

```

- <!-- ##### B.4: Drug(s) Information ##### END
  -->
- <!-- ##### A_RelevantInformationForProductReporting CMET ##### END
  -->
  </primaryRole>
  </subject1>
- <component typeCode="COMP">
- <causalityAssessment classCode="OBS" moodCode="EVN">
  <code code="InterventionCharacterization" codeSystem="2.16.840.1.113883.5.4" />
  <value code="1" codeSystem="0.2.999.5.21" xsi:type="CE" />
- <!-- @@@ B.4.k.1: Characterization of Drug Role
  -->
- <subject2 typeCode="SUBJ">
- <productUseReference classCode="ACT" moodCode="EVN">
  <id extension="1095" root="0.2.999.1.0.6" />
- <!-- ### drug reference ID
  -->
  </productUseReference>
  </subject2>
  </causalityAssessment>
  </component>
- <component typeCode="COMP">
- <causalityAssessment classCode="OBS" moodCode="EVN">
  <code code="InterventionCharacterization" codeSystem="2.16.840.1.113883.5.4" />
  <value code="1" codeSystem="0.2.999.5.21" xsi:type="CE" />
- <!-- @@@ B.4.k.1: Characterization of Drug Role
  -->
- <subject2 typeCode="SUBJ">
- <productUseReference classCode="ACT" moodCode="EVN">
  <id extension="1096" root="0.2.999.1.0.6" />
- <!-- ### drug reference ID
  -->
  </productUseReference>
  </subject2>
  </causalityAssessment>
  </component>
- <!-- ##### B.4.k.9: Drug-reaction(s)/event(s) matrix ##### STRAT
  -->
- <component typeCode="COMP">
- <causalityAssessment classCode="OBS" moodCode="EVN">
  <code code="Causality" codeSystem="0.2.999.5.30" />
  <value xsi:type="ST">可能性大</value>
- <!-- @@@ B.4.k.9.i.2.r.3: Result of Assessment
  -->
- <author typeCode="AUT">
- <assignedEntity classCode="ASSIGNED">

```

```

- <code>
  <originalText>reporter</originalText>
- <!-- @@@ B.4.k.9.i.2.r.1: Source of Assessment
  -->
  </code>
  </assignedEntity>
  </author>
- <subject1 typeCode="SUBJ">
- <adverseEffectReference classCode="ACT" moodCode="EVN">
  <id extension="1019" root="0.2.999.1.0.5" />
  </adverseEffectReference>
  </subject1>
- <subject2 typeCode="SUBJ">
- <productUseReference classCode="ACT" moodCode="EVN">
  <id extension="1095" root="0.2.999.1.0.6" />
  </productUseReference>
  </subject2>
  </causalityAssessment>
  </component>
- <component typeCode="COMP">
- <causalityAssessment classCode="OBS" moodCode="EVN">
  <code code="Causality" codeSystem="0.2.999.5.30" />
  <value xsi:type="ST">可能性大</value>
- <!-- @@@ B.4.k.9.i.2.r.3: Result of Assessment
  -->
- <author typeCode="AUT">
- <assignedEntity classCode="ASSIGNED">
- <code>
  <originalText>reporter</originalText>
- <!-- @@@ B.4.k.9.i.2.r.1: Source of Assessment
  -->
  </code>
  </assignedEntity>
  </author>
- <subject1 typeCode="SUBJ">
- <adverseEffectReference classCode="ACT" moodCode="EVN">
  <id extension="1019" root="0.2.999.1.0.5" />
  </adverseEffectReference>
  </subject1>
- <subject2 typeCode="SUBJ">
- <productUseReference classCode="ACT" moodCode="EVN">
  <id extension="1096" root="0.2.999.1.0.6" />
  </productUseReference>
  </subject2>
  </causalityAssessment>
  </component>

```

```

- <!-- ##### B.4.k.9: Drug-reaction(s)/event(s) matrix ##### END
  -->
- <component1 typeCode="COMP">
- <observationEvent classCode="OBS" moodCode="EVN">
  <code code="comment" codeSystem="0.2.999.5.6" />
  <value mediaType="text/plain" xsi:type="ED">レビワへ服用の妊婦での二分脊椎児出産は文献的にも報告が多く、
  出生翌日の児の血中レビワへ濃度からも、関連があると考え。</value>
- <!-- @@@ B.5.2: Reporter's Comments
  -->
- <author typeCode="AUT">
- <assignedEntity classCode="ASSIGNED">
  <code code="sourceReporter" codeSystem="0.2.999.5.25" />
</assignedEntity>
</author>
</observationEvent>
</component1>
- <component1 typeCode="COMP">
- <observationEvent classCode="OBS" moodCode="EVN">
  <code code="comment" codeSystem="0.2.999.5.6" />
  <value mediaType="text/plain" xsi:type="ED">「使用上の注意」にも記載しており、本剤による可能性は高いと考え
  る。</value>
- <!-- @@@ B.5.4: Sender's Comments
  -->
- <author typeCode="AUT">
- <assignedEntity classCode="ASSIGNED">
  <code code="Sender" codeSystem="0.2.999.5.25" />
</assignedEntity>
</author>
</observationEvent>
</component1>
</adverseEventAssessment>
</component>
- <!-- ##### B.1: Patient characteristics ##### END
  -->
- <component typeCode="COMP">
- <observationEvent classCode="OBS" moodCode="EVN">
  <code code="additionalDocumentsAvailable" codeSystem="0.2.999.5.6" />
  <value value="false" xsi:type="BL" />
- <!-- @@@ A.1.8.1: Are Additional Documents Available?
  -->
</observationEvent>
</component>
- <component typeCode="COMP">
- <observationEvent classCode="OBS" moodCode="EVN">
  <code code="localCriteriaForExpedited" codeSystem="0.2.999.5.6" />
  <value value="true" xsi:type="BL" />

```

```

- <!-- @@@ A.1.9: Does this Case Fulfill the Local Criteria for an Expedited Report?
-->
  </observationEvent>
</component>
- <component typeCode="COMP">
- <observationEvent classCode="OBS" moodCode="EVN">
  <code code="summaryAndComment" codeSystem="0.2.999.5.6" />
  <value language="jpn" mediaType="text/plain" xsi:type="ED">頭部外傷によるてんかん発作に対して、2000年頃
からハフォレピチーレを投与していたが、副作用出現のため2001年頃からソケオンリゲに変更。2004年5月に発作コ
ントロール不十分のため当施設受診。2004年5月15日からコピドンの投与を開始。その後妊娠が判明。2006年8月2日、
当施設参加にて在胎39週で第一子を出産した所、児に二分脊椎がみられた。尚、妊娠中、発作はコントロールされて
おり、血液検査上も特に異常はなかった。出生翌日の児のレビワペ濃度は38µg/ml。医師総合判定でも関連ありとされ、
「使用上の注意」にも記載されており、本剤による可能性は高い。</value>
- <!-- @@@ B.5.5.r.1: Case Summary and Reporter's Comments Text
-->
- <!-- @@@ B.5.5.r.2: Case Summary and Reporter's Comments Language
-->
- <author typeCode="AUT">
- <assignedEntity classCode="ASSIGNED">
  <code code="Reporter" codeSystem="0.2.999.5.25" />
</assignedEntity>
</author>
</observationEvent>
</component>
- <component typeCode="COMP">
- <observationEvent classCode="OBS" moodCode="EVN">
  <code code="DateOfDayZero" codeSystem="0.2.999.5.6" />
  <value value="20060828" xsi:type="TS" />
- <!-- @@@ J.3a: The date of day 0 for reporting time frame
-->
  </observationEvent>
</component>
- <component typeCode="COMP">
- <observationEvent classCode="OBS" moodCode="EVN">
  <code code="ActionToBeTaken" codeSystem="0.2.999.5.6" />
  <value mediaType="text/plain" xsi:type="ED">今後も注意してモニターする。</value>
- <!-- @@@ J.9: Company's action to be taken
-->
  </observationEvent>
</component>
- <component typeCode="COMP">
- <observationEvent classCode="OBS" moodCode="EVN">
  <code code="OtherReference" codeSystem="0.2.999.5.6" />
  <value mediaType="text/plain" xsi:type="ED">海外については不明</value>
- <!-- @@@ J.10: Other references
-->

```

```

    </observationEvent>
  </component>
- <sourceOf typeCode="SPRT">
- <relatedInvestigation classCode="INVSTG" moodCode="EVN">
  <code code="initialReport" codeSystem="0.2.999.5.2" />
- <subjectOf2 typeCode="SUBJ">
- <controlActEvent classCode="CACT" moodCode="EVN">
- <author typeCode="AUT">
- <assignedEntity classCode="ASSIGNED">
  <code code="2" codeSystem="0.2.999.5.7" />
- <!-- @@@ A.1.10.2: First Sender of this Case
-->
  </assignedEntity>
  </author>
  </controlActEvent>
  </subjectOf2>
  </relatedInvestigation>
  </sourceOf>
- <sourceOf typeCode="SPRT">
- <relatedInvestigation classCode="INVSTG" moodCode="EVN">
  <code nullFlavor="NA" />
- <subjectOf2 typeCode="SUBJ">
- <controlActEvent classCode="CACT" moodCode="EVN">
  <id extension="JP-AbabPharm-0002" root="0.2.999.10.2.1" />
- <!-- @@@ A.1.12.r: Identification Number of the Report Which Is Linked to this Report
-->
  </controlActEvent>
  </subjectOf2>
  </relatedInvestigation>
  </sourceOf>
- <!-- ##### A.2: Primary Source(s) of Information ##### START
-->
- <sourceOf typeCode="SPRT">
  <priorityNumber value="1" />
- <!-- @@@ A.2.r.1.5: Primary source for regulatory purposes
-->
- <relatedInvestigation classCode="INVSTG" moodCode="EVN">
  <code code="sourceReport" codeSystem="0.2.999.5.2" />
- <subjectOf2 typeCode="SUBJ">
- <controlActEvent classCode="CACT" moodCode="EVN">
- <author typeCode="AUT">
- <assignedEntity classCode="ASSIGNED">
- <addr>
  <streetAddressLine>千代田町1111</streetAddressLine>
  <city>千代田区</city>
  <state>東京都</state>

```

```

    <postalCode>Privacy</postalCode>
  </addr>
  <telecom value="tel:Privacy" />
- <assignedPerson determinerCode="INSTANCE" classCode="PSN">
- <name>
  <prefix>医師</prefix>
- <!-- @@@ A.2.r.1.1a: Reporter Identifier (Reporter title)
  -->
  <given>一郎</given>
- <!-- @@@ A.2.r.1.1b: Reporter Identifier (Reporter given name)
  -->
  <family>神内</family>
- <!-- @@@ A.2.r.1.1d: Reporter Identifier (Reporter family name)
  -->
  </name>
- <asQualifiedEntity classCode="QUAL">
  <code code="1" codeSystem="0.2.999.5.8" />
- <!-- @@@ A.2.r.1.4: Qualification
  -->
  </asQualifiedEntity>
- <asLocatedEntity classCode="LOCE">
- <location determinerCode="INSTANCE" classCode="COUNTRY">
  <code code="392" codeSystem="1.0.3166.1.2" />
- <!-- @@@ A.2.r.1.3: Country (Reporter country code)
  -->
  </location>
  </asLocatedEntity>
  </assignedPerson>
- <representedOrganization determinerCode="INSTANCE" classCode="ORG">
  <name>神経内科</name>
- <!-- @@@ A.2.r.1.2b: Reporter's Address and Telephone (Reporter department)
  -->
- <assignedEntity classCode="ASSIGNED">
- <representedOrganization determinerCode="INSTANCE" classCode="ORG">
  <name>千代田病院</name>
- <!-- @@@ A.2.r.1.2a: Reporter's Address and Telephone (Reporter organization)
  -->
  </representedOrganization>
  </assignedEntity>
  </representedOrganization>
  </assignedEntity>
  </author>
  </controlActEvent>
  </subjectOf>
  </relatedInvestigation>
  </sourceOf>

```

```

- <!-- ##### A.2: Primary Source(s) of Information ##### END
  -->
- <!-- ##### A.3: Information on Sender of Case Safety Report ##### START
  -->
- <subjectOf1 typeCode="SUBJ">
- <controlActEvent classCode="CACT" moodCode="EVN">
- <author typeCode="AUT">
- <assignedEntity classCode="ASSIGNED">
  <code code="1" codeSystem="0.2.999.5.11" />
- <!-- @@@ A.3.1: Sender Type
  -->
- <addr>
  <streetAddressLine>何処町1 2 3 1 </streetAddressLine>
  <city>中央区</city>
  <state>東京</state>
  <postalCode>1230001</postalCode>
  </addr>
  <telecom value="tel:+81-3-1234-5678" />
  <telecom value="fax:+81-3-1234-5688" />
  <telecom value="mailto:oote@ababpharm.co.jp" />
- <assignedPerson determinerCode="INSTANCE" classCode="PSN">
- <name>
  <prefix>1122333</prefix>
- <!-- @@@ A.3.3b: Sender's Title
  -->
  <given>町男</given>
- <!-- @@@ A.3.3c: Sender's Given Name
  -->
  <family>大手</family>
- <!-- @@@ A.3.3e: Sender's Family Name
  -->
  </name>
- <asLocatedEntity classCode="LOCE">
- <location determinerCode="INSTANCE" classCode="COUNTRY">
  <code code="392" codeSystem="1.0.3166.1.2" />
- <!-- @@@ A.3.4e: Sender's Country Code
  -->
  </location>
  </asLocatedEntity>
  </assignedPerson>
- <representedOrganization determinerCode="INSTANCE" classCode="ORG">
  <name />
- <assignedEntity classCode="ASSIGNED">
- <representedOrganization determinerCode="INSTANCE" classCode="ORG">
  <name>東京第一営業所</name>
- <!-- @@@ A.3.3a: Sender's Department

```

```

-->
</representedOrganization>
</assignedEntity>
- <asIdentifiedEntity classCode="IDENT">
  <id extension="ABAB製薬株式会社" root="0.2.15.1" />
- <!-- @@@ A.3.2: Sender's Organization
-->
</asIdentifiedEntity>
</representedOrganization>
</assignedEntity>
</author>
</controlActEvent>
</subjectOf1>
- <!-- ##### A.3: Information on Sender of Case Safety Report ##### END
-->
- <subjectOf2 typeCode="SUBJ">
- <investigationCharacteristic classCode="OBS" moodCode="EVN">
  <code code="ichReportType" codeSystem="0.2.999.5.3" />
  <value code="1" codeSystem="0.2.999.5.1" xsi:type="CE" />
- <!-- @@@ A.1.4: Type of Report
-->
</investigationCharacteristic>
</subjectOf2>
- <subjectOf2 typeCode="SUBJ">
- <investigationCharacteristic classCode="OBS" moodCode="EVN">
  <code code="CaseIdentifierCategory" codeSystem="0.2.999.5.3" />
  <value code="2" codeSystem="0.2.999.5.31" xsi:type="CE" />
- <!-- @@@ J.1a: Case identifier (category)
-->
</investigationCharacteristic>
</subjectOf2>
- <subjectOf2 typeCode="SUBJ">
- <investigationCharacteristic classCode="OBS" moodCode="EVN">
  <code code="NumberOfFrequency" codeSystem="0.2.999.5.3" />
  <value value="1" xsi:type="INT" />
- <!-- @@@ J.2: Number of frequency for reporting to PMDA
-->
</investigationCharacteristic>
</subjectOf2>
</investigationEvent>
</subject>
</controlActProcess>
</PORR_IN049016UV>

```


症例16 : 症例15について、子の報告として作成

```
<PORR_IN049016UV xsi:schemaLocation="urn:hl7-org:v3 PORR_IN049016UV.xsd" ITSVersion="XML_1.0">
-
<!--
##### ICSR Implementation Guide v2_47 Revision April 6, 2010 #####
-->
<id extension="11112" root="0.2.3.4.5.1.1"/>
<!-- @@@ M.1.4: Message Number -->
<creationTime value="20100508090000"/>
<!-- @@@ M.1.7: Message Date -->
<interactionId extension="PORR_IN049016UV" root="2.16.840.1.113883.1.6"/>
<!-- HL7 V3 Interaction ID -->
<profileId extension="3.0" root="0.2.1.10.1"/>
<!-- @@@ M.1.2: Message Format Version -->
<profileId extension="2.0" root="0.2.1.10.2"/>
<!-- @@@ M.1.3: Message Format Release -->
<processingCode code="P"/>
-
<!--
defines whether the message is part of a production, training, or debugging system
-->
<processingModeCode code="T"/>
-
<!--
defines whether the message is being set in current processing
-->
<acceptAckCode code="AL"/>
<!-- Always send an acknowledgement -->
-
<receiver>
-
<device determinerCode="INSTANCE" classCode="DEV">
<id extension="RS001" root="0.2.5.6.7.1.2"/>
-
<asAgent classCode="AGNT">
-
<representedOrganization determinerCode="INSTANCE" classCode="ORG">
<id extension="PMDA" root="0.2.5.6.7"/>
<!-- @@@ M.1.6: Message Receiver Identifier -->
</representedOrganization>
</asAgent>
</device>
</receiver>
-
<sender>
```

```

-
<device determinerCode="INSTANCE" classCode="DEV">
<id extension="SV1" root="0.2.3.4.5.1.2"/>
-
<asAgent classCode="AGNT">
-
<representedOrganization determinerCode="INSTANCE" classCode="ORG">
<id extension="ABABPharma" root="0.2.3.4.5"/>
<!-- @@@ M.1.5: Message Sender Identifier -->
</representedOrganization>
</asAgent>
</device>
</sender>
-
<controlActProcess classCode="CACT" moodCode="EVN">
<effectiveTime value="20100508234525"/>
<!-- @@@ A.1.3: Date of Transmission -->
-
<subject typeCode="SUBJ">
-
<investigationEvent classCode="INVSTG" moodCode="EVN">
<id extension="JP-AbabPharm-0002" root="0.2.999.10.2.1"/>
-
<!--
@@@ A.1.0.1: Sender's (case) Safety Report Unique Identifier
-->
<id extension="JP-AbabPharm-0002" root="0.2.999.10.3"/>
<!-- @@@ A.1.10.1: Worldwide Unique Case Identifier -->
<id extension="10900002" root="0.2.999.10.4"/>
<!-- @@@ J.1b: Case identifier (number) -->
<code code="Ichicsr" codeSystem="0.2.999.5.27"/>
<!-- @@@ M.1.1: Message Type -->
<text mediaType="text/plain">母親が2006年に当施設参加にて在胎39週で第一子を出産したところ、この児に二分脊
椎が見られた。</text>
-
<!--
@@@ B.5.1: Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant
Information
-->
<statusCode code="completed"/>
<!-- @@@ J.4: Complete or incomplete -->
-
<effectiveTime>
<low value="20060828"/>
-
<!--

```

```

    @@@ A.1.6: Date Report Was First Received from Source
-->
</effectiveTime>
<availabilityTime value="20060828"/>
-
<!--
    @@@ A.1.7: Date of Most Recent Information for this Case
-->
-
<!--
    ##### B.1: Patient characteristics ##### START
-->
-
<component typeCode="COMP">
-
<adverseEventAssessment classCode="INVSTG" moodCode="EVN">
-
<subject1 typeCode="SBJ">
-
<primaryRole classCode="INVSBJ">
-
<player1 determinerCode="INSTANCE" classCode="PSN">
<name nullFlavor="UNK"/>
<!-- @@@ B.1.1: Patient (name or initial) -->
<administrativeGenderCode code="0" codeSystem="0.2.999.6.1"/>
<!-- @@@ B.1.5: Sex -->
-
<!--
    ##### B.1.10: For a Parent-child/Fetus Report, Information Concerning the Parent ##### START
-->
-
<role classCode="ROL">
<code code="PRN"/>
-
<associatedPerson determinerCode="INSTANCE" classCode="PSN">
<name>A.A</name>
<!-- @@@ B.1.10.1: Parent Identification -->
<administrativeGenderCode code="2" codeSystem="0.2.999.6.1"/>
<!-- @@@ B.1.10.6: Sex of Parent -->
</associatedPerson>
-
<subjectOf2 typeCode="SBJ">
-
<observation classCode="OBS" moodCode="EVN">
<code code="age" codeSystem="0.2.999.5.13"/>
<value unit="a" value="30" xsi:type="PQ"/>

```

```

<!-- @@@ B.1.10.2.2a: Age of Parent (age value) -->
<!-- @@@ B.1.10.2.2b: Age of Parent (age unit) -->
</observation>
</subjectOf2>
-
<subjectOf2 typeCode="SBJ">
-
<!--
##### B.1.10.7: Relevant Medical History and Concurrent Conditions of Parent ##### START
-->
-
<organizer>
<code code="relevantMedicalHistoryAndconcurrentConditions" codeSystem="0.2.999.5.16"/>
-
<component typeCode="COMP">
-
<observation classCode="OBS" moodCode="EVN">
<code code="10039203" codeSystemVersion="13.0" codeSystem="2.16.840.1.113883.6.70"/>
-
<!--
@@@ B.1.10.7.1.r.a.1: MedDRA Version for Parent Medical History
-->
-
<!--
@@@ B.1.10.7.1.r.a.2: Structured Information (disease / surgical procedure/ etc.)
-->
<text>交通事故</text>
<!-- @@@ B.1.10.7.1.r.g: Comments -->
-
<effectiveTime xsi:type="IVL_TS">
<low value="2000"/>
<!-- @@@ B.1.10.7.1.r.c: Start Date -->
</effectiveTime>
-
<targetOf typeCode="REFR">
-
<observation classCode="OBS" moodCode="EVN">
<code code="Continuing" codeSystem="0.2.999.5.13"/>
<value nullFlavor="UNK" xsi:type="BL"/>
<!-- @@@ B.1.10.7.1.r.d: Continuing -->
</observation>
</targetOf>
</observation>
</component>
-
<component typeCode="COMP">

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-
<observation classCode="OBS" moodCode="EVN">
<code code="10049615" codeSystemVersion="13.0" codeSystem="2.16.840.1.113883.6.70"/>
-
<!--
  @@@ B.1.10.7.1.r.a.1: MedDRA Version for Parent Medical History
-->
-
<!--
  @@@ B.1.10.7.1.r.a.2: Structured Information (disease / surgical procedure/ etc.)
-->
<text>頭部外傷後遺症</text>
<!-- @@@ B.1.10.7.1.r.g: Comments -->
-
<effectiveTime xsi:type="IVL_TS">
<low value="2000"/>
<!-- @@@ B.1.10.7.1.r.c: Start Date -->
</effectiveTime>
-
<targetOf typeCode="REFR">
-
<observation classCode="OBS" moodCode="EVN">
<code code="Continuing" codeSystem="0.2.999.5.13"/>
<value nullFlavor="UNK" xsi:type="BL"/>
<!-- @@@ B.1.10.7.1.r.d: Continuing -->
</observation>
</targetOf>
</observation>
</component>
</organizer>
-
<!--
  ##### B.1.10.7: Relevant Medical History and Consurrent Conditions of Parent ##### END
-->
</subjectOf2>
-
<subjectOf2 typeCode="SBJ">
-
<!--
  ##### B.1.10.8: Relevant Past Drug History of Parent ##### START
-->
-
<organizer>
<code code="drugHistory" codeSystem="0.2.999.5.16"/>
-
<component typeCode="COMP">

```

```

-
<substanceAdministration classCode="SBADM" moodCode="EVN">
<effectiveTime xsi:type="IVL_TS">
    <effectiveTime>
-
<consumable>
-
<instanceOfKind classCode="INST">
-
<kindOfProduct determinerCode="KIND" classCode="MMAT">
<code nullFlavor="NI"/>
<name>ハフオレビチーレ</name>
<!-- @@@ B.1.10.8.r.a0: Name of Drug as Reported -->
</kindOfProduct>
</instanceOfKind>
</consumable>
-
<sourceOf2 typeCode="CAUS">
-
<observation classCode="OBS" moodCode="EVN">
<code code="reaction" codeSystem="0.2.999.5.13"/>
<value code="10024670" codeSystemVersion="13.0" codeSystem="2.16.840.1.113883.6.70" xsi:type="CE"/>
<!-- @@@ B.1.10.8.r.g.1: MedDRA Version for Reaction -->
<!-- @@@ B.1.10.8.r.g.2: Reactions (if any and known) -->
</observation>
</sourceOf2>
</substanceAdministration>
</component>
</organizer>
-
<!--
##### B.1.10.8: Relevant Past Drug History of Parent ##### END
-->
</subjectOf2>
</role>
-
<!--
##### B.1.10: For a Parent-child/Fetus report, Information Concerning the Parent ##### END
-->
</player1>
-
<!--
##### A_RelevantInformationForProductReporting CMET ##### START
-->
-
<subjectOf2 typeCode="SBJ">

```

```

-
<observation classCode="OBS" moodCode="EVN">
<code code="ageGroup" codeSystem="0.2.999.5.13"/>
<value code="2" codeSystem="0.2.999.5.15" xsi:type="CE"/>
<!-- @@@ B.1.2.3: Patient Age Group -->
</observation>
</subjectOf2>
-
<subjectOf2 typeCode="SBJ">
-
<observation classCode="OBS" moodCode="EVN">
<code code="bodyWeight" codeSystem="0.2.999.5.13"/>
<value unit="kg" value="2.67" xsi:type="PQ"/>
<!-- @@@ B.1.3: Body Weight (kg) -->
</observation>
</subjectOf2>
-
<subjectOf2 typeCode="SBJ">
-
<observation classCode="OBS" moodCode="EVN">
<code code="height" codeSystem="0.2.999.5.13"/>
<value unit="cm" value="48.5" xsi:type="PQ"/>
<!-- @@@ B.1.4: Height (cm) -->
</observation>
</subjectOf2>
-
<!--
##### B.2: Reaction(s)/Event(s) ##### START
-->
-
<subjectOf2 typeCode="SBJ">
-
<observation classCode="OBS" moodCode="EVN">
<id extension="1020" root="0.2.999.1.0.5"/>
<!-- For ActReference -->
<code code="reaction" codeSystem="2.16.840.1.113883.5.4"/>
-
<effectiveTime xsi:type="IVL_TS">
<low value="20060802"/>
<!-- @@@ B.2.i.3: Date of Start of Reaction / Event -->
</effectiveTime>
-
<value code="10041524" codeSystemVersion="13.0" codeSystem="2.16.840.1.113883.6.70" xsi:type="CE">
-
<!--
@@@ B.2.i.1.a: MedDRA Version for Reaction / Event

```

```

-->
-
<!--
  @@@ B.2.i.1.b: Reaction / Event in MedDRA Terminology
-->
<originalText mediaType="text/plain">二分脊椎</originalText>
-
<!--
  @@@ B.2.i.0: Reaction / Event as Reported by the Primary Source
-->
</value>
-
<location typeCode="LOC">
-
<locatedEntity classCode="LOCE">
-
<locatedPlace determinerCode="INSTANCE" classCode="COUNTRY">
<code code="392" codeSystem="1.0.3166.1.2"/>
-
<!--
  @@@ B.2.i.8: Identification of the Country Where the Reaction / Event Occurred
-->
</locatedPlace>
</locatedEntity>
</location>
-
<sourceOf2 typeCode="PERT">
-
<observation classCode="OBS" moodCode="EVN">
<code code="termHighlightedByReporter" codeSystem="0.2.999.5.13"/>
<value value="true" xsi:type="BL"/>
<!-- @@@ B.2.i.2.1: Term Highlighted by the Reporter -->
</observation>
</sourceOf2>
-
<sourceOf2 typeCode="PERT">
-
<observation classCode="OBS" moodCode="EVN">
<code code="congenitalAnomalyBirthDefect" codeSystem="0.2.999.5.13"/>
<value value="true" xsi:type="BL"/>
-
<!--
  @@@ B.2.i.2.2.e: Seriousness Criteria at Event Level (Congenital Anomaly / Birth Defect)
-->
</observation>
</sourceOf2>

```


-
<sourceOf2 typeCode="PERT">

-
<observation classCode="OBS" moodCode="EVN">
<code code="outcome" codeSystem="0.2.999.5.13"/>
<value code="3" codeSystem="0.2.999.5.18" xsi:type="CE"/>

-
<!--
@@@ B.2.i.6: Outcome of Reaction / Event at the Time of Last Observation

-->
</observation>

</sourceOf2>

-
<sourceOf2 typeCode="PERT">

-
<observation classCode="OBS" moodCode="EVN">
<code code="medicalConfirmationByHealthProfessional" codeSystem="0.2.999.5.13"/>
<value value="true" xsi:type="BL"/>

-
<!--
@@@ B.2.i.7: Medical Confirmation by Health Professional

-->
</observation>

</sourceOf2>

</observation>

</subjectOf2>

-
<!--
B.2: Reaction(s)/Event(s) ##### END

-->
-
<!--
B.3: Results of tests and procedures relevant to the investigation of the patient ##### START

-->
-
<subjectOf2 typeCode="SBJ">

-
<organizer classCode="CATEGORY" moodCode="EVN">
<code code="testsAndProceduresRelevantToTheInvestigation" codeSystem="0.2.999.5.16"/>

-
<component typeCode="COMP">

-
<observation classCode="OBS" moodCode="EVN">
<code code="10059466" codeSystemVersion="13.0" codeSystem="2.16.840.1.113883.6.70"/>

<!-- @@@ B.3.r.c1: Test Name -->

<!-- @@@ B.3.r.c2: MedDRA Version for Test Name -->

```

<effectiveTime value="20060803" xsi:type="TVL_TS"/>
<!-- @@@ B.3.r.b: Test Date -->
-
<sourceOf2 typeCode="PERT">
-
<observation classCode="OBS" moodCode="EVN">
<code code="comment" codeSystem="0.2.999.5.13"/>
<value mediaType="text/plain" xsi:type="ED">出生翌日の児の血中レビワベ濃度が38µg/ml</value>
<!-- @@@ B.3.r.3: Comments (free text) -->
</observation>
</sourceOf2>
-
<sourceOf2 typeCode="REFR">
-
<observation classCode="OBS" moodCode="EVN">
<code code="moreInformationAvailable" codeSystem="0.2.999.5.13"/>
<value value="false" xsi:type="BL"/>
<!-- @@@ B.3.r.4: More Information Available -->
</observation>
</sourceOf2>
</observation>
</component>
-
<component typeCode="COMP">
-
<observation classCode="OBS" moodCode="EVN">
<code code="10019179" codeSystemVersion="13.0" codeSystem="2.16.840.1.113883.6.70"/>
<!-- @@@ B.3.r.c1: Test Name -->
<!-- @@@ B.3.r.c2: MedDRA Version for Test Name -->
<effectiveTime value="20051018" xsi:type="TVL_TS"/>
<!-- @@@ B.3.r.b: Test Date -->
<value mediaType="text/plain" xsi:type="ED">%</value>
-
<!--
@@@ B.3.r.f: Result Unstructured Data (free text)
-->
<value value="8.1" xsi:type="PQ"/>
<!-- @@@ B.3.r.d: Test Result(Value and qualifier) -->
</observation>
</component>
</organizer>
</subjectOf2>
-
<!--
##### B.3: Results of tests and procedures relevant to the investigation of the patient ##### END
-->

```

```

-
<!--
##### B.4: Drug(s) Information ##### START
-->
-
<subjectOf2 typeCode="SBJ">
-
<organizer classCode="CATEGORY" moodCode="EVN">
<code code="drugInformation" codeSystem="0.2.999.5.16"/>
<!-- ##### Drug Information (1) ##### START -->
-
<component typeCode="COMP">
-
<substanceAdministration classCode="SBADM" moodCode="EVN">
<id extension="1097" root="0.2.999.1.0.6"/>
-
<consumable>
-
<instanceOfKind classCode="INST">
-
<kindOfProduct determinerCode="KIND" classCode="MMAT">
-
<code code="312456789" codeSystem="0.2.999.6.2">
<!-- @@@ B.4.k.2.1.1a: MPID -->
<originalText>コピド</originalText>
-
<!--
@@@ B.4.k.2.2: Medicinal Product Name as Reported by the Primary Source
-->
</code>
-
<asManufacturedProduct classCode="MANU">
-
<subjectOf typeCode="SBJ">
-
<approval1 classCode="CNTRCT" moodCode="EVN">
<id extension="9876ABABpharm00111" root="0.2.1.5.1"/>
-
<!--
@@@ B.4.k.3.1: Authorization / Application Number
-->
-
<holder typeCode="HLD">
-
<role classCode="ROL">
-

```

```

<playingOrganization determinerCode="INSTANCE" classCode="ORG">
<name>ABABpharm</name>
<!-- @@@ B.4.k.3.3: Name of Holder / Applicant -->
</playingOrganization>
</role>
</holder>
-
<author typeCode="AUT">
-
<territorialAuthority classCode="TERR">
-
<territory determinerCode="INSTANCE" classCode="NAT">
<code code="392" codeSystem="1.0.3166.1.2"/>
-
<!--
@@@ B.4.k.3.2: Country of Authorization / Application
-->
</territory>
</territorialAuthority>
</author>
</approval1>
</subjectOf>
-
<subjectOf typeCode="SBJ">
-
<characteristic classCode="OBS" moodCode="EVN">
<code code="StatusOfSuspectDrug" codeSystem="0.2.999.5.21"/>
<value code="5" codeSystem="0.2.999.5.34" xsi:type="CE"/>
<!-- @@@ J.6: Category of drug -->
</characteristic>
</subjectOf>
</asManufacturedProduct>
-
<!--
##### B.4.k.2.3.r: Substance/Specified Substance Identifier and Strength (1) ##### START
-->
-
<ingredient classCode="ACTI">
-
<ingredient determinerCode="KIND" classCode="MMAT">
<name>ハフオレビチーレ</name>
-
<!--
@@@ B.4.k.2.3.r.1: Substance / Specified Substance Name
-->
</ingredient>

```