

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_TEO49016UV" codeSystem="2.16.840.1.113883.1.18"/>
      <!-- HL7 Trigger Event ID -->
      <effectiveTime value="20101214151617"/>
      <!-- C.1.2: Date of Creation -->
      <subject typeCode="SUBJ">
        <investigationEvent classCode="INVSTG" moodCode="EVN">
          <id extension="C.1.1" root="2.16.840.1.113883.3.989.2.1.3.1"/>
          <!-- C.1.1: Sender's (case) Safety Report Unique Identifier -->
          <id extension="C.1.8.1" root="2.16.840.1.113883.3.989.2.1.3.2"/>
          <!-- C.1.8.1: Worldwide Unique Case Identification Number -->
          <id extension="J2.1b" root="2.16.840.1.113883.3.989.5.1.3.2.3.1"/>
          <!-- @@@J2.1b: 識別番号 (番号) -->
          <code code="PAT_ADV_EVNT" codeSystem="2.16.840.1.113883.5.4"/>
          <text>H.1</text>
          <!-- H.1: Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant Information -->
          <statusCode code="active"/>
          <!-- @@@J2.7.1 完了、未完了区分 -->
          <effectiveTime>
            <low value="20090101"/>
            <!-- C.1.4: Date Report Was First Received from Source -->
          </effectiveTime>
          <availabilityTime value="20090101"/>
          <!-- C.1.5: Date of Most Recent Information for This Report -->
          <reference typeCode="REFR">
            <document classCode="DOC" moodCode="EVN">
              <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" 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 -->
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        <representedOrganization classCode="ORG" determinerCode="INSTANCE">
          <asLocatedEntity classCode="LOCE">
            <location classCode="COUNTRY" determinerCode="INSTANCE">
              <code code="J2.15.r" codeSystem="1.0.3166.1.2.2"/>
              <!-- @@@J2.15.r 公表国 #2 -->
            </location>
          </asLocatedEntity>
        </representedOrganization>
      </assignedEntity>
    </participation>
  </document>
</reference>
<component typeCode="COMP">
  <adverseEventAssessment classCode="INVTG" moodCode="EVN">
    <subject1 typeCode="SBJ">
      <primaryRole classCode="INVSBJ">
        <player1 classCode="FSN" 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>
        </player1>
      </primaryRole>
    </subject1>
  </adverseEventAssessment>
</component>

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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="PRSN">
  <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>
        </observation>
      </component>
    </organizer>
  </subjectOf2>
  <component typeCode="COMP">
    <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>
  </component typeCode="COMP">

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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="ED">D.7.1.r.5</value>
            <!-- D.7.1.r.5: Comments #1 -->
          </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="EXPL">
          <observation classCode="OBS" moodCode="EVN">
            <code code="38" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" 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>
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      <observation classCode="OBS" moodCode="EVN">
        <code code="I0" 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>
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        <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? -->
    <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>
  </observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" 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"/>

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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"/>
    <!-- 000J2.14.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: Terms 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·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 #2 -->
  </observation>
</outboundRelationship2>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430adf"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" 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>
</subjectOf2>

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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"/>
      <!-- @@@J2.14.i 未知·既知 #4 -->
    </observation>
  </outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" 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"/>
    <!-- 000J2.14.i 未知·既知 #5 -->
  </observation>
</outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="1f927283-10b6-4334-9d43-e925640fb18f"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" 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"/>
    <!-- 000J2.14.i 未知·既知 #6 -->
  </observation>
</outboundRelationship2>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" 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="a15bc092-8070-426d-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>
</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>

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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="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">
  <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="MAT" 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="MAT" determinerCode="KIND">
    <code code="G.k.2.3.r.2b" codeSystem="TBD-Substance" codeSystemVersion="G.k.2.3.r.2a"/>
    <!-- G.k.2.3.r.2a: Substance / Specified Substance TermID Version Date / Number #1-2 -->
    <!-- G.k.2.3.r.2b: Substance / Specified Substance TermID #1-2 -->
    <name>G.k.2.3.r.1</name>
    <!-- G.k.2.3.r.1: Substance / Specified Substance Name #1-2 -->
  </ingredientSubstance>
</ingredient>
</kindOfProduct>
<subjectOf typeCode="SBJ">
  <productEvent classCode="ACT" moodCode="EVN">
    <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.18" 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>
    <outboundRelationship 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>
    </outboundRelationship>
    <outboundRelationship 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>
    </outboundRelationship>
    <outboundRelationship 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>
    </outboundRelationship>
    <outboundRelationship 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>
    </outboundRelationship>
    <outboundRelationship 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>
    </outboundRelationship>
    <outboundRelationship 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>
    </outboundRelationship>
    <outboundRelationship 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>
    </outboundRelationship>
    <outboundRelationship 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>
  </outboundRelationship>
  <outboundRelationship 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-83c1-34f9ddb7ca6d"/>
    </actReference>
  </outboundRelationship>
  <outboundRelationship 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-83c1-34f9ddb7ca6d"/>
  </actReference>
  </outboundRelationship>
  <outboundRelationship 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>
  </outboundRelationship>
  <outboundRelationship 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>
  </outboundRelationship>
  <outboundRelationship 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="e0342969-38bc-423f-b6bb-ce14bc279d8e"/>
    </actReference>
  </outboundRelationship>
  <outboundRelationship 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="e0342969-38bc-423f-b6bb-ce14bc279d8e"/>
  </actReference>
  </outboundRelationship>
  <outboundRelationship 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="a15bc092-8070-426d-af04-6863263443e0"/>
    </actReference>
  </outboundRelationship>
  <outboundRelationship 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="SKPR_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="CSH">
      <instanceOfKind classCode="INST">
        <productInstance classCode="MMAT" determinerCode="INSTANCE">
          <lotNumberText>G.k.4.r.7</lotNumberText>
          <!-- G.k.4.r.7: Batch / Lot Number #1-1 -->
        </productInstance>
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm" codeSystemVersion="G.k.4.r.9.2a">
            <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-1 -->
            <!-- 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="SXPRTS">
        <comp xsi:type="PIVLTS">
          <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="IVLTS" 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="IMAT" determinerCode="INSTANCE">
            <lotNumberText>G.k.4.r.7</lotNumberText>
            <!-- G.k.4.r.7: Batch / Lot Number #1-2 -->
          </productInstanceInstance>
          <kindOfProduct classCode="IMAT" determinerCode="KIND">
            <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm" codeSystemVersion="G.k.4.r.9.2a">
              <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-2 -->
              <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #1-2 -->
              <originalText>G.k.4.r.9.1</originalText>
              <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #1-2 -->
            </formCode>
          </kindOfProduct>
        </instanceOfKind>
      </consumable>
    </substanceAdministration>
  </outboundRelationship2>
  <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 #1-2 -->
        <!-- 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="SXPRTS">
      <comp xsi:type="PIVLTS">
        <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="IVLTS" 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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11.2a

11.2a

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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">
    <productInstance classCode="MMAT" determinerCode="INSTANCE">
      <lotNumberText>G.k.4.r.7</lotNumberText>
      <!-- G.k.4.r.7: Batch / Lot Number #1-3 -->
    </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 #1-3 -->
        <!-- 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.8: Dosage and Relevant Information (repeat as necessary) #1-4 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #1-4 -->
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <period value="10" unit="G.k.4.r.3"/>
        <!-- G.k.4.r.2: Number of Units in the Interval #1-4 -->
        <!-- G.k.4.r.3: Definition of the Time Interval Unit #1-4 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <width value="4" unit="G.k.4.r.6b"/>
        <!-- G.k.4.r.6a: Duration of Drug Administration (number) #1-4 -->
        <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #1-4 -->
        <high value="20090101"/>
        <!-- G.k.4.r.5: Date and Time of Last Administration #1-4 -->
      </comp>
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14" 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">
        <productInstance classCode="MMAT" determinerCode="INSTANCE">
          <lotNumberText>G.k.4.r.7</lotNumberText>
          <!-- G.k.4.r.7: Batch / Lot Number #1-4 -->
        </productInstance>
      </instanceOfKind>
    </consumable>
  </substanceAdministration>
</outboundRelationship2>
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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>
</outboundRelationship2>
<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>

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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="SXPRTS">
            <comp xsi:type="IVL_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="MBAT" determinerCode="INSTANCE">
                    <lotNumberText>G.k.4.r.7</lotNumberText>
                    <!-- G.k.4.r.7: Batch / Lot Number #1-1 -->
                </productInstanceInstance>
                <kindOfProduct classCode="MBAT" 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>
    </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 #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="SXPRTS">

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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.
11.2a">
      <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #1-7 -->
      <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-7 -->
      <originalText>G.k.4.r.11.1</originalText>
      <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-7 -->
    </value>
  </observation>
</inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="SUMM">
  <observation classCode="OBS" moodCode="EVN">
    <code code="14" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" 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 -->
  <outboundRelationship1 typeCode="REFR">
    <actReference classCode="OBS" moodCode="EVN">
      <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>

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11.2a"

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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">

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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"/>
    <!-- @@@J2.6.k: 一般用医薬品の入手経路 #2 -->
  </observationEvent>
</subjectOf>
</instanceOfKind>
</consumable>
<outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
  <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number) Drug #2,
Reaction #1-->
  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit) Drug #2,
Reaction #1 -->
</outboundRelationship1>
<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 -->
</outboundRelationship1>
<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 -->
</outboundRelationship1>
<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 -->
</outboundRelationship1>
<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 -->
</outboundRelationship1>
<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>
  </outboundRelationship>
  <outboundRelationship 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>
  </outboundRelationship>
  <outboundRelationship 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>
  </outboundRelationship>
  <outboundRelationship 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>
  </outboundRelationship>
  <outboundRelationship 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>
  </outboundRelationship>
  <outboundRelationship 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>
  </outboundRelationship>
  <outboundRelationship 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>
  </outboundRelationship>
  <outboundRelationship 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>
  </outboundRelationship>
  <outboundRelationship 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="2.16.840.1.113883.3.999.2.1.1.19" 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="2.16.840.1.113883.3.999.2.1.1.14" codeSystemVersion="G.k.4.r.10.2a">
        <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-1 -->
        <!-- G.k.4.r.10.2b: Route of Administration TermID #2-1 -->
        <originalText>G.k.4.r.10.1</originalText>
        <!-- G.k.4.r.10.1: Route of Administration (free text) #2-1 -->
      </routeCode>
      <doseQuantity value="10" unit="G.k.4.r.1b"/>
      <!-- G.k.4.r.1a Dose (number) #2-1 -->
      <!-- G.k.4.r.1b: Dose (unit) #2-1 -->
      <consumable typeCode="CSM">
        <instanceOfKind classCode="INST">
          <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
            <lotNumberText>G.k.4.r.7</lotNumberText>
            <!-- G.k.4.r.7: Batch / Lot Number #2-1 -->
          </productInstanceInstance>
          <kindOfProduct classCode="MMAT" determinerCode="KIND">
            <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm" codeSystemVersion="G.k.4.r.9.2a">
              <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-1 -->
              <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-1 -->
              <originalText>G.k.4.r.9.1</originalText>
              <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-1 -->
            </formCode>
          </kindOfProduct>
        </instanceOfKind>
      </consumable>
    </substanceAdministration>
    <inboundRelationship typeCode="REFR">
      <observation classCode="OBS" moodCode="EVN">
        <code code="28" codeSystem="2.16.840.1.113883.3.999.2.1.1.19" displayName="parentRouteOfAdministration"/>
        <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.999.2.1.1.14" 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="CSH">
            <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 -->
                    </formCode>
                    <originalText>G.k.4.r.9.1</originalText>
                    <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-2 -->
                </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>
</outboundRelationship2>

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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.
    <!-- 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 -->
    <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>
  </substanceAdministration>
</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="CSH">
  <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.
11.2a">
      <!-- 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="CSH">
      <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>

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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>
    <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 #2-8 -->
        <!-- 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.
11.2a">
      <!-- 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.4: 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"/>
                <!-- 000J2.13.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>
                <!-- 000J2.13.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"/>
                <!-- 000J2.13.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>
</subjectOf2>

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    <!-- 000J2.13.r.4: 投票中の症例の有無 #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="投票中の症例の有無"/>
        <value xsi:type="BL" value="false"/>
        <!-- 000J2.13.r.4: 投票中の症例の有無 #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-93c9-5b860b314220"/>
      </adverseEffectReference>
    </subject1>
    <subject2 typeCode="SUBJ">
      <productUseReference classCode="SBADM" moodCode="EVN">
        <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
      </productUseReference>
    </subject2>
  </causalityAssessment>
</component>
<component typeCode="COMP">
  <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>
</component>
<component 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>
</component>
<component 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>
</component>
<component 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="感染症の週及調査"/>
    <value xsi:type="ED">J2.9</value>
    <!-- @J2.9: 感染症の週及調査 -->
  </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>
        </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>
    </controlActEvent>
  </subjectOf1>
</outboundRelationship>

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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: 受信者 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"/>

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    <!-- @@@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>
<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"/>
    <!-- @@@J2.8.1: 報告対象外フラグ -->
  </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic classCode="OBS" moodCode="EVN">
    <code code="6" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" displayName="報告対象外の理由"/>
    <value xsi:type="ED">J2.8.2</value>
    <!-- @@@J2.8.2: 報告対象外の理由 -->
  </investigationCharacteristic>
</subjectOf2>
</investigationEvent>
</subject>
</controlActProcess>
</PORR_IN049016UV>
<!-- Message #1 -->
<!-- Message #2 -->
<!-- PORR_IN049016UV -->
<!-- /PORR_IN049016UV -->
<!-- Message #2 -->
<receiver typeCode="RCV">
  <device classCode="DEV" determinerCode="INSTANCE">
    <id extension="N.1.4" root="2.16.840.1.113883.3.989.2.1.3.14"/>
    <!-- N.1.4: Batch Receiver Identifier -->
  </device>
</receiver>
<sender typeCode="SND">
  <device classCode="DEV" determinerCode="INSTANCE">
    <id extension="N.1.3" root="2.16.840.1.113883.3.989.2.1.3.13"/>
    <!-- N.1.3: Batch Sender Identifier -->
  </device>
</sender>
</MCCI_IN200100UV01>

```

XML参照インスタンス (研究報告)

```
<?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"/>
              <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>
                  </assignedEntity>
                </participation>
              </document>
            </reference>
          </subject>
        </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>
    <!-- 000J2.17.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"/>
              <!-- 000J2.15.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>
  </adverseEventAssessment>
</component>

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<component typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="3c91bd5-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"/>
                    <!-- 000J2.5.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"/>
                <!-- 000J2.4.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>
                  <!-- 00J2.12: 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>
        </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 #1 -->
          </observationEvent>
        </subjectOf>
      </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="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"/>

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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"/>
    <!-- @00J2.1a: 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"/>
    <!-- @00J2.2.1: 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>
    <!-- @00J2.2.2: 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>
</HCCL_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_TEO49016UV" codeSystem="2.16.840.1.113883.1.16"/>
      <!-- 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_EVT" 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"/>
              <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>
            <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>
          </reference>
        </investigationEvent>
      </subject>
    </controlActProcess>
  </PORR_IN049016UV>

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    </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"/>
    <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>
  </adverseEventAssessment>
</component typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
    <consumable typeCode="CSH">

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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">
          <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>
  <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"/>
      <!-- @@@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="治療の概要"/>
<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="治療の概要"/>
    <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 -->
    <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>

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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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厚生労働省システム管理用データ項目（J項目）の属性

J2.1a 識別番号（報告分類）	
項目説明	本通知別添の「1. 報告分類」に基づく報告分類を示す。
記載方法	別紙 5 より該当する報告分類を選択して記載する。
データ型	2A
許容値	別紙 5 参照
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.12']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.1']/@code
J2.1b 識別番号（番号）	
項目説明	機構が付与した識別番号を示す。
記載方法	第一報については、完了報告・未完了報告の如何に関わらず、空欄とする。また、第二報以降については、機構が付与した識別番号を記載する。完了報告、未完了報告であるにかかわらず第一報報告は、本項目を空欄とすることとし、機構による識別番号の付与をもって受付完了となる。
データ型	8N
許容値	該当なし
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.5.1.3.2.3.1']][1]/@extension
J2.2.1 報告起算日	
項目説明	当該報告について、報告の起算となる日を示す。通常、規則第 253 条第 1 項及び第 3 項もしくは第 273 条第 1 項及び第 2 項に定める事項を知った日となる。
記載方法	最低限 CCYYMMDD まで記載すること。
データ型	CCYYMMDDhhmmss.UUUU[+ -ZZzz]
許容値	日付

XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.12']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='TS']/@value
J2.2.2 報告起算日に関するコメント	
項目説明	「J2.2.1 報告起算日」について、以下に示す場合等、説明が必要な場合に記載する。 <ul style="list-style-type: none"> ・ 第一報において、「C.1.4 情報源から最初に報告が入手された日」と「J2.2.1 報告起算日」が異なる場合 ・ 規則第 253 条第 1 項及び第 3 項もしくは第 273 条第 1 項に定める報告期限を超過していることを、製造販売業者または外国特例承認取得者が把握している場合 ・ 30 日以内の報告対象であると考えていたところ、第 1 報を報告する前に追加情報により 15 日以内の報告の対象であることが判明した場合
記載方法	なし
データ型	10000J
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.12']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.3 即時報告フラグ	
項目説明	副作用症例報告、感染症症例報告、外国措置報告において、市販後局長通知の記の 4 (1) ②に該当する報告の場合、本項目を記載する。
記載方法	該当する場合のみ「1=即時報告」を記載すること。
データ型	1N
許容値	1=即時報告

XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='4']][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.12']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.2']/@code
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J2.4.k 新医薬品等の状況区分

項目説明	自社被疑薬の各区分を示す。
記載方法	別紙5より適切なコード値を選択して記載する。 <ul style="list-style-type: none"> ・全ての自社被疑薬について、一般用医薬品以外の医薬品の場合は、「1=市販直後調査中」から「5=該当なし」の中からそれぞれ選択し記載すること。 ・全ての自社被疑薬について、一般用医薬品の場合は「5=該当なし」から「7=PMS期間中（OTC）」の中からそれぞれ選択し記載すること。

データ型	1N
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許容値	別紙5参照
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XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/asManufacturedProduct[@classCode='MANU']/subjectOf[@typeCode='SBJ'][characteristic][1]/characteristic[code[@code='1']][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']][1][@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.3']/@code
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J2.5.k 一般用医薬品等のリスク区分等

項目説明	自社被疑薬が、一般用医薬品の場合のリスク区分、または薬局製造販売医薬品であることを示す。
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記載方法	別紙5より適切なコード値を選択して記載すること。
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	<ul style="list-style-type: none"> ・ 自社被疑薬が一般用医薬品の場合は、それぞれの自社被疑薬について「01=第一類医薬品」から「03=第三類医薬品」及び「2S=指定第二類医薬品」の中から選択し記載すること。 ・ 自社被疑薬が薬局製造販売医薬品の場合は、それぞれの自社被疑薬について「04=薬局製造販売医薬品」を記載すること。
データ型	2AN
許容値	別紙 5 参照
XPath	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/asManufacturedProduct[@classCode='MANU']/subjectOf[@typeCode='SBJ'][approval[1]/approval[@classCode='CNTRCT'][@moodCode='EVN']/pertinentInformation[@typeCode='PERT'][1]/policy[@classCode='POLICY'][@moodCode='EVN']/code[@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.4']]/@code </pre>
J2.6.k 一般用医薬品の入手経路	
項目説明	自社被疑薬が一般用医薬品の場合の入手経路を示す。
記載方法	自社被疑薬が一般用医薬品の場合は、それぞれの自社被疑薬について別紙 5 より適切なコード値を選択して記載すること。
データ型	1A
許容値	別紙 5 参照

XPath (value)	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/subjectOf[@typeCode='SBJ']/observationEvent[code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']][1][@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.5']/@code
XPath (null flavor)	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][1]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/subjectOf[@typeCode='SBJ']/observationEvent[code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']][1][@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.5']/@nullFlavor
J2.7.1 完了、未完了区分	
項目説明	当該報告について、未完了報告又は完了報告の区分を示す。
記載方法	報告すべき事項の調査が完了していない場合は、未完了報告として報告すること。なお、完了報告後に新たな情報を入手した場合は、改めて完了報告として報告する。HL7により定義されたコードを用いて記載すること。
データ型	HL7 コード 10A
許容値	active=未完了 completed=完了

XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'] [1]/investigationEvent [@classCode='INVSTG'][@moodCode='EVN']/statusCode/@code
J2.7.2 未完了に関するコメント	
項目説明	未完了報告の場合は、未完了報告の理由を示す。
記載方法	なし
データ型	10000J
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'] [1]/investigationEvent [@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] [adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'] [moodCode='EVN']/component1[@typeCode='COMP'] [observationEvent[code=@code='3'] [@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]] [1]/observationEvent [classCode='OBS'] [moodCode='EVN']/value [xsi:type='ED']/text()
J2.8.1 報告対象外フラグ	
項目説明	副作用症例報告又は感染症症例報告において、報告対象外の追加報告の場合に記載する。
記載方法	該当する場合のみ「1=報告対象外」を記載すること。
データ型	1N
許容値	1=報告対象外
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'] [moodCode='EVN']/subject [typeCode='SUBJ'] [1]/investigationEvent [classCode='INVSTG'] [moodCode='EVN']/subjectOf2 [typeCode='SUBJ'] [investigationCharacteristic/code [code='5'] [codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.12']]] [1]/investigationCharacteristic [classCode='OBS'] [moodCode='EVN'] /value [xsi:type='CE'] [codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.6'] /@code
J2.8.2 報告対象外の理由	
項目説明	副作用症例報告又は感染症症例報告において、報告対象外の追加報告を行う場合に報告対象外である理由を記載する。
記載方法	なし

データ型	10000J
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'] [1]/investigationEvent[@classCode='INVSTG'] [@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'] [investigationCharacteristic/code[@code='6'] [@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.12']][1]/investigationCharacteristic [@classCode='OBS'] [@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.9 感染症の遡及調査	
項目説明	感染症症例報告の場合は、平成24年3月6日付薬食発0306号厚生労働省医薬食品局長通知「「血液製剤等に係る遡及調査ガイドライン」の一部改正について」の別添「血液製剤等に係る遡及調査ガイドライン」により示された調査内容を記載する。
記載方法	なし
データ型	10000J
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'] [@moodCode='EVN']/subject[@typeCode='SUBJ'] [1]/investigationEvent[@classCode='INVSTG'] [@moodCode='EVN']/component[@typeCode='COMP'] [adverseEventAssessment][1]/adverseEventAssessment [@classCode='INVSTG'] [@moodCode='EVN']/component1[@typeCode='COMP'] [observationEvent[code[@code='4'] [@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]] [1]/observationEvent [@classCode='OBS'] [@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.10 今後の対応	
項目説明	当該報告の副作用等に対する送信者の評価に基づく処置と今後の対応について記載する。
記載方法	なし
データ型	10000J
許容値	自由記載

XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='5']][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.11 その他参考事項等	
項目説明	その他参考となる事項を記載する。
記載方法	なし
データ型	10000J
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='6']][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.12 治験成分記号	
項目説明	治験計画届書に記載している成分記号を示す。
記載方法	治験計画届書を提出していない場合には、治験実施計画書に記載している開発コードを記載すること。
データ型	70J
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4']][@codeSystem='2.16.840.

	1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'] [substanceAdministration/id]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN'] [consumable/instanceOfKind/kindOfProduct/asSpecializedKind/generalizedMaterialKind/code/originalText][1]/consumable[@typeCode='CSM'] [1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/asSpecializedKind[@classCode='GEN'] [1]/generalizedMaterialKind[@classCode='MAT'][@determinerCode='KIND']/code/originalText/text()
J2.13.r.1 届出回数	
項目説明	治験ごとに、治験計画届書の届出回数を記載する。
記載方法	治験計画届書を提出していない場合には、空欄とすること。
データ型	2N
許容値	該当なし
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'] [1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] [adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'] [moodCode='EVN']/subject1[@typeCode='SBJ'] [1]/primaryRole[@classCode='INVSBJ'] /subjectOf2[@typeCode='SBJ'] [organizer/code[@code='1'] [codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.11']][r]/organizer[@classCode='CATEGORY'] [moodCode='EVN']/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']] /value[@xsi:type='INT'] /@value
J2.13.r.2 対象疾患	
項目説明	治験ごとに、治験計画届書に記載されている対象疾患を記載する。
記載方法	治験計画届出書を提出している場合には、記載を省略することができる。なお、治験計画届書を提出していない場合には、治験実施計画書に記載している対象疾患を記載すること。同一の治験実施計画書での複数の疾患を対象とする場合は、カンマで区切って記載すること。
データ型	1000J
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'] [moodCode='EVN']/subject[@typeCode='SUBJ'] [1]/investigationEvent [classCode='INVSTG'] [moodCode='EVN']/component[@typeCode='COMP'] [adv

	<pre> erseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@mo odCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840. 1.113883.3.989.5.1.3.2.1.11']][r]/organizer[@classCode='CATEGORY'][@mood Code='EVN']/component[@typeCode='COMP']/observation[@classCode='OBS'][@mood Code='EVN'][code[@code='8'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]/value[@xsi:type='ED']/text() </pre>
J2.13.r.3 開発相	
項目説明	治験計画届書に記載されている開発相を示す。
記載方法	治験計画届出書を提出している場合には、記載を省略することができる。なお、治験計画届書を提出していない場合には、別紙5より適切なコード値を選択して記載すること。
データ型	1N
許容値	別紙5参照
XPath	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7- org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCod e='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent [@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][/adv erseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@mo odCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840. 1.113883.3.989.5.1.3.2.1.11']][r]/organizer[@classCode='CATEGORY'][@mood Code='EVN']/component[@typeCode='COMP']/observation[@classCode='OBS'][@mood Code='EVN'][code[@code='9'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.7']/@cod e </pre>
J2.13.r.4 投薬中の症例の有無	
項目説明	当該報告の治験成分を投薬中の被験者の有無を示す。
記載方法	コード値ではなくブール型で該当者がいる場合は「True=有」を、いない場合は「False=無」を選択すること。
データ型	ブール型 10A
許容値	true=有 false=無

XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] [adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'] [organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.11']][r]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/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']]/value[@xsi:type='BL']/@value
J2.14.i 未知・既知	
項目説明	治験の場合、当該報告の副作用等が治験薬概要書から予測できないものである場合は未知、その他の場合は既知とする。ICSR 項目の E.i.2.1b 副作用／有害事象 (MedDRA コード) と関連づけられ、副作用毎に未知・既知を付与する。(予測性の判断基準は、本通知別添の「8. その他の治験副作用等報告に際しての注意事項」の(1)を参照すること。)
記載方法	コード値から選択して記載すること。
データ型	1N
許容値	1=未知 2=既知
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] [adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'] [observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'] [observation/code[@code='11'] [codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'] [codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.8']]/@code
J2.15.r. 公表国	
項目説明	研究報告及び外国措置報告において、外国において報告内容が公表されている場合、公表国を示す。

記載方法	<p>国コードから適切なコードを選択して記載すること。</p> <p>研究報告の場合、報告者/文献著者等の所属又は、試験実施場所の国を記載すること。</p> <p>また、外国措置報告の場合、措置を行った国を記載すること。</p> <p>措置報告において、複数国の規制当局によって同一の措置がなされた場合、1つの報告として報告して差し支えない。その際には代表国を1番目に記載し、繰り返しを利用して、二番目以降にその他の公表国を記載すること。</p> <p>後日、同一の措置が他国でなされた場合には、当該公表国について追加報告する。その際には、前回報告の後に続けて当該追加報告の代表国を記載すること。当該報告の公表国が複数ある場合は繰り返しを利用すること。</p> <p>なお、各国の措置内容が異なる場合は、別報告とすること。</p>
データ型	2A
許容値	ISO 3166-1 アルファ-2の国コード
XPath	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']][r]/document[@classCode='DOC'][@moodCode='EVN']/participation[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/asLocatedEntity[@classCode='LOCE']/location[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/@code </pre>
J2.16 報告内容の要点	
項目説明	研究報告及び外国措置報告の場合、当該報告の問題の要点を示す。
記載方法	なし
データ型	500J
許容値	自由記載
XPath	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='12'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text() </pre>
J2.17.r 試験/研究の分類	

項目説明	研究報告の場合、「臨床試験／研究」又は「非臨床試験／研究」の別を示す。
記載方法	なし
データ型	1N
許容値	1=臨床試験／研究 2=非臨床試験／研究
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']][r]/document[@classCode='DOC'][@moodCode='EVN']/title/text()
J2.18.1 受信者組織名	
項目説明	ICSR の受信者の組織名を示す。
記載方法	独立行政法人医薬品医療機器総合機構と記載する。
データ型	100J
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/primaryInformationRecipient][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/primaryInformationRecipient[@typeCode='PRCP']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/text()
J2.18.2 受信者職名	
項目説明	ICSR の受信者の肩書きを示す。
記載方法	理事長と記載する。
データ型	100J
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/primaryInformationRecipient][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/primaryInformationRecipient[@typeCode='PRCP']/assign

	edEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/prefix[1]/text()
J2.18.3 受信者姓	
項目説明	ICSR の受信者の姓を示す。
記載方法	機構の理事長の姓を記載する。
データ型	100J
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/primaryInformationRecipient][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/primaryInformationRecipient[@typeCode='PRCP']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/family[1]/text()
J2.18.4 受信者名	
項目説明	ICSR の受信者の名を示す。
記載方法	機構の理事長の名を記載する。
データ型	100J
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/primaryInformationRecipient][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/primaryInformationRecipient[@typeCode='PRCP']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[1]/text()
J2.19 備考 1	
項目説明	予備項目
記載方法	なし
データ型	10000J
許容値	自由記述
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCod

	e='CACT'[@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='13'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.20 備考 2	
項目説明	予備項目
記載方法	なし
データ型	10000J
許容値	自由記述
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='14'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.21 備考 3	
項目説明	予備項目
記載方法	なし
データ型	10000J
許容値	自由記述
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='15'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.22 備考 4	
項目説明	予備項目
記載方法	なし
データ型	10000J

許容値	自由記述
XPath	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent [@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@mo odCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code=' 16'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]]][1]/observationEvent[@ classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text() </pre>

厚生労働省システム管理用データ項目（J項目）のコード値

コード値	J2.1a 識別番号（報告分類）	市販後／ 治験
AA	国内感染症症例報告（市販後）	市販後
AB	国内副作用症例報告（市販後）	市販後
AC	外国感染症症例報告（市販後）	市販後
AD	外国副作用症例報告（市販後）	市販後
AE	感染症研究報告（市販後）	市販後
AF	副作用研究報告（市販後）	市販後
AG	外国における製造等の中止、回収、廃棄等の措置報告（市販後）	市販後
BC	医薬部外品研究報告	市販後
BD	化粧品研究報告	市販後
DA	国内感染症症例報告（治験）	治験
DB	国内副作用症例報告（治験）	治験
DC	外国感染症症例報告（治験）	治験
DD	外国副作用症例報告（治験）	治験
DE	感染症研究報告（治験）	治験
DF	副作用研究報告（治験）	治験
DG	外国における製造等の中止、回収、廃棄等の措置報告（治験）	治験

コード値	J2.4.k 新医薬品等の状況区分	市販後／ 治験
1	市販直後調査中	市販後
2	承認2年以内	市販後
3	未承認	治験
4	一変治験中	治験
5	該当なし	市販後
6	再審査期間中（OTC）	市販後
7	PMS 期間中（OTC）	市販後

コード値	J2.5.k 一般用医薬品等のリスク区分等	市販後／ 治験
01	第一類医薬品	市販後
02	第二類医薬品	市販後
2S	指定第二類医薬品	市販後
03	第三類医薬品	市販後
04	薬局製造販売医薬品	市販後

コード値	J2.6.k 一般用医薬品の入手経路	市販後／ 治験
S	薬局等の店頭での販売の場合	市販後
H	配置販売の場合	市販後
I	インターネットによる通信販売の場合	市販後
T	その他の通信販売（電話等）の場合	市販後
nullFlavor=ASKU	確認を行ったが、情報が入手できなかった場合	市販後
nullFlavor=UNK	やむを得ない理由により確認不能で、不明の場合	市販後

コード値	J2.13.r.3 開発相	市販後／ 治験
0	マイクロドーズ試験等	治験
1	第Ⅰ相	治験
2	第Ⅰ/Ⅱ相	治験
3	第Ⅱ相	治験
4	第Ⅱ/Ⅲ相	治験
5	第Ⅲ相	治験
6	その他	治験

個別症例安全性報告等確認応答メッセージデータ項目

記号・略語等の解説

■記載項目

- ◎＝第一報から必ず記載する項目
- ＝完了報告の際に必ず記載する項目
- ◇＝条件付きで第一報から記載が必要な項目
- △＝条件付きで完了報告の際に記載が必要な項目
- ▲＝可能な限り記載する項目
(取下げ報告を行う場合は、「不要であるが記載されていてもエラーにならない項目」)
- ×＝記載してはいけない項目

■データ型

- A = 英字型
- AN = 英数字型
- N = 数字型
- J = 日本語型

データ項目番号	データ項目名	全報告分類	フィールド長	同一の値となる ICSR項目番号
ACK.M.1	確認応答バッチ番号	◎	100AN	
ACK.M.2	確認応答バッチ送信者識別子	◎	60AN	N.1.4
ACK.M.3	確認応答バッチ受信者識別子	◎	60AN	N.1.3
ACK.M.4	バッチ伝送の確認応答日	◎	date	
ACK.A.1	ICSRバッチ番号	◎	100AN	N.1.2
ACK.A.2	確認応答地域メッセージ番号	◎	100AN	
ACK.A.3	ICSRバッチ伝送日	◎	date	N.1.5
ACK.A.4	伝送確認応答コード	◎	2A	
ACK.A.5	バッチバリデーションエラー	◇	250J	
ACK.B.r.1	ICSRメッセージ番号	◎	100AN	N.2.r.1, C.1.1
ACK.B.r.2	地域報告番号	◎	100AN	
ACK.B.r.3	ICSRメッセージ確認応答受信者	◎	60AN	N.2.r.2
ACK.B.r.4	ICSRメッセージ確認応答送信者	◎	60AN	N.2.r.3
ACK.B.r.5	ICSRメッセージ作成日	◎	date	N.2.r.4, C.1.2
ACK.B.r.6	ICSRメッセージの確認応答コード	◎	2A	
ACK.B.r.7	エラー／警告メッセージ又は意見	◇	250J	