

```

<?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>

```

```

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

```

```

        <!-- 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>
  </organizer>
</subjectOf2>
<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"

```

```

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">
    <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 #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 typeCode="COMP">

```

```

        <name>D.10.8.r.1</name>
        <!-- D.10.8.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.10.8.r.6b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.8.r.6a"/>
        <!-- D.10.8.r.6a: MedDRA Version for Indication #2 -->
        <!-- D.10.8.r.6b: Indication (MedDRA code) #2 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="CAUS">
    <observation classCode="OBS" moodCode="EVN">
        <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
        <value xsi:type="CE" code="D.10.8.r.7b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.8.r.7a"/>
        <!-- D.10.8.r.7a: MedDRA Version for Reaction #2 -->
        <!-- D.10.8.r.7b: Reactions (MedDRA code) #2 -->
    </observation>
</outboundRelationship2>
</substanceAdministration>
</component>
</organizer>
</subjectOf2>
</role>
</player1>
<subjectOf1 typeCode="SBJ">
    <researchStudy classCode="CLNTRL" moodCode="EVN">
        <id extension="C.5.3" root="2.16.840.1.113883.3.989.2.1.3.5"/>
        <!-- C.5.3: Sponsor Study Number -->
        <code code="C.5.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.8" codeSystemVersion="2.0"/>
        <!-- C.5.4: Study Type Where Reaction(s) / Event(s) Were Observed -->
        <title>C.5.2</title>
        <!-- C.5.2: Study Name -->
        <authorization typeCode="AUTH">
            <studyRegistration classCode="ACT" moodCode="EVN">
                <id extension="C.5.1.r.1" root="2.16.840.1.113883.3.989.2.1.3.6"/>
                <!-- C.5.1.r.1: Study Registration Number #1 -->
                <author typeCode="AUT">
                    <territorialAuthority classCode="TERR">
                        <governingPlace classCode="COUNTRY" determinerCode="INSTANCE">
                            <code code="C.5.1.r.2" codeSystem="1.0.3166.1.2.2"/>
                            <!-- C.5.1.r.2: Study Registration Country #1 -->
                        </governingPlace>
                    </territorialAuthority>
                </author>
            </studyRegistration>
        </authorization>
        <authorization typeCode="AUTH">
            <studyRegistration classCode="ACT" moodCode="EVN">
                <id extension="C.5.1.r.1" root="2.16.840.1.113883.3.989.2.1.3.6"/>
                <!-- C.5.1.r.1 Study Registration Number #2 -->
                <author typeCode="AUT">
                    <territorialAuthority classCode="TERR">
                        <governingPlace classCode="COUNTRY" determinerCode="INSTANCE">
                            <code code="C.5.1.r.2" codeSystem="1.0.3166.1.2.2"/>
                            <!-- C.5.1.r.2: Study Registration Country #2 -->
                        </governingPlace>
                    </territorialAuthority>
                </author>
            </studyRegistration>
        </authorization>
    </researchStudy>
</subjectOf1>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="age"/>
        <value xsi:type="PQ" value="10" unit="D.2.2b"/>
        <!-- D.2.2a: Age at Time of Onset of Reaction / Event (number) -->
        <!-- D.2.2b: Age at Time of Onset of Reaction / Event (unit) -->
    </observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <code code="16" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
gestationPeriod"/>
        <value xsi:type="PQ" value="10" unit="D.2.2.1b"/>
        <!-- D.2.2.1a: Gestation Period When Reaction / Event Was Observed in the Foetus (number) -->
        <!-- D.2.2.1b: Gestation Period When Reaction / Event Was Observed in the Foetus (unit) -->
    </observation>
</subjectOf2>

```

```

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

```

```

        <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"/>

```

```

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

```

```

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>

```

```

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

```

```

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

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

```

```

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

```

```

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

```

```

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

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

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

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

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

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

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

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

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

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

```

```

<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>

```



```

</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
isLifeThreatening"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2b: Life Threatening #6 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
requiresInpatientHospitalization"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #6 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
resultsInPersistentOrSignificantDisability"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2d: Disabling / Incapacitating #6 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
congenitalAnomalyBirthDefect"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #6 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
otherMedicallyImportantCondition"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2f: Other Medically Important Condition #6 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
outcome"/>
    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="2.
0"/>
    <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #6 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
medicalConfirmationByHealthProfessional"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.8: Medical Confirmation by Healthcare Professional #6 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
未知·既知"/>
    <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.1"/>
    <!-- @J2.14.i 未知·既知 #6 -->
  </observation>
</outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reaction"/>
    <effectiveTime xsi:type="IVL_TS">
      <width value="24" unit="E.i.6b"/>
      <!-- E.i.6a: Duration of Reaction / Event (number) #7 -->
      <!-- E.i.6b: Duration of Reaction / Event (unit) #7 -->
    </effectiveTime>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
      <!-- E.i.2.1a: MedDRA Version for Reaction / Event #7 -->
      <!-- E.i.2.1b: Reaction / Event (MedDRA code) #7 -->
      <originalText language="E.i.1.lb">E.i.1.1a</originalText>
      <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #7 -->
    </value>
  </observation>
</subjectOf2>

```

```

        <!-- 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>

```

```

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

```

```

</outboundRelationship2>
<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">

```

```

        <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 -->
    </observation>
</component>
displayname="comment"/>
displayname="moreInformationAvailable"/>

```

```

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

```

```

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

```

```

Event (number) Drug #1, Reaction #1 -->
Event (unit) Drug #1, Reaction #1 -->
Drug #1, Reaction #1 -->
Drug #1, Reaction #1 -->
Event (number) Drug #1, Reaction #2 -->
Event (unit) Drug #1, Reaction #2 -->
Drug #1, Reaction #2 -->
Drug #1, Reaction #2 -->
Event (number) Drug #1, Reaction #3 -->
Event (unit) Drug #1, Reaction #3 -->
Drug #1, Reaction #3 -->
Drug #1, Reaction #3 -->
Event (number) Drug #1, Reaction #4 -->
Event (unit) Drug #1, Reaction #4 -->
Drug #1, Reaction #4 -->
Drug #1, Reaction #4 -->
Event (number) Drug #1, Reaction #5 -->
Event (unit) Drug #1, Reaction #5 -->
<!-- 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 /
<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)
<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 /
<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)
<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 /
<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)
<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 /
<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)
<actReference classCode="OBS" moodCode="EVN">
  <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
</actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
<!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction /
<!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /

```



```

        <actReference classCode="OBS" moodCode="EVN">
            <id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
        </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAE">
        <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
        <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number)

Drug #1, Reaction #5 -->
        <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)

Drug #1, Reaction #5 -->
        <actReference classCode="OBS" moodCode="EVN">
            <id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
        </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAS">
        <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
        <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction /

Event (number) Drug #1, Reaction #6 -->
        <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /

Event (unit) Drug #1, Reaction #6 -->
        <actReference classCode="OBS" moodCode="EVN">
            <id root="1f927283-10b6-4334-9d43-e925640fb18f"/>
        </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAE">
        <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
        <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number)

Drug #1, Reaction #6 -->
        <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)

Drug #1, Reaction #6 -->
        <actReference classCode="OBS" moodCode="EVN">
            <id root="1f927283-10b6-4334-9d43-e925640fb18f"/>
        </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAS">
        <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
        <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction /

Event (number) Drug #1, Reaction #7 -->
        <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /

Event (unit) Drug #1, Reaction #7 -->
        <actReference classCode="OBS" moodCode="EVN">
            <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
        </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAE">
        <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
        <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number)

Drug #1, Reaction #7 -->
        <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)

Drug #1, Reaction #7 -->
        <actReference classCode="OBS" moodCode="EVN">
            <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
        </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAS">
        <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
        <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction /

Event (number) Drug #1, Reaction #8 -->
        <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /

Event (unit) Drug #1, Reaction #8 -->
        <actReference classCode="OBS" moodCode="EVN">
            <id root="a15be092-8070-426d-af04-6863263443e0"/>
        </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAE">
        <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
        <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number)

Drug #1, Reaction #8 -->
        <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)

Drug #1, Reaction #8 -->
        <actReference classCode="OBS" moodCode="EVN">
            <id root="a15be092-8070-426d-af04-6863263443e0"/>
        </actReference>
    </outboundRelationship1>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="6" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"

displayName="blinded"/>
            <value xsi:type="BL" value="true"/>
            <!-- G.k.2.5: Investigational Product Blinded #1 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="COMP">
        <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #1-1 -->

```

```

<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"
codeSystemVersion="G. k. 4. r. 10. 2a">
  <!-- G. k. 4. r. 10. 2a: Route of Administration TermID Version Date / Number #1-1 -->
  <!-- G. k. 4. r. 10. 2b: Route of Administration TermID #1-1 -->
  <originalText>G. k. 4. r. 10. 1</originalText>
  <!-- G. k. 4. r. 10. 1: Route of Administration (free text) #1-1 -->
</routeCode>
  <doseQuantity value="10" unit="G. k. 4. r. 1b"/>
  <!-- G. k. 4. r. 1a Dose (number) #1-1 -->
  <!-- G. k. 4. r. 1b: Dose (unit) #1-1 -->
  <consumable typeCode="CSM">
    <instanceOfKind classCode="INST">
      <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
        <lotNumberText>G. k. 4. r. 7</lotNumberText>
        <!-- G. k. 4. r. 7: Batch / Lot Number #1-1 -->
      </productInstanceInstance>
      <kindOfProduct classCode="MMAT" determinerCode="KIND">
        <formCode code="G. k. 4. r. 9. 2b" codeSystem="TBD-DoseForm" codeSystemVersion="G. k. 4.
r. 9. 2a">
          <!-- G. k. 4. r. 9. 2a: Pharmaceutical Dose Form TermID Version Date / Number #1-1
-->
          <!-- G. k. 4. r. 9. 2b: Pharmaceutical Dose Form TermID #1-1 -->
          <originalText>G. k. 4. r. 9. 1</originalText>
          <!-- G. k. 4. r. 9. 1: Pharmaceutical Dose Form (free text) #1-1 -->
        </formCode>
      </kindOfProduct>
    </instanceOfKind>
  </consumable>
  <inboundRelationship typeCode="REFR">
    <observation classCode="OBS" moodCode="EVN">
      <code code="28" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 19" codeSystemVersion="1. 1"
displayName="parentRouteOfAdministration"/>
      <value xsi:type="CE" code="G. k. 4. r. 11. 2b" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1.
14" codeSystemVersion="G. k. 4. r. 11. 2a">
        <!-- G. k. 4. r. 11. 2a: Parent Route of Administration TermID Version Date / Number
#1-1 -->
        <!-- G. k. 4. r. 11. 2b: Parent Route of Administration TermID #1-1 -->
        <originalText>G. k. 4. r. 11. 1</originalText>
        <!-- G. k. 4. r. 11. 1: Parent Route of Administration (free text) #1-1 -->
      </value>
    </observation>
  </inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G. k. 4. r. Dosage and Relevant Information (repeat as necessary) #1-2 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G. k. 4. r. 8</text>
    <!-- G. k. 4. r. 8: Dosage Text #1-2 -->
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <period value="10" unit="G. k. 4. r. 3"/>
        <!-- G. k. 4. r. 2: Number of Units in the Interval #1-2 -->
        <!-- G. k. 4. r. 3: Definition of the Time Interval Unit #1-2 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <low value="20090101"/>
        <!-- G. k. 4. r. 4: Date and Time of Start of Drug #1-2 -->
        <high value="20090101"/>
        <!-- G. k. 4. r. 5: Date and Time of Last Administration #1-2 -->
      </comp>
    </effectiveTime>
    <routeCode code="G. k. 4. r. 10. 2b" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 14"

```

```

codeSystemVersion="G.k.4.r.10.2a">
    <!-- 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"
displayName="parentRouteOfAdministration"/>
        <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.
14" codeSystemVersion="G.k.4.r.11.2a">
            <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number
#1-2 -->
            <!-- 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>
    </substanceAdministration>
    <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>

```

```

                <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">
                <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
                    <lotNumberText>G.k.4.r.7</lotNumberText>
                    <!-- G.k.4.r.7: Batch / Lot Number #1-4 -->
                </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 #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>

```

```

</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"
codeSystemVersion="G.k.4.r.10.2a">
      <!-- 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">
        <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
          <lotNumberText>G.k.4.r.7</lotNumberText>
          <!-- G.k.4.r.7: Batch / Lot Number #1-5 -->
        </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 #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"
displayName="parentRouteOfAdministration"/>
        <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.
14" codeSystemVersion="G.k.4.r.11.2a">
          <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number
#1-5 -->
          <!-- 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>

```

```

    </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 #1-6 -->
    <!-- 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">
      <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
        <lotNumberText>G.k.4.r.7</lotNumberText>
        <!-- G.k.4.r.7: Batch / Lot Number #1-1 -->
      </productInstanceInstance>
      <kindOfProduct classCode="MMAT" determinerCode="KIND">
        <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm" codeSystemVersion="G.k.4.
r.9.2a">
          <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-6
-->
          <!-- 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"
displayName="parentRouteOfAdministration"/>
      <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.
14" codeSystemVersion="G.k.4.r.11.2a">
        <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number
#1-6 -->
        <!-- 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"
codeSystemVersion="G.k.4.r.10.2a">
    <!-- 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">
      <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
        <lotNumberText>G.k.4.r.7</lotNumberText>
        <!-- G.k.4.r.7: Batch / Lot Number #1-7 -->
      </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 #1-7
-->

```

```

-->
                                <!-- 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"
displayName="parentRouteOfAdministration"/>
                                        <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.
14" codeSystemVersion="G.k.4.r.11.2a">
                                            <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number
#1-7 -->
                                            <!-- 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"
displayName="cumulativeDoseToReaction"/>
                                        <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"
displayName="gestationPeriod"/>
                                        <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"
displayName="recurrenceOfReaction"/>
                                        <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
codeSystemVersion="2.0"/>
                                        <!-- 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"
displayName="recurrenceOfReaction"/>
                                        <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
codeSystemVersion="2.0"/>
                                        <!-- 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"
displayName="codedDrugInformation"/>
                                        <value xsi:type="CE" code="G.k.10.r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"
codeSystemVersion="2.0"/>
                                        <!-- G.k.10.r: Additional Information on Drug (coded) (repeat as necessary) #1-1 -->
                                        </observation>
                                </outboundRelationship2>
                                <outboundRelationship2 typeCode="REFR">
                                    <observation classCode="OBS" moodCode="EVN">
                                        <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="codedDrugInformation"/>
                                        <value xsi:type="CE" code="G.k.10.r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"

```

```

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.2b" 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.2b" 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="SBADM" 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">

```



```

        <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"
codeSystemVersion="1. 1"/>
            <!-- @@J2. 5. k: 一般用医薬品等のリスク区分等 #2 -->
        </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"
codeSystemVersion="1. 0" displayName="新医薬品等の状況区分"/>
        <value xsi:type="CE" code="J2. 4. k" codeSystem="2. 16. 840. 1. 113883. 3. 989. 5. 1. 3.
2. 1. 3" codeSystemVersion="1. 1"/>
        <!-- @@J2. 4. k: 新医薬品等の状況区分 #2 -->
    </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.
2a"/>
        <!-- G. k. 2. 3. r. 2a: Substance / Specified Substance TermID Version Date / Number
#2-1 -->
        <!-- G. k. 2. 3. r. 2b Substance / Specified Substance TermID #2-1 -->
        <name>G. k. 2. 3. r. 1</name>
        <!-- G. k. 2. 3. r. 1: Substance / Specified Substance Name #2-1 -->
    </ingredientSubstance>
</ingredient>
<ingredient classCode="ACTI">
    <quantity>
        <numerator value="10" unit="G. k. 2. 3. r. 3b"/>
        <!-- G. k. 2. 3. r. 3a: Strength (number) #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.
2a"/>
        <!-- G. k. 2. 3. r. 2a: Substance / Specified Substance TermID Version Date/Number #2-
2 -->
        <!-- G. k. 2. 3. r. 2b Substance / Specified Substance TermID #2-2 -->
        <name>G. k. 2. 3. r. 1</name>
        <!-- G. k. 2. 3. r. 1: Substance / Specified Substance Name #2-2 -->
    </ingredientSubstance>
</ingredient>
</kindOfProduct>
<subjectOf typeCode="SBJ">
    <productEvent classCode="ACT" moodCode="EVN">
        <code code="1" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 18" codeSystemVersion="1. 0"
displayName="retailSupply"/>
        <performer typeCode="PRF">
            <assignedEntity classCode="ASSIGNED">
                <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                    <addr>
                        <country>G. k. 2. 4</country>
                        <!-- G. k. 2. 4: Identification of the Country Where the Drug Was
Obtained #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" displayName="一般用医薬品の入手経路"/>
        <value xsi:type="CE" code="J2. 6. k" codeSystem="2. 16. 840. 1. 113883. 3. 989. 5. 1. 3. 2. 1. 5"
codeSystemVersion="1. 1"/>

```

```

                <!-- @J2.6.k: 一般用医薬品の入手経路 #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 /
Event (number) Drug #2, Reaction #1 -->
    <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /
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)
Drug #2, Reaction #1 -->
    <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)
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 /
Event (number) Drug #2, Reaction #2 -->
    <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /
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)
Drug #2, Reaction #2 -->
    <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)
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 /
Event (number) Drug #2, Reaction #3 -->
    <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /
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)
Drug #2, Reaction #3 -->
    <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)
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 /
Event (number) Drug #2, Reaction #4 -->
    <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction /
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)
Drug #2, Reaction #4 -->
    <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)
Drug #2, Reaction #4 -->
    <actReference classCode="OBS" moodCode="EVN">
        <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
    </actReference>
</outboundRelationship1>

```

```

</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-ce14bc279d8e"/>
  </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAE">
  <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
  <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number)
Drug #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-ce14bc279d8e"/>
  </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
  <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction /
Event (number) Drug #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"

```

```

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"
codeSystemVersion="G.k.4.r.10.2a">
            <!-- 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>
    </substanceAdministration>
    <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
#2-1 -->
                <!-- 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"
codeSystemVersion="G.k.4.r.10.2a">
            <!-- 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">

```

```

<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">
      #2-2 -->
      <!-- 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 #2-2 -->
      <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">
              #2-3 -->
              <!-- 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 #2-3 -->
              <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>

```

```

        </observation>
      </inboundRelationship>
    </substanceAdministration>
  </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="SXPRTS">
      <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 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 #2-4 -->
      <!-- G.k.4.r.10.2b: Route of Administration TermID #2-4 -->
      <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 -->
    <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 #2-4 -->
        </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 #2-4
-->
            <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-4 -->
            <originalText>G.k.4.r.9.1</originalText>
            <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-4 -->
          </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.
14" codeSystemVersion="G.k.4.r.11.2a">
        <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number
#2-4 -->
        <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-4 -->
        <originalText>G.k.4.r.11.1</originalText>
        <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-4 -->
      </value>
    </observation>
  </inboundRelationship>
</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="SXPRTS">
      <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 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 #2-5 -->
      <!-- G.k.4.r.10.2b: Route of Administration TermID #2-5 -->

```

```

        <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>
<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">
                <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>

```

```

</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"
#2-6 -->
      <!-- 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="PVL_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"
codeSystemVersion="G.k.4.r.10.2a"
    <!-- 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.
r.9.2a"
-->
        <!-- 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"
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"
#2-7 -->
      <!-- 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"
codeSystemVersion="G.k.4.r.10.2a"
    <!-- 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 -->
  </substanceAdministration>
</outboundRelationship2>

```



```

        <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">
                <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number
#2-8 -->
                <!-- 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">
            <!-- 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
-->
                    <!-- 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>

```

#2-9 -->

```

        <!-- 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">
                    <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
                        <lotNumberText>G.k.4.r.7</lotNumberText>
                        <!-- G.k.4.r.7: Batch / Lot Number #2-10 -->
                    </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-
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>
            <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
#2-10 -->
                        <!-- 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"

```

```

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"
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 #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"
displayName="codedDrugInformation"/>
codeSystemVersion="2.0"/>
<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">
    <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="codedDrugInformation"/>
codeSystemVersion="2.0"/>
<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"
displayName="additionalInformation"/>
<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"
displayName="indication"/>
"G.k.7.r.2a">
<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>
<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"/>
"G.k.7.r.2a">
<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">
  <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="2.16.840.1.113883.3.989.5.1.3.2.1.15" 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">
    <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 #2 -->
      </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 #2 -->
      </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 #2 -->
      </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="false"/>
          <!-- @@@J2.13.r.4: 投薬中の症例の有無 #2 -->
        </observation>
      </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">
  <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>
<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 #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">

```

```

        <adverseEffectReference classCode="OBS" moodCode="EVN">
          <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
        </adverseEffectReference>
      </subject1>
      <subject2 typeCode="SUBJ">
        <productUseReference classCode="SBADM" moodCode="EVN">
          <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
        </productUseReference>
      </subject2>
    </causalityAssessment>
  </component>
  <component typeCode="COMP">
    <causalityAssessment classCode="OBS" moodCode="EVN">
      <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" 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 #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">
          <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 #1 -->
          </code>
        </assignedEntity>
      </author>
      <subject1 typeCode="SUBJ">
        <adverseEffectReference classCode="OBS" moodCode="EVN">
          <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
        </adverseEffectReference>
      </subject1>
      <subject2 typeCode="SUBJ">
        <productUseReference classCode="SBADM" moodCode="EVN">
          <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
        </productUseReference>
      </subject2>
    </causalityAssessment>
  </component>
  <component typeCode="COMP">
    <causalityAssessment classCode="OBS" moodCode="EVN">
      <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" 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">
          <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
        </adverseEffectReference>
      </subject1>
      <subject2 typeCode="SUBJ">
        <productUseReference classCode="SBADM" moodCode="EVN">
          <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
        </productUseReference>
      </subject2>
    </causalityAssessment>
  </component>
  <component1 typeCode="COMP">
    <observationEvent classCode="OBS" moodCode="EVN">
      <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" 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">

```

```

<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">
    <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>
<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
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>
<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">

```

```

        <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">
        <code code="15" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="備考3"/>
        <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.r" root="2.16.840.1.113883.3.989.2.1.3.2"/>
            </controlActEvent>
        </subjectOf2>
    </relatedInvestigation>
</outboundRelationship>

```



```

        <!-- 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>

```

```

        <!-- 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"/>
                <!-- 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"/>

```

```

        <!-- 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>
</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: 受信名 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">
        <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>

```

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:h17-org:v3 MCCI_IN200100UV01.xsd" xmlns="urn:h17-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="2" 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>

```

```

    <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>
<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 #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">
      <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 #2 -->
            </location>
          </asLocatedEntity>
        </representedOrganization>
      </assignedEntity>
    </participation>
  </document>
</reference>
<component typeCode="COMP">
  <adverseEventAssessment classCode="INVSTG" moodCode="EVN">
    <subject1 typeCode="SBJ">
      <primaryRole classCode="INVSBJ">
        <player1 classCode="PSN" determinerCode="INSTANCE">
          <name>D.1</name>
          <!-- D.1: Patient (name or initials) -->
          <administrativeGenderCode code="D.5" codeSystem="1.0.5218"/>
          <!-- D.5 Sex -->
          <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>
          <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 -->
            </studyRegistration>
          </authorization>
        </researchStudy>
      </subjectOf1>
    </subject1>
  </adverseEventAssessment>
</component>

```

```

        <author typeCode="AUT">
            <territorialAuthority classCode="TERR">
                <governingPlace classCode="COUNTRY" determinerCode="INSTANCE">
                    <code code="C.5.1.r.2" codeSystem="1.0.3166.1.2.2"/>
                    <!-- C.5.1.r.2: Study Registration Country #2 -->
                </governingPlace>
            </territorialAuthority>
        </author>
    </studyRegistration>
</authorization>
</researchStudy>
</subjectOf1>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="age"/>
        <value xsi:type="PQ" value="10" unit="D.2.2b"/>
        <!-- D.2.2a: Age at Time of Onset of Reaction / Event (number) -->
        <!-- D.2.2b: Age at Time of Onset of Reaction / Event (unit) -->
    </observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <code code="16" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="
gestationPeriod"/>
        <value xsi:type="PQ" value="10" unit="D.2.2.1b"/>
        <!-- D.2.2.1a: Gestation Period When Reaction / Event Was Observed in the Foetus (number) -->
        <!-- D.2.2.1b: Gestation Period When Reaction / Event Was Observed in the Foetus (unit) -->
    </observation>
</subjectOf2>
<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>

```

```

        <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>
</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">
                <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 -->

```



```

        <!-- 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>
</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 -->
        </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">
        <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">
            <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>

```

```

    </observation>
  </subjectOf2>
  <subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
      <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
      <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reaction"/>

      <effectiveTime xsi:type="SXPR_TS">
        <comp xsi:type="IVL_TS">
          <low value="20090101"/>
          <!-- E.i.4: Date of Start of Reaction / Event #4 -->
          <high value="20101201"/>
          <!-- E.i.5: Date of End of Reaction / Event #4 -->
        </comp>
        <comp xsi:type="IVL_TS" operator="A">
        </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>
    </observation>
  </subjectOf2>
  <subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
      <id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
      <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reaction"/>

      <effectiveTime xsi:type="IVL_TS">
        <low value="20090101"/>
        <!-- E.i.4: Date of Start of Reaction / Event #5 -->
      </effectiveTime>
      <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
        <!-- E.i.2.1a: MedDRA Version for Reaction / Event #5 -->
        <!-- E.i.2.1b: Reaction / Event (MedDRA code) #5 -->
        <originalText>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>
    </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>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>

```

```

    </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" />
                <!-- @J2.24.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>

```

```

        </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"
codeSystemVersion="1.0" displayName="新医薬品等の状況区分"/>
        <value xsi:type="CE" code="J2.4.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.
2.1.3" codeSystemVersion="1.1"/>
        <!-- @@@J2.4.k: 新医薬品等の状況区分 #1 -->
    </characteristic>
</subjectOf>
</asManufacturedProduct>
<asNamedEntity>
    <name xml:lang="ja">J2.23.k</name>
    <!-- @@@J2.23.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"
codeSystemVersion="1.0" />
                <!-- @@@J2.25.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"
codeSystemVersion="1.0" />
                <!-- @@@J2.25.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">

```

```

        <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>
</outboundRelationship2>

```

```

</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) #1-1 -->
    <!-- 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) #1-7 -->
  <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"
displayName="recurrenceOfReaction"/>
codeSystemVersion="2.0"/>

```

```

        <!-- 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"
displayName="recurrenceOfReaction"/>
        <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
codeSystemVersion="2.0"/>
    </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"
codeSystemVersion="1.0" />
                    <!-- @@J2.24.k 製品種別 #2 -->
                    <asManufacturedProduct classCode="MANU">
                        <subjectOf typeCode="SBJ">
                            <approval classCode="NTRCT" 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"
codeSystemVersion="1.0" displayName="新医薬品等の状況区分"/>
                            <value xsi:type="CE" code="J2.4.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.
2.1.3" codeSystemVersion="1.1"/>
                            <!-- @@J2.4.k: 新医薬品等の状況区分 #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 -->
            </ingredientSubstance>
        </ingredient>
    </substanceAdministration>
</component>

```

```

        <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"
codeSystemVersion="1.0" />
                <!-- @@@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"
codeSystemVersion="1.0" />
                    <!-- @@@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>

```



```

</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>
    </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>

```

```

        <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"
          displayName="recurrenceOfReaction"/>
        <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
          codeSystemVersion="2.0"/>
        <!-- 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"
          displayName="recurrenceOfReaction"/>
        <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
          codeSystemVersion="2.0"/>
        <!-- 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>
</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>
<component1 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>
<component1 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>
<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
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>
<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>
  </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>
        </controlActEvent>
      </subjectOf2>
    </relatedInvestigation>
  </outboundRelationship>

```

```

        </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" />
                <!-- @J2.27.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"/>
                <!-- @J2.29.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>
      </assignedEntity>
    </author>
  </controlActEvent>
</subjectOf1>

```

```

    </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: 受信名 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">

```

```

    <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>

```