XML 参照インスタンス（個別症例安全性報告）

```xml
<?xml version="1.0" encoding="UTF-8"?>
<MCCI_IN200100UV01 ITSVersion="XML_1.0" xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd" xmlns="urn:hl7-org:v3"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  <id extension="N.1.2" root="2.16.840.1.113883.3.989.2.1.3.22"/>
  <!-- N.1.2: Batch Number -->
  <creationTime value="20101214151617"/>
  <!-- N.1.5: Date of Batch Transmission -->
  <responseModeCode code="D"/>
  <interactionId extension="MCCI_IN200100UV01" root="2.16.840.1.113883.1.6"/>
  <name code="N.1.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.1" codeSystemVersion="1.01"/>
  <!-- N.1.1: Type of Messages in Batch -->
  <!-- Message #1 -->
  <PORR_IN049016UV>
    <id extension="N.2.r.1" root="2.16.840.1.113883.3.989.2.1.3.1"/>
    <!-- N.2.r.1: Message Identifier -->
    <creationTime value="20101214151617"/>
    <!-- N.2.r.4: Date of Message Creation -->
    <interactionId extension="PORR_IN049016UV" root="2.16.840.1.113883.1.6"/>
    <processingCode code="P"/>
    <processingModeCode code="T"/>
    <acceptAckCode code="AL"/>
    <receiver typeCode="RCV">
      <device classCode="DEV" determinerCode="INSTANCE">
        <id extension="N.2.r.3" root="2.16.840.1.113883.3.989.2.1.3.12"/>
        <!-- N.2.r.3: Message Receiver Identifier -->
      </device>
    </receiver>
    <sender typeCode="SND">
      <device classCode="DEV" determinerCode="INSTANCE">
        <id extension="N.2.r.2" root="2.16.840.1.113883.3.989.2.1.3.11"/>
        <!-- N.2.r.2: Message Sender Identifier -->
      </device>
    </sender>
    <controlActProcess classCode="CACT" moodCode="EVN">
      <code code="PORR_TE049016UV" codeSystem="2.16.840.1.113883.1.18"/>
      <!-- HL7 Trigger Event ID -->
      <effectiveTime value="20101214151617"/>
      <!-- C.1.2: Date of Creation -->
      <subject typeCode="SUBJ">
        <investigationEvent classCode="INVSTG" moodCode="EVN">
          <id extension="C.1.1" root="2.16.840.1.113883.3.989.2.1.3.1"/>
          <!-- C.1.1: Sender's (case) Safety Report Unique Identifier -->
          <id extension="C.1.8.1" root="2.16.840.1.113883.3.989.2.1.3.2"/>
          <!-- C.1.8.1: Worldwide Unique Case Identification Number -->
          <id extension="J2.1b" root="2.16.840.1.113883.3.989.5.1.3.2.3.1"/>
          <!-- @@@J2.1b: 識別番号（番号） -->
          <code code="PAT_ADV_EVNT" codeSystem="2.16.840.1.113883.5.4"/>
          <text>H.1</text>
          <!-- H.1: Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant
Information -->
          <statusCode code="active"/>
          <!-- @@@J2.7.1 完了、未完了区分 -->
          <effectiveTime>
            <low value="20090101"/>
            <!-- C.1.4: Date Report Was First Received from Source -->
          </effectiveTime>
          <availabilityTime value="20090101"/>
          <!-- C.1.5: Date of Most Recent Information for This Report -->
          <reference typeCode="REFR">
            <document classCode="DOC" moodCode="EVN">
              <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" codeSystemVersion="1.0"
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                          displayName="documentsHeldBySender"/>
                          <title>C.1.6.1.r.1</title>
                          <!-- C.1.6.1.r.1: Documents Held by Sender (repeat as necessary) #1 -->
                          <text mediaType="application/pdf" representation="B64">C.1.6.1.r.2</text>
                          <!-- C.1.6.1.r.2: Included Documents #1 -->
                       </document>
                    </reference>
                    <reference typeCode="REFR">
                       <document classCode="DOC" moodCode="EVN">
                          <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" codeSystemVersion="1.0"
displayName="documentsHeldBySender"/>
                          <title>C.1.6.1.r.1</title>
                          <!-- C.1.6.1.r.1: Documents Held by Sender (repeat as necessary) #2 -->
                          <text mediaType="image/jpeg" representation="B64" compression="DF">C.1.6.1.r.2</text>
                          <!-- C.1.6.1.r.2: Included Documents #2 -->
                       </document>
                    </reference>
                    <reference typeCode="REFR">
                       <document classCode="DOC" moodCode="EVN">
                          <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" codeSystemVersion="1.0"
displayName="literatureReference"/>
                          <title>J2.17.r</title>
                          <!-- @@@J2.17.r 試験／研究の分類 #1 -->
                          <text mediaType="application/pdf" representation="B64">C.4.r.2</text>
                          <!-- C.4.r.2: Included Documents #1 -->
                          <bibliographicDesignationText>C.4.r.1</bibliographicDesignationText>
                          <!-- C.4.r.1: Literature Reference(s) #1 -->
                          <participation typeCode="AUT">
                            <assignedEntity classCode="ASSIGNED">
                               <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                                 <asLocatedEntity classCode="LOCE">
                                   <location classCode="COUNTRY" determinerCode="INSTANCE">
                                     <code code="J2.15.r" codeSystem="1.0.3166.1.2.2"/>
                                     <!-- @@@J2.15.r 公表国 #1 -->
                                   </location>
                                 </asLocatedEntity>
                               </representedOrganization>
                            </assignedEntity>
                          </participation>
                       </document>
                    </reference>
                    <reference typeCode="REFR">
                       <document classCode="DOC" moodCode="EVN">
                          <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" codeSystemVersion="1.0"
displayName="literatureReference"/>
                          <title>J2.17.r</title>
                          <!-- @@@J2.17.r 試験／研究の分類 #2 -->
                          <text mediaType="application/pdf" representation="B64">C.4.r.2</text>
                          <!-- C.4.r.2: Included Documents #2 -->
                          <bibliographicDesignationText>C.4.r.1</bibliographicDesignationText>
                          <!-- C.4.r.1: Literature Reference(s) #2 -->
                          <participation typeCode="AUT">
                            <assignedEntity classCode="ASSIGNED">
                               <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                                 <asLocatedEntity classCode="LOCE">
                                   <location classCode="COUNTRY" determinerCode="INSTANCE">
                                     <code code="J2.15.r" codeSystem="1.0.3166.1.2.2"/>
                                     <!-- @@@J2.15.r 公表国 #2 -->
                                   </location>
                                 </asLocatedEntity>
                               </representedOrganization>
                            </assignedEntity>
                          </participation>
                       </document>
                    </reference>
                    <component typeCode="COMP">
                       <adverseEventAssessment classCode="INVSTG" moodCode="EVN">
                          <subject1 typeCode="SBJ">
                            <primaryRole classCode="INVSBJ">
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<player1 classCode="PSN" determinerCode="INSTANCE">
  <name>D.1</name>
  <!-- D.1: Patient (name or initials) -->
  <administrativeGenderCode code="D.5" codeSystem="1.0.5218"/>
  <!-- D.5 Sex -->
  <birthTime value="20090101"/>
  <!-- D.2.1: Date of Birth -->
  <deceasedTime value="20090101"/>
  <!-- D.9.1: Date of Death -->
  <asIdentifiedEntity classCode="IDENT">
    <id extension="D.1.1.1" root="2.16.840.1.113883.3.989.2.1.3.7"/>
    <!-- D.1.1.1: Patient Medical Record Number(s) and Source(s) of the Record Number (GP Medical
Record Number) -->
    <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" codeSystemVersion="1.0"
displayName="GP"/>
  </asIdentifiedEntity>
  <asIdentifiedEntity classCode="IDENT">
    <id extension="D.1.1.2" root="2.16.840.1.113883.3.989.2.1.3.8"/>
    <!-- D.1.1.2: Patient Medical Record Number(s) and Source(s) of the Record Number (Specialist
Record Number) -->
    <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" codeSystemVersion="1.0"
displayName="Specialist"/>
  </asIdentifiedEntity>
  <asIdentifiedEntity classCode="IDENT">
    <id extension="D.1.1.3" root="2.16.840.1.113883.3.989.2.1.3.9"/>
    <!-- D.1.1.3: Patient Medical Record Number(s) and Source(s) of the Record Number (Hospital Record
Number) -->
    <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" codeSystemVersion="1.0"
displayName="Hospital Record"/>
  </asIdentifiedEntity>
  <asIdentifiedEntity classCode="IDENT">
    <id extension="D.1.1.4" root="2.16.840.1.113883.3.989.2.1.3.10"/>
    <!-- D.1.1.4: Patient Medical Record Number(s) and Source(s) of the Record Number (Investigation
Number) -->
    <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" codeSystemVersion="1.0"
displayName="Investigation"/>
  </asIdentifiedEntity>
  <role classCode="PRS">
    <code code="PRN" codeSystem="2.16.840.1.113883.5.111"/>
    <associatedPerson classCode="PSN" determinerCode="INSTANCE">
      <name>D.10.1</name>
      <!-- D.10.1: Parent Identification -->
      <administrativeGenderCode code="D.10.6" codeSystem="1.0.5218"/>
      <!-- D.10.6: Sex of Parent -->
      <birthTime value="20090101"/>
      <!-- D.10.2.1: Date of Birth of Parent -->
    </associatedPerson>
    <subjectOf2 typeCode="SBJ">
      <observation classCode="OBS" moodCode="EVN">
        <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="age"/>
        <value xsi:type="PQ" value="10" unit="D.10.2.2b"/>
        <!-- D.10.2.2a: Age of Parent (number) -->
        <!-- D.10.2.2b: Age of Parent (unit) -->
      </observation>
    </subjectOf2>
    <subjectOf2 typeCode="SBJ">
      <observation classCode="OBS" moodCode="EVN">
        <code code="22" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="lastMenstrualPeriodDate"/>
        <value xsi:type="TS" value="20090101"/>
        <!-- D.10.3: Last Menstrual Period Date of Parent -->
      </observation>
    </subjectOf2>
    <subjectOf2 typeCode="SBJ">
      <observation classCode="OBS" moodCode="EVN">
        <code code="7" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="bodyWeight"/>
        <value xsi:type="PQ" value="50" unit="kg"/>
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                    <!-- D.10.4: Body Weight (kg) of Parent -->
                  </observation>
                </subjectOf2>
                <subjectOf2 typeCode="SBJ">
                  <observation classCode="OBS" moodCode="EVN">
                    <code code="17" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="height"/>
                    <value xsi:type="PQ" value="160" unit="cm"/>
                    <!-- D.10.5: Height (cm) of Parent -->
                  </observation>
                </subjectOf2>
                <subjectOf2 typeCode="SBJ">
                  <organizer classCode="CATEGORY" moodCode="EVN">
                    <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" codeSystemVersion="1.0"
displayName="relevantMedicalHistoryAndConcurrentConditions"/>
                    <component typeCode="COMP">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="D.10.7.1.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.7.1.r.1a"/>
                        <!-- D.10.7.1.r.1a: MedDRA Version for Medical History #1 -->
                        <!-- D.10.7.1.r.1b: Medical History (disease / surgical procedure/ etc.) (MedDRA code) #1 -
->
                        <effectiveTime xsi:type="IVL_TS">
                          <low value="20090101"/>
                          <!-- D.10.7.1.r.2: Start Date #1 -->
                          <high value="20090101"/>
                          <!-- D.10.7.1.r.4: End Date #1 -->
                        </effectiveTime>
                        <outboundRelationship2 typeCode="COMP">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="comment"/>
                            <value xsi:type="ED">D.10.7.1.r.5</value>
                            <!-- D.10.7.1.r.5: Comments #1 -->
                          </observation>
                        </outboundRelationship2>
                        <inboundRelationship typeCode="REFR">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="continuing"/>
                            <value xsi:type="BL" value="true"/>
                            <!-- D.10.7.1.r.3: Continuing #1 -->
                          </observation>
                        </inboundRelationship>
                      </observation>
                    </component>
                    <component typeCode="COMP">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="D.10.7.1.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.7.1.r.1a"/>
                        <!-- D.10.7.1.r.1a: MedDRA Version for Medical History #2 -->
                        <!-- D.10.7.1.r.1b: Medical History (disease / surgical procedure/ etc.) (MedDRA code) #2 -
->
                        <effectiveTime xsi:type="IVL_TS">
                          <low value="20090101"/>
                          <!-- D.10.7.1.r.2: Start Date #2 -->
                          <high value="20090101"/>
                          <!-- D.10.7.1.r.4: End Date #2 -->
                        </effectiveTime>
                        <outboundRelationship2 typeCode="COMP">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
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">
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                                                <code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="continuing"/>
                                                <value xsi:type="BL" value="true"/>
                                                <!-- D.10.7.1.r.3: Continuing #2 -->
                                            </observation>
                                        </inboundRelationship>
                                    </observation>
                                </component>
                                <component typeCode="COMP">
                                    <observation classCode="OBS" moodCode="EVN">
                                        <code code="18" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="historyAndConcurrentConditionText"/>
                                        <value xsi:type="ED">D.10.7.2</value>
                                        <!-- D.10.7.2: Text for Relevant Medical History and Concurrent Conditions of Parent -->
                                    </observation>
                                </component>
                            </organizer>
                        </subjectOf2>
                        <subjectOf2 typeCode="SBJ">
                            <organizer classCode="CATEGORY" moodCode="EVN">
                                <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" codeSystemVersion="1.0"
displayName="drugHistory"/>
                                <component typeCode="COMP">
                                    <substanceAdministration classCode="SBADM" moodCode="EVN">
                                        <effectiveTime xsi:type="IVL_TS">
                                            <low value="20090101"/>
                                            <!-- D.10.8.r.4: Start Date #1 -->
                                            <high value="20090101"/>
                                            <!-- D.10.8.r.5: End Date #1 -->
                                        </effectiveTime>
                                        <consumable typeCode="CSM">
                                            <instanceOfKind classCode="INST">
                                                <kindOfProduct classCode="MMAT" determinerCode="KIND">
                                                    <code code="D.10.8.r.2b" codeSystem="TBD-MPID" codeSystemVersion="D.10.8.r.2a"/>
                                                    <!-- D.10.8.r.2a: MPID Version Date / Number #1 -->
                                                    <!-- D.10.8.r.2b: Medicinal Product Identifier (MPID) #1 -->
                                                    <name>D.10.8.r.1</name>
                                                    <!-- D.10.8.r.1: Name of Drug as Reported #1 -->
                                                </kindOfProduct>
                                            </instanceOfKind>
                                        </consumable>
                                        <outboundRelationship2 typeCode="RSON">
                                            <observation classCode="OBS" moodCode="EVN">
                                                <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="indication"/>
                                                <value xsi:type="CE" code="D.10.8.r.6b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.8.r.6a"/>
                                                <!-- D.10.8.r.6a: MedDRA Version for Indication #1 -->
                                                <!-- D.10.8.r.6b: Indication (MedDRA code) #1 -->
                                            </observation>
                                        </outboundRelationship2>
                                        <outboundRelationship2 typeCode="CAUS">
                                            <observation classCode="OBS" moodCode="EVN">
                                                <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
                                                <value xsi:type="CE" code="D.10.8.r.7b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.8.r.7a"/>
                                                <!-- D.10.8.r.7a: MedDRA Version for Reaction #1 -->
                                                <!-- D.10.8.r.7b: Reactions (MedDRA code) #1 -->
                                            </observation>
                                        </outboundRelationship2>
                                    </substanceAdministration>
                                </component>
                                <component typeCode="COMP">
                                    <substanceAdministration classCode="SBADM" moodCode="EVN">
                                        <effectiveTime xsi:type="IVL_TS">
                                            <low value="20090101"/>
                                            <!-- D.10.8.r.4: Start Date #2 -->
                                            <high value="20090101"/>
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                                <!-- D.10.8.r.5: End Date #2 -->
                            </effectiveTime>
                            <consumable typeCode="CSM">
                              <instanceOfKind classCode="INST">
                                <kindOfProduct classCode="MMAT" determinerCode="KIND">
                                  <code code="D.10.8.r.3b" codeSystem="TBD-PhPID" codeSystemVersion="D.10.8.r.3a"/>
                                  <!-- D.10.8.r.3a: PhPID Version Date / Number #2 -->
                                  <!-- D.10.8.r.3b: Pharmaceutical Product Identifier (PhPID) #2 -->
                                  <name>D.10.8.r.1</name>
                                  <!-- D.10.8.r.1: Name of Drug as Reported #2 -->
                                </kindOfProduct>
                              </instanceOfKind>
                            </consumable>
                            <outboundRelationship2 typeCode="RSON">
                              <observation classCode="OBS" moodCode="EVN">
                                <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="indication"/>
                                <value xsi:type="CE" code="D.10.8.r.6b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.8.r.6a"/>
                                <!-- D.10.8.r.6a: MedDRA Version for Indication #2 -->
                                <!-- D.10.8.r.6b: Indication (MedDRA code) #2 -->
                              </observation>
                            </outboundRelationship2>
                            <outboundRelationship2 typeCode="CAUS">
                              <observation classCode="OBS" moodCode="EVN">
                                <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
                                <value xsi:type="CE" code="D.10.8.r.7b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.8.r.7a"/>
                                <!-- D.10.8.r.7a: MedDRA Version for Reaction #2 -->
                                <!-- D.10.8.r.7b: Reactions (MedDRA code) #2 -->
                              </observation>
                            </outboundRelationship2>
                          </substanceAdministration>
                        </component>
                      </organizer>
                    </subjectOf2>
                  </role>
                </player1>
                <subjectOf1 typeCode="SBJ">
                  <researchStudy classCode="CLNTRL" moodCode="EVN">
                    <id extension="C.5.3" root="2.16.840.1.113883.3.989.2.1.3.5"/>
                    <!-- C.5.3: Sponsor Study Number -->
                    <code code="C.5.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.8" codeSystemVersion="1.0"/>
                    <!-- C.5.4: Study Type Where Reaction(s) / Event(s) Were Observed -->
                    <title>C.5.2</title>
                    <!-- C.5.2: Study Name -->
                    <authorization typeCode="AUTH">
                      <studyRegistration classCode="ACT" moodCode="EVN">
                        <id extension="C.5.1.r.1" root="2.16.840.1.113883.3.989.2.1.3.6"/>
                        <!-- C.5.1.r.1: Study Registration Number #1 -->
                        <author typeCode="AUT">
                          <territorialAuthority classCode="TERR">
                            <governingPlace classCode="COUNTRY" determinerCode="INSTANCE">
                              <code code="C.5.1.r.2" codeSystem="1.0.3166.1.2.2"/>
                              <!-- C.5.1.r.2: Study Registration Country #1 -->
                            </governingPlace>
                          </territorialAuthority>
                        </author>
                      </studyRegistration>
                    </authorization>
                    <authorization typeCode="AUTH">
                      <studyRegistration classCode="ACT" moodCode="EVN">
                        <id extension="C.5.1.r.1" root="2.16.840.1.113883.3.989.2.1.3.6"/>
                        <!-- C.5.1.r.1 Study Registration Number #2 -->
                        <author typeCode="AUT">
                          <territorialAuthority classCode="TERR">
                            <governingPlace classCode="COUNTRY" determinerCode="INSTANCE">
                              <code code="C.5.1.r.2" codeSystem="1.0.3166.1.2.2"/>
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                    <!-- C.5.1.r.2: Study Registration Country #2 -->
                  </governingPlace>
                </territorialAuthority>
              </author>
            </studyRegistration>
          </authorization>
        </researchStudy>
      </subjectOf1>
      <subjectOf2 typeCode="SBJ">
        <observation classCode="OBS" moodCode="EVN">
          <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="age"/>
          <value xsi:type="PQ" value="10" unit="D.2.2b"/>
          <!-- D.2.2a: Age at Time of Onset of Reaction / Event (number) -->
          <!-- D.2.2b: Age at Time of Onset of Reaction / Event (unit) -->
        </observation>
      </subjectOf2>
      <subjectOf2 typeCode="SBJ">
        <observation classCode="OBS" moodCode="EVN">
          <code code="16" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="gestationPeriod"/>
          <value xsi:type="PQ" value="10" unit="D.2.2.1b"/>
          <!-- D.2.2.1a: Gestation Period When Reaction / Event Was Observed in the Foetus (number) -->
          <!-- D.2.2.1b: Gestation Period When Reaction / Event Was Observed in the Foetus (unit) -->
        </observation>
      </subjectOf2>
      <subjectOf2 typeCode="SBJ">
        <observation classCode="OBS" moodCode="EVN">
          <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="ageGroup"/>
          <value xsi:type="CE" code="D.2.3" codeSystem="2.16.840.1.113883.3.989.2.1.1.9"
codeSystemVersion="1.0"/>
          <!-- D.2.3: Patient Age Group (as per reporter) -->
        </observation>
      </subjectOf2>
      <subjectOf2 typeCode="SBJ">
        <observation classCode="OBS" moodCode="EVN">
          <code code="7" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="bodyWeight"/>
          <value xsi:type="PQ" value="48.2" unit="kg"/>
          <!-- D.3: Body Weight (kg) -->
        </observation>
      </subjectOf2>
      <subjectOf2 typeCode="SBJ">
        <observation classCode="OBS" moodCode="EVN">
          <code code="17" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="height"/>
          <value xsi:type="PQ" value="152" unit="cm"/>
          <!-- D.4: Height (cm) -->
        </observation>
      </subjectOf2>
      <subjectOf2 typeCode="SBJ">
        <observation classCode="OBS" moodCode="EVN">
          <code code="22" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="lastMenstrualPeriodDate"/>
          <value xsi:type="TS" value="20090101"/>
          <!-- D.6: Last Menstrual Period Date -->
        </observation>
      </subjectOf2>
      <subjectOf2 typeCode="SBJ">
        <organizer classCode="CATEGORY" moodCode="EVN">
          <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" codeSystemVersion="1.0"
displayName="relevantMedicalHistoryAndConcurrentConditions"/>
          <component typeCode="COMP">
            <observation classCode="OBS" moodCode="EVN">
              <code code="D.7.1.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.7.1.r.1a"/>
              <!-- D.7.1.r.1a: MedDRA Version for Medical History #1 -->
              <!-- D.7.1.r.1b: Medical History (disease / surgical procedure / etc.) (MedDRA code) #1 -->
              <effectiveTime xsi:type="IVL_TS">
```

```xml
                              <low value="20090101"/>
                              <!-- D.7.1.r.2: Start Date #1 -->
                              <high value="20090101"/>
                              <!-- D.7.1.r.4: End Date #1 -->
                            </effectiveTime>
                            <outboundRelationship2 typeCode="COMP">
                              <observation classCode="OBS" moodCode="EVN">
                                <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="comment"/>
                                <value xsi:type="ED">D.7.1.r.5</value>
                                <!-- D.7.1.r.5: Comments #1 -->
                              </observation>
                            </outboundRelationship2>
                            <outboundRelationship2 typeCode="EXPL">
                              <observation classCode="OBS" moodCode="EVN">
                                <code code="38" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="familyHistory"/>
                                <value xsi:type="BL" value="true"/>
                                <!-- D.7.1.r.6: Family History #1 -->
                              </observation>
                            </outboundRelationship2>
                            <inboundRelationship typeCode="REFR">
                              <observation classCode="OBS" moodCode="EVN">
                                <code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="continuing"/>
                                <value xsi:type="BL" value="true"/>
                                <!-- D.7.1.r.3: Continuing #1 -->
                              </observation>
                            </inboundRelationship>
                          </observation>
                        </component>
                        <component typeCode="COMP">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="D.7.1.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.7.1.r.1a"/>
                            <!-- D.7.1.r.1a: MedDRA Version for Medical History #2 -->
                            <!-- D.7.1.r.1b: Medical history (disease / surgical procedure / etc.) (MedDRA code) #2 -->
                            <effectiveTime xsi:type="IVL_TS">
                              <low value="20090101"/>
                              <!-- D.7.1.r.2: Start Date #2 -->
                              <high value="20090101"/>
                              <!-- D.7.1.r.4: End Date #2 -->
                            </effectiveTime>
                            <outboundRelationship2 typeCode="COMP">
                              <observation classCode="OBS" moodCode="EVN">
                                <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="comment"/>
                                <value xsi:type="ED">D.7.1.r.5</value>
                                <!-- D.7.1.r.5: Comments #2 -->
                              </observation>
                            </outboundRelationship2>
                            <outboundRelationship2 typeCode="EXPL">
                              <observation classCode="OBS" moodCode="EVN">
                                <code code="38" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="familyHistory"/>
                                <value xsi:type="BL" value="true"/>
                                <!-- D.7.1.r.6: Family History #2 -->
                              </observation>
                            </outboundRelationship2>
                            <inboundRelationship typeCode="REFR">
                              <observation classCode="OBS" moodCode="EVN">
                                <code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="continuing"/>
                                <value xsi:type="BL" value="true"/>
                                <!-- D.7.1.r.3: Continuing #2 -->
                              </observation>
                            </inboundRelationship>
                          </observation>
                        </component>
                        <component typeCode="COMP">
```

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

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

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                    <outboundRelationship2 typeCode="DRIV">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="8" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="causeOfDeath"/>
                        <value xsi:type="CE" code="D.9.4.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.9.4.r.1a">
                          <!-- D.9.4.r.1a: MedDRA Version for Autopsy-determined Cause(s) of Death #1 -->
                          <!-- D.9.4.r.1b Autopsy-determined Cause(s) of Death (MedDRA code) #1 -->
                          <originalText>D.9.4.r.2</originalText>
                          <!-- D.9.4.r.2: Autopsy-determined Cause(s) of Death (free text) #1 -->
                        </value>
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="DRIV">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="8" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="causeOfDeath"/>
                        <value xsi:type="CE" code="D.9.4.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.9.4.r.1a">
                          <!-- D.9.4.r.1a: MedDRA Version for Autopsy-determined Cause(s) of Death #2 -->
                          <!-- D.9.4.r.1b Autopsy-determined Cause(s) of Death (MedDRA code) #2 -->
                          <originalText>D.9.4.r.2</originalText>
                          <!-- D.9.4.r.2: Autopsy-determined Cause(s) of Death (free text) #2 -->
                        </value>
                      </observation>
                    </outboundRelationship2>
                  </observation>
                </subjectOf2>
                <subjectOf2 typeCode="SBJ">
                  <observation classCode="OBS" moodCode="EVN">
                    <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
                    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
                    <effectiveTime xsi:type="IVL_TS">
                      <low value="20090101"/>
                      <!-- E.i.4: Date of Start of Reaction / Event #1 -->
                      <high value="20090102"/>
                      <!-- E.i.5: Date of End of Reaction / Event #1 -->
                    </effectiveTime>
                    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
                      <!-- E.i.2.1a: MedDRA Version for Reaction / Event #1 -->
                      <!-- E.i.2.1b: Reaction / Event (MedDRA code) #1 -->
                      <originalText language="E.i.1.1b">E.i.1.1a</originalText>
                      <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #1 -->
                      <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #1 -->
                    </value>
                    <location typeCode="LOC">
                      <locatedEntity classCode="LOCE">
                        <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
                          <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
                          <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #1 -->
                        </locatedPlace>
                      </locatedEntity>
                    </location>
                    <outboundRelationship2 typeCode="PERT">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reactionForTranslation"/>
                        <value xsi:type="ED">E.i.1.2</value>
                        <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #1 -->
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="PERT">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="termHighlightedByReporter"/>
                        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"
codeSystemVersion="1.0"/>
```

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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" codeSystemVersion="1.1"
displayName="resultsInDeath"/>
              <value xsi:type="BL" value="true"/>
              <!-- E.i.3.2a: Results in Death #1 -->
            </observation>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
              <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="isLifeThreatening"/>
              <value xsi:type="BL" nullFlavor="NI"/>
              <!-- E.i.3.2b: Life Threatening #1 -->
            </observation>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
              <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="requiresInpatientHospitalization"/>
              <value xsi:type="BL" value="true"/>
              <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #1 -->
            </observation>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
              <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInPersistentOrSignificantDisability"/>
              <value xsi:type="BL" nullFlavor="NI"/>
              <!-- E.i.3.2d: Disabling / Incapacitating #1-->
            </observation>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
              <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="congenitalAnomalyBirthDefect"/>
              <value xsi:type="BL" nullFlavor="NI"/>
              <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #1 -->
            </observation>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
              <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="otherMedicallyImportantCondition"/>
              <value xsi:type="BL" value="true"/>
              <!-- E.i.3.2f: Other Medically Important Condition #1 -->
            </observation>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
              <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="outcome"/>
              <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"
codeSystemVersion="1.0"/>
              <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #1 -->
            </observation>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
              <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="medicalConfirmationByHealthProfessional"/>
              <value xsi:type="BL" value="true"/>
              <!-- E.i.8: Medical Confirmation by Healthcare Professional #1 -->
            </observation>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="PERT">
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                            <observation classCode="OBS" moodCode="EVN">
                                <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="未知・既知"/>
                                <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.0"/>
                                <!-- @@@J2.14.i 未知・既知 #1 -->
                            </observation>
                        </outboundRelationship2>
                    </observation>
                </subjectOf2>
                <subjectOf2 typeCode="SBJ">
                    <observation classCode="OBS" moodCode="EVN">
                        <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
                        <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
                        <effectiveTime xsi:type="IVL_TS">
                            <low value="20090101"/>
                            <!-- E.i.4: Date of Start of Reaction / Event #2 -->
                            <width value="24" unit="E.i.6b"/>
                            <!-- E.i.6a: Duration of Reaction / Event (number) #2 -->
                            <!-- E.i.6b: Duration of Reaction / Event (unit) #2 -->
                        </effectiveTime>
                        <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
                            <!-- E.i.2.1a: MedDRA Version for Reaction / Event #2 -->
                            <!-- E.i.2.1b: Reaction / Event (MedDRA code) #2 -->
                            <originalText language="E.i.1.1b">E.i.1.1a</originalText>
                            <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #2 -->
                            <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #2 -->
                        </value>
                        <location typeCode="LOC">
                            <locatedEntity classCode="LOCE">
                                <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
                                    <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
                                    <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #2 -->
                                </locatedPlace>
                            </locatedEntity>
                        </location>
                        <outboundRelationship2 typeCode="PERT">
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="30" codeSystem="2.16.840.1.113883.2.1.1.19" codeSystemVersion="1.1"
displayName="reactionForTranslation"/>
                                <value xsi:type="ED">E.i.1.2</value>
                                <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #2 -->
                            </observation>
                        </outboundRelationship2>
                        <outboundRelationship2 typeCode="PERT">
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="termHighlightedByReporter"/>
                                <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"
codeSystemVersion="1.0"/>
                                <!-- E.i.3.1:Term Highlighted by the Reporter #2 -->
                            </observation>
                        </outboundRelationship2>
                        <outboundRelationship2 typeCode="PERT">
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInDeath"/>
                                <value xsi:type="BL" value="true"/>
                                <!-- E.i.3.2a: Results in Death #2 -->
                            </observation>
                        </outboundRelationship2>
                        <outboundRelationship2 typeCode="PERT">
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="isLifeThreatening"/>
                                <value xsi:type="BL" nullFlavor="NI"/>
                                <!-- E.i.3.2b: Life Threatening #2 -->
```

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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" codeSystemVersion="1.1"
displayName="requiresInpatientHospitalization"/>
                <value xsi:type="BL" value="true"/>
                <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #2 -->
              </observation>
            </outboundRelationship2>
            <outboundRelationship2 typeCode="PERT">
              <observation classCode="OBS" moodCode="EVN">
                <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInPersistentOrSignificantDisability"/>
                <value xsi:type="BL" nullFlavor="NI"/>
                <!-- E.i.3.2d: Disabling / Incapacitating #2 -->
              </observation>
            </outboundRelationship2>
            <outboundRelationship2 typeCode="PERT">
              <observation classCode="OBS" moodCode="EVN">
                <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="congenitalAnomalyBirthDefect"/>
                <value xsi:type="BL" nullFlavor="NI"/>
                <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #2 -->
              </observation>
            </outboundRelationship2>
            <outboundRelationship2 typeCode="PERT">
              <observation classCode="OBS" moodCode="EVN">
                <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="otherMedicallyImportantCondition"/>
                <value xsi:type="BL" value="true"/>
                <!-- E.i.3.2f: Other Medically Important Condition #2 -->
              </observation>
            </outboundRelationship2>
            <outboundRelationship2 typeCode="PERT">
              <observation classCode="OBS" moodCode="EVN">
                <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="outcome"/>
                <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"
codeSystemVersion="1.0"/>
                <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #2 -->
              </observation>
            </outboundRelationship2>
            <outboundRelationship2 typeCode="PERT">
              <observation classCode="OBS" moodCode="EVN">
                <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="medicalConfirmationByHealthProfessional"/>
                <value xsi:type="BL" value="true"/>
                <!-- E.i.8: Medical Confirmation by Healthcare Professional #2 -->
              </observation>
            </outboundRelationship2>
            <outboundRelationship2 typeCode="PERT">
              <observation classCode="OBS" moodCode="EVN">
                <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="未知・既知"/>
                <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.0"/>
                <!-- @@@J2.14.i 未知・既知 #2 -->
              </observation>
            </outboundRelationship2>
          </observation>
        </subjectOf2>
        <subjectOf2 typeCode="SBJ">
          <observation classCode="OBS" moodCode="EVN">
            <id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430adf"/>
            <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
            <effectiveTime xsi:type="IVL_TS">
              <width value="24" unit="E.i.6b"/>
```

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                    <!-- E.i.6a: Duration of Reaction / Event (number) #3 -->
                    <!-- E.i.6b: Duration of Reaction / Event (unit) #3 -->
                    <high value="20101201"/>
                    <!-- E.i.5: Date of End of Reaction / Event #3 -->
                </effectiveTime>
                <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
                    <!-- E.i.2.1a: MedDRA Version for Reaction / Event #3 -->
                    <!-- E.i.2.1b: Reaction / Event (MedDRA code) #3 -->
                    <originalText language="E.i.1.1b">E.i.1.1a</originalText>
                    <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #3 -->
                    <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #3 -->
                </value>
                <location typeCode="LOC">
                    <locatedEntity classCode="LOCE">
                        <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
                            <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
                            <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #3 -->
                        </locatedPlace>
                    </locatedEntity>
                </location>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reactionForTranslation"/>
                        <value xsi:type="ED">E.i.1.2</value>
                        <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #3 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="termHighlightedByReporter"/>
                        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"
codeSystemVersion="1.0"/>
                        <!-- E.i.3.1:Term Highlighted by the Reporter #3 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInDeath"/>
                        <value xsi:type="BL" value="true"/>
                        <!-- E.i.3.2a: Results in Death #3 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="isLifeThreatening"/>
                        <value xsi:type="BL" nullFlavor="NI"/>
                        <!-- E.i.3.2b: Life Threatening #3 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="requiresInpatientHospitalization"/>
                        <value xsi:type="BL" value="true"/>
                        <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #3 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInPersistentOrSignificantDisability"/>
                        <value xsi:type="BL" nullFlavor="NI"/>
                        <!-- E.i.3.2d: Disabling / Incapacitating #3 -->
                    </observation>
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                        </outboundRelationship2>
                        <outboundRelationship2 typeCode="PERT">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="congenitalAnomalyBirthDefect"/>
                            <value xsi:type="BL" nullFlavor="NI"/>
                            <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #3 -->
                          </observation>
                        </outboundRelationship2>
                        <outboundRelationship2 typeCode="PERT">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="otherMedicallyImportantCondition"/>
                            <value xsi:type="BL" value="true"/>
                            <!-- E.i.3.2f: Other Medically Important Condition #3 -->
                          </observation>
                        </outboundRelationship2>
                        <outboundRelationship2 typeCode="PERT">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="outcome"/>
                            <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"
codeSystemVersion="1.0"/>
                            <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #3 -->
                          </observation>
                        </outboundRelationship2>
                        <outboundRelationship2 typeCode="PERT">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="medicalConfirmationByHealthProfessional"/>
                            <value xsi:type="BL" value="true"/>
                            <!-- E.i.8: Medical Confirmation by Healthcare Professional #3 -->
                          </observation>
                        </outboundRelationship2>
                        <outboundRelationship2 typeCode="PERT">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="未知・既知"/>
                            <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.0"/>
                            <!-- @@@J2.14.i 未知・既知 #3 -->
                          </observation>
                        </outboundRelationship2>
                      </observation>
                    </subjectOf2>
                    <subjectOf2 typeCode="SBJ">
                      <observation classCode="OBS" moodCode="EVN">
                        <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
                        <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
                        <effectiveTime xsi:type="SXPR_TS">
                          <comp xsi:type="IVL_TS">
                            <low value="20090101"/>
                            <!-- E.i.4: Date of Start of Reaction / Event #4 -->
                            <high value="20101201"/>
                            <!-- E.i.5: Date of End of Reaction / Event #4 -->
                          </comp>
                          <comp xsi:type="IVL_TS" operator="A">
                            <width value="24" unit="E.i.6b"/>
                            <!-- E.i.6a: Duration of Reaction / Event (number) #4 -->
                            <!-- E.i.6b: Duration of Reaction / Event (unit) #4 -->
                          </comp>
                        </effectiveTime>
                        <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
                          <!-- E.i.2.1a: MedDRA Version for Reaction / Event #4 -->
                          <!-- E.i.2.1b: Reaction / Event (MedDRA code) #4 -->
                          <originalText language="E.i.1.1b">E.i.1.1a</originalText>
                          <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #4 -->
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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" codeSystemVersion="1.1"
displayName="reactionForTranslation"/>
            <value xsi:type="ED">E.i.1.2</value>
            <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #4 -->
          </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
          <observation classCode="OBS" moodCode="EVN">
            <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="termHighlightedByReporter"/>
            <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"
codeSystemVersion="1.0"/>
            <!-- E.i.3.1:Term Highlighted by the Reporter #4 -->
          </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
          <observation classCode="OBS" moodCode="EVN">
            <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInDeath"/>
            <value xsi:type="BL" value="true"/>
            <!-- E.i.3.2a: Results in Death #4 -->
          </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
          <observation classCode="OBS" moodCode="EVN">
            <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="isLifeThreatening"/>
            <value xsi:type="BL" nullFlavor="NI"/>
            <!-- E.i.3.2b: Life Threatening #4 -->
          </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
          <observation classCode="OBS" moodCode="EVN">
            <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="requiresInpatientHospitalization"/>
            <value xsi:type="BL" value="true"/>
            <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #4 -->
          </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
          <observation classCode="OBS" moodCode="EVN">
            <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInPersistentOrSignificantDisability"/>
            <value xsi:type="BL" nullFlavor="NI"/>
            <!-- E.i.3.2d: Disabling / Incapacitating #4 -->
          </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
          <observation classCode="OBS" moodCode="EVN">
            <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="congenitalAnomalyBirthDefect"/>
            <value xsi:type="BL" nullFlavor="NI"/>
            <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #4 -->
          </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
          <observation classCode="OBS" moodCode="EVN">
```

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                                    <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="otherMedicallyImportantCondition"/>
                                    <value xsi:type="BL" value="true"/>
                                    <!-- E.i.3.2f: Other Medically Important Condition #4 -->
                                </observation>
                            </outboundRelationship2>
                            <outboundRelationship2 typeCode="PERT">
                                <observation classCode="OBS" moodCode="EVN">
                                    <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="outcome"/>
                                    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"
codeSystemVersion="1.0"/>
                                    <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #4 -->
                                </observation>
                            </outboundRelationship2>
                            <outboundRelationship2 typeCode="PERT">
                                <observation classCode="OBS" moodCode="EVN">
                                    <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="medicalConfirmationByHealthProfessional"/>
                                    <value xsi:type="BL" value="true"/>
                                    <!-- E.i.8: Medical Confirmation by Healthcare Professional #4 -->
                                </observation>
                            </outboundRelationship2>
                            <outboundRelationship2 typeCode="PERT">
                                <observation classCode="OBS" moodCode="EVN">
                                    <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="未知・既知"/>
                                    <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.0"/>
                                    <!-- @@@J2.14.i 未知・既知 #4 -->
                                </observation>
                            </outboundRelationship2>
                        </observation>
                    </subjectOf2>
                    <subjectOf2 typeCode="SBJ">
                        <observation classCode="OBS" moodCode="EVN">
                            <id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
                            <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
                            <effectiveTime xsi:type="IVL_TS">
                                <low value="20090101"/>
                                <!-- E.i.4: Date of Start of Reaction / Event #5 -->
                            </effectiveTime>
                            <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
                                <!-- E.i.2.1a: MedDRA Version for Reaction / Event #5 -->
                                <!-- E.i.2.1b: Reaction / Event (MedDRA code) #5 -->
                                <originalText language="E.i.1.1b">E.i.1.1a</originalText>
                                <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #5 -->
                                <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #5 -->
                            </value>
                            <location typeCode="LOC">
                                <locatedEntity classCode="LOCE">
                                    <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
                                        <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
                                        <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #5 -->
                                    </locatedPlace>
                                </locatedEntity>
                            </location>
                            <outboundRelationship2 typeCode="PERT">
                                <observation classCode="OBS" moodCode="EVN">
                                    <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reactionForTranslation"/>
                                    <value xsi:type="ED">E.i.1.2</value>
                                    <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #5 -->
                                </observation>
                            </outboundRelationship2>
                            <outboundRelationship2 typeCode="PERT">
                                <observation classCode="OBS" moodCode="EVN">
```

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                        <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="termHighlightedByReporter"/>
                        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"
codeSystemVersion="1.0"/>
                        <!-- E.i.3.1:Term Highlighted by the Reporter #5 -->
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="PERT">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInDeath"/>
                        <value xsi:type="BL" value="true"/>
                        <!-- E.i.3.2a: Results in Death #5 -->
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="PERT">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="isLifeThreatening"/>
                        <value xsi:type="BL" nullFlavor="NI"/>
                        <!-- E.i.3.2b: Life Threatening #5 -->
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="PERT">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="requiresInpatientHospitalization"/>
                        <value xsi:type="BL" value="true"/>
                        <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #5 -->
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="PERT">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInPersistentOrSignificantDisability"/>
                        <value xsi:type="BL" nullFlavor="NI"/>
                        <!-- E.i.3.2d: Disabling / Incapacitating #5 -->
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="PERT">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="congenitalAnomalyBirthDefect"/>
                        <value xsi:type="BL" nullFlavor="NI"/>
                        <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #5 -->
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="PERT">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="otherMedicallyImportantCondition"/>
                        <value xsi:type="BL" value="true"/>
                        <!-- E.i.3.2f: Other Medically Important Condition #5 -->
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="PERT">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="outcome"/>
                        <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"
codeSystemVersion="1.0"/>
                        <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #5 -->
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="PERT">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="medicalConfirmationByHealthProfessional"/>
                        <value xsi:type="BL" value="true"/>
```

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                                <!-- E.i.8: Medical Confirmation by Healthcare Professional #5 -->
                            </observation>
                        </outboundRelationship2>
                        <outboundRelationship2 typeCode="PERT">
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="未知・既知"/>
                                <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8" codeSystemVersion="1.0"/>
                                <!-- @@@J2.14.i 未知・既知 #5 -->
                            </observation>
                        </outboundRelationship2>
                    </observation>
                </subjectOf2>
                <subjectOf2 typeCode="SBJ">
                    <observation classCode="OBS" moodCode="EVN">
                        <id root="1f927283-10b6-4334-9d43-e925640fb18f"/>
                        <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reaction"/>
                        <effectiveTime xsi:type="IVL_TS">
                            <high value="20090101"/>
                            <!-- E.i.4: Date of Start of Reaction / Event #6 -->
                        </effectiveTime>
                        <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
                            <!-- E.i.2.1a: MedDRA Version for Reaction / Event #6 -->
                            <!-- E.i.2.1b: Reaction / Event (MedDRA code) #6 -->
                            <originalText language="E.i.1.1b">E.i.1.1a</originalText>
                            <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #6 -->
                            <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #6 -->
                        </value>
                        <location typeCode="LOC">
                            <locatedEntity classCode="LOCE">
                                <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
                                    <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
                                    <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #6 -->
                                </locatedPlace>
                            </locatedEntity>
                        </location>
                        <outboundRelationship2 typeCode="PERT">
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reactionForTranslation"/>
                                <value xsi:type="ED">E.i.1.2</value>
                                <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #6 -->
                            </observation>
                        </outboundRelationship2>
                        <outboundRelationship2 typeCode="PERT">
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="termHighlightedByReporter"/>
                                <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="1.0"/>
                                <!-- E.i.3.1:Term Highlighted by the Reporter #6 -->
                            </observation>
                        </outboundRelationship2>
                        <outboundRelationship2 typeCode="PERT">
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="resultsInDeath"/>
                                <value xsi:type="BL" value="true"/>
                                <!-- E.i.3.2a: Results in Death #6 -->
                            </observation>
                        </outboundRelationship2>
                        <outboundRelationship2 typeCode="PERT">
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="isLifeThreatening"/>
                                <value xsi:type="BL" nullFlavor="NI"/>
```

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                        <!-- E.i.3.2b: Life Threatening #6 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="requiresInpatientHospitalization"/>
                        <value xsi:type="BL" value="true"/>
                        <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #6 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInPersistentOrSignificantDisability"/>
                        <value xsi:type="BL" nullFlavor="NI"/>
                        <!-- E.i.3.2d: Disabling / Incapacitating #6 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="congenitalAnomalyBirthDefect"/>
                        <value xsi:type="BL" nullFlavor="NI"/>
                        <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #6 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="otherMedicallyImportantCondition"/>
                        <value xsi:type="BL" value="true"/>
                        <!-- E.i.3.2f: Other Medically Important Condition #6 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="outcome"/>
                        <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"
codeSystemVersion="1.0"/>
                        <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #6 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="medicalConfirmationByHealthProfessional"/>
                        <value xsi:type="BL" value="true"/>
                        <!-- E.i.8: Medical Confirmation by Healthcare Professional #6 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="未知・既知"/>
                        <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.0"/>
                        <!-- @@@J2.14.i 未知・既知 #6 -->
                    </observation>
                </outboundRelationship2>
            </observation>
        </subjectOf2>
        <subjectOf2 typeCode="SBJ">
            <observation classCode="OBS" moodCode="EVN">
                <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
                <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
                <effectiveTime xsi:type="IVL_TS">
```

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                    <width value="24" unit="E.i.6b"/>
                    <!-- E.i.6a: Duration of Reaction / Event (number) #7 -->
                    <!-- E.i.6b: Duration of Reaction / Event (unit) #7 -->
                </effectiveTime>
                <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
                    <!-- E.i.2.1a: MedDRA Version for Reaction / Event #7 -->
                    <!-- E.i.2.1b: Reaction / Event (MedDRA code) #7 -->
                    <originalText language="E.i.1.1b">E.i.1.1a</originalText>
                    <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #7 -->
                    <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #7 -->
                </value>
                <location typeCode="LOC">
                    <locatedEntity classCode="LOCE">
                        <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
                            <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
                            <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #7 -->
                        </locatedPlace>
                    </locatedEntity>
                </location>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reactionForTranslation"/>
                        <value xsi:type="ED">E.i.1.2</value>
                        <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #7 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="termHighlightedByReporter"/>
                        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"
codeSystemVersion="1.0"/>
                        <!-- E.i.3.1:Term Highlighted by the Reporter #7 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInDeath"/>
                        <value xsi:type="BL" value="true"/>
                        <!-- E.i.3.2a: Results in Death #7 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="isLifeThreatening"/>
                        <value xsi:type="BL" nullFlavor="NI"/>
                        <!-- E.i.3.2b: Life Threatening #7 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="requiresInpatientHospitalization"/>
                        <value xsi:type="BL" value="true"/>
                        <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #7 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="PERT">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInPersistentOrSignificantDisability"/>
                        <value xsi:type="BL" nullFlavor="NI"/>
                        <!-- E.i.3.2d: Disabling / Incapacitating #7 -->
                    </observation>
                </outboundRelationship2>
```

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                        <outboundRelationship2 typeCode="PERT">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="congenitalAnomalyBirthDefect"/>
                            <value xsi:type="BL" nullFlavor="NI"/>
                            <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #7 -->
                          </observation>
                        </outboundRelationship2>
                        <outboundRelationship2 typeCode="PERT">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="otherMedicallyImportantCondition"/>
                            <value xsi:type="BL" value="true"/>
                            <!-- E.i.3.2f: Other Medically Important Condition #7 -->
                          </observation>
                        </outboundRelationship2>
                        <outboundRelationship2 typeCode="PERT">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="outcome"/>
                            <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"
codeSystemVersion="1.0"/>
                            <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #7 -->
                          </observation>
                        </outboundRelationship2>
                        <outboundRelationship2 typeCode="PERT">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="medicalConfirmationByHealthProfessional"/>
                            <value xsi:type="BL" value="true"/>
                            <!-- E.i.8: Medical Confirmation by Healthcare Professional #7 -->
                          </observation>
                        </outboundRelationship2>
                        <outboundRelationship2 typeCode="PERT">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="未知・既知"/>
                            <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.0"/>
                            <!-- @@@J2.14.i 未知・既知 #7 -->
                          </observation>
                        </outboundRelationship2>
                      </observation>
                    </subjectOf2>
                    <subjectOf2 typeCode="SBJ">
                      <observation classCode="OBS" moodCode="EVN">
                        <id root="a15be092-8070-426d-af04-6863263443e0"/>
                        <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
                        <effectiveTime xsi:type="SXPR_TS">
                          <comp xsi:type="IVL_TS">
                            <low value="20090101"/>
                            <!-- E.i.4: Date of Start of Reaction / Event #8 -->
                            <width value="24" unit="E.i.6b"/>
                            <!-- E.i.6a: Duration of Reaction / Event (number) #8 -->
                            <!-- E.i.6b: Duration of Reaction / Event (unit) #8 -->
                          </comp>
                          <comp xsi:type="IVL_TS" operator="A">
                            <high value="20101201"/>
                            <!-- E.i.5: Date of End of Reaction / Event #8 -->
                          </comp>
                        </effectiveTime>
                        <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
                            <!-- E.i.2.1a: MedDRA Version for Reaction / Event #8 -->
                            <!-- E.i.2.1b: Reaction / Event (MedDRA code) #8 -->
                            <originalText language="E.i.1.1b">E.i.1.1a</originalText>
                            <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #8 -->
                            <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #8 -->
```

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          </value>
          <location typeCode="LOC">
            <locatedEntity classCode="LOCE">
              <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
                <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
                <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #8 -->
              </locatedPlace>
            </locatedEntity>
          </location>
          <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
              <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reactionForTranslation"/>
              <value xsi:type="ED">E.i.1.2</value>
              <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #8 -->
            </observation>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
              <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="termHighlightedByReporter"/>
              <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"
codeSystemVersion="1.0"/>
              <!-- E.i.3.1:Term Highlighted by the Reporter #8 -->
            </observation>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
              <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInDeath"/>
              <value xsi:type="BL" value="true"/>
              <!-- E.i.3.2a: Results in Death #8 -->
            </observation>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
              <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="isLifeThreatening"/>
              <value xsi:type="BL" nullFlavor="NI"/>
              <!-- E.i.3.2b: Life Threatening #8 -->
            </observation>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
              <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="requiresInpatientHospitalization"/>
              <value xsi:type="BL" value="true"/>
              <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #8 -->
            </observation>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
              <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInPersistentOrSignificantDisability"/>
              <value xsi:type="BL" nullFlavor="NI"/>
              <!-- E.i.3.2d: Disabling / Incapacitating #8 -->
            </observation>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
              <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="congenitalAnomalyBirthDefect"/>
              <value xsi:type="BL" nullFlavor="NI"/>
              <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #8 -->
            </observation>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
              <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
```

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                            displayName="otherMedicallyImportantCondition"/>
                              <value xsi:type="BL" value="true"/>
                              <!-- E.i.3.2f: Other Medically Important Condition #8 -->
                            </observation>
                          </outboundRelationship2>
                          <outboundRelationship2 typeCode="PERT">
                            <observation classCode="OBS" moodCode="EVN">
                              <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="outcome"/>
                              <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"
codeSystemVersion="1.0"/>
                              <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #8 -->
                            </observation>
                          </outboundRelationship2>
                          <outboundRelationship2 typeCode="PERT">
                            <observation classCode="OBS" moodCode="EVN">
                              <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="medicalConfirmationByHealthProfessional"/>
                              <value xsi:type="BL" value="true"/>
                              <!-- E.i.8: Medical Confirmation by Healthcare Professional #8 -->
                            </observation>
                          </outboundRelationship2>
                          <outboundRelationship2 typeCode="PERT">
                            <observation classCode="OBS" moodCode="EVN">
                              <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="未知・既知"/>
                              <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.0"/>
                              <!-- @@@J2.14.i 未知・既知 #8 -->
                            </observation>
                          </outboundRelationship2>
                        </observation>
                      </subjectOf2>
                      <subjectOf2 typeCode="SBJ">
                        <organizer classCode="CATEGORY" moodCode="EVN">
                          <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" codeSystemVersion="1.0"
displayName="testsAndProceduresRelevantToTheInvestigation"/>
                          <component typeCode="COMP">
                            <observation classCode="OBS" moodCode="EVN">
                              <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
                                <!-- F.r.2.2a: MedDRA Version for Test Name #1 -->
                                <!-- F.r.2.2b: Test Name (MedDRA code) #1 -->
                                <originalText>F.r.2.1</originalText>
                                <!-- F.r.2.1: Test Name (free text) #1 -->
                              </code>
                              <effectiveTime value="20090101"/>
                              <!-- F.r.1: Test Date #1 -->
                              <value xsi:type="IVL_PQ">
                                <center value="10" unit="mg/dl"/>
                                <!-- F.r.3.2: Test Result (value / qualifier) #1 -->
                                <!-- F.r.3.3: Test Result (unit) #1 -->
                              </value>
                              <interpretationCode code="F.r.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.12"
codeSystemVersion="1.0"/>
                              <!-- F.r.3.1: Test Result (code) #1 -->
                              <referenceRange typeCode="REFV">
                                <observationRange classCode="OBS" moodCode="EVN.CRT">
                                  <value xsi:type="PQ" value="40" unit="mg/dl"/>
                                  <!-- F.r.4: Normal Low Value #1 -->
                                  <interpretationCode code="L" codeSystem="2.16.840.1.113883.5.83"/>
                                </observationRange>
                              </referenceRange>
                              <referenceRange typeCode="REFV">
                                <observationRange classCode="OBS" moodCode="EVN.CRT">
                                  <value xsi:type="PQ" value="110" unit="mg/dl"/>
                                  <!-- F.r.5:  Normal High Value #1-->
                                  <interpretationCode code="H" codeSystem="2.16.840.1.113883.5.83"/>
                                </observationRange>
                              </referenceRange>
```

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                            <outboundRelationship2 typeCode="PERT">
                              <observation classCode="OBS" moodCode="EVN">
                                <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="comment"/>
                                <value xsi:type="ED">F.r.6</value>
                                <!-- F.r.6: Comments (free text) #1 -->
                              </observation>
                            </outboundRelationship2>
                            <outboundRelationship2 typeCode="REFR">
                              <observation classCode="OBS" moodCode="EVN">
                                <code code="25" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="moreInformationAvailable"/>
                                <value xsi:type="BL" value="true"/>
                                <!--F.r.7: More Information Available #1 -->
                              </observation>
                            </outboundRelationship2>
                          </observation>
                        </component>
                        <component typeCode="COMP">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
                              <!-- F.r.2.2a: MedDRA Version for Test Name #2 -->
                              <!-- F.r.2.2b: Test Name (MedDRA code) #2 -->
                              <originalText>F.r.2.1</originalText>
                              <!-- F.r.2.1: Test Name (free text) #2 -->
                            </code>
                            <effectiveTime value="20090101"/>
                            <!-- F.r.1: Test Date #2 -->
                            <value xsi:type="IVL_PQ">
                              <low nullFlavor="NINF"/>
                              <high value="10" unit="mg/dl" inclusive="false"/>
                            </value>
                            <!-- F.r.3.2: Test Result (value / qualifier) #2 -->
                            <!-- F.r.3.3: Test Result (unit) #2 -->
                            <!-- LT 10 mg/dl #2 -->
                          </observation>
                        </component>
                        <component typeCode="COMP">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
                              <!-- F.r.2.2a: MedDRA Version for Test Name #3 -->
                              <!-- F.r.2.2b: Test Name (MedDRA code) #3 -->
                              <originalText>F.r.2.1</originalText>
                              <!-- F.r.2.1: Test Name (free text) #3 -->
                            </code>
                            <effectiveTime value="20090101"/>
                            <!-- F.r.1: Test Date #3 -->
                            <value xsi:type="IVL_PQ">
                              <low nullFlavor="NINF"/>
                              <high value="10" unit="mg/dl" inclusive="true"/>
                            </value>
                            <!-- F.r.3.2: Test Result (value / qualifier) #3 -->
                            <!-- F.r.3.3: Test Result (unit) #3 -->
                            <!-- LE 10 mg/dl  #3-->
                          </observation>
                        </component>
                        <component typeCode="COMP">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
                              <!-- F.r.2.2a: MedDRA Version for Test Name #4 -->
                              <!-- F.r.2.2b: Test Name (MedDRA code) #4 -->
                              <originalText>F.r.2.1</originalText>
                              <!-- F.r.2.1: Test Name (free text) #4 -->
                            </code>
                            <effectiveTime value="20090101"/>
                            <!-- F.r.1: Test Date #4 -->
                            <value xsi:type="IVL_PQ">
                              <low value="10" unit="mg/dl" inclusive="false"/>
                              <high nullFlavor="PINF"/>
```

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          </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" codeSystemVersion="1.0"
displayName="drugInformation"/>
      <!-- G.k Drug(s) Information (repeat as necessary) #1 -->
      <component typeCode="COMP">
        <substanceAdministration classCode="SBADM" moodCode="EVN">
          <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
          <consumable typeCode="CSM">
            <instanceOfKind classCode="INST">
              <kindOfProduct classCode="MMAT" determinerCode="KIND">
                <code code="G.k.2.1.1b" codeSystem="TBD-MPID" codeSystemVersion="G.k.2.1.1a"/>
                <!-- G.k.2.1.1a: MPID Version Date / Number #1 -->
                <!-- G.k.2.1.1b: Medicinal Product Identifier (MPID) #1 -->
                <name>G.k.2.2</name>
                <!-- G.k.2.2: Medicinal Product Name as Reported by the Primary Source #1 -->
                <asManufacturedProduct classCode="MANU">
                  <subjectOf typeCode="SBJ">
                    <approval classCode="CNTRCT" moodCode="EVN">
                      <id extension="G.k.3.1" root="2.16.840.1.113883.3.989.2.1.3.4"/>
                      <!-- G.k.3.1: Authorisation / Application Number #1 -->
                      <holder typeCode="HLD">
                        <role classCode="HLD">
                          <playingOrganization classCode="ORG" determinerCode="INSTANCE">
                            <name>G.k.3.3</name>
                            <!-- G.k.3.3: Name of Holder / Applicant #1 -->
                          </playingOrganization>
                        </role>
```

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          </holder>
          <author typeCode="AUT">
            <territorialAuthority classCode="TERR">
              <territory classCode="NAT" determinerCode="INSTANCE">
                <code code="G.k.3.2" codeSystem="1.0.3166.1.2.2"/>
                <!-- G.k.3.2: Country of Authorisation / Application #1 -->
              </territory>
            </territorialAuthority>
          </author>
          <pertinentInformation typeCode="PERT">
            <policy classCode="POLICY" moodCode="EVN">
              <code code="J2.5.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.4"
codeSystemVersion="1.0"/>
              <!-- @@@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"
codeSystemVersion="1.0" displayName="新医薬品等の状況区分"/>
          <value xsi:type="CE" code="J2.4.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.3"
codeSystemVersion="1.0"/>
          <!-- @@@J2.4.k: 新医薬品等の状況区分 #1 -->
        </characteristic>
      </subjectOf>
    </asManufacturedProduct>
    <asSpecializedKind classCode="GEN">
      <generalizedMaterialKind classCode="MAT" determinerCode="KIND">
        <code>
          <originalText>J2.12</originalText>
          <!-- @@J2.12: 治験成分記号 -->
        </code>
      </generalizedMaterialKind>
    </asSpecializedKind>
    <ingredient classCode="ACTI">
      <quantity>
        <numerator value="10" unit="G.k.2.3.r.3b"/>
        <!-- G.k.2.3.r.3a: Strength (number) #1-1 -->
        <!-- G.k.2.3.r.3b: Strength (unit) #1-1 -->
        <denominator value="1"/>
      </quantity>
      <ingredientSubstance classCode="MMAT" determinerCode="KIND">
        <code code="G.k.2.3.r.2b" codeSystem="TBD-Substance"
codeSystemVersion="G.k.2.3.r.2a"/>
        <!-- G.k.2.3.r.2a: Substance / Specified Substance TermID Version Date / Number #1-1
-->
        <!-- G.k.2.3.r.2b: Substance / Specified Substance TermID #1-1 -->
        <name>G.k.2.3.r.1</name>
        <!-- G.k.2.3.r.1: Substance / Specified Substance Name #1-1 -->
      </ingredientSubstance>
    </ingredient>
    <ingredient classCode="ACTI">
      <quantity>
        <numerator value="10" unit="G.k.2.3.r.3b"/>
        <!-- G.k.2.3.r.3a: Strength (number) #1-2 -->
        <!-- G.k.2.3.r.3b: Strength (unit) #1-2 -->
        <denominator value="1"/>
      </quantity>
      <ingredientSubstance classCode="MMAT" determinerCode="KIND">
        <code code="G.k.2.3.r.2b" codeSystem="TBD-Substance"
codeSystemVersion="G.k.2.3.r.2a"/>
        <!-- G.k.2.3.r.2a: Substance / Specified Substance TermID Version Date / Number #1-2
-->
        <!-- G.k.2.3.r.2b: Substance / Specified Substance TermID #1-2 -->
        <name>G.k.2.3.r.1</name>
        <!-- G.k.2.3.r.1: Substance / Specified Substance Name #1-2 -->
      </ingredientSubstance>
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                            </ingredient>
                        </kindOfProduct>
                        <subjectOf typeCode="SBJ">
                            <productEvent classCode="ACT" moodCode="EVN">
                                <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.18" codeSystemVersion="1.0"
displayName="retailSupply"/>
                                <performer typeCode="PRF">
                                    <assignedEntity classCode="ASSIGNED">
                                        <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                                            <addr>
                                                <country>G.k.2.4</country>
                                                <!-- G.k.2.4: Identification of the Country Where the Drug Was Obtained #1 -->
                                            </addr>
                                        </representedOrganization>
                                    </assignedEntity>
                                </performer>
                            </productEvent>
                        </subjectOf>
                        <subjectOf typeCode="SBJ">
                            <observationEvent classCode="OBS" moodCode="EVN">
                                <code code="2" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10"
codeSystemVersion="1.0" displayName="一般用医薬品の入手経路"/>
                                <value xsi:type="CE" code="J2.6.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.5"
codeSystemVersion="1.0"/>
                                <!-- @@@J2.6.k: 一般用医薬品の入手経路 #1 -->
                            </observationEvent>
                        </subjectOf>
                    </instanceOfKind>
                </consumable>
                <outboundRelationship1 typeCode="SAS">
                    <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
                    <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #1, Reaction #1 -->
                    <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit)  Drug #1, Reaction #1 -->
                    <actReference classCode="OBS" moodCode="EVN">
                        <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
                    </actReference>
                </outboundRelationship1>
                <outboundRelationship1 typeCode="SAE">
                    <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
                    <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number)  Drug #1, Reaction #1 -->
                    <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit)  Drug #1, Reaction #1 -->
                    <actReference classCode="OBS" moodCode="EVN">
                        <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
                    </actReference>
                </outboundRelationship1>
                <outboundRelationship1 typeCode="SAS">
                    <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
                    <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #1, Reaction #2 -->
                    <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit)  Drug #1, Reaction #2 -->
                    <actReference classCode="OBS" moodCode="EVN">
                        <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
                    </actReference>
                </outboundRelationship1>
                <outboundRelationship1 typeCode="SAE">
                    <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
                    <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number)  Drug #1, Reaction #2 -->
                    <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit)  Drug #1, Reaction #2 -->
                    <actReference classCode="OBS" moodCode="EVN">
                        <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
                    </actReference>
                </outboundRelationship1>
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                    <outboundRelationship1 typeCode="SAS">
                      <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
                      <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #1, Reaction #3 -->
                      <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit)  Drug #1, Reaction #3 -->
                      <actReference classCode="OBS" moodCode="EVN">
                        <id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430adf"/>
                      </actReference>
                    </outboundRelationship1>
                    <outboundRelationship1 typeCode="SAE">
                      <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
                      <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number)  Drug #1, Reaction #3 -->
                      <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit)  Drug #1, Reaction #3 -->
                      <actReference classCode="OBS" moodCode="EVN">
                        <id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430adf"/>
                      </actReference>
                    </outboundRelationship1>
                    <outboundRelationship1 typeCode="SAS">
                      <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
                      <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #1, Reaction #4 -->
                      <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit)  Drug #1, Reaction #4 -->
                      <actReference classCode="OBS" moodCode="EVN">
                        <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
                      </actReference>
                    </outboundRelationship1>
                    <outboundRelationship1 typeCode="SAE">
                      <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
                      <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number)  Drug #1, Reaction #4 -->
                      <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit)  Drug #1, Reaction #4 -->
                      <actReference classCode="OBS" moodCode="EVN">
                        <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
                      </actReference>
                    </outboundRelationship1>
                    <outboundRelationship1 typeCode="SAS">
                      <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
                      <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #1, Reaction #5 -->
                      <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit)  Drug #1, Reaction #5 -->
                      <actReference classCode="OBS" moodCode="EVN">
                        <id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
                      </actReference>
                    </outboundRelationship1>
                    <outboundRelationship1 typeCode="SAE">
                      <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
                      <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number)  Drug #1, Reaction #5 -->
                      <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit)  Drug #1, Reaction #5 -->
                      <actReference classCode="OBS" moodCode="EVN">
                        <id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
                      </actReference>
                    </outboundRelationship1>
                    <outboundRelationship1 typeCode="SAS">
                      <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
                      <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #1, Reaction #6 -->
                      <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit)  Drug #1, Reaction #6 -->
                      <actReference classCode="OBS" moodCode="EVN">
                        <id root="1f927283-10b6-4334-9d43-e925640fb18f"/>
                      </actReference>
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                    </outboundRelationship1>
                    <outboundRelationship1 typeCode="SAE">
                      <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
                      <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number)  Drug #1, Reaction #6 -->
                      <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit)  Drug #1, Reaction #6 -->
                      <actReference classCode="OBS" moodCode="EVN">
                        <id root="1f927283-10b6-4334-9d43-e925640fb18f"/>
                      </actReference>
                    </outboundRelationship1>
                    <outboundRelationship1 typeCode="SAS">
                      <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
                      <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #1, Reaction #7 -->
                      <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit)  Drug #1, Reaction #7 -->
                      <actReference classCode="OBS" moodCode="EVN">
                        <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
                      </actReference>
                    </outboundRelationship1>
                    <outboundRelationship1 typeCode="SAE">
                      <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
                      <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number)  Drug #1, Reaction #7 -->
                      <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit)  Drug #1, Reaction #7 -->
                      <actReference classCode="OBS" moodCode="EVN">
                        <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
                      </actReference>
                    </outboundRelationship1>
                    <outboundRelationship1 typeCode="SAS">
                      <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
                      <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #1, Reaction #8 -->
                      <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit)  Drug #1, Reaction #8 -->
                      <actReference classCode="OBS" moodCode="EVN">
                        <id root="a15be092-8070-426d-af04-6863263443e0"/>
                      </actReference>
                    </outboundRelationship1>
                    <outboundRelationship1 typeCode="SAE">
                      <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
                      <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number)  Drug #1, Reaction #8 -->
                      <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit)  Drug #1, Reaction #8 -->
                      <actReference classCode="OBS" moodCode="EVN">
                        <id root="a15be092-8070-426d-af04-6863263443e0"/>
                      </actReference>
                    </outboundRelationship1>
                    <outboundRelationship2 typeCode="PERT">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="6" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="blinded"/>
                        <value xsi:type="BL" value="true"/>
                        <!-- G.k.2.5: Investigational Product Blinded #1 -->
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="COMP">
                      <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #1-1 -->
                      <substanceAdministration classCode="SBADM" moodCode="EVN">
                        <text>G.k.4.r.8</text>
                        <!-- G.k.4.r.8: Dosage Text #1-1 -->
                        <effectiveTime xsi:type="SXPR_TS">
                          <comp xsi:type="PIVL_TS">
                            <period value="10" unit="G.k.4.r.3"/>
                            <!-- G.k.4.r.2: Number of Units in the Interval #1-1 -->
                            <!-- G.k.4.r.3: Definition of the Time Interval Unit #1-1 -->
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                    </comp>
                    <comp xsi:type="IVL_TS" operator="A">
                      <low value="20090101"/>
                      <!-- G.k.4.r.4: Date and Time of Start of Drug #1-1 -->
                      <high value="20090101"/>
                      <!-- G.k.4.r.5: Date and Time of Last Administration #1-1 -->
                    </comp>
                    <comp xsi:type="IVL_TS" operator="A">
                      <width value="4" unit="G.k.4.r.6b"/>
                      <!-- G.k.4.r.6a: Duration of Drug Administration (number) #1-1 -->
                      <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #1-1 -->
                    </comp>
                  </effectiveTime>
                  <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
                    <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #1-1 -->
                    <!-- G.k.4.r.10.2b: Route of Administration TermID #1-1 -->
                    <originalText>G.k.4.r.10.1</originalText>
                    <!-- G.k.4.r.10.1: Route of Administration (free text) #1-1 -->
                  </routeCode>
                  <doseQuantity value="10" unit="G.k.4.r.1b"/>
                  <!-- G.k.4.r.1a Dose (number) #1-1 -->
                  <!-- G.k.4.r.1b: Dose (unit) #1-1 -->
                  <consumable typeCode="CSM">
                    <instanceOfKind classCode="INST">
                      <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
                        <lotNumberText>G.k.4.r.7</lotNumberText>
                        <!-- G.k.4.r.7: Batch / Lot Number #1-1 -->
                      </productInstanceInstance>
                      <kindOfProduct classCode="MMAT" determinerCode="KIND">
                        <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
                          <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-1 -->
                          <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #1-1 -->
                          <originalText>G.k.4.r.9.1</originalText>
                          <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #1-1 -->
                        </formCode>
                      </kindOfProduct>
                    </instanceOfKind>
                  </consumable>
                  <inboundRelationship typeCode="REFR">
                    <observation classCode="OBS" moodCode="EVN">
                      <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
                      <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
                        <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #1-1
-->
                        <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-1 -->
                        <originalText>G.k.4.r.11.1</originalText>
                        <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-1 -->
                      </value>
                    </observation>
                  </inboundRelationship>
                </substanceAdministration>
              </outboundRelationship2>
              <outboundRelationship2 typeCode="COMP">
                <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #1-2 -->
                <substanceAdministration classCode="SBADM" moodCode="EVN">
                  <text>G.k.4.r.8</text>
                  <!-- G.k.4.r.8: Dosage Text #1-2 -->
                  <effectiveTime xsi:type="SXPR_TS">
                    <comp xsi:type="PIVL_TS">
                      <period value="10" unit="G.k.4.r.3"/>
                      <!-- G.k.4.r.2: Number of Units in the Interval #1-2 -->
                      <!-- G.k.4.r.3: Definition of the Time Interval Unit #1-2 -->
                    </comp>
                    <comp xsi:type="IVL_TS" operator="A">
                      <low value="20090101"/>
```

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

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              <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #1-3 -->
              <!-- G.k.4.r.10.2b: Route of Administration TermID #1-3 -->
              <originalText>G.k.4.r.10.1</originalText>
              <!-- G.k.4.r.10.1: Route of Administration (free text) #1-3 -->
            </routeCode>
            <doseQuantity value="10" unit="G.k.4.r.1b"/>
            <!-- G.k.4.r.1a Dose (number) #1-3 -->
            <!-- G.k.4.r.1b: Dose (unit) #1-3 -->
            <consumable typeCode="CSM">
              <instanceOfKind classCode="INST">
                <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
                  <lotNumberText>G.k.4.r.7</lotNumberText>
                  <!-- G.k.4.r.7: Batch / Lot Number #1-3 -->
                </productInstanceInstance>
                <kindOfProduct classCode="MMAT" determinerCode="KIND">
                  <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
                    <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-3 -->
                    <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #1-3 -->
                    <originalText>G.k.4.r.9.1</originalText>
                    <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #1-3 -->
                  </formCode>
                </kindOfProduct>
              </instanceOfKind>
            </consumable>
            <inboundRelationship typeCode="REFR">
              <observation classCode="OBS" moodCode="EVN">
                <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
                <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
                  <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #1-3
-->
                  <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-3 -->
                  <originalText>G.k.4.r.11.1</originalText>
                  <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-3 -->
                </value>
              </observation>
            </inboundRelationship>
          </substanceAdministration>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="COMP">
          <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #1-4 -->
          <substanceAdministration classCode="SBADM" moodCode="EVN">
            <text>G.k.4.r.8</text>
            <!-- G.k.4.r.8: Dosage Text #1-4 -->
            <effectiveTime xsi:type="SXPR_TS">
              <comp xsi:type="PIVL_TS">
                <period value="10" unit="G.k.4.r.3"/>
                <!-- G.k.4.r.2: Number of Units in the Interval #1-4 -->
                <!-- G.k.4.r.3: Definition of the Time Interval Unit #1-4 -->
              </comp>
              <comp xsi:type="IVL_TS" operator="A">
                <width value="4" unit="G.k.4.r.6b"/>
                <!-- G.k.4.r.6a: Duration of Drug Administration (number) #1-4 -->
                <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #1-4 -->
                <high value="20090101"/>
                <!-- G.k.4.r.5: Date and Time of Last Administration #1-4 -->
              </comp>
            </effectiveTime>
            <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 -->
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            <!-- G.k.4.r.1b: Dose (unit) #1-4 -->
            <consumable typeCode="CSM">
              <instanceOfKind classCode="INST">
                <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
                  <lotNumberText>G.k.4.r.7</lotNumberText>
                  <!-- G.k.4.r.7: Batch / Lot Number #1-4 -->
                </productInstanceInstance>
                <kindOfProduct classCode="MMAT" determinerCode="KIND">
                  <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.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" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
                <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
                       <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #1-4
-->
                       <!-- 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">
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                                <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
                                    <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-5 -->
                                    <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #1-5 -->
                                    <originalText>G.k.4.r.9.1</originalText>
                                    <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #1-5 -->
                                </formCode>
                            </kindOfProduct>
                        </instanceOfKind>
                    </consumable>
                    <inboundRelationship typeCode="REFR">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
                        <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
                            <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #1-5
-->
                            <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-5 -->
                            <originalText>G.k.4.r.11.1</originalText>
                            <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-5 -->
                        </value>
                      </observation>
                    </inboundRelationship>
                  </substanceAdministration>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="COMP">
                  <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #1-6 -->
                  <substanceAdministration classCode="SBADM" moodCode="EVN">
                    <text>G.k.4.r.8</text>
                    <!-- G.k.4.r.8: Dosage Text #1-6 -->
                    <effectiveTime xsi:type="SXPR_TS">
                      <comp xsi:type="PIVL_TS">
                        <period value="10" unit="G.k.4.r.3"/>
                        <!-- G.k.4.r.2: Number of Units in the Interval #1-6 -->
                        <!-- G.k.4.r.3: Definition of the Time Interval Unit #1-6 -->
                      </comp>
                      <comp xsi:type="IVL_TS" operator="A">
                        <low value="20090101"/>
                        <!-- G.k.4.r.4: Date and Time of Start of Drug #1-6 -->
                        <width value="4" unit="G.k.4.r.6b"/>
                        <!-- G.k.4.r.6a: Duration of Drug Administration (number) #1-6 -->
                        <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #1-6 -->
                      </comp>
                      <comp xsi:type="IVL_TS" operator="A">
                        <high value="20090101"/>
                        <!-- G.k.4.r.5: Date and Time of Last Administration #1-6 -->
                      </comp>
                    </effectiveTime>
                    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
                        <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #1-6 -->
                        <!-- G.k.4.r.10.2b: Route of Administration TermID #1-6 -->
                        <originalText>G.k.4.r.10.1</originalText>
                        <!-- G.k.4.r.10.1: Route of Administration (free text) #1-6 -->
                    </routeCode>
                    <doseQuantity value="10" unit="G.k.4.r.1b"/>
                    <!-- G.k.4.r.1a Dose (number) #1-1 -->
                    <!-- G.k.4.r.1b: Dose (unit) #1-1 -->
                    <consumable typeCode="CSM">
                      <instanceOfKind classCode="INST">
                        <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
                          <lotNumberText>G.k.4.r.7</lotNumberText>
                          <!-- G.k.4.r.7: Batch / Lot Number #1-1 -->
                        </productInstanceInstance>
                        <kindOfProduct classCode="MMAT" determinerCode="KIND">
                          <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
                              <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-6 -->
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                                <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #1-6 -->
                                <originalText>G.k.4.r.9.1</originalText>
                                <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #1-6 -->
                            </formCode>
                        </kindOfProduct>
                    </instanceOfKind>
                </consumable>
                <inboundRelationship typeCode="REFR">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
                        <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
                            <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #1-6
-->
                            <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-6 -->
                            <originalText>G.k.4.r.11.1</originalText>
                            <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-6 -->
                        </value>
                    </observation>
                </inboundRelationship>
            </substanceAdministration>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="COMP">
            <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #1-7 -->
            <substanceAdministration classCode="SBADM" moodCode="EVN">
                <text>G.k.4.r.8</text>
                <!-- G.k.4.r.8: Dosage Text #1-7 -->
                <effectiveTime xsi:type="SXPR_TS">
                    <comp xsi:type="IVL_TS">
                        <low value="20090101"/>
                        <!-- G.k.4.r.4: Date and Time of Start of Drug #1-7 -->
                        <width value="4" unit="G.k.4.r.6b"/>
                        <!-- G.k.4.r.6a: Duration of Drug Administration (number) #1-7 -->
                        <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #1-7 -->
                    </comp>
                    <comp xsi:type="IVL_TS" operator="A">
                        <high value="20090101"/>
                        <!-- G.k.4.r.5: Date and Time of Last Administration #1-7 -->
                    </comp>
                </effectiveTime>
                <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
                    <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #1-7 -->
                    <!-- G.k.4.r.10.2b: Route of Administration TermID #1-7 -->
                    <originalText>G.k.4.r.10.1</originalText>
                    <!-- G.k.4.r.10.1: Route of Administration (free text) #1-7 -->
                </routeCode>
                <doseQuantity value="10" unit="G.k.4.r.1b"/>
                <!-- G.k.4.r.1a Dose (number) #1-7 -->
                <!-- G.k.4.r.1b: Dose (unit) #1-7 -->
                <consumable typeCode="CSM">
                    <instanceOfKind classCode="INST">
                        <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
                            <lotNumberText>G.k.4.r.7</lotNumberText>
                            <!-- G.k.4.r.7: Batch / Lot Number #1-7 -->
                        </productInstanceInstance>
                        <kindOfProduct classCode="MMAT" determinerCode="KIND">
                            <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
                                <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-7 -->
                                <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #1-7 -->
                                <originalText>G.k.4.r.9.1</originalText>
                                <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #1-7 -->
                            </formCode>
                        </kindOfProduct>
                    </instanceOfKind>
                </consumable>
                <inboundRelationship typeCode="REFR">
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                    <observation classCode="OBS" moodCode="EVN">
                        <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
                        <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
                            <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #1-7
-->
                            <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-7 -->
                            <originalText>G.k.4.r.11.1</originalText>
                            <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-7 -->
                        </value>
                    </observation>
                </inboundRelationship>
            </substanceAdministration>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="SUMM">
            <observation classCode="OBS" moodCode="EVN">
                <code code="14" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="cumulativeDoseToReaction"/>
                <value xsi:type="PQ" value="10" unit="G.k.5b"/>
                <!-- G.k.5a: Cumulative Dose to First Reaction (number) #1 -->
                <!-- G.k.5b: Cumulative Dose to First Reaction (unit) #1 -->
            </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
                <code code="16" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="gestationPeriod"/>
                <value xsi:type="PQ" value="10" unit="G.k.6b"/>
                <!-- G.k.6a: Gestation Period at Time of Exposure (number) #1 -->
                <!-- G.k.6b: Gestation Period at Time of Exposure (unit) #1 -->
            </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
                <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="recurranceOfReaction"/>
                <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
codeSystemVersion="1.0"/>
                <!-- G.k.9.i.4: Did Reaction Recur on Re-administration? Drug #1, Reaction #1 -->
                <outboundRelationship1 typeCode="REFR">
                    <actReference classCode="OBS" moodCode="EVN">
                        <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
                    </actReference>
                </outboundRelationship1>
            </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
                <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="recurranceOfReaction"/>
                <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
codeSystemVersion="1.0"/>
                <!-- G.k.9.i.4: Did Reaction Recur on Re-administration? Drug #1, Reaction #2 -->
                <outboundRelationship1 typeCode="REFR">
                    <actReference classCode="OBS" moodCode="EVN">
                        <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
                    </actReference>
                </outboundRelationship1>
            </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="REFR">
            <observation classCode="OBS" moodCode="EVN">
                <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="codedDrugInformation"/>
                <value xsi:type="CE" code="G.k.10.r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"
codeSystemVersion="1.0"/>
                <!-- G.k.10.r: Additional Information on Drug (coded)(repeat as necessary) #1-1 -->
            </observation>
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              </outboundRelationship2>
              <outboundRelationship2 typeCode="REFR">
                <observation classCode="OBS" moodCode="EVN">
                  <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="codedDrugInformation"/>
                  <value xsi:type="CE" code="G.k.10.r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"
codeSystemVersion="1.0"/>
                  <!-- G.k.10.r: Additional Information on Drug (coded)(repeat as necessary) #1-2 -->
                </observation>
              </outboundRelationship2>
              <outboundRelationship2 typeCode="REFR">
                <observation classCode="OBS" moodCode="EVN">
                  <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="additionalInformation"/>
                  <value xsi:type="ST">G.k.11</value>
                  <!-- G.k.11: Additional Information on Drug (free text) #1 -->
                </observation>
              </outboundRelationship2>
              <inboundRelationship typeCode="RSON">
                <observation classCode="OBS" moodCode="EVN">
                  <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="indication"/>
                  <value xsi:type="CE" code="G.k.7.r.2b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="G.k.7.r.2a">
                    <!-- G.k.7.r.2a: MedDRA Version for Indication #1-1 -->
                    <!-- G.k.7.r.2b: Indication (MedDRA code)  #1-1 -->
                    <originalText>G.k.7.r.1</originalText>
                    <!-- G.k.7.r.1: Indication as Reported by the Primary Source #1-1 -->
                  </value>
                  <performer typeCode="PRF">
                    <assignedEntity classCode="ASSIGNED">
                      <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="sourceReporter"/>
                    </assignedEntity>
                  </performer>
                </observation>
              </inboundRelationship>
              <inboundRelationship typeCode="RSON">
                <observation classCode="OBS" moodCode="EVN">
                  <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="indication"/>
                  <value xsi:type="CE" code="G.k.7.r.2b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="G.k.7.r.2a">
                    <!-- G.k.7.r.2a: MedDRA Version for Indication #1-2 -->
                    <!-- G.k.7.r.2b: Indication (MedDRA code)  #1-2 -->
                    <originalText>G.k.7.r.1</originalText>
                    <!-- G.k.7.r.1: Indication as Reported by the Primary Source #1-2 -->
                  </value>
                  <performer typeCode="PRF">
                    <assignedEntity classCode="ASSIGNED">
                      <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="sourceReporter"/>
                    </assignedEntity>
                  </performer>
                </observation>
              </inboundRelationship>
              <inboundRelationship typeCode="CAUS">
                <act classCode="ACT" moodCode="EVN">
                  <code code="G.k.8" codeSystem="2.16.840.1.113883.3.989.2.1.1.15" codeSystemVersion="1.0"/>
                  <!-- G.k.8: Action(s) Taken with Drug #1 -->
                </act>
              </inboundRelationship>
            </substanceAdministration>
          </component>
          <!-- G.k Drug(s) Information (repeat as necessary) #2 -->
          <component typeCode="COMP">
            <substanceAdministration classCode="SBADM" moodCode="EVN">
              <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
              <consumable typeCode="CSM">
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<instanceOfKind classCode="INST">
  <kindOfProduct classCode="MMAT" determinerCode="KIND">
    <code code="G.k.2.1.2b" codeSystem="TBD-PhPID" codeSystemVersion="G.k.2.1.2a"/>
    <!-- G.k.2.1.2a: PhPID Version Date / Number #2 -->
    <!-- G.k.2.1.2b: Pharmaceutical Product Identifier (PhPID) #2 -->
    <name>G.k.2.2</name>
    <!-- G.k.2.2: Medicinal Product Name as Reported by the Primary Source #2 -->
    <asManufacturedProduct classCode="MANU">
      <subjectOf typeCode="SBJ">
        <approval classCode="CNTRCT" moodCode="EVN">
          <id extension="G.k.3.1" root="2.16.840.1.113883.3.989.2.1.3.4"/>
          <!-- G.k.3.1: Authorisation / Application Number #2 -->
          <holder typeCode="HLD">
            <role classCode="HLD">
              <playingOrganization classCode="ORG" determinerCode="INSTANCE">
                <name>G.k.3.3</name>
                <!-- G.k.3.3: Name of Holder / Applicant #2 -->
              </playingOrganization>
            </role>
          </holder>
          <author typeCode="AUT">
            <territorialAuthority classCode="TERR">
              <territory classCode="NAT" determinerCode="INSTANCE">
                <code code="G.k.3.2" codeSystem="1.0.3166.1.2.2"/>
                <!-- G.k.3.2: Country of Authorisation / Application #2 -->
              </territory>
            </territorialAuthority>
          </author>
          <pertinentInformation typeCode="PERT">
            <policy classCode="POLICY" moodCode="EVN">
              <code code="J2.5.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.4"
codeSystemVersion="1.0"/>
              <!-- @@@J2.5.k: 一般用医薬品等のリスク区分等 #2 -->
            </policy>
          </pertinentInformation>
        </approval>
      </subjectOf>
      <subjectOf typeCode="SBJ">
        <characteristic classCode="OBS" moodCode="EVN">
          <code code="1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10"
codeSystemVersion="1.0" displayName="新医薬品等の状況区分"/>
          <value xsi:type="CE" code="J2.4.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.3"
codeSystemVersion="1.0"/>
          <!-- @@@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 -->
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                                <denominator value="1"/>
                            </quantity>
                            <ingredientSubstance classCode="MMAT" determinerCode="KIND">
                                <code code="G.k.2.3.r.2b" codeSystem="TBD-Substance"
codeSystemVersion="G.k.2.3.r.2a"/>
                                <!-- G.k.2.3.r.2a: Substance / Specified Substance TermID Version Date/Number #2-2 -->
                                <!-- G.k.2.3.r.2b Substance / Specified Substance TermID #2-2 -->
                                <name>G.k.2.3.r.1</name>
                                <!-- G.k.2.3.r.1: Substance / Specified Substance Name #2-2 -->
                            </ingredientSubstance>
                        </ingredient>
                    </kindOfProduct>
                    <subjectOf typeCode="SBJ">
                        <productEvent classCode="ACT" moodCode="EVN">
                            <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.18" codeSystemVersion="1.0"
displayName="retailSupply"/>
                            <performer typeCode="PRF">
                                <assignedEntity classCode="ASSIGNED">
                                    <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                                        <addr>
                                            <country>G.k.2.4</country>
                                            <!-- G.k.2.4: Identification of the Country Where the Drug Was Obtained #2 -->
                                        </addr>
                                    </representedOrganization>
                                </assignedEntity>
                            </performer>
                        </productEvent>
                    </subjectOf>
                    <subjectOf typeCode="SBJ">
                        <observationEvent classCode="OBS" moodCode="EVN">
                            <code code="2" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10"
codeSystemVersion="1.0" displayName="一般用医薬品の入手経路"/>
                            <value xsi:type="CE" code="J2.6.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.5"
codeSystemVersion="1.0"/>
                            <!-- @@@J2.6.k: 一般用医薬品の入手経路　#2 -->
                        </observationEvent>
                    </subjectOf>
                </instanceOfKind>
            </consumable>
            <outboundRelationship1 typeCode="SAS">
                <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
                <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #2, Reaction #1-->
                <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit)  Drug #2, Reaction #1 -->
                <actReference classCode="OBS" moodCode="EVN">
                    <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
                </actReference>
            </outboundRelationship1>
            <outboundRelationship1 typeCode="SAE">
                <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
                <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #2, Reaction #1 -->
                <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit)  Drug #2, Reaction #1 -->
                <actReference classCode="OBS" moodCode="EVN">
                    <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
                </actReference>
            </outboundRelationship1>
            <outboundRelationship1 typeCode="SAS">
                <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
                <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #2, Reaction #2 -->
                <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit)  Drug #2, Reaction #2 -->
                <actReference classCode="OBS" moodCode="EVN">
                    <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
                </actReference>
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						</outboundRelationship1>
						<outboundRelationship1 typeCode="SAE">
							<pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
							<!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number)  Drug #2, Reaction #2 -->
							<!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit)  Drug #2, Reaction #2 -->
							<actReference classCode="OBS" moodCode="EVN">
								<id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
							</actReference>
						</outboundRelationship1>
						<outboundRelationship1 typeCode="SAS">
							<pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
							<!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #2, Reaction #3 -->
							<!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit)  Drug #2, Reaction #3 -->
							<actReference classCode="OBS" moodCode="EVN">
								<id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430adf"/>
							</actReference>
						</outboundRelationship1>
						<outboundRelationship1 typeCode="SAE">
							<pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
							<!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number)  Drug #2, Reaction #3 -->
							<!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit)  Drug #2, Reaction #3 -->
							<actReference classCode="OBS" moodCode="EVN">
								<id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430adf"/>
							</actReference>
						</outboundRelationship1>
						<outboundRelationship1 typeCode="SAS">
							<pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
							<!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #2, Reaction #4 -->
							<!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit)  Drug #2, Reaction #4 -->
							<actReference classCode="OBS" moodCode="EVN">
								<id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
							</actReference>
						</outboundRelationship1>
						<outboundRelationship1 typeCode="SAE">
							<pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
							<!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number)  Drug #2, Reaction #4 -->
							<!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit)  Drug #2, Reaction #4 -->
							<actReference classCode="OBS" moodCode="EVN">
								<id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
							</actReference>
						</outboundRelationship1>
						<outboundRelationship1 typeCode="SAS">
							<pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
							<!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #2, Reaction #5 -->
							<!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit)  Drug #2, Reaction #5 -->
							<actReference classCode="OBS" moodCode="EVN">
								<id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
							</actReference>
						</outboundRelationship1>
						<outboundRelationship1 typeCode="SAE">
							<pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
							<!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number)  Drug #2, Reaction #5 -->
							<!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit)  Drug #2, Reaction #5 -->
							<actReference classCode="OBS" moodCode="EVN">
								<id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
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                            </actReference>
                        </outboundRelationship1>
                        <outboundRelationship1 typeCode="SAS">
                            <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
                            <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #2, Reaction #6 -->
                            <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit)  Drug #2, Reaction #6 -->
                            <actReference classCode="OBS" moodCode="EVN">
                                <id root="1f927283-10b6-4334-9d43-e925640fb18f"/>
                            </actReference>
                        </outboundRelationship1>
                        <outboundRelationship1 typeCode="SAE">
                            <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
                            <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number)  Drug #2, Reaction #6 -->
                            <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit)  Drug #2, Reaction #6 -->
                            <actReference classCode="OBS" moodCode="EVN">
                                <id root="1f927283-10b6-4334-9d43-e925640fb18f"/>
                            </actReference>
                        </outboundRelationship1>
                        <outboundRelationship1 typeCode="SAS">
                            <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
                            <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #2, Reaction #7 -->
                            <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit)  Drug #2, Reaction #7 -->
                            <actReference classCode="OBS" moodCode="EVN">
                                <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
                            </actReference>
                        </outboundRelationship1>
                        <outboundRelationship1 typeCode="SAE">
                            <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
                            <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number)  Drug #2, Reaction #7 -->
                            <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit)  Drug #2, Reaction #7 -->
                            <actReference classCode="OBS" moodCode="EVN">
                                <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
                            </actReference>
                        </outboundRelationship1>
                        <outboundRelationship1 typeCode="SAS">
                            <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
                            <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #2, Reaction #8 -->
                            <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit)  Drug #2, Reaction #8 -->
                            <actReference classCode="OBS" moodCode="EVN">
                                <id root="a15be092-8070-426d-af04-6863263443e0"/>
                            </actReference>
                        </outboundRelationship1>
                        <outboundRelationship1 typeCode="SAE">
                            <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
                            <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number)  Drug #2, Reaction #8 -->
                            <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit)  Drug #2, Reaction #8 -->
                            <actReference classCode="OBS" moodCode="EVN">
                                <id root="a15be092-8070-426d-af04-6863263443e0"/>
                            </actReference>
                        </outboundRelationship1>
                        <outboundRelationship2 typeCode="PERT">
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="6" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="blinded"/>
                                <value xsi:type="BL" value="true"/>
                                <!-- G.k.2.5: Investigational Product Blinded #2 -->
                            </observation>
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              </outboundRelationship2>
              <outboundRelationship2 typeCode="COMP">
                <!-- G.k.4.r : Dosage and Relevant Information (repeat as necessary) #2-1 -->
                <substanceAdministration classCode="SBADM" moodCode="EVN">
                  <text>G.k.4.r.8</text>
                  <!-- G.k.4.r.8: Dosage Text #2-1 -->
                  <effectiveTime xsi:type="IVL_TS">
                    <low value="20090101"/>
                    <!-- G.k.4.r.4: Date and Time of Start of Drug #2-1 -->
                    <high value="20090101"/>
                    <!-- G.k.4.r.5: Date and Time of Last Administration #2-1 -->
                  </effectiveTime>
                  <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
                    <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-1 -->
                    <!-- G.k.4.r.10.2b: Route of Administration TermID #2-1 -->
                    <originalText>G.k.4.r.10.1</originalText>
                    <!-- G.k.4.r.10.1: Route of Administration (free text) #2-1 -->
                  </routeCode>
                  <doseQuantity value="10" unit="G.k.4.r.1b"/>
                  <!-- G.k.4.r.1a Dose (number) #2-1 -->
                  <!-- G.k.4.r.1b: Dose (unit) #2-1 -->
                  <consumable typeCode="CSM">
                    <instanceOfKind classCode="INST">
                      <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
                        <lotNumberText>G.k.4.r.7</lotNumberText>
                        <!-- G.k.4.r.7: Batch / Lot Number #2-1 -->
                      </productInstanceInstance>
                      <kindOfProduct classCode="MMAT" determinerCode="KIND">
                        <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
                          <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-1 -->
                          <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-1 -->
                          <originalText>G.k.4.r.9.1</originalText>
                          <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-1 -->
                        </formCode>
                      </kindOfProduct>
                    </instanceOfKind>
                  </consumable>
                  <inboundRelationship typeCode="REFR">
                    <observation classCode="OBS" moodCode="EVN">
                      <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
                      <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
                        <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-1
-->
                        <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-1 -->
                        <originalText>G.k.4.r.11.1</originalText>
                        <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-1 -->
                      </value>
                    </observation>
                  </inboundRelationship>
                </substanceAdministration>
              </outboundRelationship2>
              <outboundRelationship2 typeCode="COMP">
                <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-2 -->
                <substanceAdministration classCode="SBADM" moodCode="EVN">
                  <text>G.k.4.r.8</text>
                  <!-- G.k.4.r.8: Dosage Text #2-2 -->
                  <effectiveTime xsi:type="IVL_TS">
                    <low value="20090101"/>
                    <!-- G.k.4.r.4: Date and Time of Start of Drug #2-2 -->
                    <width value="4" unit="G.k.4.r.6b"/>
                    <!-- G.k.4.r.6a: Duration of Drug Administration (number) #2-2 -->
                    <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #2-2 -->
                  </effectiveTime>
                  <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
```

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                            <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-2 -->
                            <!-- G.k.4.r.10.2b: Route of Administration TermID #2-2 -->
                            <originalText>G.k.4.r.10.1</originalText>
                            <!-- G.k.4.r.10.1: Route of Administration (free text) #2-2 -->
                        </routeCode>
                        <doseQuantity value="10" unit="G.k.4.r.1b"/>
                        <!-- G.k.4.r.1a Dose (number) #2-2 -->
                        <!-- G.k.4.r.1b: Dose (unit) #2-2 -->
                        <consumable typeCode="CSM">
                          <instanceOfKind classCode="INST">
                            <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
                              <lotNumberText>G.k.4.r.7</lotNumberText>
                              <!-- G.k.4.r.7: Batch / Lot Number #2-2 -->
                            </productInstanceInstance>
                            <kindOfProduct classCode="MMAT" determinerCode="KIND">
                              <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
                                  <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-2 -->
                                  <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-2 -->
                                  <originalText>G.k.4.r.9.1</originalText>
                                  <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-2 -->
                              </formCode>
                            </kindOfProduct>
                          </instanceOfKind>
                        </consumable>
                        <inboundRelationship typeCode="REFR">
                          <observation classCode="OBS" moodCode="EVN">
                            <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
                            <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
                                <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-2
-->
                                <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-2 -->
                                <originalText>G.k.4.r.11.1</originalText>
                                <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-2 -->
                            </value>
                          </observation>
                        </inboundRelationship>
                      </substanceAdministration>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="COMP">
                      <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-3 -->
                      <substanceAdministration classCode="SBADM" moodCode="EVN">
                        <text>G.k.4.r.8</text>
                        <!-- G.k.4.r.8: Dosage Text #2-3 -->
                        <effectiveTime xsi:type="IVL_TS">
                          <width value="4" unit="G.k.4.r.6b"/>
                          <!-- G.k.4.r.6a: Duration of Drug Administration (number) #2-3 -->
                          <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #2-3 -->
                          <high value="20090101"/>
                          <!-- G.k.4.r.5: Date and Time of Last Administration #2-3 -->
                        </effectiveTime>
                        <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
                            <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-3 -->
                            <!-- G.k.4.r.10.2b: Route of Administration TermID #2-3 -->
                            <originalText>G.k.4.r.10.1</originalText>
                            <!-- G.k.4.r.10.1: Route of Administration (free text) #2-3 -->
                        </routeCode>
                        <doseQuantity value="10" unit="G.k.4.r.1b"/>
                        <!-- G.k.4.r.1a Dose (number) #2-3 -->
                        <!-- G.k.4.r.1b: Dose (unit) #2-3 -->
                        <consumable typeCode="CSM">
                          <instanceOfKind classCode="INST">
                            <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
                              <lotNumberText>G.k.4.r.7</lotNumberText>
                              <!-- G.k.4.r.7: Batch / Lot Number #2-3 -->
                            </productInstanceInstance>
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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 #2-3 -->
                                            <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-3 -->
                                            <originalText>G.k.4.r.9.1</originalText>
                                            <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-3 -->
                                        </formCode>
                                    </kindOfProduct>
                                </instanceOfKind>
                            </consumable>
                            <inboundRelationship typeCode="REFR">
                                <observation classCode="OBS" moodCode="EVN">
                                    <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
                                    <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
                                        <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-3
-->
                                        <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-3 -->
                                        <originalText>G.k.4.r.11.1</originalText>
                                        <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-3 -->
                                    </value>
                                </observation>
                            </inboundRelationship>
                        </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>
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                    </consumable>
                    <inboundRelationship typeCode="REFR">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
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 #2-4
-->
                            <!-- 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>
                    <inboundRelationship typeCode="REFR">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
                        <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
                            <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-5
-->
                            <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-5 -->
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            <originalText>G.k.4.r.11.1</originalText>
            <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-5 -->
          </value>
        </observation>
      </inboundRelationship>
    </substanceAdministration>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="COMP">
    <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-6 -->
    <substanceAdministration classCode="SBADM" moodCode="EVN">
      <text>G.k.4.r.8</text>
      <!-- G.k.4.r.8: Dosage Text #2-6 -->
      <effectiveTime xsi:type="SXPR_TS">
        <comp xsi:type="PIVL_TS">
          <period value="10" unit="G.k.4.r.3"/>
          <!-- G.k.4.r.2: Number of Units in the Interval #2-6 -->
          <!-- G.k.4.r.3: Definition of the Time Interval Unit #2-6 -->
        </comp>
        <comp xsi:type="IVL_TS" operator="A">
          <width value="4" unit="G.k.4.r.6b"/>
          <!-- G.k.4.r.6a: Duration of Drug Administration (number) #2-6 -->
          <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #2-6 -->
        </comp>
      </effectiveTime>
      <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
        <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-6 -->
        <!-- G.k.4.r.10.2b: Route of Administration TermID #2-6 -->
        <originalText>G.k.4.r.10.1</originalText>
        <!-- G.k.4.r.10.1: Route of Administration (free text) #2-6 -->
      </routeCode>
      <doseQuantity value="10" unit="G.k.4.r.1b"/>
      <!-- G.k.4.r.1a Dose (number) #2-6 -->
      <!-- G.k.4.r.1b: Dose (unit) #2-6 -->
      <consumable typeCode="CSM">
        <instanceOfKind classCode="INST">
          <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
            <lotNumberText>G.k.4.r.7</lotNumberText>
            <!-- G.k.4.r.7: Batch / Lot Number #2-6 -->
          </productInstanceInstance>
          <kindOfProduct classCode="MMAT" determinerCode="KIND">
            <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
              <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-6 -->
              <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-6 -->
              <originalText>G.k.4.r.9.1</originalText>
              <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-6 -->
            </formCode>
          </kindOfProduct>
        </instanceOfKind>
      </consumable>
      <inboundRelationship typeCode="REFR">
        <observation classCode="OBS" moodCode="EVN">
          <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
          <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
            <!-- 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 -->
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<substanceAdministration classCode="SBADM" moodCode="EVN">
  <text>G.k.4.r.8</text>
  <!-- G.k.4.r.8: Dosage Text #2-7 -->
  <effectiveTime xsi:type="PIVL_TS">
    <period value="10" unit="G.k.4.r.3"/>
    <!-- G.k.4.r.2: Number of Units in the Interval #2-7 -->
    <!-- G.k.4.r.3: Definition of the Time Interval Unit #2-7 -->
  </effectiveTime>
  <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
    <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-7 -->
    <!-- G.k.4.r.10.2b: Route of Administration TermID #2-7 -->
    <originalText>G.k.4.r.10.1</originalText>
    <!-- G.k.4.r.10.1: Route of Administration (free text) #2-7 -->
  </routeCode>
  <doseQuantity value="10" unit="G.k.4.r.1b"/>
  <!-- G.k.4.r.1a Dose (number) #2-7 -->
  <!-- G.k.4.r.1b: Dose (unit) #2-7 -->
  <consumable typeCode="CSM">
    <instanceOfKind classCode="INST">
      <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
        <lotNumberText>G.k.4.r.7</lotNumberText>
        <!-- G.k.4.r.7: Batch / Lot Number #2-7 -->
      </productInstanceInstance>
      <kindOfProduct classCode="MMAT" determinerCode="KIND">
        <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
          <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-7 -->
          <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-7 -->
          <originalText>G.k.4.r.9.1</originalText>
          <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-7 -->
        </formCode>
      </kindOfProduct>
    </instanceOfKind>
  </consumable>
  <inboundRelationship typeCode="REFR">
    <observation classCode="OBS" moodCode="EVN">
      <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
      <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
        <!-- 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 -->
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              <!-- G.k.4.r.1b: Dose (unit) #2-8 -->
              <consumable typeCode="CSM">
                <instanceOfKind classCode="INST">
                  <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
                    <lotNumberText>G.k.4.r.7</lotNumberText>
                    <!-- G.k.4.r.7: Batch / Lot Number #2-8 -->
                  </productInstanceInstance>
                  <kindOfProduct classCode="MMAT" determinerCode="KIND">
                    <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
                        <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-8 -->
                        <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-8 -->
                        <originalText>G.k.4.r.9.1</originalText>
                        <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-8 -->
                    </formCode>
                  </kindOfProduct>
                </instanceOfKind>
              </consumable>
              <inboundRelationship typeCode="REFR">
                <observation classCode="OBS" moodCode="EVN">
                  <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
                  <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
                      <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-8
-->
                      <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-8 -->
                      <originalText>G.k.4.r.11.1</originalText>
                      <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-8 -->
                  </value>
                </observation>
              </inboundRelationship>
            </substanceAdministration>
          </outboundRelationship2>
          <outboundRelationship2 typeCode="COMP">
            <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-9 -->
            <substanceAdministration classCode="SBADM" moodCode="EVN">
              <text>G.k.4.r.8</text>
              <!-- G.k.4.r.8: Dosage Text #2-9 -->
              <effectiveTime xsi:type="IVL_TS">
                <high value="20090101"/>
                <!-- G.k.4.r.5: Date and Time of Last Administration #2-9 -->
              </effectiveTime>
              <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
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>
```

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        </consumable>
        <inboundRelationship typeCode="REFR">
          <observation classCode="OBS" moodCode="EVN">
            <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
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: Dosage and Relevant Information (repeat as necessary) #2-10 -->
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <text>G.k.4.r.8</text>
        <!-- G.k.4.r.8: Dosage Text #2-10 -->
        <effectiveTime xsi:type="IVL_TS">
          <width value="4" unit="G.k.4.r.6b"/>
          <!-- G.k.4.r.6a: Duration of Drug Administration (number) #2-10 -->
          <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #2-10 -->
        </effectiveTime>
        <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
            <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-10 -->
            <!-- G.k.4.r.10.2b: Route of Administration TermID #2-10 -->
            <originalText>G.k.4.r.10.1</originalText>
            <!-- G.k.4.r.10.1: Route of Administration (free text) #2-10 -->
        </routeCode>
        <doseQuantity value="10" unit="G.k.4.r.1b"/>
        <!-- G.k.4.r.1a Dose (number) #2-10 -->
        <!-- G.k.4.r.1b: Dose (unit) #2-10 -->
        <consumable typeCode="CSM">
          <instanceOfKind classCode="INST">
            <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
              <lotNumberText>G.k.4.r.7</lotNumberText>
              <!-- G.k.4.r.7: Batch / Lot Number #2-10 -->
            </productInstanceInstance>
            <kindOfProduct classCode="MMAT" determinerCode="KIND">
              <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
                  <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-10 -->
                  <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-10 -->
                  <originalText>G.k.4.r.9.1</originalText>
                  <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-10 -->
              </formCode>
            </kindOfProduct>
          </instanceOfKind>
        </consumable>
        <inboundRelationship typeCode="REFR">
          <observation classCode="OBS" moodCode="EVN">
            <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
            <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
                <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-10
-->
                <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-10 -->
                <originalText>G.k.4.r.11.1</originalText>
                <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-10 -->
            </value>
          </observation>
        </inboundRelationship>
      </substanceAdministration>
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                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="SUMM">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="14" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="cumulativeDoseToReaction"/>
                        <value xsi:type="PQ" value="10" unit="G.k.5b"/>
                        <!-- G.k.5a: Cumulative Dose to First Reaction (number) #2 -->
                        <!-- G.k.5b: Cumulative Dose to First Reaction (unit) #2 -->
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="PERT">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="16" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="gestationPeriod"/>
                        <value xsi:type="PQ" value="10" unit="G.k.6b"/>
                        <!-- G.k.6a: Gestation Period at Time of Exposure (number) #2 -->
                        <!-- G.k.6b: Gestation Period at Time of Exposure (unit) #2 -->
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="PERT">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="recurranceOfReaction"/>
                        <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
codeSystemVersion="1.0"/>
                        <!-- G.k.9.i.4: Did Reaction Recur on Re-administration? Drug #2, Reaction #1 -->
                        <outboundRelationship1 typeCode="REFR">
                          <actReference classCode="OBS" moodCode="EVN">
                            <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
                          </actReference>
                        </outboundRelationship1>
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="PERT">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="recurranceOfReaction"/>
                        <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
codeSystemVersion="1.0"/>
                        <!-- G.k.9.i.4: Did Reaction Recur on Re-administration? Drug #2, Reaction #2 -->
                        <outboundRelationship1 typeCode="REFR">
                          <actReference classCode="OBS" moodCode="EVN">
                            <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
                          </actReference>
                        </outboundRelationship1>
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="REFR">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="codedDrugInformation"/>
                        <value xsi:type="CE" code="G.k.10.r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"
codeSystemVersion="1.0"/>
                        <!-- G.k.10.r: Additional Information on Drug (coded)(repeat as necessary) #2-1 -->
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="REFR">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="codedDrugInformation"/>
                        <value xsi:type="CE" code="G.k.10.r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"
codeSystemVersion="1.0"/>
                        <!-- G.k.10.r: Additional Information on Drug (coded)(repeat as necessary) #2-2 -->
                      </observation>
                    </outboundRelationship2>
                    <outboundRelationship2 typeCode="REFR">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="additionalInformation"/>
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                        <value xsi:type="ST">G.k.11</value>
                        <!-- G.k.11: Additional Information on Drug (free text) #2 -->
                      </observation>
                    </outboundRelationship2>
                    <inboundRelationship typeCode="RSON">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="indication"/>
                        <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" codeSystemVersion="1.0"
displayName="sourceReporter"/>
                          </assignedEntity>
                        </performer>
                      </observation>
                    </inboundRelationship>
                    <inboundRelationship typeCode="RSON">
                      <observation classCode="OBS" moodCode="EVN">
                        <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="indication"/>
                        <value xsi:type="CE" code="G.k.7.r.2b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="G.k.7.r.2a">
                          <!-- G.k.7.r.2a: MedDRA Version for Indication #2-2 -->
                          <!-- G.k.7.r.2b: Indication (MedDRA code)  #2-2 -->
                          <originalText>G.k.7.r.1</originalText>
                          <!-- G.k.7.r.1: Indication as Reported by the Primary Source #2-2 -->
                        </value>
                        <performer typeCode="PRF">
                          <assignedEntity classCode="ASSIGNED">
                            <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="sourceReporter"/>
                          </assignedEntity>
                        </performer>
                      </observation>
                    </inboundRelationship>
                    <inboundRelationship typeCode="CAUS">
                      <act classCode="ACT" moodCode="EVN">
                        <code code="G.k.8" codeSystem="2.16.840.1.113883.3.989.2.1.1.15" codeSystemVersion="1.0"/>
                        <!-- G.k.8: Action(s) Taken with Drug #2 -->
                      </act>
                    </inboundRelationship>
                  </substanceAdministration>
                </component>
              </organizer>
            </subjectOf2>
            <subjectOf2 typeCode="SBJ">
              <organizer classCode="CATEGORY" moodCode="EVN">
                <code code="1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.11" codeSystemVersion="1.0"
displayName="治験の概要"/>
                <component typeCode="COMP">
                  <observation classCode="OBS" moodCode="EVN">
                    <code code="7" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="届出回数"/>
                    <value xsi:type="INT" value="1"/>
                    <!-- @@@J2.13.r.1: 届出回数 #1 -->
                  </observation>
                </component>
                <component typeCode="COMP">
                  <observation classCode="OBS" moodCode="EVN">
                    <code code="8" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="対象疾患"/>
                    <value xsi:type="ED">J2.13.r.2</value>
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                                        <!-- @@@J2.13.r.2: 対象疾患 #1 -->
                                    </observation>
                                </component>
                                <component typeCode="COMP">
                                    <observation classCode="OBS" moodCode="EVN">
                                        <code code="9" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="開発相"/>
                                        <value xsi:type="CE" code="J2.13.r.3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.7" codeSystemVersion="1.0"/>
                                        <!-- @@@J2.13.r.3: 開発相 #1 -->
                                    </observation>
                                </component>
                                <component typeCode="COMP">
                                    <observation classCode="OBS" moodCode="EVN">
                                        <code code="10" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="投薬中の症例の有無"/>
                                        <value xsi:type="BL" value="true"/>
                                        <!-- @@@J2.13.r.4: 投薬中の症例の有無 #1 -->
                                    </observation>
                                </component>
                            </organizer>
                        </subjectOf2>
                        <subjectOf2 typeCode="SBJ">
                            <organizer classCode="CATEGORY" moodCode="EVN">
                                <code code="1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.11" codeSystemVersion="1.0" displayName="治験の概要"/>
                                <component typeCode="COMP">
                                    <observation classCode="OBS" moodCode="EVN">
                                        <code code="7" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="届出回数"/>
                                        <value xsi:type="INT" value="1"/>
                                        <!-- @@@J2.13.r.1: 届出回数 #2 -->
                                    </observation>
                                </component>
                                <component typeCode="COMP">
                                    <observation classCode="OBS" moodCode="EVN">
                                        <code code="8" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="対象疾患"/>
                                        <value xsi:type="ED">J2.13.r.2</value>
                                        <!-- @@@J2.13.r.2: 対象疾患 #2 -->
                                    </observation>
                                </component>
                                <component typeCode="COMP">
                                    <observation classCode="OBS" moodCode="EVN">
                                        <code code="9" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="開発相"/>
                                        <value xsi:type="CE" code="J2.13.r.3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.7" codeSystemVersion="1.0"/>
                                        <!-- @@@J2.13.r.3: 開発相 #2 -->
                                    </observation>
                                </component>
                                <component typeCode="COMP">
                                    <observation classCode="OBS" moodCode="EVN">
                                        <code code="10" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="投薬中の症例の有無"/>
                                        <value xsi:type="BL" value="false"/>
                                        <!-- @@@J2.13.r.4: 投薬中の症例の有無 #2 -->
                                    </observation>
                                </component>
                            </organizer>
                        </subjectOf2>
                    </primaryRole>
                </subject1>
                <component typeCode="COMP">
                    <causalityAssessment classCode="OBS" moodCode="EVN">
                        <code code="20" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="interventionCharacterization"/>
                        <value xsi:type="CE" code="G.k.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.13" codeSystemVersion="1.0"/>
```

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              <!-- G.k.1: Characterisation of Drug Role Drug #1 -->
              <subject2 typeCode="SUBJ">
                <productUseReference classCode="SBADM" moodCode="EVN">
                  <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
                </productUseReference>
              </subject2>
            </causalityAssessment>
          </component>
          <component typeCode="COMP">
            <causalityAssessment classCode="OBS" moodCode="EVN">
              <code code="20" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="interventionCharacterization"/>
              <value xsi:type="CE" code="G.k.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.13"
codeSystemVersion="1.0"/>
              <!-- G.k.1: Characterisation of Drug Role Drug #2 -->
              <subject2 typeCode="SUBJ">
                <productUseReference classCode="SBADM" moodCode="EVN">
                  <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
                </productUseReference>
              </subject2>
            </causalityAssessment>
          </component>
          <component typeCode="COMP">
            <causalityAssessment classCode="OBS" moodCode="EVN">
              <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="causality"/>
              <value xsi:type="ST">G.k.9.i.2.r.3</value>
              <!-- G.k.9.i.2.r.3: Result of Assessment Drug #1, Reaction #1, Assessment #1 -->
              <methodCode>
                <originalText>G.k.9.i.2.r.2</originalText>
                <!-- G.k.9.i.2.r.2: Method of Assessment Drug #1, Reaction #1, Assessment #1 -->
              </methodCode>
              <author typeCode="AUT">
                <assignedEntity classCode="ASSIGNED">
                  <code>
                    <originalText>G.k.9.i.2.r.1</originalText>
                    <!-- G.k.9.i.2.r.1: Source of Assessment Drug #1, Reaction #1, Assessment #1 -->
                  </code>
                </assignedEntity>
              </author>
              <subject1 typeCode="SUBJ">
                <adverseEffectReference classCode="OBS" moodCode="EVN">
                  <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
                </adverseEffectReference>
              </subject1>
              <subject2 typeCode="SUBJ">
                <productUseReference classCode="SBADM" moodCode="EVN">
                  <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
                </productUseReference>
              </subject2>
            </causalityAssessment>
          </component>
          <component typeCode="COMP">
            <causalityAssessment classCode="OBS" moodCode="EVN">
              <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="causality"/>
              <value xsi:type="ST">G.k.9.i.2.r.3</value>
              <!--G.k.9.i.2.r.3: Result of Assessment Drug #1, Reaction #2, Assessment #1 -->
              <methodCode>
                <originalText>G.k.9.i.2.r.2</originalText>
                <!--G.k.9.i.2.r.2: Method of Assessment Drug #1, Reaction #2, Assessment #1 -->
              </methodCode>
              <author typeCode="AUT">
                <assignedEntity classCode="ASSIGNED">
                  <code>
                    <originalText>G.k.9.i.2.r.1</originalText>
                    <!-- G.k.9.i.2.r.1: Source of Assessment Drug #1, Reaction #2, Assessment #1 -->
                  </code>
                </assignedEntity>
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            </author>
            <subject1 typeCode="SUBJ">
              <adverseEffectReference classCode="OBS" moodCode="EVN">
                <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
              </adverseEffectReference>
            </subject1>
            <subject2 typeCode="SUBJ">
              <productUseReference classCode="SBADM" moodCode="EVN">
                <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
              </productUseReference>
            </subject2>
          </causalityAssessment>
        </component>
        <component typeCode="COMP">
          <causalityAssessment classCode="OBS" moodCode="EVN">
            <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="causality"/>
            <value xsi:type="ST">G.k.9.i.2.r.3</value>
            <!--G.k.9.i.2.r.3: Result of Assessment Drug #2, Reaction #2, Assessment #1 -->
            <methodCode>
              <originalText>G.k.9.i.2.r.2</originalText>
              <!--G.k.9.i.2.r.2: Method of Assessment Drug #2, Reaction #2, Assessment #1 -->
            </methodCode>
            <author typeCode="AUT">
              <assignedEntity classCode="ASSIGNED">
                <code>
                  <originalText>G.k.9.i.2.r.1</originalText>
                  <!-- G.k.9.i.2.r.1: Source of Assessment Drug #2, Reaction #2, Assessment #1 -->
                </code>
              </assignedEntity>
            </author>
            <subject1 typeCode="SUBJ">
              <adverseEffectReference classCode="OBS" moodCode="EVN">
                <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
              </adverseEffectReference>
            </subject1>
            <subject2 typeCode="SUBJ">
              <productUseReference classCode="SBADM" moodCode="EVN">
                <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
              </productUseReference>
            </subject2>
          </causalityAssessment>
        </component>
        <component typeCode="COMP">
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            <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="causality"/>
            <value xsi:type="ST">G.k.9.i.2.r.3</value>
            <!--G.k.9.i.2.r.3: Result of Assessment Drug #2, Reaction #2, Assessment #2 -->
            <methodCode>
              <originalText>G.k.9.i.2.r.2</originalText>
              <!--G.k.9.i.2.r.2: Method of Assessment Drug #2, Reaction #2, Assessment #2 -->
            </methodCode>
            <author typeCode="AUT">
              <assignedEntity classCode="ASSIGNED">
                <code>
                  <originalText>G.k.9.i.2.r.1</originalText>
                  <!-- G.k.9.i.2.r.1: Source of Assessment Drug #2, Reaction #2, Assessment #2 -->
                </code>
              </assignedEntity>
            </author>
            <subject1 typeCode="SUBJ">
              <adverseEffectReference classCode="OBS" moodCode="EVN">
                <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
              </adverseEffectReference>
            </subject1>
            <subject2 typeCode="SUBJ">
              <productUseReference classCode="SBADM" moodCode="EVN">
                <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
```

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                        </productUseReference>
                      </subject2>
                    </causalityAssessment>
                  </component>
                  <component1 typeCode="COMP">
                    <observationEvent classCode="OBS" moodCode="EVN">
                      <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="comment"/>
                      <value xsi:type="ED">H.2</value>
                      <!-- H.2: Reporter's Comments -->
                      <author typeCode="AUT">
                        <assignedEntity classCode="ASSIGNED">
                          <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="sourceReporter"/>
                        </assignedEntity>
                      </author>
                    </observationEvent>
                  </component1>
                  <component1 typeCode="COMP">
                    <observationEvent classCode="OBS" moodCode="EVN">
                      <code code="15" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="diagnosis"/>
                      <value xsi:type="CE" code="H.3.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="H.3.r.1a"/>
                      <!-- H.3.r.1a: MedDRA Version for Sender's Diagnosis / Syndrome and / or Reclassification of Reaction /
Event #1 -->
                      <!-- H.3.r.1b: Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event  (MedDRA
code) #1 -->
                      <author typeCode="AUT">
                        <assignedEntity classCode="ASSIGNED">
                          <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="sender"/>
                        </assignedEntity>
                      </author>
                    </observationEvent>
                  </component1>
                  <component1 typeCode="COMP">
                    <observationEvent classCode="OBS" moodCode="EVN">
                      <code code="15" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="diagnosis"/>
                      <value xsi:type="CE" code="H.3.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="H.3.r.1a"/>
                      <!-- H.3.r.1a: MedDRA Version for Sender's Diagnosis / Syndrome and / or Reclassification of Reaction /
Event #2 -->
                      <!-- H.3.r.1b: Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event  (MedDRA
code) #2 -->
                      <author typeCode="AUT">
                        <assignedEntity classCode="ASSIGNED">
                          <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="sender"/>
                        </assignedEntity>
                      </author>
                    </observationEvent>
                  </component1>
                  <component1 typeCode="COMP">
                    <observationEvent classCode="OBS" moodCode="EVN">
                      <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="comment"/>
                      <value xsi:type="ED">H.4</value>
                      <!-- H.4: Sender's Comments -->
                      <author typeCode="AUT">
                        <assignedEntity classCode="ASSIGNED">
                          <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="sender"/>
                        </assignedEntity>
                      </author>
                    </observationEvent>
                  </component1>
                  <component1 typeCode="COMP">
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                    <observationEvent classCode="OBS" moodCode="EVN">
                        <code code="3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
未完了に対するコメント"/>
                        <value xsi:type="ED">J2.7.2</value>
                        <!-- @@@J2.7.2: 未完了に対するコメント -->
                    </observationEvent>
                </component1>
                <component1 typeCode="COMP">
                    <observationEvent classCode="OBS" moodCode="EVN">
                        <code code="4" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
感染症の遡及調査"/>
                        <value xsi:type="ED">J2.9</value>
                        <!-- @@@J2.9: 感染症の遡及調査 -->
                    </observationEvent>
                </component1>
                <component1 typeCode="COMP">
                    <observationEvent classCode="OBS" moodCode="EVN">
                        <code code="5" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
今後の対応"/>
                        <value xsi:type="ED">J2.10</value>
                        <!-- @@@J2.10: 今後の対応 -->
                    </observationEvent>
                </component1>
                <component1 typeCode="COMP">
                    <observationEvent classCode="OBS" moodCode="EVN">
                        <code code="6" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
その他参考事項等"/>
                        <value xsi:type="ED">J2.11</value>
                        <!-- @@@J2.11: その他参考事項等 -->
                    </observationEvent>
                </component1>
                <component1 typeCode="COMP">
                    <observationEvent classCode="OBS" moodCode="EVN">
                        <code code="12" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
報告内容の要点"/>
                        <value xsi:type="ED">J2.16</value>
                        <!-- @@@J2.16: 報告内容の要点 -->
                    </observationEvent>
                </component1>
                <component1 typeCode="COMP">
                    <observationEvent classCode="OBS" moodCode="EVN">
                        <code code="13" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
備考1"/>
                        <value xsi:type="ED">J2.19</value>
                        <!-- @@@J2.19: 備考1 -->
                    </observationEvent>
                </component1>
                <component1 typeCode="COMP">
                    <observationEvent classCode="OBS" moodCode="EVN">
                        <code code="14" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
備考2"/>
                        <value xsi:type="ED">J2.20</value>
                        <!-- @@@J2.20: 備考2 -->
                    </observationEvent>
                </component1>
                <component1 typeCode="COMP">
                    <observationEvent classCode="OBS" moodCode="EVN">
                        <code code="15" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
備考3"/>
                        <value xsi:type="ED">J2.21</value>
                        <!-- @@@J2.21: 備考3 -->
                    </observationEvent>
                </component1>
                <component1 typeCode="COMP">
                    <observationEvent classCode="OBS" moodCode="EVN">
                        <code code="16" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
備考4"/>
                        <value xsi:type="ED">J2.22</value>
                        <!-- @@@J2.22: 備考4 -->
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          </observationEvent>
        </component1>
      </adverseEventAssessment>
    </component>
    <component typeCode="COMP">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="additionalDocumentsAvailable"/>
        <value xsi:type="BL" value="true"/>
        <!-- C.1.6.1: Are Additional Documents Available? -->
      </observationEvent>
    </component>
    <component typeCode="COMP">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code code="23" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="localCriteriaForExpedited"/>
        <value xsi:type="BL" value="true"/>
        <!-- C.1.7: Does This Case Fulfil the Local Criteria for an Expedited Report? -->
      </observationEvent>
    </component>
    <component typeCode="COMP">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code code="36" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="summaryAndComment"/>
        <value xsi:type="ED" language="H.5.r.1b">H.5.r.1a</value>
        <!-- H.5.r.1a: Case Summary and Reporter's Comments Text  #1 -->
        <!-- H.5.r.1b: Case Summary and Reporter's Comments Language #1 -->
        <author typeCode="AUT">
          <assignedEntity classCode="ASSIGNED">
            <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="reporter"/>
          </assignedEntity>
        </author>
      </observationEvent>
    </component>
    <component typeCode="COMP">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code code="36" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="summaryAndComment"/>
        <value xsi:type="ED" language="H.5.r.1b">H.5.r.1a</value>
        <!-- H.5.r.1a: Case Summary and Reporter's Comments Text  #2 -->
        <!-- H.5.r.1b: Case Summary and Reporter's Comments Language #2 -->
        <author typeCode="AUT">
          <assignedEntity classCode="ASSIGNED">
            <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="reporter"/>
          </assignedEntity>
        </author>
      </observationEvent>
    </component>
    <outboundRelationship typeCode="SPRT">
      <relatedInvestigation classCode="INVSTG" moodCode="EVN">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" codeSystemVersion="1.0"
displayName="initialReport"/>
        <subjectOf2 typeCode="SUBJ">
          <controlActEvent classCode="CACT" moodCode="EVN">
            <author typeCode="AUT">
              <assignedEntity classCode="ASSIGNED">
                <code code="C.1.8.2" codeSystem="2.16.840.1.113883.3.989.2.1.1.3" codeSystemVersion="1.0"/>
                <!-- C.1.8.2: First Sender of This Case -->
              </assignedEntity>
            </author>
          </controlActEvent>
        </subjectOf2>
      </relatedInvestigation>
    </outboundRelationship>
    <outboundRelationship typeCode="SPRT">
      <relatedInvestigation classCode="INVSTG" moodCode="EVN">
        <code nullFlavor="NA"/>
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                <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 -->
            <relatedInvestigation classCode="INVSTG" moodCode="EVN">
              <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" codeSystemVersion="1.0"
displayName="sourceReport"/>
              <subjectOf2 typeCode="SUBJ">
                <controlActEvent classCode="CACT" moodCode="EVN">
                  <author typeCode="AUT">
                    <assignedEntity classCode="ASSIGNED">
                      <addr>
                        <streetAddressLine>C.2.r.2.3</streetAddressLine>
                        <!-- C.2.r.2.3: Reporter's Street #1 -->
                        <city>C.2.r.2.4</city>
                        <!-- C.2.r.2.4: Reporter's City #1 -->
                        <state>C.2.r.2.5</state>
                        <!-- C.2.r.2.5: Reporter's State or Province #1 -->
                        <postalCode>C.2.r.2.6</postalCode>
                        <!-- C.2.r.2.6: Reporter's Postcode #1 -->
                      </addr>
                      <telecom value="tel:C.2.r.2.7"/>
                      <!-- C.2.r.2.7: Reporter's Telephone #1 -->
                      <assignedPerson classCode="PSN" determinerCode="INSTANCE">
                        <name>
                          <prefix>C.2.r.1.1</prefix>
                          <!-- C.2.r.1.1: Reporter's Title #1 -->
                          <given>C.2.r.1.2</given>
                          <!-- C.2.r.1.2: Reporter's Given Name #1 -->
                          <given>C.2.r.1.3</given>
                          <!-- C.2.r.1.3: Reporter's Middle Name #1 -->
                          <family>C.2.r.1.4</family>
                          <!-- C.2.r.1.4: Reporter's Family Name #1 -->
                        </name>
                        <asQualifiedEntity classCode="QUAL">
                          <code code="C.2.r.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.6" codeSystemVersion="1.0"/>
                          <!-- C.2.r.4: Qualification #1 -->
                        </asQualifiedEntity>
                        <asLocatedEntity classCode="LOCE">
                          <location classCode="COUNTRY" determinerCode="INSTANCE">
                            <code code="C.2.r.3" codeSystem="1.0.3166.1.2.2"/>
                            <!-- C.2.r.3: Reporter's Country Code #1 -->
                          </location>
                        </asLocatedEntity>
                      </assignedPerson>
                      <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                        <name>C.2.r.2.2</name>
                        <!-- C.2.r.2.2: Reporter's Department #1 -->
                        <assignedEntity classCode="ASSIGNED">
```

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                    <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                      <name>C.2.r.2.1</name>
                      <!-- C.2.r.2.1: Reporter's Organisation #1 -->
                    </representedOrganization>
                  </assignedEntity>
                </representedOrganization>
              </assignedEntity>
            </author>
          </controlActEvent>
        </subjectOf2>
      </relatedInvestigation>
    </outboundRelationship>
    <outboundRelationship typeCode="SPRT">
      <relatedInvestigation classCode="INVSTG" moodCode="EVN">
        <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" codeSystemVersion="1.0"
displayName="sourceReport"/>
        <subjectOf2 typeCode="SUBJ">
          <controlActEvent classCode="CACT" moodCode="EVN">
            <author typeCode="AUT">
              <assignedEntity classCode="ASSIGNED">
                <addr>
                  <streetAddressLine>C.2.r.2.3</streetAddressLine>
                  <!-- C.2.r.2.3: Reporter's Street #2 -->
                  <city>C.2.r.2.4</city>
                  <!-- C.2.r.2.4: Reporter's City #2 -->
                  <state>C.2.r.2.5</state>
                  <!-- C.2.r.2.5: Reporter's State or Province #2 -->
                  <postalCode>C.2.r.2.6</postalCode>
                  <!-- C.2.r.2.6: Reporter's Postcode #2 -->
                </addr>
                <telecom value="tel:C.2.r.2.7"/>
                <!-- C.2.r.2.7: Reporter's Telephone #2 -->
                <assignedPerson classCode="PSN" determinerCode="INSTANCE">
                  <name>
                    <prefix>C.2.r.1.1</prefix>
                    <!-- C.2.r.1.1: Reporter's Title #2 -->
                    <given>C.2.r.1.2</given>
                    <!-- C.2.r.1.2: Reporter's Given Name #2 -->
                    <given>C.2.r.1.3</given>
                    <!-- C.2.r.1.3: Reporter's Middle Name #2 -->
                    <family>C.2.r.1.4</family>
                    <!-- C.2.r.1.4: Reporter's Family Name #2 -->
                  </name>
                  <asQualifiedEntity classCode="QUAL">
                    <code code="C.2.r.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.6" codeSystemVersion="1.0"/>
                    <!-- C.2.r.4: Qualification #2 -->
                  </asQualifiedEntity>
                  <asLocatedEntity classCode="LOCE">
                    <location classCode="COUNTRY" determinerCode="INSTANCE">
                      <code code="C.2.r.3" codeSystem="1.0.3166.1.2.2"/>
                      <!-- C.2.r.3: Reporter's Country Code #2 -->
                    </location>
                  </asLocatedEntity>
                </assignedPerson>
                <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                  <name>C.2.r.2.2</name>
                  <!-- C.2.r.2.2: Reporter's Department #2 -->
                  <assignedEntity classCode="ASSIGNED">
                    <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                      <name>C.2.r.2.1</name>
                      <!-- C.2.r.2.1: Reporter's Organisation #2 -->
                    </representedOrganization>
                  </assignedEntity>
                </representedOrganization>
              </assignedEntity>
            </author>
          </controlActEvent>
        </subjectOf2>
      </relatedInvestigation>
```

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        </outboundRelationship>
        <subjectOf1 typeCode="SUBJ">
          <controlActEvent classCode="CACT" moodCode="EVN">
            <author typeCode="AUT">
              <assignedEntity classCode="ASSIGNED">
                <code code="C.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.7" codeSystemVersion="1.0"/>
                <!-- C.3.1: Sender Type -->
                <addr>
                  <streetAddressLine>C.3.4.1</streetAddressLine>
                  <!-- C.3.4.1: Sender's Street Address -->
                  <city>C.3.4.2</city>
                  <!-- C.3.4.2: Sender's City -->
                  <state>C.3.4.3</state>
                  <!-- C.3.4.3: Sender's State or Province -->
                  <postalCode>C.3.4.4</postalCode>
                  <!-- C.3.4.4: Sender's Postcode -->
                </addr>
                <telecom value="tel:C.3.4.6"/>
                <!-- C.3.4.6: Sender's Telephone -->
                <telecom value="fax:C.3.4.7"/>
                <!-- C.3.4.7: Sender's Fax -->
                <telecom value="mailto:C.3.4.8"/>
                <!-- C.3.4.8: Sender's E-mail Address -->
                <assignedPerson classCode="PSN" determinerCode="INSTANCE">
                  <name>
                    <prefix>C.3.3.2</prefix>
                    <!-- C.3.3.2: Sender's Title -->
                    <given>C.3.3.3</given>
                    <!-- C.3.3.3: Sender's Given Name -->
                    <given>C.3.3.4</given>
                    <!-- C.3.3.4: Sender's Middle Name -->
                    <family>C.3.3.5</family>
                    <!-- C.3.3.5: Sender's Family Name -->
                  </name>
                  <asLocatedEntity classCode="LOCE">
                    <location classCode="COUNTRY" determinerCode="INSTANCE">
                      <code code="C.3.4.5" codeSystem="1.0.3166.1.2.2"/>
                      <!-- C.3.4.5: Sender's Country Code -->
                    </location>
                  </asLocatedEntity>
                </assignedPerson>
                <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                  <name>C.3.3.1</name>
                  <!-- C.3.3.1: Sender's Department -->
                  <assignedEntity classCode="ASSIGNED">
                    <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                      <name>C.3.2</name>
                      <!-- C.3.2: Sender's Organisation -->
                    </representedOrganization>
                  </assignedEntity>
                </representedOrganization>
              </assignedEntity>
            </author>
            <primaryInformationRecipient typeCode="PRCP">
              <assignedEntity classCode="ASSIGNED">
                <assignedPerson classCode="PSN" determinerCode="INSTANCE">
                  <name>
                    <prefix>J2.18.2</prefix>
                    <!-- @@@J2.18.2: 受信者　肩書き -->
                    <family>J2.18.3</family>
                    <!-- @@@J2.18.3: 受信者　姓 -->
                    <given>J2.18.4</given>
                    <!-- @@@J2.18.4: 受信名　名 -->
                  </name>
                </assignedPerson>
                <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                  <name>J2.18.1</name>
                  <!-- @@@J2.18.1: 受信者　組織名 -->
                </representedOrganization>
```

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          </assignedEntity>
        </primaryInformationRecipient>
      </controlActEvent>
    </subjectOf1>
    <subjectOf1 typeCode="SUBJ">
      <controlActEvent classCode="CACT" moodCode="EVN">
        <id assigningAuthorityName="C.1.9.1.r.1" extension="C.1.9.1.r.2" root="2.16.840.1.113883.3.989.2.1.3.3"/>
        <!-- C.1.9.1.r.1: Source(s) of the Case Identifier (repeat as necessary) #1 -->
        <!-- C.1.9.1.r.2 Case Identifier(s) #1 -->
      </controlActEvent>
    </subjectOf1>
    <subjectOf1 typeCode="SUBJ">
      <controlActEvent classCode="CACT" moodCode="EVN">
        <id assigningAuthorityName="C.1.9.1.r.1" extension="C.1.9.1.r.2" root="2.16.840.1.113883.3.989.2.1.3.3"/>
        <!-- C.1.9.1.r.1: Source(s) of the Case Identifier (repeat as necessary) #2 -->
        <!-- C.1.9.1.r.2 Case Identifier(s) #2 -->
      </controlActEvent>
    </subjectOf1>
    <subjectOf2 typeCode="SUBJ">
      <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" codeSystemVersion="1.0" displayName="ichReportType"/>
        <value xsi:type="CE" code="C.1.3" codeSystem="2.16.840.1.113883.3.989.2.1.1.2" codeSystemVersion="1.0"/>
        <!-- C.1.3 Type of Report -->
      </investigationCharacteristic>
    </subjectOf2>
    <subjectOf2 typeCode="SUBJ">
      <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" codeSystemVersion="1.0" displayName="otherCaseIds"/>
        <value xsi:type="BL" value="true"/>
        <!-- C.1.9.1 Other Case Identifiers in Previous Transmissions -->
      </investigationCharacteristic>
    </subjectOf2>
    <subjectOf2 typeCode="SUBJ">
      <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" codeSystemVersion="1.0" displayName="nullificationAmendmentCode"/>
        <value xsi:type="CE" code="C.1.11.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.5" codeSystemVersion="1.0"/>
        <!-- C.1.11.1: Report Nullification / Amendment -->
      </investigationCharacteristic>
    </subjectOf2>
    <subjectOf2 typeCode="SUBJ">
      <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" codeSystemVersion="1.0" displayName="nullificationAmendmentReason"/>
        <value xsi:type="CE">
          <originalText>C.1.11.2</originalText>
          <!-- C.1.11.2: Reason for Nullification / Amendment -->
        </value>
      </investigationCharacteristic>
    </subjectOf2>
    <subjectOf2 typeCode="SUBJ">
      <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="識別番号（報告分類）"/>
        <value xsi:type="CE" code="J2.1a" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.1" codeSystemVersion="1.0"/>
        <!-- @@@J2.1a: 識別番号（報告分類） -->
      </investigationCharacteristic>
    </subjectOf2>
    <subjectOf2 typeCode="SUBJ">
      <investigationCharacteristic classCode="OBS" moodCode="EVN">
        <code code="2" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="報告起算日"/>
        <value xsi:type="TS" value="20130107"/>
        <!-- @@@J2.2.1: 報告起算日 -->
      </investigationCharacteristic>
    </subjectOf2>
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```xml
            <subjectOf2 typeCode="SUBJ">
              <investigationCharacteristic classCode="OBS" moodCode="EVN">
                <code code="3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="報告
起算日に関するコメント"/>
                <value xsi:type="ED">J2.2.2</value>
                <!-- @@@J2.2.2: 報告起算日に関するコメント -->
              </investigationCharacteristic>
            </subjectOf2>
            <subjectOf2 typeCode="SUBJ">
              <investigationCharacteristic classCode="OBS" moodCode="EVN">
                <code code="4" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="即時
報告フラグ"/>
                <value xsi:type="CE" code="J2.3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.2" codeSystemVersion="1.0"/>
                <!-- @@@J2.3: 即時報告フラグ -->
              </investigationCharacteristic>
            </subjectOf2>
            <subjectOf2 typeCode="SUBJ">
              <investigationCharacteristic classCode="OBS" moodCode="EVN">
                <code code="5" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="報告
対象外フラグ"/>
                <value xsi:type="CE" code="J2.8.1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.6"
codeSystemVersion="1.0"/>
                <!-- @@@J2.8.1: 報告対象外フラグ -->
              </investigationCharacteristic>
            </subjectOf2>
            <subjectOf2 typeCode="SUBJ">
              <investigationCharacteristic classCode="OBS" moodCode="EVN">
                <code code="6" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="報告
対象外の理由"/>
                <value xsi:type="ED">J2.8.2</value>
                <!-- @@@J2.8.2: 報告対象外の理由 -->
              </investigationCharacteristic>
            </subjectOf2>
          </investigationEvent>
        </subject>
      </controlActProcess>
    </PORR_IN049016UV>
    <!-- Message #1 -->
    <!-- Message #2 -->
    <!-- PORR_IN049016UV -->
    <!-- /PORR_IN049016UV -->
    <!-- Message #2 -->
    <receiver typeCode="RCV">
      <device classCode="DEV" determinerCode="INSTANCE">
        <id extension="N.1.4" root="2.16.840.1.113883.3.989.2.1.3.14"/>
        <!-- N.1.4: Batch Receiver Identifier -->
      </device>
    </receiver>
    <sender typeCode="SND">
      <device classCode="DEV" determinerCode="INSTANCE">
        <id extension="N.1.3" root="2.16.840.1.113883.3.989.2.1.3.13"/>
        <!-- N.1.3: Batch Sender Identifier -->
      </device>
    </sender>
</MCCI_IN200100UV01>
```