```
</ingredient>
−
<!--
 ##### B.4.k.2.3.r: Substance/Specified Substance Identifier and Strength (1) ##### END
-->
</kindOfProduct>
−
<subjectOf typeCode="SBJ">
−
<productEvent classCode="ACT" moodCode="EVN">
<code code="retailSupply" codeSystem="0.2.999.5.22"/>
−
<performer typeCode="PRF">
−
<assignedEntity classCode="ASSIGNED">
−
<representedOrganization determinerCode="INSTANCE" classCode="ORG">
−
<addr>
<country>392</country>
−
<!--
 @@@ B.4.k.2.4: Identification of the Country Where the Drug Was Obtained
-->
</addr>
</representedOrganization>
</assignedEntity>
</performer>
</productEvent>
</subjectOf>
</instanceOfKind>
</consumable>
−
<sourceOf1 typeCode="SAS">
<pauseQuantity unit="a" value="2"/>
−
<!--
 @@@ B.4.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reactoin / Event
(number)
-->
−
<!--
 @@@ B.4.k.9.i.3.1b: Time Interval between Beginning of Drug Administartion and Start of Reaction / Event (unit)
-->
−
<actReference classCode="ACT" moodCode="EVN">
```

```xml
<id extension="1020" root="0.2.999.1.0.5"/>
</actReference>
</sourceOf1>

<sourceOf2 typeCode="PERT">

<observation classCode="OBS" moodCode="EVN">
<code code="recurranceOfReaction" codeSystem="0.2.999.5.13"/>
<value nullFlavor="UNK" xsi:type="BL"/>

<!--
 @@@ B.4.k.9.i.4: Did Reactoin Recur on Re-administration?
-->

<sourceOf1 typeCode="REFR">

<actReference classCode="ACT" moodCode="EVN">
<id extension="1020" root="0.2.999.1.0.5"/>
</actReference>
</sourceOf1>
</observation>
</sourceOf2>

<!--
 ##### B.4.k.4: Dosage Information (1) ##### START
-->

<sourceOf2 typeCode="COMP">

<substanceAdministration classCode="SBADM" moodCode="EVN">

<effectiveTime xsi:type="SXPR_TS">

<comp xsi:type="PIVL_TS">
<period unit="d" value="0.5"/>
<!-- @@@ B.4.k.4.r.4: Number of Units in the Interval -->

<!--
 @@@ B.4.k.4.r.5: Definition of the Time Interval Unit
-->
</comp>

<comp operator="A" xsi:type="IVL_TS">
<low value="20040515"/>
<!-- @@@ B.4.k.4.r.6: Date and Time of Start of Drug -->
</comp>
```

```xml
</effectiveTime>
<doseQuantity unit="mg" value="400"/>
<!-- @@@ B.4.k.4.r.1: Dose (number) -->
<!-- @@@ B.4.k.4.r.2: Dose (unit) -->

<consumable typeCode="CSM">

<instanceOfKind classCode="INST">

<kindOfProduct determinerCode="KIND" classCode="MMAT">

<formCode nullFlavor="OTH">
<originalText>錠剤</originalText>

<!--
 @@@ B.4.k.4.r.11.1: Pharmaceutical Dose Form Text
-->
</formCode>
</kindOfProduct>
</instanceOfKind>
</consumable>

<targetOf typeCode="REFR">

<observation classCode="OBS" moodCode="EVN">
<code code="parentRouteOfAdministration" codeSystem="0.2.999.5.13"/>

<value xsi:type="CE">
<originalText>経口</originalText>

<!--
 @@@ B.4.k.4.r.13.1: Parent Route of Administration
-->
</value>
</observation>
</targetOf>
</substanceAdministration>
</sourceOf2>
<!-- ##### B.4.k.4: Dosage Information (1) ##### END -->

<!--
 ##### B.4.k.7: Indication for Use in case (1) ##### START
-->

<targetOf typeCode="RSON">
```

```xml
<observation classCode="OBS" moodCode="EVN">
<code code="indication" codeSystem="0.2.999.5.13"/>
—
<value code="10015037" codeSystemVersion="13.0" codeSystem="2.16.840.1.113883.6.70" xsi:type="CE">
—
<!--
 @@@ B.4.k.7.r.2b: Indication in MedDRA Terminology (LLT code)
-->
—
<!--
 @@@ B.4.k.7.r.2a: Indication in MedDRA Terminology (version)
-->
<originalText>てんかん</originalText>
—
<!--
 @@@ B.4.k.7.r.1: Indication as Reported by the Primary Source
-->
</value>
—
<performer>
—
<assignedEntity>
<code code="sourceReporter" codeSystem="0.2.999.5.7"/>
</assignedEntity>
</performer>
</observation>
</targetOf>
—
<!--
 ##### B.4.k.7: Indication for Use in case (1) ##### END
-->
—
<targetOf typeCode="CAUS">
—
<act classCode="ACT" moodCode="EVN">
<code code="4" codeSystem="0.2.999.5.13"/>
<!-- @@@ B.4.k.8: Action Taken with Drug -->
</act>
</targetOf>
</substanceAdministration>
</component>
<!-- ##### Drug Information (1) ##### END -->
<!-- ##### Drug Information (2) ##### START -->
—
<component typeCode="COMP">
—
```

```xml
<substanceAdministration classCode="SBADM" moodCode="EVN">
<id extension="1098" root="0.2.999.1.0.6"/>
—
<consumable>
—
<instanceOfKind classCode="INST">
—
<kindOfProduct determinerCode="KIND" classCode="MMAT">
—
<code code="124567893" codeSystem="0.2.999.6.2">
<!-- @@@ B.4.k.2.1.1a: MPID -->
<originalText>ソケオンリゲ</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="5432CDCDpharm00222" 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>CDCDpharm</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"/>
```

```xml
<!--
  @@@ 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>レビワベ</name>

<!--
  @@@ B.4.k.2.3.r.1: Substance / Specified Substance Name
-->
</ingredient>
</ingredient>

<!--
  ##### B.4.k.2.3.r: Substance/Specified Substance Identifier and Strength (1) ##### END
-->
</kindOfProduct>

<subjectOf typeCode="SBJ">

<productEvent classCode="ACT" moodCode="EVN">
<code code="retailSupply" codeSystem="0.2.999.5.22"/>

<performer typeCode="PRF">
```

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```xml
<assignedEntity classCode="ASSIGNED">

<representedOrganization determinerCode="INSTANCE" classCode="ORG">

<addr>
<country>392</country>

<!--
 @@@ B.4.k.2.4: Identification of the Country Where the Drug Was Obtained
-->
</addr>
</representedOrganization>
</assignedEntity>
</performer>
</productEvent>
</subjectOf>
</instanceOfKind>
</consumable>

<sourceOf1 typeCode="SAS">
<pauseQuantity unit="a" value="5"/>

<!--
 @@@ B.4.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of Reactoin / Event
(number)
-->

<!--
 @@@ B.4.k.9.i.3.1b: Time Interval between Beginning of Drug Administartion and Start of Reaction / Event (unit)
-->

<actReference classCode="ACT" moodCode="EVN">
<id extension="1020" root="0.2.999.1.0.5"/>
</actReference>
</sourceOf1>

<sourceOf2 typeCode="PERT">

<observation classCode="OBS" moodCode="EVN">
<code code="recurranceOfReaction" codeSystem="0.2.999.5.13"/>
<value nullFlavor="UNK" xsi:type="BL"/>

<!--
 @@@ B.4.k.9.i.4: Did Reactoin Recur on Re-administration?
-->
```

```
—
<sourceOf1 typeCode="REFR">
—
<actReference classCode="ACT" moodCode="EVN">
<id extension="1020" root="0.2.999.1.0.5"/>
</actReference>
</sourceOf1>
</observation>
</sourceOf2>
—
<!--
  ##### B.4.k.4: Dosage Information (1) ##### START
-->
—
<sourceOf2 typeCode="COMP">
—
<substanceAdministration classCode="SBADM" moodCode="EVN">
—
<effectiveTime xsi:type="SXPR_TS">
—
<comp xsi:type="PIVL_TS">
<period unit="d" value="0.5"/>
<!-- @@@ B.4.k.4.r.4: Number of Units in the Interval -->
—
<!--
  @@@ B.4.k.4.r.5: Definition of the Time Interval Unit
-->
</comp>
—
<comp operator="A" xsi:type="IVL_TS">
<low value="2001"/>
<!-- @@@ B.4.k.4.r.6: Date and Time of Start of Drug -->
</comp>
</effectiveTime>
<doseQuantity unit="mg" value="100"/>
<!-- @@@ B.4.k.4.r.1: Dose (number) -->
<!-- @@@ B.4.k.4.r.2: Dose (unit) -->
—
<consumable typeCode="CSM">
—
<instanceOfKind classCode="INST">
—
<kindOfProduct determinerCode="KIND" classCode="MMAT">
—
<formCode nullFlavor="OTH">
<originalText>錠剤</originalText>
```

```xml
-
<!--
  @@@ B.4.k.4.r.11.1: Pharmaceutical Dose Form Text
-->
</formCode>
</kindOfProduct>
</instanceOfKind>
</consumable>
-
<targetOf typeCode="REFR">
-
<observation classCode="OBS" moodCode="EVN">
<code code="parentRouteOfAdministration" codeSystem="0.2.999.5.13"/>
-
<value xsi:type="CE">
<originalText>経口</originalText>
-
<!--
  @@@ B.4.k.4.r.13.1: Parent Route of Administration
-->
</value>
</observation>
</targetOf>
</substanceAdministration>
</sourceOf2>
<!-- ##### B.4.k.4: Dosage Information (1) ##### END -->
-
<!--
  ##### B.4.k.7: Indication for Use in case (1) ##### START
-->
-
<targetOf typeCode="RSON">
-
<observation classCode="OBS" moodCode="EVN">
<code code="indication" codeSystem="0.2.999.5.13"/>
-
<value code="10015037" codeSystemVersion="13.0" codeSystem="2.16.840.1.113883.6.70" xsi:type="CE">
-
<!--
  @@@ B.4.k.7.r.2b: Indication in MedDRA Terminology (LLT code)
-->
-
<!--
  @@@ B.4.k.7.r.2a: Indication in MedDRA Terminology (version)
-->
<originalText>てんかん</originalText>
```

```
—
<!--
  @@@ B.4.k.7.r.1: Indication as Reported by the Primary Source
-->
</value>
—
<performer>
—
<assignedEntity>
<code code="sourceReporter" codeSystem="0.2.999.5.7"/>
</assignedEntity>
</performer>
</observation>
</targetOf>
—
<!--
  ##### B.4.k.7: Indication for Use in case (1) ##### END
-->
—
<targetOf typeCode="CAUS">
—
<act classCode="ACT" moodCode="EVN">
<code code="4" codeSystem="0.2.999.5.13"/>
<!-- @@@ B.4.k.8: Action Taken with Drug -->
</act>
</targetOf>
</substanceAdministration>
</component>
<!-- ##### Drug Information (2) ##### END -->
</organizer>
</subjectOf2>
—
<!--
  ########## 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"/>
```

```xml
<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="1097" 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="1098" 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>
```

```xml
<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="1020" root="0.2.999.1.0.5"/>
</adverseEffectReference>
</subject1>
—
<subject2 typeCode="SUBJ">
—
<productUseReference classCode="ACT" moodCode="EVN">
<id extension="1097" 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="1020" root="0.2.999.1.0.5"/>
</adverseEffectReference>
</subject1>
```

```
—
<subject2 typeCode="SUBJ">
—
<productUseReference classCode="ACT" moodCode="EVN">
<id extension="1098" 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">
レビワペ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ペ濃度からも、関連が
あると考える。
</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"/>
```

```xml
</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">
母親が頭部外傷によるてんかん発作に対して、2000年頃からハフォレビ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、この児に
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>
—
```

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```xml
<!--
  @@@ 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>
```

```xml
<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-0001" 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"/>
```

```xml
<!-- @@@ 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>
</subjectOf2>
</relatedInvestigation>
</sourceOf>
‒
<!--
 ########## A.2: Primary Source(s) of Information ########## END
-->
‒
<!--
 ########## A.3: Information on Sender of Case Safety Report ########## START
-->
‒
<subjectOf1 typeCode="SUBJ">
```

```xml
<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>
```

```xml
<!-- @@@ 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>
```