfKind>
</consumable>
<outboundRelationship2 typeCode="COMP">
    <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #1-1 -->
    <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>
        </effectiveTime>
        <routeCode codeSystem="2.16.840.1.113883.3.989.2.1.1.14">

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        <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 -->
</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 codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
            <originalText>G.k.4.r.10.1</originalText>
            <!-- G.k.4.r.10.1: Route of Administration (free text) #1-2 -->
        </routeCode>
        <doseQuantity value="10" unit="G.k.4.r.1b"/>
        <!-- G.k.4.r.1a Dose (number) #1-2 -->
        <!-- G.k.4.r.1b: Dose (unit) #1-2 -->
    </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
    <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #1-3 -->
    <substanceAdministration classCode="SBADM" moodCode="EVN">
        <text>G.k.4.r.8</text>
        <!-- G.k.4.r.8: Dosage Text #1-3 -->
        <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 #1-3 -->
                <!-- G.k.4.r.3: Definition of the Time Interval Unit #1-3 -->
            </comp>
            <comp xsi:type="IVL_TS" operator="A">
                <low value="20090101"/>
                <!-- G.k.4.r.4: Date and Time of Start of Drug #1-3 -->
            </comp>
        </effectiveTime>
        <routeCode codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
            <originalText>G.k.4.r.10.1</originalText>
            <!-- G.k.4.r.10.1: Route of Administration (free text) #1-3 -->
        </routeCode>
        <doseQuantity value="10" unit="G.k.4.r.1b"/>
        <!-- G.k.4.r.1a Dose (number) #1-3 -->
        <!-- G.k.4.r.1b: Dose (unit) #1-3 -->
    </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
    <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #1-4 -->
    <substanceAdministration classCode="SBADM" moodCode="EVN">
        <text>G.k.4.r.8</text>
        <!-- G.k.4.r.8: Dosage Text #1-4 -->
        <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 #1-4 -->
                <!-- G.k.4.r.3: Definition of the Time Interval Unit #1-4 -->
            </comp>
            <comp xsi:type="IVL_TS" operator="A">
                <high value="20090101"/>
                <!-- G.k.4.r.5: Date and Time of Last Administration #1-4 -->
            </comp>
        </effectiveTime>
        <routeCode codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
            <originalText>G.k.4.r.10.1</originalText>
            <!-- G.k.4.r.10.1: Route of Administration (free text) #1-4 -->
        </routeCode>
        <doseQuantity value="10" unit="G.k.4.r.1b"/>
        <!-- G.k.4.r.1a Dose (number) #1-4 -->
        <!-- G.k.4.r.1b: Dose (unit) #1-4 -->
    </substanceAdministration>

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</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #1-5 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #1-5 -->
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="IVL_TS">
        <low value="20090101"/>
        <!-- G.k.4.r.4: Date and Time of Start of Drug #1-5 -->
        <high value="20090101"/>
        <!-- G.k.4.r.5: Date and Time of Last Administration #1-5 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
      </comp>
    </effectiveTime>
    <routeCode codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #1-5 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #1-5 -->
    <!-- G.k.4.r.1b: Dose (unit) #1-5 -->
  </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #1-6 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #1-6 -->
    <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 #1-6 -->
        <!-- G.k.4.r.3: Definition of the Time Interval Unit #1-6 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <low value="20090101"/>
        <!-- G.k.4.r.4: Date and Time of Start of Drug #1-6 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <high value="20090101"/>
        <!-- G.k.4.r.5: Date and Time of Last Administration #1-6 -->
      </comp>
    </effectiveTime>
    <routeCode codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #1-6 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #1-6 -->
    <!-- G.k.4.r.1b: Dose (unit) #1-6 -->
  </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #1-7 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #1-7 -->
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="IVL_TS">
        <low value="20090101"/>
        <!-- G.k.4.r.4: Date and Time of Start of Drug #1-7 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <high value="20090101"/>
        <!-- G.k.4.r.5: Date and Time of Last Administration #1-7 -->
      </comp>
    </effectiveTime>
    <routeCode codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #1-7 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #1-7 -->
    <!-- G.k.4.r.1b: Dose (unit) #1-7 -->
  </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
    <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"

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displayName="recurrenceOfReaction"/>

codeSystemVersion="2.0"/>

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<!-- G.k.9.i.4: Did Reaction Recur on Re-administration? Drug #1, Reaction #1 -->
<outboundRelationship1 typeCode="REFR">
  <actReference classCode="OBS" moodCode="EVN">
    <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
  </actReference>
</outboundRelationship1>
</observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
      <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
        <!-- G.k.9.i.4: Did Reaction Recur on Re-administration? Drug #1, Reaction #2 -->
        <outboundRelationship1 typeCode="REFR">
          <actReference classCode="OBS" moodCode="EVN">
            <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
          </actReference>
        </outboundRelationship1>
        </observation>
      </outboundRelationship2>
    </substanceAdministration>
  </component>
  <!-- G.k Drug(s) Information (repeat as necessary) #2 -->
  <component typeCode="COMP">
    <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
      <consumable typeCode="CSM">
        <instanceOfKind classCode="INST">
          <kindOfProduct classCode="MMAT" determinerCode="KIND">
            <name>G.k.2.2</name>
            <!-- G.k.2.2: Medicinal Product Name as Reported by the Primary Source #2 -->
            <formCode code="J2.24.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.13"
              <!-- @J2.24.k 製品種別 #2 -->
              <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 #2 -->
                    <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 #2 -->
                        </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 #2 -->
                        </territory>
                      </territorialAuthority>
                    </author>
                  </approval>
                </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"
                      <value xsi:type="CE" code="J2.4.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.
                        <!-- @J2.4.k: 新医薬品等の状況区分 #2 -->
                        </characteristic>
                      </subjectOf>
                    </asManufacturedProduct>
                    <asNamedEntity>
                      <name xml:lang="ja">J2.23.k</name>
                      <!-- @J2.23.k 愛称 #2 -->
                      <assigningTerritory>
                        <code code="JP" codeSystem="1.0.3166.1.2.2" />
                      </assigningTerritory>
                    </asNamedEntity>
                    <ingredient classCode="ACTI">
                      <quantity>
                        <numerator/>
                        <denominator value="1"/>
                      </quantity>
                      <ingredientSubstance classCode="MMAT" determinerCode="KIND">
                        <name>G.k.2.3.r.1</name>
                        <!-- G.k.2.3.r.1: Substance / Specified Substance Name #2-1 -->

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codeSystemVersion="1.0" />
<asSpecializedKind classCode="GEN">
  <generalizedMaterialKind classCode="MAT" determinerCode="KIND">
    <code code="J2.25.k.r" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.17"

    <!-- @J2.25.k.r 成分の区分 #2-1 -->
    </generalizedMaterialKind>
  </asSpecializedKind>
  </ingredientSubstance>
</ingredient>
<ingredient classCode="ACTI">
  <quantity>
    <numerator/>
    <denominator value="1"/>
  </quantity>
  <ingredientSubstance classCode="MMAT" determinerCode="KIND">
    <name>G.k.2.3.r.1</name>
    <!-- G.k.2.3.r.1: Substance / Specified Substance Name #2-2 -->
    <asSpecializedKind classCode="GEN">
      <generalizedMaterialKind classCode="MAT" determinerCode="KIND">
        <code code="J2.25.k.r" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.17"

        <!-- @J2.25.k.r 成分の区分 #2-2 -->
        </generalizedMaterialKind>
      </asSpecializedKind>
    </ingredientSubstance>
  </ingredient>
</kindOfProduct>
</instanceOfKind>
</consumable>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r : Dosage and Relevant Information (repeat as necessary) #2-1 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-1 -->
    <effectiveTime xsi:type="IVL_TS">
      <low value="20090101"/>
      <!-- G.k.4.r.4: Date and Time of Start of Drug #2-1 -->
      <high value="20090101"/>
      <!-- G.k.4.r.5: Date and Time of Last Administration #2-1 -->
    </effectiveTime>
    <routeCode codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-1 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-1 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-1 -->
  </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r : Dosage and Relevant Information (repeat as necessary) #2-2 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-2 -->
    <effectiveTime xsi:type="IVL_TS">
      <low value="20090101"/>
      <!-- G.k.4.r.4: Date and Time of Start of Drug #2-2 -->
    </effectiveTime>
    <routeCode codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-2 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-2 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-2 -->
  </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r : Dosage and Relevant Information (repeat as necessary) #2-3 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-3 -->
    <effectiveTime xsi:type="IVL_TS">
      <high value="20090101"/>
      <!-- G.k.4.r.5: Date and Time of Last Administration #2-3 -->
    </effectiveTime>
    <routeCode codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-3 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-3 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-3 -->
  </substanceAdministration>

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</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-4 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-4 -->
    <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 #2-4 -->
        <!-- G.k.4.r.3: Definition of the Time Interval Unit #2-4 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <low value="20090101"/>
        <!-- G.k.4.r.4: Date and Time of Start of Drug #2-4 -->
      </comp>
    </effectiveTime>
    <routeCode codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-4 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-4 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-4 -->
  </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-5 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-5 -->
    <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 #2-5 -->
        <!-- G.k.4.r.3: Definition of the Time Interval Unit #2-5 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <high value="20090101"/>
        <!-- G.k.4.r.5: Date and Time of Last Administration #2-5 -->
      </comp>
    </effectiveTime>
    <routeCode codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-5 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-5 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-5 -->
  </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-6 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-6 -->
    <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 #2-6 -->
        <!-- G.k.4.r.3: Definition of the Time Interval Unit #2-6 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <comp>
        </comp>
      </comp>
    </effectiveTime>
    <routeCode codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-6 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-6 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-6 -->
  </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-7 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-7 -->
    <effectiveTime xsi:type="PIVL_TS">
      <period value="10" unit="G.k.4.r.3"/>
      <!-- G.k.4.r.2: Number of Units in the Interval #2-7 -->
      <!-- G.k.4.r.3: Definition of the Time Interval Unit #2-7 -->
    </effectiveTime>

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<routeCode codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
  <originalText>G.k.4.r.10.1</originalText>
  <!-- G.k.4.r.10.1: Route of Administration (free text) #2-7 -->
</routeCode>
<doseQuantity value="10" unit="G.k.4.r.1b"/>
<!-- G.k.4.r.1a Dose (number) #2-7 -->
<!-- G.k.4.r.1b: Dose (unit) #2-7 -->
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #2-8 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-8 -->
    <effectiveTime xsi:type="IVL_TS">
      <low value="20090101"/>
      <!-- G.k.4.r.4: Date and Time of Start of Drug #2-8 -->
    </effectiveTime>
    <routeCode codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-8 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-8 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-8 -->
  </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #2-9 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-9 -->
    <effectiveTime xsi:type="IVL_TS">
      <high value="20090101"/>
      <!-- G.k.4.r.5: Date and Time of Last Administration #2-9 -->
    </effectiveTime>
    <routeCode codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-9 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-9 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-9 -->
  </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #2-10 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-10 -->
    <effectiveTime xsi:type="IVL_TS">
      </effectiveTime>
    <routeCode codeSystem="2.16.840.1.113883.3.989.2.1.1.14">
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-10 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-10 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-10 -->
  </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
      <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
        <!-- G.k.9.i.4: Did Reaction Recur on Re-administration? Drug #2, Reaction #1 -->
      </value>
    </code>
    <outboundRelationship1 typeCode="REFR">
      <actReference classCode="OBS" moodCode="EVN">
        <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
      </actReference>
    </outboundRelationship1>
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
      <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
        <!-- G.k.9.i.4: Did Reaction Recur on Re-administration? Drug #2, Reaction #2 -->
      </value>
    </code>
    <outboundRelationship1 typeCode="REFR">
      <actReference classCode="OBS" moodCode="EVN">

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        <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
        </actReference>
        </outboundRelationship1>
        </observation>
        </outboundRelationship2>
        </substanceAdministration>
        </component>
        </organizer>
        </subjectOf2>
        </primaryRole>
        </subject1>
        <component typeCode="COMP">
          <causalityAssessment classCode="OBS" moodCode="EVN">
            <code code="20" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
interventionCharacterization"/>
            <value xsi:type="CE" code="G.k.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.13" codeSystemVersion="2.0"/>
            <!-- G.k.1: Characterisation of Drug Role Drug #1 -->
            <subject2 typeCode="SUBJ">
              <productUseReference classCode="SBADM" moodCode="EVN">
                <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
              </productUseReference>
            </subject2>
          </causalityAssessment>
        </component>
        <component typeCode="COMP">
          <causalityAssessment classCode="OBS" moodCode="EVN">
            <code code="20" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
interventionCharacterization"/>
            <value xsi:type="CE" code="G.k.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.13" codeSystemVersion="2.0"/>
            <!-- G.k.1: Characterisation of Drug Role Drug #2 -->
            <subject2 typeCode="SUBJ">
              <productUseReference classCode="SBADM" moodCode="EVN">
                <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
              </productUseReference>
            </subject2>
          </causalityAssessment>
        </component>
        <component typeCode="COMP">
          <observationEvent 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">H.2</value>
            <!-- H.2: Reporter's Comments -->
            <author typeCode="AUT">
              <assignedEntity classCode="ASSIGNED">
                <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0" displayName="
sourceReporter"/>
              </assignedEntity>
            </author>
          </observationEvent>
        </component1>
        <component typeCode="COMP">
          <observationEvent 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">H.4</value>
            <!-- H.4: Sender's Comments -->
            <author typeCode="AUT">
              <assignedEntity classCode="ASSIGNED">
                <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0" displayName="sender"/>
              </assignedEntity>
            </author>
          </observationEvent>
        </component1>
        <component typeCode="COMP">
          <observationEvent classCode="OBS" moodCode="EVN">
            <code code="3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="未完了に対するコ
メント"/>
            <value xsi:type="ED">J2.7.2</value>
            <!-- @J2.7.2: 未完了に対するコメント -->
          </observationEvent>
        </component1>
        <component typeCode="COMP">
          <observationEvent classCode="OBS" moodCode="EVN">
            <code code="5" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="今後の対応"/>
            <value xsi:type="ED">J2.10</value>
            <!-- @J2.10: 今後の対応 -->
          </observationEvent>
        </component1>
        <component typeCode="COMP">
          <observationEvent classCode="OBS" moodCode="EVN">
            <code code="6" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="その他参考事項等
"/>
            <value xsi:type="ED">J2.11</value>
            <!-- @J2.11: その他参考事項等 -->
          </observationEvent>

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    </component1>
    <component1 typeCode="COMP">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code code="12" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="報告内容の要点"
          <value xsi:type="ED">J2.16</value>
          <!-- J2.16: 報告内容の要点 -->
        </observationEvent>
      </component1>
    </adverseEventAssessment>
  </component>
  <component typeCode="COMP">
    <observationEvent classCode="OBS" moodCode="EVN">
      <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
additionalDocumentsAvailable"/>
      <value xsi:type="BL" value="true"/>
      <!-- C.1.6.1: Are Additional Documents Available? -->
    </observationEvent>
  </component>
  <component typeCode="COMP">
    <observationEvent classCode="OBS" moodCode="EVN">
      <code code="23" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="localCriteriaForExpedited"/
      <value xsi:type="BL" value="true"/>
      <!-- C.1.7: Does This Case Fulfil the Local Criteria for an Expedited Report? -->
    </observationEvent>
  </component>
  <outboundRelationship typeCode="SPRT">
    <relatedInvestigation classCode="INVSTG" moodCode="EVN">
      <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" codeSystemVersion="1.0" displayName="initialReport"/>
      <subjectOf2 typeCode="SUBJ">
        <controlActEvent classCode="CACT" moodCode="EVN">
          <author typeCode="AUT">
            <assignedEntity classCode="ASSIGNED">
              <code code="C.1.8.2" codeSystem="2.16.840.1.113883.3.989.2.1.1.3" codeSystemVersion="2.0"/>
              <!-- C.1.8.2: First Sender of This Case -->
            </assignedEntity>
          </author>
        </controlActEvent>
      </subjectOf2>
    </relatedInvestigation>
  </outboundRelationship>
  <outboundRelationship typeCode="SPRT">
    <relatedInvestigation classCode="INVSTG" moodCode="EVN">
      <code nullFlavor="NA"/>
      <subjectOf2 typeCode="SUBJ">
        <controlActEvent classCode="CACT" moodCode="EVN">
          <id extension="C.1.10.r" root="2.16.840.1.113883.3.989.2.1.3.2"/>
          <!-- C.1.10.r: Identification Number of the Report Which Is Linked to This Report (repeat as necessary). #1 -->
        </controlActEvent>
      </subjectOf2>
    </relatedInvestigation>
  </outboundRelationship>
  <outboundRelationship typeCode="SPRT">
    <relatedInvestigation classCode="INVSTG" moodCode="EVN">
      <code nullFlavor="NA"/>
      <subjectOf2 typeCode="SUBJ">
        <controlActEvent classCode="CACT" moodCode="EVN">
          <id extension="C.1.10.r" root="2.16.840.1.113883.3.989.2.1.3.2"/>
          <!-- C.1.10.r: Identification Number of the Report Which Is Linked to this Report (repeat as necessary) #2 -->
        </controlActEvent>
      </subjectOf2>
    </relatedInvestigation>
  </outboundRelationship>
  <outboundRelationship typeCode="SPRT">
    <relatedInvestigation classCode="INVSTG" moodCode="EVN">
      <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" codeSystemVersion="1.0" displayName="sourceReport"/>
      <subjectOf2 typeCode="SUBJ">
        <controlActEvent classCode="CACT" moodCode="EVN">
          <author typeCode="AUT">
            <assignedEntity classCode="ASSIGNED">
              <assignedPerson classCode="PSN" determinerCode="INSTANCE">
                <asIdentifiedEntity classCode="IDENT">
                  <code code="J2.27.r" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.15" codeSystemVersion="1.0" />
                  <!-- J2.27.r 日付フラグ #1 -->
                </asIdentifiedEntity>
                <asIdentifiedEntity classCode="IDENT">
                  <code code="J2.29.r" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.9" codeSystemVersion="1.0"/>
                  <!-- J2.29.r 情報入手元 #1 -->
                </asIdentifiedEntity>
                <asLocatedEntity classCode="LOCE">
                  <location classCode="COUNTRY" determinerCode="INSTANCE">
                    <code code="C.2.r.3" codeSystem="1.0.3166.1.2.2"/>
                    <!-- C.2.r.3: Reporter's Country Code #1 -->
                  </location>
                </asLocatedEntity>
              </assignedPerson>
            </author>
          </assignedEntity>
        </controlActEvent>
      </subjectOf2>
    </relatedInvestigation>
  </outboundRelationship>

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        </location>
      </asLocatedEntity>
    </assignedPerson>
  </assignedEntity>
</author>
</controlActEvent>
</subjectOf2>
</relatedInvestigation>
</outboundRelationship>
<outboundRelationship typeCode="SPRT">
  <relatedInvestigation classCode="INVSTG" moodCode="EVN">
    <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" codeSystemVersion="1.0" displayName="sourceReport"/>
    <subjectOf2 typeCode="SUBJ">
      <controlActEvent classCode="CACT" moodCode="EVN">
        <author typeCode="AUT">
          <assignedEntity classCode="ASSIGNED">
            <assignedPerson classCode="PSN" determinerCode="INSTANCE">
              <asIdentifiedEntity classCode="IDENT">
                <code code="J2.27.r" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.15" codeSystemVersion="1.0" />
                <!-- 000J2.27.r 日付フラグ #2 -->
              </asIdentifiedEntity>
              <asIdentifiedEntity classCode="IDENT">
                <code code="J2.29.r" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.9" codeSystemVersion="1.0"/>
                <!-- 000J2.29.r 情報入手元 #2 -->
              </asIdentifiedEntity>
              <asLocatedEntity classCode="LOCE">
                <location classCode="COUNTRY" determinerCode="INSTANCE">
                  <code code="C.2.r.3" codeSystem="1.0.3166.1.2.2"/>
                  <!-- C.2.r.3: Reporter's Country Code #2 -->
                </location>
              </asLocatedEntity>
            </assignedPerson>
          </assignedEntity>
        </author>
      </controlActEvent>
    </subjectOf2>
  </relatedInvestigation>
</outboundRelationship>
<subjectOf1 typeCode="SUBJ">
  <controlActEvent classCode="CACT" moodCode="EVN">
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code code="C.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.7" codeSystemVersion="2.0"/>
        <!-- C.3.1: Sender Type -->
      </addr>
      <streetAddressLine>C.3.4.1</streetAddressLine>
      <!-- C.3.4.1: Sender's Street Address -->
      <city>C.3.4.2</city>
      <!-- C.3.4.2: Sender's City -->
      <state>C.3.4.3</state>
      <!-- C.3.4.3: Sender's State or Province -->
      <postalCode>C.3.4.4</postalCode>
      <!-- C.3.4.4: Sender's Postcode -->
    </addr>
    <telecom value="tel:C.3.4.6"/>
    <!-- C.3.4.6: Sender's Telephone -->
    <telecom value="fax:C.3.4.7"/>
    <!-- C.3.4.7: Sender's Fax -->
    <assignedPerson classCode="PSN" determinerCode="INSTANCE">
      <name>
        <prefix>C.3.3.2</prefix>
        <!-- C.3.3.2: Sender's Title -->
        <given>C.3.3.3</given>
        <!-- C.3.3.3: Sender's Given Name -->
        <given>C.3.3.4</given>
        <!-- C.3.3.4: Sender's Middle Name -->
        <family>C.3.3.5</family>
        <!-- C.3.3.5: Sender's Family Name -->
      </name>
      <asLocatedEntity classCode="LOCE">
        <location classCode="COUNTRY" determinerCode="INSTANCE">
          <code code="C.3.4.5" codeSystem="1.0.3166.1.2.2"/>
          <!-- C.3.4.5: Sender's Country Code -->
        </location>
      </asLocatedEntity>
    </assignedPerson>
    <representedOrganization classCode="ORG" determinerCode="INSTANCE">
      <assignedEntity classCode="ASSIGNED">
        <representedOrganization classCode="ORG" determinerCode="INSTANCE">
          <name>C.3.2</name>
          <!-- C.3.2: Sender's Organisation -->
        </representedOrganization>
      </assignedEntity>
    </representedOrganization>
  </subjectOf1>

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        </assignedEntity>
    </author>
    <primaryInformationRecipient typeCode="PRCP">
        <assignedEntity classCode="ASSIGNED">
            <assignedPerson classCode="PSN" determinerCode="INSTANCE">
                <name>
                    <prefix>J2.18.2</prefix>
                    <!-- @@@J2.18.2: 受信者 肩書き -->
                    <family>J2.18.3</family>
                    <!-- @@@J2.18.3: 受信者 姓 -->
                    <given>J2.18.4</given>
                    <!-- @@@J2.18.4: 受信者 名 -->
                </name>
            </assignedPerson>
            <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                <name>J2.18.1</name>
                <!-- @@@J2.18.1: 受信者 組織名 -->
            </representedOrganization>
        </assignedEntity>
    </primaryInformationRecipient>
</controlActEvent>
</subjectOf1>
<subjectOf1 typeCode="SUBJ">
    <controlActEvent classCode="CACT" moodCode="EVN">
        <id assigningAuthorityName="C.1.9.1.r.1" extension="C.1.9.1.r.2" root="2.16.840.1.113883.3.989.2.1.3.3"/>
        <!-- C.1.9.1.r.1: Source(s) of the Case Identifier (repeat as necessary) #1 -->
        <!-- C.1.9.1.r.2 Case Identifier(s) #1 -->
    </controlActEvent>
</subjectOf1>
<subjectOf1 typeCode="SUBJ">
    <controlActEvent classCode="CACT" moodCode="EVN">
        <id assigningAuthorityName="C.1.9.1.r.1" extension="C.1.9.1.r.2" root="2.16.840.1.113883.3.989.2.1.3.3"/>
        <!-- C.1.9.1.r.1: Source(s) of the Case Identifier (repeat as necessary) #2 -->
        <!-- C.1.9.1.r.2 Case Identifier(s) #2 -->
    </controlActEvent>
</subjectOf1>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" codeSystemVersion="1.0" displayName="ichReportType"/>
        <value xsi:type="CE" code="C.1.3" codeSystem="2.16.840.1.113883.3.989.2.1.1.2" codeSystemVersion="2.0"/>
        <!-- C.1.3 Type of Report -->
    </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" codeSystemVersion="1.0" displayName="otherCaseIds"/>
        <value xsi:type="BL" value="true"/>
        <!-- C.1.9.1 Other Case Identifiers in Previous Transmissions -->
    </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" codeSystemVersion="1.0" displayName="nullificationAmendmentCode"/>
        <value xsi:type="CE" code="C.1.11.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.5" codeSystemVersion="2.0"/>
        <!-- C.1.11.1: Report Nullification / Amendment -->
    </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" codeSystemVersion="1.0" displayName="nullificationAmendmentReason"/>
        <value xsi:type="CE">
            <originalText>C.1.11.2</originalText>
            <!-- C.1.11.2: Reason for Nullification / Amendment -->
        </value>
    </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="識別番号 (報告分類)"/>
        <value xsi:type="CE" code="J2.1a" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.1" codeSystemVersion="1.1"/>
        <!-- @@@J2.1a: 識別番号 (報告分類) -->
    </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="2" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="報告起算日"/>
        <value xsi:type="TS" value="20130107"/>
        <!-- @@@J2.2.1: 報告起算日 -->
    </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
    <investigationCharacteristic classCode="OBS" moodCode="EVN">

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    <code code="3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="報告起算日に関するコメン
ト"/>
    <value xsi:type="ED">J2.2.2</value>
    <!-- @@@J2.2.2: 報告起算日に関するコメント -->
  </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic classCode="OBS" moodCode="EVN">
    <code code="5" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="報告対象外フラグ"/>
    <value xsi:type="CE" code="J2.8.1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.6" codeSystemVersion="1.1"/>
    <!-- @@@J2.8.1: 報告対象外フラグ -->
  </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic classCode="OBS" moodCode="EVN">
    <code code="6" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="報告対象外の理由"/>
    <value xsi:type="ED">J2.8.2</value>
    <!-- @@@J2.8.2: 報告対象外の理由 -->
  </investigationCharacteristic>
</subjectOf2>
</investigationEvent>
</subject>
</controlActProcess>
</PORR_IN049016UV>
<!-- Message #1 -->
<!-- Message #2 -->
<!-- PORR_IN049016UV -->
<!-- /PORR_IN049016UV -->
<!-- Message #2 -->
<receiver typeCode="RCV">
  <device classCode="DEV" determinerCode="INSTANCE">
    <id extension="N.1.4" root="2.16.840.1.113883.3.989.2.1.3.14"/>
    <!-- N.1.4: Batch Receiver Identifier -->
  </device>
</receiver>
<sender typeCode="SND">
  <device classCode="DEV" determinerCode="INSTANCE">
    <id extension="N.1.3" root="2.16.840.1.113883.3.989.2.1.3.13"/>
    <!-- N.1.3: Batch Sender Identifier -->
  </device>
</sender>
</MCCI_IN200100UV01>

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