

XML参照インスタンス (個別症例安全性報告)

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<?xml version="1.0" encoding="UTF-8"?>
<MCCI_IN200100UV01 ITSVersion="XML_1.0" xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd" xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  <id extension="N.1.2" root="2.16.840.1.113883.3.989.2.1.3.22"/>
  <!-- N.1.2: Batch Number -->
  <creationTime value="20101214151617"/>
  <!-- N.1.5: Date of Batch Transmission -->
  <responseModeCode code="D"/>
  <interactionId extension="MCCI_IN200100UV01" root="2.16.840.1.113883.1.6"/>
  <name code="N.1.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.1"/>
  <!-- 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.</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" 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" 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>
        </investigationEvent>
      </subject>
    </controlActProcess>
  </PORR_IN049016UV>
</MCCI_IN200100UV01>

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<reference typeCode="REFR">
  <document classCode="DOC" moodCode="EVN">
    <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" displayName="literatureReference"/>
    <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 -->
    <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" 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" 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" 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" displayName="Hospital Record"/>
          </asIdentifiedEntity>
          <asIdentifiedEntity classCode="IDENT">

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<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" 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" 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" 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" 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" 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" 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" 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" displayName="continuing"/>
              <value xsi:type="BL" value="true"/>
              <!-- D.10.7.1.r.3: Continuing #1 -->
            </observation>
          </inboundRelationship>
        </component>
      </organizer>
    </subjectOf2>
  <observation classCode="OBS" moodCode="EVN">

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<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" 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" 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" 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" 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" 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" 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>
  </subjectOf2>
</component typeCode="COMP">

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

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    </authorization>
  </researchStudy>
</subjectOf1>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="age"/>
    <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" 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" displayName="ageGroup"/>
    <value xsi:type="CE" code="D.2.3" codeSystem="2.16.840.1.113883.3.989.2.1.1.9"/>
    <!-- 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" 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" 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" 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" 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" displayName="comment"/>
            <value xsi:type="BD">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" displayName="familyHistory"/>
            <value xsi:type="BL" value="true"/>
            <!-- D.7.1.r.6: Family History #1 -->
          </observation>
        </outboundRelationship2>
      </component>
    </organizer>
  </subjectOf2>

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<inboundRelationship typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="continuing"/>
    <value xsi:type="BL" value="true"/>
    <!-- D.7.1.r.3: Continuing #1 -->
  </observation>
</inboundRelationship>
</observation>
</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>
    <outboundRelationship2 typeCode="COMP">
      <observation classCode="OBS" moodCode="EVN">
        <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="comment"/>
        <value xsi:type="ED">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" 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" 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" 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" 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" 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 -->
            </kindOfProduct>
          </instanceOfKind>
        </consumable>
      </substanceAdministration>
    </component>
  </organizer>
</subjectOf2>

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        <!-- 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" 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" 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" displayName="indication"/>
                <value xsi:type="CE" code="D.8.r.6b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.8.r.6a"/>
                <!-- D.8.r.6a: MedDRA Version for Indication #2 -->
                <!-- D.8.r.6b: Indication (MedDRA code) #2 -->
            </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="CAUS">
            <observation classCode="OBS" moodCode="EVN">
                <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="reaction"/>
                <value xsi:type="CE" code="D.8.r.7b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.8.r.7a"/>
                <!-- D.8.r.7a: MedDRA Version for Reaction #2 -->
                <!-- D.8.r.7b: Reaction (MedDRA code) #2 -->
            </observation>
        </outboundRelationship2>
    </substanceAdministration>
</component>
</organizer>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <code code="32" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="reportedCauseOfDeath"/>
        <value xsi:type="CE" code="D.9.2.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.9.2.r.1a">
            <!-- D.9.2.r.1a: MedDRA Version for Reported Cause(s) of Death #1 -->
            <!-- D.9.2.r.1b: Reported Cause(s) of Death (MedDRA code) #1 -->
            <originalText>D.9.2.r.2</originalText>
            <!-- D.9.2.r.2: Reported Cause(s) of Death (free text) #1 -->
        </value>
    </observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">

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<observation classCode="OBS" moodCode="EVN">
  <code code="32" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="reportedCauseOfDeath"/>
  <value xsi:type="CE" code="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" displayName="autopsy"/>
    <value xsi:type="BL" value="true"/>
    <!-- D.9.3 Was Autopsy Done? -->
  </observation>
  <outboundRelationship2 typeCode="DRIV">
    <observation classCode="OBS" moodCode="EVN">
      <code code="8" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="causeOfDeath"/>
      <value xsi:type="CE" code="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" 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>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="reaction"/>
    <effectiveTime xsi:type="IVL_TS">
      <low value="20090101"/>
      <!-- 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" 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" displayName="termHighlightedByReporter"/>
        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"/>
      </observation>
    </outboundRelationship2>
  </observation>

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    <!-- 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" 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" 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" 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" 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" 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" 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" displayName="outcome"/>
    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"/>
    <!-- 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" 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" 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"/>
    <!-- @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" displayName="reaction"/>
    <effectiveTime xsi:type="IVL_TS">
      <low value="20090101"/>
      <!-- E.i.4: Date of Start of Reaction / Event #2 -->
    </effectiveTime>
  </observation>

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<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" 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" displayName="termHighlightedByReporter"/>
    <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"/>
    <!-- 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" 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" 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" 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" 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" 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" displayName="otherMedicallyImportantCondition"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2f: Other Medically Important Condition #2 -->
  </observation>
</outboundRelationship2>

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<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="outcome"/>
    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"/>
    <!-- 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" 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" displayName="未知·已知"/>
    <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"/>
    <!-- @@@J2.14.i 未知·已知 #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" 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" 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" displayName="termHighlightedByReporter"/>
        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"/>
        <!-- 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" 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" displayName="isLifeThreatening"/>
        <value xsi:type="BL" nullFlavor="NI"/>
        <!-- E.i.3.2b: Life Threatening #3 -->
      </observation>
    </outboundRelationship2>
  </subjectOf2>

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    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="requiresInpatientHospitalization"/>
      <value xsi:type="BL" value="true"/>
      <!-- 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" displayName="resultsInPersistentOrSignificantDisability"/>
      <value xsi:type="BL" nullFlavor="NI"/>
      <!-- E.i.3.2d: Disabling / Incapacitating #3 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="congenitalAnomalyBirthDefect"/>
      <value xsi:type="BL" nullFlavor="NI"/>
      <!-- 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" 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" displayName="outcome"/>
      <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"/>
      <!-- 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" 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" 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"/>
      <!-- @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" 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 -->
    </value>
  </observation>

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    <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #4 -->
  </value>
  <location typeCode="LOC">
    <locatedEntity classCode="LOCE">
      <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
        <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
        <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #4 -->
      </locatedPlace>
    </locatedEntity>
  </location>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" 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" displayName="termHighlightedByReporter"/>
      <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"/>
      <!-- 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" 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" 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" 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" 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" 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" 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" displayName="outcome"/>
      <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"/>
      <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #4 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">

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    <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" 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" 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"/>
    <!-- 000J2.14.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" 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" 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" displayName="termHighlightedByReporter"/>
        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"/>
        <!-- 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" 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" 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" 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" displayName="resultsInPersistentOrSignificantDisability"/>

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    <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" 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" 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" displayName="outcome"/>
    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"/>
    <!-- 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" 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" 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"/>
    <!-- @J2.14.i 未知·既知 #5 -->
  </observation>
</outboundRelationship2>
</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" 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" 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" displayName="termHighlightedByReporter"/>
        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"/>

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    <!-- 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" 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" 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" 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" 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" 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" 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" displayName="outcome"/>
    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"/>
    <!-- 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" 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" 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"/>
    <!-- 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-cel4bc279d8e"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="reaction"/>
    <effectiveTime xsi:type="IVL_TS">
      <width value="24" unit="E.i.6b"/>
      <!-- E.i.6a: Duration of Reaction / Event (number) #7 -->
    </effectiveTime>
  </observation>

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<!-- E.i.6b: Duration of Reaction / Event (unit) #7 -->
</effectiveTime>
<value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
  <!-- E.i.2.1a: MedDRA Version for Reaction / Event #7 -->
  <!-- E.i.2.1b: Reaction / Event (MedDRA code) #7 -->
  <originalText language="E.i.1.1b">E.i.1.1a</originalText>
  <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #7 -->
  <!-- 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" 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" displayName="termHighlightedByReporter"/>
    <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"/>
    <!-- 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" 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" 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" 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" 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" 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" 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">

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    <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="outcome"/>
    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"/>
    <!-- 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" 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" 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"/>
    <!-- @@@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" 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" 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" displayName="termHighlightedByReporter"/>
        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"/>
        <!-- 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" displayName="resultsInDeath"/>
        <value xsi:type="BL" value="true"/>
        <!-- E.i.3.2a: Results in Death #8 -->
      </observation>
    </outboundRelationship2>
  </subjectOf2>
</outboundRelationship2 typeCode="PERT">

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<observation classCode="OBS" moodCode="EVN">
  <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="isLifeThreatening"/>
  <value xsi:type="BL" nullFlavor="NI"/>
  <!-- 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" 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" 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" 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" 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" displayName="outcome"/>
    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"/>
    <!-- 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" 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" 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"/>
    <!-- @@@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" 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>
      </observation>
    </component>
  </organizer>
</subjectOf2>

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<interpretationCode code="F.r.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.12"/>
<!-- 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" displayName="comment"/>
    <value xsi:type="ED">F.r.6</value>
    <!-- F.r.6: Comments (free text) #1 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="25" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="moreInformationAvailable"/>
    <value xsi:type="BL" value="true"/>
    <!--F.r.7: More Information Available #1 -->
  </observation>
</outboundRelationship2>
</observation>
</component>
<component typeCode="COMP">
  <observation classCode="OBS" moodCode="EVN">
    <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
      <!-- F.r.2.2a: MedDRA Version for Test Name #2 -->
      <!-- F.r.2.2b: Test Name (MedDRA code) #2 -->
      <originalText>F.r.2.1</originalText>
      <!-- F.r.2.1: Test Name (free text) #2 -->
    </code>
    <effectiveTime value="20090101"/>
    <!-- F.r.1: Test Date #2 -->
    <value xsi:type="IVL_PQ">
      <low nullFlavor="NINF"/>
      <high value="10" unit="mg/dl" inclusive="false"/>
    </value>
    <!-- F.r.3.2: Test Result (value / qualifier) #2 -->
    <!-- F.r.3.3: Test Result (unit) #2 -->
    <!-- LT 10 mg/dl #2 -->
  </observation>
</component>
<component typeCode="COMP">
  <observation classCode="OBS" moodCode="EVN">
    <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
      <!-- F.r.2.2a: MedDRA Version for Test Name #3 -->
      <!-- F.r.2.2b: Test Name (MedDRA code) #3 -->
      <originalText>F.r.2.1</originalText>
      <!-- F.r.2.1: Test Name (free text) #3 -->
    </code>
    <effectiveTime value="20090101"/>
    <!-- F.r.1: Test Date #3 -->
    <value xsi:type="IVL_PQ">
      <low nullFlavor="NINF"/>
      <high value="10" unit="mg/dl" inclusive="true"/>
    </value>
    <!-- F.r.3.2: Test Result (value / qualifier) #3 -->
    <!-- F.r.3.3: Test Result (unit) #3 -->
    <!-- LE 10 mg/dl #3-->
  </observation>
</component>
<component typeCode="COMP">
  <observation classCode="OBS" moodCode="EVN">
    <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
      <!-- F.r.2.2a: MedDRA Version for Test Name #4 -->
      <!-- F.r.2.2b: Test Name (MedDRA code) #4 -->
    </code>

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    <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 -->
  <!-- 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" 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">
              <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 -->
                  <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>
                    </author>
                  </approval>
                </subjectOf>
              </asManufacturedProduct>
            </instanceOfKind>
          </consumable>
        </substanceAdministration>
      </component>
    </organizer>
  </subjectOf2>
</subjectOf2>

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    </territorialAuthority>
  </author>
  <pertinentInformation typeCode="PERT">
    <policy classCode="POLICY" moodCode="EVN">
      <code code="J2.5.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.4"/>
      <!-- @@@J2.5.k: 一般用医薬品等のリスク区分等 #1 -->
    </policy>
  </pertinentInformation>
</approval>
</subjectOf>
<subjectOf typeCode="SBJ">
  <characteristic classCode="OBS" moodCode="EVN">
    <code code="I" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" displayName="新医薬品等の状況区分"/>
    <value xsi:type="CB" code="J2.4.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.3"/>
    <!-- @@@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="I" codeSystem="2.16.840.1.113883.3.989.2.1.1.18" 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" displayName="一般用医薬品の入手経路"/>

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        <value xsi:type="CE" code="J2.6.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.5"/>
        <!-- 000J2.6.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"/>
    <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number) Drug #1,
Reaction #1 -->
    <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit) Drug #1,
Reaction #1 -->
    <actReference classCode="OBS" moodCode="EVN">
    <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
    </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAE">
    <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
    <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number) Drug #1, Reaction #1 --
>
    <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit) Drug #1, Reaction #1 -->
    <actReference classCode="OBS" moodCode="EVN">
    <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
    </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAS">
    <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
    <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number) Drug #1,
Reaction #2 -->
    <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit) Drug #1,
Reaction #2 -->
    <actReference classCode="OBS" moodCode="EVN">
    <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
    </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAE">
    <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
    <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number) Drug #1, Reaction #2 --
>
    <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit) Drug #1, Reaction #2 -->
    <actReference classCode="OBS" moodCode="EVN">
    <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
    </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAS">
    <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
    <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number) Drug #1,
Reaction #3 -->
    <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit) Drug #1,
Reaction #3 -->
    <actReference classCode="OBS" moodCode="EVN">
    <id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430adf"/>
    </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAE">
    <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
    <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number) Drug #1, Reaction #3 --
>
    <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit) Drug #1, Reaction #3 -->
    <actReference classCode="OBS" moodCode="EVN">
    <id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430adf"/>
    </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAS">
    <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
    <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number) Drug #1,
Reaction #4 -->
    <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit) Drug #1,
Reaction #4 -->
    <actReference classCode="OBS" moodCode="EVN">
    <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
    </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAE">
    <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>

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<!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event (number) Drug #1, Reaction #4 --
>
<!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event (unit) Drug #1, Reaction #4 -->
<actReference classCode="OBS" moodCode="EVN">
  <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
</actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
<!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number) Drug #1,
Reaction #5 -->
<!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit) Drug #1,
Reaction #5 -->
<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">

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<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" 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>
  </substanceAdministration>
  <inboundRelationship typeCode="REFR">
    <observation classCode="OBS" moodCode="EVN">
      <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="parentRouteOfAdministration"/>
      <value xsi:type="CE" code="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>

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</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.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" 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 -->
      </comp>
    </effectiveTime>
  </substanceAdministration>
</outboundRelationship2>

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<!-- G.k.4.r.6b: Duration of Drug Administration (unit) #1-3 -->
</comp>
</effectiveTime>
<routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14" codeSystemVersion="G.k.4.r.10.2a">
  <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #1-3 -->
  <!-- G.k.4.r.10.2b: Route of Administration TermID #1-3 -->
  <originalText>G.k.4.r.10.1</originalText>
  <!-- G.k.4.r.10.1: Route of Administration (free text) #1-3 -->
</routeCode>
<doseQuantity value="10" unit="G.k.4.r.1b"/>
<!-- G.k.4.r.1a Dose (number) #1-3 -->
<!-- G.k.4.r.1b: Dose (unit) #1-3 -->
<consumable typeCode="CSM">
  <instanceOfKind classCode="INST">
    <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
      <lotNumberText>G.k.4.r.7</lotNumberText>
      <!-- G.k.4.r.7: Batch / Lot Number #1-3 -->
    </productInstanceInstance>
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
      <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm" codeSystemVersion="G.k.4.r.9.2a">
        <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-3 -->
        <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #1-3 -->
        <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" 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 #1-3 -->
      <!-- 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>
  </substanceAdministration>
</outboundRelationship2>
<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 #1-4 -->
  <!-- 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>
  </instanceOfKind>
</consumable>
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</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 #1-4 -->
    <!-- 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" 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 #1-4 -->
      <!-- 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>
  </substanceAdministration>
  <inboundRelationship typeCode="REFR">
    <observation classCode="OBS" moodCode="EVN">
      <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="parentRouteOfAdministration"/>
      <value xsi:type="CE" code="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 -->
      </value>
    </observation>
  </inboundRelationship>
</outboundRelationship2>
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        <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>
        <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" 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">

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<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">
    <productInstance classCode="MMAT" determinerCode="INSTANCE">
      <lotNumberText>G.k.4.r.7</lotNumberText>
      <!-- G.k.4.r.7: Batch / Lot Number #1-7 -->
    </productInstance>
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
      <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm" codeSystemVersion="G.k.4.r.9.2a">
        <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-7 -->
        <!-- 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" 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.
    <!-- 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" 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" 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" displayName="recurrenceOfReaction"/>
    <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"/>
    <!-- G.k.9.i.4: Did Reaction Recur on Re-administration? Drug #1, Reaction #1 -->
  </observation>
  <outboundRelationship1 typeCode="REFR">
    <actReference classCode="OBS" moodCode="EVN">
      <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>

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    </actReference>
  </outboundRelationship1>
</observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="recurrenceOfReaction"/>
    <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"/>
    <!-- G.k.9.i.4: Did Reaction Recur on Re-administration? Drug #1, Reaction #2 -->
    <outboundRelationship1 typeCode="REFR">
      <actReference classCode="OBS" moodCode="EVN">
        <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
      </actReference>
    </outboundRelationship1>
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="codedDrugInformation"/>
    <value xsi:type="CE" code="G.k.10.r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"/>
    <!-- G.k.10.r: Additional Information on Drug (coded) (repeat as necessary) #1-1 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="codedDrugInformation"/>
    <value xsi:type="CE" code="G.k.10.r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"/>
    <!-- G.k.10.r: Additional Information on Drug (coded) (repeat as necessary) #1-2 -->
  </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" 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" 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" displayName="sourceReporter"/>
      </assignedEntity>
    </performer>
  </observation>
</inboundRelationship>
<inboundRelationship typeCode="RSON">
  <observation classCode="OBS" moodCode="EVN">
    <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="indication"/>
    <value xsi:type="CE" code="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" 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"/>
    <!-- G.k.8: Action(s) Taken with Drug #1 -->
  </act>
</inboundRelationship>

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    </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 -->
                  <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"/>
                      <!-- @@@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" 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"/>
                <!-- @@@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">
  </component>

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<productEvent classCode="ACT" moodCode="EVN">
  <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.18" displayName="retailSupply"/>
  <performer typeCode="PRF">
    <assignedEntity classCode="ASSIGNED">
      <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" 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"/>
    <!-- 000J2.6.k: 一般用医薬品の入手経路 #2 -->
  </observationEvent>
</subjectOf>
</instanceOfKind>
</consumable>
<outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
  <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction / 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 -->

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    <!-- 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 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 --

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    <!-- 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" 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>
    </inboundRelationship typeCode="REFR">
      <observation classCode="OBS" moodCode="EVN">
        <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="parentRouteOfAdministration"/>
        <value xsi:type="CE" code="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 -->
        </value>
      </observation>
    </inboundRelationship>
  </outboundRelationship2>

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        <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">
                <productInstance classCode="MMAT" determinerCode="INSTANCE">
                    <lotNumberText>G.k.4.r.7</lotNumberText>
                    <!-- G.k.4.r.7: Batch / Lot Number #2-2 -->
                </productInstance>
                <kindOfProduct classCode="MMAT" determinerCode="KIND">
                    <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm" codeSystemVersion="G.k.4.r.9.2a">
                        <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-2 -->
                        <!-- 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>
    </substanceAdministration typeCode="REFR">
        <observation classCode="OBS" moodCode="EVN">
            <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="parentRouteOfAdministration"/>
            <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14" codeSystemVersion="G.k.4.r.
11.2a">
                <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-2 -->
                <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-2 -->
                <originalText>G.k.4.r.11.1</originalText>
                <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-2 -->
            </value>
        </observation>
    </inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
    <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #2-3 -->
    <substanceAdministration classCode="SBADM" moodCode="EVN">
        <text>G.k.4.r.8</text>
        <!-- G.k.4.r.8: Dosage Text #2-3 -->
        <effectiveTime xsi:type="IVL_TS">
            <width value="4" unit="G.k.4.r.6b"/>
            <!-- G.k.4.r.6a: Duration of Drug Administration (number) #2-3 -->
            <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #2-3 -->
            <high value="20090101"/>
            <!-- G.k.4.r.5: Date and Time of Last Administration #2-3 -->
        </effectiveTime>
        <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14" codeSystemVersion="G.k.4.r.10.2a">
            <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-3 -->
            <!-- G.k.4.r.10.2b: Route of Administration TermID #2-3 -->
            <originalText>G.k.4.r.10.1</originalText>
            <!-- G.k.4.r.10.1: Route of Administration (free text) #2-3 -->
        </routeCode>
    </substanceAdministration>

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</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" displayName="parentRouteOfAdministration"/>
    <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14" codeSystemVersion="G.k.4.r.
11.2a">
      <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-3 -->
      <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-3 -->
      <originalText>G.k.4.r.11.1</originalText>
      <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-3 -->
    </value>
  </observation>
</inboundRelationship>
</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 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 -->
  </substanceAdministration>
  <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>
</outboundRelationship2>
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<inboundRelationship typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="parentRouteOfAdministration"/>
    <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14" codeSystemVersion="G.k.4.r.
      <!-- 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="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 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>
  </substanceAdministration>
  <inboundRelationship typeCode="REFR">
    <observation classCode="OBS" moodCode="EVN">
      <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="parentRouteOfAdministration"/>
      <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14" codeSystemVersion="G.k.4.r.
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<!-- 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">
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<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" 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.
      <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-6 -->
      <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-6 -->
      <originalText>G.k.4.r.11.1</originalText>
      <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-6 -->
    </value>
  </observation>
</inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-7 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-7 -->
    <effectiveTime xsi:type="PIVL_TS">
      <period value="10" unit="G.k.4.r.3"/>
      <!-- G.k.4.r.2: Number of Units in the Interval #2-7 -->
      <!-- G.k.4.r.3: Definition of the Time Interval Unit #2-7 -->
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14" 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>
      </instanceOfKind>
    </consumable>
  </substanceAdministration>
</outboundRelationship2>

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<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" 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 #2-7 -->
      <!-- 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 -->
      <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>
  </substanceAdministration typeCode="REFR">
    <observation classCode="OBS" moodCode="EVN">
      <code code="28" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 19" displayName="parentRouteOfAdministration"/>
      <value xsi:type="CE" code="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">
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<text>G.k.4.r.8</text>
<!-- G.k.4.r.8: Dosage Text #2-9 -->
<effectiveTime xsi:type="IVL_TS">
  <high value="20090101"/>
  <!-- G.k.4.r.5: Date and Time of Last Administration #2-9 -->
</effectiveTime>
<routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14" codeSystemVersion="G.k.4.r.10.2a">
  <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-9 -->
  <!-- G.k.4.r.10.2b: Route of Administration TermID #2-9 -->
  <originalText>G.k.4.r.10.1</originalText>
  <!-- G.k.4.r.10.1: Route of Administration (free text) #2-9 -->
</routeCode>
<doseQuantity value="10" unit="G.k.4.r.1b"/>
<!-- G.k.4.r.1a Dose (number) #2-9 -->
<!-- G.k.4.r.1b: Dose (unit) #2-9 -->
<consumable typeCode="CSM">
  <instanceOfKind classCode="INST">
    <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
      <lotNumberText>G.k.4.r.7</lotNumberText>
      <!-- G.k.4.r.7: Batch / Lot Number #2-9 -->
    </productInstanceInstance>
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
      <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm" codeSystemVersion="G.k.4.r.9.2a">
        <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-9 -->
        <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-9 -->
        <originalText>G.k.4.r.9.1</originalText>
        <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-9 -->
      </formCode>
    </kindOfProduct>
  </instanceOfKind>
</consumable>
<inboundRelationship typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" 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.
      <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #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>
          </formCode>
        </kindOfProduct>
      </instanceOfKind>
    </consumable>
  </substanceAdministration>
</outboundRelationship2>

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<!-- 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" 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" 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" 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" displayName="recurrenceOfReaction"/>
    <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" displayName="recurrenceOfReaction"/>
    <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" displayName="codedDrugInformation"/>
    <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" displayName="codedDrugInformation"/>
    <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">
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<code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" 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" 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 #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" displayName="sourceReporter"/>
      </assignedEntity>
    </performer>
  </observation>
</inboundRelationship>
<inboundRelationship typeCode="RSON">
  <observation classCode="OBS" moodCode="EVN">
    <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="indication"/>
    <value xsi:type="CE" code="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 #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" 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"/>
    <!-- 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" 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" 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" 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" 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"/>
        <!-- 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" displayName="投薬中の症例の有無"/>
        <value xsi:type="BL" value="true"/>
      </observation>
    </component>
  </organizer>

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    <!-- 000J2.13.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" 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" displayName="届出回数"/>
        <value xsi:type="INT" value="1"/>
        <!-- 000J2.13.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" displayName="対象疾患"/>
        <value xsi:type="ED">J2.13.r.2</value>
        <!-- 000J2.13.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" 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"/>
        <!-- 000J2.13.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" displayName="投薬中の症例の有無"/>
        <value xsi:type="BL" value="false"/>
        <!-- 000J2.13.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" displayName="interventionCharacterization"/>
    <value xsi:type="CE" code="G.k.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.13"/>
    <!-- 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" displayName="interventionCharacterization"/>
    <value xsi:type="CE" code="G.k.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.13"/>
    <!-- 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" 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">

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    <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" 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" 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>

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</component>
<component typeCode="COMP">
  <causalityAssessment classCode="OBS" moodCode="EVN">
    <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="causality"/>
    <value xsi:type="ST">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" 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" displayName="sourceReporter"/>
      </assignedEntity>
    </author>
  </observationEvent>
</component1>
<component1 typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="15" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="diagnosis"/>
    <value xsi:type="CE" code="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" displayName="sender"/>
      </assignedEntity>
    </author>
  </observationEvent>
</component1>
<component1 typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="15" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="diagnosis"/>
    <value xsi:type="CE" code="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" displayName="sender"/>
      </assignedEntity>
    </author>
  </observationEvent>
</component1>
<component1 typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="comment"/>
    <value xsi:type="ED">H.4</value>
    <!-- H.4: Sender's Comments -->
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">

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        <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" displayName="sender"/>
      </assignedEntity>
    </author>
  </observationEvent>
</component1>
<component1 typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" 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" 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" 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" 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" 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" 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" 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" 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" 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" displayName="additionalDocumentsAvailable"/>
    <value xsi:type="BL" value="true"/>
    <!-- C.1.6.1: Are Additional Documents Available? -->
  </observationEvent>

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</observationEvent>
</component>
<component typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="23" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="localCriteriaForExpedited"/>
    <value xsi:type="BL" value="true"/>
    <!-- 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" 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" 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" 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" displayName="reporter"/>
      </assignedEntity>
    </author>
  </observationEvent>
</component>
<outboundRelationship typeCode="SPRT">
  <relatedInvestigation classCode="INVSTG" moodCode="EVN">
    <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" displayName="initialReport"/>
    <subjectOf2 typeCode="SUBJ">
      <controlActEvent classCode="CACT" moodCode="EVN">
        <author typeCode="AUT">
          <assignedEntity classCode="ASSIGNED">
            <code code="C.1.8.2" codeSystem="2.16.840.1.113883.3.989.2.1.1.3"/>
            <!-- 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">
  <priorityNumber value="1"/>
  <!-- C.2.r.5: Primary Source for Regulatory Purposes #1 -->

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<relatedInvestigation classCode="INVSTG" moodCode="EVN">
  <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" displayName="sourceReport"/>
  <subjectOf2 typeCode="SUBJ">
    <controlActEvent classCode="CACT" moodCode="EVN">
      <author typeCode="AUT">
        <assignedEntity classCode="ASSIGNED">
          <addr>
            <streetAddressLine>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"/>
              <!-- 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" 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 -->
          </assignedEntity>
        </author>
      </controlActEvent>
    </subjectOf2>
  </relatedInvestigation>
</outboundRelationship>

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<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"/>
    <!-- C.2.r.4: Qualification #2 -->
  </asQualifiedEntity>
  <asLocatedEntity classCode="LOCE">
    <location classCode="COUNTRY" determinerCode="INSTANCE">
      <code code="C.2.r.3" codeSystem="1.0.3166.1.2.2"/>
      <!-- C.2.r.3: Reporter's Country Code #2 -->
    </location>
  </asLocatedEntity>
</assignedPerson>
<representedOrganization classCode="ORG" determinerCode="INSTANCE">
  <name>C.2.r.2.2</name>
  <!-- C.2.r.2.2: Reporter's Department #2 -->
  <assignedEntity classCode="ASSIGNED">
    <representedOrganization classCode="ORG" determinerCode="INSTANCE">
      <name>C.2.r.2.1</name>
      <!-- C.2.r.2.1: Reporter's Organisation #2 -->
    </representedOrganization>
  </assignedEntity>
</representedOrganization>
</assignedEntity>
</author>
</controlActEvent>
</subjectOf2>
</relatedInvestigation>
</outboundRelationship>
<subjectOf1 typeCode="SUBJ">
  <controlActEvent classCode="CACT" moodCode="EVN">
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code code="C.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.7"/>
        <!-- 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 -->
        </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 -->
      </assignedEntity>
      <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>
    </author>
  </controlActEvent>
</subjectOf1>

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    </assignedPerson>
    <representedOrganization classCode="ORG" determinerCode="INSTANCE">
      <name>C.3.2</name>
      <!-- C.3.2: Sender's Organisation -->
    </representedOrganization>
  </assignedEntity>
</author>
<primaryInformationRecipient typeCode="PRCP">
  <assignedEntity classCode="ASSIGNED">
    <assignedPerson classCode="PSN" determinerCode="INSTANCE">
      <name>
        <prefix>J2.18.2</prefix>
        <!-- 000J2.18.2: 受信者 肩書き -->
        <family>J2.18.3</family>
        <!-- 000J2.18.3: 受信者 姓 -->
        <given>J2.18.4</given>
        <!-- 000J2.18.4: 受信名 名 -->
      </name>
    </assignedPerson>
    <representedOrganization classCode="ORG" determinerCode="INSTANCE">
      <name>J2.18.1</name>
      <!-- 000J2.18.1: 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" displayName="ichReportType"/>
    <value xsi:type="CE" code="C.1.3" codeSystem="2.16.840.1.113883.3.989.2.1.1.2"/>
    <!-- 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" 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" displayName="nullificationAmendmentCode"/>
    <value xsi:type="CE" code="C.1.11.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.5"/>
    <!-- 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" 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" 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"/>
  </investigationCharacteristic>
</subjectOf2>

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    <!-- 000J2.1a: 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" displayName="報告起算日"/>
    <value xsi:type="TS" value="20130107"/>
    <!-- 000J2.2.1: 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" displayName="報告起算日に関するコメント"/>
    <value xsi:type="ED">J2.2.2</value>
    <!-- 000J2.2.2: 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" displayName="即時報告フラグ"/>
    <value xsi:type="ED">J2.3</value>
    <!-- 000J2.3: 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" 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"/>
    <!-- 000J2.8.1: 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" displayName="報告対象外の理由"/>
    <value xsi:type="ED">J2.8.2</value>
    <!-- 000J2.8.2: 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 (研究報告)

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<?xml version="1.0" encoding="UTF-8"?>
<MCCI_IN200100UV01 ITSVersion="XML_1.0" xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd" xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  <id extension="N.1.2" root="2.16.840.1.113883.3.989.2.1.3.22"/>
  <!-- N.1.2: Batch Number -->
  <creationTime value="20101214151617"/>
  <!-- N.1.5: Date of Batch Transmission -->
  <responseModeCode code="D"/>
  <interactionId extension="MCCI_IN200100UV01" root="2.16.840.1.113883.1.6"/>
  <name code="N.1.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.1"/>
  <!-- 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"/>
          <!-- 000J2.1b: 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"/>
          <!-- 000J2.7.1 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="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" displayName="literatureReference"/>
              <title>J2.17.r</title>
              <!-- 000J2.17.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 -->
              <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"/>
                        <!-- 000J2.15.r 公表国 #1 -->
                      </location>
                    </asLocatedEntity>
                  </representedOrganization>
                </assignedEntity>
              </participation>
            </document>
          </reference>
        </investigationEvent>
      </subject>
    </controlActProcess>
  </PORR_IN049016UV>
</MCCI_IN200100UV01>
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    </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" 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"/>
        <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"/>
            <!-- 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">
      <organizer classCode="CATEGORY" moodCode="EVN">
        <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" displayName="drugInformation"/>
        <!-- G.k Drug(s) Information (repeat as necessary) #1 -->
      </organizer>
    </subjectOf2>
  </subject1>

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<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"/>
          <!-- 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 -->
                <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"/>
                    <!-- @@@J2.5.k: 一般用医薬品等のリスク区分等 #1 -->
                  </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" 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"/>
                <!-- @@@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">
            <ingredientSubstance classCode="MMAT" determinerCode="KIND">
              <code code="G.k.2.3.r.2b" codeSystem="TBD-Substance"/>
              <!-- 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">
            <ingredientSubstance classCode="MMAT" determinerCode="KIND">
              <code code="G.k.2.3.r.2b" codeSystem="TBD-Substance"/>
              <!-- 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>
      </instanceOfKind>
    </consumable>
  </substanceAdministration>
</component>

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</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" 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" 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" 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" 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"/>
        <!-- @@@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" 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" 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" 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" 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" 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"/>
        <!-- @@@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" 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>
<component1 typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="comment"/>
    <value xsi:type="ED">H.4</value>
    <!-- H.4: Sender's Comments -->
  </observationEvent>

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    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" displayName="sender"/>
      </assignedEntity>
    </author>
  </observationEvent>
</component1>
<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" 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" 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" 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" 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="23" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" 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" 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"/>
            <!-- 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">

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      <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>
<subjectOf1 typeCode="SUBJ">
  <controlActEvent classCode="CACT" moodCode="EVN">
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <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 -->
        </addr>
        <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="LOC" >
            <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">
          <name>C.3.2</name>
          <!-- C.3.2: Sender's Organisation -->
        </representedOrganization>
      </assignedEntity>
    </author>
  </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" displayName="ichReportType"/>
    <value xsi:type="CE" code="C.1.3" codeSystem="2.16.840.1.113883.3.989.2.1.1.2"/>
    <!-- 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" 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" displayName="nullificationAmendmentCode"/>

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    <value xsi:type="CE" code="C.1.11.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.5"/>
    <!-- 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" 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" 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"/>
    <!-- 000J2.1a: 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" displayName="報告起算日"/>
    <value xsi:type="TS" value="20130107"/>
    <!-- 000J2.2.1: 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" displayName="報告起算日に関するコメント"/>
    <value xsi:type="ED">J2.2.2</value>
    <!-- 000J2.2.2: 報告起算日に関するコメント -->
  </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 (外国措置報告)

```

<?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"/>
  <!-- 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="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" displayName="literatureReference"/>
              <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>
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                <representedOrganization classCode="ORG" determinerCode="INSTANCE">
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                      <!-- @@@J2.15.r 公表国 #1 -->
                    </location>
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                </representedOrganization>
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            </participation>
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    </participation>
  </document>
</reference>
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    <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 -->
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            <location classCode="COUNTRY" determinerCode="INSTANCE">
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              <!-- 000J2.15.r 公表国 #2 -->
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        </representedOrganization>
      </assignedEntity>
    </participation>
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</reference>
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      <primaryRole classCode="INVSEBJ">
        <player1 classCode="PSN" determinerCode="INSTANCE"/>
        <subjectOf1 typeCode="SBJ">
          <researchStudy classCode="CLNTRL" moodCode="EVN">
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            <!-- C.5.3: Sponsor Study Number -->
            <code code="C.5.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.8"/>
            <!-- 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>
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        <organizer classCode="CATEGORY" moodCode="EVN">
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          <!-- G.k Drug(s) Information (repeat as necessary) #1 -->
        </organizer typeCode="COMP">
          <substanceAdministration classCode="SBADM" moodCode="EVN">
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<instanceOfKind classCode="INST">
  <kindOfProduct classCode="MMAT" determinerCode="KIND">
    <code code="G.k.2.1.1b" codeSystem="TBD-MPID"/>
    <!-- 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 -->
          <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"/>
              <!-- J2.5.k: 一般用医薬品等のリスク区分等 #1 -->
            </policy>
          </pertinentInformation>
        </approval>
      </subjectOf>
      <subjectOf typeCode="SBJ">
        <characteristic classCode="OBS" moodCode="EVN">
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          <value xsi:type="CE" code="J2.4.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.3"/>
          <!-- J2.4.k: 新医薬品等の状況区分 #1 -->
        </characteristic>
      </subjectOf>
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  </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">
    <ingredientSubstance classCode="MMAT" determinerCode="KIND">
      <code code="G.k.2.3.r.2b" codeSystem="TBD-Substance"/>
      <!-- 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">
    <ingredientSubstance classCode="MMAT" determinerCode="KIND">
      <code code="G.k.2.3.r.2b" codeSystem="TBD-Substance"/>
      <!-- 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>
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  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="2" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" 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"/>
    <!-- J2.6.k: 一般用医薬品の入手経路 #1 -->
  </observationEvent>
</subjectOf>
</instanceOfKind>
</consumable>
</substanceAdministration>
</component>
</organizer>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <organizer classCode="CATEGORY" moodCode="EVN">

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<code code="1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.11" 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" 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" 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" 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"/>
    <!-- @@@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" 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" displayName="治験の概要"/>
    <component typeCode="COMP">
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        <!-- @@@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" 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" 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"/>
        <!-- @@@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" 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>
<component1 typeCode="COMP">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="comment"/>
    <value xsi:type="ED">H.4</value>
    <!-- H.4: Sender's Comments -->
  </observationEvent>
  <author typeCode="AUT">
    <assignedEntity classCode="ASSIGNED">
      <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" displayName="sender"/>
    </assignedEntity>
  </author>

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    </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" 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" 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" 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" 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="23" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" 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" 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"/>
            <!-- 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>

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</relatedInvestigation>
</outboundRelationship>
<subjectOf1 typeCode="SUBJ">
  <controlActEvent classCode="CACT" moodCode="EVN">
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <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 -->
        </addr>
        <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">
          <name>C. 3. 2</name>
          <!-- C. 3. 2: Sender's Organisation -->
        </representedOrganization>
      </assignedEntity>
    </author>
  </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" displayName="ichReportType"/>
    <value xsi:type="CE" code="C. 1. 3" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 2"/>
    <!-- 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" 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" displayName="nullificationAmendmentCode"/>
    <value xsi:type="CE" code="C. 1. 11. 1" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 5"/>
    <!-- C. 1. 11. 1: Report Nullification / Amendment -->
  </investigationCharacteristic>
</subjectOf2>

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<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic classCode="OBS" moodCode="EVN">
    <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" displayName="nullificationAmendmentReason"/>
    <value xsi:type="CE">
      <originalText>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" 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"/>
    <!-- @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" 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" 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" 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"/>
    <!-- @J2.3: 即時報告フラグ -->
  </investigationCharacteristic>
</subjectOf2>
</investigationEvent>
</subject>
</controlActProcess>
</PORR_IN049016UV>
<!-- Message #1 -->
<!-- Message #2 -->
<!-- PORR_IN049016UV -->
<!-- /PORR_IN049016UV -->
<!-- Message #2 -->
<receiver typeCode="RCV">
  <device classCode="DEV" determinerCode="INSTANCE">
    <id extension="N.1.4" root="2.16.840.1.113883.3.989.2.1.3.14"/>
    <!-- N.1.4: Batch Receiver Identifier -->
  </device>
</receiver>
<sender typeCode="SND">
  <device classCode="DEV" determinerCode="INSTANCE">
    <id extension="N.1.3" root="2.16.840.1.113883.3.989.2.1.3.13"/>
    <!-- N.1.3: Batch Sender Identifier -->
  </device>
</sender>
</MCCI_IN200100UV01>

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